NOVOCASTRA ANTIBODIES, KREATECH PROBES, BOND REAGENTS, BOND SYSTEM & THERMOBRITE

IHC & ISH PRODUCT CATALOG

Advancing Cancer Diagnostics
Improving Lives

Leica
BIOSYSTEMS

CONTENTS

HOW TO USE THIS CATALOG

Products in this catalog are listed alphabetically in sections according to their product type. The Primary Antibodies and ISH Probes sections include products in manual and BOND Ready-to-Use formats. This makes it easy to search for the required antibody and to identify the best available format for the intended application.

To find a product, either use the contents page to locate the appropriate section and then go directly to the product, or use the product name index at the back of the catalog.

ADDITIONAL INFORMATION

Products are listed with their product code and volume/approximate number of tests. Primary antibody listings include the clone, format, tissue utility and recommended retrieval.

Regional product availability is defined by three categories, which are detailed below:

US
United States of America.

EU
Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Malta, Netherlands, Portugal, Spain, Sweden, Switzerland, United Kingdom.

ROW
All other countries not listed above.

For more specific information regarding availability in your region, please consult your Leica Biosystems sales representative.

KEY

IVD	*In vitro* diagnostic use
RUO	For Research Use Only. Not for use in diagnostic procedures
ASR	Analyte Specific Reagent. Analytical and performance characteristics are not established
GPR	General Purpose Reagent
F	Frozen
P	Paraffin
O	Other applications
W	Western blotting
P (HIER)	Paraffin sections with heat induced epitope retrieval recommended
P (ENZYME)	Paraffin sections with enzyme digestion recommended
P (ENZYME+HIER)	Parffin sections with enzyme digestion followed by heat induced epitope retrieval recommended
P (ENZYME/HIER)	Paraffin sections with enzyme digestion or heat induced epitope retrieval recommended - optimum pretreatment to be determined by end user

The first letters of the product code indicate the product type.

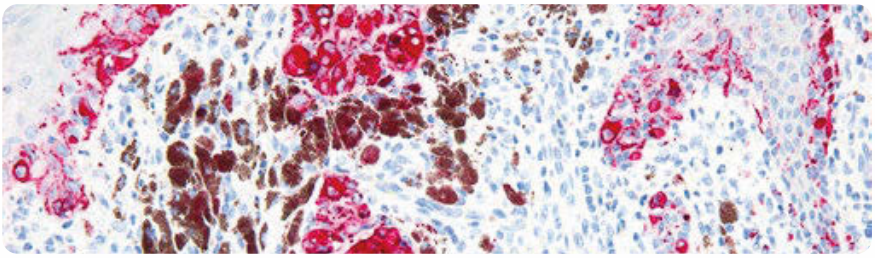
NCL	Concentrated primary antibody or miscellaneous products
RTU	Ready-to-Use primary antibody
RE	Manual detection or ancillary reagent
PA	BOND format primary antibody
PB	BOND format ISH probe
AR	BOND ancillary reagent
DS	BOND detection system
KBI	Kreatech IVD products
KI	Kreatech RUO products

AUTOMATED


BOND-III

BOND ECOSYSTEM

A complete IHC and ISH solution that delivers optimal results

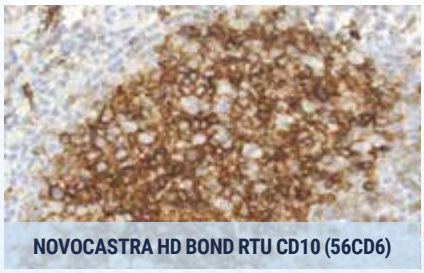


BOND DETECTION SYSTEMS

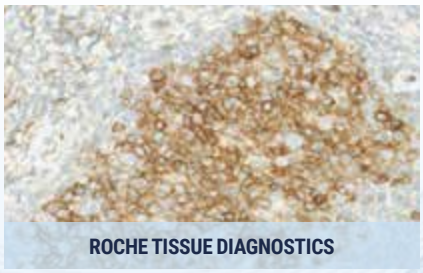
- BOND Polymer Refine Detection (Brown)
- BOND Polymer Refine Red Detection
- ChromoPlex 1 Dual Detection for BOND

BOND READY-TO-USE ANTIBODIES USING TRUSTED NOVOCASTRA CLONES

Comprehensive range of ready-to-use antibodies spanning across 14 pathology menus.



NOVOCASTRA HD BOND RTU CD10 (56CD6)



ROCHE TISSUE DIAGNOSTICS

NOVOCASTRA HD ANTIBODIES

The BOND RTU range includes Novocastra HD antibodies that have been independently validated by NordiQC for optimal performance.

BOND ANCILLARIES AND CONSUMABLES

Ready-to-use solutions designed to be used on the BOND system

BOND Universal Covertile facilitates gentle, even reagent flow over tissue

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent

FULLY AUTOMATED, CLINICAL, IHC & ISH STAINERS

BOND-III

For high throughput labs who require exceptional slide TAT (turnaround time), coupled with high quality staining.

2.5 HOUR SLIDE TAT

Finish earlier. BOND-III consistently completes IHC slides in 2.5 hours whether your workflow is batch or continuous.

BOND-MAX

With a case throughput superior to larger instruments, BOND-MAX is ideal for space-constrained laboratories.

SMALL FOOTPRINT

Meet the demands of ever-increasing slide volumes with the space you have.

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent

FULLY AUTOMATED, CLINICAL, IHC & ISH STAINERS

BOND RTU

Optimized and validated for use on BOND systems.

High quality results in three easy steps:

1. LOAD **2. SELECT** **3. RUN**

Eliminate mixing, titration and dilution.

OPTIMAL STAINING

The BOND platform used in conjunction with Novocastra HD Antibodies and BOND detection systems is a fully integrated solution delivering optimal staining outcomes.

LEICA BIOSYSTEMS		ROCHE TISSUE DIAGNOSTICS
70%	vs	33%
Novocastra HD Antibodies classified as optimal staining*		Roche Antibodies classified as optimal staining*

* Based on a comparison of 67 equivalent RTU antibodies

DESIGNED WITH THE USER IN MIND

BOND Platform software features an intuitive user interface incorporating highly visual modular iconography which is easy to use and learn.

INTERCONNECTIVITY SUITE

With BOND in your lab, you can connect with tools designed to make your life easier. Turn your lab into a paragon of efficiency and reap the results.

- CEREBRO Specimen Tracking and Workflow Management
- BOND LIS-ip, bidirectional LIS interface
- BOND-ADVANCE Network, deploy up to 30 instruments on a single unified network

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent

FULLY AUTOMATED, RESEARCH STAINERS

BOND RX

For research labs and academical centres who want to accelerate their test program.

BOND RX^{m}

For labs with limited space who want to explore their ideas.

FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent

A WHOLE SUITE OF OPEN INNOVATION PARTNERS TO CHOOSE FROM

FREEDOM TO DISCOVER

EXPLORE YOUR IDEAS

IF IMMUNOFLUORESCENCE	CTC CIRCULATING TUMOUR CELLS	bDNA BRANCHED DNA ASSAYS
TSA TYRAMIDE SIGNAL AMPLIFICATION	FISH FLUORESCENCE IN SITU HYBRIDIZATION	LNA LOCKED NUCELIC ACID
CISH CHROMOGENIC IN SITU HYBRIDIZATION	TUNEL TERMINAL DEOXYNUCLEOTIDYL TRANSFERASE DUTP NICK END LABELING ASSAY	miRNA MICRORNA

Customize your protocols

ACCELERATE YOUR TEST PROGRAM

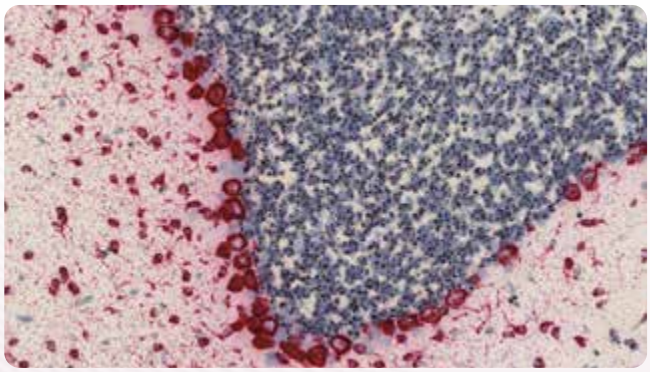
Complete your test program sooner with speed, consistency and efficiency

COMMERCIALIZE YOUR DISCOVERY

A path from research to the clinic

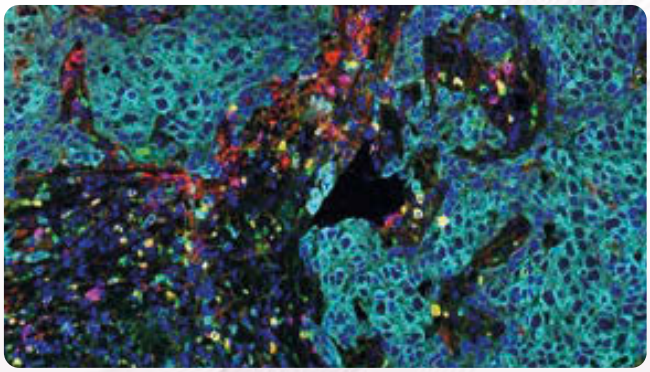
OPEN INNOVATION PARTNERS

Choose from an expanding range of innovation partners bringing new technologies to the research lab, automated for use on BOND RX and BOND RX^{m}



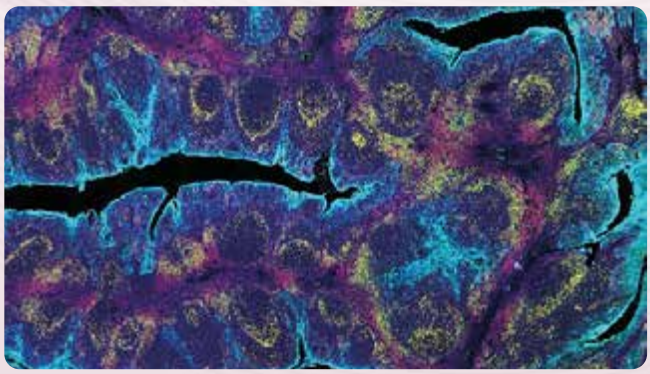
ACD

Fully integrated RNA ISH solution



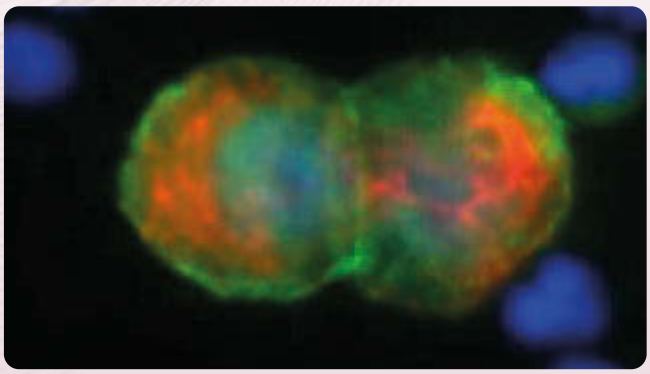
AKOYA

Walk away multiplexing



ULTIVUE

Single step multiplexing



RARECYTE

CTC analysis from whole blood

FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.

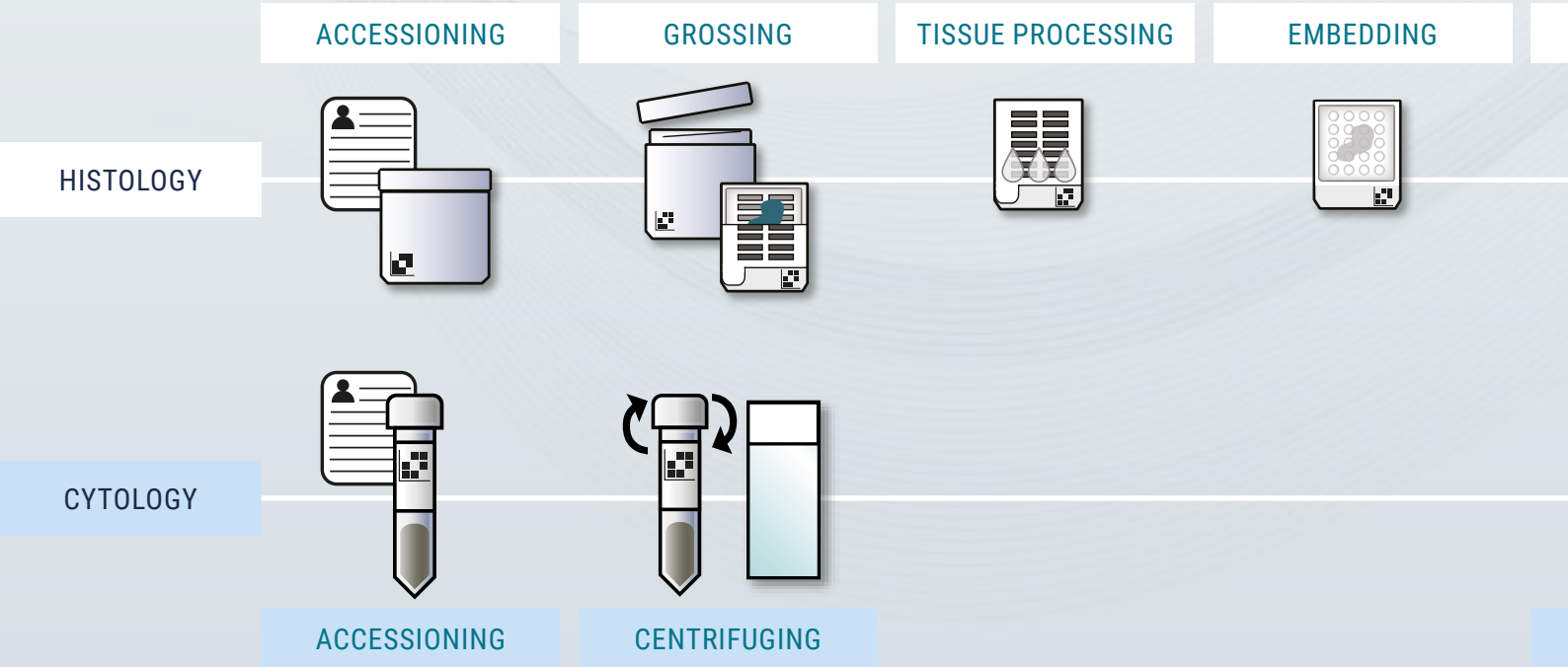
* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent

SPECIMEN TRACKING AND WORKFLOW MANAGEMENT

CEREBRO

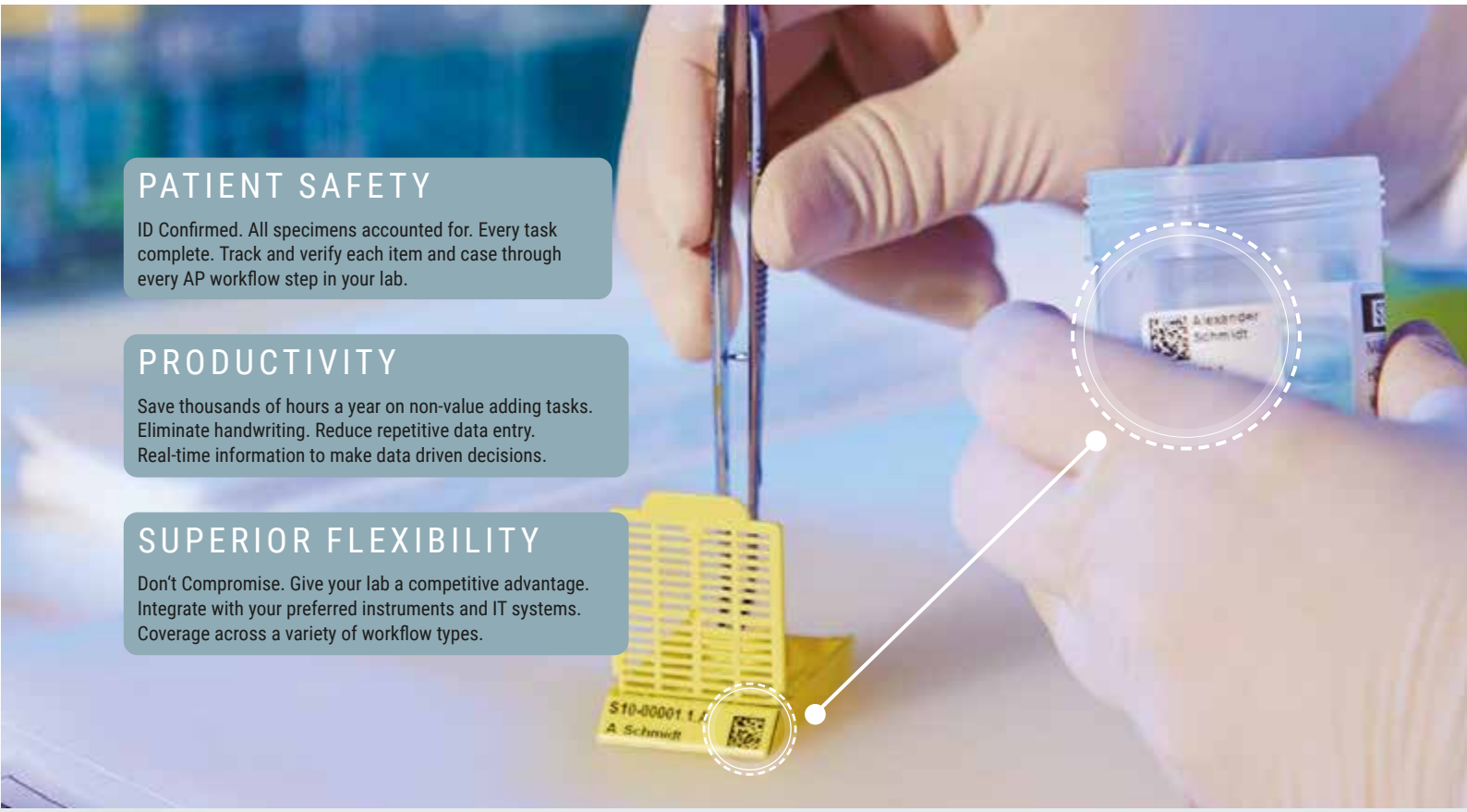
Go home at the end of each day confident that every patient specimen will reach the pathologist for diagnosis as quickly as possible.

A DOCUMENTED CHAIN OF CUSTODY FOR ALL ANATOMIC PATHOLOGY AND CYTOLOGY SPECIMENS



* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.

DON'T LET IDENTIFICATION ERRORS LEAD TO PATIENT HARM



PATIENT SAFETY

ID Confirmed. All specimens accounted for. Every task complete. Track and verify each item and case through every AP workflow step in your lab.

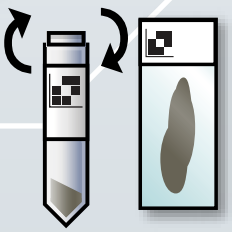
PRODUCTIVITY

Save thousands of hours a year on non-value adding tasks. Eliminate handwriting. Reduce repetitive data entry. Real-time information to make data driven decisions.

SUPERIOR FLEXIBILITY

Don't Compromise. Give your lab a competitive advantage. Integrate with your preferred instruments and IT systems. Coverage across a variety of workflow types.

SECTIONING



SMEARING

STAINING

SEND-OUT

REPORTING

UNIVERSAL

Additional fixation
Decalcification
Frozen section
Specimen storage
Slide archival
Block archival
Tracking referred cases
Delivery to pathologist
Pathologist review
Queued work

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.

THERMOBRITE

Automates the denaturation and hybridization steps in slide-based FISH procedures, and provides walk-away convenience for clinical and research personnel. The low cost unit accepts a wide range of sample types, is easy to use, and reduces hands-on time by more than 50% while ensuring overall precision and accuracy in FISH assays.

USER PROGRAMMABLE SETTINGS

- 40 user defined protocols and 3 operating modes
- Easy to read backlit display
- Numeric keypad allows for easy programming
- Fixed temperature setting for slide baking

EASY TO USE

- Reduces hands-on time during ISH procedures
- Does not need to be fully loaded to maintain temperature accuracy
- Slide separator keeps slides in place and allows for one hand removal

ADVANTAGES OVER MANUAL PROCESSING

- Replaces water bath and hybridization oven
- Superior temperature control compared to water bath
- No need to denature slides in toxic formamide
- No need to denature probes separately
- Eliminates many manual steps

PRODUCT DESCRIPTION	PRODUCT CODE
ThermoBrite Slide Denaturation/Hybridization System 120V	3800-004852-001
ThermoBrite Slide Denaturation/Hybridization System 240V	3800-004852-002
Humidity Card, 10pk	3800-004970-001
ThermoBrite Temperature Verification Kit	3800-006418-001

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use RUO For Research Use Only. Not for use in diagnostic procedures ASR Analyte Specific Reagent GPR General Purpose Reagent

THERMOBRITE ELITE

Automates and standardizes the FISH slide preparation process including deparaffinization, pretreatment, denaturation/hybridization and post hybridization wash. Application of probe, counterstain and cover slipping are the only manual steps. Just load your slides and walk away.

Minimal hands-on time frees up technologists for other important tasks. The ThermoBrite Elite hybridizes with temperature controlled to +/- 1°C and can process up to twelve slides per run with the ability to adapt to smaller batches. For higher throughput, transfer slides to a standard ThermoBrite instrument to denature/hybridize and continue using your ThermoBrite Elite for new runs. The included intuitive software enables users to run preload protocols for solid tumor/FFPE, urine, or to create up to 1,000 user defined protocols. The instrument can be programmed to work with nearly any probe or protocol, allowing the selection of up to ten input reagents and three separate waste paths.

FEATURES

- Small bench top unit
- Automated fluidic system
- Hybridization temperature precision to +/- 1°C
- Workflow based software navigation
- Open system—preloaded & custom protocols

SPEED & EFFICIENCY

- Fast protocol setup and start of run
- Hands on time reduced to 3 steps from >30 (FFPE)
- Free up technologists for other tasks
- Flexible and easy-to-use
- Increases laboratory productivity

FLEXIBILITY

- Histology (solid tumor/FFPE specimens)
- Cytology (urine and other fluids)
- Hematology (blood/bone marrow)
- Cytogenetics (metaphase/interphase, tissue)

PRODUCT DESCRIPTION	PRODUCT CODE
ThemoBrite Elite 120V	3800-007000-001
ThemoBrite Elite 240 V	3800-007000-001
Peritubes 2 tubes	3800-010022-001
Peritubes 12 tubes	3801-010021-001
Pretreatment Solution A (1 L)	LK-110C

PRODUCT DESCRIPTION	PRODUCT CODE
TBE Wash buffer (250 mL 10x)	LK-141B
20 x SSC	LK-061A
Pretreatment Solution B	LK-100C
Pretreatment Solution A	LK-110C
Wash Buffer V (10x)	LK-141B
Wash Buffer V (10x)	LK-141C

PRODUCT DESCRIPTION	PRODUCT CODE
20 x SSC	LKU-061A
Pretreatment Solution B	LKU-100C
Pretreatment Solution A	LKU-110C
Wash Buffer V (10x)	LKU-141B
Wash Buffer V (10x)	LKU-141C

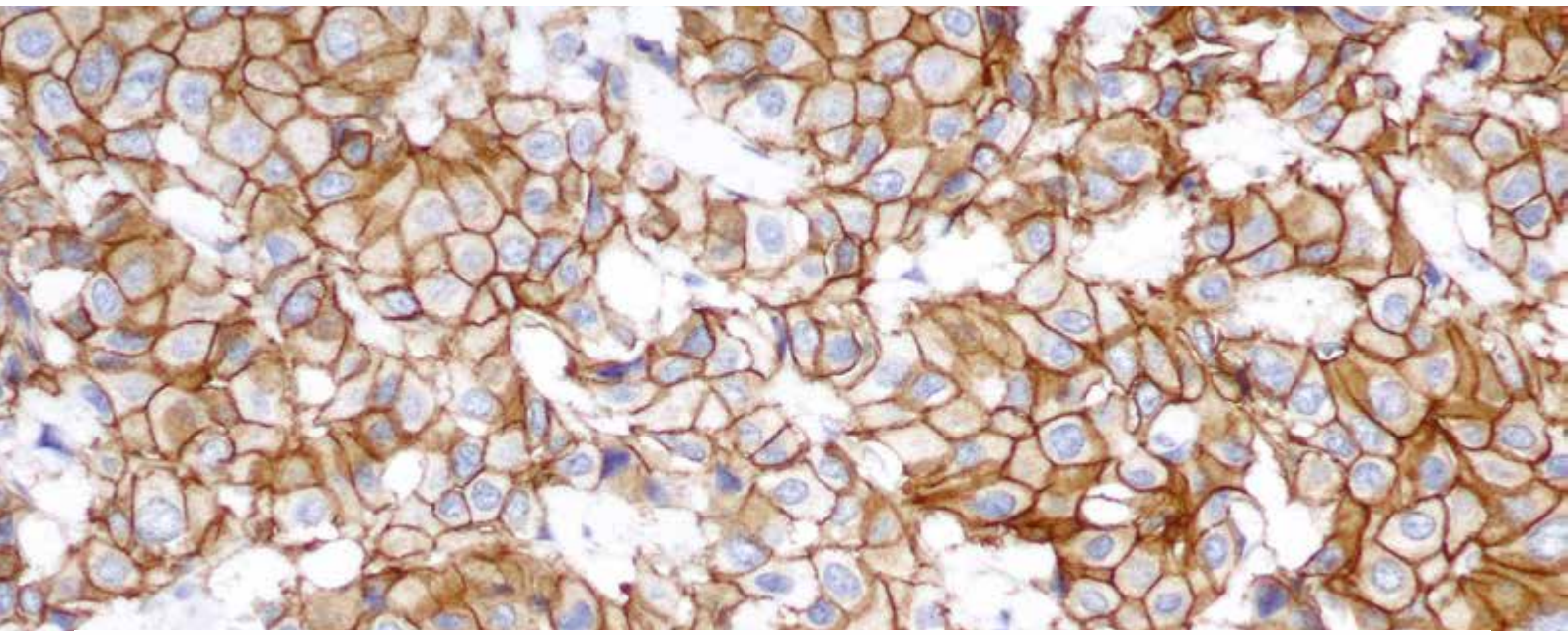
* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent

COMPANION DIAGNOSTICS

BOND ORACLE HER2 IHC SYSTEM

WITH TREATMENT DECISIONS DEPENDENT ON A STAINED SLIDE, YOU NEED CONFIDENCE THAT YOUR HER2 IHC STAINING IS CONSISTENT AND ACCURATE.

The BOND Oracle HER2 IHC system gives you the confidence that comes with demonstrated HER2 IHC FISH concordance and complete assay validation. With the Oracle system, you get the accurate results needed for effective patient management.



PRODUCT CODE:	CLONE:	NO. OF TESTS:	KIT CONTENTS:
TA9145	CB11	60 tests (150 slides)	HER2 Control Slides (x15)
			HER2 Primary Antibody
			HER2 Negative Control
			Integrated DAB Detection System

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent

COMPANION DIAGNOSTICS

MAXIMIZE EFFICIENCY

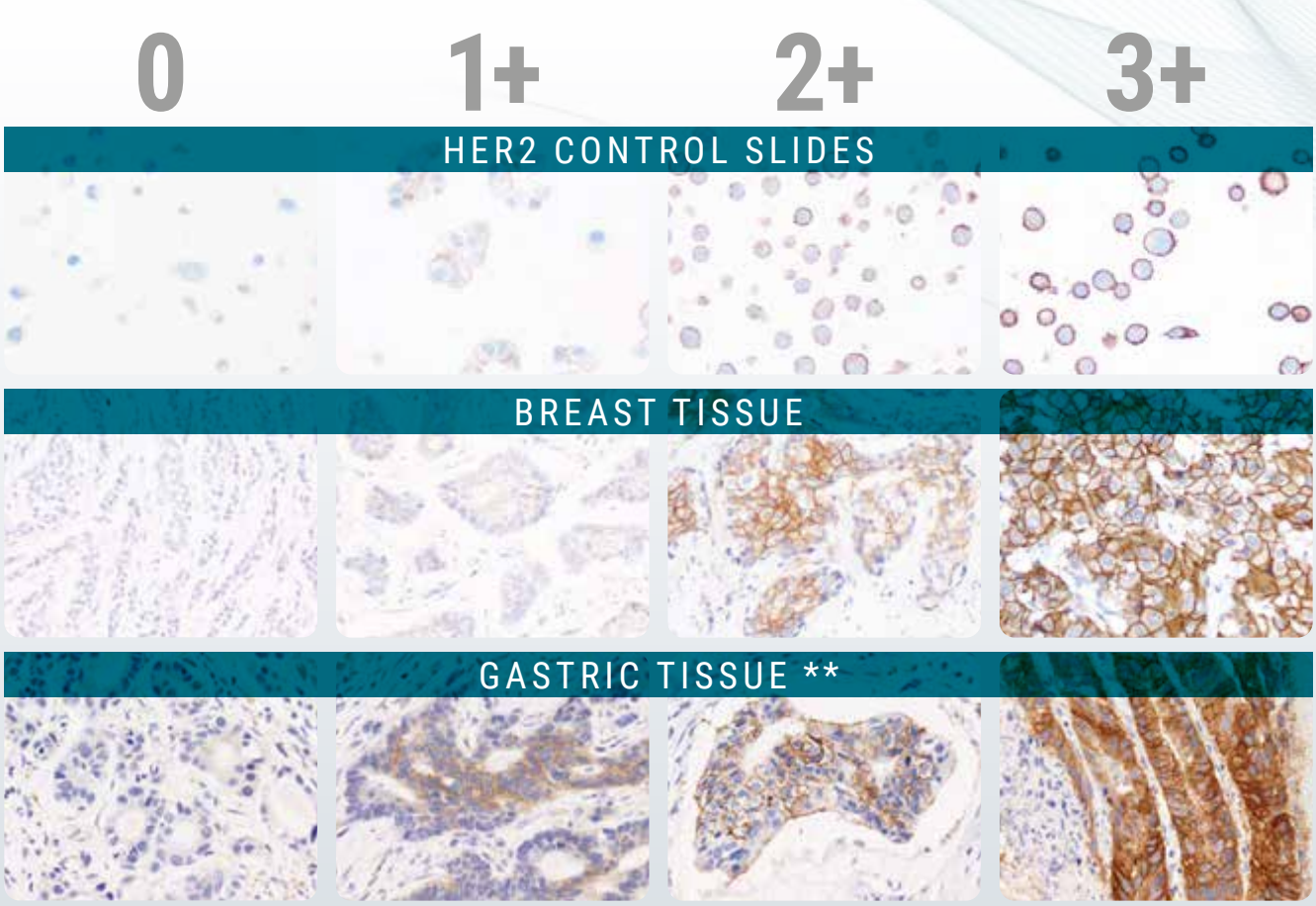
A complete solution of Ready-to-Use reagents, HER2 Control Slides, BOND automation and a validated, standardized protocol reduce the potential for repeat testing and free skilled staff for other high-value tasks.

DRIVE CONSISTENCY

A validated, standardized protocol for uniform staining consistency is supported by convenient e-learning which reinforces and tests consistent interpretation of Oracle HER2 IHC staining.

INCREASE CONFIDENCE

Confidence in HER2 testing is enhanced by HER2 control slides demonstrating 0, 1+ , 2+ and 3+ staining, and excellent FISH concordance.



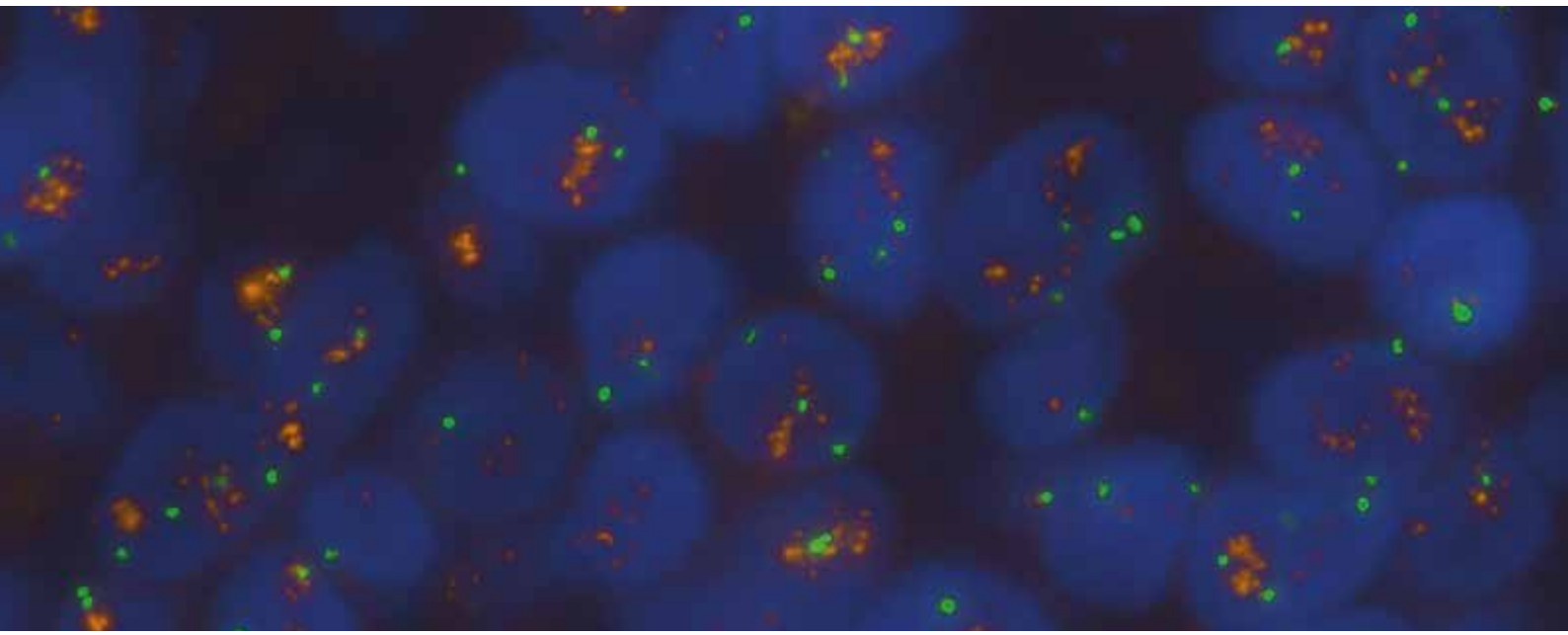
**** This product is not for use in gastric cancer in the USA.**

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent

LEICA HER2 FISH SYSTEM

FULLY AUTOMATED LEICA HER2 FISH SYSTEM FOR BOND

Contains PathVysion®** FISH Probes supplied by Abbott Molecular Inc.



PRODUCT CODE:	CLONE:	NO. OF TESTS:	KIT CONTENTS:
TA9217	-	30 tests (30 slides)	RTU LSI HER2/CEP17 dual probe
			Post Hybridization Wash Solution 2
			BOND Enzyme Diluent
			BOND Enzyme Concentrate 2
			BOND Open Containers

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent

COMPANION DIAGNOSTICS

EASY

Eliminate complexity and reduce human errors that may compromise patient care.

With fully automated staining, laboratories will find it easy to produce the consistent, high-quality stained slides that pathologists rely on.

SUPERIOR QUALITY & STANDARDIZATION

The Leica HER2 FISH System is a complete and fully compatible diagnostic kit, containing all the components required to run the entire test on the BOND System.

REDUCED ERRORS & LOWER REPEAT RATES

Leica Biosystems recommended BOND protocols provide uniform staining consistency. Precise BOND automation ensures reduced process variation to dramatically reduce the number of repeats and save valuable hands-on time.

EFFICIENT

Work smarter, increase efficiency and provide an improved service to your clinicians and customers. BOND automation brings optimized workflow to HER2 FISH staining. With automation, an optimized protocol and standardized Ready-to-Use reagents, the HER2 FISH System provides the flexibility, reduced hands-on time and reduced turnaround time that today's Lean workflow demands.

FULLY AUTOMATED & FLEXIBLE

Three independent slide trays mean the BOND System keeps your cases organized while providing the flexibility for optimal workflow scheduling of your IHC and ISH tests.

MAXIMIZE EFFICIENCY & MINIMIZE COSTS

Free your skilled staff for other high-value tasks by automating labor intensive FISH techniques. The Leica HER2 FISH System brings time, workflow and ultimately cost efficiencies to your laboratory.

ACCURATE

The Leica HER2 FISH System provides a Total Solution. The system combines Abbott Molecular Inc's HER2 FISH probes with the BOND automated platform. The reduction in variation delivers a high level of diagnostic confidence when combined with proprietary HER2 FISH Control Slides.

QUICKLY DELIVER ACCURATE RESULTS

The easy-to-read, single slide, dual probe fluorescent staining provides the highest quality result for the assessment of HER2 gene status.

DIAGNOSTIC CONFIDENCE

Now you can be confident you have done everything to deliver the accurate results needed for effective patient care.

COMPANION DIAGNOSTICS

CUTTING EDGE COLLABORATION

PARTNER WITH THE LEICA BIOSYSTEMS COMPANION DIAGNOSTICS (CDX) TEAM FOR YOUR NEXT DIAGNOSTIC DEVELOPMENT PROJECT.

Our CDx team collaborates with leading biotechnology and pharmaceutical companies. Together, we develop and commercialize cutting-edge diagnostic test solutions that help identify patients who are likely to benefit from our partners' emerging therapies, a critical element of personalized medicine.

We are uniquely positioned to drive personalized healthcare by ensuring patients receive a timely and accurate diagnosis, a critical part of VISION24, our vision statement. Partnering with Leica Biosystems for your CDx needs provides:

- DEDICATED AND EXPERIENCED CDX TEAM
- FLEXIBLE DEVELOPMENT AND PARTNERSHIP MODELS
- TRANSPARENT PARTNERSHIPS
- GLOBAL NETWORKS AND STRATEGIC PARTNERSHIPS
- UNIQUELY POSITIONED TO ADDRESS FUTURE CDX UNMET NEEDS

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent

COMPANION DIAGNOSTICS

A DEDICATED TEAM

OUR STRATEGIES ARE FLEXIBLE AND RESPONSIVE TO THE PHARMA PARTNER'S DEVELOPMENT SCHEDULE AND OBJECTIVES.

Each CDx project is assigned to a cross-functional team that works closely with our Pharma Partners throughout the IVD development process. The cross functional teams support:

ASSAY DEVELOPMENT

Our dedicated and experienced CDx team leverages our flexible development and partnership models to function with transparency and economic consciousness for our Pharma Partners' needs.

Assay development is carried out under Design Control standards. A standardized process also allows for consistent output and robust diagnostic products.

CLINICAL AFFAIRS

Our clinical affairs team's relevant IVD industry expertise across Asia, Europe, and the Americas ensures successful coordination and execution of global clinical programs.

We have the flexibility to work with contract research organizations (CROs) and trial sites selected by our Pharma Partners.

REGULATORY AFFAIRS

This team includes professionals with deep experience in CDx development, using an established regulatory infrastructure that lets us support Pharma Partners worldwide.

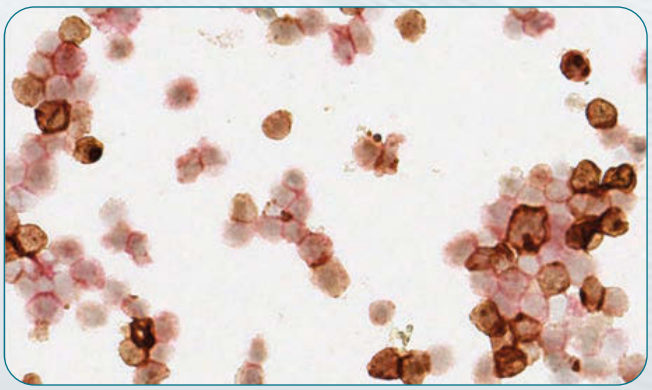
We take a global lifecycle approach to regulatory planning and execution, with extensive experience in drug and device submissions in countries across the world.

COMMERCIALIZATION

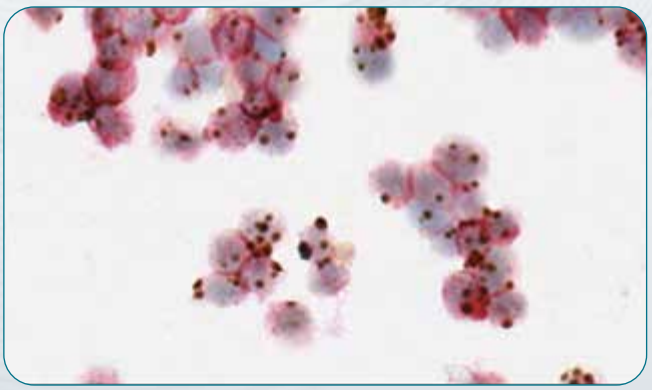
CDx products are launched using Danaher Business System (DBS) tools, which provide lean and commercial support to numerous companies across a variety of industries.

Our team of Market Access professionals has expertise in: health policy, payer relations (Government and Private), clinical outcomes and health economic evidence, which are needed to meet HTA requirements.

WE SUPPORT THE CURRENT AND FUTURE CDX UNMET NEEDS INCLUDING: DIGITAL PATHOLOGY SOLUTIONS, MULTI-MODAL TECHNOLOGY, AND MULTIPLEXING USING OUR IHC, ISH, AND RNA ISH SOLUTIONS.



Marker 1(Brown) and Marker 2(Red) IHC



Marker 3(RNAscope-BROWN) + Marker1/Marker2 (IHC Cocktail-RED)

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent

BOND Polymer Refine Detection

FORMAT	CODE	USAGE	STATUS
200-300 Tests	DS9800	-	IVD

APPLICATION

Immunohistochemistry (IHC)

Primary antibody binding to tissue sections can be visualized using BOND Polymer Refine Detection, where it provides intense, high resolution staining. A range of BOND Ready-to-Use primary antibodies are available, or alternatively, use antibody concentrates diluted with BOND Primary Antibody Diluent (AR9352).

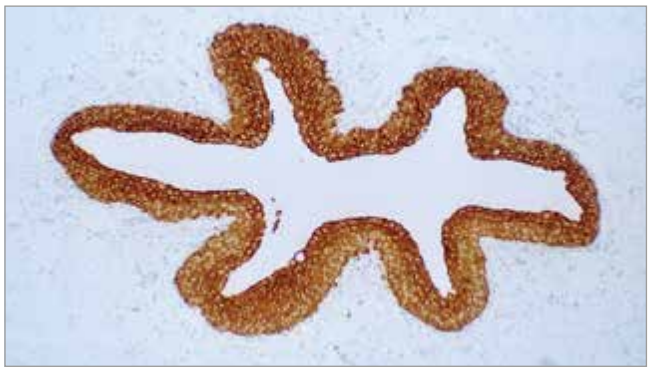
Chromogenic *in situ* Hybridization (ISH)

BOND Polymer Refine Detection produces highly specific, sensitive and reproducible demonstration of nucleic acid sequences through controlled hybridization reactions.

COMPONENTS

A state-of-the-art Compact Polymer detection system HRP horseradish peroxidase (HRP) polymer for use in both immunohistochemistry and chromogenic *in situ* hybridization. Small multifunctional linkers enhance tissue penetration, producing unsurpassed sensitivity. The system is biotin-free.

BOND Polymer Refine Detection contains a peroxide block, post primary, polymer reagent, DAB chromogen and hematoxylin counterstain. It is supplied ready-to-use for the automated BOND system.



Colon mucosa: immunohistochemical staining with BOND Ready-to-Use Cytokeratin 8/18 (5D3) (PA0067) using BOND Polymer Refine Detection.

BOND Polymer Refine Detection.

BOND Polymer Refine Red Detection

FORMAT	CODE	USAGE	STATUS
100 Tests	DS9390	-	IVD

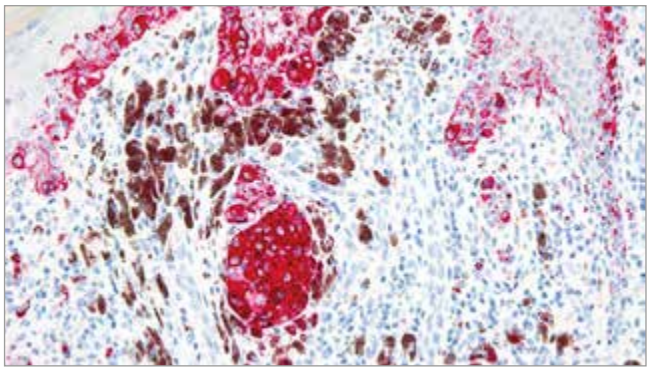
APPLICATION

Immunohistochemistry (IHC)

Primary antibody binding to tissue sections can be visualized using the BOND Polymer Refine Red Detection, providing an intense and high resolution stain.

COMPONENTS

BOND Polymer Refine Red Detection is an IVD labeled red detection system for the automated BOND system. BOND Polymer Refine Red Detection is biotin-free, utilizing alkaline phosphatase (AP)-linked compact polymer to provide enhanced tissue penetration and unsurpassed reagent sensitivity. It contains post primary, polymer reagent, Fast Red chromogen, and hematoxylin counterstain and is supplied in a convenient, Ready-to-Use format.



Human skin stained for melanoma marker HMB45 using BOND Polymer Refine Red Detection. Note intense cytoplasmic staining of melanocytes in contrast to the brown endogenous melanin.

BOND Polymer Refine Red Detection.

ChromoPlex 1 Dual Detection

FORMAT	CODE	USAGE	STATUS
50 Tests	DS9665	-	IVD
100 Tests	DS9477	-	IVD

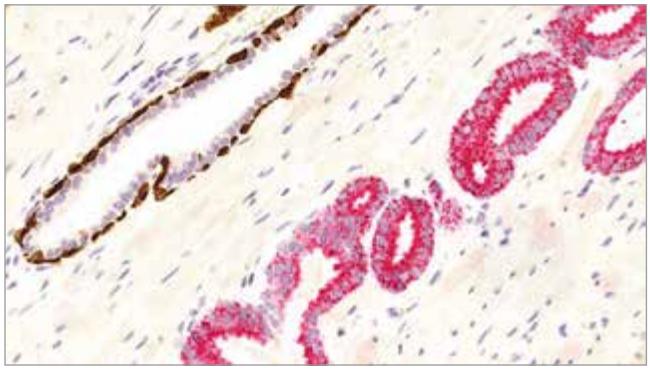
APPLICATION

Immunohistochemistry (IHC)

When tissue is limited and a diagnosis is required, the most effective use of tissue sections becomes imperative. With ChromoPlex 1 Dual Detection for BOND, you can view multiple antibodies using two distinctive chromogens on a single slide, to give you a faster, more comprehensive result for clinical assessment.

COMPONENTS

ChromoPlex 1 Dual Detection is a biotin-free, polymeric horseradish peroxidase (HRP)-linker and polymeric alkaline phosphatase (AP)-linker antibody conjugate system for the detection of tissue-bound mouse and rabbit IgG primary antibodies. It is intended for parallel staining sections of formalin-fixed, paraffin-embedded tissue on the BOND automated system.



Sensitive and specific staining of the basal cell layer of a prostate biopsy with DAB chromogen. Excellent staining intensity of malignant cells detected with Fast Red chromogen. Prostate Biopsy stained with ChromoPlex 1 Dual Detection and a prostate cocktail (PIN-4).

BOND FISH Kit

FORMAT	CODE	USAGE	STATUS
60 Tests	DS9636	-	IVD
60 Tests	DS9374	-	GPR

APPLICATION

Fluorescent *in situ* Hybridization (FISH)

The BOND FISH Kit enables the user to perform fluorescence *in situ* hybridization (FISH) on the automated BOND system. It is intended for use with nucleic acid probes on formalin-fixed, paraffin embedded (FFPE) tissue. The kit consists of a formamide mixture which reduces non-specific hybridization of nucleic acid probes.

RESTRICTIONS

DS9636 is not available for sale in the US.

DS9374 is only available in the US.

BOND FISH Kit.

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent

BOND Intense R Detection

FORMAT	CODE	USAGE	STATUS
200 Tests	DS9263	-	RUO

APPLICATION

Immunohistochemistry (IHC)

By allowing a free choice of biotinylated secondary antibody, BOND Intense R Detection is ideal for the detection of primary antibodies from any species. Research applications such as IHC staining of mouse tissues can be accommodated in this manner. The intense deposition of DAB reaction product produces strong immunostaining.

COMPONENTS

BOND Intense R Detection is a peroxidase detection system optimized for use on the automated BOND system and is ideal for research applications. It contains a peroxide block, streptavidin/peroxidase conjugate, DAB chromogen and hematoxylin counterstain. Users must supply a biotinylated secondary antibody of their choice.

BOND Intense R Detection.

BOND Research Detection

FORMAT	CODE	USAGE	STATUS
200 Tests	DS9455	-	RUO
200 Tests	DS9777	-	RUO

APPLICATION

BOND Research Detection offers researchers the ability to tailor applications and fully automate staining for ease of use.

COMPONENTS

BOND Research Detection System (DS9455), this open detection system consists of six standard 30 mL open containers in a reagent tray.

BOND Research Detection System 2 (DS9777), this open detection system consists of nine standard 30 mL open containers in a reagent tray.

BOND Research Detection.

BOND RNAscope Detection Reagents - BROWN

FORMAT	CODE	USAGE	STATUS
60 Tests	DS9790	-	GPR

APPLICATION

The BOND RNAscope Detection Reagents - BROWN consists of a series of reagents that enable visualization of RNA in FFPE (formalin fixed, paraffin-embedded) tissue following hybridization with a target RNA specific oligonucleotide probe. The sequential addition of the reagents after probe hybridization results in RNA target and signal amplification, visualized through chromogenic conversion of DAB by HRP. The detection reagents enable chromogenic RNA ISH to be performed on the automated BOND-III system.

COMPONENTS

BOND RNAscope Detection Reagents – BROWN is ready to use. Reconstitution, mixing, dilution or titration of this reagent is not required. This product contains:

- RNAscope Rinse
- Hematoxylin
- DAB Part 1
- DAB Part B
- RNAscope Bluing
- RNAscope AMP 1 DAB
- RNAscope AMP 2 DAB
- RNAscope AMP 3 DAB
- RNAscope AMP 4 DAB
- RNAscope AMP 5 DAB
- RNAscope AMP 6 DAB
- RNAscope H2O2BOND RNAscope

BOND RNAscope Detection Reagents - BROWN

BOND RTUS

ENHANCE LABORATORY PRODUCTIVITY

NAME	CLONE	7 ML	30 ML
ALK	5A4	PA0306	-
ALK	5A4	PA0831	-
Alpha Fetoprotein	C3	PA0963	-
Alpha-Methylacyl-CoA Racemase (AMACR, p504s)	EPMU1	PA0210	-
B Cell Specific Octamer Binding Protein-1 (BOB-1)	TG14	PA0558	-
Bcl-2 Oncoprotein	bcl-2/100/D5	PA0117	-
Bcl-6 Oncoprotein	LN22	PA0204	-
Beta-Catenin	17C2	PA0083	-
CA125 (Ovarian Cancer Antigen)	Ov185:1	PA0539	-
CA19-9 (Sialyl Lewisa)	C241:5:1:4	PA0424	-
Calcitonin	Polyclonal	PA0406	-
Calponin (Basic)	26A11	PA0416	-
Calretinin	CAL6	PA0346	-
Carcinoembryonic Antigen (CD66e)	COL-1	PA0848	-
CD10	56C6	PA0270	PA0131
CD103	EP206	PA0374	-
CD117	EP10	PA0007	-
CD11c	5D11	PA0554	-
CD13	38C12	PA0304	-
CD138 (Syndecan 1)	MI15	PA0088	-
CD15	MMA	PA0473	-
CD163	10D6	PA0090	-
CD19	BT51E	PA0843	-
CD1a	MTB1	PA0235	-
CD2 (LFA-2)	11F11	PA0271	-
CD20	L26	PA0200	PA0359
CD21	2G9	PA0171	-
CD22	FPC1	PA0249	-
CD23	1B12	PA0169	-
CD25	4C9	PA0305	-
CD3	LN10	PA0553	PA0122
CD30	JCM182	PA0790	-
CD31 (PECAM-1)	JC70A	PA0414	-
CD33	PWS44	PA0555	-
CD34 (Endothelial Cell Marker)	QBEnd/10	PA0212	PA0354
CD4	4B12	PA0427	-

NAME	CLONE	7 ML	30 ML
CD43	MT1	PA0938	-
CD45	X16/99	PA0042	-
CD45RO	UCHL1	PA0146	-
CD5	4C7	PA0168	-
CD56 (NCAM)	CD564	PA0191	-
CD57	NK-1	PA0443	-
CD61 (GPIIIa)	2f2	PA0308	-
CD68	514H12	PA0273	-
CD7	LP15	PA0266	-
CD79a	11E3	PA0192	-
CD79a	JCB117	PA0599	-
CD8	4B11	PA0183	-
CDX2	EP25	PA0375	-
c-erbB-2 Oncoprotein (HER-2) Antibodies	CB11	PA0983	PA0571 (13.5 mL)
Chromogranin A	5H7	PA0515	-
Cyclin D1	EP12	PA0046	-
Cytokeratin (8/18)	5D3	PA0067	-
Cytokeratin 14	LL002	PA0074	-
Cytokeratin 17	E3	PA0114	-
Cytokeratin 19	b170	PA0799	-
Cytokeratin 20	Ks20.8	PA0022	PA0037
Cytokeratin 5	XM26	PA0468	-
Cytokeratin 7	RN7	PA0942	PA0138
Cytokeratin 8	TS1	PA0567	-
Cytokeratin, Multi (1/5/10/14)	34βE12	PA0134	-
Cytokeratin, Multi (AE1/AE3)	AE1/AE3	PA0094	-
Cytokeratin, Multi (AE1/AE3) 2	AE1/AE3	PA0909	-
Desmin	DE-R-11	PA0032	-
DOG-1	K9	PA0219	-
E-Cadherin	36B5	PA0387	-
Epithelial Membrane Antigen	GP1.4	PA0035	-
Estrogen Receptor	6F11	PA0151	PA0009
EZH2 (Enhancer of Zeste Homolog 2 (Drosophila))	6A10	PA0575	-
Factor XIIIa (Blood Coagulation Factor XIIIa)	E980.1	PA0449	-
Fascin	IM20	PA0420	-

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent

BOND RTUS

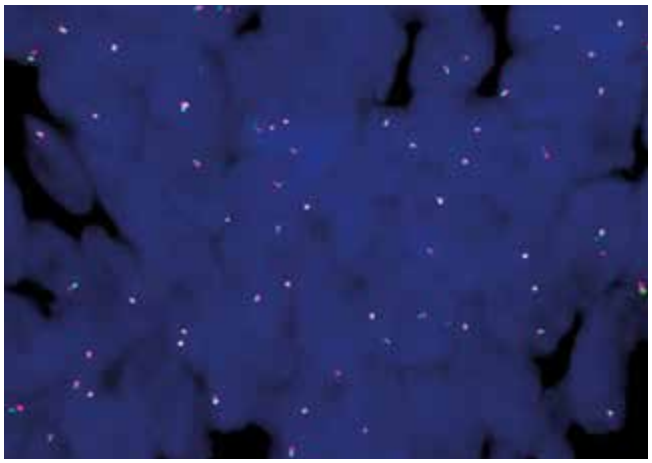
IMMUNOHISTOCHEMISTRY HAS NEVER BEEN EASIER

NAME	CLONE	7 ML	30 ML
Galectin-3	9C4	PA0238	-
Gastrin	Polyclonal	PA0681	-
Glial Fibrillary Acidic Protein	GA5	PA0026	-
Granzyme B	11F1	PA0291	-
Gross Cystic Disease Fluid Protein-15	23A3	PA0708	-
Human Chorionic Gonadotrophin (beta)	Polyclonal	PA0014	-
Human Follicle Stimulating Hormone (beta 2) (HFSH)	INN-hFSH-60	PA0693	-
Human Growth Hormone (HGH)	Polyclonal	PA0704	-
Human Herpesvirus 8 (HHV8)	13B10	PA0050	-
Immunoglobulin D	DRN1C	PA0061	-
Immunoglobulin G	RWP49	PA0905	-
Immunoglobulin M	8H6	PA0278	-
Inhibin Alpha	R1	PA0488	-
Insulin	2D11-H5	PA0620	-
Kappa Light Chain	CH15	PA0606	-
Ki67 Antigen	K2	PA0230	-
Ki67 Antigen	MM1	PA0118	PA0410
Lambda Light Chain	SHL53	PA0570	-
Lysozyme (Muramidase)	Polyclonal	PA0391	-
Mammaglobin	EP249	PA0378	-
Mast Cell Tryptase	10D11	PA0019	-
Melan A	A103	PA0233	PA0044
Melanoma Marker (HMB45)	HMB45	PA0027	PA0625
Mesothelin	5B2	PA0373	-
Mismatch Repair Protein (MLH1)	ES05	PA0610	-
Mismatch Repair Protein (MLH1)	ES05	PA0988	-
Mismatch Repair Protein (MSH2)	25D12	PA0048	-
Mismatch Repair Protein (MSH2)	25D12	PA0989	-
Mismatch Repair Protein (MSH6)	EP49	PA0990	-
Mismatch Repair Protein (PMS2)	EP51	PA0991	-
Muc-1 Glycoprotein	Ma695	PA0051	-
Muc-2 Glycoprotein	Ccp58	PA0155	-
Muc-5AC Glycoprotein	CLH2	PA0052	-
Muc-6 Glycoprotein	CLH5	PA0053	-
Multiple Myeloma Oncogene 1 (MUM-1)	EAU32	PA0129	-
Muscle Specific Actin	HHF35	PA0258	-

NAME	CLONE	7 ML	30 ML
Myeloperoxidase	59A5	PA0491	-
Myogenin (Myf-4)	LO26	PA0226	-
Myoglobin	MYO18	PA0727	-
Myosin Heavy Chain Antibodies	S131	PA0493	-
Napsin A	IP64	PA0064	-
Negative Control (Mouse)	MOPC-21	PA0996	-
Negative Control (Rabbit)	n/a	PA0777	-
Neurofilament 200kD	N52.1.7	PA0371	-
Neuron Specific Enolase	22C9	PA0435	-
Oct-2	Oct-207	PA0532	-
Oct-3/4	N1NK	PA0193	-
p120 Catenin	EP66	PA0379	-
p16	6H12	PA0016	-
p53 Protein	DO-7	PA0057	-
p63 Protein	7JUL	PA0103	-
Pax-5	1EW	PA0552	-
PD-L1	73-10	PA0832	-
Placental Alkaline Phosphatase	8A9	PA0161	-
Progesterone Receptor	16	PA0312	-
Prostate Specific Antigen	35H9	PA0431	-
Prostatic Acid Phosphatase	PASE/4LJ	PA0006	-
Protein Gene Product 9.5	10A1	PA0286	-
S-100B	EP32	PA0031	-
Serotonin	Polyclonal	PA0736	-
SMA (Alpha Smooth Muscle Actin)	alpha sm-1	PA0943	-
Synaptophysin	27G12	PA0299	-
Tartrate-Resistant Acid Phosphatase (TRAP)	2600000	PA0093	-
Terminal Deoxynucleotidyl Transferase	SEN28	PA0339	-
Thyroid Stimulating Hormone	QB2/6	PA0776	-
Thyroid Transcription Factor-1	SPT24	PA0364	-
Tyrosinase	T311	PA0322	-
Vimentin	V9	PA0640	-
von Willebrand Factor (Factor VIII-related antigen)	36B11	PA0055	-
Wilms' Tumor	WT49	PA0562	-
Zap-70	L453R	PA0998	-

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent

2p23 ALK (2p23) Break



Adenocarcinoma of the lung stained using Kreatech ALK (2p23) Break - XL probe for BOND (KBI-XL001).

ALK (2p23) Break

CODE	COLOR	FORMAT	STATUS
KBI-XL001	Green/Red	2 x 1 mL (10 x concentrate)	IVD

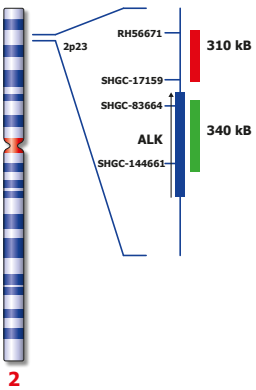
MENU

LUNG PATHOLOGY

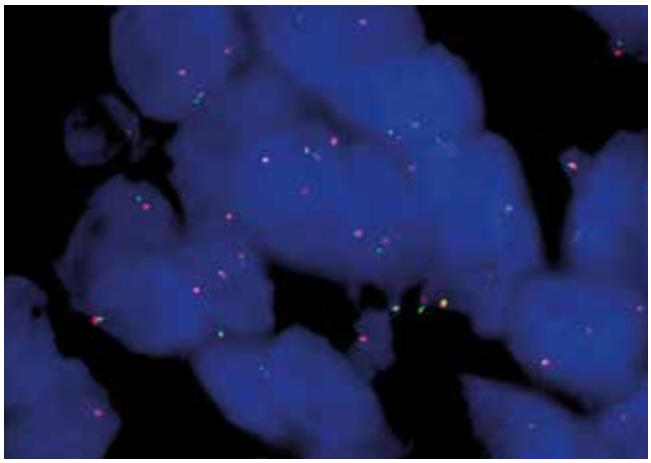
BACKGROUND

ALK (2p23) Break - XL for BOND FISH probe detects genomic translocations involving the ALK gene. ALK (2p23) Proximal - XL and ALK (2p23) Distal - XL probes are optimized to detect the genomic regions proximal and distal to break points in the ALK gene region.

When combined, both probes are used to detect translocations involving the ALK gene at 2p23.



6q22 ROS1 (6q22) Break



Adenocarcinoma of the lung stained using Kreatech ROS1 (6q22) Break - XL probe for BOND (KBI-XL002).

ROS1 (6q22) Break

CODE	COLOR	FORMAT	STATUS
KBI-XL002	Green/Red	2 x 1 mL (10 x concentrate)	IVD

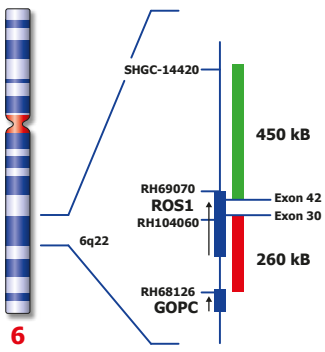
MENU

LUNG PATHOLOGY

BACKGROUND

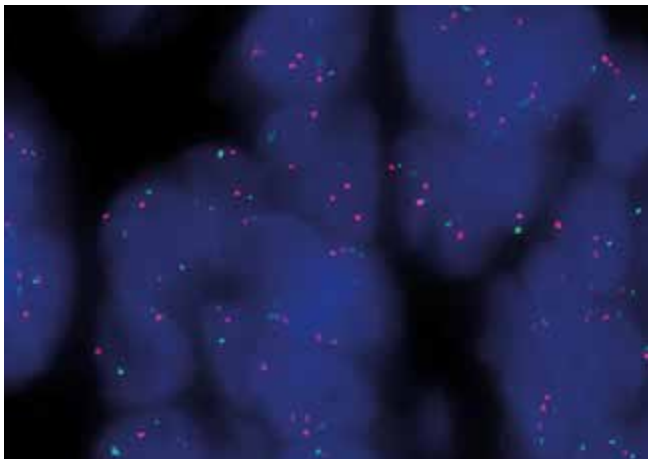
ROS1 (6q22) Break - XL for BOND FISH probe detects genomic translocations involving the ROS1 gene. ROS1 (6q22) Proximal - XL and ROS1 (6q22) Distal - XL probes are optimized to detect the genomic regions proximal and distal to break points in the ROS1 gene region.

When combined, both probes are used to detect translocations involving the ROS1 gene at 6q22.



* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use RUO For Research Use Only. Not for use in diagnostic procedures ASR Analyte Specific Reagent GPR General Purpose Reagent

7q31 MET (7q31) / SE7 (D7Z1)



Adenocarcinoma of the lung stained using Kreatech MET (7q31) / SE7(D7Z1) - XL probe for BOND (KBI-XL003).

MET (7q31) / SE7 (D7Z1)

CODE	COLOR	FORMAT	STATUS
KBI-XL003	Green/Red	2 x 1 mL (10 x concentrate)	IVD

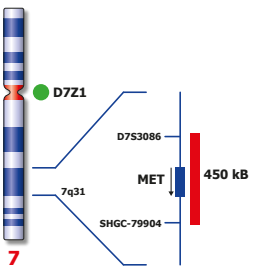
MENU

LUNG PATHOLOGY

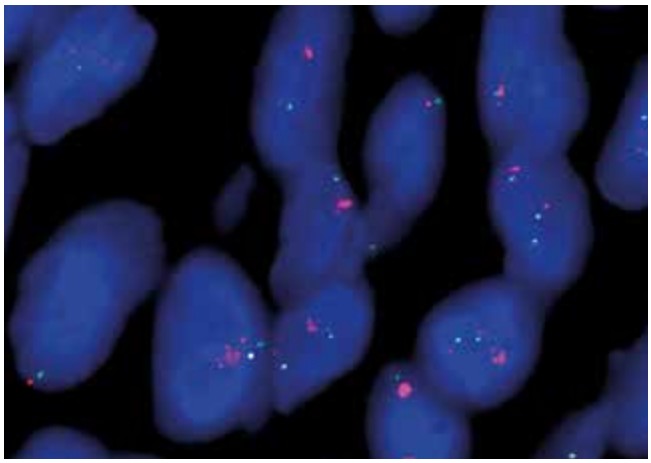
BACKGROUND

MET (7q31) / SE7 (D7Z1) - XL for BOND FISH probe detects genomic amplifications involving the MET gene. MET (7q31) - XL is optimized to detect copy numbers of the MET gene region at 7q31. SE7 (D7Z1) - XL is optimized to detect copy numbers of the chromosome 7 centromere.

When combined, both probes are used to detect amplification of the MET gene at 7q31, using the centromeric probe as a control.



8p11 FGFR1 (8p11) / SE8 (D8Z1)



Squamous cell carcinoma of the lung stained using Kreatech FGFR1 (8p11) / SE8 (D8Z1) - XL probe for BOND (KBI-XL004).

FGFR1 (8p11) / SE8 (D8Z1)

CODE	COLOR	FORMAT	STATUS
KBI-XL004	Green/Red	2 x 1 mL (10 x concentrate)	IVD

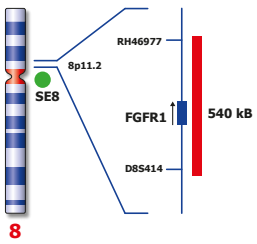
MENU

LUNG PATHOLOGY

BACKGROUND

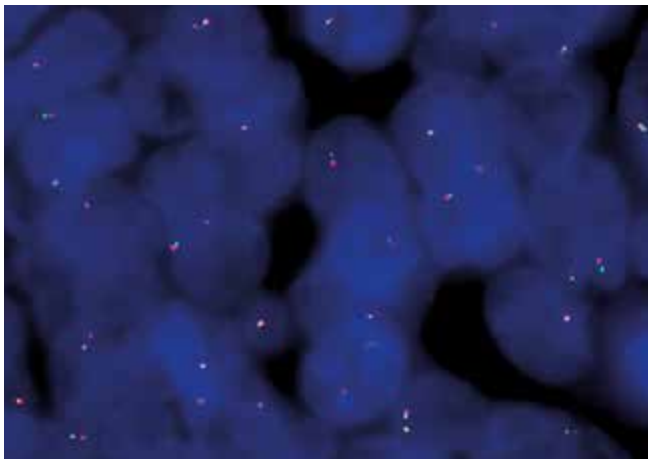
The FGFR1 (8p11) / SE8 (D8Z1) - XL for BOND probe detects genomic amplifications involving the FGFR1 gene. FGFR1 (8p11) - XL is optimized to detect copy numbers of the FGFR1 gene at 8p11. SE8 (D8Z1) - XL is optimized to detect copy numbers of the chromosome 8 centromere.

When combined, both probes are used to detect amplification of the FGFR1 gene at 8p11, using the centromeric probe as a control.



* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent

10q11 RET (10q11) Break



Adenocarcinoma of the lung stained using Kreatech RET (10q11) Break - XL probe for BOND (KBI-XL005).

RET (10q11) Break

CODE	COLOR	FORMAT	STATUS
KBI-XL005	Green/Red	2 x 1 mL (10 x concentrate)	IVD

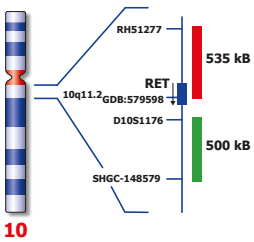
MENU

LUNG PATHOLOGY

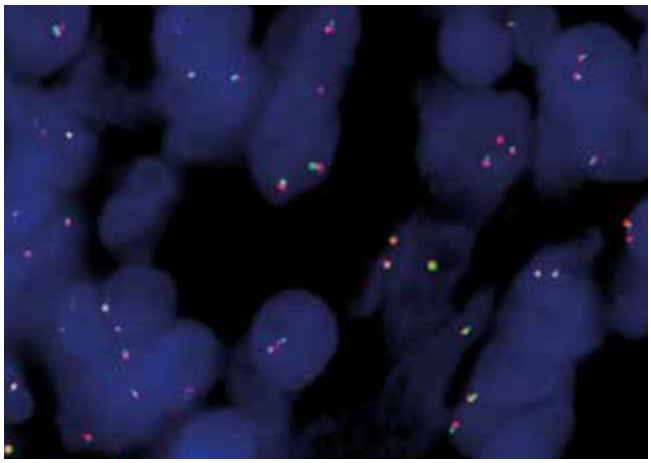
BACKGROUND

RET (10q11) Break - XL for BOND FISH probe detects genomic translocations involving the RET gene. RET (10q11) Proximal - XL and RET (10q11) Distal - XL probes are optimized to detect the genomic regions proximal and distal to break points in the RET gene region.

When combined, both probes are used to detect translocations involving the RET gene at 10q11.



8q24 MYC (8q24) Break



Diffuse Large B-Cell Lymphoma stained using Kreatech MYC (8q24) Break - XL probe for BOND (KBI-XL006).

MYC (8q24) Break

CODE	COLOR	FORMAT	STATUS
KBI-XL006	Green/Red	2 x 1 mL (10 x concentrate)	IVD

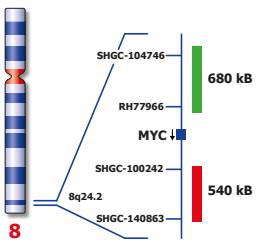
MENU

HEMATOPATHOLOGY (LYMPHOMA)

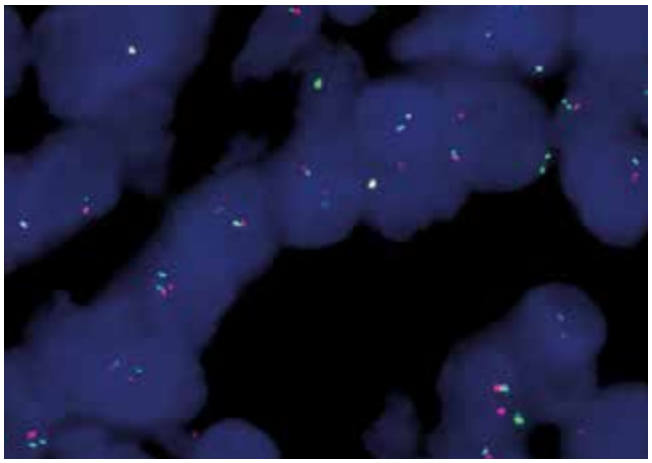
BACKGROUND

MYC (8q24) Break - XL for BOND FISH probe detects genomic translocations involving the MYC gene. MYC (8q24) Proximal - XL and MYC (8q24) Distal - XL are optimized to detect the genomic regions proximal and distal to break points in the MYC gene region.

When combined, both probes are used to detect translocations involving the MYC gene at 8q24.



14q32 IGH (14q32) Break



Diffuse Large B-Cell Lymphoma stained using Kreatech IGH (14q32) Break - XL probe for BOND (KBI-XL007).

IGH (14q32) Break

CODE	COLOR	FORMAT	STATUS
KBI-XL007	Green/Red	2 x 1 mL (10 x concentrate)	IVD

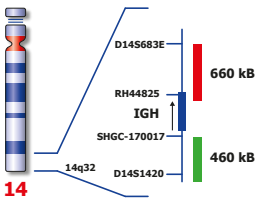
MENU

HEMATOPATHOLOGY (LYMPHOMA)

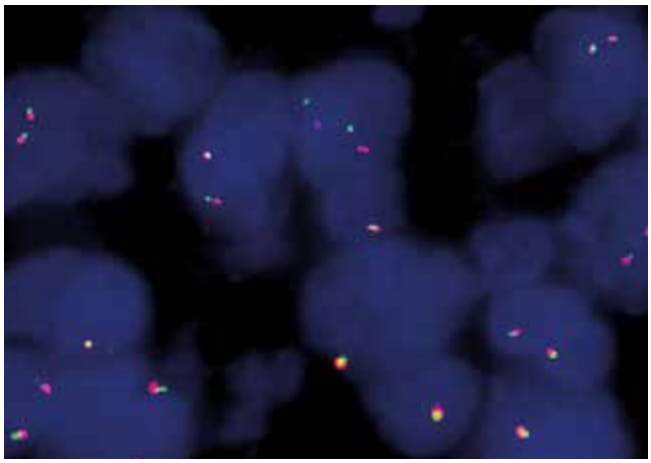
BACKGROUND

IGH (14q32) Break - XL for BOND FISH probe detects genomic translocations involving the IGH gene. IGH (14q32) Proximal - XL and IGH (14q32) Distal - XL probes are optimized to detect the genomic regions proximal and distal to break points in the IGH gene region.

When combined, both probes are used to detect translocations involving the IGH gene at 14q32.



18q21 BCL2 (18q21) Break



Diffuse Large B-Cell Lymphoma stained using Kreatech BCL2 (18q21) Break - XL probe for BOND (KBI-XL008).

BCL2 (18q21) Break

CODE	COLOR	FORMAT	STATUS
KBI-XL008	Green/Red	2 x 1 mL (10 x concentrate)	IVD

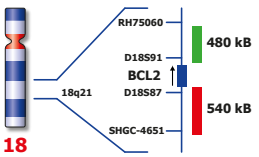
MENU

HEMATOPATHOLOGY (LYMPHOMA)

BACKGROUND

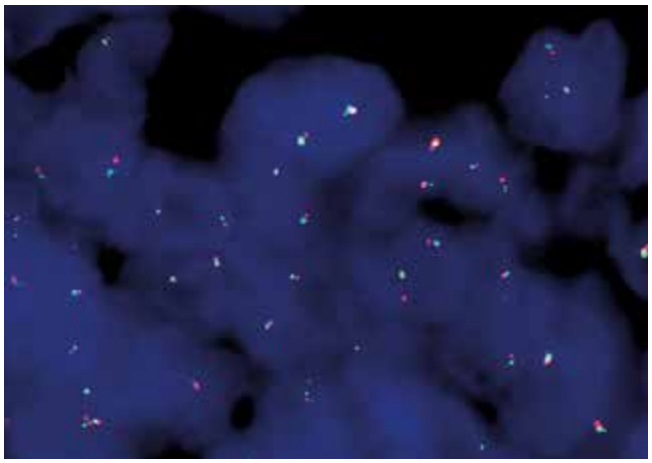
BCL2 (18q21) Break - XL for BOND FISH probe detects genomic translocations involving the BCL2 gene. BCL2 (18q21) Proximal - XL and BCL2 (18q21) Distal - XL probes are optimized to detect the genomic regions proximal and distal to break points in the BCL2 gene region.

When combined, both probes are used to detect translocations involving the BCL2 gene at 18q21.



* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use RUO For Research Use Only. Not for use in diagnostic procedures ASR Analyte Specific Reagent GPR General Purpose Reagent

3q27 BCL6 (3q27) Break



Diffuse Large B-Cell Lymphoma stained using Kreatech BCL6 (3q27) Break - XL probe for BOND (KBI-XL009).

BCL6 (3q27) Break

CODE	COLOR	FORMAT	STATUS
KBI-XL009	Green/Red	2 x 1 mL (10 x concentrate)	IVD

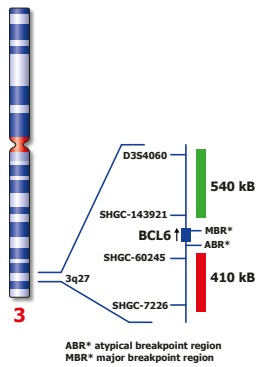
MENU

HEMATOPATHOLOGY (LYMPHOMA)

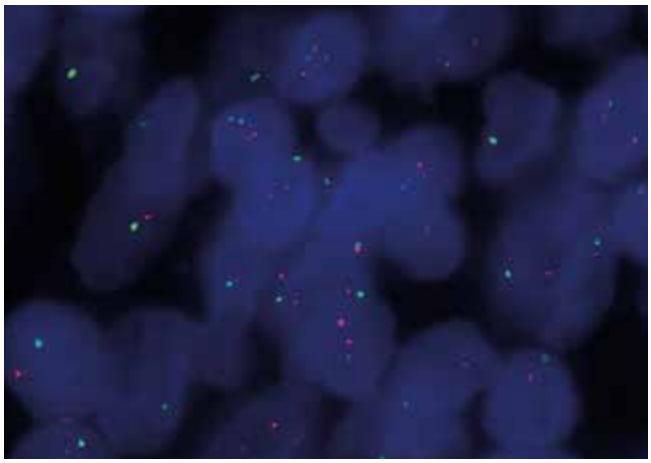
BACKGROUND

BCL6 (3q27) Break - XL for BOND FISH probe detects genomic translocations involving the BCL6 gene. BCL6 (3q27) Proximal - XL and BCL6 (3q27) Distal - XL probes are optimized to detect the genomic regions proximal and distal to break points in the BCL6 gene region.

When combined, both probes are used to detect translocations involving the BCL6 gene at 3q27.



17p13 TP53 (17p13) / SE 17



Diffuse Large B-Cell Lymphoma stained using Kreatech TP53 (17p13) / SE17 - XL probe for BOND (KBI-XL010).

TP53 (17p13) / SE 17

CODE	COLOR	FORMAT	STATUS
KBI-XL010	Green/Red	2 x 1 mL (10 x concentrate)	IVD

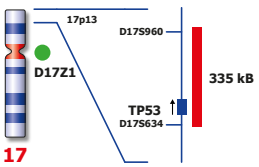
MENU

HEMATOPATHOLOGY (LYMPHOMA)

BACKGROUND

TP53 (17p13) / SE 17 - XL for BOND FISH probe detects genomic deletions involving the TP53 gene. TP53 (17p13) - XL is optimized to detect copy numbers of the TP53 gene region at 17p13. SE 17 (D17Z1) - XL is optimized to detect copy numbers of the chromosome 17 centromere.

When combined, both probes are used to detect deletion of the TP53 gene at 17p13, with the centromeric probe as a control.



BOND Kappa Probe

FORMAT	CODE	USAGE	STATUS
5.5 mL	PB0645	P	IVD

BACKGROUND

Kappa Probe is used for the qualitative identification of Kappa light chain messenger RNA (mRNA) in formalin-fixed, paraffin-embedded tissue by *in situ* hybridization (ISH) using the automated BOND system.

Immunoglobulins are glycoproteins produced in mature B-cells against a specific antigen. Each individual immunoglobulin molecule comprises two heavy and two light polypeptide chains. There are five classes of immunoglobulin, determined by the type of heavy chain.

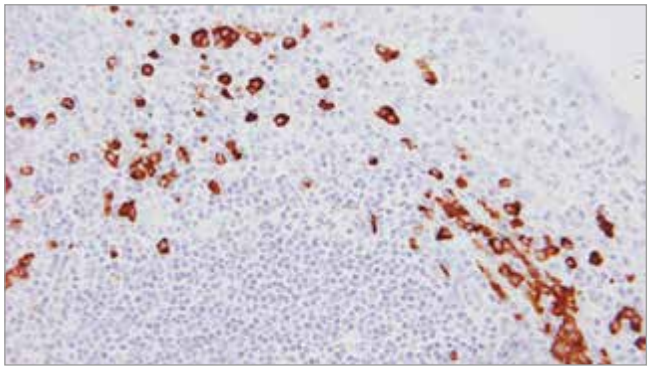
In contrast, there are only two types of light chain: Kappa or Lambda. Each individual immunogloblin molecule is composed of one of five classes of heavy chains and either Kappa or Lambda light chains. In normal human lymphoid populations, the ratio of Kappa to Lambda light chains is approximately 2:1.

B-cell neoplasms are thought to arise from a single transformed cell (monoclonal). In contrast, reactive states result in proliferation of a number of B-cells (polyclonal). Since immunoglobulins from the same B-cell contain either Kappa or Lambda light chains, light chain restriction or monoclonality can be used to make the distinction between reactive and neoplastic B cell proliferations.

Kappa Probe is used in conjunction with Lambda Probe for the detection of antibody producing B-cells in formalin-fixed, paraffin embedded tissue.

RESTRICTIONS

PB0645 is not available for sale in the US.



Human tonsil: *in situ* hybridization for kappa mRNA using Kappa Probe, Anti-Fluorescein Antibody and BOND Polymer Refine Detection.

BOND Lambda Probe

FORMAT	CODE	USAGE	STATUS
5.5 mL	PB0669	P	IVD

BACKGROUND

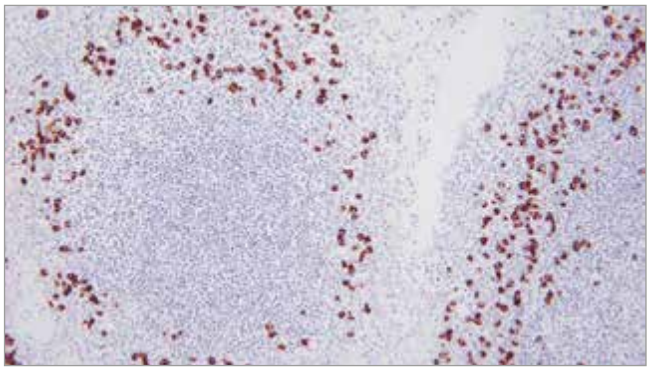
Lambda Probe is used in conjunction with Kappa Probe for the detection of antibody producing B cells in formalin-fixed, paraffin-embedded tissue.

B cell neoplasms are thought to arise from a single transformed cell (monoclonal), whereas reactive states result in proliferation of a number of B cells (polyclonal).

Since immunoglobulins from the same B cell contain either Kappa or Lambda light chains, light chain restriction or monoclonality can be used to make the distinction between reactive and neoplastic B cell proliferations.

RESTRICTIONS

PB0669 is not available for sale in the US.



Human tonsil: *in situ* hybridization for lambda mRNA using Lambda Probe, Anti-Fluorescein Antibody and BOND Polymer Refine Detection.

BOND EBER Probe

FORMAT	CODE	USAGE	STATUS
5.5 mL	PB0589	P	IVD

BACKGROUND

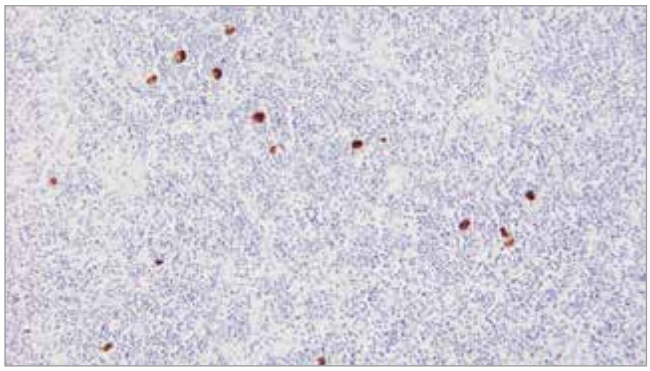
Epstein-Barr Virus (EBV) is a member of the Gamma Herpes Virus family. EBV can establish both lytic infection as well as latent infection.

Epstein-Barr Virus encoded RNA (EBER) is abundantly expressed in latent EBV infection and ISH is considered a sensitive method for the detection of latent EBV infection.

Latent EBV infection is associated with several conditions including: Hodgkin's Lymphoma, B cell Non Hodgkin's Lymphoma, nasopharyngeal carcinoma, lymphoproliferative disorders and lymphoma in the immunosuppressed, including transplant and AIDS patients, gastric cancer and some T cell lymphomas.

RESTRICTIONS

PB0589 is not available for sale in the US.



Hodgkin's lymphoma: *in situ* hybridization for Epstein-Barr virus (EBV) encoded mRNA using EBV Probe, Anti-Fluorescein Antibody and BOND Polymer Refine Detection.

BOND CMV Probe

FORMAT	CODE	USAGE	STATUS
5.5 mL	PB0614	P	IVD

BACKGROUND

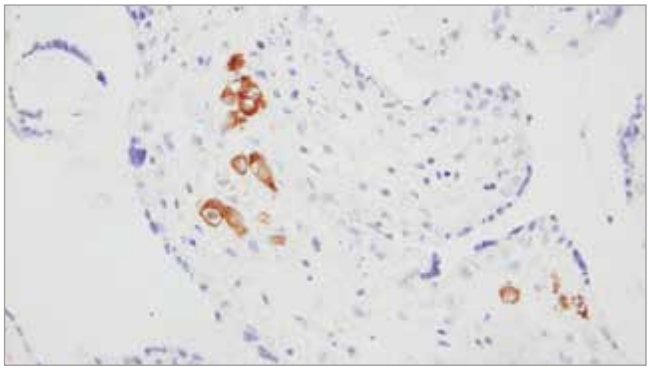
Cytomegalovirus (CMV) is a member of the Beta Herpes Virus family, transmitted via body fluids, and can establish primary infection, latent infection and subsequent viral reactivation.

CMV is a common opportunistic pathogen, capable of causing serious disease in immunocompromised individuals such as AIDS patients, transplant patients and in neonates.

Congenital CMV is a result of intrauterine infection and although the majority of children are asymptomatic, congenital CMV can result in sensorineural hearing loss, cognitive, motor and visual deficits and seizures.

RESTRICTIONS

PB0614 is not available for sale in the US.



Human placenta: *in situ* hybridization for Cytomegalovirus (CMV) mRNA using CMV Probe, Anti-Fluorescein Antibody and BOND Polymer Refine Detection.

BOND HPV (subtypes 6, 11) Probe

FORMAT	CODE	USAGE	STATUS
6.25 mL	PB0780	P	IVD

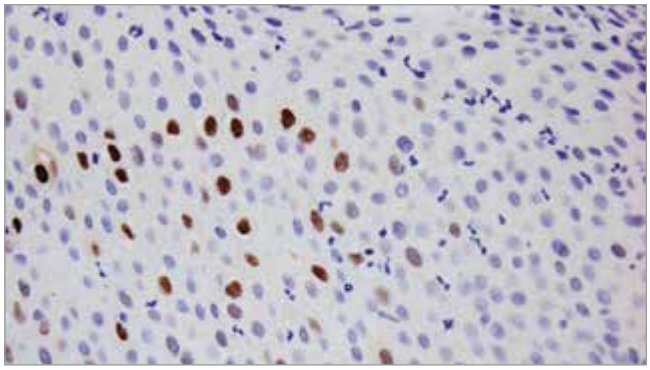
BACKGROUND

HPV Probe (Subtypes 6,11) is used for the qualitative identification of the Human Papillomavirus (HPV) DNA in formalin-fixed, paraffin-embedded tissue by *in situ* hybridization (ISH) using the automated BOND system.
This probe binds to HPV subtypes 6 and 11 and is biotin-conjugated.

There are over 100 known Human Papillomavirus types, but only about 40 are known to infect the anogenital epithelium. HPV is the most common sexually transmitted virus. HPV infections have been associated with a number of malignant and benign lesions, including genital warts, anogenital cancers and oral head and neck cancers. HPV subtypes have been associated with over 95% of cervical cancers. As a result, HPV subtypes are broadly classified as high or low risk, depending on the incidence they are associated with cervical malignant transformation (high risk) and benign lesion development (low risk). There are 12 HPV subtypes classified as low risk, including 6 and 11, which have a low association with cervical cancer progression.

RESTRICTIONS

PB0780 is not available for sale in the US.



Cervical tissue (CIN1): *in situ* hybridization for HPV, subtype 6 and 11 DNA using HPV (6,11) Probe, Anti-Biotin Antibody, Stringency Wash and BOND Polymer Refine Detection.

BOND HPV (subtypes 16, 18, 31, 33, 51) Probe

FORMAT	CODE	USAGE	STATUS
6.25 mL	PB0829	P	IVD

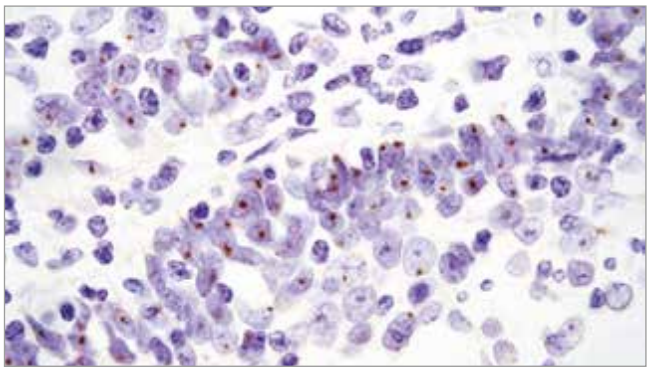
BACKGROUND

HPV Probe (Subtypes 16, 18, 31, 33, 51) is used for the qualitative identification of the Human Papillomavirus (HPV) DNA in formalin-fixed, paraffin-embedded tissue by *in situ* hybridization (ISH) using the automated BOND system. This probe binds to HPV 16, 18, 31, 33 and 51 and is biotin-conjugated.

There are over 100 known Human Papillomavirus types, but only about 40 are known to infect the anogenital epithelium. HPV is the most common sexually transmitted virus. HPV infections have been associated with a number of malignant and benign lesions, including genital warts, anogenital cancers and oral head and neck cancers. HPV subtypes have been associated with over 95% of cervical cancers. As a result, HPV subtypes are broadly classified as high or low risk, depending on the incidence they are associated with cervical malignant transformation (high risk) and benign lesion development (low risk). There are 15 HPV subtypes classified as high risk, including 16, 18, 31, 33 and 51, but HPV subtypes 16 and 18 are the most frequent subtypes associated with cervical carcinogenesis and are detected in up to 71% of cervical cancers. It is now widely accepted that a HPV infection is necessary for cervical cancer progression; however, additional cellular events, such as HPV DNA integration status and viral load, are also key factors associated with cancer progression.

RESTRICTIONS

PB0829 is not available for sale in the US.



Cervical tissue, abnormal epithelia (CINII) stained with HPV (subtypes 16, 18, 31,33, 51) Probe Anti-Biotin Antibody, Stringency Wash and BOND Polymer Refine Detection.

BOND DNA Positive Control

FORMAT	CODE	USAGE	STATUS
6.25 mL	PB0682	P	IVD

BACKGROUND

Positive control probes should be run on patient tissue to validate reagent performance, to provide information on the preservation of nucleic acids in the tissue and to confirm accessibility of nucleic acids to the probe.

The DNA Positive Control Probe is intended for use as a positive control in formalin-fixed, paraffin-embedded tissue by DNA *in situ* hybridization (ISH) using the automated BOND system.

It is designed to specifically hybridize to the genomic ALU repeat sequences, which represent approximately 10% of the human genome. The DNA Positive Control Probe is biotin-labeled.

RESTRICTIONS

PB0682 is not available for sale in the US.

BOND DNA Negative Control

FORMAT	CODE	USAGE	STATUS
6.25 mL	PB0731	P	IVD

BACKGROUND

The DNA Negative Control is intended for use as a negative control in formalin-fixed, paraffin-embedded tissue by DNA *in situ* hybridization (ISH) using the automated BOND system.

DNA Negative Control is used in place of the probe, to enable the identification of background staining resulting from non-specific interactions with the specimen sample under investigation.

RESTRICTIONS

PB0731 is not available for sale in the US.

BOND RNA Positive Control Probe

FORMAT	CODE	USAGE	STATUS
5.5 mL	PB0785	P	IVD

BACKGROUND

RNA is very susceptible to degradation by RNases, therefore, the RNA Positive Control Probe is ideally used as a screening tool to detect the preservation of mRNA in cells.

RESTRICTIONS

PB0785 is not available for sale in the US.

BOND RNA Negative Control Probe

FORMAT	CODE	USAGE	STATUS
5.5 mL	PB0809	P	IVD

BACKGROUND

RNA Negative Control Probe is intended for use in the identification of background staining resulting from non-specific interactions in formalin-fixed, paraffin-embedded tissue by *in situ* hybridization (ISH) using the automated BOND system.

RNA Negative Control Probe is a single oligonucleotide, designed from zebra fish DNA and analyzed using Basic Local Alignment Search Tool (BLAST) analysis to confirm that the sequence bears no homology with any human sequences. The RNA Negative Control Probe is generated with a fluorescein label using the same procedures as applied to other oligonucleotide probes used in the detection of RNA on BOND. Therefore, RNA Negative Control Probe is ideal as a negative control probe for RNA ISH on BOND.

RESTRICTIONS

PB0809 is not available for sale in the US.

BOND Dewax Solution

FORMAT	CODE	USAGE	STATUS
1 L	AR9222	P	IVD

APPLICATION

The use of BOND Dewax Solution allows paraffin wax to be removed from tissue sections before rehydration and staining on BOND. It is specially formulated to be compatible with the automated BOND system, and efficiently removes wax from slides while retaining the integrity of tissue antigens and probe binding sites. BOND Dewax Solution is less harmful than alternative deparaffinization solutions such as xylene.

COMPONENTS

BOND Dewax Solution is a deparaffinization solution specifically designed for use on the automated BOND system. It is provided ready-to-use in 1 L bottles and can be poured directly into the appropriate bulk reagent container on the instrument.

BOND Dewax Solution.

BOND Wash Solution 10X Concentrate

FORMAT	CODE	USAGE	STATUS
1 L	AR9590	P	IVD

APPLICATION

BOND Wash Solution is the only wash buffer that should be used in BOND automated staining procedures. It is formulated for optimal reagent flow under the BOND Covertile to help ensure that excess reagent is removed from the tissue section before new reagent is added.

COMPONENTS

BOND Wash Solution 10X Concentrate is a concentrated buffer solution specifically for use on the automated BOND system. It is available in 1 L quantities, and when diluted will make up 10 L of working solution.

BOND Wash Solution 10X Concentrate.

BOND Epitope Retrieval Solution 1

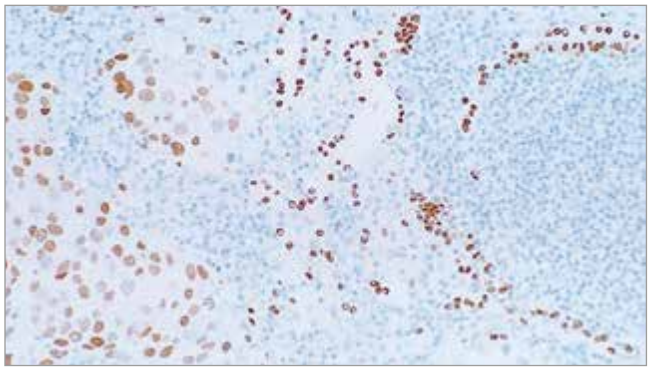
FORMAT	CODE	USAGE	STATUS
1 L	AR9961	P	IVD

APPLICATION

BOND Epitope Retrieval Solution 1 is for use on formalin-fixed, paraffin-embedded tissue sections to expose epitopes within tissue that have been masked during fixation. The solution is gentle on sections as it has a reduced boiling temperature and utilizes BOND Covertile technology to prevent reagent evaporation.

COMPONENTS

BOND Epitope Retrieval Solution 1 is a 1 L ready-to-use, citrate-based pH 6.0 solution. It is specifically for heat-induced epitope retrieval (HIER) on the automated BOND system.



Human lung stained for TTF-1 with BOND Ready-to-Use Thyroid Transcription Factor-1 (SPT24, PA0364), using BOND Polymer Refine Detection and BOND Epitope Retrieval Solution 1.

BOND Epitope Retrieval Solution 1.

BOND Epitope Retrieval Solution 2

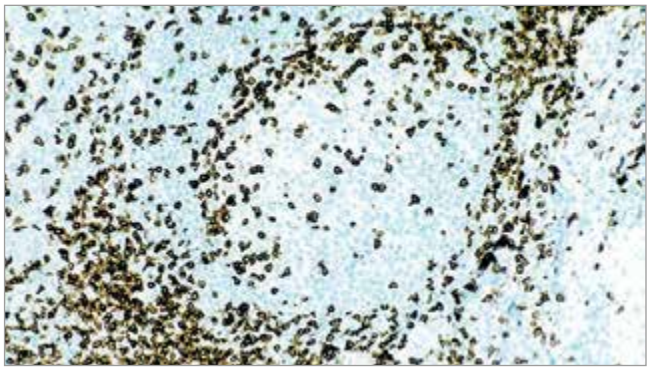
FORMAT	CODE	USAGE	STATUS
1 L	AR9640	P	IVD

APPLICATION

BOND Epitope Retrieval Solution 2 is for use on formalin-fixed, paraffin-embedded tissue sections to expose epitopes within tissue that have been masked during fixation. The solution is gentle on sections as it has a reduced boiling temperature and utilizes BOND Covertile technology to prevent reagent evaporation.

COMPONENTS

BOND Epitope Retrieval Solution 2 is a 1 L ready-to-use, EDTA-based pH 9.0 solution. It is specifically for heat-induced epitope retrieval (HIER) on the BOND system.



Human tonsil stained for CD3 with BOND Ready-to-Use CD3 (LN10, PA0533), using BOND Polymer Refine Detection and BOND Epitope Retrieval Solution 2.

BOND Epitope Retrieval Solution 2.

BOND Universal Covertile

FORMAT	CODE	USAGE	STATUS
160 Pack	S21.4611	P	IVD

APPLICATION

The BOND Universal Covertile is a patented technology that facilitates gentle, even reagent flow over tissue. It prevents reagent evaporation and minimizes waste generation. The Covertile is re-usable and can also be recycled once its staining life is over.

BOND Universal Covertile.

BOND Primary Antibody Diluent

FORMAT	CODE	USAGE	STATUS
500 mL	AR9352	P	IVD

APPLICATION

BOND Primary Antibody Diluent is specifically for diluting concentrated primary antibodies for use on the automated BOND system. It is not intended for the reconstitution of lyophilized reagents.

COMPONENTS

BOND Primary Antibody Diluent is ready-to-use and available in a quantity of 500 mL.

BOND Primary Antibody Diluent.

BOND Enzyme Pretreatment Kit

FORMAT	CODE	USAGE	STATUS
1 Kit	AR9551	P	IVD

APPLICATION

Immunohistochemistry (IHC)

The BOND Enzyme Pretreatment Kit can be used for enzymatic digestion on formalin-fixed, paraffin-embedded tissue sections to assist in epitope exposure. Enzymatic pretreatment improves the staining of some antibodies by exposing epitopes within tissue that have been masked during fixation.

In situ Hybridization (ISH)

The diluted enzyme solution can also be used for ISH. Enzymatic digestion of tissue assists in the penetration of probes and facilitates binding.

COMPONENTS

- BOND Enzyme Concentrate, 1 mL
- BOND Enzyme Diluent, 200 mL
- 3 x BOND Open Containers, 7 mL

The enzyme is diluted before use in the BOND Open Containers supplied. The diluted enzyme solution is used for enzymatic digestion on the automated BOND system.

BOND Enzyme Pretreatment Kit.

BOND DAB Enhancer

FORMAT	CODE	USAGE	STATUS
30 mL	AR9432	P	IVD

APPLICATION

BOND DAB Enhancer changes the color of the DAB reaction deposit from golden to dark brown, providing an increase in contrast between chromogen-specific staining and the slide back drop. This can assist in qualitative identification of antigens.

COMPONENTS

BOND DAB Enhancer is a heavy metal solution for use on the automated BOND system. The no-mix, ready-to-use format simplifies laboratory workflow.

BOND DAB Enhancer.

BOND Anti-Fluorescein Antibody

FORMAT	CODE	USAGE	STATUS
3.75 mL	AR0833	P	IVD
15 mL	AR0222	P	IVD

APPLICATION

In situ hybridization (ISH) allows the detection and visualization of specific nucleic acids in tissues sections. ISH probes used for the detection of mRNA or DNA on BOND contain a fluorescein label. The BOND Anti-Fluorescein Antibody allows linking of the oligonucleotide probe with the detection reagents, and consequently, visualization of a chromogenic product by light microscopy.

COMPONENTS

BOND Anti-Fluorescein Antibody is a purified IgG fraction of a mouse monoclonal antibody. It is supplied ready-to-use.

BOND Hybridization Solution

FORMAT	CODE	USAGE	STATUS
100 mL	AR9037	-	IVD
100 mL	AR9013	-	RUO

APPLICATION

BOND Hybridization Solution is intended to be used for the dilution of individual *In situ* hybridization (ISH) probes for use on the automated BOND system.

BOND Anti-Biotin Antibody

FORMAT	CODE	USAGE	STATUS
7.5 mL	AR0584	P	IVD

APPLICATION

In situ hybridization (ISH) allows the detection and visualization of specific nucleic acids in tissue sections. Some ISH probes used for detection of DNA on the BOND system contain a biotin label. The Anti-Biotin Antibody allows the linking of the probe with the detection reagents and consequently visualization of a chromogenic product by light microscopy.

COMPONENTS

Anti-Biotin Antibody is a purified anti-biotin, IgG1 isotype. It is supplied ready-to-use.

Anti-Biotin Antibody

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent

BOND Stringency Wash

FORMAT	CODE	USAGE	STATUS
3.75 mL	AR0633	P	IVD

APPLICATION

In situ hybridization (ISH) allows the detection and visualization of specific nucleic acids in tissue sections. The BOND Stringency Wash Solution is intended for use with DNA probes to reduce non-specific DNA hybridization in formalin-fixed, paraffin-embedded tissue using the automated BOND system.

COMPONENTS

The BOND Stringency Wash Solution is a formamide mixture used with the BOND DNA ISH Probes. This solution reduces non-specific hybridization of DNA probes.

Stringency Wash.

BOND RNAscope Protease

FORMAT	CODE	USAGE	STATUS
12 mL	AR9773	P	GPR

APPLICATION

The BOND RNAscope Protease reagent is used for pretreatment of FFPE (formalin fixed, paraffin-embedded) tissue in conjunction with BOND reagents on the automated BOND-III system. The enzyme pretreatment permeabilizes the tissue and prepares the sample for hybridization with a target RNA specific oligonucleotide probe and subsequent detection using the BOND RNAscope Detection Reagents.

COMPONENTS

Total volume = 12 mL, sufficient for 60 tests.

BOND RNAscope Protease is ready to use. Reconstitution, mixing, dilution or titration of this reagent is not required.

BOND Aspirating Probe Cleaning System

FORMAT	CODE	USAGE	STATUS
15 Cleaning Cycles	CS9100	-	-

PRODUCT DESCRIPTION

The BOND Aspirating Probe Cleaning System contains reagents optimized to clean the aspirating probe of residual DAB. Sold in a standard reagent tray, the system is loaded onto BOND where a predefined cleaning protocol ensures maximum wash efficiency.

BOND Mixing Stations

FORMAT	CODE	USAGE	STATUS
5 Pack	S21.1971	-	IVD

PRODUCT DESCRIPTION

BOND Mixing Stations are reusable inserts with six vials for mixing and catalyzing chromogens prior to slide application. Fresh chromogen promotes high quality staining. Replacing the mixing stations at recommended intervals ensures that the mixed chromogen does not become contaminated.

BOND Mixing Stations.

BOND Open Containers 7 mL

FORMAT	CODE	USAGE	STATUS
10 Pack, Minimum 200 Tests/Container	OP79193	-	IVD

PRODUCT DESCRIPTION

BOND Open 7 mL Containers allow the use of reagents from any source on the BOND system. Each container can be refilled until a total of 40 mL has been dispensed from it. They are ideal for reagents that are consumed intermittently and have a short shelf life.

BOND Open Containers 7 mL.

BOND Open Containers 30 mL

FORMAT	CODE	USAGE	STATUS
10 Pack, Minimum 200 Tests/Container	OP309700	-	IVD

PRODUCT DESCRIPTION

BOND Open 30 mL Containers allow the use of reagents from any source on the BOND system. Each container holds 30 mL and can be refilled until a total of 40 mL has been dispensed from it. They are ideal for high throughput reagents that are consumed on a daily basis and their use can minimize reagent preparation time.

BOND Open Containers 30 mL.

BOND Titration Kit

FORMAT	CODE	USAGE	STATUS
10 Titration Containers and 50 Titration Container Inserts	OPT9049	-	IVD

PRODUCT DESCRIPTION

The BOND Titration Kit contains BOND Titration Container Inserts and BOND Titration Containers. The kit allows users to optimize primary antibody concentrates on the BOND system. The kits can be re-used for different antibodies and are designed with minimal dead volume to preserve reagent.

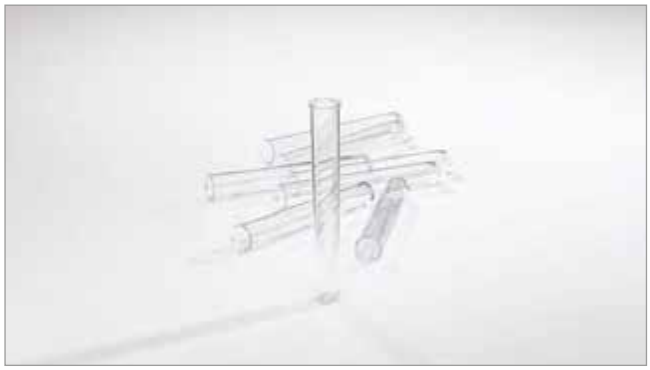
BOND Titration Kit.

BOND Titration Container Inserts

FORMAT	CODE	USAGE	STATUS
50 Pack	OPT9719	-	IVD

PRODUCT DESCRIPTION

BOND Titration Container Inserts are tubes that fit directly into the BOND Titration Containers. They enable use of up to 40 mL of reagent per titration container.



BOND Titration Container Inserts.

BOND Slide Label and Print Ribbon Kit

FORMAT	CODE	USAGE	STATUS
1 Pack, 3000 Labels	S21.4564	Zebra	IVD
1 Pack, 3000 Labels	S21.4604	Cognitive	IVD
6 Pack, 18000 Labels	S21.4610	Cognitive	IVD

PRODUCT DESCRIPTION

The BOND Slide Label and Print Ribbon Kit produces high-quality, solvent-resistant slide labels for use on the BOND system. This assists in preserving the integrity of slide identification and patient data records on BOND slides. The BOND Universal Slide labels adhere to slides for easy and secure identification.

BOND Slide Label and Print Ribbon Kit.

BOND Reagent Tray

FORMAT	CODE	USAGE	STATUS
1 Tray	S21.1003	-	-

PRODUCT DESCRIPTION

Additional BOND Reagent Trays let laboratories setup reagents for upcoming runs while other reagent trays are in use. This reduces setup delays and improves laboratory workflow.

BOND Reagent Tray.

BOND Slide Tray

FORMAT	CODE	USAGE	STATUS
1 Tray	S21.4586	-	-

PRODUCT DESCRIPTION

The BOND slide tray offers keying cues to improve usability and Covertile placement. Additional BOND Slide Trays to allow laboratories to prepare slides while other trays are running. This reduces setup delays and improves laboratory workflow. This tray can be used with all BOND Covertiles.

BOND Slide Tray.

BOND Syringe (for 9-Port Pump)

FORMAT	CODE	USAGE	STATUS
1 Syringe	S21.2131	-	-
4 Syringes	S21.4565	P	-

PRODUCT DESCRIPTION

The BOND Syringe precisely measures reagent volumes to be dispensed onto the slides. The syringe must be replaced at regular intervals as prompted by the software or if problems are found during scheduled fluidics checks. This part is for BOND-MAX instruments with a 9-Port valve.

BOND Syringe.

BOND Plus Slides

FORMAT	CODE	USAGE	STATUS
20 Boxes x 72 Slides/Box	S21.2113	P	IVD

PRODUCT DESCRIPTION

BOND Plus Slides are positively charged glass microscopic slides designed for use on the BOND system. They include defined margins to enable the accurate placement of tissue for staining in the 100 µL and the 150 µL dispense modes, which helps in maintaining the integrity of staining quality.

BOND Plus Slides.

BOND Covertile Cleaning Rack

FORMAT	CODE	USAGE	STATUS
1 Rack	S21.4588	-	-

PRODUCT DESCRIPTION

The BOND Covertile Cleaning Rack makes Covertile cleaning even easier. It is easy to load, securely locks the Covertiles in place, and sits either vertically or horizontally.

BOND Covertile Cleaning Rack.

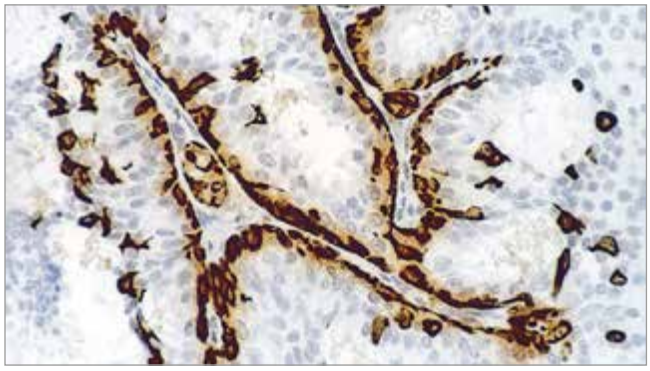
MANUAL

Novolink Max Polymer Detection System

FORMAT	CODE	USAGE	STATUS
1250 Tests	RE7280-K	P	IVD

PRODUCT DESCRIPTION

The Novolink Polymer Detection Systems utilize a novel Compact Polymer technology. Therefore, the problem of non-specific staining that can occur with Streptavidin/Biotin detection systems due to endogenous biotin does not occur. Novolink Polymer Detection Systems contain pre-diluted, reagents in color coded bottles for ease of use and ultimate convenience. These systems can be used for the visualization of mouse IgG, mouse IgM and rabbit IgG primary antibodies. These detection systems contain Peroxidase Block, Protein Block, Post Primary Block, Novolink Polymer, DAB Chromogen, Novolink DAB Substrate Buffer (Polymer) and Hematoxylin.



Novolink Polymer Detection System (RE7150-K) staining for Cytokeratin 5 with NCL-L-CK5 on breast carcinoma. Paraffin section.

Novolink Polymer Detection System

FORMAT	CODE	USAGE	STATUS
250 Tests	RE7140-K	P	IVD
500 Tests	RE7150-K	P	IVD

PRODUCT DESCRIPTION

The Novolink Polymer Detection Systems utilize a novel Compact Polymer technology. Therefore, the problem of non-specific staining that can occur with Streptavidin/Biotin detection systems due to endogenous biotin does not occur. Novolink Polymer Detection Systems contain pre-diluted, reagents in color coded bottles for ease of use and ultimate convenience. These systems can be used for the visualization of mouse IgG, mouse IgM and rabbit IgG primary antibodies. These detection systems contain Peroxidase Block, Protein Block, Post Primary Block, Novolink Polymer, DAB Chromogen, Novolink DAB Substrate Buffer (Polymer) and Hematoxylin.

Novolink Min Polymer Detection System

FORMAT	CODE	USAGE	STATUS
50 Tests	RE7290-K	P	IVD

PRODUCT DESCRIPTION

The Novolink Polymer Detection Systems utilize a novel Compact Polymer technology. Therefore, the problem of non-specific staining that can occur with Streptavidin/Biotin detection systems due to endogenous biotin does not occur. Novolink Polymer Detection Systems contain pre-diluted, reagents in color coded bottles for ease of use and ultimate convenience. These systems can be used for the visualization of mouse IgG, mouse IgM and rabbit IgG primary antibodies. These detection systems contain Peroxidase Block, Protein Block, Post Primary Block, Novolink Polymer, DAB Chromogen, Novolink DAB Substrate Buffer (Polymer) and Hematoxylin.

Peroxidase Block

FORMAT	CODE	USAGE	STATUS
25 mL	RE7101	P	IVD

PRODUCT DESCRIPTION

Novocastra Peroxidase Block, RE7101, is intended for use in the peroxidase based immunohistochemical (IHC) staining procedures. The presence of pseudoperoxidase (erythrocytes) and endogenous peroxidase in paraffin sections to be stained by immunoperoxidase procedures, can result in nonspecific staining. A method for the blocking of pseudoperoxidase was described (StreefkerkJG, Journal of Histochemistry and Cytochemistry. 20: 829 (1972)). This product is used in a peroxidase based IHC procedure. Incubating sections with Novocastra Peroxidase Block, RE7101, can neutralize endogenous peroxidase activity. 25 mL of reagent is supplied.

Protein Block

FORMAT	CODE	USAGE	STATUS
25 mL	RE7102	P	IVD

PRODUCT DESCRIPTION

Novocastra Protein Block, RE7102, is intended for use in immunohistochemical (IHC) staining procedures. In immunohistochemistry, diffuse non-specific staining (background) may occur as a result of hydrophobic and ionic interactions between antibodies and tissue components. Novocastra Protein Block, RE7102, is a serum-free, protein blocker. 25 mL of reagent is supplied.

Novolink Max Polymer

FORMAT	CODE	USAGE	STATUS
1250 Tests	RE7260-K	P	IVD

PRODUCT DESCRIPTION

Novolink (Polymer), RE7200-K, is a two part ready-to-use kit comprising 25 mL of Novocastra Post Primary Block, RE7111, and 25 mL of Novolink Polymer, RE7112, sufficient to perform approximately 250 tests. The larger format Novolink Max (Polymer), RE7260-K, is a two-part ready-to-use kit comprising 125 mL of Novocastra Post Primary Block, RE7159, and 125 mL of Novolink Polymer, RE7161, sufficient to perform approximately 1250 tests.

Novolink Polymer

FORMAT	CODE	USAGE	STATUS
250 Tests	RE7200-K	P	IVD

PRODUCT DESCRIPTION

Novolink (Polymer), RE7200-K, is a two part ready-to-use kit comprising 25 mL of Novocastra Post Primary Block, RE7111, and 25 mL of Novolink Polymer, RE7112, sufficient to perform approximately 250 tests. The larger format Novolink Max (Polymer), RE7260-K, is a two-part ready-to-use kit comprising 125 mL of Novocastra Post Primary Block, RE7159, and 125 mL of Novolink Polymer, RE7161, sufficient to perform approximately 1250 tests.

Novolink Max DAB (Polymer)

FORMAT	CODE	USAGE	STATUS
1250 Tests	RE7270-K	P	IVD

PRODUCT DESCRIPTION

Novolink Max DAB (Polymer) RE7270-K is a two part DAB kit comprising 150 mL of Novolink Substrate Buffer (Polymer), RE7163, and 8 mL of Novocastra DAB Chromogen, RE7162, sufficient to perform approximately 1250 tests. Novolink DAB (Polymer), RE7230-K, is a two part DAB kit comprising 30 mL of Novolink DAB Substrate Buffer, RE7143, and 3 mL of Novocastra DAB Chromogen, RE7105, sufficient to perform approximately 250 tests.

Novolink DAB (Polymer)

FORMAT	CODE	USAGE	STATUS
250 Tests	RE7230-K	P	IVD

PRODUCT DESCRIPTION

Novolink Max DAB (Polymer) RE7270-K is a two part DAB kit comprising 150 mL of Novolink Substrate Buffer (Polymer), RE7163, and 8 mL of Novocastra DAB Chromogen, RE7162, sufficient to perform approximately 1250 tests. Novolink DAB (Polymer), RE7230-K, is a two part DAB kit comprising 30 mL of Novolink DAB Substrate Buffer, RE7143, and 3 mL of Novocastra DAB Chromogen, RE7105, sufficient to perform approximately 250 tests.

Hematoxylin

FORMAT	CODE	USAGE	STATUS
25 mL	RE7107	P	IVD

PRODUCT DESCRIPTION

Novocastra Hematoxylin, RE7107, is intended for use in immunohistochemical (IHC) staining procedures. Hematoxylin stains cell nuclei and has many uses in histology, the most common of which is the Hematoxylin and Eosin stain. In IHC procedures, hematoxylin can be used as a counterstain to aid the visualization and localization of the colored end product. 25 mL of the reagent is supplied.

Peroxidase Detection Systems (Ready-To-Use)

FORMAT	CODE	USAGE	STATUS
250 Tests	RE7110-K	P	IVD
500 Tests	RE7120-K	P	IVD

PRODUCT DESCRIPTION

Novocastra Peroxidase Detection Systems (250 tests), RE7110-K, and (500 tests), RE7120-K, are for the visualization of mouse IgG, mouse IgM and rabbit IgG primary antibodies. Each detection system contains Novocastra Peroxidase Block, RE7101, Novocastra Protein Block, RE7102, Novocastra Biotinylated Secondary Antibody, RE7103, Novocastra Streptavidin-HRP, RE7104, Novocastra DAB Chromogen, RE7105, Novocastra DAB Substrate Buffer, RE7106, and Novocastra Hematoxylin, RE7107.
The components in these kits are pre-diluted, ready-to-use reagents in color coded bottles for ease of use and ultimate convenience.

Streptavidin-HRP

FORMAT	CODE	USAGE	STATUS
25 mL	RE7104	P	IVD

PRODUCT DESCRIPTION

Streptavidin-HRP is a streptavidin-conjugated horseradish peroxidase reagent. It is supplied ready-to-use in a volume of 25 mL.

Avidin/Biotin Blocking System

FORMAT	CODE	USAGE	STATUS
2 x 18 mL	RE7170-K	F P W	RUO

PRODUCT DESCRIPTION

Some tissues may bind avidin, biotinylated horseradish peroxidase, biotinylated alkaline phosphatase or other Biotin/Avidin System components without prior addition of biotinylated antibody. This binding may be due to endogenous biotin or biotin-binding proteins, lectins or non-specific binding substances present in the section. If high background is present using Avidin Biotin Complex (ABC) reagents, or other avidin conjugates in the absence of biotinylated secondary antibody, the use of the Novocastra Avidin/Biotin Blocking System RE7170-K may be of benefit. 18 mL of each reagent is supplied.

Antibody Diluent

FORMAT	CODE	USAGE	STATUS
500 mL	RE7133	F P O	IVD

PRODUCT DESCRIPTION

Novocastra IHC Diluent is intended for use as a diluent for Novocastra primary antibodies, Novocastra Concentrated Biotinylated Secondary Antibody, RE7108, and Novocastra Concentrated Streptavidin-HRP, RE7109, in immunohistochemical (IHC) procedures. Novocastra IHC Diluent is not intended for the reconstitution of lyophilized reagents.

Enzyme Proteinase K (IHC)

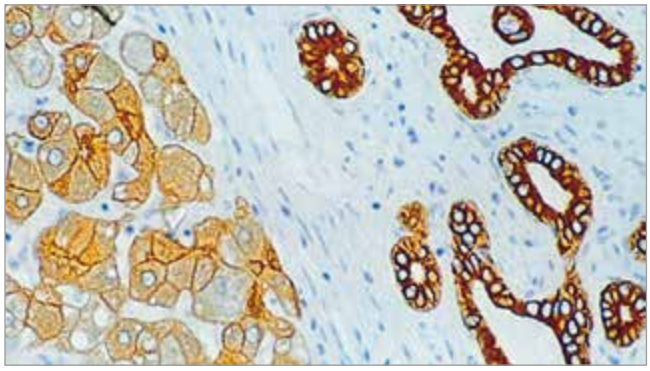
FORMAT	CODE	USAGE	STATUS
100 mL	RE7160-K	P (Enzyme)	IVD

PRODUCT DESCRIPTION

Enzyme pretreatment of formalin-fixed, paraffin-embedded tissue sections improves the staining of some antibodies by exposing epitopes within tissue that have been masked during fixation. The first proteolytic enzyme employed for epitope retrieval was trypsin. More recently, proteinase K which is commonly used in *in situ* hybridization techniques has been reported to be of use.

PRODUCT SPECIFIC INFORMATION

Novocastra Enzyme Proteinase K (IHC), RE7160-K, is intended for the enzymatic pretreatment of formalin-fixed, paraffin-embedded tissue sections prior to incubation with a primary antibody in an immunohistochemical (IHC) procedure. This product can be used for epitope retrieval with Novocastra antibodies for which trypsin is recommended, known exception to this is NCL-CYCLIN D1-GM. This two part kit comprises 0.75 mL of Enzyme Proteinase K Concentrate, RE7126, and 100 mL of Enzyme Proteinase K Buffer, RE7127, sufficient to produce 100 mL of working strength enzyme solution. This product is used in an IHC procedure, which allows the qualitative identification by light microscopy. Epitope retrieval by enzymatic pretreatment is recommended for a limited number of antibodies. Optimum conditions for epitope retrieval should be validated by the user as these are dependent upon tissue, fixation and/or primary antibody.



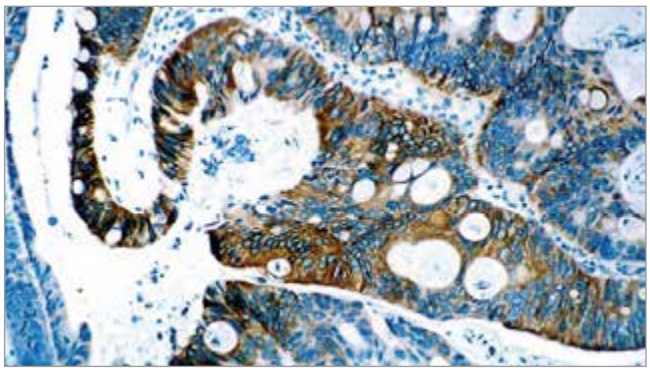
Liver pre-treated with Enzyme Proteinase K (RE7160-K). Staining for Cytokeratin 8/18 using NCL-L-5D3. Paraffin section.

Epitope Retrieval Solutions pH6

FORMAT	CODE	USAGE	STATUS
1 L pH6 (x10 Concentrate)	RE7113	P (HIER)	IVD

PRODUCT DESCRIPTION

Novocastra Epitope Retrieval Solutions are intended for Heat Induced Epitope Retrieval (HIER) on formalin-fixed, paraffin-embedded tissue sections as part of an immunohistochemical procedure. HIER using an appropriate pH solution improves the staining of some antibodies by exposing epitopes within tissue that has been masked during fixation. The development of Epitope Retrieval using heat was first reported in 1991 by Shi S-R et al. , Journal of Histochemistry and Cytochemistry 39: 741-748 (1991). Since then numerous studies have been published looking at the effects of molarity, pH and heating methods on epitope retrieval. A universal HIER technique suitable for all epitopes does not exist. A combination of different heating methods and epitope retrieval solutions may be used to optimize unmasking of antigens where this technique is recommended. HIER is not recommended for all antibodies. Optimum conditions for epitope retrieval should be validated by the user, as these are dependent upon tissue, fixation and/or primary antibody.
RE7113 is supplied as a 1 L volume, sufficient to prepare
10 L of working solution.



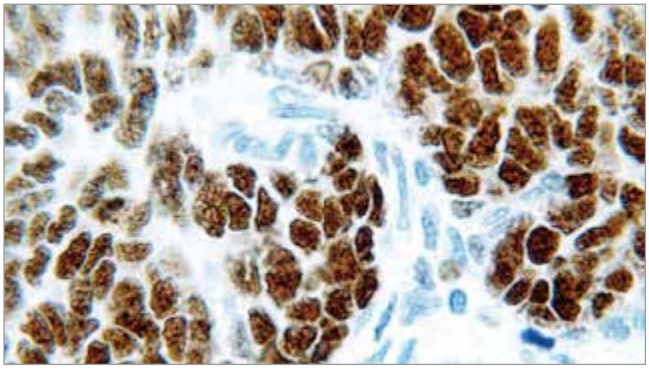
Colonic adenocarcinoma pre-treated with Epitope Retrieval Solution pH6 (RE7113). Staining for Cytokeratin 20 protein using NCL-L-CK20-561. Paraffin section.

Epitope Retrieval Solutions pH9

FORMAT	CODE	USAGE	STATUS
1 L pH9 (x10 Concentrate)	RE7119	P (HIER)	IVD

PRODUCT DESCRIPTION

Novocastra Epitope Retrieval Solutions are intended for Heat Induced Epitope Retrieval (HIER) on formalin-fixed, paraffin-embedded tissue sections as part of an immunohistochemical procedure. HIER using an appropriate pH solution improves the staining of some antibodies by exposing epitopes within tissue that has been masked during fixation. The development of Epitope Retrieval using heat was first reported in 1991 by Shi S-R et al. Journal of Histochemistry and Cytochemistry 39: 741-748 (1991). Since then numerous studies have been published looking at the effects of molarity, pH and heating methods on epitope retrieval. A universal HIER technique suitable for all epitopes does not exist. A combination of different heating methods and epitope retrieval solutions may be used to optimize unmasking of antigens where this technique is recommended. HIER is not recommended for all antibodies. Optimum conditions for epitope retrieval should be validated by the user, as these are dependent upon tissue, fixation and/or primary antibody. RE7119 is supplied as a 1 L volume, sufficient to prepare 10 L of working solution.



Kidney pre-treated with Epitope Retrieval Solution pH9 (RE7119). Staining for Wilms' Tumor protein using NCL-L-WT1-562. Paraffin section.

Manual Ancillaries - Molecular

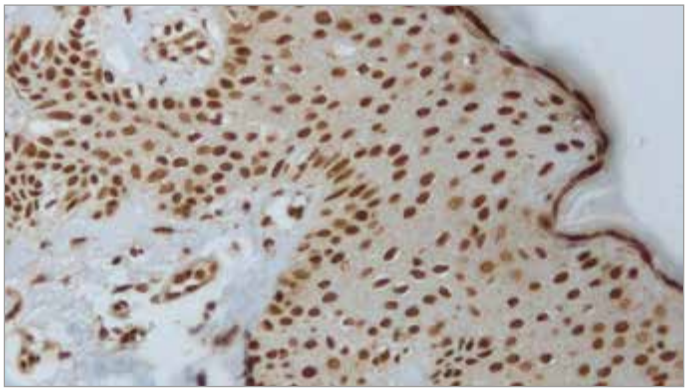
PRODUCT NAME	PRODUCT CODE	CONTENT	CONCENTRATION	CLASSIFICATION
Whole Chromosome Buffer (WCB)	KBI-WCB	10 Test	RTU	GPR
Whole Chromosome Buffer (WCB)	KI-WCB	10 Test	RTU	GPR
Tissue Digestion Kit I	KBI-60007	Kit	-	IVD
Tissue Digestion Kit I	KI-60007	Kit	-	RUO
Tissue Digestion Kit II	KBI-60004	Kit	-	IVD
Tissue Digestion Kit II	KI-60004	Kit	-	RUO
FISH Reagent Kit	KBI-60005	Kit	-	IVD
FISH Reagent Kit	KI-60005	Kit	-	RUO
FISH Digestion Kit	KBI-60006	Kit	-	IVD
FISH Digestion Kit	KI-60006	Kit	-	RUO
KREAvital Prenatal Medium (Basal)	KBI-90010	90 mL	RTU	IVD
KREAvital Prenatal Medium (Supplement)	KBI-90011	10 mL	RTU	IVD
KREAvital Prenatal Medium (Complete)	KBI-90012	100 mL	RTU	IVD
KREAvital Prenatal Medium PLUS (Complete)	KBI-90013	100 mL	RTU	IVD
KREAvital Lymphocyte Karyotyping Medium (without PHA)	KBI-90020	100 mL	RTU	IVD
KREAvital Lymphocyte Karyotyping Medium (including PHA)	KBI-90021	5 mL	RTU	IVD
KREAvital Bone Marrow Karyotyping Medium	KBI-90030	100 mL	RTU	IVD
KREAvital Myeloid Cell Medium	KBI-90031	100 mL	RTU	IVD
Colchicine Solution (10µg/ mL, in PBS)	KBI-90050	25 mL	RTU	IVD
Colcemid Solution (10µg/ mL, in PBS)	KBI-90051	10 mL	RTU	IVD
Potassium Chloride (0. 075M)	KBI-90052	100 mL	RTU	IVD
Sodium Citrate Solution (0. 8%)	KBI-90054	500 mL	RTU	IVD
Phytohaemagglutinin liquid	KBI-90056	5 mL	RTU	IVD
KREAvital Prenatal Medium (Complete)	KBI-92012	500 mL	RTU	IVD
KREAvital Lymphocyte Karyotyping Medium (without PHA)	KBI-92020	500 mL	RTU	IVD
Trypsin EDTA 10X (EDTA 0. 2%, Trypsin 0. 5%, in saline solution)	KBI-92055	100 mL	RTU	IVD
Fixogum Rubber Cement	LK-071A	125 gr	-	GPR
Pretreatment Solution B	LK-100C	1 L	-	GPR
Wash Buffer V (10x)	LK-141B	250 mL	-	GPR
Wash Buffer V (10x)	LK-141C	1 L	-	GPR
Wash Buffer II	LK-103A	100 mL	-	GPR
Wash Buffer I	LK-102A	100 mL	-	GPR
Pepsin Solution	LK-101A	2. 5 mL	RTU	GPR
Counterstain Diluent (antifade)	LK-097A	1 mL	-	GPR
DAPI Counterstain (1 µg/ mL)	LK-096A	1 mL	-	GPR
DAPI Counterstain (0. 1 µg/ mL)	LK-095A	1 mL	-	GPR
Paraffin Tissue Buffer (PTB)	KBI-PTB	10 Test	RTU	GPR
Paraffin Tissue Buffer (PTB)	KI-PTB	10 Test	RTU	GPR
FISH Hybridization Buffer (FHB)	KBI-FHB	10 Test	RTU	GPR
FISH Hybridization Buffer (FHB)	KI-FHB	10 Test	RTU	GPR

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use RUO For Research Use Only. Not for use in diagnostic procedures ASR Analyte Specific Reagent GPR General Purpose Reagent

ANTIBODIES

ANTIBODIES

Akt (Phosphorylated)



Human skin: immunohistochemical staining for Phosphorylated Akt.
Akt (Phosphorylated): clone LP18

LP18

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-Akt-Phos	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

SPECIALIZED

ANTIGEN BACKGROUND

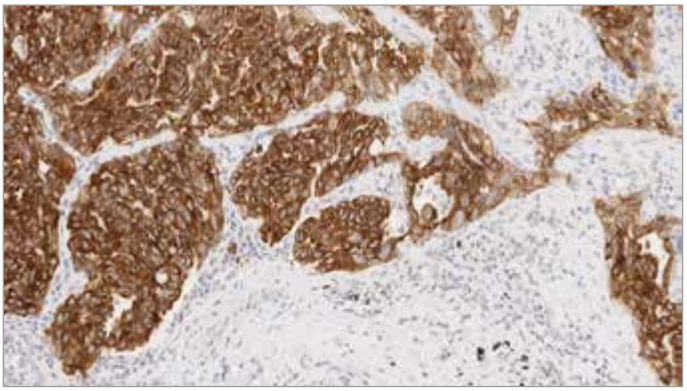
Akt-1, also referred to as protein kinase B (PKB) or Rac alpha is a member of the Akt serin/threonine protein kinase family. It plays an important role in many biological responses including metabolism, cell survival and growth by phosphorylation and inactivating several targets including GSK 3 beta, caspase 9, BAD and the forkhead transcription factor.

Akt (Phosphorylated) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Akt-Phos is not recommended for use with PBS, since the use of PBS-based wash buffers and possibly PBS-based antibody diluents gives increased background staining and decreased staining intensity. Proprietary reagents from Leica Biosystems or TBS-based wash buffer and diluents are recommended.

ALK



Non-small cell lung cancer: immunohistochemical staining for ALK. ALK: clone 5A4

5A4

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0831	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

LUNG PATHOLOGY

5A4

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0306	P(HIER)	IVD	IVD	IVD
Liquid 0.5 mL	NCL-L-ALK	P(HIER)	IVD	IVD/RUO	IVD/RUO

PATHOLOGY MENU

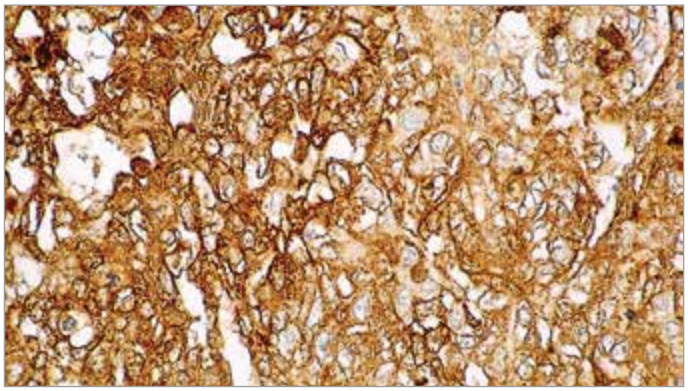
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

Anaplastic large cell lymphoma (ALCL) is usually composed of large pleomorphic cells which are reported to express CD30 antigen and epithelial membrane antigen (EMA). These tumor cells tend to occur in younger individuals and may be associated with cutaneous and extranodal involvement. A proportion of these cases contain a chromosomal translocation t(2;5) (p23;q35). This results in a hybrid gene encoding part of the nucleophosmin (NPM) gene joined to the cytoplasmic domain of the anaplastic lymphoma kinase (ALK) gene, giving rise to the protein, p80. Large cell lymphomas account for approximately 25% of all non-Hodgkin's lymphomas in children and young adults, of which one third carry the NPM-ALK gene translocation.

ALK is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Alpha Fetoprotein



Human fetal liver: immunohistochemical staining for Alpha Fetoprotein.
Alpha Fetoprotein: clone C3

C3

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0963	P	IVD	IVD	IVD
Liquid 1 mL	NCL-L-AFP	P	IVD	IVD	IVD

PATHOLOGY MENU

GYNEPATHOLOGY

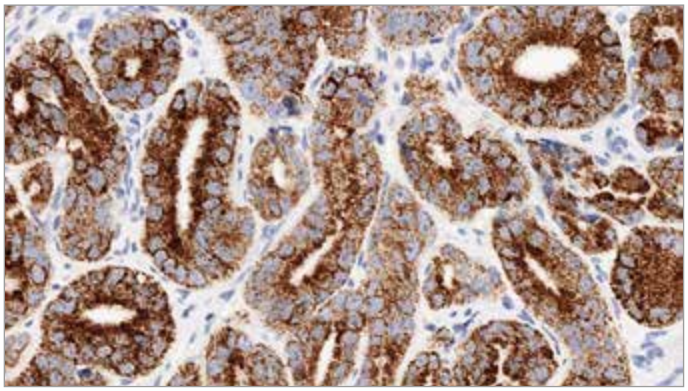
ANTIGEN BACKGROUND

Alpha fetoprotein (AFP) is an oncofetal antigen of 70 kD found in body fluids, which if detected in high concentrations has clinical implications.

AFP is expressed in fetal liver but is not present under normal circumstances in healthy adult tissues. It is reported to be expressed in a proportion of germ cell tumors, with high frequency in yolk sac tumors.

Alpha Fetoprotein is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Alpha-Methylacyl-CoA Racemase (AMACR, p504s)



Human prostatic adenocarcinoma: immunohistochemical staining for AMACR.
AMACR: clone EPMU1

EPMU1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0210	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-AMACR	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

UROPATHOLOGY

ANTIGEN BACKGROUND

Alpha-methylacyl-CoA racemase (AMACR), also known as p504s, is a mitochondrial and peroxisomal enzyme that is involved in bile acid biosynthesis and beta-oxidation of branched-chain fatty acids. AMACR is essential in lipid metabolism, and is expressed in normal liver (hepatocytes), kidney (tubular epithelial cells) and gall bladder (epithelial cells). Expression has also been found in lung (bronchial epithelial cells) and colon (colonic surface epithelium). Expression is granular and cytoplasmic. AMACR expression can also be found in hepatocellular carcinoma and kidney carcinoma. Past studies have also shown that AMACR is expressed in various colon carcinomas (well, moderately and poorly differentiated) and over expressed in prostate carcinoma.

Alpha-Methylacyl-CoA Racemase (AMACR, p504s) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Alpha-Synuclein

Human brain, Lewy body dementia: immunohistochemical staining for alpha-synuclein. Note staining of alpha-synuclein-containing Lewy bodies. Alpha-Synuclein: clone KM51

KM51

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-ASYN	P(HIER)	RUO	RUO	RUO

PATHOLOGY MENU

NEUROPATHOLOGY

ANTIGEN BACKGROUND

Alpha-synuclein is a protein of 140 amino acids and a member of the synuclein family. It shares 61% sequence homology with beta-synuclein and is highly conserved between vertebrate species. It does not possess a signal sequence suggesting that it is an intracellular protein. All synucleins have an unusual organization based around the eleven residue repeating motif and an alpha-helical secondary structure resembling those found in the lipid-binding domain of exchangeable apolipoproteins, including Apo E. This homology suggests a direct interaction of alpha-synuclein with membranes consistent with its affinity for synaptosomes.

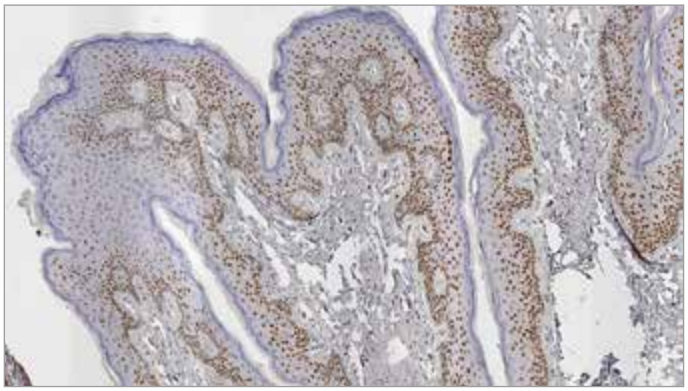
The function of alpha-synuclein may be to carry a target protein to the inner membrane of nerve terminals or to the outer surface of synaptic vesicles. Western Blot analyses of highly purified Lewy bodies from Lewy body dementia brain material has shown full-length, partially truncated and insoluble aggregates of alpha-synuclein.

Alpha-synuclein may be implicated in the formation of Lewy bodies and the selective degeneration of neurons in sporadic Parkinson's disease and Lewy body dementia.

PRODUCT SPECIFIC INFORMATION

Clone KM51 is specific for alpha-synuclein and is unreactive with beta-synuclein. Pretreatment of tissue sections with 98-100% formic acid is also recommended.

Androgen Receptor



Human skin: immunohistochemical staining for Androgen Receptor. Note the nuclear staining of the epithelial cells. Androgen Receptor: clone AR27

AR27

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-AR-318	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

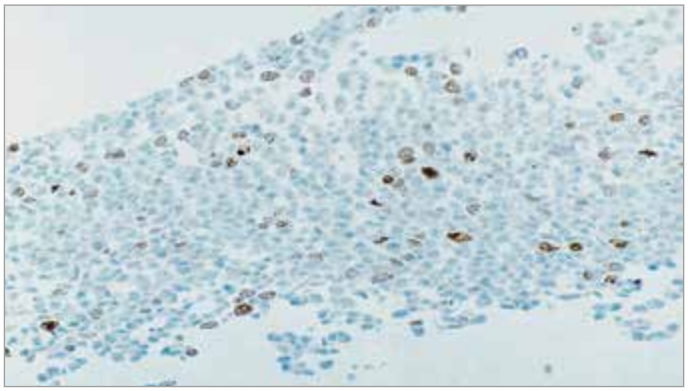
UROPATHOLOGY

ANTIGEN BACKGROUND

Androgen receptor is a member of the superfamily of ligand responsive transcription regulators. The androgen receptor functions in the nucleus where it is believed to act as a transcriptional regulator mediating the action of male sex hormones (androgens). The androgen receptor has wide distribution and can be demonstrated by immunohistochemistry in several tissues e.g. prostate, skin, and oral mucosa. Androgen receptor has been reported in a diverse range of human tumors eg osteosarcoma, and in prostatic carcinoma androgen receptor expression may be of clinical relevance. Furthermore, mutation of the gene encoding androgen receptor has been reported in prostatic carcinoma.

Androgen Receptor is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Aurora Kinase 2



HeLa cell line: immunohistochemical staining for Aurora Kinase. Note nuclear staining of a proportion of cells. Aurora Kinase 2: clone JLM28

JLM28

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-AK2	-	ASR	RUO	RUO

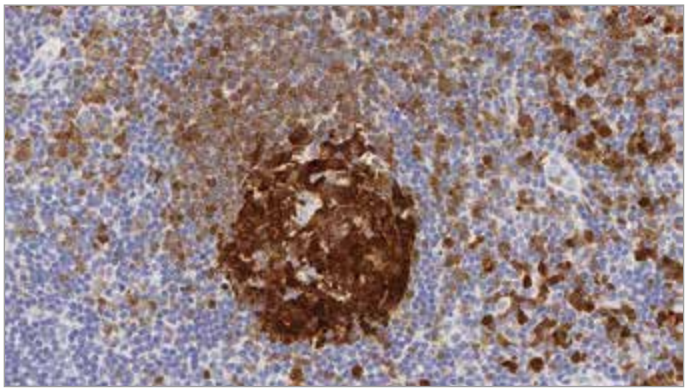
PATHOLOGY MENU

SPECIALIZED

ANALYTE SPECIFIC REAGENT

Analyte Specific Reagent. Analytical and performance characteristics are not established.

B Cell Specific Octamer Binding Protein-1 (BOB-1)



Human tonsil: Immunohistochemical staining for BOB-1. Note nuclear and cytoplasmic staining of B cells with BOB-1: clone TG14

TG14

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0558	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-BOB-1	-	ASR	RUO	RUO

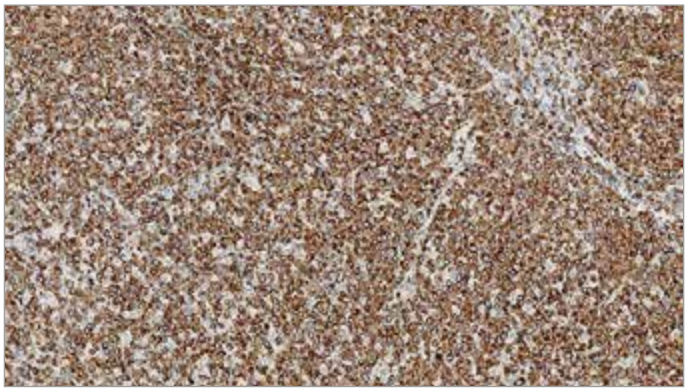
PATHOLOGY MENU

HEMATOPATHOLOGY

ANALYTE SPECIFIC REAGENT

Analyte Specific Reagent. Analytical and performance characteristics are not established.

Bcl-2 Oncoprotein



Human follicular lymphoma: immunohistochemical staining for Bcl-2. Bcl-2: clone bcl-2/100/D5

bcl-2/100/D5

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0117	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-bcl-2	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

HEMATOPATHOLOGY

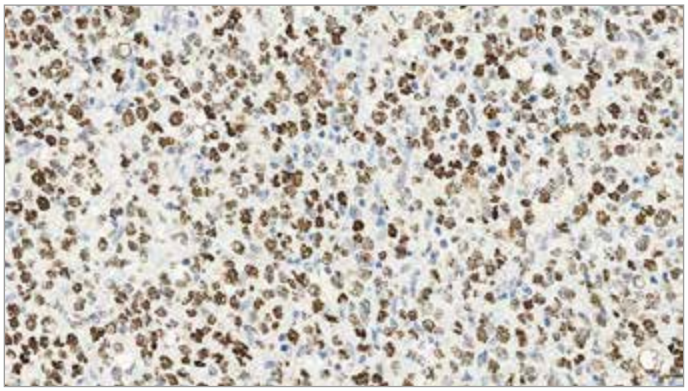
ANTIGEN BACKGROUND

Bcl-2 is a member of a family of proteins that are involved in apoptosis. Bcl-2 is an integral inner mitochondrial membrane protein of 25 kD and has a wide tissue distribution. It is considered to act as an inhibitor of apoptosis. For this reason, bcl-2 expression is inhibited in germinal centers where apoptosis forms part of the B cell production pathway.

In 90% of follicular lymphomas a translocation occurs which juxtaposes the bcl-2 gene at 18q21, to an immunoglobulin gene. This t(14;18) translocation can deregulate gene expression and bcl-2 over-expression can be demonstrated immunohistochemically in the vast majority of follicular lymphomas.

Bcl-2 Oncoprotein is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Bcl-6 Oncoprotein



Human diffuse large B cell lymphoma: immunohistochemical staining for Bcl-6. Bcl-6: clone LN22

LN22

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0204	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-Bcl-6-564	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

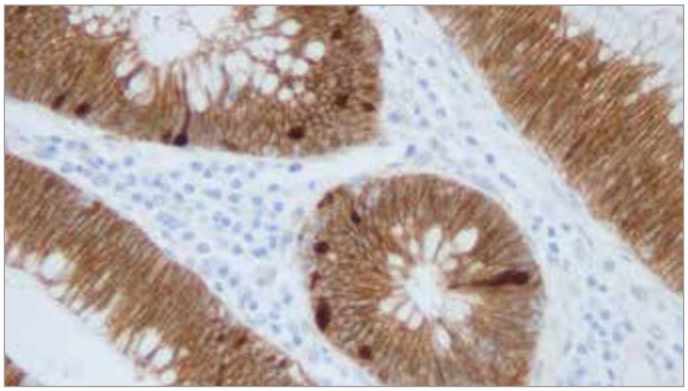
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

Bcl-6 is a proto-oncogene that encodes a Kruppel-type zinc-finger protein of 95 kD and shares homology with other transcription factors. Bcl-6 protein is mainly expressed in normal germinal center B cells and related lymphomas. It has been shown that the Bcl-6 proto-oncogene is involved in chromosome rearrangements at 3q27 in non-Hodgkin's lymphomas and Bcl-6 rearrangements have also been detected in 33-45% of diffuse large B cell lymphomas. Immunohistochemistry has been reported to show the Bcl-6 gene product to be detectable in follicular lymphomas, diffuse large B cell lymphomas, Burkitt's lymphomas and in nodular, lymphocyte predominant Hodgkin's disease.

Bcl-6 Oncoprotein is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Beta-Catenin



Human colon polyp: immunohistochemical staining for Beta-Catenin. Note the abnormal translocation of the protein to the nucleus. Beta-Catenin: clone 17C2

17C2

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0083	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-B-CAT	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

SOFT TISSUE PATHOLOGY

ANTIGEN BACKGROUND

The catenins, (alpha, beta and gamma) are cytoplasmic proteins which bind to the highly conserved tail of the E-cadherin molecule. Beta-catenin is a component of the adherens junction, a multiprotein complex which supports Ca^{2+} -dependent cell-to-cell contact, which in itself is critical for adhesion, signal transmission and for anchoring the actin cytoskeleton. Beta-catenin's role is as a transcription effector of the wnt-signaling pathway. Immunohistochemistry is the best way to demonstrate nuclear expression of beta-catenin and wnt-pathway activation. This aberrant expression is observed in human tumorigenesis, and especially in colorectal cancer.

Beta-Catenin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Beta-Dystroglycan

Human skeletal muscle: immunohistochemical staining on a frozen longitudinal section. Staining is localized in the sarcolemma of the fibers. Beta-Dystroglycan: clone 43DAG1/8D5

43DAG1/8D5

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-b-DG	F	IVD	IVD	IVD

PATHOLOGY MENU

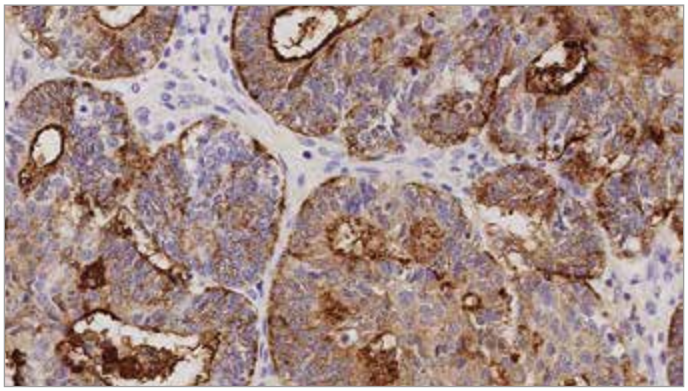
MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

Dystrophin associated glycoproteins (DAGs) are involved in the attachment of dystrophin to muscle membranes. The biological significance of this dystrophin/glycoprotein complex is not fully understood, but it appears to form an essential linkage between actin on the inside of the muscle fiber and muscle laminin in the basal lamina which surrounds the fiber. Beta-dystroglycan spans the sarcolemma and it has been suggested that it is the member of the complex which binds directly to dystrophin.

Beta-Dystroglycan is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CA125 (Ovarian Cancer Antigen)



Human adenocarcinoma of endometrium: immunohistochemical staining on CA125.
CA125: clone Ov185:1

Ov185:1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0539	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CA125	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

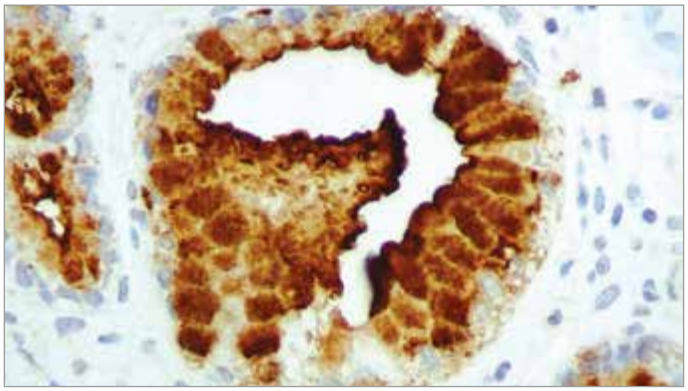
GYNEPATHOLOGY

ANTIGEN BACKGROUND

CA125 antigen is usually associated with ovarian epithelial malignancies. Serum assays are widely used to detect this protein in the monitoring of ovarian cancers. CA125 antigen may also be detected by immunohistochemistry and expression has been found in neoplasms such as seminal vesicle carcinoma and anaplastic lymphoma. CA125 antigen is not found exclusively in malignant tumors. CA125 is also known as MUC16.

CA125 (Ovarian Cancer Antigen) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CA19-9 (Sialyl Lewis [a])



Colonic adenocarcinoma: immunohistochemical staining for Sialyl Lewis [a] antigen.
CA19-9: clone C241:5:1:4

C241:5:1:4

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0424	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CA19-9	P(HIER)	RUO	RUO	RUO

PATHOLOGY MENU

GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

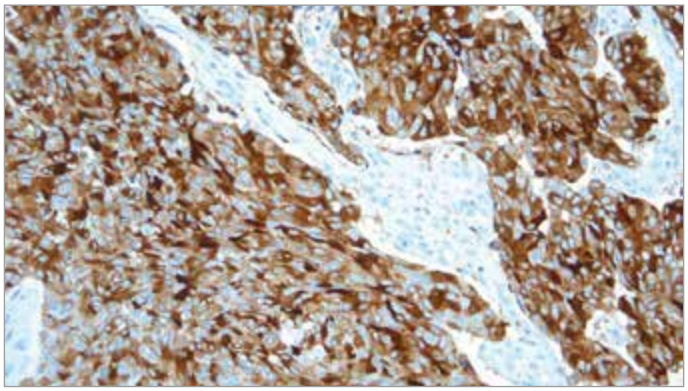
CA19-9 is an epitope on the sialylated Lewisa carbohydrate structure. Sialylated Lewisa plays a role in cell adhesion by acting as a functional ligand for the inducible adhesion molecule E-selectin. In carcinoma of the pancreas, it is reported that the immunohistochemical expression of both CA19-9 and CA50 correlates with tumor differentiation, where the strongest staining is observed in well-differentiated tumors. These two markers are also reported in a number of benign lesions such as chronic pancreatitis.

CA19-9 (Sialyl Lewis a) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Clone C241:5:1:4 reacts specifically with Sialyl Lewis a - containing glycolipids, showing no crossreaction with Lewis a, Lewis b, or other structurally related molecules. The epitope recognized by NCL-L-CA19-9 is designated CA19-9.

Calcitonin



Human medullary thyroid carcinoma: immunohistochemical staining for Calcitonin.
Calcitonin: clone CL1948

CL1948

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CALCITONIN	P(ENZYME)	IVD	IVD	IVD

Polyclonal

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0406	P(ENZYME)	IVD	IVD	IVD

PATHOLOGY MENU

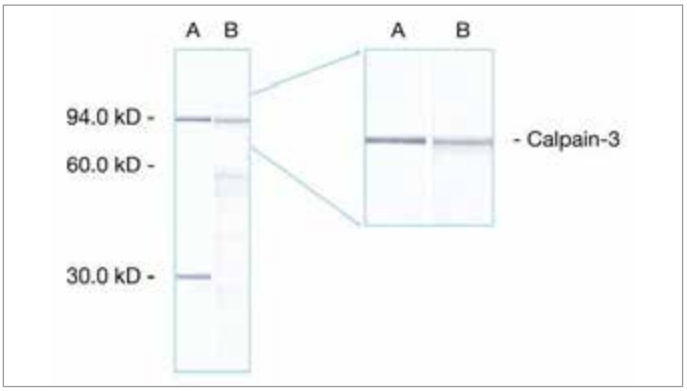
HEAD, NECK AND ENDOCRINE

ANTIGEN BACKGROUND

Calcitonin (CT) is a 32 amino acid peptide synthesized by the parafollicular C cells of the thyroid. It acts through its receptors to inhibit osteoclast mediated bone resorption, decrease calcium resorption by the kidney and decrease calcium absorption by the intestines. The action of calcitonin is therefore to cause a reduction in serum calcium, an effect opposite to that of parathyroid hormone. The calcitonin gene transcript also encodes the calcitonin gene-related peptide (CGRP), which is thought to be a potent vasodilator. The tissue specificity of the transcript produced depends on alternative splicing of the CT/CGRP gene transcript. In the parafollicular cells of the thyroid 95% of the CT/CGRP is processed and translated to produce CT, however, in neuronal cells 99% of the CT/CGRP RNA is translated into CGRP. The C cells of the thyroid give rise to an endocrine tumor, medullary thyroid carcinoma (MTC), which occurs in a sporadic (75% of cases) and hereditary form (25% of cases). Familial MTC is associated with C cell hyperplasia (CCH), whereas sporadic MTC is thought not to be. However, in the general population CCH is present in 20-30% of thyroid glands, either with normal histology, thyroiditis or follicular tumors.

Calcitonin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Calpain Antibodies



Western Blot: analysis of human skeletal muscle showing detection of calpain 3 proteins. Lane A, calpain 3 bands at 94 and 30 kD detected with CALP-2C4. Lane B, Calpain 3 bands at 94 and approximately 60 kD detected with CALP-12A2. Calpain: clone Calc3d/2C4
Calpain: clone Calp3c/12A2

Calp3c/12A2

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 2.5 mL	NCL-CALP-12A2	W	RUO	RUO	RUO

Calp3d/2C4

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 2.5 mL	NCL-CALP-2C4	W	RUO	RUO	RUO

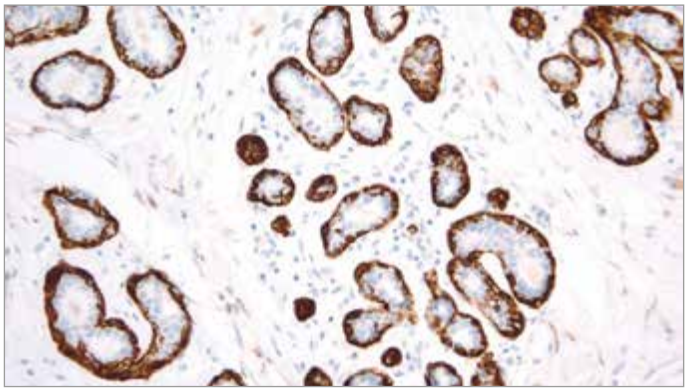
PATHOLOGY MENU

MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

The gene responsible for LGMD2A has been identified as the chromosome 15q15-encoded muscle-specific calcium-activated neutral protease, calpain 3. Calpain 3 enzyme is only stable in human muscle when homogenized in treatment buffer immediately after harvest (Anderson LVB et al. Am. J. of Pathol. 153(4), 1169-1179 (1998)), and in homogenates containing SDS and is therefore well suited for analysis by Western Blot. CALP-2C4 reacts with the full-size calpain 3 (94kD) and an additional fragment (30kD) in human skeletal muscle. CALP-12A2 reacts with full-size protein plus apparent degradation products at approximately 60kD.

Calponin (Basic)



Human prostate: immunohistochemical staining for Calponin (Basic). Note staining of basal cells. Calponin (Basic): clone 26A11

26A11

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0416	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

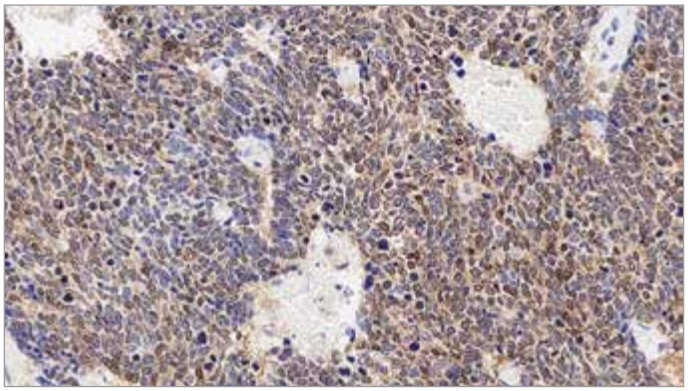
MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

Basic calponin (calponin-h1) is a 34 kD protein which exhibits a high degree of homology to acidic and neutral calponins at its N-terminal region. It is an actin, tropomyosin and calmodulin binding protein thought to be involved in the regulation of smooth muscle contraction. The expression of basic calponin is reported to be restricted to smooth muscle cells and is a marker of the differentiated contractile phenotype of developing smooth muscle. Vascular smooth muscle cells convert to a synthetic dedifferentiated phenotype when this protein is lost and this is a key stage in both atherosclerosis and restenosis of coronary arteries after balloon angioplasty. It is thought that basic calponin exerts its effect via the cortical actin cytoskeleton, and therefore influences proliferation, the transformed phenotype and the metastatic potential of tumor cells. Basic calponin mRNA is expressed in smooth muscle of prostate, bowel and aorta, whereas neutral and acidic calponin mRNAs are expressed in non-smooth muscle tissues such as heart, placenta, lung, kidney, pancreas, spleen, testis and ovary as well as in smooth muscle-containing tissues.

Calponin (Basic) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Calretinin



Human small cell lung carcinoma: immunohistochemical staining for Calretinin. Calretinin: clone CAL6

CAL6

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0346	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CALRET-566	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

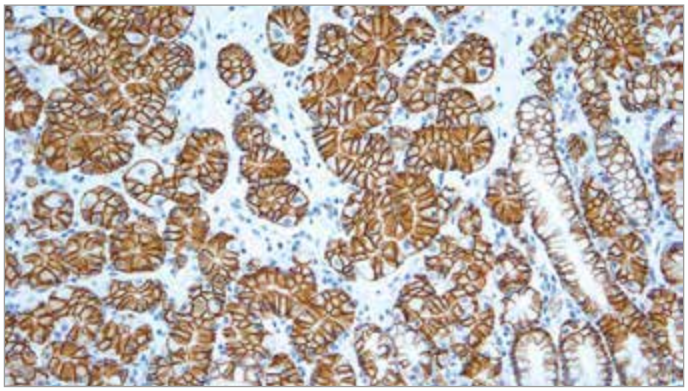
LUNG PATHOLOGY

ANTIGEN BACKGROUND

Calretinin is a calcium-binding protein of 29 kD that is a member of the family of so-called EF-hand proteins that also includes S-100 proteins. Calretinin is reported to be abundantly expressed in neurons. Outside the nervous system, calretinin is reported to be expressed in a range of cell types including mesothelial cells, steroid producing cells, (for example adrenal cortical cells, Leydig cells, ovarian theca interna cells, Sertoli cells, some neuroendocrine cells, eccrine sweat glands) and other cell types.

Calretinin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Carbonic Anhydrase IX



Human stomach: immunohistochemical staining for Carbonic Anhydrase IX. Note intense membrane and cytoplasmic staining of the deep glands. Carbonic Anhydrase IX: clone TH22

TH22

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CAIX	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

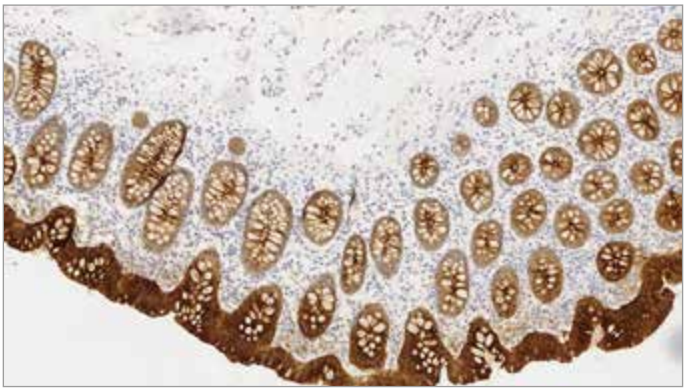
UROPATHOLOGY

ANTIGEN BACKGROUND

Carbonic anhydrase (CA) is an enzyme that assists rapid interconversion of carbon dioxide and water into carbonic acid, protons, and bicarbonate ions. Originally named MN/G250, carbonic anhydrase IX (CAIX) is a cell surface transmembrane protein, which is predominantly found in the gastrointestinal tract and gallbladder. The glandular regions of normal colon are reported to be negative, but in the case of adenocarcinoma, the glands are positive. CAIX is also reported to be expressed in common epithelial tumors such as carcinomas of the esophagus, lung, colon, kidney, cervix and non-small cell lung carcinoma.In breast carcinomas, CAIX expression has been reported to be associated with malignant tissue. Expression of CAIX is reported to be absent in normal kidney, chromophobe carcinomas or oncocytomas; however, it is specifically expressed in clear cell renal carcinomas.

Carbonic Anhydrase IX is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Carcinoembryonic Antigen (CD66e)



Human bowel: immunohistochemical staining for CD66e. Note cytoplasmic staining of epithelial cells. CD66e: clone 12-140-10

COL-1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0848	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CEA-609	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

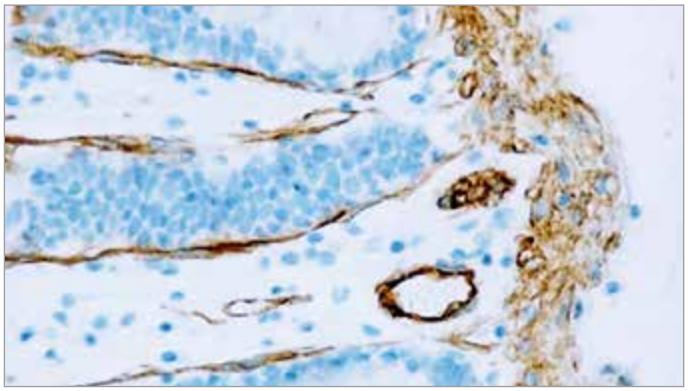
GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

Carcinoembryonic antigen (CEA) is a heterogeneous cell surface glycoprotein produced by cells of fetal colon. Low levels are also found on normal mucosal epithelia of the adult colon and a variety of other normal tissues. CEA is encoded by the CEA gene, which is located on chromosome 19. It is a member of the CEA gene family, which in turn is a subfamily of the immunoglobulin superfamily. Cell adhesion properties are now well recognized for CEA. It is believed that the expression of this glycoprotein in conjunction with other known adhesion molecules will influence the cell-cell interaction.

Carcinoembryonic Antigen (CD66e) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Caveolin-1



Normal human colon: immunohistochemical staining for Caveolin-1. Note cytoplasmic staining of smooth muscle and endothelium. Caveolin-1: clone 4D6

4D6

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-Caveolin-1	P(HIER)	RUO	RUO	RUO

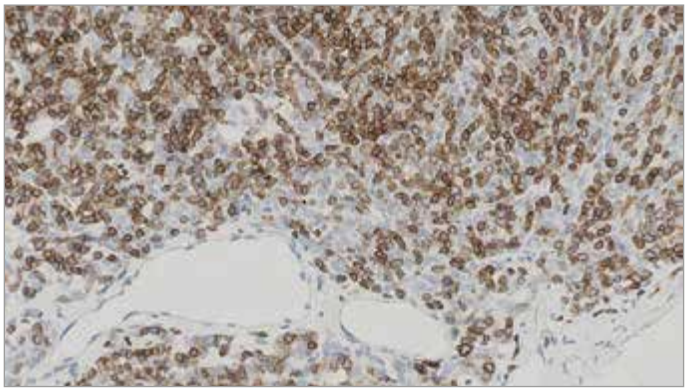
PATHOLOGY MENU

SPECIALIZED

ANTIGEN BACKGROUND

Caveolin-1 is a major structural component of caveolae, which are vesicular invaginations present on the plasma membrane of different cell types. It plays a regulatory role in several signaling pathways and is reported to be most abundantly expressed in terminally differentiated mesenchymal cells such as smooth muscle cells, adipocytes and endothelial cells. High levels are also reported in fibroblasts where a fine granular membranous and diffuse cytoplasmic staining pattern is described.

CD1a



Human thymoma: immunohistochemical staining for CD1a. CD1a: clone MTB1

MTB1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0235	P(HIER)	IVD	IVD	IVD
Liquid 0.5 mL	NCL-L-CD1a-235	P(HIER)	IVD	IVD	IVD/RUO
Liquid 1 mL	NCL-L-CD1a-235	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

DERMATOPATHOLOGY

ANTIGEN BACKGROUND

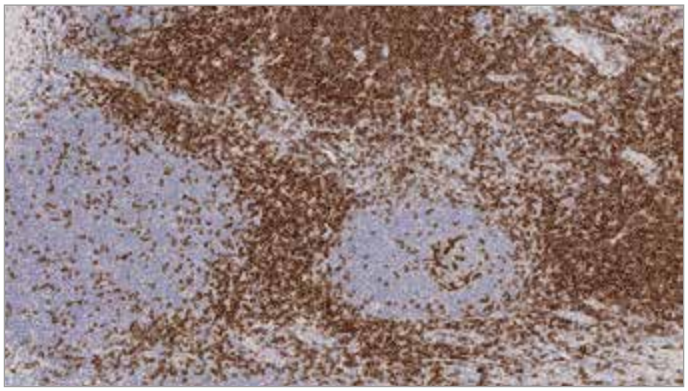
CD1a is a protein of 43 to 49 kD expressed on dendritic cells and cortical thymocytes. CD1a antigen expression has been shown to be useful in differentiating Langerhans cells, powerful antigen presenting cells present in skin and epithelia, from interdigitating cells. Immunohistochemical studies for CD1a antigen have reported a reduction in epidermal Langerhans cells in graft versus host disease and the participation of CD1a antigen-positive dendritic cells in atherosclerotic lesion formation and asthmatic inflammation.

CD1a is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Clone MTB1 detects cortical thymocytes, Langerhans cells in epidermis, interdigitating cells of dermis and interdigitating cells of stratified squamous epithelium of tonsil. Clone MTB1 may also detect small focal groups of lymphocytes outside the germinal centers of tonsil indicating a cross-reaction with CD1b antigen.

CD2 (LFA-2)



Human tonsil: immunohistochemical staining for CD2. Note membrane staining of T lymphocytes. CD2: clone 11F11

11F11

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0271	P(HIER)	IVD	IVD	IVD

AB75

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CD2-271	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

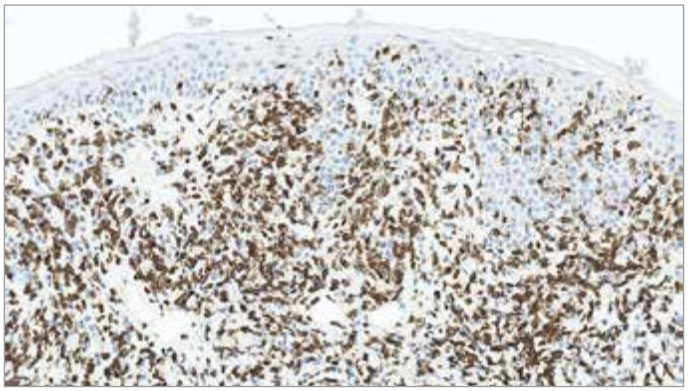
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD2 antigen (LFA-2) is a monomeric 45 to 58 kD glycoprotein. It is an accessory molecule important in mediating the adhesion of activated T cells and thymocytes with antigen-presenting cells and target cells.

CD2 (LFA-2) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD3



Human skin with mycosis fungoides: immunohistochemical staining for CD3. Note the extensively infiltrated positive cells. CD3: clone LN10

LN10

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0553	P(HIER)	IVD	IVD	IVD
BOND 30 mL	PA0122	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD3-565	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

HEMATOPATHOLOGY

ANTIGEN BACKGROUND

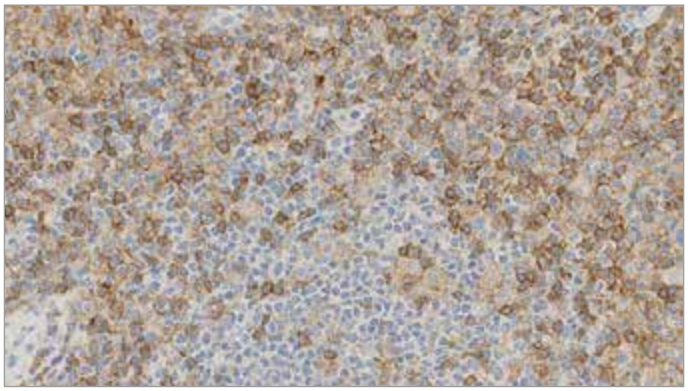
The CD3 molecule consists of five different polypeptide chains with molecular weights ranging from 16 to 28 kD. The CD3 antigen is first detected in early thymocytes and its appearance probably represents one of the earliest signs of commitment to the T cell lineage.

CD3 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Clone LN10 is specific for the non-glycosylated epsilon chain of the human CD3 molecule. Clone LN10 recognizes T cells in thymus, bone marrow, peripheral lymphoid tissue and blood and is a pan T cell marker.

CD4



T-Cell Lymphoma: immunohistochemical staining of CD4. CD4: clone 4B12

4B12

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0427	P(HIER)	IVD	IVD	IVD
Liquid 0.5 mL	NCL-L-CD4-368	P(HIER)	IVD	IVD	IVD/RUO
Liquid 1 mL	NCL-L-CD4-368	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

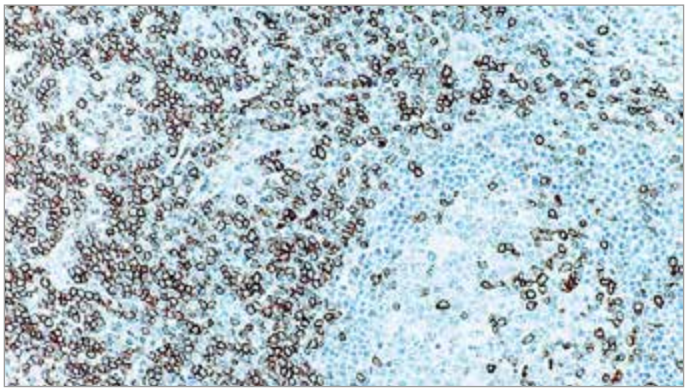
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD4 molecule (T4) is a single chain transmembrane glycoprotein with a molecular weight of 59 kD. The CD4 antigen is expressed on a T cell subset (helper/inducer) representing 45% of peripheral blood lymphocytes and at a lower level on monocytes and germinal center macrophages. Most cases of cutaneous T cell lymphoma, including mycosis fungoides, express the CD4 antigen and HTLV-1 associated adult T cell leukemia/lymphoma is also generally CD4 positive.

CD4 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD5



Human mantle cell lymphoma: immunohistochemical staining for CD5. CD5: clone 4C7

4C7

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0168	P(HIER)	IVD	IVD	IVD
Liquid 0.5 mL	NCL-L-CD5-4C7	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD5-4C7	P(HIER)	IVD	IVD/RUO	IVD/RUO

PATHOLOGY MENU

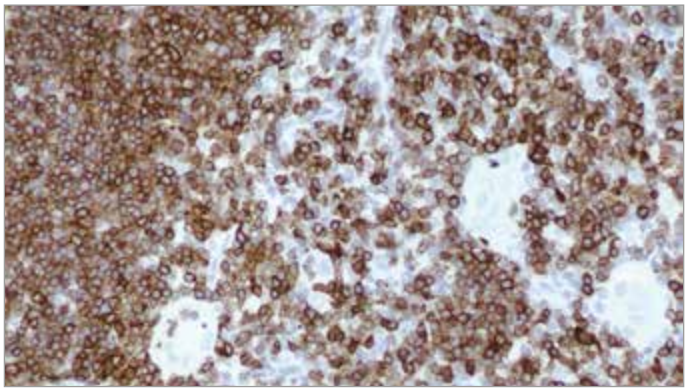
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

CD5 antigen is reported to be expressed on 95% of thymocytes and 72% of peripheral blood lymphocytes. In lymph nodes, the main reactivity is observed on T cells. CD5 antigen is also expressed by many T cell leukemias, lymphomas, activated T cells and on a subset of B cells located primarily in the mantle zones of normal lymph nodes. CD5 antigen expression is also reported in T cell acute lymphocytic leukemias (T-ALL), some B cell chronic lymphocytic leukemias (B-CLL) as well as B and T cell lymphomas.

CD5 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD7



T cell lymphoma: immunohistochemical staining for CD7. CD7: clone LP15

LP15

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0266	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD7-580	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

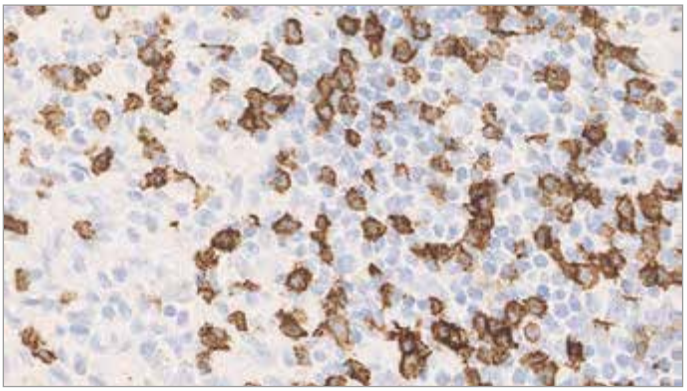
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD7 molecule is a membrane-bound glycoprotein of 40 kD and is the earliest T cell specific antigen to be expressed in lymphocytes. CD7 antigen is also the only early marker to persist throughout differentiation. The function and role of the CD7 molecule has not yet been fully identified, although the activation of T cells with gamma/delta receptors has been proposed based on mAb-induced activation. CD7 antigen is reported to be found on the majority of peripheral blood T cells, most natural killer cells and thymocytes.

CD7 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD8



Human lymph node, T cell lymphoma: immunohistochemical staining for CD8.
CD8: clone 4B11

4B11

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0183	P(HIER)	IVD	IVD	IVD
Liquid 0.5 mL	NCL-L-CD8-4B11	P(HIER)	IVD	IVD	IVD/RUO
Liquid 1 mL	NCL-L-CD8-4B11	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

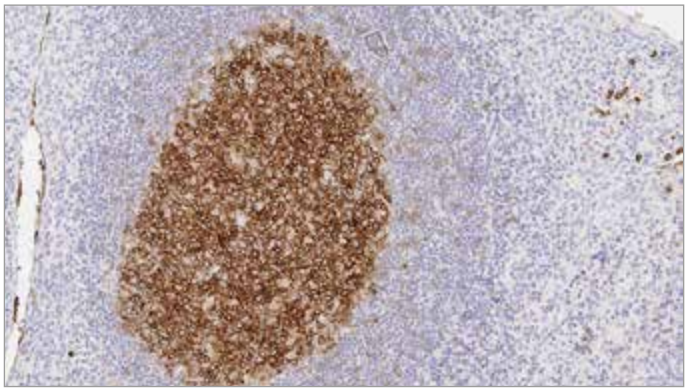
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD8 molecule is composed of two chains and has a molecular weight of 32 kD. It is found on a T cell subset of normal cytotoxic/suppressor cells which make up approximately 20-35% of human peripheral blood lymphocytes.The CD8 antigen is reported to be detected on natural killer cells, 80% of thymocytes, on a subpopulation of 30% of peripheral blood null cells and 15-30% of bone marrow cells.

CD8 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD10



Human tonsil: immunohistochemical staining for CD10. Note membrane staining of germinal centre B cells. CD10: clone 56C6

56C6

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0270	P(HIER)	IVD	IVD	IVD
BOND 30 mL	PA0131	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD10-270	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

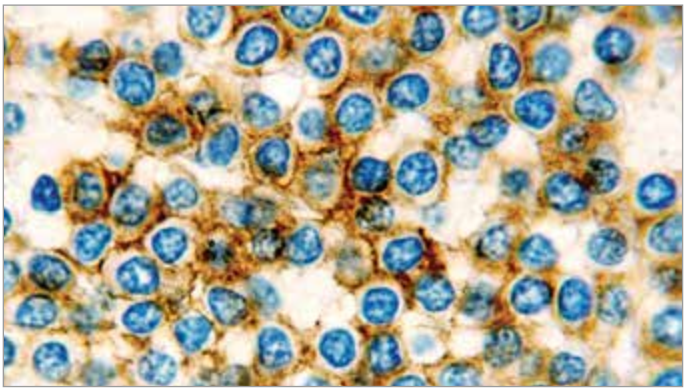
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

CD10 antigen, also called neprilysin, is a 100 kD cell surface metalloendopeptidase which inactivates a variety of biologically active peptides. It was initially identified as the common acute lymphoblastic leukemia antigen (CALLA) and was thought to be tumor-specific. Subsequent studies, however, have shown that CD10 antigen is expressed on the surface of a wide variety of normal and neoplastic cells. In other lymphoid malignancies, CD10 antigen is reported to be expressed on cells of lymphoblastic, Burkitt's and follicular lymphomas. CD10 antigen has been identified on the surface of normal early lymphoid progenitor cells, immature B cells within adult bone marrow and germinal center B cells within lymphoid tissue. It is also expressed in various non-lymphoid cells and tissues, such as breast myoepithelial cells, bile canaliculi, fibroblasts, with especially high expression on the brush border of kidney and gut epithelial cells. (G. McIntosh et al. American Journal of Pathology. 154(1): 77-82 (1999)).

CD10 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD11c



Human hairy cell leukemia: immunohistochemical staining for CD11c. CD11c: clone 5D11

5D11

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0554	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD11c-563	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

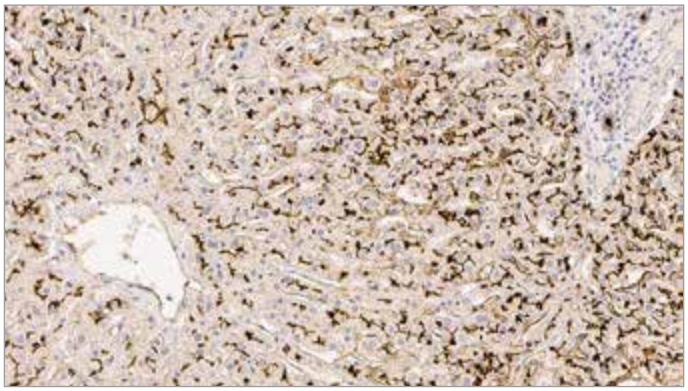
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

CD11c is a member of the leukocyte integrin family of adhesion proteins. It is reported to be expressed in normal tissues, mainly on myeloid cells, for example, in bone marrow myelocytes, premyelocytes, metamyelocytes, non-segmented and segmented neutrophils with high levels reported on tissue macrophages and monocytes and with lowest levels in granulocytes. It is also reported to be expressed on NK cells, activated T cells, lymphoid cell lines, including hairy cell leukemias and a proportion of interdigitating dendritic cells.

CD11c is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD13



Human liver: immunohistochemical staining for CD13. Note staining of the bile canaliculi.
CD13: clone 38C12

38C12

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0304	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD13-304	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

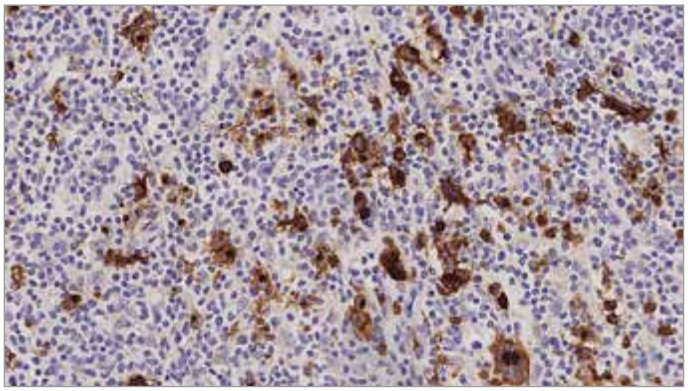
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

CD13 antigen, also known as aminopeptidase N, is a member of type II integral membrane metalloproteases, which also includes the leukocyte antigens CD10, CD26, CD73 and BP-1. CD13 antigen is a receptor for the coronaviruses which cause respiratory disease in humans and several animal species. The antigen functions as a zinc-binding metalloprotease which plays a role in cell surface antigen presentation by trimming the N-terminal amino acids from MHC class II-bound peptides. CD13 antigen is reported to be expressed on granulocytes, monocytes and their precursors, most acute myeloid leukemias and a smaller proportion of acute lymphoid leukemias. Non-hematopoietic cells which express CD13 antigen include epithelial cells, renal proximal tubules, intestinal brush border, endothelial cells, fibroblasts, brain cells, bone marrow, osteoclasts and cells lining the bile canaliculi.

CD13 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD15



Hodgkin's disease, mixed cellularity: immunohistochemical staining for CD15.
CD15: clone MMA

MMA

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0473	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD15-605	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

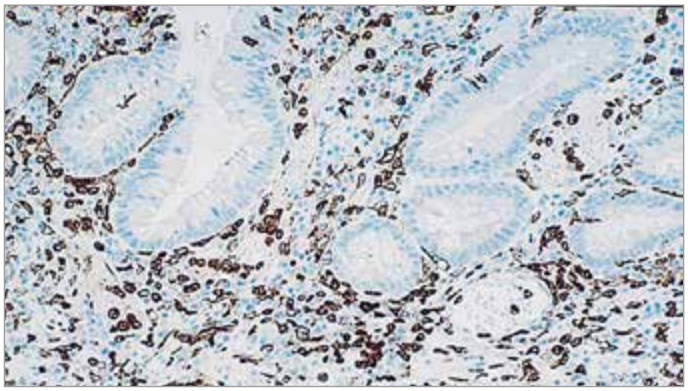
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

CD15 antigen, also known as X-hapten, is reported to be expressed on 90% of circulating human granulocytes, 30-60% of circulating monocytes and is absent from normal lymphocytes. The CD15 antigen is also expressed on Reed Sternberg cells of Hodgkin's disease and some leukemias.

CD15 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD16



Human colon, ulcerative colitis: immunohistochemical staining for CD16. CD16: clone 2H7

2H7

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CD16	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

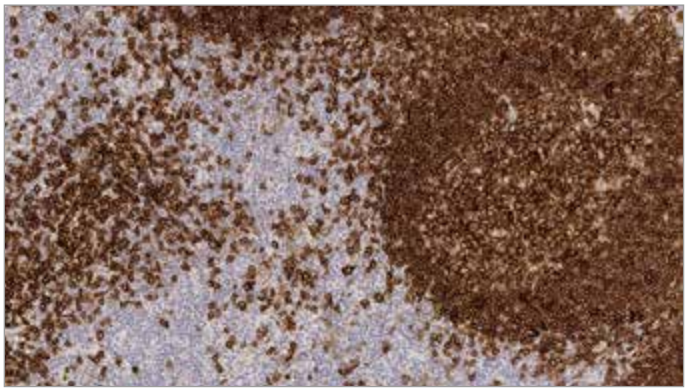
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

CD16 antigen has a molecular weight of 50 to 70 kD and is a low affinity Fc receptor for complexed IgG, Fc/gamma RIII, expressed on natural killer (NK) cells, granulocytes, activated macrophages and a subset of T cells expressing alpha-beta or gamma-delta T cell antigen receptors. The CD16 antigen exists both as a glycosyl-phosphatidylinositol (GPI)-anchored protein in polymorphonuclear cells and as a transmembrane protein in NK cells.

CD16 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD19



Human tonsil: immunohistochemical staining for CD19. Note membrane staining of B cells. CD19: clone BT51E

BT51E

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0843	P(HIER)	IVD	IVD	IVD
Liquid 0.5 mL	NCL-L-CD19-163	P(HIER)	IVD	IVD	IVD/RUO
Liquid 1 mL	NCL-L-CD19-163	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

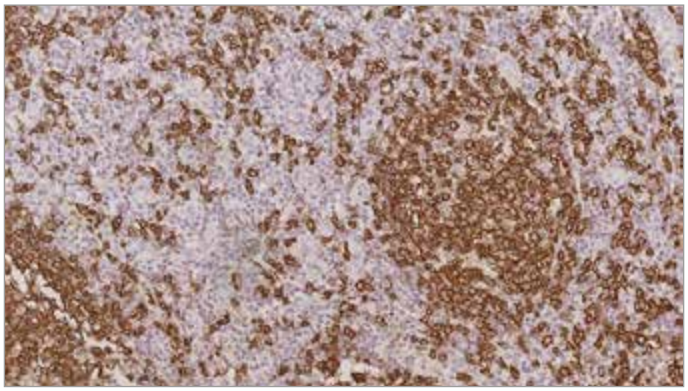
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

CD19 is a member of the immunoglobulin superfamily and has two Ig like domains. It is a single chain glycoprotein present on the surface of B lymphocytes and follicular dendritic cells of the hematopoietic system. CD19 is a crucial regulator in B cell development, activation and differentiation. On B cells, CD19 associates with CD21, CD81 and CD225 (Leu-13) forming a signal transduction complex. CD19 is expressed from the earliest recognizable B cell lineage stage, through development to B cell differentiation but is lost on maturation to plasma cells.

CD19 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD20



Follicular B cell lymphoma. immunohistochemical staining for CD20. CD20: Clone L26

L26

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0200	P(HIER)	IVD	IVD	IVD
BOND 30 mL	PA0359	P(HIER)	IVD	IVD	IVD
Liquid 0.5 mL	NCL-L-CD20-L26	P(HIER)	IVD	IVD	IVD/RUO
Liquid 1 mL	NCL-L-CD20-L26	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

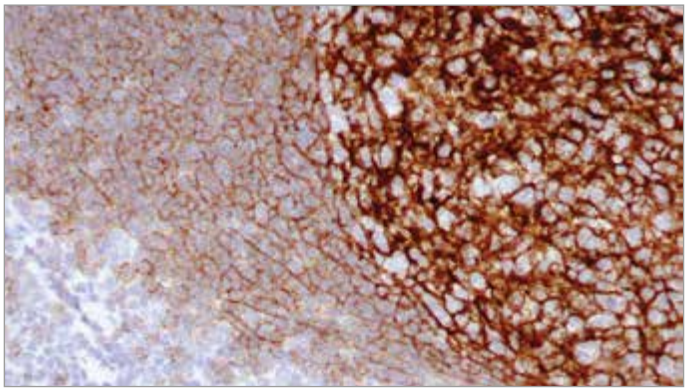
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD20 antigen is a non-glycosylated phosphoprotein of approximately 33kD which is expressed on normal and malignant human B cells and is thought to act as a receptor during B cell activation and differentiation. CD20 antigen has been reported to be expressed on normal B cells from peripheral blood, lymph node, spleen, tonsil, bone marrow, acute leukemias and chronic lymphocytic leukemias.

CD20 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD21



Human tonsil: immunohistochemical staining for CD21 antigen. Note intense membrane staining of follicular dendritic cells. CD21: clone 2G9

2G9

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0171	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD21-2G9	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

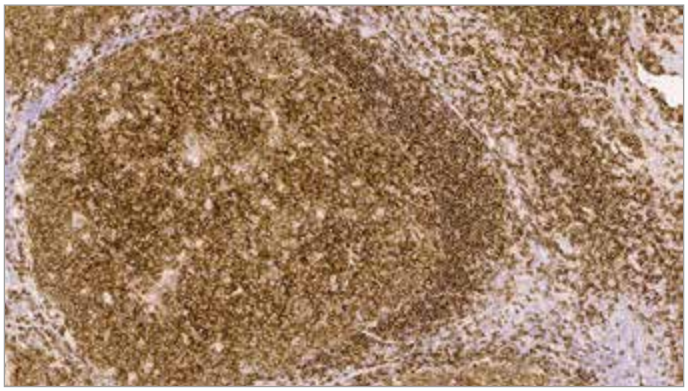
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

CD21 antigen is a type I integral membrane glycoprotein of molecular weight 140 kD, which functions as the receptor for the C3d fragment of the third complement component. The CD21 molecule, present on mature B cells, is involved in transmitting growth-promoting signals to the interior of the B cell and acts as a receptor for Epstein-Barr virus. CD21 antigen is reported to be found in B cell chronic lymphocytic leukemias and in a subset of T cell acute lymphocytic leukemias but is absent on T lymphocytes, monocytes and granulocytes. CD21 antigen is also reported to be expressed in follicular dendritic cells and in follicular and mantle cell lymphomas, mature leukemias and lymphomas.

CD21 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD22



Human tonsil: immunohistochemical staining for CD22. Note the mantle zone is staining stronger than the germinal center. CD22: clone FPC1

FPC1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0249	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

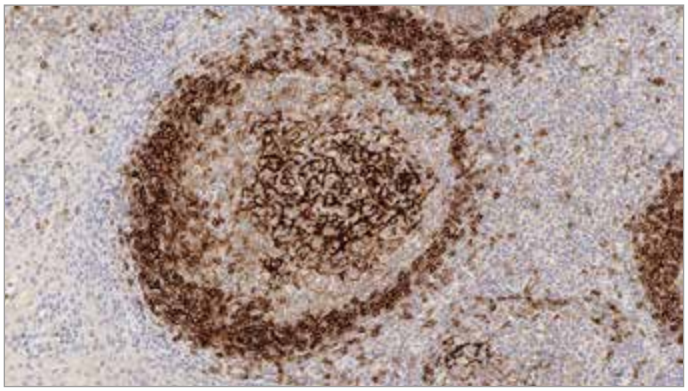
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD22 antigen (BL-CAM) is a type 1 integral membrane glycoprotein with a molecular weight of 130 to 140 kD. It is a heterodimer of two independently expressed glycoprotein chains present both on the membrane and in the cytoplasm of B lymphocytes. Expression of the CD22 antigen is reported to appear early in B cell lymphocyte differentiation at approximately the same stage as that of the CD19 antigen expression. Surface antigen expression is variable and may be lost upon differentiation. CD22 antigen is also reported to be weakly expressed on myeloid leukemias and non-T cell acute lymphoblastic leukemias and is strongly expressed on hairy cell leukemias. It is absent on peripheral blood T cells, T cell leukemias, granulocytes and monocytes.

CD22 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD23



Human tonsil: immunohistochemical staining for CD23. Note intense staining of follicular dendritic cell network and weaker staining of mantle zone cells. CD23: clone 1B12

1B12

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0169	P(HIER)	IVD	IVD	IVD
Liquid 0.5 mL	NCL-L-CD23-1B12	P(HIER)	IVD	IVD	IVD/RUO
Liquid 1 mL	NCL-L-CD23-1B12	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

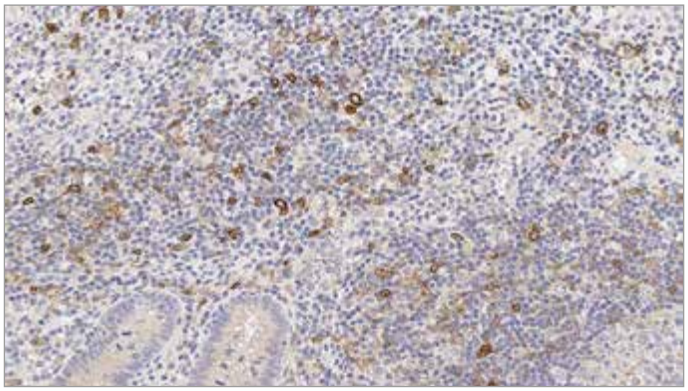
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD23 molecule is the low affinity IgE receptor found on B cells. It is a membrane glycoprotein of 45 kD and is reported to be found on a a sub-population of peripheral blood cells, B lymphocytes and on EBV-transformed B lymphoblastoid cell lines. Expression of CD23 antigen has been reported on monocytes and dendritic cells.

CD23 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD25



Human appendix: immunohistochemical staining for CD25. Note staining of activated lymphocytes. CD25: clone 4C9

4C9

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0305	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

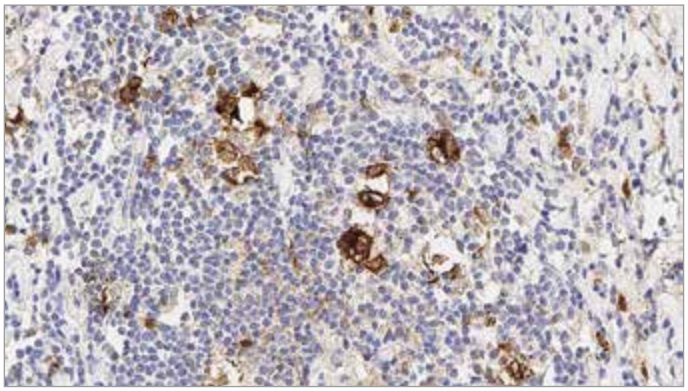
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

CD25 antigen, the alpha subunit of interleukin-2 receptor, is a single-chain glycoprotein with a molecular weight of 55 kD. Following the activation of T cells interleukin-2 (IL-2) is rapidly synthesized and secreted. In response to this a subpopulation of T cells expresses high affinity receptors for IL-2. These cells proliferate, expanding the T cell population which is capable of mediating helper, suppressor and cytotoxic functions. IL-2 receptor is not exclusively found on T cells, and is reported to be expressed on HTLV-transformed T and B cells, EBV-transformed B cells, myeloid precursors and oligodendrocytes. It is absent on thymocytes, resting T cells, non-activated B cells and null cells. IL-2 receptor expression is reported to be associated with inflammatory and malignant conditions, lymphoid neoplasia, auto-immune diseases and allograft rejection.

CD25 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD30



Human lymph node, nodular sclerosing Hodgkin's disease: immunohistochemical staining for CD30. CD30: clone JCM182

JCM182

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0790	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD30-591	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

HEMATOPATHOLOGY

ANTIGEN BACKGROUND

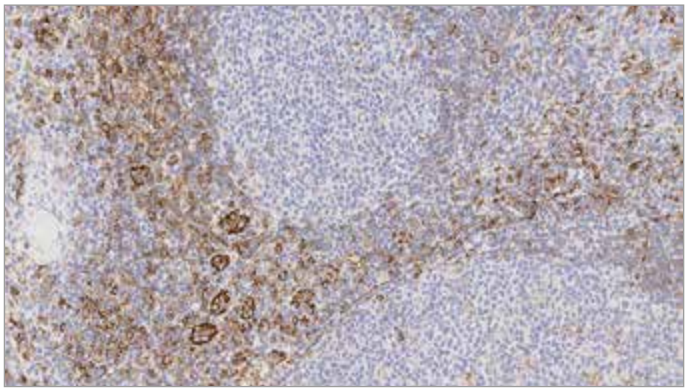
The CD30 antigen is a single chain glycoprotein with a molecular weight of 120 kD. CD30 antigen is known to act as a receptor for a cytokine ligand, CD30L, and may also play a role in the regulation of cellular growth and transformation. CD30 antigen is reported to be expressed on the surface of multinucleated Reed Sternberg cells, mononuclear Hodgkin's cells and in the majority of anaplastic large cell lymphomas. The CD30 antigen is expressed in non-Hodgkin's lymphoma and virally transformed cells, for example, EBV-transformed B cells.

CD30 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Using retrieval solutions other than that recommended for clone JCM182 in the datasheet may increase background reactivity.

CD31 (PECAM-1)



Human lymphoma: immunohistochemical staining for CD31. Note the membrane staining of endothelial cells. CD31: Clone JC70A

JC70A

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0414	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD31-607	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

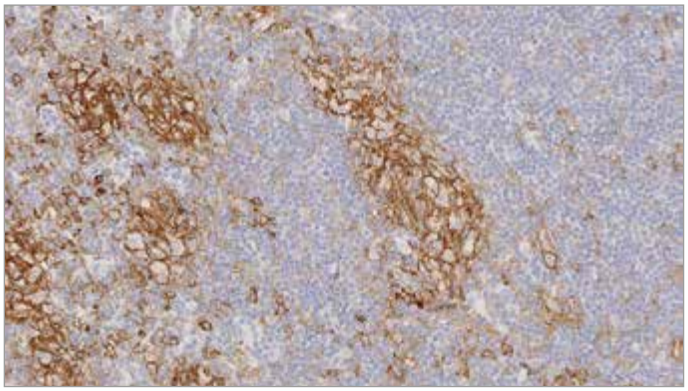
SOFT TISSUE PATHOLOGY

ANTIGEN BACKGROUND

CD31 antigen (PECAM-1) is a single chain transmembrane glycoprotein with a molecular weight of 130 to 140 kD. The CD31 molecule is expressed on the surface of platelets, monocytes, granulocytes, B cells and at the endothelial intracellular junction. The molecule has an extracellular domain that contains six Ig-like homology units of C2 subclass, typical of cell to cell adhesion molecules. This domain mediates endothelial cell to cell adhesion, plays a role in endothelial contact and may serve to stabilize the endothelial cell monolayer. The CD31 molecule also has a cytoplasmic domain with potential sites for phosphorylation after cellular activation. The properties of CD31 antigen suggest that it is involved in interactive events during angiogenesis, thrombosis and wound healing. Angiogenesis is essential for tumor growth and metastases.

CD31 (PECAM-1) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD33



Human lymph node, anaplastic lymphoma: immunohistochemical staining for CD33. CD33: clone PWS44

PWS44

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0555	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD33	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

HEMATOPATHOLOGY

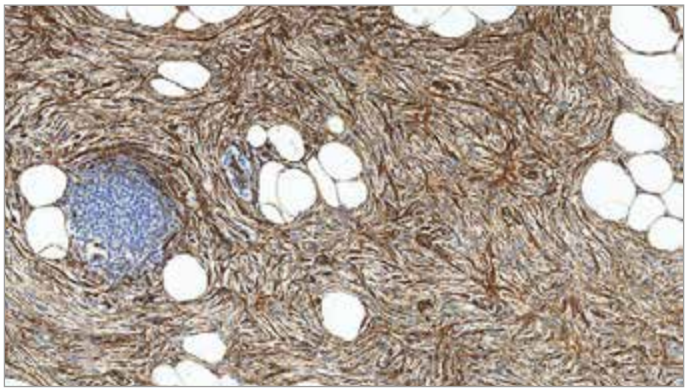
ANTIGEN BACKGROUND

CD33 antigen is reported to appear on myelomonocytic precursor cells after CD34 antigen expression. It then continues to be expressed on both the myeloid and monocyte lineages, although it is reported to be absent on granulocytes. It has been reported that expression of CD33 is restricted to monocytes, premyelocytes, myeloid blasts, some acute undifferentiated leukemias and acute lymphoblastic leukemias.

CD33 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent
F Frozen P Paraffin O Other Applications W Western blotting BOND BOND Ready-to-Use format Liquid Liquid Concentrate format

CD34 (Endothelial Cell Marker)



Dermatofibrosarcoma protuberans: immunohistochemical staining for CD34.
CD34: clone QBEnd/10

QBEnd/10

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0212	P(HIER)	IVD	IVD	IVD
BOND 30 mL	PA0354	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-END	P(ENZYME)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

SOFT TISSUE PATHOLOGY

ANTIGEN BACKGROUND

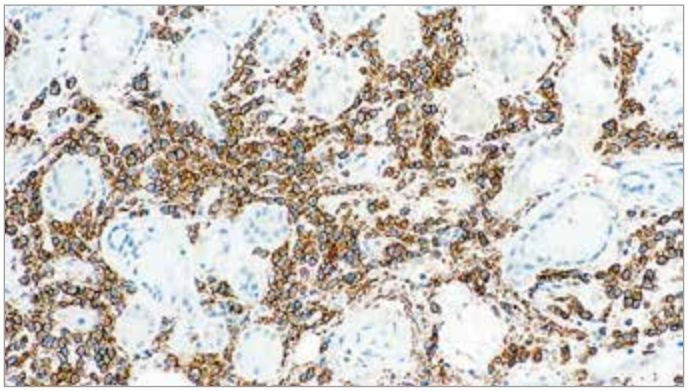
The CD34 antigen is a single chain transmembrane glycoprotein with a molecular weight of 110 kD. The CD34 protein is selectively expressed in human lymphoid and myeloid hematopoietic progenitor cells. The CD34 antigen is also expressed in vascular enothelium.

CD34 (Endothelial Cell Marker) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Enzyme digestion of paraffin sections is recommended with clone QBEnd/10 in perference to heat induced epitope retrieval as it produces stronger staining and reduces background elastin staining

CD38



Chronically inflamed human bronchus: immunohistochemical staining CD38.
CD38: clone SPC32

SPC32

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CD38-290	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

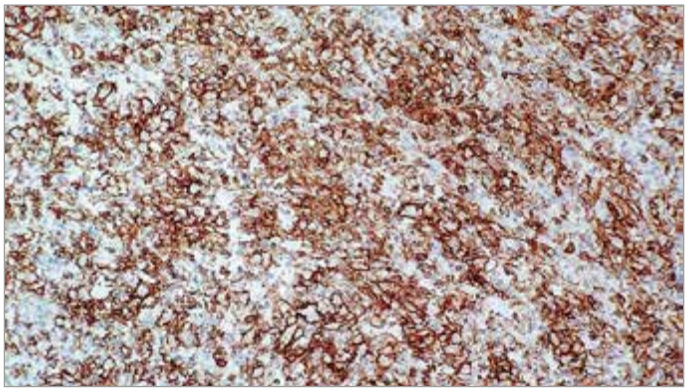
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD38 molecule is a type II single transmembrane glycoprotein with a molecular weight of 46 kD. It is an ectoenzyme with the activities of ADP-ribosyl cyclase, cyclic ADP-ribose hydrolase, NAD glycohydrolase and is involved in both the formation and hydrolysis of cADPR, a second messenger that regulates the mobilization of intracellular Ca^{2+} ions. Although the CD38 molecule was originally identified as a T lymphocyte differentiation antigen, it is reported to be expressed in a wide range of cells and tissues. CD38 antigen can deliver potent growth and differentiation signals to lymphoid and myeloid cells. It is found on immature cells of the B and T cell lineages but not on most mature resting peripheral lymphocytes. It is also present on thymocytes, pre-B cells, germinal center B cells, mitogen-activated T cells, Ig-secreting plasma cells, monocytes, NK cells, erythroid and myeloid progenitors in the bone marrow and brain cells. CD38 antigen has also been reported in neurofibrillary tangles, the pathological indicator of Alzheimer's disease that occurs in the neuronal perikarya and proximal dendrites.

CD38 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD43



Diffuse large B cell lymphoma: immunohistochemical staining for CD43. CD43: clone MT1

MT1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0938	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-MT1	P	IVD	RUO	RUO

PATHOLOGY MENU

HEMATOPATHOLOGY

ANTIGEN BACKGROUND

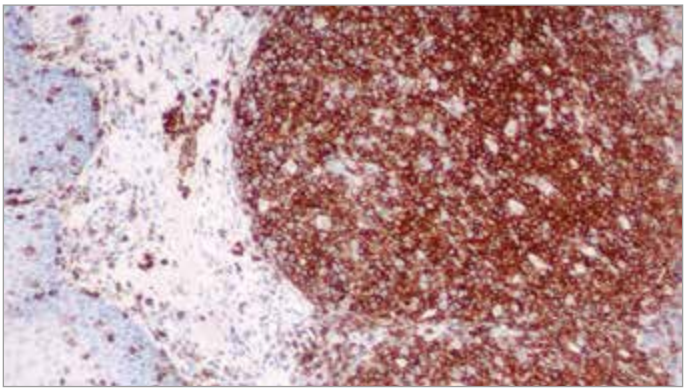
The CD43 antigen is expressed on the membrane and in the cytoplasm of T cells and cells of myeloid lineage. The molecule itself exhibits molecular weight heterogeneity with bands of 90 to 140 kD observed on SDS-PAGE between different cell lines. Cells expressing the CD43 antigen are reported to include normal and neoplastic T cells. A small proportion of B cell chronic leukemias and diffuse large B cell lymphomas are also reported to express CD43 antigen.

CD43 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

An enzyme pretreatment can be used to enhance staining in some cases.

CD45



Human tonsil: immunohistochemical staining of CD45 or leukocyte common antigen (LCA) in various hematolymphoid cells. CD45: clone X16/99

X16/99

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0042	P(HIER)	IVD	IVD	IVD
Liquid 0.5 mL	NCL-L-LCA	P(HIER)	IVD	IVD	IVD/RUO
Liquid 1 mL	NCL-L-LCA	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

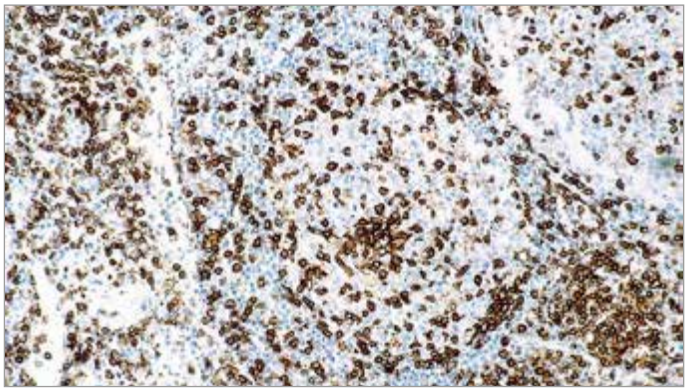
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD45 antigen (leukocyte common antigen) is a family of five or more high molecular weight glycoproteins present on the surface of the majority of the human leukocytes (including lymphocytes, monocytes and eosinophils) but absent from erythrocytes and platelets. Various isoforms of CD45 are generated by alternative splicing of three exons. Expression of CD45 is necessary for signaling through the T cell receptor.

CD45 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD45RO



Human tonsil: immunohistochemical staining with CD45RO: clone UCHL1

UCHL1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0146	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-UCHL1	P(HIER)	RUO	RUO	RUO

PATHOLOGY MENU

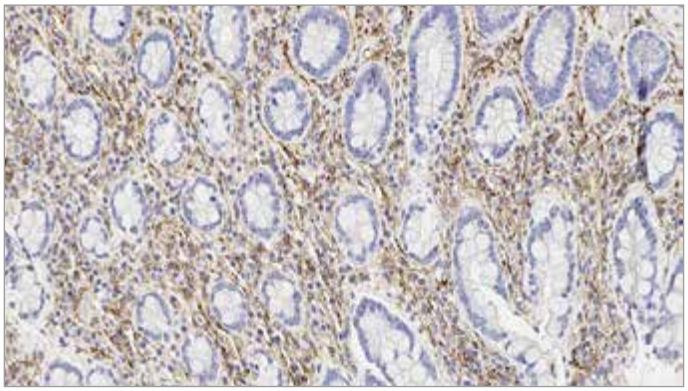
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD45RO molecule, a 180 kD isoform of CD45, is reported to be expressed on 48% of peripheral blood T lymphocytes, 37% of CD4 positive lymphocytes, 80% of thymocytes and on the majority of T cell malignancies. Monocytes and granulocytes show surface expression of the antigen whereas tissue macrophages exhibit cytoplasmic expression.

CD45RO is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD56 (NCAM)



Human tonsil: immunohistochemical staining for CD56. Note the NK cells and CD4/CD8 double positive T cells show a weak to moderate and distinct membrane staining reaction while the majority of lymphocytes are unstained. CD56: clone CD564

CD564

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0191	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD56-504	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

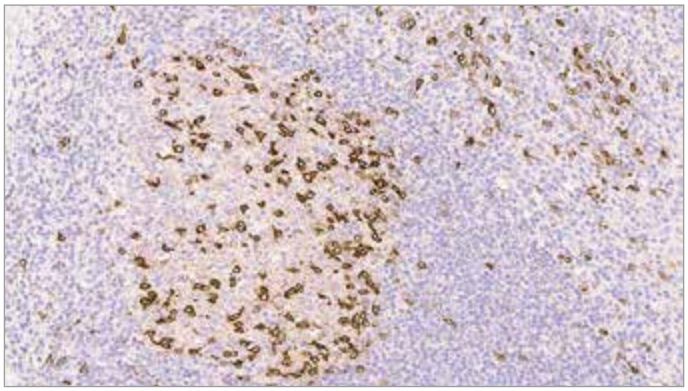
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The neural cell adhesion molecules are a family of closely-related cell surface glycoproteins thought to play a role in embryogenesis, development and contact-mediated interactions between neural cells. The CD56 antigen (NCAM) consists of four major isoforms generated by differential splicing of the RNA transcript from a single gene located on chromosome 5. The CD56 antigen is expressed on neurons, astrocytes, Schwann cells, NK cells and a subset of activated T lymphocytes.

CD56 (NCAM) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD57



Human tonsil: immunohistochemical staining of T lymphocytes. CD57: clone NK-1

NK-1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0443	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

HEMATOPATHOLOGY

ANTIGEN BACKGROUND

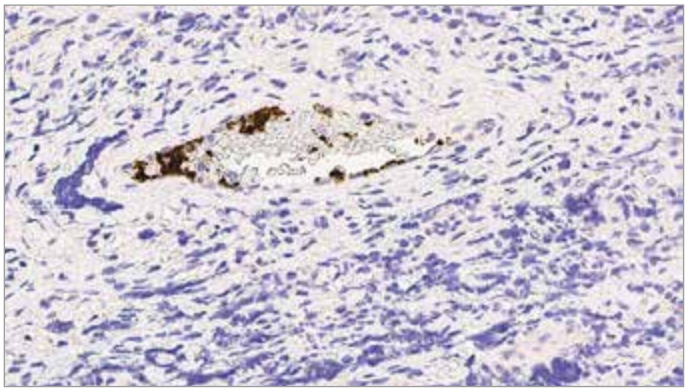
The CD57 glycoprotein, also known as HNK-1, has a molecular weight of 110 kD. It is found on a subset of mononuclear cells with natural killer activity and on neuroectodermal cells expressing myelin-associated glycoprotein. Many cells which co-express CD57 and CD8 proteins are a subset of suppressor/cytotoxic T cells. These cells play a role in the rejection of grafts in acute graft versus host disease. The CD57 molecule is not expressed on erythrocytes or platelets.

CD57 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

An enzyme pretreatment can be used to enhance staining in some cases.

CD61 (GPIIIa)



Human tonsil: immunohistochemical staining of CD61 antigen (GPIIIa) on platelets within the blood vessel. CD61 (GPIIIa): clone 2f2

2f2

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0308	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

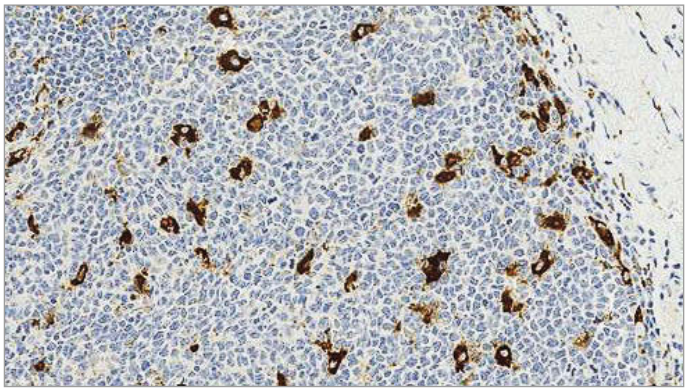
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD61 antigen, also known as GPIIIa, is a glycoprotein of 105 kD found on platelets, monocytes, endothelial cells, smooth muscle cells, B cells, macrophages, mast cells and fibroblasts. CD61 antigen plays a role in platelet aggregation and also as a receptor for fibrinogen, fibronectin, von Willebrand factor and vitronectin. Individuals with Glanzmann's thrombasthenia are reported to express little or no CD61 antigen. CD61 antigen is also reported to be expressed in most cases of megakaryocytic leukemias.

CD61 (GPIIIa) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD68



Human tonsil: immunohistochemical staining for CD68. Note the germinal centre macrophages show a strong cytoplasmic staining reaction, while the interfollicular macrophages show correct weak to moderate staining reaction. CD68: clone 514H12

514H12

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0273	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD68	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

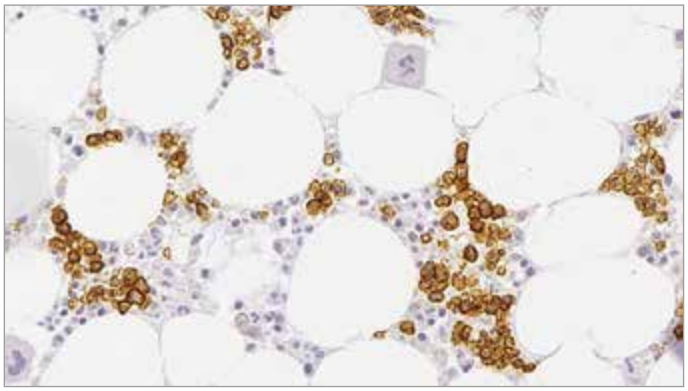
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD68 molecule is a 110 kD intracellular glycoprotein primarily reported to be associated with cytoplasmic granules and to a lesser extent the membranes of macrophages. Markers to CD68 antigen are the most frequently used for the identification of macrophages in immunohistochemistry; however, CD68 is also found in monocytes, neutrophils, basophils and large lymphocytes. The function of the CD68 molecule is not certain but these lysosomal membrane proteins are major components and may protect the membranes from attack by acid hydrolases. It is unclear if the surface-associated CD68 protein is functionally significant or due to leakage from the lysosomes. CD68 protein expression has been demonstrated in stimulated T cells and NK cells and non-hematopoietic tissues such as liver and renal tubules.

CD68 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD71



Human bone marrow: immunohistochemical staining for CD71. Note membrane staining of erythroid progenitor cells. CD71: clone 10F11

10F11

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CD71-309	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

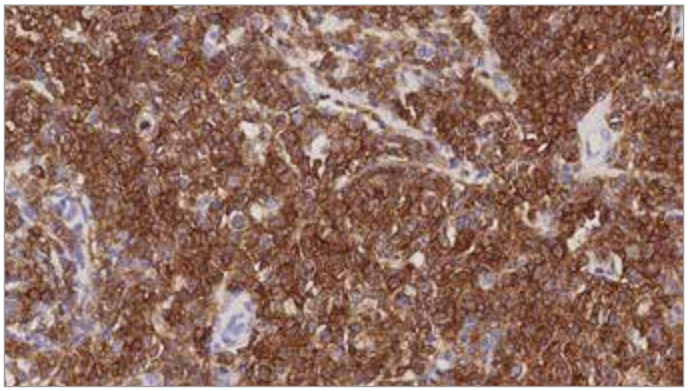
SPECIALIZED

ANTIGEN BACKGROUND

The CD71 molecule is a type II membrane glycoprotein with a molecular weight of approximately 180 kD. It is known as the transferrin receptor and is composed of two disulfide-BONDed 90 kD subunits. The CD71 molecule plays a critical role in cell proliferation by controlling the supply of iron, an essential component for many metabolic pathways, through the binding and endocytosis of transferrin, the major iron-carrying protein. CD71 protein is reported to be expressed on activated B and T cells, macrophages, proliferating cells and metabolically active cells, for example, neurons.

CD71 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD79a



Human diffuse large B cell lymphoma: immunohistochemical staining for CD79a. CD79a: clone JCB117

JCB117

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0599	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD79a-599	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

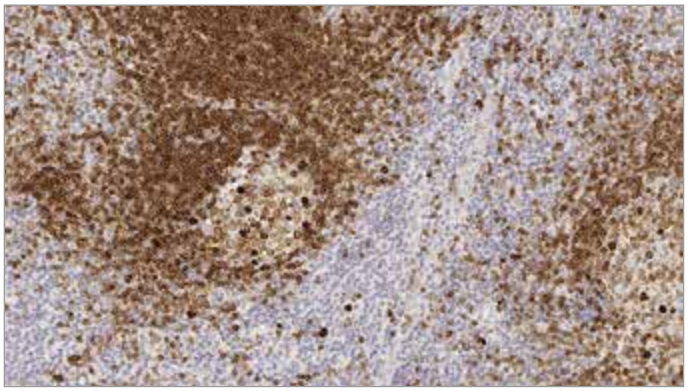
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD79 complex is a disulfide-linked heterodimer which is non-covalently associated with membrane-bound immunoglobulins on B cells. This complex of polypeptides and immunoglobulin constitute the B cell antigen receptor. The two components of this complex are designated CD79a and CD79b. The CD79a antigen is reported to first appear at the pre-B cell stage, early in maturation, and persist until the plasma cell stage where it is found as an intracellular component. It is not present in myeloid or T cell lines.

CD79a is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD79b



Human tonsil: immunohistochemical staining for CD79b. Note intense membrane staining of B cells. CD79b: clone JS01

JS01

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CD79b	P(HIER)	RUO	RUO	RUO

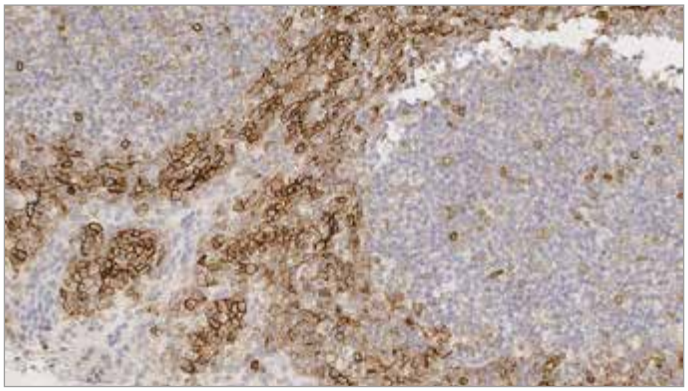
PATHOLOGY MENU

HEMATOPATHOLOGY

ANTIGEN BACKGROUND

CD79b, also known as B29 and Ig-beta is thought to function in the cellular activation and signaling that occurs when surface immunoglobulin (Ig) on B cells binds antigen or becomes cross-linked by anti-Ig antibody. This function occurs with the formation of a membrane signaling complex that is associated with Ig at the surface of B cells. CD79b, together with CD79a, forms the B cell antigen receptor (mIg) complex.

CD99



Human tonsil: immunohistochemical staining for CD99. Note membrane staining of vessel endothelium and a subpopulation of lymphocytes. CD99: clone PCB1

PCB1

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CD99-187	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

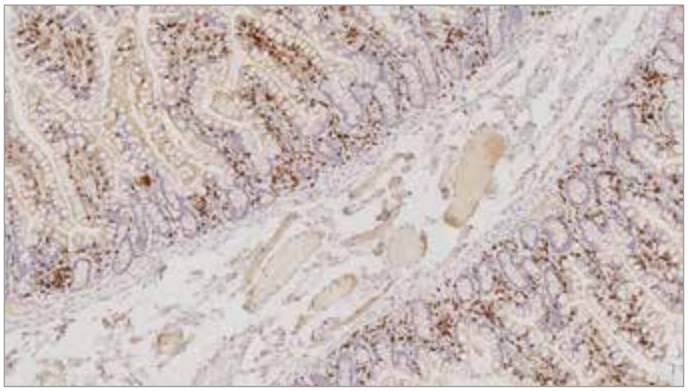
SOFT TISSUE PATHOLOGY

ANTIGEN BACKGROUND

CD99 is a 32 kDa transmembrane glycoprotein, encoded by the MIC2 gene, which is located in the pseudoautosomal region of the human X and Y chromosomes. Recently, the MIC2 gene has been shown to encode two distinct proteins which are produced by alternative splicing of the CD99 gene transcript and are identified as bands of 30 and 32 kDa (p30/32).

CD99 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD103



Human normal small bowel immunohistochemical staining of CD103. Note membrane and cytoplasmic staining of Intraepithelial T lymphocytes. CD103: clone EP206

EP206

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0374	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

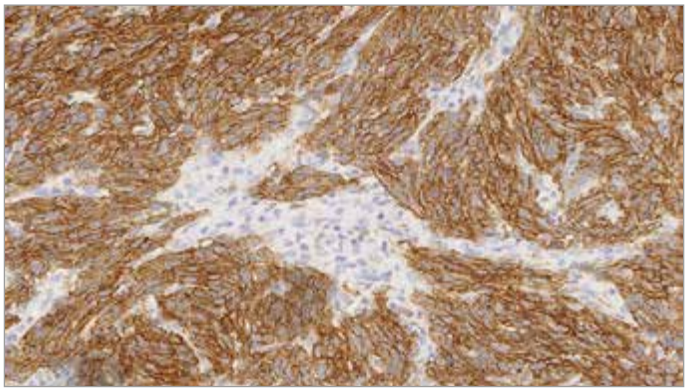
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

CD103, also known as alpha E integrin and human mucosal lymphocyte antigen 1, is an integrin protein with expression on intraepithelial T cells and some peripheral regulatory T cells. CD103 is expressed at high levels on tumor-infiltrating FOXP3-positive regulatory T cells in cancer. CD103-positive T cells are strongly associated with patient survival in high-grade serous ovarian cancer. CD103 expression has been suggested as a definitive marker of intraepithelial, tumor-specific infiltrating lymphocytes. In addition, CD103-positive cells have also been identified in a small proportion of breast cancers.

CD103 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD117



Human colon, gastrointestinal stromal tumor: immunohistochemical staining for CD117. CD117: clone EP10

EP10

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0007	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD117-032	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

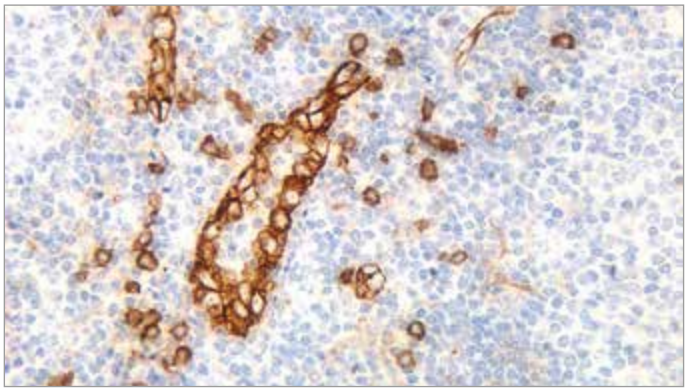
GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

The c-kit proto-oncogene encodes a transmembrane receptor with tyrosine kinase activity, c-kit (CD117), which is closely-related to the platelet-derived growth factor receptor family. c-kit plays a role during hematopoiesis, gametogenesis and melanogenesis. The expression of CD117 antigen is of particular interest in the study of gastrointestinal stromal tumors (GIST), small lung cell carcinomas and in melanomas.

CD117 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD123



Human high walled venule endothelium and plasmacytoid dendritic cells: immunohistochemical staining for CD123: clone BR4MS

BR4MS

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CD123	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

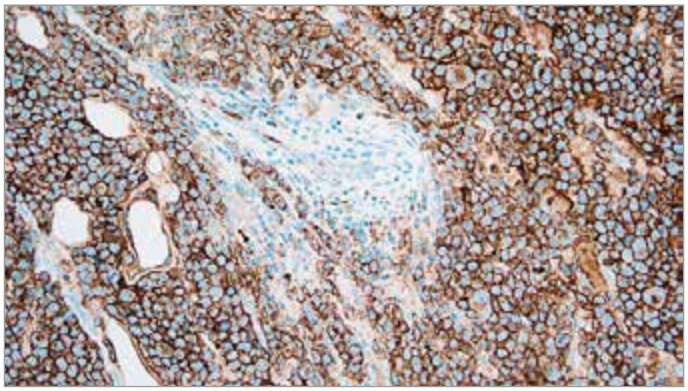
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD123 antigen is also known as the alpha subunit of the human interleukin-3 receptor. It is a type I transmembrane glycoprotein and is a member of the cytokine receptor superfamily. CD123 forms a heterodimer with CD131 (the beta subunit of the interleukin-3 receptor) to form the interleukin-3 receptor, where the cytokine specificity is provided by the alpha subunit and the signal transduction function is provided by the beta subunit. The interleukin-3 receptor is reported to be expressed on monocytes, neutrophils, basophils, eosinophils, megakaryocytes, erythroid precursors, mast cells, macrophages and a subpopulation of B cells, where it mediates proliferation and differentiation of these cells. Outside the hematopoietic system CD123 is reported to be expressed in Leydig cells of the testis, some endothelial cells, and cells of the placenta and brain.

CD123 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD138 (Syndecan 1)



Plasmacytoma: immunohistochemical staining for CD138. CD138: clone MI15

MI15

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0088	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

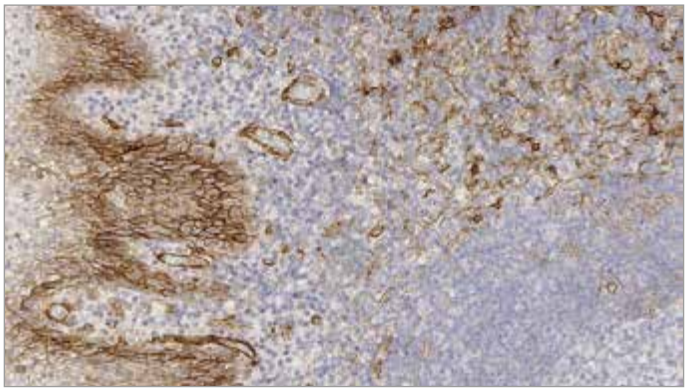
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD138 molecule is a transmembrane heparan sulphate glycoprotein expressed at distinct stages of differentiation in normal lymphoid cells such as pre-B cells, immature B cells and Ig-producing plasma cells as well as being expressed in stratified and simple epithelia. The loss of CD138 expression from atypical cells is reported to be an early event during cervical carcinogenesis whereas CD138 antigen expression shows a close association with preserved epithelial morphology and differentiation; however, the major utility of CD138 as a marker in immunohistochemistry is the quantification of plasma cells.

CD138 (Syndecan 1) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD141 (Thrombomodulin)



Human tonsil: immunohistochemical staining for CD141. Note membrane staining of the basal cells of the squamous mucosa, endothelium and a subset of dentritic cells. CD141: clone 15C8

15C8

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CD141	P(HIER)	IVD	-	-

PATHOLOGY MENU

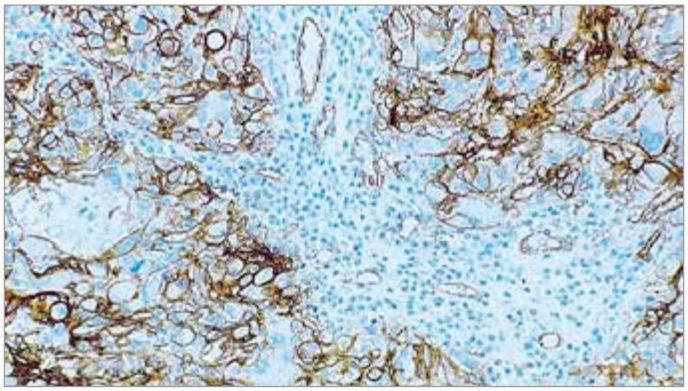
SPECIALIZED

ANTIGEN BACKGROUND

Thrombomodulin is a transmembrane glycoprotein of 75 kD which can accelerate the activation of protein C. Activated protein C functions as an anticoagulant by combining with protein S to inactivate factors Va and VIIIa of the blood coagulation pathway and by binding thrombin. Several factors regulate thrombomodulin expression. Downregulation of thrombomodulin may be induced by the cytokine interleukin-1, tumor necrosis factor and endotoxin. Agents which increase cyclic AMP such as forskolin may upregulate thrombomodulin activity in endothelial cells. Thrombomodulin has been identified within a number of normal tissues. These include the lining cells of arteries, veins, capillaries and the lymphatics as well as mesothelial cells, meningeal lining cells, synovial cells, syncytiotrophoblasts, megakaryocytes and platelets.

CD141 (Thrombomodulin) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD146 (MCAM)



Human malignant melanoma: immunohistochemical staining for CD146. CD146: clone N1238

N1238

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CD146	P(HIER)	IVD	-	-

PATHOLOGY MENU

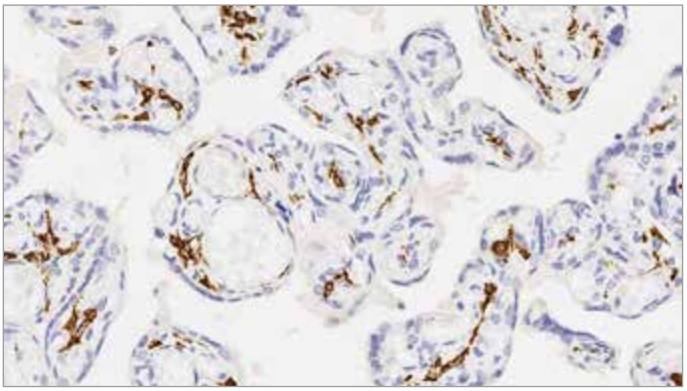
DERMATOPATHOLOGY

ANTIGEN BACKGROUND

CD146 protein is also known as the melanoma metastasis-associated surface molecule, MUC18, A32 antigen, S-Endo-1 and the melanoma cell adhesion molecule, MCAM or Mel-CAM. Originally, the CD146 molecule was defined as a marker of tumor progression and metastasis formation in human melanoma. More recently, it has been reported to be expressed on endothelial cells, smooth muscle and cerebellar cortex. Structurally, CD146 is an integral membrane glycoprotein of 113 kD with the characteristic V-V-C2-C2-C2 immunoglobulin-like domain structure. It shares considerable homology with chicken neural adhesion molecule, chicken gicerin, goldfish neurolin and is also closely related to the human blood group glycoprotein, lutheran. Although CD146 molecule functions as a cell adhesion molecule it interacts with an as yet uncharacterized ligand. CD146 can be induced on all T cells via PHA, recall antigen, superantigen and T cell receptor/CD3 stimulation. Furthermore reports suggest that the CD146 molecule is involved in the extravasation and homing of activated T cells. CD146 protein can promote tumor progression in human melanoma, possibly through enhanced interaction between melanoma cells and endothelial cells. In contrast, CD146 protein may act as a tumor suppressor in breast carcinoma with expression frequently lost in some cases.

CD146 (MCAM) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CD163



Human placenta: immunohistochemical staining for CD163. Note cytoplasmic staining of Hofbauer cells. CD163: clone 10D6

10D6

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0090	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CD163	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

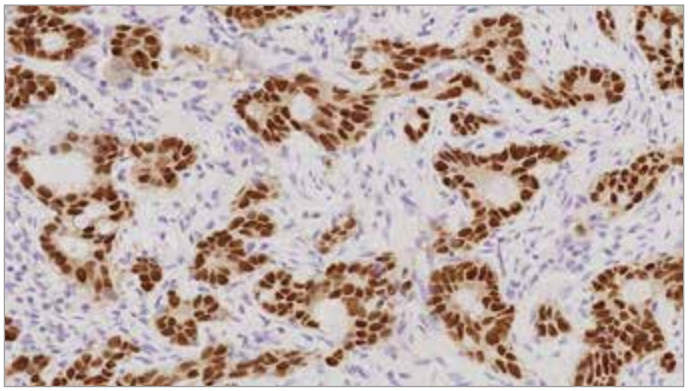
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The CD163 molecule is a type I membrane protein also known as M130 antigen, Ber-Mac3, Ki-M8 or SM4. CD163 protein is restricted in its expression to the monocytic/macrophage lineage. It is reported to be present on all circulating monocytes and most tissue macrophages except those found in the mantle zone and germinal centers of lymphoid follicles, interdigitating reticulum cells and Langerhans cells. In addition, multi-nucleated cells within inflammatory lesions are reported not to express CD163 protein. The protein is upregulated by glucocorticoids and downregulated by the immunosuppressant cyclosporin A and by phorbol esters, while lipopolysaccharide, an inflammatory mediator, has no influence on expression. It has been proposed that a specific release mechanism of soluble CD163 antigen by human monocytes may play an important role in modulating inflammatory processes.

CD163 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CDX2



Human colonic adenocarcinoma: immunohistochemical staining for CDX2. CDX2: clone EP25

EP25

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0375	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

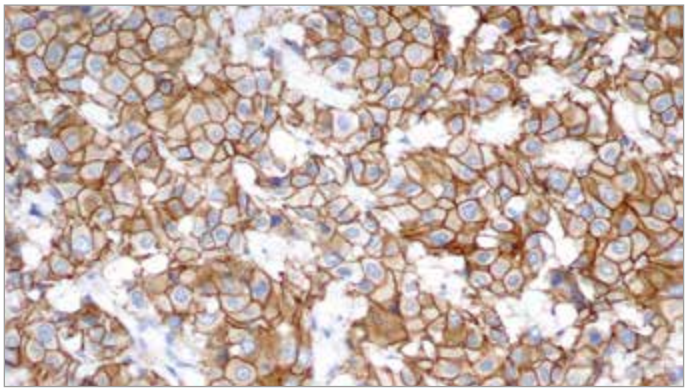
CDX2 is a caudal-type homeobox, intestine-specific transcription factor expressed early in intestinal development and may be involved in the regulation of proliferation and differentiation of intestinal epithelial cells. CDX2, as well as CDX1, is of particular interest as the intestine is the only organ that contains detectable levels of either gene product.

This pattern of restricted expression is unusual for homeobox genes. Phosphorylation of the CDX2 activation domain can modulate its function and different spatial expression patterns in the intestinal epithelium. CDX2 is primarily expressed on the surface of the villus and in the crypts. In contrast to CDX1, intense CDX2 expression is reported to occur in all but the distal portions of the developing intestine.

The loss of CDX2 has been reported to contribute towards the progression of some sporadic colorectal cancers. It has been reported that CDX2 may also be associated with carcinogenesis of the stomach as expression of CDX2 mRNA progressively decreases with the transition from well differentiated to poorly differentiated gastric cancer cell lines.

CDX2 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

c-erbB-2 Oncoprotein (HER-2) Antibodies



Human breast: invasive ductal carcinoma: immunohistochemical staining for c-erbB-2 Oncoprotein (HER-2): clone CB11

CB11

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0983	P(HIER)	IVD	IVD	IVD
BOND 30 mL	PA0571	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CB11	P	-	IVD	IVD

10A7

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CBE-356	P	-	IVD	IVD/RUO

PATHOLOGY MENU

BREAST PATHOLOGY

ANTIGEN BACKGROUND

The c-erbB-2 oncoprotein is closely related in structure to the epidermal growth factor receptor and is a member of a large family of cell surface growth factor receptors. c-erbB-2 oncoprotein is reported to be detectable in a proportion of breast and other adenocarcinomas as well as transitional cell carcinomas. c-erbB-2 oncoprotein is present in a wide variety of cell types in a range of normal human fetal and adult tissues, including breast, stomach and ovary. CB11 detects the internal domain of the c-erbB-2 oncoprotein. CBE-356 detects the external domain of the c-erbB-2 oncoprotein.

c-erbB-2 Oncoprotein (HER-2) Antibodies are recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

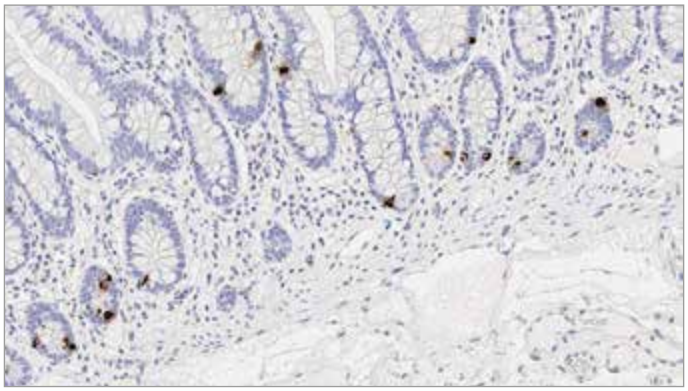
PRODUCT SPECIFIC INFORMATION

The use of the heat induced epitope retrieval (HIER) technique can enhance staining in some cases.

INTENDED USE

This reagent is for in vitro diagnostic use. The c-erbB-2 Oncoprotein (CB11) monoclonal antibody is intended to be used for the qualitative identification by light microscopy of c-erbB-2 oncoprotein in formalin-fixed, paraffin-embedded tissue by immunohistochemical staining.

Chromogranin A



Human small bowel: immunohistochemical staining for Chromogranin A. Note cytoplasmic staining of neuroedocrine cells. Chromogranin A: clone 5H7

5H7

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0515	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CHROM-430	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

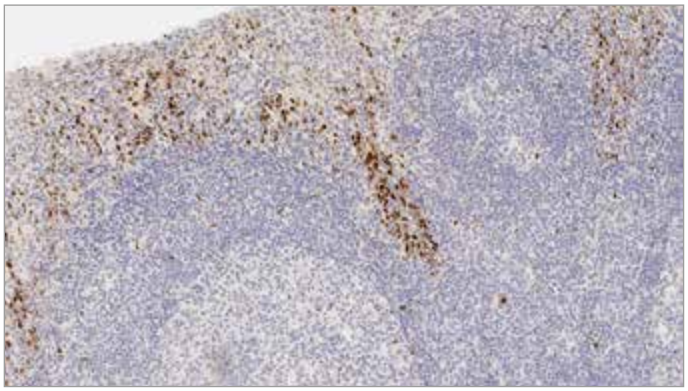
HEAD, NECK AND ENDOCRINE

ANTIGEN BACKGROUND

Chromogranin A is a 68 kD acidic protein which is reported to be widely expressed in neural tissues and in secretory granules of human endocrine cells, for example, parathyroid gland, adrenal medulla, anterior pituitary gland, islet cells of the pancreas and C cells of the thyroid. Chromogranin A expression has been reported in neuroendocrine tumors such as pituitary adenomas, islet cell tumors, phaeochromocytomas, medullary thyroid carcinomas, Merkel cell tumors and carcinoids.

Chromogranin A is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Cyclin D1



Human mantle cell lymphoma: immunohistochemical staining for Cyclin D1.
Cyclin D1: clone EP12

EP12

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0046	P(HIER)	IVD	IVD	IVD

P2D11F11

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CYCLIND1-GM	P(ENZYME/HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

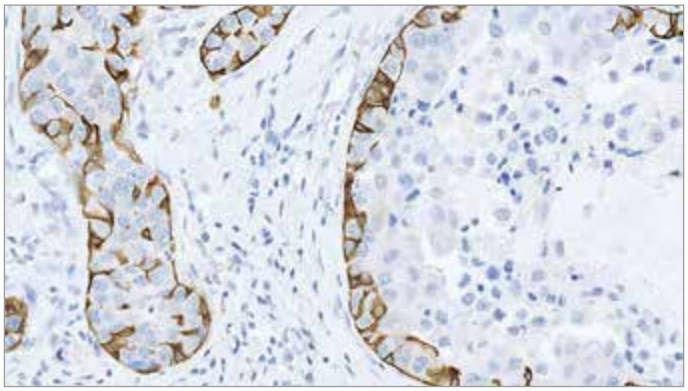
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The D-type cyclins are a family of proteins which function primarily by regulating the activity of cyclin dependent kinases in the G1 phase of the cell cycle. Cyclin D1, a protein of 36 kD, is also known as PRAD1 or bcl-1. Maximum expression of cyclin D1 occurs at a critical point in mid to late G1 phase of the cell cycle. The cyclin D1 gene, located on 11q13 has been reported to be overexpressed in mantle cell lymphomas due to the chromosomal translocation t(11;18).

Cyclin D1 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Cytokeratin 5



Human breast, ductal carcinoma in situ: immunohistochemical staining for Cytokeratin 5.
Cytokeratin 5: clone XM26

XM26

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0468	P(HIER)	IVD	IVD	IVD
Liquid 0.5 mL	NCL-L-CK5	P(HIER)	IVD	IVD	IVD/RUO
Liquid 1 mL	NCL-L-CK5	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

UROPATHOLOGY

ANTIGEN BACKGROUND

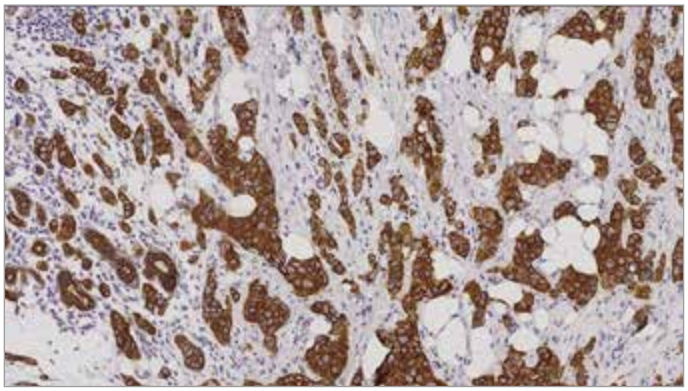
Cytokeratins are a large family of cytoskeletal proteins found in epithelial cells. They are co-ordinately synthesized in pairs so that at least one member of each family is expressed in each epithelial cell. Cytokeratins assemble into obligatory heteropolymers composed of type I (acidic) and type II (basic) polypeptides to form higher order tetramers and protofilaments. Basal cells of human epidermis express acidic keratin 14 and basic cytokeratin 5. Cytokeratin 5 is a 58 kD protein that is closely related to cytokeratin 6. They share similar tissue distribution and are found in various proportions in many non-keratinizing stratified squamous epithelia, for example, tongue mucosa, as well as in basal epithelia of trachea, basal cells of epidermis, hair follicles, sebaceous and sweat glands of skin, luminal cells of the mammary gland, basal cells of prostate, urothelium, vagina and endocervical mucosa. Cytokeratins 5 and 6 are also expressed in basal cell epitheliomas, squamous cell carcinomas of skin, tongue, epiglottis and of the rectal-anal region. Point mutations in the cytokeratin 5 gene at locus 12q11-q13 can cause various types of epidermolysis bullosa simplex. Cytokeratin 5 is also reported to be expressed in most epithelial and biphasic mesotheliomas.

Cytokeratin 5 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Clone XM26 is specific for the 58 kD intermediate filament protein known as cytokeratin 5. It is not cross-reactive with cytokeratin 6.

Cytokeratin 7



Invasive breast carcinoma: immunohistochemical staining for Cytokeratin 7.
Cytokeratin 7: clone RN7

RN7

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0942	P(HIER)	IVD	IVD	IVD
BOND 30 mL	PA0138	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CK7-560	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

TUMOR DIFFERENTIATION

ANTIGEN BACKGROUND

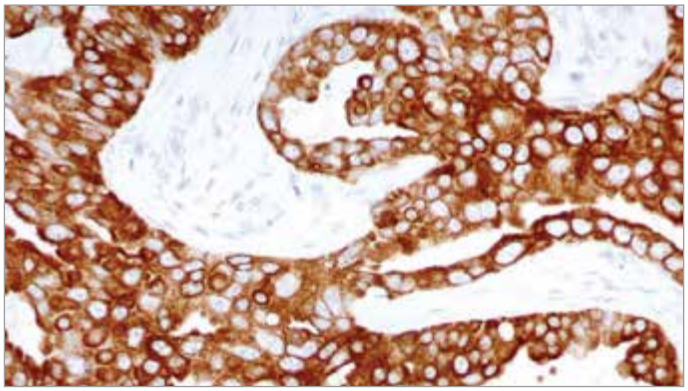
Cytokeratins are intermediate filament proteins present in epithelial cells. They are expressed in a tissue-specific manner in normal organs and the tumors that arise from them. Cytokeratin 7 belongs to the neutral basic type B subfamily of cytokeratins. Its distribution is confined to glandular and transitional epithelia. Cytokeratin 7 is reported to be expressed in abundance in cultured bronchial and mesothelial cells but only at lower levels in cultured epidermal cells. The predicted amino acid sequence of this keratin has revealed a striking difference between this keratin and the type II keratins expressed in epidermal cells. Cytokeratin 7 has been reported in adenocarcinomas of the lung, breast, endometrium, ovary, thyroid as well as in carcinomas of the bladder and chromophobe renal cell carcinoma. Cytokeratin 7 and Cytokeratin 20 expression have been reported to show characteristic patterns on primary and metastatic lung and colorectal adenocarcinomas.

Cytokeratin 7 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Where clone OV-TL 12/30 can produce unwanted staining of endothelial cells, clone RN7 does not stain these cell types. The choice of epitope retrieval, heat or enzyme, to provide the best result with clone OV-TL 12/30 should be determined and validated by the user. Clones RN7 and OV-TL 12/30 react with the human cytokeratin intermediate filament protein (54 kD) identified as cytokeratin 7.

Cytokeratin 8



Immunohistochemical staining for Cytokeratin 8: clone TS1

TS1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0567	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CK8-TS1	-	ASR	RUO	RUO

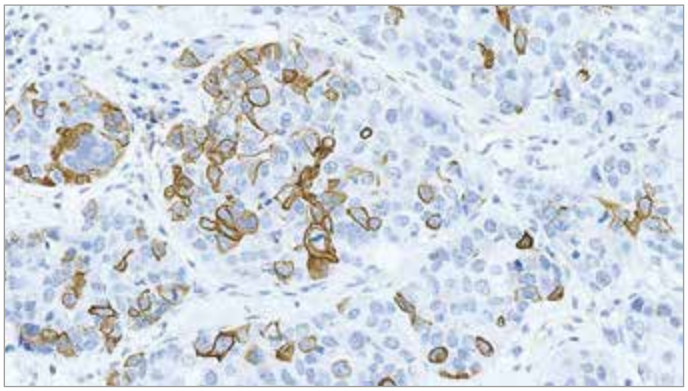
PATHOLOGY MENU

TUMOR DIFFERENTIATION

ANALYTE SPECIFIC REAGENT

Analyte Specific Reagent. Analytical and performance characteristics are not established.

Cytokeratin 14



Invasive breast cancer: immunohistochemical staining for the Cytokeratin 14. Cytokeratin 14: clone LL002

LL002

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0074	P(HIER)	IVD	IVD	IVD
Liquid 0.5 mL	NCL-L-LL002	P(HIER)	IVD	IVD	IVD/RUO
Liquid 1 mL	NCL-L-LL002	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

TUMOR DIFFERENTIATION

ANTIGEN BACKGROUND

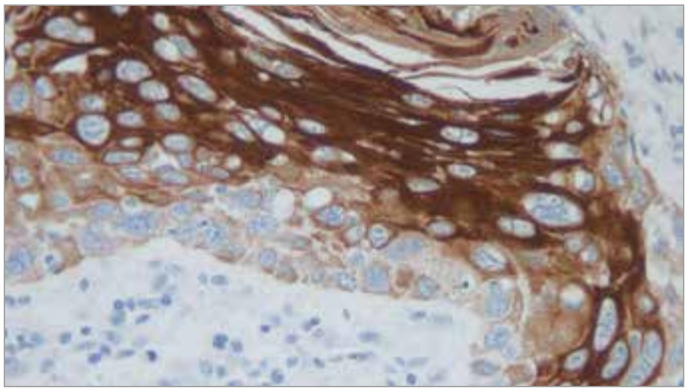
Cytokeratins 14 and 5 are useful to distinguish stratified epithelial cell types from simple epithelial cell types. Cytokeratin 14 has been reported to be expressed in neoplasms of squamous cell origin.

Cytokeratin 14 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Clone LL002 reacts with the human cytokeratin intermediate filament protein (50 kD) identified as cytokeratin 14.

Cytokeratin 17



Human squamous cell carcinoma, floor of the mouth: immunohistochemical staining for Cytokeratin 17. Cytokeratin 17: clone E3

E3

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0114	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CK17	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

TUMOR DIFFERENTIATION

ANTIGEN BACKGROUND

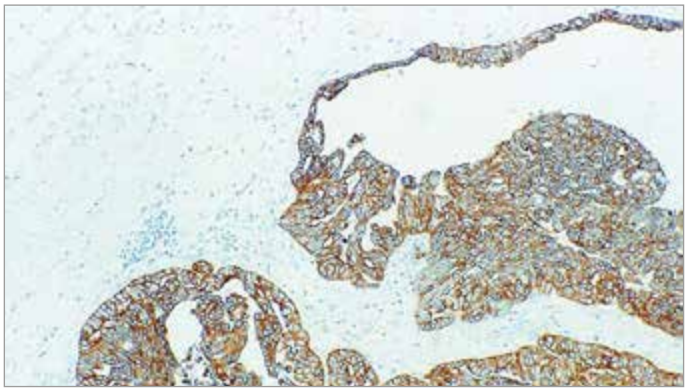
In normal tissues cytokeratin 17 is reported to be expressed in basal cells of complex epithelia, for example, basal cells of pseudostratified epithelium in the trachea, larynx, bronchi, myoepithelial cells in salivary glands and sweat glands. In neoplastic tissue, cytokeratin 17 is reported to be expressed in squamous cell carcinomas of the lung, cervix and oral cavity.

Cytokeratin 17 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

CK17 reacts with the human cytokeratin intermediate filament protein (46 kD) identified as cytokeratin 17.

Cytokeratin 18



Human colonic adenocarcinoma: immunohistochemical staining for Cytokeratin 18. Cytokeratin 18: clone DC-10

DC-10

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CK18	P(HIER)	IVD	-	-

PATHOLOGY MENU

TUMOR DIFFERENTIATION

ANTIGEN BACKGROUND

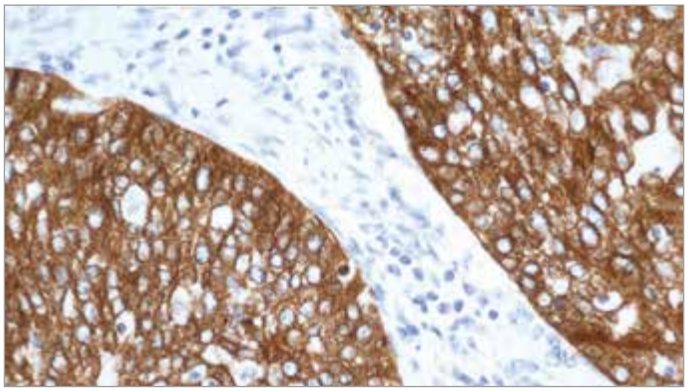
Cytokeratin 18 is normally co-expressed with cytokeratin 8 and is found in most simple ductal and glandular epithelia.

Cytokeratin 18 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

CK18 reacts with the acidic cytokeratin intermediate filament protein (45 kD) identified as cytokeratin 18. Cytokeratin 18 is reported not to be expressed in stratified squamous epithelium on most squamous cell carcinomas.

Cytokeratin 19



Human rectal adenocarcinoma: immunohistochemical staining for Cytokeratin 19. Cytokeratin 19: clone b170

b170

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0799	P(ENZYME)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-CK19	P(HIER)	IVD	-	-

PATHOLOGY MENU

TUMOR DIFFERENTIATION

ANTIGEN BACKGROUND

The smallest human cytokeratin filament protein (40 kD) has been identified as cytokeratin 19 and has been reported to be expressed in a large number of epithelial cell types, including many ductal and glandular epithelia.

Cytokeratin 19 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Clone b170 produces a complex heterogeneous staining pattern in non-keratinizing squamous epithelia and hair follicles, with strong staining of the basal layer observed.

Cytokeratin 20

Human colon: immunohistochemical staining for Cytokeratin 20. Note the intense staining of surface mucosa. Cytokeratin 20: clone Ks.20.8

Ks20.8

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0022	P(HIER)	IVD	IVD	IVD
BOND 30 mL	PA0037	P(HIER)	IVD	IVD	IVD
Liquid 0.5 mL	NCL-L-CK20	P(HIER)	IVD	IVD	IVD/RUO
Liquid 1 mL	NCL-L-CK20	P(HIER)	IVD	IVD	IVD/RUO

PW31

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CK20-561	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

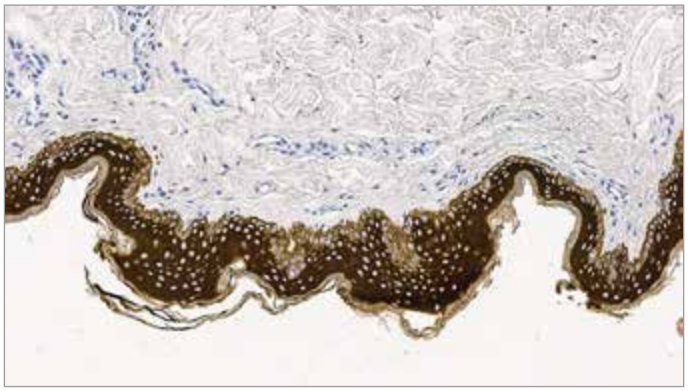
TUMOR DIFFERENTIATION

ANTIGEN BACKGROUND

Cytokeratin 20 has been demonstrated to be almost entirely confined to the gastric and intestinal epithelium, urothelium and Merkel cells of the skin. Cytokeratin 20 is less acidic than other type I cytokeratins and is of interest due to its restricted tissue expression. In normal tissue, cytokeratin 20 is expressed in intestinal epithelium, gastric foveolar epithelium, a number of endocrine cells in the upper portions of the pyloric glands, urothelium and Merkel cells in epidermis. In tumors it is reported, there is a marked difference in the expression of cytokeratin 20 within different carcinomas. Neoplasms expressing cytokeratin 20 are derived from normal epithelia which themselves expressed cytokeratin 20. Colorectal carcinomas consistently express cytokeratin 20, while gastric adenocarcinomas express cytokeratin 20 to a lesser degree. Adenocarcinomas of the gall bladder and bile duct, ductal cell adenocarcinomas of the pancreas, mucinous ovarian tumors, Merkel cell tumors and transitional cell carcinomas have also been reported to express cytokeratin 20.

Cytokeratin 20 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Cytokeratin (5/6/18)



Human skin: immunohistochemical staining of LP34 (cytokeratins 5/6/18) localized throughout the epidermis, with the strongest staining in the stratum spinosum. There is an absence of staining in the dermis. Cytokeratin (5/6/18): clone LP34

LP34

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-LP34	P(ENZYME)	IVD	RUO	RUO

PATHOLOGY MENU

UROPATHOLOGY

ANTIGEN BACKGROUND

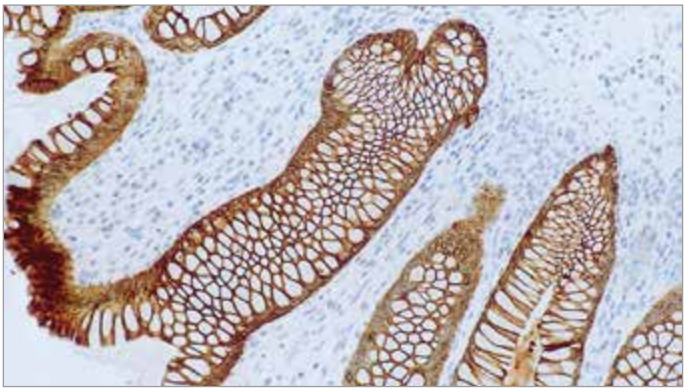
Cytokeratins 5, 6 and 18 are reported to be expressed in a broad range of human epithelial tissues, from simple glandular epithelia to stratified squamous epithelia. These include epithelial cells that are ectodermal, mesodermal, or endodermal in origin. These cytokeratins have been reported to be expressed in tumor cells of epithelial origin and less commonly of mesothelial origin. Non-epithelial tumors such as lymphomas do not express these cytokeratins.

Cytokeratin (5/6/18) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

The recognition of cytokeratin 18 on formalin fixed paraffin embedded sections using clone LP34 may be variable.

Cytokeratin (8/18)



Colon mucosa: immunohistochemical staining for Cytokeratin 8/18: clone 5D3

5D3

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0067	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-5D3	P(ENZYME)	IVD	IVD	IVD

PATHOLOGY MENU

TUMOR DIFFERENTIATION

ANTIGEN BACKGROUND

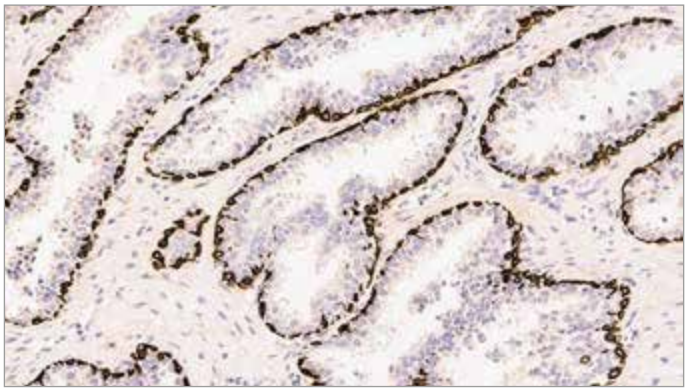
In normal tissues, cytokeratins 8 and 18 are reported to be expressed in all simple and glandular epithelium and in neoplastic tissues, they have been reported to be expressed in adenocarcinomas and most squamous cell carcinomas. These cytokeratins are absent from keratinizing squamous carcinomas.

Cytokeratin (8/18) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Clone 5D3 reacts with human cytokeratin intermediate filament proteins of 52.5 kD and 45 kD, identified as cytokeratins 8 and 18, respectively. Clone 5D3 shares similar specificities to clone CAM5.2 (Angus B et al. Journal of Pathology. 153: 377-384 (1987)).

Cytokeratin, Multi (1/5/10/14) (High Molecular Weight)



Human prostate: immunohistochemical staining of the basal cells of the prostate with anti-cytokeratin (high molecular weight) antibody. Cytokeratin, Multi (1/5/10/14): clone 34βE12

34βE12

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0134	P(ENZYME)	IVD	IVD	IVD

PATHOLOGY MENU

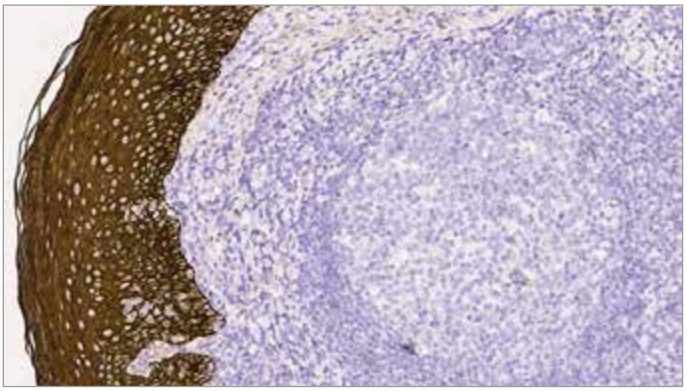
TUMOR DIFFERENTIATION

ANTIGEN BACKGROUND

34βE12 reacts with human cytokeratin intermediate filament proteins 1, 5, 10 and 14. The antibody is reported to react with squamous epithelium and sweat ducts in normal skin, some pneumocytes, bronchial epithelium and mesothelium in normal lung and bile ducts in normal liver. It also reacts with ductal cells of the normal pancreas, some acinar and ductal cells of normal breast, some follicular epithelia of normal thyroid and some epithelia and mesothelium of the normal small and large bowel.

Cytokeratin, Multi (1/5/10/14) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Cytokeratin, Multi (4/5/6/8/10/13/18)



Human tonsil: immunohistochemical staining for cytokeratin, Multi. Note the cytokeratins demonstrated in stratified squamous epithelium. The negative cells in the epithelium are infiltrating lymphocytes. Cytokeratin, Multi (4/5/6/8/10/13/18): clone C-11

C-11

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-C11	P(HIER)	IVD	-	-

PATHOLOGY MENU

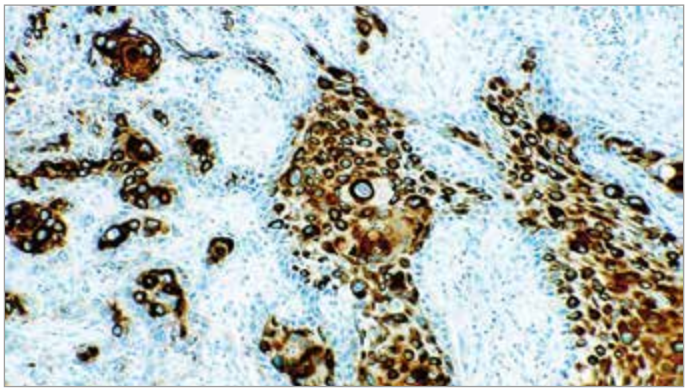
TUMOR DIFFERENTIATION

ANTIGEN BACKGROUND

Cytokeratins 4, 5, 6, 8, 10, 13 and 18 are differentially expressed between a variety of normal, reactive and neoplastic epithelia and also simple epithelium and both basal and suprabasal layers of cornifying and noncornifying squamous epithelium.

Cytokeratin, Multi (4/5/6/8/10/13/18) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Cytokeratin, Multi (5/6/8/18)



Human squamous cell carcinoma of the floor of the mouth: immunohistochemical staining for cytokeratins. Cytokeratin, Multi (5/6/8/18): clone 5D3/LP34

5D3/LP34

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-CK5/6/8/18	P(ENZYME)	RUO	RUO	RUO

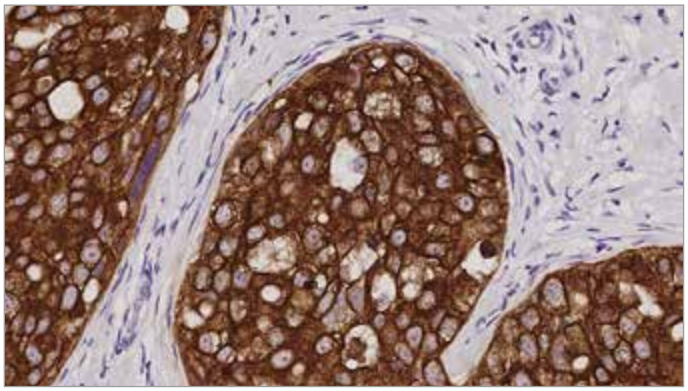
PATHOLOGY MENU

TUMOR DIFFERENTIATION

ANTIGEN BACKGROUND

CK5/6/8/18 reacts with human cytokeratins 5, 6, 8 and 18. These products are cocktails of monoclonal antibodies designed to recognize cytokeratins reported to be expressed in almost all epithelial tissues.

Cytokeratin, Multi (AE1/AE3)



Human invasive ductal carcinoma of breast: immunohistochemical staining for AE1/AE3. Multi-Cytokeratin: clone AE1/AE3

AE1/AE3

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0094	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-AE1/AE3-601	P(HIER)	IVD	IVD	IVD

AE1/AE3 (Previous Formulation)

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0909	P(ENZYME)	IVD	IVD	IVD

PATHOLOGY MENU

TUMOR DIFFERENTIATION

ANTIGEN BACKGROUND

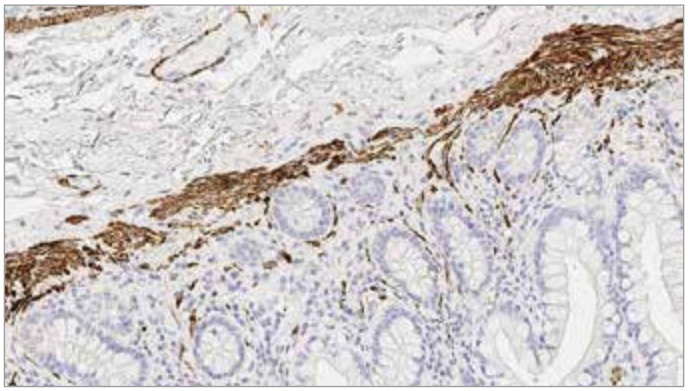
Keratins are a family of water insoluble proteins of 40 to 70 kD. These proteins form tonofilaments, a class of intermediate filament, in epidermis as well as in almost all other epithelia. The process of normal epidermal differentiation is characterized by a series of morphological and biochemical changes as cells progress from the germinative basal layer through the spinous and granular layers to the outer cornified layer. The 65 to 67 kD cytokeratins are reported to be present only above the basal layer, the 58 kD cytokeratin is reported to be expressed throughout the entire epidermis including the basal layer and the 56 kD cytokeratin is reported to be absent from the basal layer and is normally eliminated during stratum corneum formation. The 56 and 65 to 67 kD cytokeratins are reported to be characteristic of epidermal cells undergoing terminal differentiation and may be considered as molecular markers for keratinization.

Cytokeratin, Multi (AE1/AE3) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Clones AE1 and AE3 are specific for the 56.5, 50, 50', 48 and 40 kD acidic cytokeratins as well as the 65 to 67, 64, 59, 58, 56 and 52 kD basic cytokeratins. The cocktail of clones AE1 and AE3 exhibit broad reactivity with two families of cytokeratin, acidic and basic.

Desmin



Human bowel: immunohistochemical staining for desmin. Note cytoplasmic staining of smooth muscle containing cells. Desmin: clone DE-R-11

DE-R-11

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0032	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-DES-DERII	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

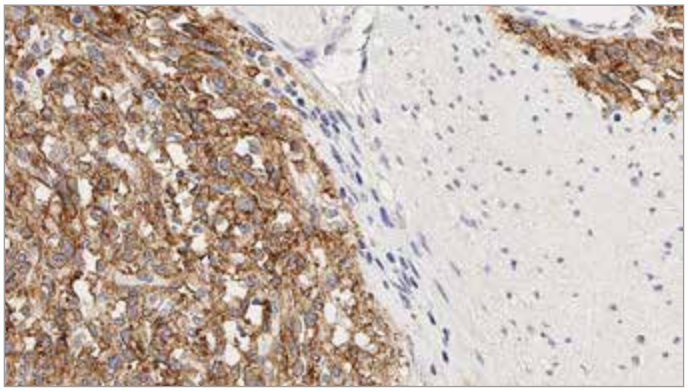
SOFT TISSUE PATHOLOGY

ANTIGEN BACKGROUND

DES-DERII reacts with an 18 kD rod piece of the intermediate filament protein desmin (53 kD) in muscle cells. The antibody does not appear to recognize other intermediate filament proteins. In normal tissues, Clone DE-R-11 reacts with both striated (skeletal and cardiac) and smooth muscle cells. The labeling is confined to the Z bands in skeletal and cardiac muscle giving a characteristic striated appearance.

Desmin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

DOG-1



Human colon, gastrointestinal stromal tumor: immunohistochemical staining for DOG-1. DOG-1: clone K9

K9

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0219	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-DOG-1	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

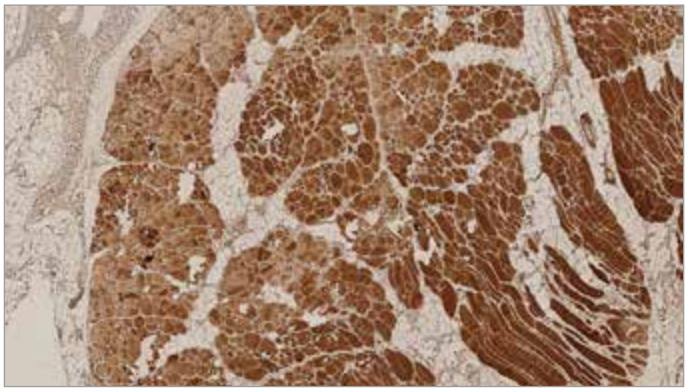
DOG-1, a 986 amino acid protein of unknown function, is expressed predominantly on the plasma membrane of gastrointestinal stromal tumors (GISTs) and is rarely expressed in other soft tissue tumors, which, due to appearance, can be confused with GISTs. Reactivity for DOG-1 has been suggested to aid in the identification of GISTs, including Platelet-Derived Growth Factor Receptor Alpha mutants that fail to express KIT antigen.

DOG-1 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

The use of PBS-based diluents may result in increased background staining.

Dysferlin Antibodies



Human skeletal muscle: immunohistochemical staining of HAMLET: HAMLET: clone Ham1/7B6

Ham1/7B6

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-HAMLET	F;P(HIER)	IVD	IVD	IVD

Ham3/17B2

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-HAMLET-2	F;P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

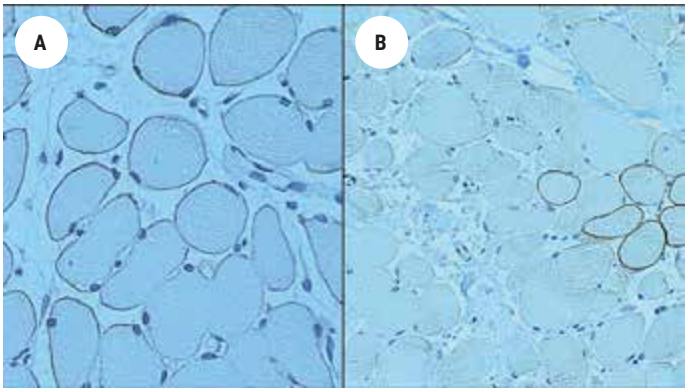
Dysferlin is the protein product of the 2p13 gene that is defective in patients with Limb-Girdle Muscular Dystrophy type 2B (LGMD2B) and Miyoshi Myopathy (MM). Dysferlin is normally localized to the muscle plasma membrane. In patients with LGMD2B and MM, immunoreactivity to dysferlin is severely reduced or lost. Patients with other neuromuscular conditions demonstrate normal labeling patterns.

Dysferlin Antibodies are recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

The use of the heat induced epitope retrieval (HIER) technique can enhance staining in some cases.

Dystrophin Antibodies



Human skeletal muscle: immunohistochemical staining for Dystrophin. Note membrane staining of normal muscle fibers (A) and reduced and variable staining of revertant muscle fibers (B). Dystrophin: clone 13H6

DYSA (Rod Domain): clone 13H6

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-DYSA	P(HIER)	RUO	RUO	RUO

DYSB (N-terminus): clone 34C5

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-DYSB	P(HIER)	RUO	RUO	RUO

DYS1 (Rod Domain): clone Dy4/6D3

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 2.5 mL	NCL-DYS1	F	IVD	IVD	IVD

DYS2 (C-terminus) : clone Dy8/6C5

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 2.5 mL	NCL-DYS2	F	IVD	IVD	IVD

DYS3 (N-terminus) : clone Dy10/12B2

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 2.5 mL	NCL-DYS3	F	IVD	IVD	IVD

PATHOLOGY MENU

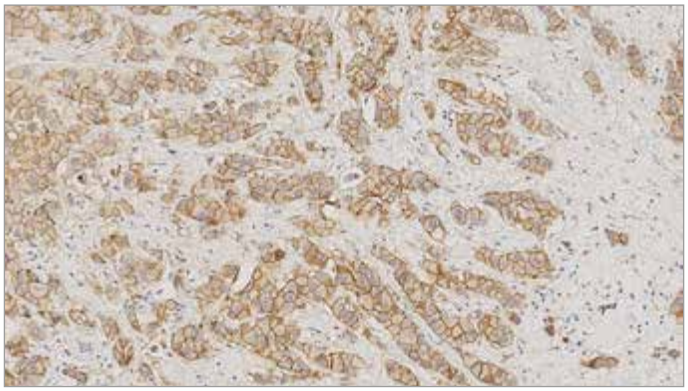
MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

Duchenne Muscular dystrophy (DMD) is the most common of the muscular dystrophies resulting in progressive muscular wasting and death. Dystrophin is the 427kD protein product of the DMD gene located on the X chromosome at position Xp21. Abnormalities in protein expression occur in patients with DMD/BMD and dystrophin analysis may be used to distinguish these conditions from other neuromuscular diseases. Severe Duchenne muscular dystrophy is associated with a marked dystrophin deficiency, whereas patients with the milder form of Becker muscular dystrophy show less pronounced abnormalities of protein expression. The immunolabeling patterns for DYS1, DYS2 and DYS3 are similar; however, the use of all three antibodies is recommended to avoid the possibility of occasional false negative results.

Dystrophin Antibodies are recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

E-Cadherin



Invasive breast carcinoma: immunohistochemical staining for E-Cadherin.
E-Cadherin: clone 36B5

36B5

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0387	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-E-Cad	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

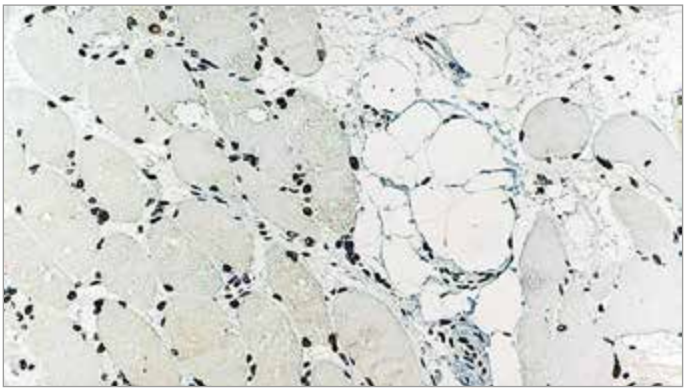
BREAST PATHOLOGY

ANTIGEN BACKGROUND

E-cadherin is a Ca^{2+}-dependent, transmembrane cell adhesion molecule. It plays an important role in the growth, development and the intercellular adhesion of epithelial cells. Most tumors have an abnormal architecture and any subsequent loss of adhesiveness is thought to be an important step in the development of local invasion. E-cadherin may have a role in neoplastic progression, particularly as a suppressor of invasion. In prostate cancers, for example, the expression of E-cadherin is reported to be reduced or absent in comparison with its expression in normal prostate which is uniformly strong. Reduced expression or absence of E-cadherin in addition to alpha, beta and gamma-catenin in primary breast carcinomas has also been reported and these four proteins are associated with the development of metastases.

E-Cadherin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Emerin



Human skeletal muscle: immunohistochemical staining for Emerin. Note perinuclear staining of all cell nuclei. Emerin: clone 4G5

4G5

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-EMERIN	F;P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

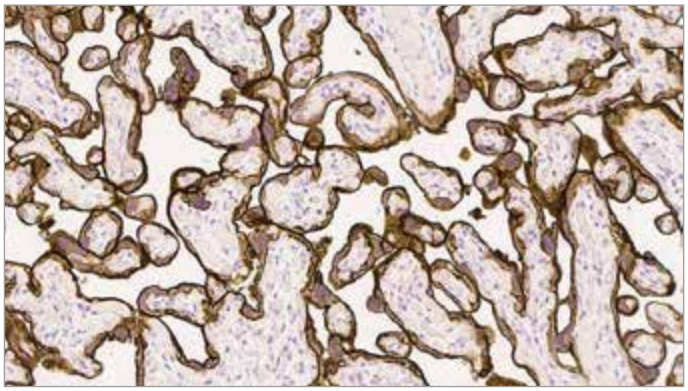
MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

Emery-Dreifuss muscular dystrophy (EDMD) is a late onset, X-linked, recessive disorder characterized by slowly progressing contractures, wasting of skeletal muscle and cardiomyopathy usually presented as heart block. Contractures are seen in the elbows, Achilles tendons and post cervical muscles with humero-peroneal distribution early in the course of the disease. The STA gene, at Xq28 locus, encodes a serine-rich 34kD protein, emerin, which is ubiquitous in tissues and is found in highest concentration in skeletal and cardiac muscle. Emerin is localized in the nuclear membrane of normal muscle cells and its deficiency plays a crucial part in the pathology of EDMD.

Emerin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Epidermal Growth Factor Receptor



Human Placenta: immunohistochemical staining for Epidermal Growth Factor Receptor. Epidermal Growth Factor Receptor: clone EGFR.113

EGFR.113

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-EGFR	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

LUNG PATHOLOGY

ANTIGEN BACKGROUND

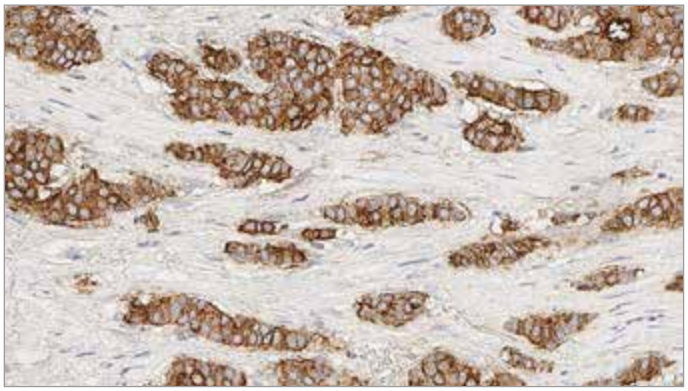
Epidermal growth factor receptor (EGFR) is a transmembrane protein receptor of 170 kD with tyrosine kinase activity. Increased levels of EGFR are reported to be linked with malignant transformation of squamous cells, for example, in squamous cell carcinoma of the lung, head, neck, skin, cervix and esophagus. EGFR may also play a role in the development and progression of hepatocellular carcinomas where recurrence rates are higher in EGFR-positive cases. This correlation has similarly been reported in colorectal cancers where EGFR, produced by tumor cells, plays an important role in the invasiveness and proliferation of colorectal cancers. The majority of published studies of EGFR expression in human breast cancer has similarly shown an association with EGFR expression where it is inversely related to estrogen receptor status.

Epidermal Growth Factor Receptor is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Clone EGFR.113 is raised to the extracellular domain of the EGFR molecule.

Epithelial Membrane Antigen



Human breast cancer: immunohistochemical staining for Epithelial Membrane Antigen. Epithelial Membrane Antigen: clone GP1.4

GP1.4

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0035	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-EMA	P	IVD	IVD	IVD/RUO

PATHOLOGY MENU

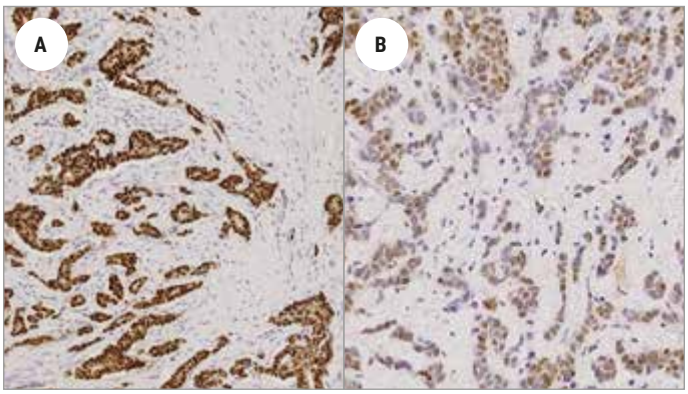
TUMOR DIFFERENTIATION

ANTIGEN BACKGROUND

Epithelial membrane antigen (EMA), also known as episialin, is reported to be expressed in a variety of normal and neoplastic epithelia. It has been reported that markers to CD45 (LCA) when used in conjunction with markers to EMA are useful in labeling cells of lymphoid origin, whereas the combination of anti-cytokeratin antibodies together with EMA is useful to characterize cells of epithelial origin. EMA is also notably described to be expressed in a subset of Hodgkin's lymphomas.

Epithelial Membrane Antigen is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Estrogen Receptor



Left: Invasive ductal carcinoma (high expressor): intense nuclear staining in nearly 100% of tumor cells. Right: Invasive ductal carcinoma (moderate expressor): immunohistochemical staining for estrogen receptor. Estrogen Receptor: clone 6F11

6F11

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0151	P(HIER)	IVD	IVD	IVD
BOND 30 mL	PA0009	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-ER-6F11	P(HIER)	IVD	IVD	IVD
Liquid 2 mL	NCL-L-ER-6F11/2	P(HIER)	-	IVD	IVD

PATHOLOGY MENU

BREAST PATHOLOGY

ANTIGEN BACKGROUND

Estrogen receptor (ER) content of breast cancer tissue is an important parameter in the prediction of prognosis and response to endocrine therapy. The introduction of highly specific monoclonal antibodies to ER has allowed the determination of receptor status of breast tumors to be carried out in routine histopathology laboratories.

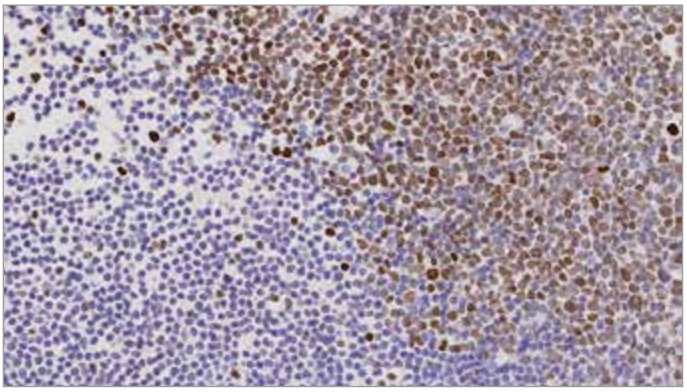
Estrogen Receptor is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Clone 6F11 is raised to the full length alpha form of the estrogen receptor molecule.

Refer to the IFU for appropriate use instructions.

EZH2 (Enhancer of Zeste Homolog 2 (Drosophila))



T-Cell Lymphoma: immunohistochemical staining for EZH2 antigen. EZH2 (Enhancer of Zeste Homolog 2 (Drosophila)): clone 6A10

6A10

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0575	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-EZH2	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

SPECIALIZED

ANTIGEN BACKGROUND

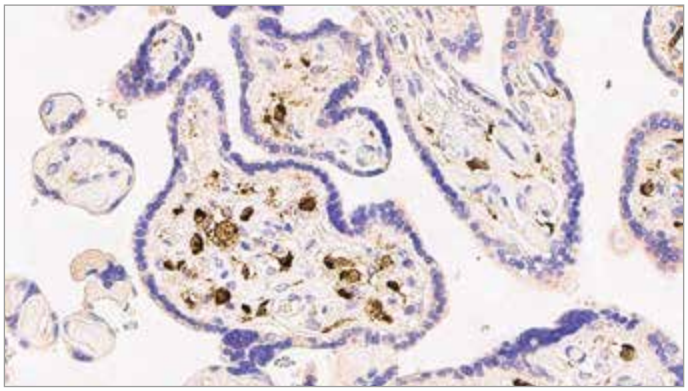
Polycomb-group proteins (PcG) such as EZH2 (Enhancer of Zeste Homolog 2 (Drosophila)) form multimeric gene repressing complexes involved in axial patterning, hematopoiesis and cell cycle regulation. PcG proteins ensure correct embryonic development by expressing homeobox genes as well as contributing to the regulation of lymphopoiesis.

EZH2 (Enhancer of Zeste Homolog 2 (Drosophila)) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

EZH2 stains optimally when used in TBS-based wash buffer and diluent systems.

Factor XIIIa (Blood Coagulation Factor XIIIa)



Human placenta: immunohistochemical staining of Factor XIIIa localized in the Hofbauer cells of the placental villi. Factor XIIIa (Blood Coagulation Factor XIIIa): clone E980.1

E980.1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0449	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-FXIIIa	P(HIER)	IVD	-	-

PATHOLOGY MENU

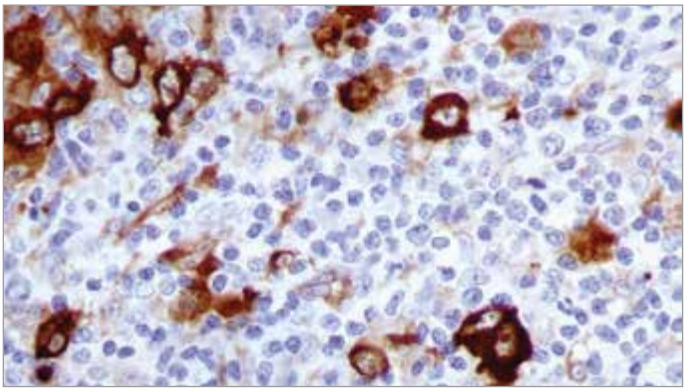
SPECIALIZED

ANTIGEN BACKGROUND

Factor XIIIa, also known as fibrinoligase and fibrin-stabilizing factor, is the last enzyme generated in the blood coagulation cascade. It is a Ca^{2+}-dependent transglutaminase or transamidating enzyme which forms intermolecular gamma-glutamyl-epsilon-lysine crosslinks between fibrin molecules resulting in the mechanical stabilization of the fibrin clot and its resistance to proteolysis. Factor XIIIa may also function to stabilize cell surface molecules and membranes. Ca^{2+}-dependent trans-glutaminases with thiol active centers are widespread in animal tissues and have been associated with cell proliferation, embryonic development and growth through the proliferation of mammary stroma and epithelial elements. Normal mammary stroma, like most collagenous connective tissue contains resident populations of CD34 positive dendritic interstitial cells and scattered Factor XIIIa positive collagen-associated dendrophages. Factor XIIIa has been examined to determine its expression in normal and inflamed skin. Factor XIIIa positive cells in human skin represent a specific population of bone marrow dermal dendritic cells, distinct from Langerhans cells which share some features common to mononuclear phagocytes. In benign skin conditions such as inflammatory dermatoses, for example, atopic eczema and psoriasis, an increased number of factor XIIIa positive cells in the upper dermis, closely associated with lymphocytes, has been described.

Factor XIIIa (Blood Coagulation Factor XIIIa) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Fascin



Hodgkin's lymphoma: immunohistochemical staining with Fascin: clone IM20

IM20

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0420	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-FASCIN	P(HIER); W	RUO	RUO	RUO

PATHOLOGY MENU

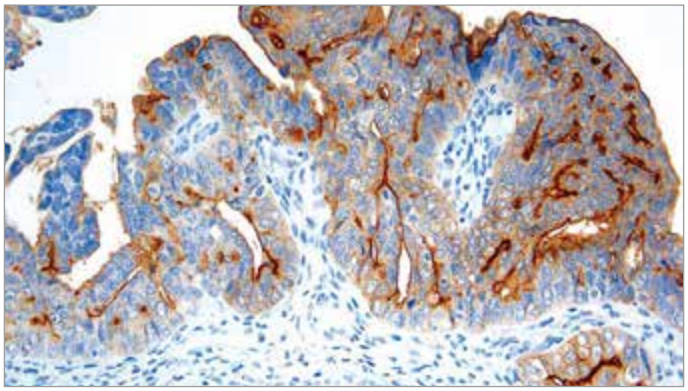
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

Human fascin is a 55 to 58 kD actin-bundling protein, whose actin binding ability is regulated by phosphorylation. In normal tissues the detection of fascin is reported to be predominantly restricted to dendritic cells, and in the thymus has been observed only in medullary dendritic cells. In reactive nodes, interdigitating reticulum cells of T cell zones, cells in subcapsular areas, and cells of the reticular network express fascin. Variable expression is seen in follicular dendritic cells and endothelial cells. Lymphoid cells, myeloid cells and plasma cells do not express fascin; however, in cases of Hodgkin's disease, including nodular sclerosis, mixed cellularity lymphocyte depletion and unclassified cases, most or all Reed Sternberg cells are reported to be positive for fascin. Fascin expression may be induced by Epstein-Barr virus (EBV) infection of B cells with the possibility that viral induction of fascin in lymphoid or other cell types must also be considered in EBV-positive cases.

Fascin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Folate Receptor Alpha



Ovarian tumor: immunohistochemical staining for Folate Receptor Alpha.
Folate Receptor Alpha: clone BN3.2

BN3.2

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-FRalpha	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

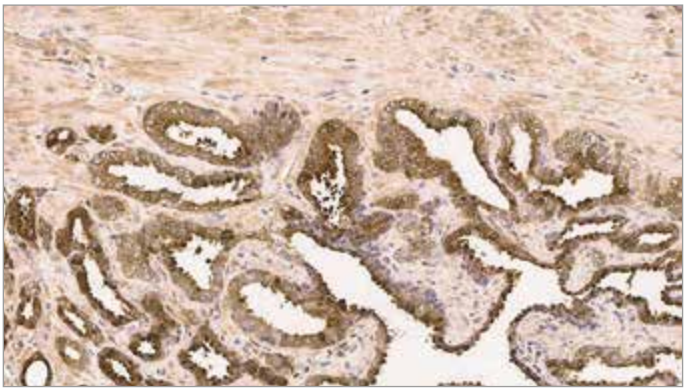
SPECIALIZED

ANTIGEN BACKGROUND

Folate is a basic component of cell metabolism and DNA synthesis and repair. It is involved in essential one-carbon transfer reactions and is a vitamin required by both normal and tumor cells. Folate entry into cells is facilitated via two different systems: the reduced folate carrier, which utilizes a bidirectional anion-exchange mechanism, and the folate receptor system. Folate receptor alpha is a membrane-bound member of the folate receptor family, facilitating folate transport via a mechanism termed potocytosis where the receptor is internalized and then recycled back to the cell membrane. Staining patterns are both membranous and cytoplasmic due to this mechanism. Members of the folate receptor family share highly conserved sequences in the open reading frames, but differ in amino acids in the 5' untranslated regions and as a consequence can differ in function and tissue expression. Folate receptor alpha expression is reported to be highly restricted in normal tissues and only selectively overexpressed in a limited number of epithelial malignancies.

Folate Receptor Alpha is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Galectin-3



Prostate carcinoma: immunohistochemical staining of Galectin-3. Galectin-3: clone 9C4

9C4

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0238	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

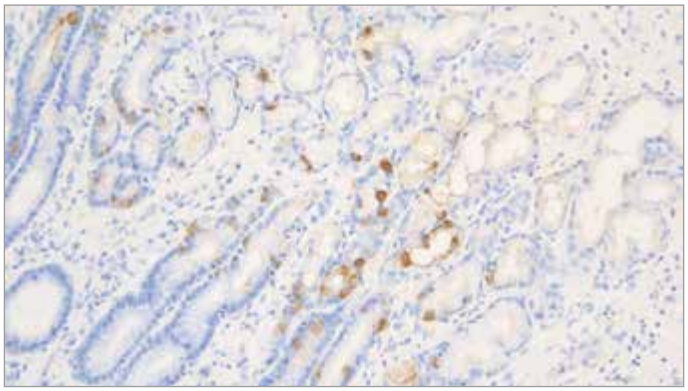
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

Galectin-3 is a member of the beta-galactosidase-binding lectin family. It is involved in several biological events including binding to the basement membrane glycoprotein laminin. Cell surface galectin-3 may be involved in homotypical cell adhesion and is downregulated in colon cancer as the disease progresses. This downregulation has also been examined in breast carcinoma with a similar correlation of expression reported. Downregulation of galectin-3 could be one of the many events that enable cancer cells to interact with laminin to facilitate invasion and metastasis and may indicate activation of the invasive phenotype in various tumor types.

Galectin-3 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Gastrin



Normal human stomach: immunohistochemical staining for Gastrin. Note: intense cytoplasmic staining of neuroendocrine cells. Gastrin: Polyclonal

Polyclonal

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0681	P	IVD	IVD	IVD

PATHOLOGY MENU

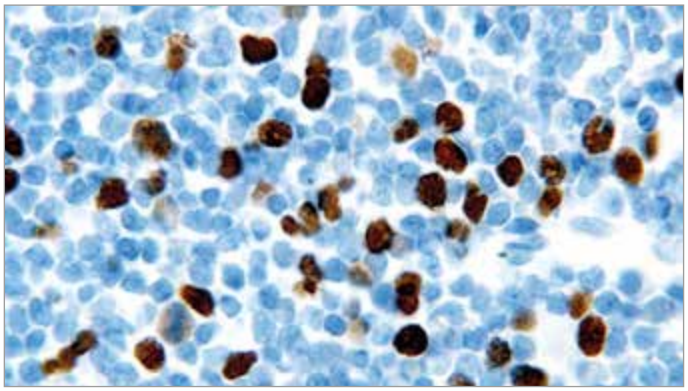
GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

Gastrin, a polypeptide hormone, occurs naturally in three forms: gastrin-14, gastrin-17 and gastrin-34. Both primary and secondary G cell hyperplasia are reported to be characterized by clustering of the immunoreactive cells which sometimes project buds from the mucous glands.

Gastrin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Geminin



Human chronic lymphocytic leukemia: immunohistochemical staining for Geminin. Geminin: clone EM6

EM6

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-Geminin	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

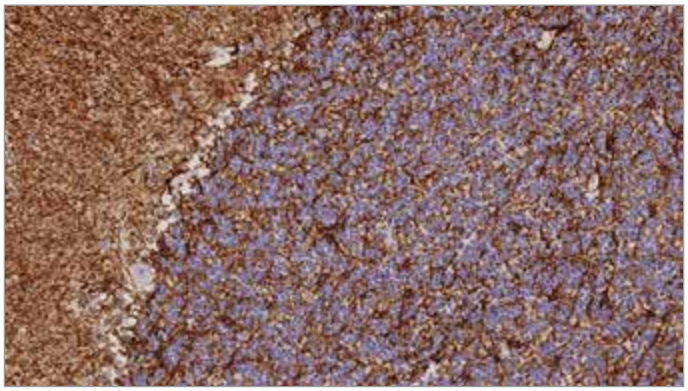
SPECIALIZED

ANTIGEN BACKGROUND

Geminin is a protein of 209 amino acids thought to be involved in the control of DNA replication via the interaction with Cdt1. Geminin is not found in the G1 phase of the cell cycle, but is first expressed in the G1 to S transition phase, with expression levels rising through the rest of the cell cycle and levels reaching a maximum during mitosis. It has been proposed that geminin may be a tumor suppressor protein. Geminin is reported to be expressed in proliferating lymphocytes and epithelial cells, for example, germinal centers in tonsil as well as in colon, spermatocytes, seminiferous tubules of the testes, within the basal layers of the squamous epithelium of the skin and breast. Geminin is reported to be upregulated in cancers such as non-Hodgkin's lymphoma, B cell lymphoma, breast carcinoma and colon carcinoma.

Geminin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Glial Fibrillary Acidic Protein



Normal brain: immunohistochemical staining for Glial Fibrillary Acidic Protein.
Glial Fibrillary Acidic Protein: clone GA5

GA5

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0026	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-GFAP-GA5	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

NEUROPATHOLOGY

ANTIGEN BACKGROUND

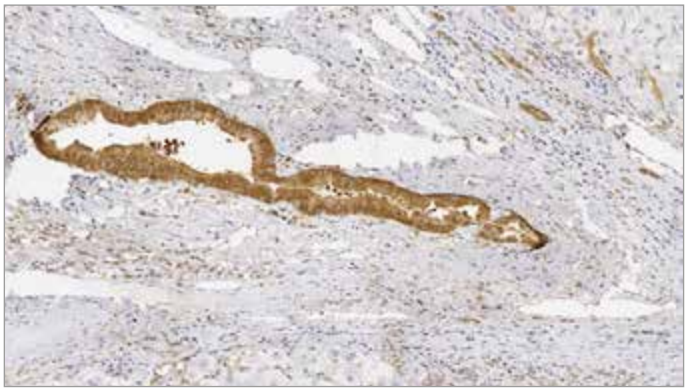
Glial fibrillary acidic protein (GFAP) is an intermediate filament protein of 52kD reported to be expressed in glial cells, for example, astrocytes and ependymal cells. In the peripheral nervous system, GFAP has been reported to be expressed in Schwann cells, enteric glial cells and satellite cells of human sensory ganglia and in neoplastic tissues GFAP has been reported to be expressed in astrocytomas and ependymomas.

Glial Fibrillary Acidic Protein is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

The use of the heat induced epitope retrieval (HIER) technique can enhance staining in some cases.

Glutathione S-Transferase (GST) Antibody



Human liver: immunohistochemical staining for GSTpi. Note staining of bile ducts.
Glutathione S-transferase pi: clone LW29

LW29

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-GSTpi-438	P	IVD	-	-

PATHOLOGY MENU

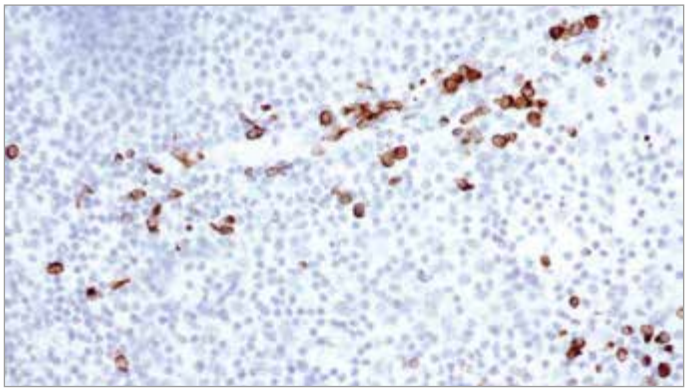
SPECIALIZED

ANTIGEN BACKGROUND

The glutathione S-transferases (GSTs) are a multigene family of isoenzymes which catalyze the conjugation of glutathione to electrophilic substrates. These enzymes are involved in the detoxification of both endogenous and exogenous electrophiles which can react with cellular components such as DNA. The modification of DNA by reactive compounds can initiate carcinogenesis and the GSTs are believed to play a role in neutralizing carcinogens. The cytosolic GST isoenzymes have been classified into four evolutionary classes; alpha, mu, pi and theta. These isoenzymes are reported to be singly or multi-expressed in a variety of normal tissues, including stomach, bowel, brain, heart, liver, pancreas, breast, kidney and skin at differing levels. In gastric cancers, the levels of GSTalpha and pi are reported to differ from normal gastric tissue with GSTalpha showing decreased levels and GSTpi increased levels.

Glutathione S-Transferase (GST) Antibody is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Granzyme B



Human tonsil: immunohistochemical staining for Granzyme B: clone 11F1

11F1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0291	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-GRAN-B	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

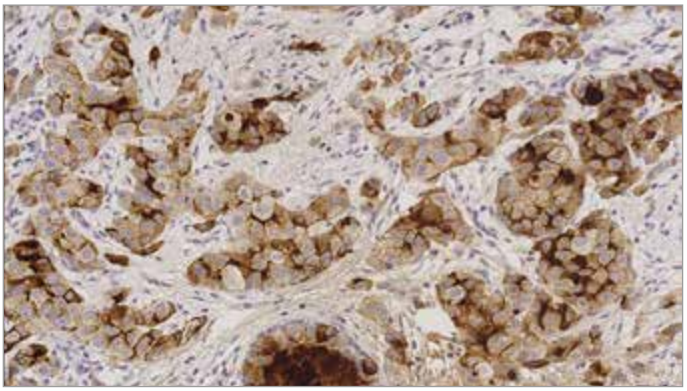
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

Granzymes are neutral serine proteases which are stored in specialized lytic granules of cytotoxic T lymphocytes (CTL) and in natural killer (NK) cells. These CTL and NK cells are heavily involved in the elimination of neoplastic and virally infected cells. Secretory granules containing perforin and granzymes are instrumental in undertaking cytolytic activity. Granzyme B is understood to enter a target cell through a perforin pore-formed channel to induce DNA fragmentation and apoptosis. Granzyme B has also been described in neoplastic CTL and NK cells.

Granzyme B is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Gross Cystic Disease Fluid Protein-15



Invasive breast carcinoma: immunohistochemical staining for Gross Cystic Disease Fluid Protien-15. Gross Cystic Disease Fluid Protein-15: clone 23A3

23A3

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0708	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-GCDFP15	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

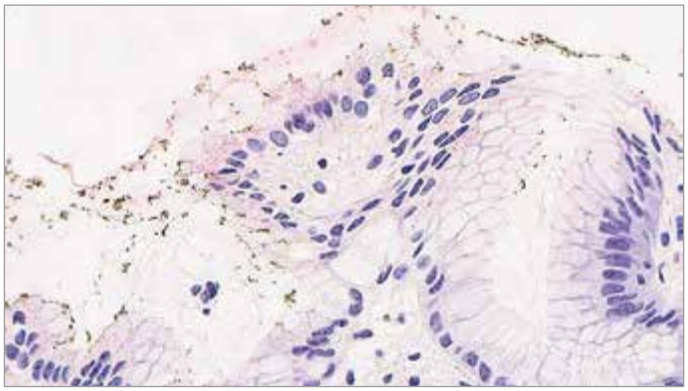
BREAST PATHOLOGY

ANTIGEN BACKGROUND

Gross cystic disease of the breast is a benign premenopausal disorder in which cysts are a predominant pathological lesion. These cysts appear to be formed from excessive apocrine cystic secretions. This fluid is composed of several glycoproteins including a unique 15 kD monomer protein, GCDFP15. It has been reported that cytosolic analysis of normal tissue from all major organs has demonstrated GCDFP15 in apocrine epithelia, lacrimal, ceruminous and Moll's glands and in numerous serous cells of the submandibular, tracheal, bronchial, sublingual and minor salivary glands. Cytosol from breast carcinoma lesions are reported to contain GCDFP15 at a wide range of concentrations. The concentration is reported to be highest in more differentiated carcinomas and GCDFP15 shows only a few positive individual epithelial cells within lobules and small ducts in normal breast. Expression has also been reported in fibroadenomas within areas of apocrine metaplasia.

Gross Cystic Disease Fluid Protein-15 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Helicobacter pylori



Immunohistochemical staining for Helicobacter pylori: clone ULC3R

Polyclonal

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 7 mL	IHC5994-A	-	ASR	-	-

ULC3R

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-Hpylori	-	ASR	IVD	IVD

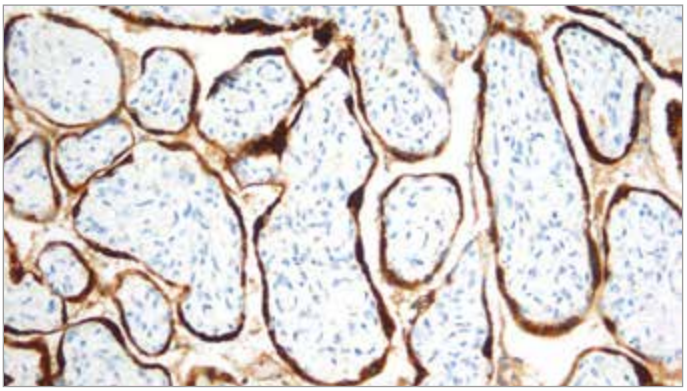
PATHOLOGY MENU

GASTROINTESTINAL PATHOLOGY

ANALYTE SPECIFIC REAGENT

Analyte Specific Reagent. Analytical and performance characteristics are not established.

Human Chorionic Gonadotrophin (beta)



Human placenta: immunohistochemical staining with Human Chorionic Gonadotrophin (beta): Polyclonal

Polyclonal

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0014	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

GYNEPATHOLOGY

ANTIGEN BACKGROUND

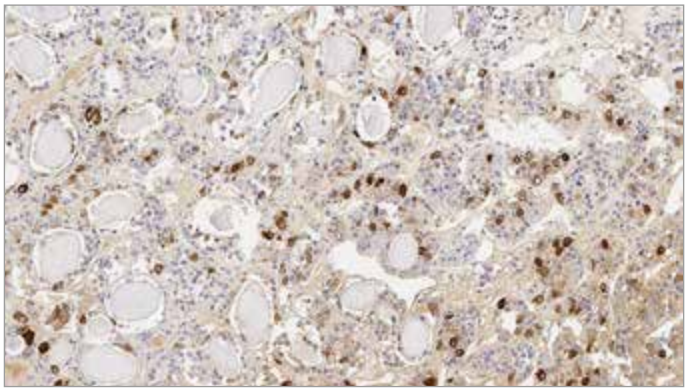
Human chorionic gonadotrophin (hCG) is a glycoprotein hormone produced by trophoblastic cells of the placenta beginning 10 to 12 days after conception. Maintenance of the fetus in the first trimester of pregnancy requires the production of hCG, which binds to the corpus luteum of the ovary which is stimulated to produce progesterone which in turn maintains the secretory endometrium. hCG is composed of two subunits, alpha and beta. The alpha subunit of hCG is identical to the subunit of luteinising hormone, thyroid stimulating hormone and follicle stimulating hormone. The common alpha chain and the hormone-specific beta chains have molecular weights of 14 kD and 17 kD, respectively. The hCG beta-subunit is unique in the family of beta-containing glycoprotein hormones in that it contains an extension of 29 amino acids at its COOH end. It is believed that the C-terminal region of the HCG-beta subunit plays a role in the intracellular behavior of the heterodimer.

Human Chorionic Gonadotrophin (beta) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

HCGp was raised to the isolated beta-chain of human chorionic gonadotrophin and reacts with placental trophoblasts. HCGp shows a slight cross-reaction with luteinising hormone and may, therefore, stain basophil cells in the pituitary.

Human Follicle Stimulating Hormone (beta 2) (HFSH)



Human pituitary: immunohistochemical staining for HFSH. Note cytoplasmic staining of gonadotrophic cells. Human Follicle Stimulating Hormone (beta 2): clone INN-hFSH-60

INN-hFSH-60

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0693	P(ENZYME)	IVD	IVD	IVD

PATHOLOGY MENU

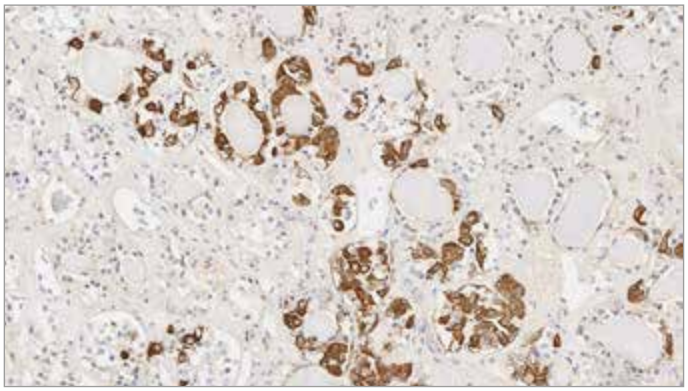
HEAD, NECK AND ENDOCRINE

ANTIGEN BACKGROUND

Follicle stimulating hormone (FSH) is a pituitary hormone of 35 kD which is involved in the maturation of ovarian follicles and estrogen secretion in females. In males, FSH stimulates the secretion of testosterone.

Human Follicle Stimulating Hormone (beta 2) (HFSH) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Human Growth Hormone (HGH)



Human pituitary: immunohistochemical staining for HGH. Note cytoplasmic staining of somatotrophic cells. Human Growth Hormone: Polyclonal

Polyclonal

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0704	P	IVD	IVD	IVD

PATHOLOGY MENU

HEAD, NECK AND ENDOCRINE

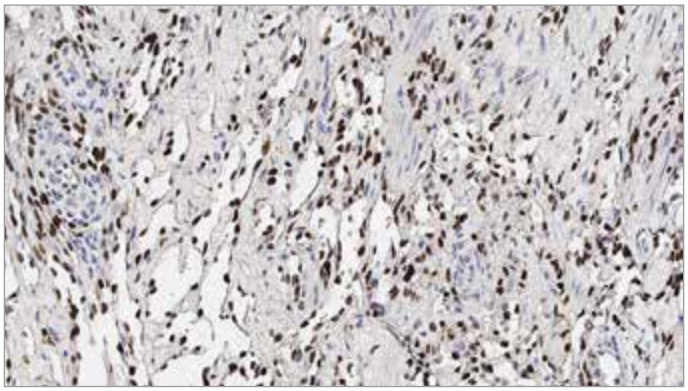
ANTIGEN BACKGROUND

Growth hormone (GH), somatotropin, is the primary hormone responsible for regulating overall body growth and is also important in organic metabolism. It is synthesized by acidophilic or somatotropic cells of the anterior pituitary gland. Human GH has a molecular weight of 22 kD.

GH stimulates growth indirectly by promoting the liver's production of somatomedins, which act directly on bone and soft tissue to cause growth. GH exerts direct metabolic effects on the liver, adipose tissue and muscle. In general, growth hormone enhances protein synthesis, conserves carbohydrates and uses up fat stores.

Human Growth Hormone (HGH) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Human Herpesvirus 8 (HHV8)



Human skin, Kaposi's sarcoma: immunohistochemical staining for HHV8.
Human Herpesvirus 8: clone 13B10

13B10

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0050	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-HHV8-LNA	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

DERMATOPATHOLOGY

ANTIGEN BACKGROUND

Human herpesvirus type 8 (HHV8), is the proposed etiological agent of Kaposi's sarcoma (KS). It is reported that HHV8 has been demonstrated in KS tissues by immunohistochemistry, in situ PCR and also in situ hybridization. HHV8 encodes a latent nuclear antigen (LNA) which is the product of the viral gene ORF73. LNA is capable of forming a complex with retinoblastoma susceptibility gene product which may be related to its oncogenic activity. HHV8 has been reported to be expressed in multicentric Castleman's disease (MCD) and in angioimmunoblastic lymphadenopathies. The localization of HHV8 in subcapsular spindle cell proliferations, which is where early intranodal KS begins, and endothelial cells in Castleman's disease may explain the link between intranodal KS and MCD. In MCD, HHV8 is reported to be expressed in mantle zone large immunoblastic B cells.

Human Herpesvirus 8 (HHV8) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Immunoglobulin A

Human appendix: immunohistochemical staining for Immunoglobulin A. Note the intense staining of plasma cells and secreted Immunoglobulin A: clone N1CLA

N1CLA

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-IgA	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

HEMATOPATHOLOGY

ANTIGEN BACKGROUND

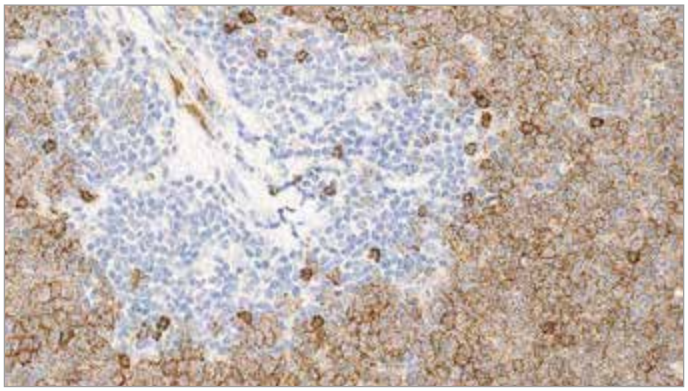
IgA is a member of the antibody class of the immunoglobulin superfamily. There are several classes and subclasses (isotypes) of antibody, the antibody isotype being defined by the immunoglobulin heavy chain present in the molecule. The basic structure of an immunoglobulin molecule consists of two identical heavy chains (gamma , mu, alpha , delta , epsilon) and two identical light chains, either kappa or lambda. IgA contains the alpha -chain and may be present in a serum or secretory form. In serum, 90% of IgA is monomeric, while in its secretory form it is the main immunoglobulin found in secretions including tears, saliva, intestinal and bronchial mucous, sweat, colostrum, and secretions from the prostate and respiratory epithelia, where it has the job of defending exposed external surfaces of the body against attack from micro organisms. Secretory IgA is synthesized locally by plasma cells and dimerized intracellularly with a cysteine-rich J-chain.

Immunoglobulin A is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Clone N1CLA was developed to produce reduced background staining that is associated with polyclonal antibodies on paraffin sections.

Immunoglobulin D



Mantle cell lymphoma: immunohistochemical staining for Immunoglobulin D.
Immunoglobulin D: clone DRN1C

DRN1C

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0061	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-IgD	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

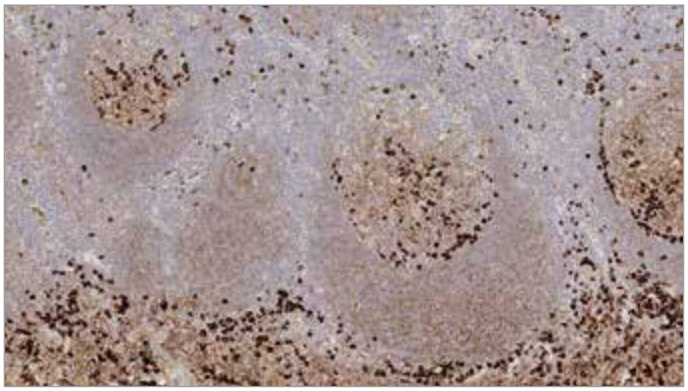
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

IgD, together with IgM, are the major immunoglobulins expressed on the surface of B cells where it seems they may operate as mutually interacting antigen receptors for the control of lymphocyte activation and suppression. The greater susceptibility of IgD to proteolysis in combination with antigen could well be implicated in such a function.

Immunoglobulin D is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Immunoglobulin G



Human tonsil: immunohistochemical staining for Immunoglobulin G. Note intense staining of plasma cells, weaker staining of follicular dendritic cell network and some B cells.
Immunoglobulin G: clone RWP49

RWP49

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0905	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-IgG	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

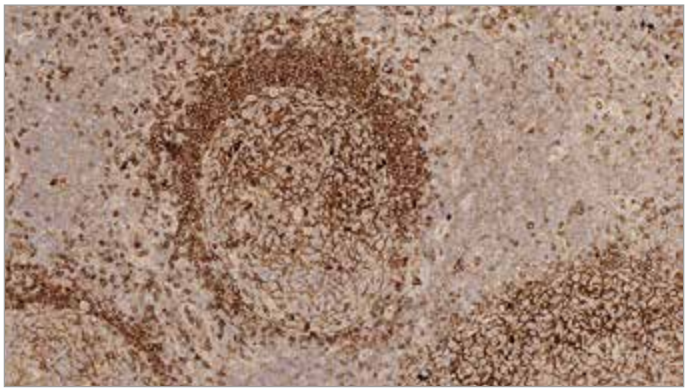
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The human immunoglobulins consist of two identical heavy chains (~50 kD) and two identical light chains, which are linked together by disulphide bonds. The light chains can be either kappa or lambda. The five immunoglobulins IgA, IgD, IgE, IgG and IgM differ in their heavy chains, and IgA and IgM differ as they can occur in polymeric forms. The heavy chain of IgG is named the gamma-chain. In humans, IgG consists of four sub classes that differ only marginally in their amino acid composition. Antibodies to IgG have been reported to be useful in the identification of plasma cells, lymphoid cells containing IgG and classifying B cell derived neoplasms. The normal B cell population is Polyclonal, expressing a range of different immunoglobulins. In contrast, the majority of B cell neoplasms are characterized by the proliferation of monoclonal cells expressing one type of light chain, whereas more than one type of heavy chain can be expressed by the same cell.

Immunoglobulin G is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Immunoglobulin M



Human tonsil: immunohistochemical staining for Immunoglobulin M. Note intense staining of plasma cells, weaker staining of follicular dendritic cell network and some B cells. Immunoglobulin M: clone 8H6

8H6

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0278	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-IgM	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

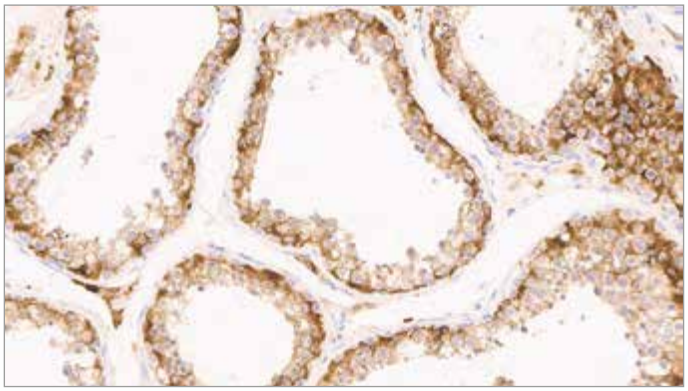
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

IgM, together with IgD, is the major immunoglobulin expressed on the surface of B cells and normally constitutes about 10 per cent of serum immunoglobulin. IgM antibody is prominent in early immune responses to most antigens and predominates in certain antibody responses such as natural blood group antibodies.

Immunoglobulin M is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Inhibin Alpha



Human testis: immunohistochemical staining for inhibin alpha showing cytoplasmic staining of Sertoli cells. Inhibin Alpha: clone R1

R1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0488	P(HIER)	IVD	IVD	IVD

AMY82

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-InhibinA	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

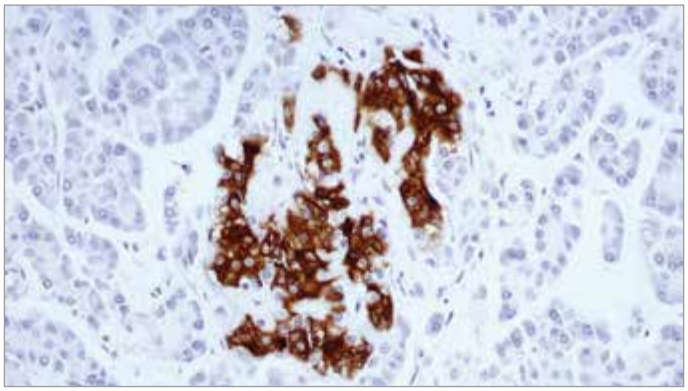
GYNEPATHOLOGY

ANTIGEN BACKGROUND

Inhibins and activins are members of the transforming growth factor beta (TGFβ) family of cytokines. Inhibins are heterodimers consisting of a common α-subunit linked to either a βA subunit (α-βA, forming inhibin A) or a βB subunit (α-βB, forming inhibin B). Activins share the β-subunit with the inhibins and may be homo or heterodimers of β-subunits forming activin A (βA-βA), activin AB (βA-βB) or activin B (βB-βB). The expression of the α-subunit, and therefore of inhibins appears to be more restricted than that of the β-subunit, and therefore of activins. Inhibins and activins play a role in the regulation of pituitary follicle stimulating hormone (FSH) secretion. The actions of inhibins and activins are thought to oppose one another, with inhibins suppressing FSH secretion and activins stimulating FSH secretion. Inhibins are secreted by granulosa cells in female follicles and Sertoli cells of the testis in the male. Inhibins are thought to have local regulatory roles in a variety of tissues, in addition to the ovary, including the brain, adrenal glands, bone marrow, fetus and placenta.

Inhibin Alpha is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Insulin



Human pancreas: immunohistochemical staining for insulin-containing cells. Note intense cytoplasmic staining. Insulin: clone 2D11-H5

2D11-H5

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0620	P	IVD	IVD	IVD
Liquid 1 mL	NCL-L-INSULIN	P	IVD	-	-

PATHOLOGY MENU

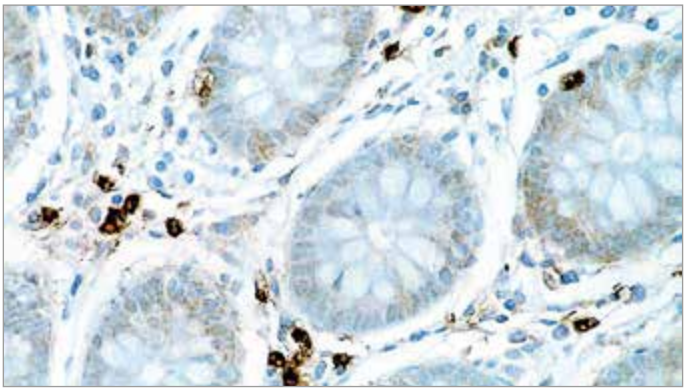
HEAD, NECK AND ENDOCRINE

ANTIGEN BACKGROUND

Insulin is a hormone secreted by the beta cells of the islets of Langerhans in the pancreas. It promotes glycogen storage, formation of triglycerides, and synthesis of protein and nucleic acids. Reports of immunocytochemical investigation reveal the presence of insulin in the cytoplasm of certain islet tumors. However, in some instances insulin-positive granules are sparse and form a margin against the cell membrane.

Insulin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Interleukin 6



Human colon: immunohistochemical staining for Interleukin 6. Note cytoplasmic staining of a proportion of lymphoid cells. Interleukin 6: clone 10C12

10C12

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-IL6	P	RUO	RUO	RUO

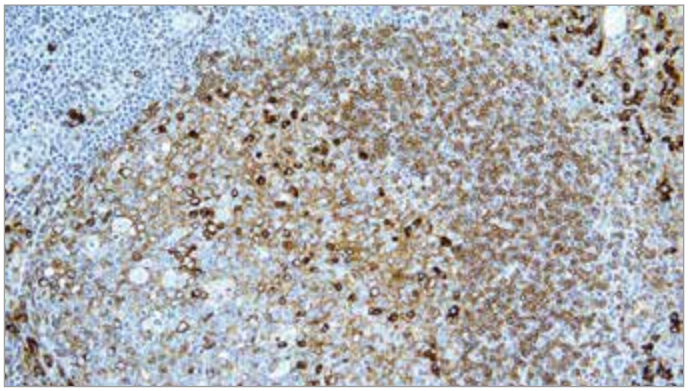
PATHOLOGY MENU

HEMATOPATHOLOGY

ANTIGEN BACKGROUND

IL-6 is a multifunctional cytokine that is secreted by both lymphoid and non-lymphoid cells. It plays a key role in immune responses, hematopoiesis and is an important cytokine in cell proliferation and differentiation. It may also play an important role as an autocrine growth factor in metastatic prostate cancer. IL-6 has been reported to play a role in secretion or release of pituitary hormone in pituitary hormone secreting cells and adenomas. In addition, IL-6 has been suggested to have a trophic effect in nerve cells and to have a direct pathogenic role in CNS disorders. There are an increasing number of reports that cytokines of the IL-6 family play an important regulatory role in heart physiology.

Kappa Light Chain



Human tonsil: immunohistochemical staining with Kappa Light Chain: clone CH15

CH15

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0606	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-KAP-581	P(ENZYME)	IVD	IVD	IVD

PATHOLOGY MENU

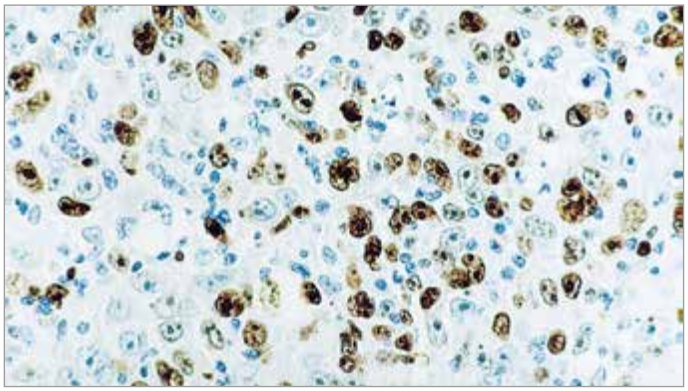
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

Immunoglobulins are polypeptides and comprise five major classes; immunoglobulin G (IgG), IgA, IgM, IgD and IgE. Each immunoglobulin consists of two identical heavy (H) chains and two identical light (L) chains.These are also subdivided into sub classes, for example, IgG1. There are two classes of light chain; kappa and lambda. The ratio of kappa chains and light chains varies between Ig classes and sub classes, but is also species specific. In humans, approximately 60% of light chains are kappa; however, in any particular immunoglobulin molecule the light chain will be either kappa or lambda. B cells contain either kappa or lambda mRNA.

Kappa Light Chain is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Ki67 Antigen



Diffuse large B cell lymphoma: immunohistochemical staining for Ki67. Ki67: clone MM1

MM1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0118	P(HIER)	IVD	IVD	IVD
BOND 30 mL	PA0410	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-KI67-MM1	P(HIER)	IVD	IVD	IVD/RUO

K2

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0230	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-ACK02	P(HIER)	RUO	RUO	RUO

PATHOLOGY MENU

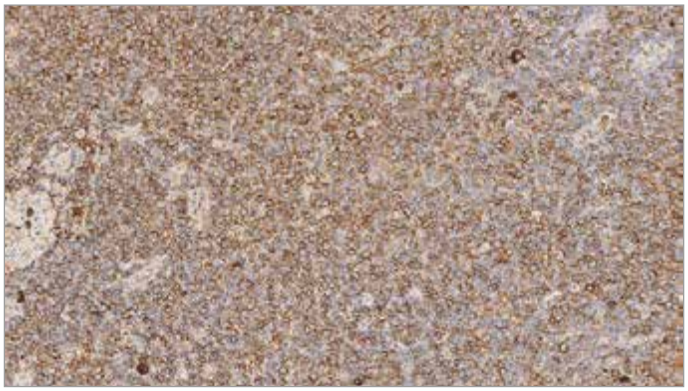
BREAST PATHOLOGY

ANTIGEN BACKGROUND

The Ki67 antigen is a nuclear protein which is expressed in all active parts of the cell cycle (G1, S, G2 and mitosis) but is absent in resting cells (G0). In contrast to many other cell cycle-associated proteins, the Ki67 antigen is consistently absent in quiescent cells and is not detectable during DNA repair processes. Thus, the presence of Ki67 antigen is strictly associated with the cell cycle and confined to the nucleus, suggesting an important role in the maintenance and/or regulation of the cell division cycle.

Ki67 Antigen is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Lambda Light Chain



B cell chronic lymphocytic leukemia: immunohistochemical staining for Lambda Light Chain. Lambda Light Chain: clone SHL53

SHL53

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0570	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-LAM-578	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

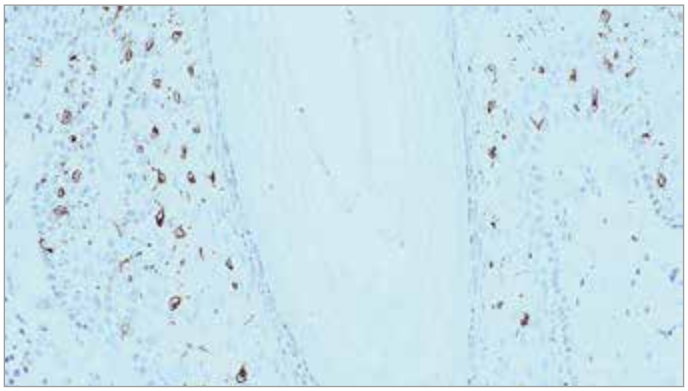
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The basic structure of an immunoglobulin molecule consists of two identical heavy chains, either gamma, alpha, delta, or epsilon and two identical light chains, either kappa or lambda. Any heavy chain can associate with either light chain but on any immunoglobulin molecule both light chains are of the same type. The ratio of kappa and lambda light chains varies between Ig classes and subclasses. In a polyclonal population the ratio of kappa to lambda bearing B cells is approximately 2:1, with individual B cells thought to express kappa or lambda light chains, never both. The majority of kappa and lambda chains are bound to heavy chain immunoglobulin, however in normal individuals low levels of free light chain are present in serum. The occurrence of a mixture of kappa and lambda chain expressing cells suggests a polyclonal population and a reactive or non-neoplastic proliferation of B cells.

Lambda Light Chain is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Langerin



Human skin: immunohistochemical staining for langerin. Langerin: clone 12D6

12D6

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-LANGERIN	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

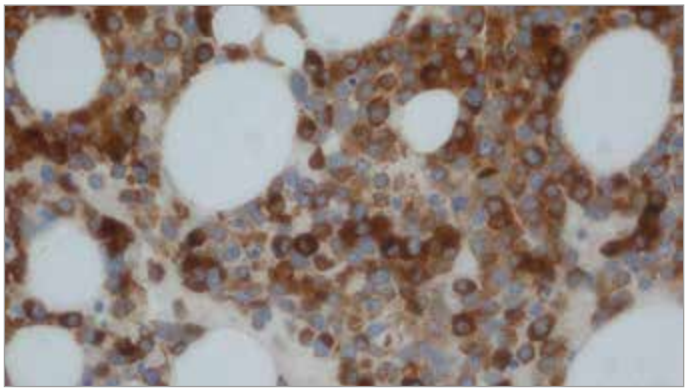
SPECIALIZED

ANTIGEN BACKGROUND

Langerin is a type II transmembrane C-type lectin which has mannose-binding specificity. It is a 40 kD protein restricted to Langerhans cells that is involved in the internalization of cell surface material in these immature dendritic cells. Dendritic cells are antigen-presenting cells that are required for initiation of a specific T cell-driven immune response. These cells are found in non-lymphoid tissue as immature cells whose primary function is to capture antigen through specialized surface membrane endocytic structures or through macropinocytosis. The dendritic cells migrate to secondary lymphoid tissue and mature into efficient antigen presenting cells. A part of the maturation process includes the loss of adhesion receptors such as E-cadherin and the disappearance of Birbeck granules. Although Langerin is reported to be located on the cell surface, it can be rapidly internalized following ligand capture into Birbeck granules. In fact, Langerin is a potent inducer of membrane superimposition and zippering leading to Birbeck granule formation. In reports it has been suggested that the induction of Birbeck granules is a consequence of the antigen-capture function of Langerin allowing passage into these organelles and providing access to a non-classical antigen processing pathway.

Langerin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Lysozyme (Muramidase)



Bone marrow: immunohistochemical staining of myeloid cells using Lysozyme: Polyclonal

Polyclonal

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0391	P(ENZYME)	IVD	IVD	IVD

PATHOLOGY MENU

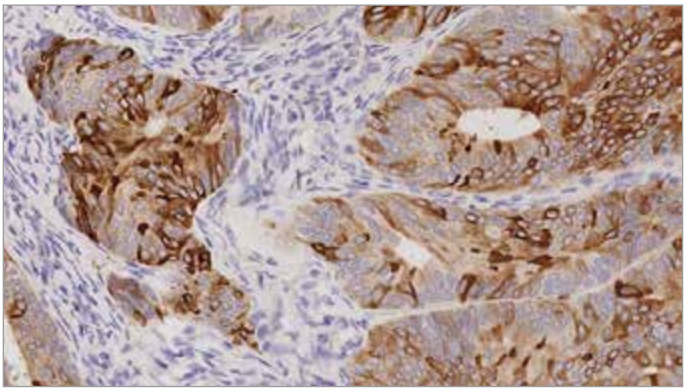
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

Intracellular muramidase, also known as lysozyme, has been reported to be expressed in myeloid and monocytic cells, in leukocytes and in myelo-proliferative disorders. Muramidase is also reported to be expressed in poorly differentiated leukemic monoblasts.

Lysozyme (Muramidase) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Mammaglobin



Human ductal carcinoma of breast: immunohistochemical staining for Mammaglobin protein. Mammaglobin: clone EP249

EP249

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0378	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

BREAST PATHOLOGY

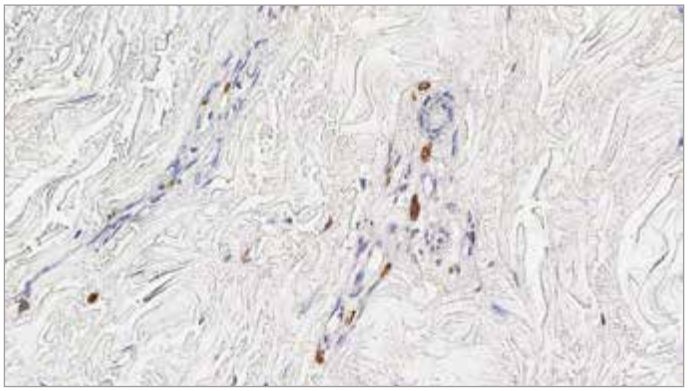
ANTIGEN BACKGROUND

Mammaglobin is a 93 kDa glycoprotein that belongs to the uteroglobin family of proteins. It was first described in 1996 and found to be overexpressed in breast cancer. Published reports suggest a role for mammaglobin in the diagnosis of metastatic breast carcinoma.

Mammaglobin has been suggested as a useful marker for carcinomas of unknown primary origin, with expression unaltered from the primary site. Additional published data suggests a role for mammaglobin in the migration and invasion of breast cancer cells.

Mammaglobin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Mast Cell Tryptase



Human skin: immunohistochemical staining for Mast Cell Tryptase. Note cytoplasmic staining of mast cells. Mast Cell Tryptase: clone 10D11

10D11

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0019	P	IVD	IVD	IVD
Liquid 1 mL	NCL-L-MCTRYP-428	P	IVD	-	-

PATHOLOGY MENU

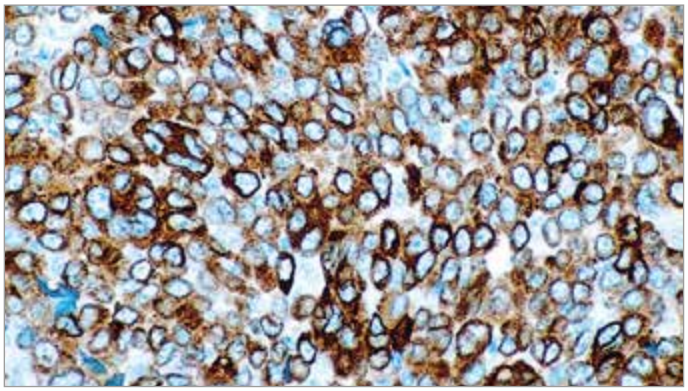
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

Mast cells contain a number of preformed chemical mediators such as histamine, chymase, carboxypeptidase and proteolytic tryptase. A substantial quantity of tryptase is reported to be found in mast cells of skin and lung and suggests this enzyme plays a major role in mast cell mediated events. In vitro studies indicate tryptase can cleave C3 to form C3a anaphylatoxin, inactivate fibrinogen as a coaguable substrate for thrombin and activate latent collagenase. Models of allergenic disease in the skin, nose and lung have each indicated elevated tryptase levels. Human mast cell tryptase has been reported to be implicated as a mediator of inflammation. Mast cell degranulation in the gut causes mucus secretion, mucosal edema, increased gut permeability and may be responsible for some of the symptoms and signs of inflammatory bowel disease.

Mast Cell Tryptase is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Melan A



Human skin, melanoma: immunohistochemical staining for Melan A. Melan A: clone A103

A103

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0233	P(HIER)	IVD	IVD	IVD
BOND 30 mL	PA0044	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-MELANA	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

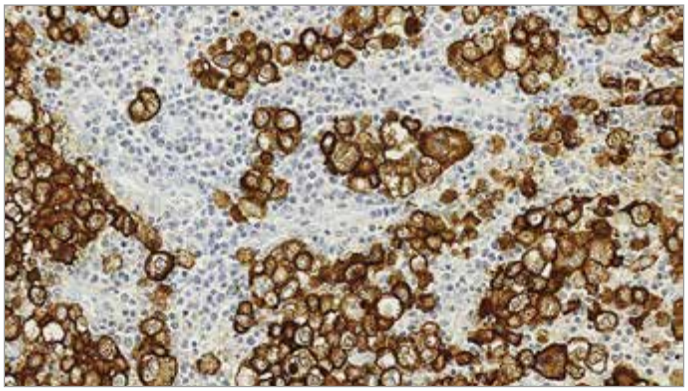
DERMATOPATHOLOGY

ANTIGEN BACKGROUND

Melan A, a product of the MART-1 gene, is a melanocyte differentiation marker recognized by autologous cytotoxic T lymphocytes. Other melanoma-associated markers recognized by autologous cytotoxic T cells are reported to include MAGE-1, MAGE-3, tyrosinase, gp100, gp75, BAGE-1 and GAGE-1. The analysis of these different molecules and their expression in individual melanomas may be of help in the study of their particular molecular roles in melanocyte differentiation and tumorigenesis.

Melan A is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Melanoma Marker (HMB45)



Human skin, melanoma: immunohistochemical staining for HMB45. Melanoma Marker (HMB45): clone HMB45

HMB45

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0027	P(ENZYME)	IVD	IVD	IVD
BOND 30 mL	PA0625	P(ENZYME)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-HMB45	P(ENZYME)	IVD	IVD	IVD

PATHOLOGY MENU

DERMATOPATHOLOGY

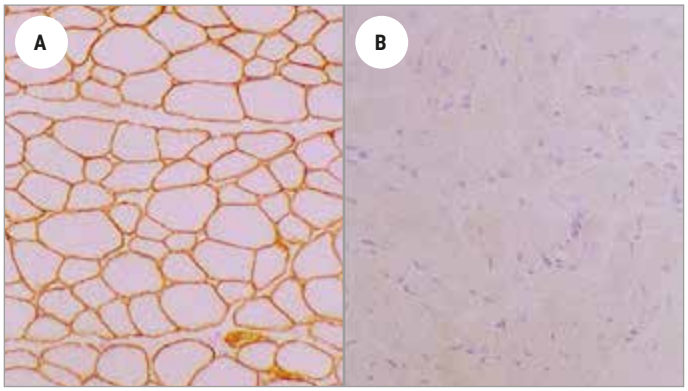
ANTIGEN BACKGROUND

The HMB45 antigen has also been identified in retinal pigment epithelium (RPE) but is reported to be reactive only with the transient prenatal and infantile RPE. No reaction is reported to be observed with intradermal nevi and normal adult melanocytes and non-melanocytic cells.

Tumor cells of epithelial, lymphoid, glial and mesenchymal origin are reported to be negative. This clone is well described in the literature. It is indicated to label an intracytoplasmic antigen in the majority of melanomas and other tumors demonstrating melanoma/melanocytic differentiation.

Melanoma Marker (HMB45) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Merosin Laminin Alpha 2 Chain



Human skeletal muscle: immunohistochemical staining for Merosin. Note membrane staining of normal muscle fibers (A) and absence of staining of muscle fibers (B). Frozen sections. Photographs supplied courtesy of Dr Louise V B Anderson. Merosin Laminin Alpha 2 Chain: clone Mer3/22B2

Mer3/22B2

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-MEROSIN	F	IVD	IVD	IVD

PATHOLOGY MENU

MUSCLE PATHOLOGY

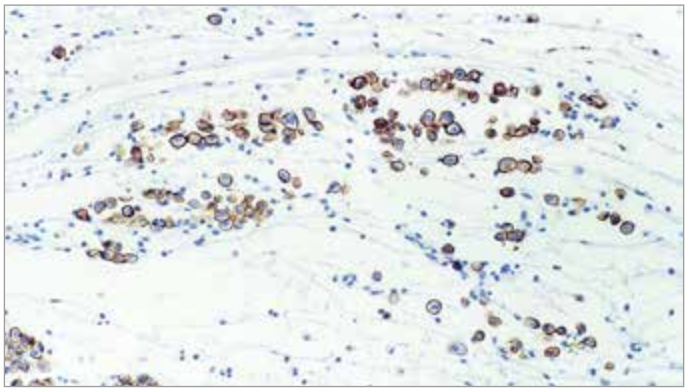
ANTIGEN BACKGROUND

The muscle-specific form of laminin, merosin, is composed of three chains: alpha 2, beta 1 and gamma 1.

Mutations in the chromosome 6 encoded gene for the laminin alpha 2 chain of merosin are responsible for a form of congenital muscular dystrophy (CMD). Merosin-negative CMD is characterized by a severe clinical phenotype and is associated with white matter changes on brain imaging.

Merosin Laminin Alpha 2 Chain is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Mesothelin



Human mesothelioma: immunohistochemical staining for Mesothelin. Mesothelin: clone 5B2

5B2

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0373	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-MESO	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

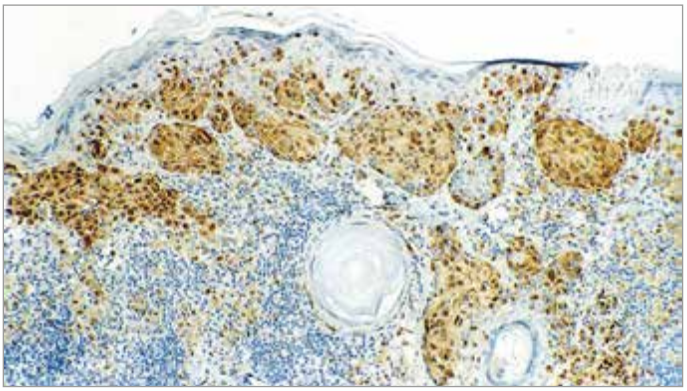
LUNG PATHOLOGY

ANTIGEN BACKGROUND

Mesothelin is a glycosyl-phosphatidylinositol-linked (GPI) glycoprotein of 40kD present on the surface of mesothelial cells, mesotheliomas, epithelial ovarian cancers and some squamous cell carcinomas. It is synthesized as a 69 kD precursor which is enzymatically processed into an N-terminal secreted form of 30 kD and the GPI-linked membrane-bound form of 40 kD. The secreted form is identical to the megakaryocyte potentiating factor, but it is the GPI-linked membrane-bound form which has generated interest. Mesothelin is abundantly expressed in the kidney and in occasional epithelial cells of the trachea, tonsil and fallopian tube. The function of mesothelin is unclear but it may have a role in cellular adhesion. Mesothelin is reported to be abundant in the normal mesothelial cells from which malignant mesotheliomas and ovarian cystadenocarcinomas are derived.

Mesothelin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Microphthalmia Transcription Factor (MITF)



Human malignant melanoma: immunohistochemical staining for Microphthalmia Transcription Factor. Microphthalmia Transcription Factor: clone 34CA5

34CA5

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-MITF	F;P(HIER)	RUO	RUO	RUO

PATHOLOGY MENU

DERMATOPATHOLOGY

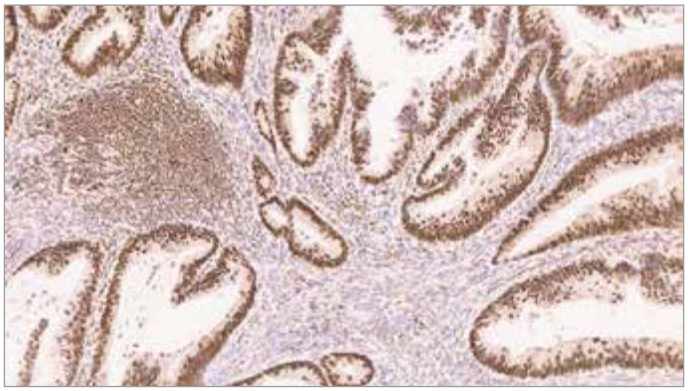
ANTIGEN BACKGROUND

Microphthalmia transcription factor (MITF) gene product, a nuclear transcription factor of the basic-helix-loop-helix type, is thought to play a role in the regulation of genes encoding the enzymes necessary for melanogenesis. These include tyrosinase, TRP-1 and TRP-2. MITF is critical for the embryonic development and postnatal viability of melanocytes. The melanocyte-specific isoform of microphthalmia transcription factor MITF-M, is reported to be expressed in normal and malignant melanocytes. The other isoforms, MITF-A, MITF-C and MITF-H, differ structurally at the N-terminus from MITF-M.

PRODUCT SPECIFIC INFORMATION

Clone 34CA5 is reported to be reactive with the MITF-M isoform.

Mismatch Repair Protein (MLH1)



Immunohistochemical staining for mismatch repair protein (MLH1). Mismatch Repair Protein (MLH1): clone ES05.

ES05

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0988	P(HIER)	IVD	IVD	-
Liquid 1 mL	NCL-L-MLH1	P(HIER)	IVD	IVD	IVD

ES05 (Previous Formulation)

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0610	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

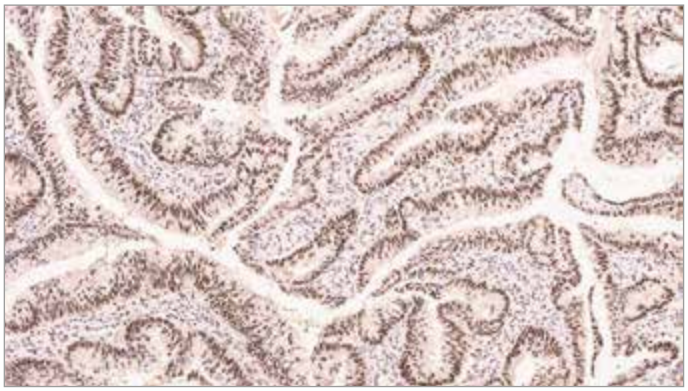
Mismatch repair gene hMLH1 is a ubiquitous gene encoding the mismatch repair protein (MMR) MutL protein homolog 1 (MLH1). MLH1 functions by repairing mutations occurring during DNA replication, in normal proliferating cells.

Mismatch Repair Protein (MLH1) is recommended for the detection of specific antigens of interest in normal and neoplastic tissue, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

The use of the heat induced epitope retrieval (HIER) technique can enhance staining in some cases. Any changes to the recommendations should be validated by the end user.

Mismatch Repair Protein (MSH2)



Immunohistochemical staining for mismatch repair protein (MSH2). Mismatch Repair Protein (MSH2): clone 79H11.

79H11

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0989	P(HIER)	IVD	IVD	-
Liquid 1 mL	NCL-L-MSH2-612	P(HIER)	IVD	IVD	IVD

25D12

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0048	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

Mismatch repair gene MutS Homolog 2 is a ubiquitous gene encoding the mismatch repair protein (MMR) MutS protein homolog 2 (MSH2). MSH2 functions by repairing mutations occurring during DNA replication, in normal proliferating cells.

Mismatch Repair Protein (MSH2) is recommended for the detection of specific antigens of interest in normal and neoplastic tissue, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Mismatch Repair Protein (MSH6)

Immunohistochemical staining for mismatch repair protein (MSH6). Mismatch Repair Protein (MSH6): clone EP49.

EP49

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0990	P(HIER)	IVD	IVD	-

PU29

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-MSH6	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

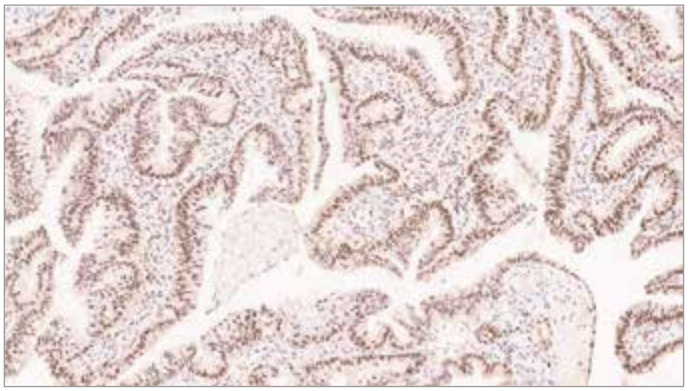
Mismatch repair gene MutS Homolog 6 is a ubiquitous gene encoding the mismatch repair protein (MMR) MutS protein homolog 6 (MSH6). MSH6 functions by repairing mutations occurring during DNA replication, in normal proliferating cells.

Mismatch Repair Protein (MSH6) is recommended for the detection of specific antigens of interest in normal and neoplastic tissue, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

The use of PBS-based diluents may result in increased background staining.

Mismatch Repair Protein (PMS2)



Immunohistochemical staining for mismatch repair protein (PMS2). Mismatch Repair Protein (PMS2): clone EP51.

EP51

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0991	P(HIER)	IVD	IVD	-

M0R4G

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-PMS2	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

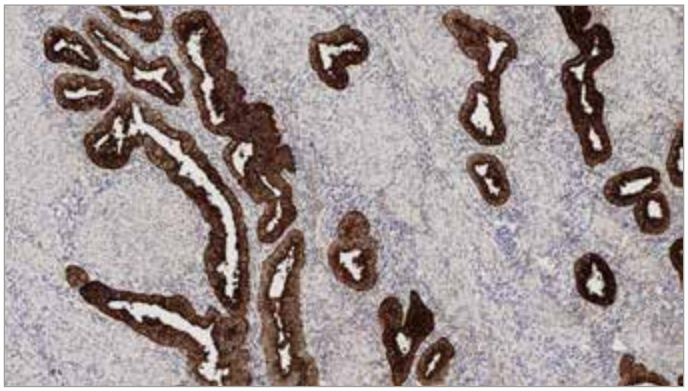
GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

Mismatch repair gene Postmeiotic segregation Increased 2, also known as PMS1 Homolog 2, is a ubiquitous gene encoding the mismatch repair protein (MMR) PMS1 protein homolog 2 (PMS2). PMS2 functions by repairing mutations occurring during DNA replication, in normal proliferating cells.

Mismatch Repair Protein (PMS2) is recommended for the detection of specific antigens of interest in normal and neoplastic tissue, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Muc-1 Glycoprotein



Human endometrium: immunohistochemical staining for Muc-1.
Muc-1 Glycoprotein: clone Ma695

Ma695

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0051	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

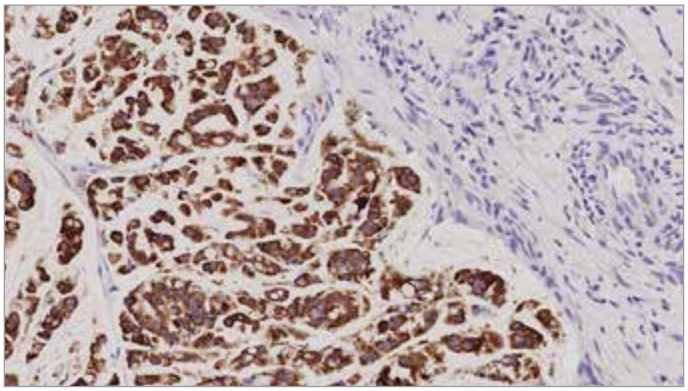
GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

Mucins are heavily glycosylated glycoproteins which constitute the major components of mucus that covers the surface of epithelial tissues. Nine distinct epithelial mucin genes (Muc-1, 2, 3, 4, 5AC, 5B, 6, 7 and 8) have been identified. Various immunohistochemical and in situ hybridization studies have shown that these mucins are differentially expressed in epithelia with cell-type specificity. The normal gastric mucosa shows cell-type specific expression of Muc-1, Muc-5AC and Muc-6 glycoproteins with the first two mucins found in superficial epithelium and Muc-6 glycoprotein in the deep glands. Muc-1 and Muc-5AC glycoproteins are expressed in many epithelia but Muc-6 glycoprotein is mainly expressed in gastric mucosa. In addition, Muc-2 glycoprotein is not expressed in normal gastric mucosa.

Muc-1 Glycoprotein is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Muc-2 Glycoprotein



Human colon: immunohistochemical staining for Muc-2 Glycoprotein: clone Ccp58

Ccp58

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0155	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

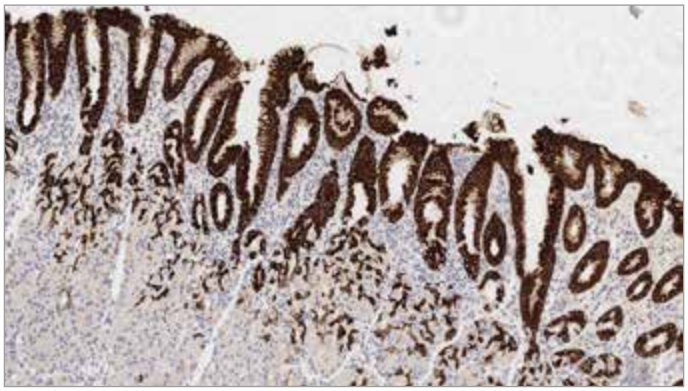
GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

Mucins are heavily glycosylated glycoproteins which constitute the major components of mucus that covers the surface of epithelial tissues. Nine distinct epithelial mucin genes (Muc-1, 2, 3, 4, 5AC, 5B, 6, 7 and 8) have been identified. Various immunohistochemical and in situ hybridization studies have shown that these mucins are differentially expressed in epithelia with cell-type specificity. The normal gastric mucosa shows cell-type specific expression of Muc-1, Muc-5AC and Muc-6 glycoproteins with the first two mucins found in superficial epithelium and Muc-6 glycoprotein in the deep glands. Muc-1 and Muc-5AC glycoproteins are expressed in many epithelia but Muc-6 glycoprotein is mainly expressed in gastric mucosa. In addition, Muc-2 glycoprotein is not expressed in normal gastric mucosa.

Muc-2 Glycoprotein is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Muc-5AC Glycoprotein



Human stomach: immunohistochemical staining for Muc- 5AC.
Muc-5AC Glycoprotein: clone CLH2

CLH2

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0052	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

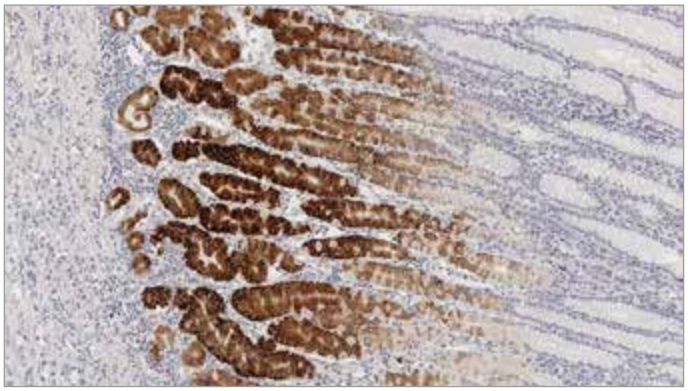
GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

Mucins are heavily glycosylated glycoproteins which constitute the major components of mucus that covers the surface of epithelial tissues. Nine distinct epithelial mucin genes (Muc-1, 2, 3, 4, 5AC, 5B, 6, 7 and 8) have been identified. Various immunohistochemical and in situ hybridization studies have shown that these mucins are differentially expressed in epithelia with cell-type specificity. The normal gastric mucosa shows cell-type specific expression of Muc-1, Muc-5AC and Muc-6 glycoproteins with the first two mucins found in superficial epithelium and Muc-6 glycoprotein in the deep glands. Muc-1 and Muc-5AC glycoproteins are expressed in many epithelia but Muc-6 glycoprotein is mainly expressed in gastric mucosa. In addition, Muc-2 glycoprotein is not expressed in normal gastric mucosa.

Muc-5AC Glycoprotein is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Muc-6 Glycoprotein



Human stomach: immunohistochemical staining for Muc-6. Muc-6 Glycoprotein: clone CLH5

CLH5

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0053	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

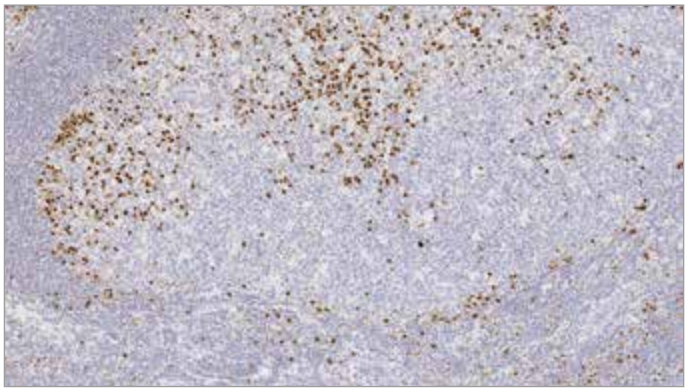
GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

Mucins are heavily glycosylated glycoproteins which constitute the major components of mucus that covers the surface of epithelial tissues. Nine distinct epithelial mucin genes (Muc-1, 2, 3, 4, 5AC, 5B, 6, 7 and 8) have been identified. Various immunohistochemical and in situ hybridization studies have shown that these mucins are differentially expressed in epithelia with cell-type specificity. The normal gastric mucosa shows cell-type specific expression of Muc-1, Muc-5AC and Muc-6 glycoproteins with the first two mucins found in superficial epithelium and Muc-6 glycoprotein in the deep glands. Muc-1 and Muc-5AC glycoproteins are expressed in many epithelia but Muc-6 glycoprotein is mainly expressed in gastric mucosa. In addition, Muc-2 glycoprotein is not expressed in normal gastric mucosa.

Muc-6 Glycoprotein is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Multiple Myeloma Oncogene 1 (MUM-1)



Human tonsil: immunohistochemical staining for MUM-1.
Multiple Myeloma Oncogene 1: clone EAU32

EAU32

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0129	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-MUM1	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

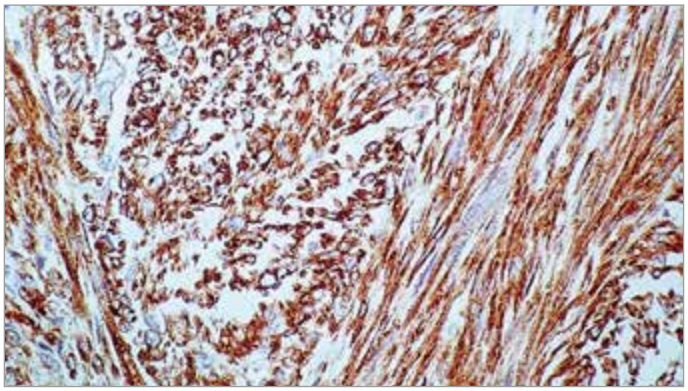
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

The MUM-1 (multiple myeloma oncogene 1) gene was originally identified because of its involvement in the t(6:14) translocation observed in multiple myeloma, which causes the juxtaposition of the MUM-1 gene to the Ig heavy chain locus. MUM-1 is expressed in late plasma cell directed stages of B cell differentiation and in activated T cells, suggesting that MUM-1 may serve as a marker for lympho-hemopoietic neoplasms derived from these cells. The morphologic spectrum of MUM-1 expressing cells has been found to range from that of a centrocyte to that of a plasmablast/plasma cell. Consequently the histogenic value of MUM-1 may be to provide a marker to aid in the identification of the transition from BCL-6 positive (germinal center B cells) to CD138 positive (immunoblasts and plasma cells).

Multiple Myeloma Oncogene 1 (MUM-1) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Muscle Specific Actin



Human leiomyosarcoma: immunohistochemical staining for Muscle Specific Actin.
Muscle Specific Actin: clone HHF35

HHF35

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0258	P	IVD	IVD	IVD
Liquid 1 mL	NCL-L-MSA	P(ENZYME)	IVD	-	-

SC28

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-MSA-594	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

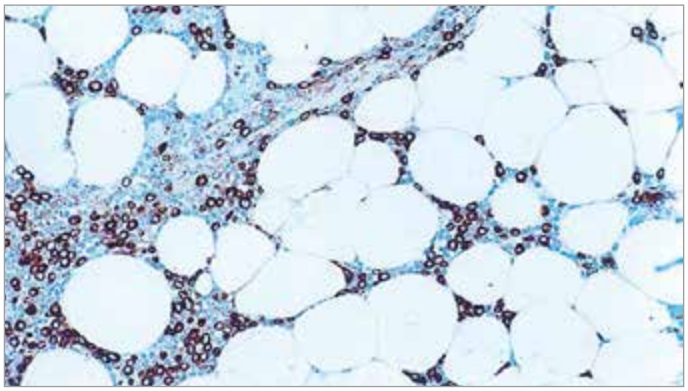
MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

Muscle specific actin (MSA) is a highly conserved, ubiquitous protein found in muscle and some non-muscle cells. Actins can be divided into three subsets, alpha actins found in muscle tissue cells, beta and gamma actins found in non-muscle cells and a small subset of gamma actins also found in muscle tissue cells. In normal tissues, expression is found in striated fibers of skeletal muscle, smooth muscle in arteries, veins and pericytes of smaller arteries, muscle in bowel, myometrium of the uterus, prostatic stroma, capsule cells of liver, kidney, lymph node and spleen, the myoepithelial layers of mammary ducts and glands, eccrine sweat glands and salivary glands. Expression is not found in epithelial cells, lymphoid cells, macrophages, connective tissue and neuronal cells. In neoplastic tissues, expression can be found in soft tissue tumors with muscle differentiation, for example, leiomyomas, leiomyosarcomas and rhabdomyosarcomas of varying subtypes. Non-muscle sarcomas, carcinomas, melanomas and lymphomas do not express muscle specific actin.

Muscle Specific Actin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Myeloperoxidase



Human bone marrow, granulocytic sarcoma: immunohistochemical staining for myeloperoxidase. Myeloperoxidase: clone 59A5

59A5

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0491	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-MYELO	P	IVD	-	-

PATHOLOGY MENU

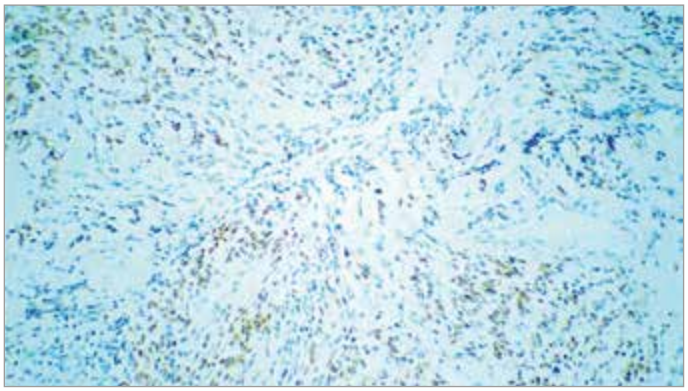
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

Myeloperoxidase is a lysosomal enzyme found in cells of the myeloid series which metabolizes most of the hydrogen peroxide generated by activated phagocytes. It is a major constituent of azurophilic cytoplasmic granules that uses hydrogen peroxide to oxidize a variety of aromatic compounds and chloride ions to hypochlorous acid (HOCl), a strong oxidant. HOCl is the most bacteriocidal oxidant known to be produced by neutrophils. HOCl reacts with proteins to form cytotoxic chloramines. Myeloperoxidase is reported to be a major component in all myeloid cells, including mature granulocytes and is a superior marker to myeloperoxidase mRNA, whose level decreases with the maturation of the cell and is not detectable from the myelocyte stage onwards. Myeloperoxidase is reported to be expressed in neutrophil granulocytes and monocytes in blood, in precursors of granulocytes in the bone marrow and in Kupffer cells of the liver.

Myeloperoxidase is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

MyoD1 (Rhabdomyosarcoma Marker)



Human rhabdomyosarcoma: immunohistochemical staining for MyoD1 protein. MyoD1: clone 5.8A

5.8A

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-MyoD1	P(HIER)	IVD	-	-

PATHOLOGY MENU

MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

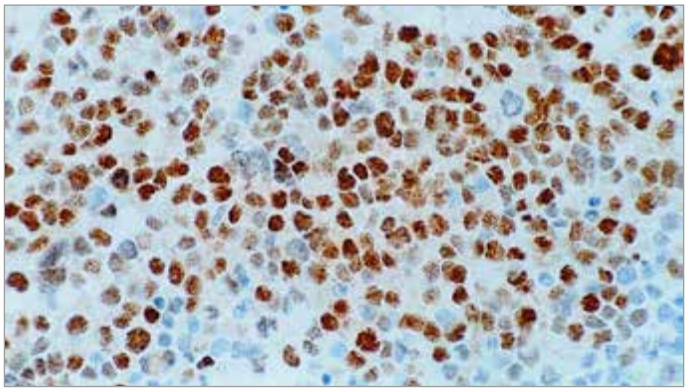
The murine MyoD1 gene encodes a phosphoprotein of 45 kD, the function of which may include the commitment, differentiation and maintenance of the myogenic lineage. MyoD1 is not expressed in normal adult tissue but is reported to be highly expressed in rhabdomyosarcomas.

MyoD1 (Rhabdomyosarcoma Marker) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

MyoD1 recognizes an epitope near the C-terminus of the MyoD1 protein (amino acids 180 to 189).

Myogenin (Myf-4)



Human rhabdomyosarcoma: immunohistochemical staining for Myf-4 protein.
Myogenin (Myf-4): clone LO26

LO26

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0226	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-Myf-4	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

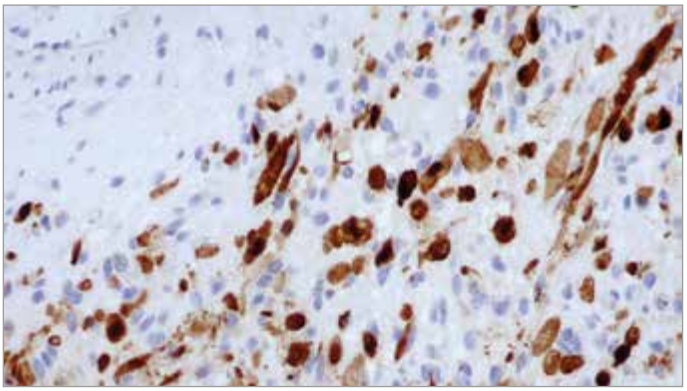
MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

Rhabdomyosarcomas are a class of myoblast-derived soft tissue sarcomas that usually express a number of muscle-specific genes and primarily affect children and young adults. Differentiation of myogenic cells is controlled by a set of regulatory genes including MyoD1, myogenin, Myf-5 and Myf-6. Myf-4 is the human homolog of myogenin. Its gene product, together with that of Myf-3, accumulates in the nucleus of differentiated cells.

Myogenin (Myf-4) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Myoglobin



Human rhabdomyosarcoma: immunohistochemical staining for myoglobin.
Myoglobin: clone MYO18

MYO18

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0727	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

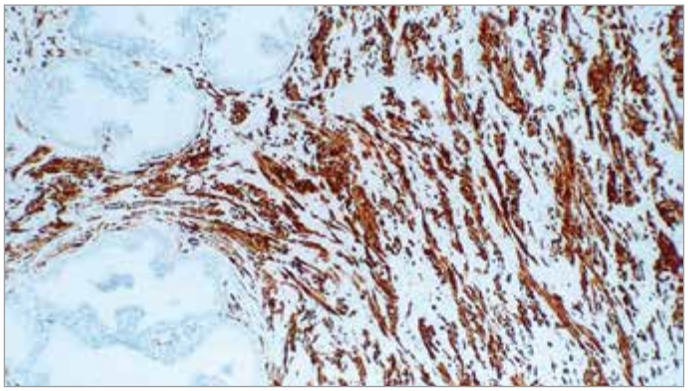
MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

Myoglobin is a cytoplasmic, single chain polypeptide of 153 amino acids that contains a single heme group. Myoglobin is reported to be expressed in skeletal and cardiac muscle but not in smooth muscle and functions as an oxygen transporting pigment.

Myoglobin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Myosin Heavy Chain Antibodies



Human prostate: immunohistochemical staining for myosin heavy chain. Note intense staining of muscle fibers. Myosin Heavy Chain (smooth muscle): clone S131

Smooth muscle: clone S131

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0493	P(HIER)	IVD	IVD	IVD

Developmental: clone RNMy2/9D2

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-MHCd	F	RUO	RUO	RUO

Fast: clone WB-MHCf

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-MHCf	F	RUO	RUO	RUO

Neonatal: clone WB-MHCn

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-MHCn	F	RUO	RUO	RUO

Slow: clone WB-MHCs

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-MHCs	F	RUO	RUO	RUO

PATHOLOGY MENU

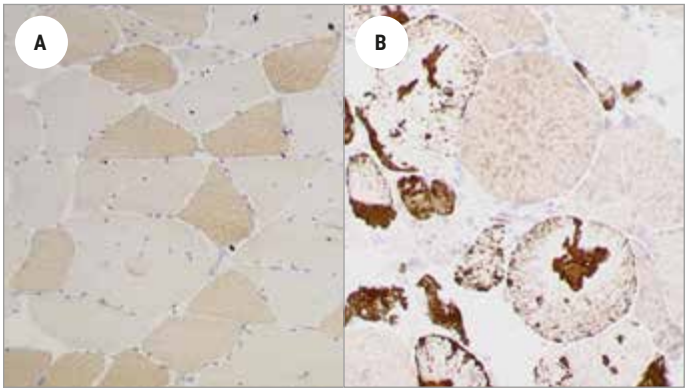
MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

Myosin is a contractile muscle specific protein composed of two heavy and four light chains. The myosin heavy chain has many isoforms which are specific for different muscles or fiber types, some of which are developmentally regulated. The range of myosin heavy chain antibodies may prove useful for investigating development of intrafusal and extrafusal muscle fibers and the course of muscle fiber regeneration. At the ultrastructural level, antibodies can reveal architectural details of the myofilament as well as the cytoplasmic and membrane sites of new myosin integration.

Myosin Heavy Chain Antibodies are recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Myotilin



Human skeletal muscle: immunohistochemical staining for Myotilin. Note sarcoplasmic staining of normal muscle fibers (A) and presence of protein aggregates (B).
Myotilin: clone RSO34

RSO34

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-MYOTILIN	F;P(HIER)	RUO	RUO	RUO

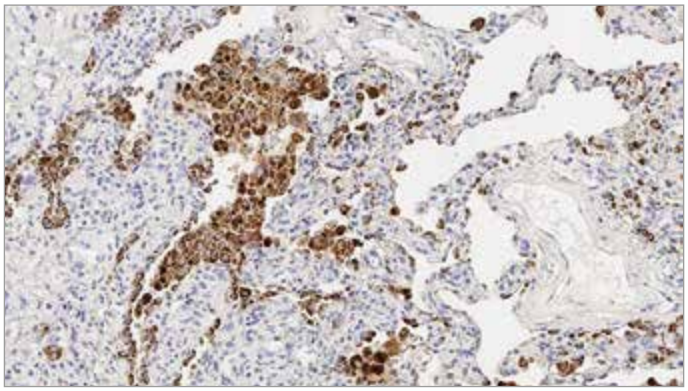
PATHOLOGY MENU

MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

The myotilin gene on chromosome 5q31 encodes a 498 amino acid polypeptide with a molecular weight of 57kD. Myotilin is a structural protein of sarcomeric Z discs and sarcolemma in human skeletal and cardiac muscle. It is homologous to palladin and titin in the two C-terminal Ig-domains and also to palladin in its unique serine-rich N-terminal region. Myotilin interacts with alpha-actinin, actin and gamma-filamin. Mutations in the myotilin gene are associated with limb-girdle muscular dystrophy 1 A (LGMD1A) and one form of Myofibrillar Myopathy. It is highly conserved between human and mouse with its expression being more widespread in the embryo than in the adult. Expression of myotilin has been reported in adult skeletal and cardiac muscle with variable expression reported in the peripheral nervous system, lung, liver and kidney. NCL-MYOTILIN will be of use in studies to determine the expression of myotilin in normal and pathological tissues.

Napsin A



Human lung: immunohistochemical staining for Napsin A. Note cytoplasmic staining of pneumocytes and alveolar macrophages. Napsin A: clone IP64

IP64

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0064	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-Napsin A	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

LUNG PATHOLOGY

ANTIGEN BACKGROUND

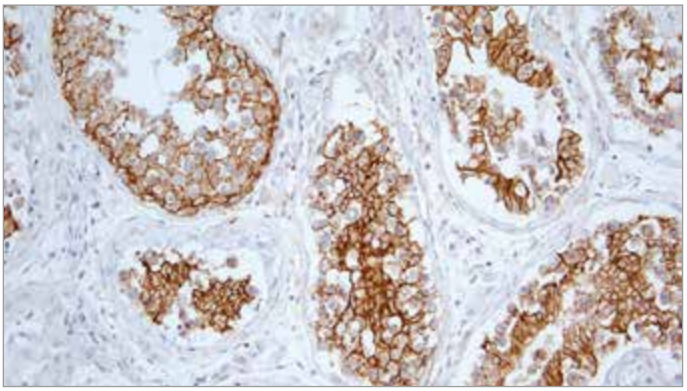
Napsin A has a specific function in normal alveolar epithelium and is proposed to play a role in the proteolytic processing of surfactant precursors.

Napsin A is reported to be predominantly expressed in lamellar bodies of type II pneumocytes, secondary lysosomes of alveolar macrophages, respiratory epithelium of terminal and respiratory bronchioles, plasma cells, within a subset of lymphocytes in normal lung, as well as in epithelial cells of renal tubules in normal kidney and is weakly expressed in normal spleen.

Studies have reported that Napsin A is expressed in 90% of primary lung adenocarcinomas.

Napsin A is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

N-Cadherin



Human testis: immunohistochemical staining for N-Cadherin. Note cytoplasmic and membrane staining of Sertoli cells. N-Cadherin: clone IAR06

IAR06

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-N-CAD	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

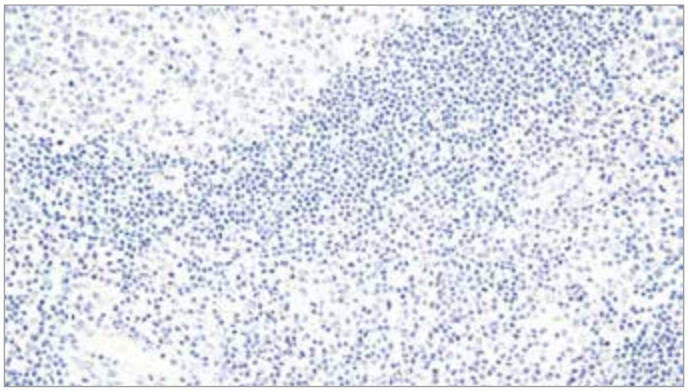
SPECIALIZED

ANTIGEN BACKGROUND

N-Cadherin is a member of the cadherin family of calcium dependent cell adhesion molecules. The classical cadherins include the E, N, R, P and VE-Cadherins which are believed to be expressed in a tissue specific manner. The classical cadherins have a characteristic structure comprising an extracellular calcium-binding domain, consisting of five repeats, a transmembrane domain and a highly conserved cytoplasmic domain, which mediates interactions with cytoskeletal components of the cell via interactions with intracellular proteins including the catenins. Cadherins play an important role in cell-cell adhesion, and are implicated in segregation and aggregation of tissues during development. N-Cadherin is reported to be expressed in various cell types including neural, myocardial and mesenchymal cells.

N-Cadherin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Negative Control (Mouse)



Human tonsil: immunohistochemical staining with BOND Ready-to-Use Negative Control (Mouse) using BOND Polymer Refine Detection. Negative Control (Mouse): clone MOPC-21

MOPC-21

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0996	P	IVD	IVD	IVD

ANTIGEN BACKGROUND

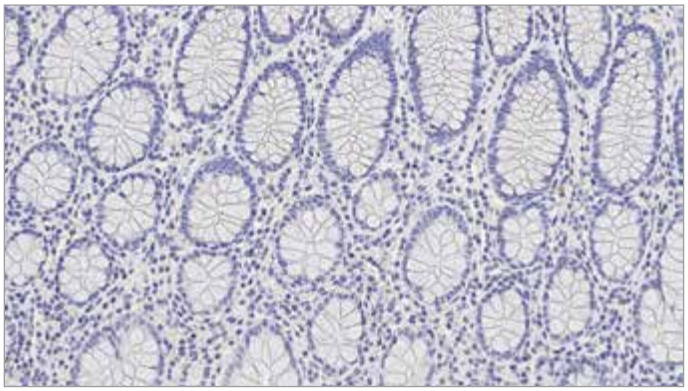
In some tissues, non-specific binding may occur, especially in neoplastic or necrotic tissue.

Negative Control (Mouse) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

The use of Negative Control (Mouse) antibody is recommended to aid in the identification of cells, tissues or tissue components, which may non-specifically bind mouse antibodies and will help with interpretation of specific staining at the antigenic site.

Negative Control (Rabbit)



Human bowel: immunohistochemical staining with BOND Ready-to-Use Negative Control (Rabbit) using BOND Polymer Refine Detection. Negative Control

-

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0777	P	IVD	IVD	IVD

ANTIGEN BACKGROUND

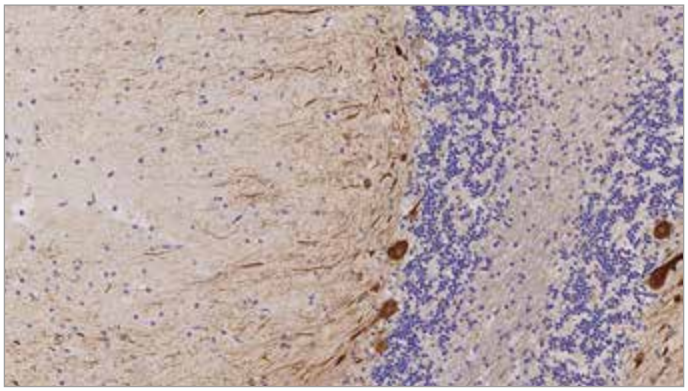
In some tissues, non-specific binding may occur, especially in neoplastic or necrotic tissue.

Negative Control (Rabbit) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

The use of Negative Control (Rabbit) antibody is recommended to aid in the identification of cells, tissues or tissue components, which may non-specifically bind mouse antibodies and will help with interpretation of specific staining at the antigenic site.

Neurofilament 200kD



Human cerebellum: immunohistochemical staining for Neurofilament 200kD. Note cytoplasmic staining of neurons and their axons. Neurofilament 200kD: clone N52.1.7

N52.1.7

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0371	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-NF200-N52	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

NEUROPATHOLOGY

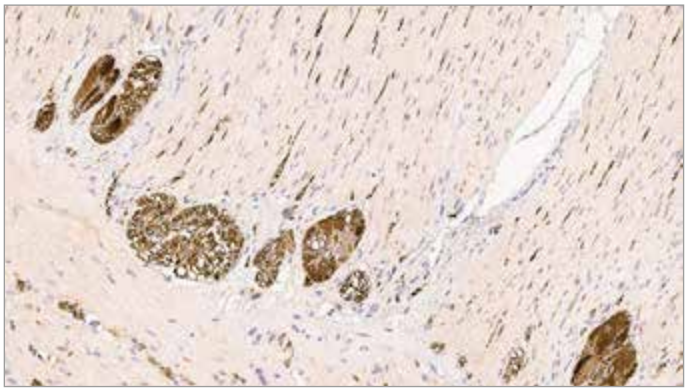
ANTIGEN BACKGROUND

Neurofilaments constitute the main structural elements of neuronal axons and dendrites. Neurofilaments are composed of three major subunits referred to as the neurofilament triplet, with molecular weights of 68 kD, 160kD and 200 kD.

Within tumors, only neoplastic cells of neural origin or those exhibiting neuronal differentiation, have been reported to express neurofilaments.

Neurofilament 200kD is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Neuron Specific Enolase



Human large bowel: immunohistochemical staining of Neuron Specific Enolase (NSE). Note the staining in the neuronal elements and the ganglia of the longitudinal and circular smooth muscle. Neuron Specific Enolase: clone 22C9

22C9

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0435	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

NEUROPATHOLOGY

ANTIGEN BACKGROUND

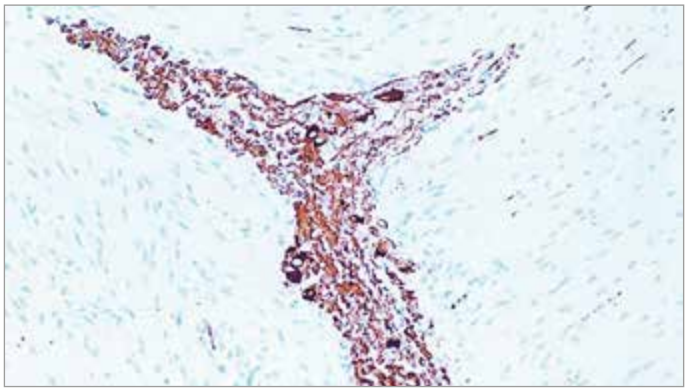
Enolase is a glycolytic enzyme catalyzing the reaction pathway between 2-phosphoglycerate and phosphoenol pyruvate. In mammals, enolase molecules are dimers composed of three distinct subunits (alpha, beta and gamma) whereas, in rats, five forms have been found. The alpha subunit and beta subunit are of approximately 47 kD and 45 kD, respectively. The gamma gamma and alpha gamma enolases are located mainly in the nervous tissue and neuroendocrine cells.

Neuron Specific Enolase is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Clone 22C9 reacts with the gamma subunit of the enolase isoenzyme.

Nitric Oxide Synthase 1



Human small intestine: immunohistochemical staining for nitric oxide synthase 1. Note cytoplasmic staining of enteric ganglia. Nitric Oxide Synthase 1: clone NOS-125

NOS-125

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-NOS-1	P(HIER)	IVD	-	-

PATHOLOGY MENU

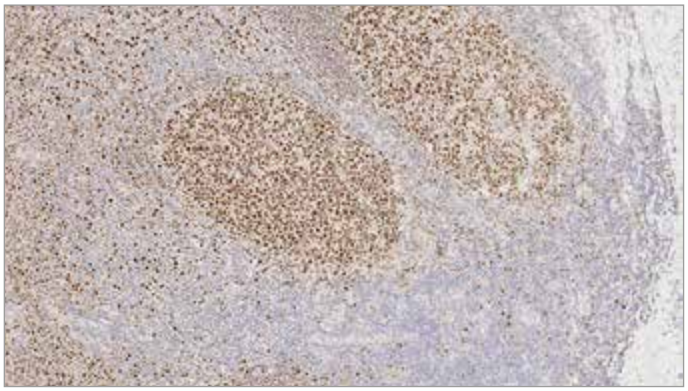
NEUROPATHOLOGY

ANTIGEN BACKGROUND

Human nitric oxide synthases are a family of enzymes responsible for the synthesis of nitric oxide (NO) from L-arginine and molecular oxygen. There are at least three nitric oxide synthases; NOS-1, also known as neuronal NOS or nNOS, NOS-2, which is referred to as inducible NOS or iNOS and NOS-3, also known as endothelial NOS or eNOS. As suggested by their nomenclature, these enzymes have different cellular distribution and are subjected to different regulatory mechanisms. NOS-3 is reported to be constitutively expressed and produces picomolar quantities of NO which play a role in signal transmission resulting in physiological effects. In the gastrointestinal tract, NO is reported to play a protective role where it has direct microbiocidal properties and acts as a first line of mucosal defence in the stomach. The function of NO in tumor development, promotion and progression is unclear. The effects may be both beneficial but also detrimental to those individuals with gastric cancer, where it is reported that NO supports tumor progression through the creation of neovasculature.

Nitric Oxide Synthase 1 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Oct-02



Human tonsil: immunohistochemical staining for Oct-2. Note strong staining of germinal centre B-cells. Oct-2: clone Oct-207

Oct-207

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0532	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

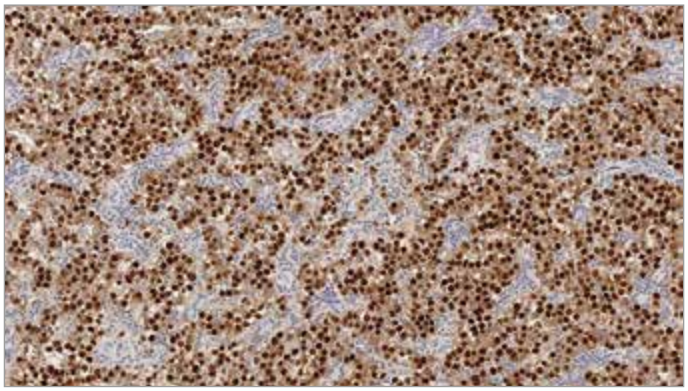
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

Oct-2 is a transcription factor belonging to the POU homeo-domain family that binds to the Ig gene octamer sites regulating B cell specific genes. It is dependent on the activity of B cell restricted coactivators such as BOB.1/OBF.1. Oct-2 protein expression is not restricted to B cells, although expression levels are much higher in these cells. Reports indicate that germinal center B cells shows higher expression for Oct-2 and BOB.1/OBF.1. In addition, Oct-2 expression is reported to be significantly greater in germinal center derived lymphomas, although other B cell lymphomas also display high levels of expression. Reed Sternberg (RS) cells represent the malignant cells in classical Hodgkin's disease and are derived from germinal center B cells. In a number of these cases, cells do not express immunoglobulin due to the presence of crippling mutations within the Ig genes. As Ig gene expression in B cells also requires an interaction between octamer sites and the transactivating factors Oct-2 and BOB.1, the absence of both Oct-2 and BOB.1 expression represents a novel mechanism for immunoglobulin gene deregulation in RS cells.

Oct-2 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Oct-3/4



Human testes, seminoma: immunohistochemical staining for Oct-3/4. Oct-3/4: clone N1NK

N1NK

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0193	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-OCT3/4	P(HIER)	IVD	IVD	IVD

N1NK (Previous Formulation)

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0934	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

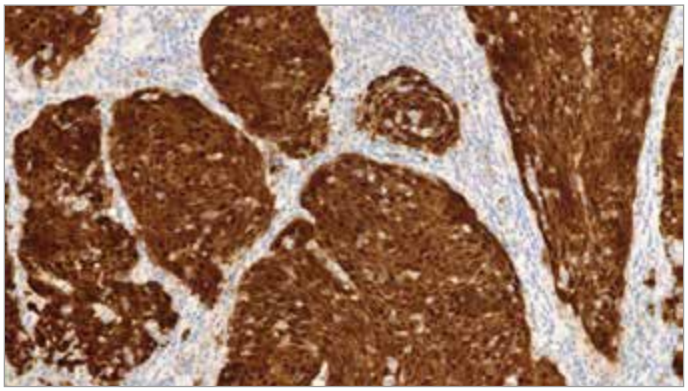
GYNEPATHOLOGY

ANTIGEN BACKGROUND

Oct-3/4 is a member of the POU homeodomain family of transcription factors, which is expressed by embryonic stem cells and germ cells. A critical amount of Oct-3/4 is required to maintain stem cell self replication. Down regulation of Oct-3/4 levels are associated with loss of pluripotency. Oct-3/4 has been proposed as a useful marker for germ cell tumors which exhibit features of pluripotentiality, including seminoma/dysgerminoma/germinoma and embryonal carcinoma, and establishing a germ cell origin for some metastatic tumors of uncertain primary origin.

Oct-3/4 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

p16



Squamous Cell Carcinoma of tonsil: immunohistochemical staining for p16. p16: clone 6H12

6H12

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0016	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

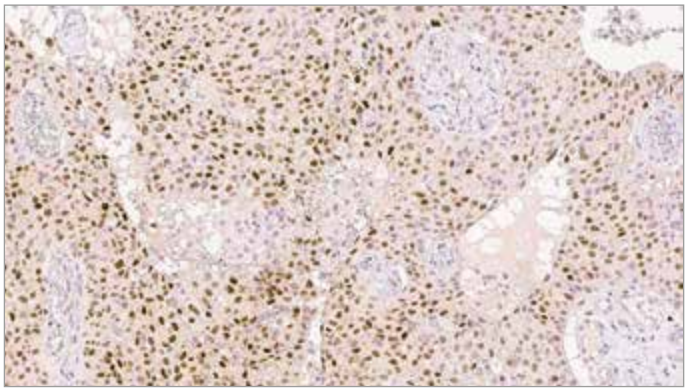
HEAD, NECK AND ENDOCRINE

ANTIGEN BACKGROUND

p16 (INK4a) (Cyclin-dependent kinase inhibitor 2A (CDKN2A)) is a tumour suppressor protein associated with cell cycle progression, specifically in the regulation of transition from G1 phase of the cell cycle in to the S phase. Oncogenic mutations in the CDKN2A gene that encodes p16 (resulting in over or under expression of the protein) is associated with a wide range of cancers and cancer precursor lesions. Immunohistochemical identification of p16 is particularly relevant in oro-pharyngeal squamous cell carcinoma (OPSCC) and uterine cervical lesions, where expression is seen in the cytoplasm and nucleus of neoplastic cells.

p16 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

p21 (WAF1 Protein)



Squamous cell carcinoma: immunohistochemical staining of p21(WAF1): clone 4D10

4D10

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-WAF-1	P(HIER)	RUO	RUO	RUO

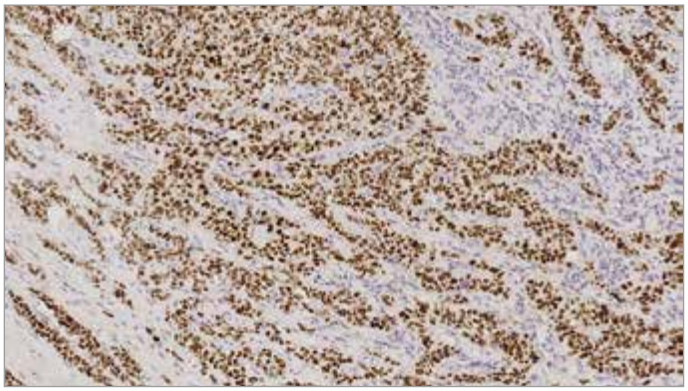
PATHOLOGY MENU

SPECIALIZED

ANTIGEN BACKGROUND

The gene encoding WAF1, also termed p21, is transcriptionally regulated by the suppressor protein, p53. Overexpression of WAF1 is growth suppressive, possibly by inhibiting the activity of cyclin/CDK complexes. One consequence of WAF1 binding to cyclin/CDK complexes is the inhibition of Rb protein phosphorylation. Induction of WAF1 expression requires wild type p53 activity in cells undergoing p53 dependent G1 arrest or apoptosis. Mutation of the p53 gene is a common event in human cancer and results in the failure to produce WAF1. The effect of this may lead to uncontrolled cell proliferation.

p53 Protein



Human ductal carcinoma of the breast: immunohistochemical staining of p53 Protein.
p53: clone DO-7

DO-7

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0057	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-p53-DO7	P	IVD	IVD	IVD/RUO

PATHOLOGY MENU

BREAST PATHOLOGY

ANTIGEN BACKGROUND

This monoclonal antibody recognizes both wild type and mutant forms of human p53 protein under denaturing and non-denaturing conditions. The epitope recognized by clone DO-7 can be destroyed by prolonged fixation in buffered formalin. The heat induced epitope retrieval technique may improve staining in some cases.

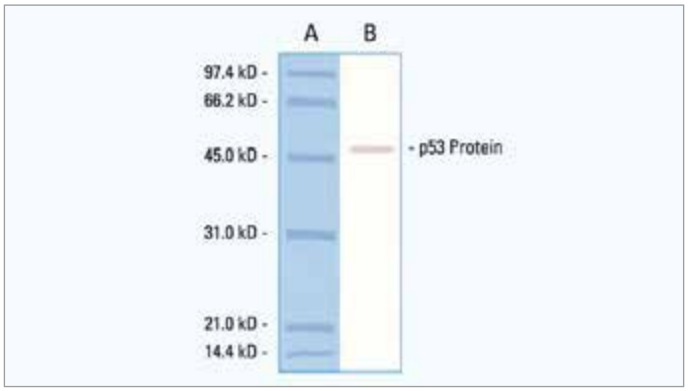
p53 Protein is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

This monoclonal antibody recognizes both wild type and mutant forms of human p53 protein under denaturing and non-denaturing conditions. The epitope recognized by clone DO-7 can be destroyed by prolonged fixation in buffered formalin.

The use of the heat induced epitope retrieval (HIER) technique can enhance staining in some cases.

p53 Protein (CM5)



Western blot: detection of p53 protein (53 kD). Lane A, molecular weight markers. Lane B, T3T3 mouse cell line immunoblotted, p53 Protein (CM5): Polyclonal

Polyclonal

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 0.5 mL	NCL-L-p53-CM5p	P(HIER)	RUO	RUO	RUO

PATHOLOGY MENU

SPECIALIZED

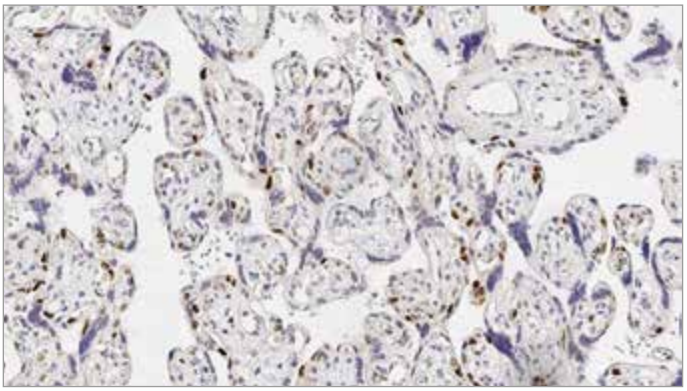
ANTIGEN BACKGROUND

The accumulation of p53 protein in response to genotoxic stress in vitro is well established and appears to induce growth arrest and apoptosis by the transcriptional regulation of other genes and possibly by other direct mechanisms.

PRODUCT SPECIFIC INFORMATION

NCL-L-p53-CM5p is specific for mouse and rat p53 protein.

p57 Protein (Kip2)



Human placenta: immunohistochemical staining for p57 protein. Note nuclear staining for cytotrophoblast and stromal cells of the villi. p57: clone 25B2

25B2

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-p57	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

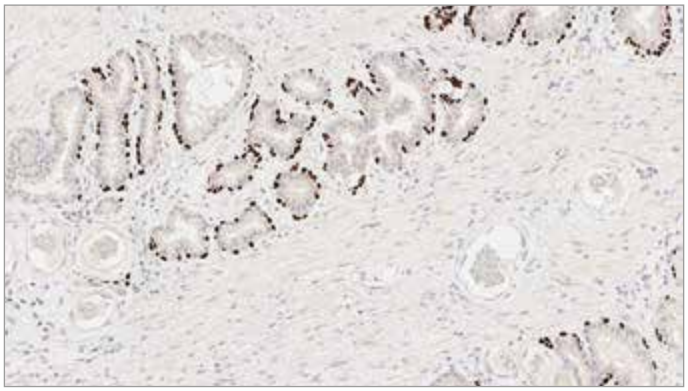
SPECIALIZED

ANTIGEN BACKGROUND

Cyclin-dependent kinases are positive regulators of cell proliferation. p57 protein acts as a tumor suppressor to counter this. It is closely related to other CDKIs such as p21 protein (CIP1) and p27 protein (Kip1) as they share a common structural N-terminal domain for binding to CDK/cyclin complexes and inhibiting their kinase activity. Human p57 protein is found on chromosome 11p15.5, a region which is reported to be a common site for loss of heterozygosity in certain sarcomas, Wilms' tumors and tumors associated with the Beckwith-Wiedemann syndrome. There is increasing interest in p57 as a marker in gestational disease. Gestational trophoblastic disease refers to a spectrum of proliferative disorders of the placental trophoblast, with a wide range of histologic appearances and clinical behaviors. Recent developments in changes in the criteria for histologic diagnosis of these lesions due to earlier clinical diagnosis have been reviewed Hui P et al., Advantages in Anatomical Pathology. 12(3): 116-125 (2005) and the ability to make more accurate diagnoses due to the introduction of newer antibodies such as p57 is discussed.

p57 Protein (Kip2) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

p63 Protein



Human prostate: immunohistochemical staining for p63. Note nuclear staining of basal cells of prostatic glands. p63: clone 7JUL

7JUL

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0103	P(HIER)	-	IVD	IVD
Liquid 1 mL	NCL-L-p63	P(HIER)	-	IVD	IVD

PATHOLOGY MENU

UROPATHOLOGY

ANTIGEN BACKGROUND

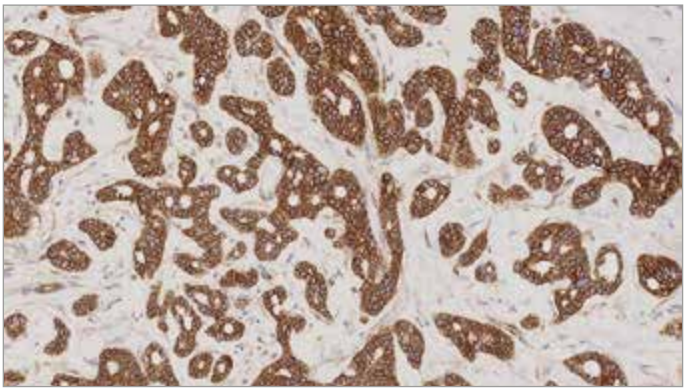
p63 is a type II integral membrane protein predominantly localized in the rough endoplasmic reticulum.

p63 is reported to be expressed in a number of normal tissues including proliferating cells of the epithelium, cervix, urothelium and prostate.

p63 is also reported to be expressed in most poorly differentiated squamous cell carcinomas.

p63 Protein is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

p120 Catenin



Human breast carcinoma: immunohistochemical staining for p120 Catenin antigen. p120 Catenin: clone EP66

EP66

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0379	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

BREAST PATHOLOGY

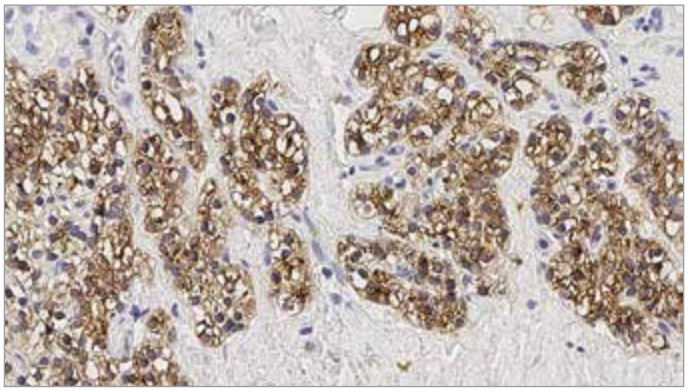
ANTIGEN BACKGROUND

p120 Catenin is a regulator of cell-cell adhesion, achieved through interaction with classical and Type II cadherins. Evidence also exists for a role in the regulation of cadherin availability on the cell surface. p120 Catenin also regulates actin dynamics, placing it as a potential master regulator of the cell motility/cell adhesion phenotypes.

Recent studies have suggested a tumor-suppression role for p120, with loss of p120 expression implicated in the development of a tumor microenvironment and induction of metastatic progression. The expression of p120 Catenin has been highlighted in early lobular breast neoplasias.

p120 Catenin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Parathyroid Hormone (PTH)



Human parathyroid adenoma: immunohistochemical staining for Parathyroid Hormone.
Parathyroid Hormone: clone 105G7

105G7

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-PTH-488	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

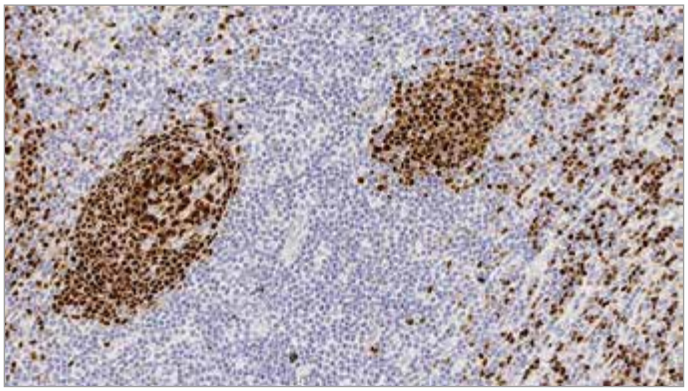
HEAD, NECK AND ENDOCRINE

ANTIGEN BACKGROUND

The parathyroid glands are small, oval, endocrine glands closely associated with the thyroid gland. The parathyroid glands regulate serum calcium and phosphate levels via parathyroid hormone (parathormone). Parathyroid hormone raises serum calcium levels directly, by increasing the rate of osteoclastic reabsorption and promoting breakdown of the bone matrix, and indirectly, by increasing the renal tubular reabsorption of calcium ions and inhibiting the reabsorption of phosphate ions from the glomerular filtrate, and finally, by promoting the absorption of calcium from the small intestine. Parathyroid hormone is the most important regulator of blood calcium levels and is essential to life, whereas calcitonin appears only to provide a complementary mechanism for fine adjustment. Chief cells are the most abundant cells in the parathyroid gland and are responsible for the secretion of parathyroid hormone.

Parathyroid Hormone (PTH) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Pax-5



Human tonsil: immunohistochemical staining for Pax-5. Note nuclear staining of B cells.
Pax-5: clone 1EW

1EW

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0552	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-PAX-5	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

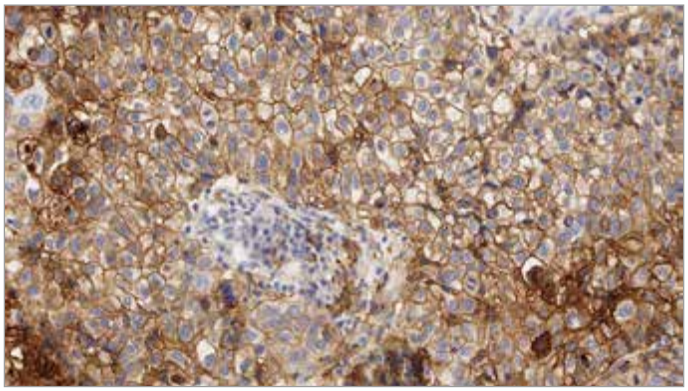
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

Pax genes are a family of developmental control genes that encode nuclear transcription factors and have been implicated in the control of mammalian development. Pax-5 is a B cell specific transcription factor that is expressed in pro B cells, pre-B and mature B cells, and subsequently in all stages of B cell development until the plasma cell stage in which it is downregulated.

Pax-5 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PD-L1



Non-small cell lung cancer: immunohistochemical staining for PD-L1. PD-L1: clone 73-10

73-10

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0832	P (HIER)	IVD	IVD	IVD

PATHOLOGY MENU

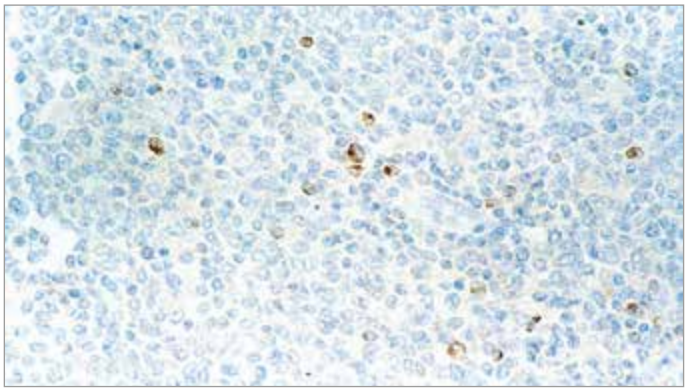
LUNG PATHOLOGY

ANTIGEN BACKGROUND

Programmed death-ligand 1 (PD-L1), CD274 or B7 Homolog 1(B7-H1) is a protein encoded by the CD274 gene. When bound to its ligands, PD-1 and B7.1, it plays an immunosuppressive role by inhibiting T-cell activity. Overexpression of PD-L1 by cancer cells may enable them to evade the host immune response, conferring a growth advantage to such tumours. PD-L1 expression levels detected by immunohistochemistry can therefore be of prognostic value in some types of cancer.

PD-L1 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Perforin



Human follicular lymphoma: immunohistochemical staining for Perforin. Perforin: clone 5B10

5B10

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-PERFORIN	P(HIER)	IVD	-	-

PATHOLOGY MENU

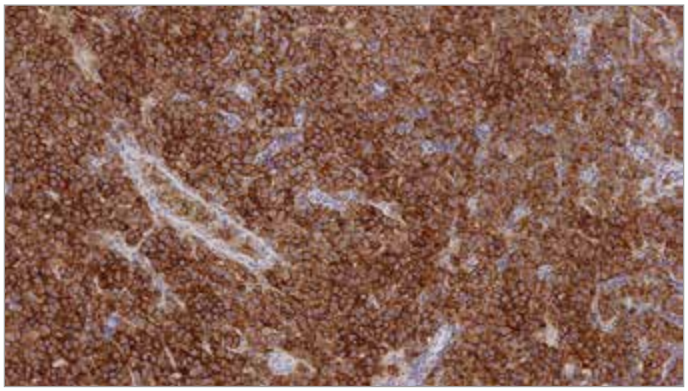
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

Perforin is a pore-forming protein found in cytoplasmic granules of cytotoxic T-lymphocytes (CTLs). CTLs bind to cells which express foreign antigens and induce them to lyze. Perforin forms circular lesions on the target cell membrane similar to those induced by complement. Perforin and C9 share a high degree of homology particularly at the membrane spanning region. Perforin is reported to be constitutively expressed in human CD3 negative, CD56 positive NK cells, CD3 positive large granular lymphocytes and gamma/delta T cells. This expression is significantly induced in CD8 positive T cells but to a lesser extent in gamma/delta T cells and NK cells. The induction of perforin mRNA is partially blocked by the immunosuppressive drug cyclosporin A.

Perforin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Placental Alkaline Phosphatase



Human seminoma: immunohistochemical staining of Placental Alkaline Phosphatase.
Placental Alkaline Phosphatase (PLAP): clone 8A9

8A9

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0161	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-PLAP-8A9	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

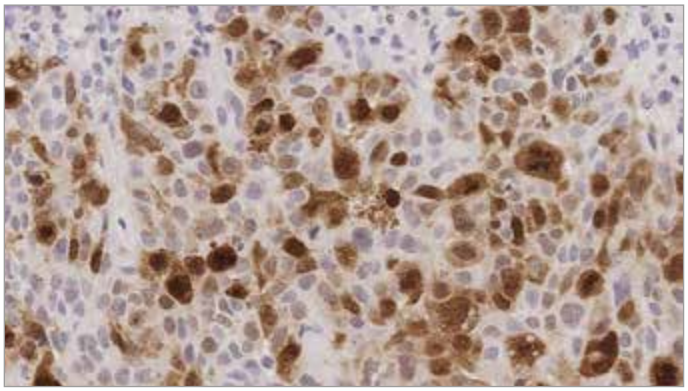
GYNEPATHOLOGY

ANTIGEN BACKGROUND

Placental alkaline phosphatase (PLAP) is a membrane-associated sialoglycoprotein enzyme normally present at high concentration in syncytiotrophoblasts within the placenta during the third trimester of gestation. The expression of PLAP was originally thought to be restricted to term placenta but a human PLAP-like variant has been described which shares more than 85% homology with PLAP itself. This high degree of homology between PLAP and PLAP-like enzyme together with cross-reacting antibodies has led to some confusion of the distribution of PLAP and PLAP-like enzyme in various tissues. PLAP is reported to be expressed only in normal term placenta, endocervix and fallopian tube and also in ovarian and proximal gastrointestinal tumors. PLAP expression is rare in malignant germ cell tumors. PLAP-like enzyme is reported to be predominantly found in normal fetal and neonatal testis, and in thymus. It is also commonly expressed in germ cell tumors and more recently described in seminomas.

Placental Alkaline Phosphatase is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Polo-Like Kinase 1 (PLK-1)



Squamous cell carcinoma of oropharangeal tissue: immunohistochemical staining of PLK-1.
Polo-Like Kinase-1: clone MJS1

MJS1

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-PLK-1	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

SPECIALIZED

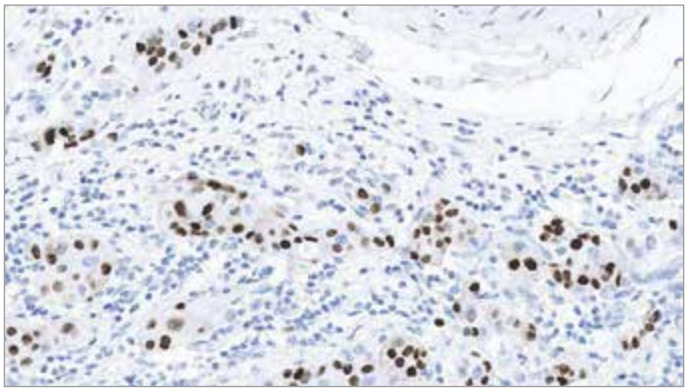
ANTIGEN BACKGROUND

Polo-Like Kinase-1 (PLK1) (also known as Serine/Threonine Protein Kinase 13) is a 66 kDa kinase. The activity of PLK-1 is crucial for mitosis and maintenance of genome stability. PLK-1 localizes to centrosomes and kinetochores where it plays a key role in late prophase and prometaphase. PLK-1 is overexpressed in many types of cancers and mediates estrogen receptor-mediated gene transcription in breast cancer cells.

Overexpression of PLK-1 is associated with tumor development, with elevated levels of expression reported in non-small cell lung cancers, head and neck, gastric, breast, ovarian, colon and several other cancer types.

Polo-Like Kinase 1 (PLK-1) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Progesterone Receptor



Breast carcinoma: immunohistochemical staining of Progesterone Receptor. Note the nuclear staining in a proportion of tumor cells. Progesterone Receptor: clone 16

16

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0312	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-PGR-312	P(HIER)	IVD	IVD	IVD
Liquid 2 mL	NCL-L-PGR-312/2	P(HIER)	-	IVD	IVD

1A6

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-PGR	P(HIER)	-	IVD	IVD

PATHOLOGY MENU

BREAST PATHOLOGY

ANTIGEN BACKGROUND

The human progesterone receptor (PR) is expressed as two isoforms, PRA (94 kD) and PRB (114 kD), which function as ligand-activated transcription factors. These two isoforms are transcribed from distinct estrogen receptor (ER)-inducible promoters within a single copy PR gene.

The PRA form is a truncated version of the PRB form, lacking the first 164 N-terminal amino acids. In humans, PRA acts as a transdominant repressor of the transcriptional activity of PRB, glucocorticoid receptor, ER, androgen receptor and mineralocorticoid receptor. PRB functions mainly as a transcriptional activator. PRB is expressed strongly in endometrial glandular and stromal nuclei in the proliferative phase of the menstrual cycle and weakly during the secretory phase and early pregnancy.

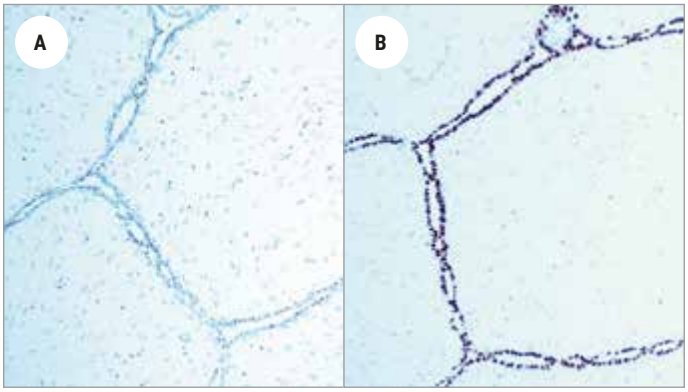
Progesterone Receptor is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

Clone 16 is specific for a region of the N-terminus of the A form of PR. The precise epitope has not been mapped but it reacts with both A and B forms of PR by Western Blot but only with the A form by immunohistochemistry. This suggests that the epitope is inaccessible in the native folded B form of the protein.

Refer to the IFU for appropriate use instructions.

Progesterone Receptor (A/B Forms)



Human fibroadenoma (serial sections): immunohistochemical staining for Progesterone Receptor (A and B forms). Note a smaller proportion of weakly staining tumor cell nuclei in A compared to B. Progesterone Receptor (A/B Forms): clones 16/SAN27

16/SAN27

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-PGR-AB	P(HIER)	-	IVD	IVD

PATHOLOGY MENU

BREAST PATHOLOGY

ANTIGEN BACKGROUND

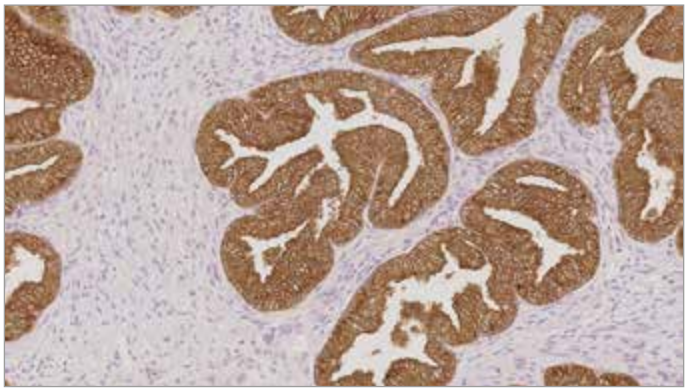
The human progesterone receptor (PR) is expressed as two isoforms, PRA (94 kD) and PRB (114 kD), which function as ligand-activated transcription factors. In vitro studies have indicated that PRA and PRB can activate different target genes and that PRA, in some circumstances, may act as a dominant inhibitor of the function of PRB and other steroid hormone receptors. PRA and PRB are both expressed in normal breast. Most endometrial carcinomas, however, are reported to express only one isoform with either PRA or PRB being expressed.

Progesterone Receptor (A/B Forms) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

The cocktail has been formulated using two clones, clone 16, specific for PRA, and SAN27, specific for PRB.

Prostate Specific Antigen



Human prostatic hyperplasia: immunohistochemical staining of Prostate Specific Antigen. Prostate Specific Antigen: clone 35H9

35H9

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0431	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-PSA-431	P	IVD	IVD	IVD

PATHOLOGY MENU

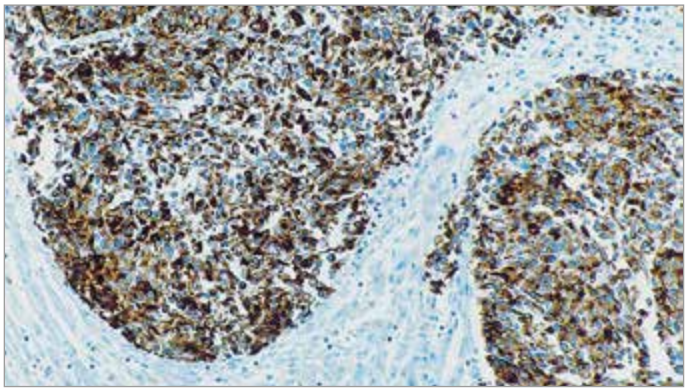
UROPATHOLOGY

ANTIGEN BACKGROUND

Prostate specific antigen (PSA) is a 34 kD protein belonging to the kallikrein family of serine proteases and was originally isolated and purified from human seminal plasma. It was found to be immunologically identical and biologically similar to a protein isolated from the prostate gland. PSA is distinct from prostatic acid phosphatase. Low levels of expression of PSA have been reported in non-prostatic tissues and tumors such as breast carcinomas.

Prostate Specific Antigen is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Prostate Specific Membrane Antigen



Human prostate: immunohistochemical staining for Prostate Specific Membrane Antigen (PSMA): clone 1D6

1D6

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-PSMA	-	ASR	RUO	RUO

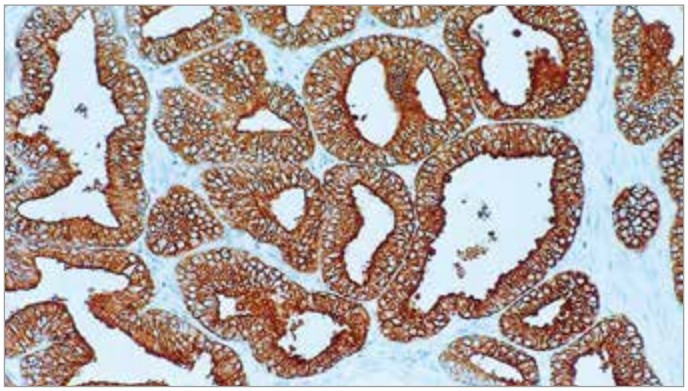
PATHOLOGY MENU

UROPATHOLOGY

ANALYTE SPECIFIC REAGENT

Analyte Specific Reagent. Analytical and performance characteristics are not established.

Prostatic Acid Phosphatase



Human prostate, adenocarcinoma: immunohistochemical staining for prostatic acid phosphatase. Prostatic Acid Phosphatase: clone PASE/4LJ

PASE/4LJ

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0006	P	IVD	IVD	IVD
Liquid 1 mL	NCL-L-PAP	F;P	RUO	RUO	RUO

PATHOLOGY MENU

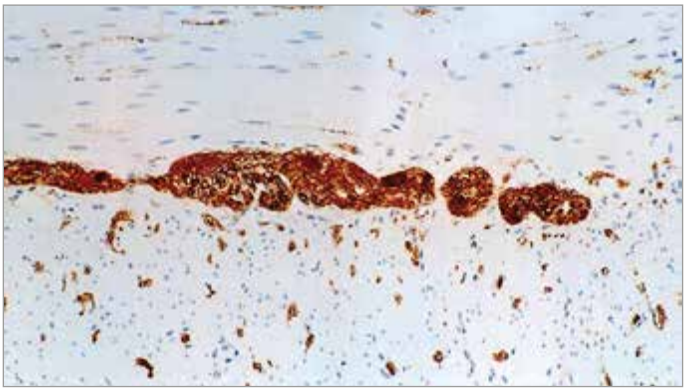
UROPATHOLOGY

ANTIGEN BACKGROUND

Prostatic acid phosphatase (PAP) is an isoenzyme of acid phosphatase found in large amounts in the prostate and seminal fluid. The precise function of PAP is unknown, but it may act as a hydrolase to split phosphoryl choline in semen and also function as a transferase. Elevated serum levels of the enzyme are reported in metastatic prostatic carcinoma.

Prostatic Acid Phosphatase is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Protein Gene Product 9.5



Human colon: immunohistochemical staining of Protein Gene Product 9.5. Note the staining in the neuronal elements and the ganglia of the longitudinal and circular smooth muscle. Protein Gene Product 9.5: clone 10A1

10A1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0286	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-PGP9.5	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

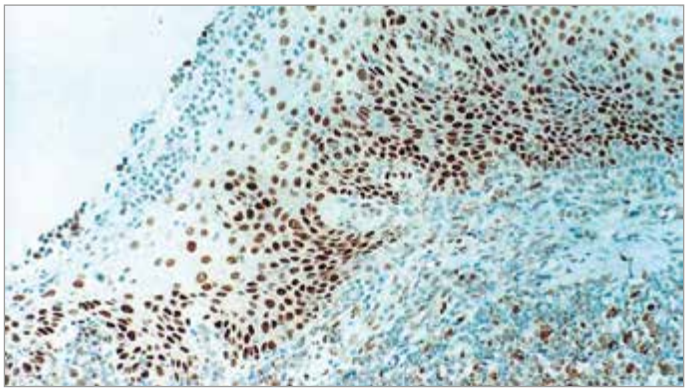
NEUROPATHOLOGY

ANTIGEN BACKGROUND

Protein gene product (PGP) 9.5 is a neuron-specific protein, structurally and immunologically distinct from neuron specific enolase. The protein which has a molecular weight of 27 kD was first identified by high resolution two dimensional PAGE. PGP9.5 expression has been reported in neurons and nerve fibers at all levels of the central and peripheral nervous system, in many neuroendocrine cells, in segments of the renal tubules, in spermatogonia and Leydig cells of the testis, in ova and in some cells of both the pregnant and non-pregnant corpus luteum. PGP9.5 is a member of the ubiquitin C-terminal hydroxylase family and is also concentrated within inclusion bodies suggesting that such structures may be metabolically active regions of the cells.

Protein Gene Product 9.5 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Retinoblastoma Gene Protein



Human tonsil: immunohistochemical staining for Retinoblastoma Gene Protein. Retinoblastoma Gene Protein: clone 13A10

13A10

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-RB-358	P(HIER);W	RUO	RUO	RUO

PATHOLOGY MENU

SPECIALIZED

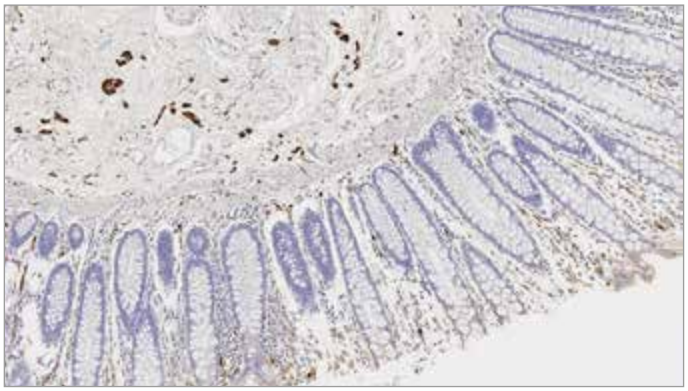
ANTIGEN BACKGROUND

Retinoblastoma (Rb) is a rare tumor of the retina associated with mutations of chromosome 13. The nuclear phosphoprotein encoded by the Rb tumor suppressor gene is present in many cells and may indirectly regulate cell growth by activating the transcription factor ATF-2. Activation of ATF-2 initiates expression of TGF-beta2, which in turn inhibits transcription of genes affecting cell growth. Bilateral mutation of the Rb gene may potentially play a role in the development of a number of malignant tumors.

PRODUCT SPECIFIC INFORMATION

NCL-L-RB-358 was raised to the N-terminal region of the Rb gene protein.

S-100



Human bowel: immunohistochemical staining for S-100. Note cytoplasmic staining of ganglia and peripheral nerve cells. S-100: Polyclonal

EP32

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0031	P(HIER)	IVD	IVD	IVD
Liquid 0.1 mL	NCL-L-S100-167	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

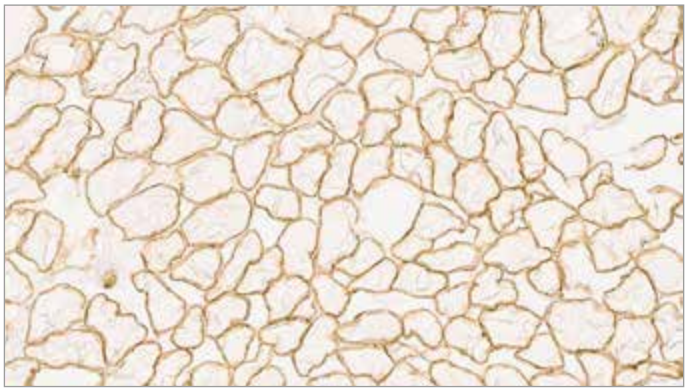
DERMATOPATHOLOGY

ANTIGEN BACKGROUND

S-100A and S-100B proteins are two members of the S-100 family of proteins. S-100A is composed of an alpha and beta chain, whereas S-100B is composed of two beta chains. S-100 protein is reported to be expressed in neuroectodermal tissue, including nerves and melanocytes. Langerhans cells in skin and interdigitating reticulum cells in the paracortex of lymph nodes are also reported to express S-100 protein. It is noteworthy that S-100 protein is highly soluble and may be eluted from frozen tissue during immunohistochemical procedures.

S-100 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Sarcoglycan Antibodies



Transverse section of skeletal muscle fibers. immunohistochemical staining for Alpha Sarcoglycan. Note the demonstration of localized Alpha Sarcoglycan to the sarcolemma of the muscle fibers. Alpha Sarcoglycan: clone Ad1/20A6

Alpha Sarcoglycan: clone Ad1/20A6

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-a-SARC	F	IVD	IVD	IVD

Beta Sarcoglycan: clone βSarc1/5B1

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-b-SARC	F	IVD	IVD	IVD

Delta Sarcoglycan: clone δSarc3/12C1

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-d-SARC	F	IVD	IVD	IVD

Gamma: clone 35DAG/21B5

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-g-SARC	F	IVD	IVD	IVD

PATHOLOGY MENU

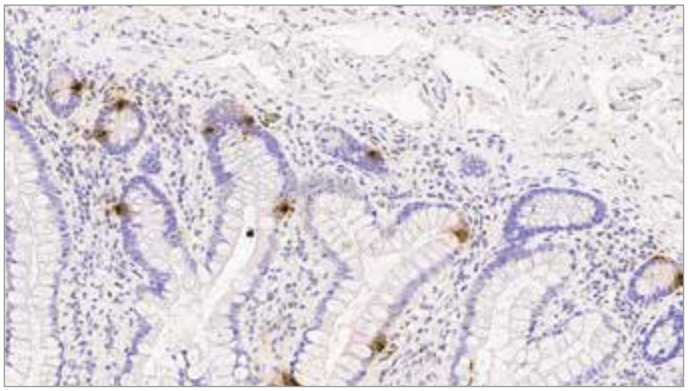
MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

In normal skeletal muscle, dystrophin, the protein product of the gene which is defective in Duchenne and Becker muscular dystrophy, is attached to the muscle membrane via a complex of proteins (dystrophin-associated glycoproteins, DAGs). Dystrophin-deficient muscle shows a generalized reduction in DAG labeling. The expression of different members of the dystrophin glycoprotein complex is altered in several types of muscular dystrophy. For example, patients with LGMD2D have mutations in the gene for alpha-sarcoglycan, those with LGM2E have mutations in the beta-sarcoglycan gene, those with LGM2C have mutations in the gamma-sarcoglycan gene and those with LGM2F have mutations in the delta-sarcoglycan gene. As the sarcoglycans function together as a sub-complex, mutations in any one of the sarcoglycan genes usually results in variable expression for the whole group.

Sarcoglycan Antibodies are recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Serotonin



Human bowel: immunohistochemical staining for Serotonin-containing mucosal cells. Serotonin: Polyclonal

Polyclonal

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0736	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

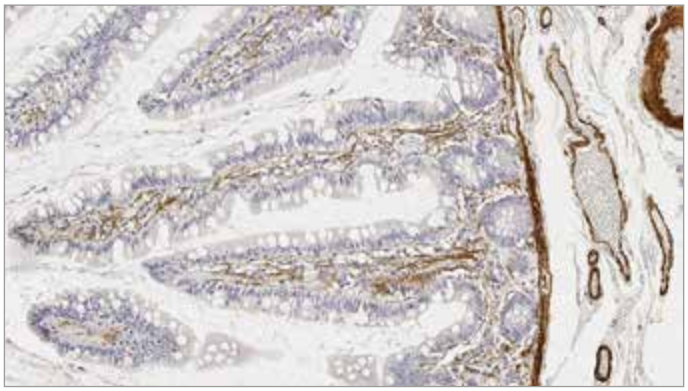
GASTROINTESTINAL PATHOLOGY

ANTIGEN BACKGROUND

Serotonin (5-hydroxytryptamine, 5-HT) is reported to be a widely distributed neurotransmitter and hormone in the mammalian peripheral and central nervous system (CNS). Serotonin is formed by the decarboxylation of 5-hydroxy-tryptophan, its intermediate, which in turn is formed by hydroxylation of L-tryptophan by tryptophan hydroxylase. In the CNS, the action of serotonin is terminated by reuptake into the presynaptic terminal by specific serotonin transporters. Serotonin has been implicated in several neuropsychiatric disorders such as anxiety, depression and schizophrenia. The majority of serotonergic nerve terminals in the CNS originate in neuronal cell bodies of the Raphe nuclei (dorsal, median), nucleus Raphe obscurus and nucleus Raphe pallidus in the brainstem which project to specific areas of the brain and spinal cord. Serotonin is thought to be an inhibitory neurotransmitter regulating a wide range of sensory, motor and cortical functions in the CNS. In the periphery, serotonin is reported to be present in neural and non-neural structures such as platelets, gastro-intestinal tract (myenteric plexus, enterochromaffin cells), lungs (neuroepithelial cells), thyroid gland and spleen.

Serotonin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

SMA (Alpha Smooth Muscle Actin)



Human small bowel: immunohistochemical staining for Alpha Smooth Muscle Actin. Note cytoplasmic staining of the muscularis mucosa, vascular walls and smooth muscle fibers in the lamina propria. SMA: clone αsm-1

αsm-1

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0943	P	IVD	IVD	IVD
Liquid 1 mL	NCL-L-SMA	P	IVD	IVD	IVD

PATHOLOGY MENU

MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

Cytoplasmic actins are part of the microfilament system of cytoskeletal proteins. Smooth muscle actin is found in vascular walls, intestinal muscularis mucosae and muscularis propria and in the stroma of various tissues.

SMA (Alpha Smooth Muscle Actin) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

An enzyme pretreatment can be used to enhance staining in some cases.

Spectrin

Human striated muscle: immunohistochemical staining for Spectrin. Note membrane staining of muscle fibers. Spectrin: clone RBC2/3D5

RBC2/3D5

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 1 mL	NCL-SPEC1	F	IVD	IVD	IVD

PATHOLOGY MENU

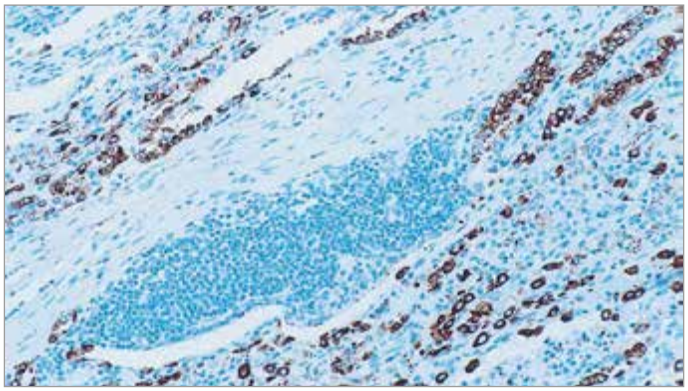
MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

Spectrin is a cytoskeletal protein which has some structural homology with dystrophin, the protein that is defective in Duchenne and Becker muscular dystrophy. Subtle membrane damage frequently occurs during the excision and freezing of muscle biopsies. Labeling for spectrin must be used to monitor membrane integrity. NCL-SPEC1 recognizes the beta chain of spectrin in erythrocytes and muscle. NCL-SPEC1 reacts with human beta-spectrin.

Spectrin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Surfactant Protein A



Human lung adenocarcinoma: immunohistochemical staining for Surfactant Protein A. Surfactant Protein A: clone 32E12

32E12

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-SP-A	P(HIER)	IVD	-	-

PATHOLOGY MENU

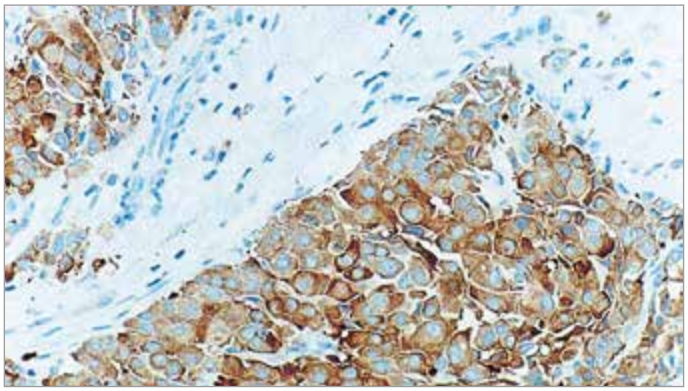
LUNG PATHOLOGY

ANTIGEN BACKGROUND

Pulmonary surfactant plays a critical role in maintaining the structural integrity of the respiratory epithelium by reducing surface tension during expiration. It is a lipoprotein complex which is synthesized and secreted into the alveoli of the lung by type II pneumocytes. Lung surfactant protein-A (SP-A) is a major phospholipid-associated glycoprotein in surfactant and is a member of the C-type lectin superfamily that also inhibits lipid secretion and enhances the uptake of phospholipid by alveolar type II cells. Levels of SP-A in amniotic fluid are reported to reflect the degree of fetal lung maturity and inadequate levels of surfactant at birth, a frequent occurrence in premature infants, results in respiratory failure.

Surfactant Protein A is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Synaptophysin



Breast carcinoma showing neuroendocrine differentiation: immunohistochemical staining for Synaptophysin. Synaptophysin: clone 27G12

27G12

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0299	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-SYNAP-299	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

HEAD, NECK AND ENDOCRINE

ANTIGEN BACKGROUND

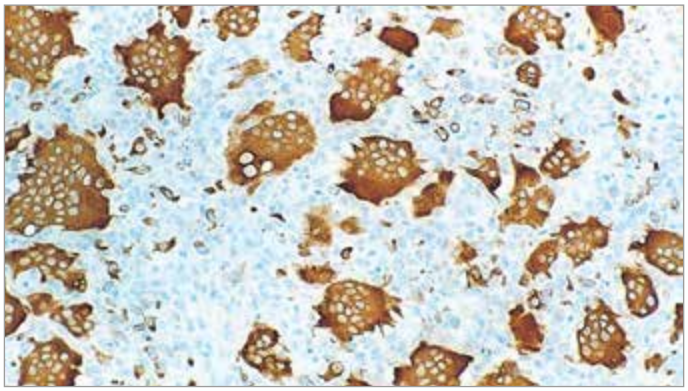
Synaptophysin is an integral membrane glycoprotein with a molecular weight of 38 kD. It is reported to occur in presynaptic vesicles of neurons in brain, spinal cord, retina, in similar vesicles of the adrenal medulla as well as in neuromuscular junctions.

Synaptophysin may be involved in synaptic vesicle formation and exocytosis. Synaptophysin is reported to be expressed in a wide spectrum of neuroendocrine tumors including neuroblastomas, ganglioneuroblastomas, phaeochromocytomas, chromaffin and non-chromaffin paragangliomas.

Synaptophysin is also reported to be expressed in neuroendocrine tumors of epithelial type including pituitary adenomas, islet cell tumors, medullary carcinomas of thyroid, parathyroid adenomas, carcinoids of the bronchopulmonary and gastrointestinal tracts, neuroendocrine carcinomas of the bronchopulmonary and gastrointestinal tract and neuronendocrine carcinomas of the skin.

Synaptophysin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Tartrate-Resistant Acid Phosphatase (TRAP)



Human osteoclastoma: immunohistochemical staining for Tartrate-Resistant Acid Phosphatase. Tartrate-Resistant Acid Phosphatase (TRAP): clone 26E5

26E5

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0093	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-TRAP	P(HIER)	IVD	-	-

PATHOLOGY MENU

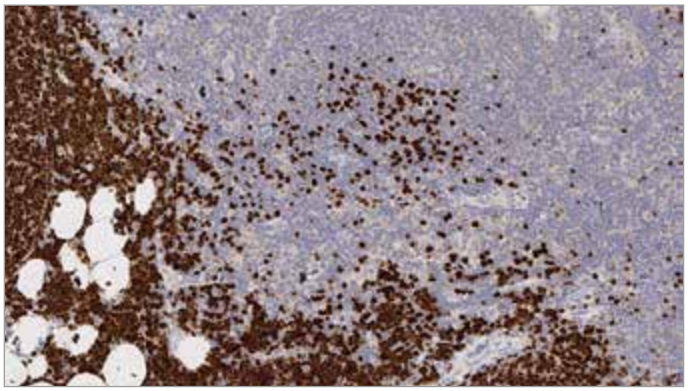
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

Tartrate-resistant acid phosphatase (TRAP) is a basic, iron-binding protein with high activity towards phosphoproteins, ATP and 4-nitrophenyl phosphate. This isoenzyme has been reported through different applications to be expressed in human alveolar macrophages, osteoclasts, spleen and liver. Expression of TRAP is reported to be increased in the spleen and monocytes of individuals with Gaucher's disease, Hodgkin's disease and the sera of individuals undergoing active bone turnover. Elevated levels are also reported to be associated with various B cell and T cell leukemias and lymphomas, decidual cells, syncytiotrophoblasts and some macrophages distributed throughout maternal and embryonic tissues.

Tartrate-Resistant Acid Phosphatase (TRAP) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Terminal Deoxynucleotidyl Transferase



Human thymus: immunohistochemical staining for Terminal Deoxynucleotidyl Transferase. Note nuclear staining for cortical thymic lymphocytes. Terminal deoxynucleotidyl transferase: clone SEN28

SEN28

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0339	P(HIER)	IVD	IVD	IVD
Liquid 0.5 mL	NCL-L-TDT-339	P(HIER)	-	IVD	IVD/RUO
Liquid 1 mL	NCL-L-TDT-339	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

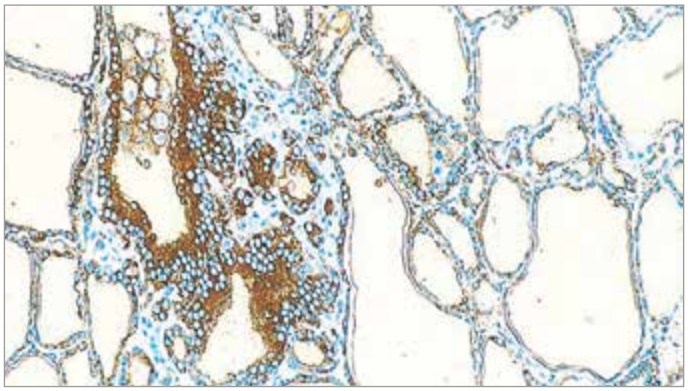
HEMATOPATHOLOGY

ANTIGEN BACKGROUND

Terminal deoxynucleotidyl transferase (TdT) is a DNA polymerase of 58 kD located in the cell nucleus which catalyzes the polymerization of deoxynucleotides at the 3' hydroxyl ends of oligo or polydeoxynucleotide initiators and functions without a template. TdT is reported to be expressed in primitive T and B lymphocytes of the normal thymus and bone marrow. The identification of TdT-positive cell populations in primary and secondary lymphoid organs during maturation of the immune system is one area of interest but it is the reported occurrence of high levels of enzyme activity in white blood cells and bone marrow in certain leukemias which is of particular interest.

Terminal Deoxynucleotidyl Transferase is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Thyroglobulin



Human Thyriod: immunohistochemical staining of Thyroglobulin in the follicular epithelial cells. Thyroglobulin: clone 1D4

1D4

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-THY	F;P	RUO	RUO	RUO

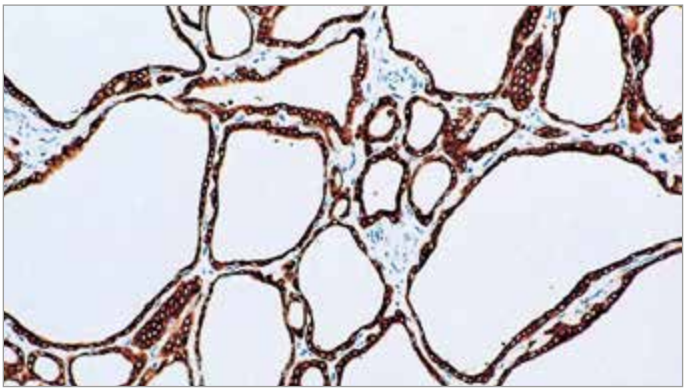
PATHOLOGY MENU

HEAD, NECK AND ENDOCRINE

ANTIGEN BACKGROUND

Thyroglobulin is a heavily glycosylated protein of 670kD composed of two identical subunits and is synthesized by the follicular epithelial cells of the thyroid. Thyroglobulin provides iodination sites for the formation of the thyroid hormones.

Thyroid Peroxidase



Thyroid, Graves' disease: immunohistochemical staining for Thyroid Peroxidase. Thyroid Peroxidase: clone AC25

AC25

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-TPO	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

HEAD, NECK AND ENDOCRINE

ANTIGEN BACKGROUND

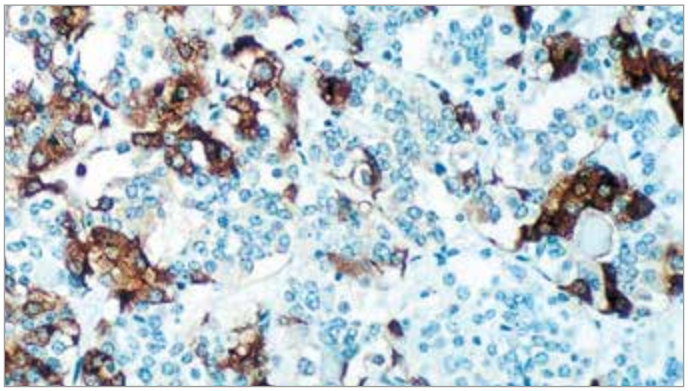
Thyroid peroxidase gene expression is under the regulation of thyroid stimulating hormone. In normal thyroid, expression of thyroid peroxidase (TPO) described immunohistochemically is reported to produce a diffuse, fine, granular cytoplasmic stain in all follicular cells. Some studies have shown qualitative, as well as quantitative differences in thyroid peroxidase expression in thyroid cancer compared to normal tissue.

Thyroid Peroxidase is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

TPO stains optimally when used in TBS-based wash buffer and diluent systems.

Thyroid Stimulating Hormone



Normal human pituitary gland: immunohistochemical staining for Thyroid Stimulating Hormone. Note cytoplasmic staining of a proportion of anterior pituitary cells. Thyroid Stimulating Hormone: clone QB2/6

QB2/6

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0776	P(ENZYME)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-TSH	P(ENZYME)	IVD	-	-

PATHOLOGY MENU

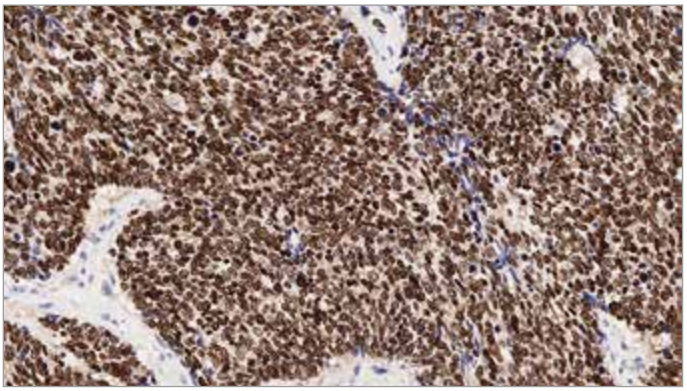
HEAD, NECK AND ENDOCRINE

ANTIGEN BACKGROUND

Thyroid stimulating hormone (TSH) is a pituitary hormone of 28 kD which stimulates thyroid growth and production of thyroid hormones. TSH is reported to be expressed in thyrotrophic cells of the pituitary and pituitary adenomas.

Thyroid Stimulating Hormone is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Thyroid Transcription Factor-1



Human small cell lung carcinoma: immunohistochemical staining with Thyroid Transcription Factor-1. Thyroid Transcription Factor-1: clone SPT24

SPT24

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0364	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-TTF-1	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

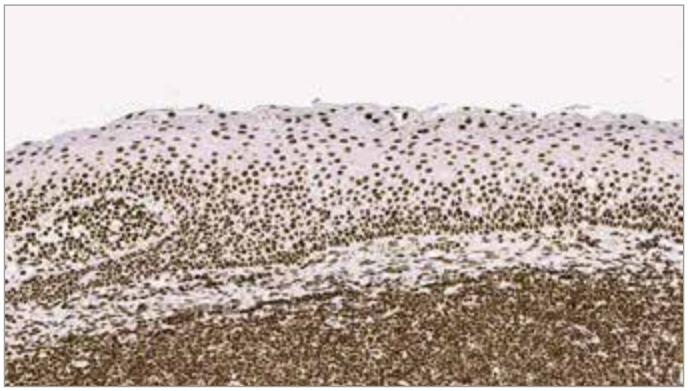
LUNG PATHOLOGY

ANTIGEN BACKGROUND

Thyroid Transcription Factor-1 (TTF-1) is a member of the homeodomain transcription factor family and plays a role in regulating genes expressed within the thyroid, lung and brain. These include thyroglobulin, thyroid peroxidase, Clara cell secretory protein and surfactant proteins. Human TTF-1 (38 kD) is a single polypeptide of 371 amino acids sharing 98% homology with the equivalent rat and mouse proteins. TTF-1 functions by binding to specific recognition sites in a manner that may be regulated by both the redox and phosphorylation status of the protein. In addition to its role as a tissue-specific transcriptional activator in adult organs, TTF-1 may also function in organogenesis. Gene targeting studies have shown TTF-1 to be essential for the proper development of the thyroid and lungs and abnormal expression may underline a number of congenital abnormalities.

Thyroid Transcription Factor-1 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Topoisomerase I



Human tonsil: immunohistochemical staining for Topoisomerase I. Topoisomerase I: clone 1D6

1D6

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-TOPO I	P(HIER)	IVD	-	-

PATHOLOGY MENU

SPECIALIZED

ANTIGEN BACKGROUND

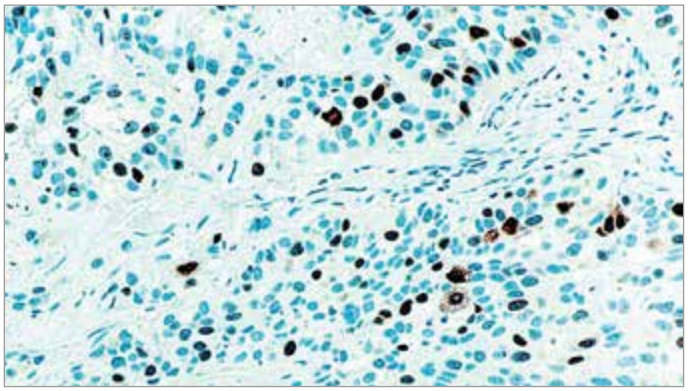
Topoisomerases are nuclear enzymes involved in a variety of cellular activities such as chromosomal condensation, DNA replication, transcription, recombination and segregation at mitosis. Human Topoisomerase I is a 100 kD protein capable of relaxing positively and negatively supercoiled DNA by performing a transient single-stranded nick which is then re-ligated at the end of the reaction. It has been shown that the enzyme is located in regions of the genome that are undergoing active RNA synthesis where it probably reduces superhelical stresses in the DNA enabling RNA polymerase to function properly. In normal eukaryotic cells, DNA topoisomerase I does not show relevant fluctuations across the cell cycle, unlike DNA topoisomerase II alpha. Both DNA topoisomerases I and II have been found to be targets of autoantibodies in the sera of individuals with certain autoimmune diseases, for example, systemic lupus erythematosus and also of some anti-tumor drugs and antibiotics. Elevated levels of DNA topoisomerase I, detected by 32P transfer assays, have been reported in colorectal tumors compared with normal colon mucosa as a result of increased transcription or mRNA stability.

Topoisomerase I is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

The use of phosphate-containing wash buffers or diluents can have an adverse effect on staining. Tris-containing wash buffers or diluents should be used instead.

Topoisomerase II Alpha



Human bladder tumor: immunohistochemical staining for Topoisomerase II alpha. Topoisomerase II Alpha: clone 3F6

3F6

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-TOPOIIA	P(HIER)	IVD	-	-

PATHOLOGY MENU

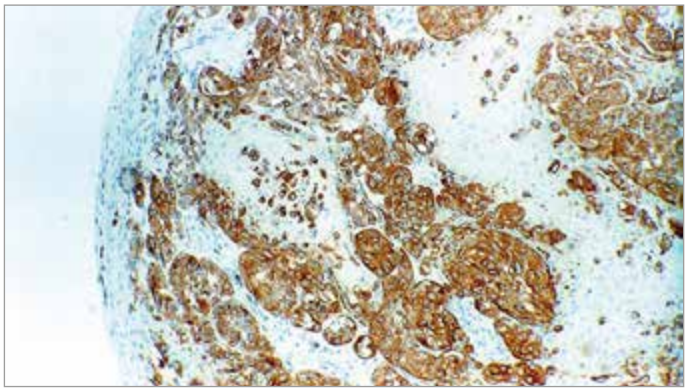
SPECIALIZED

ANTIGEN BACKGROUND

Topoisomerase II alpha is an essential nuclear enzyme involved in DNA replication and is a target for many anti-cancer drugs used for cancer therapy. Decreased expression of topoisomerase II alpha is the predominant mechanism of resistance to several chemotherapeutic agents. A significant variation in the range of expression of this protein has been reported in many different tumors. Reports of the analysis of primary breast tumors have indicated that topoisomerase II beta is more widely expressed than topoisomerase II alpha. Topoisomerase II alpha expression and activity is linked to the cell cycle and is associated with the proliferation status of cells.

Topoisomerase II Alpha is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Tyrosinase



Human malignant melanoma: immunohistochemical staining for Tyrosinase: clone T311

T311

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0322	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-TYROS	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

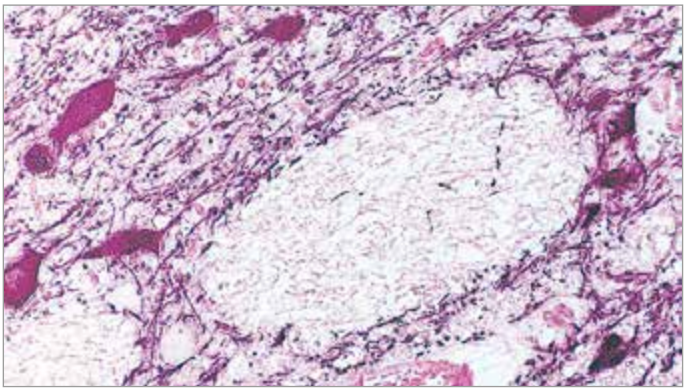
DERMATOPATHOLOGY

ANTIGEN BACKGROUND

The biosynthesis of melanin in melanocytes involves a family of enzymes, a key member of which is tyrosinase. Tyrosinase deficiency is associated with various forms of albinism and in particular oculocutaneous albinism. L-tyrosinase is the initial substrate for melanin biosynthesis and its conversion to dopaquinone is catalyzed by tyrosinase, whose expression is reported in melanocytes and melanomas.

Tyrosinase is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Tyrosine Hydroxylase



Human midbrain: immunohistochemical staining of Tyrosine Hydroxylase enzyme. Note cytoplasmic staining of catecholaminergic cells and their processes. (Peroxidase substrate: nickel DAB, Counterstain: eosin). Tyrosine Hydroxylase: clone 1B5

1B5

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-TH	P(HIER)	IVD	-	-

PATHOLOGY MENU

NEUROPATHOLOGY

ANTIGEN BACKGROUND

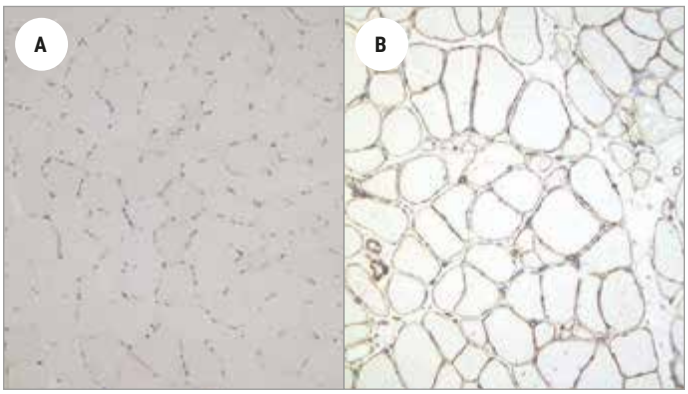
Tyrosine hydroxylase is the first enzyme in catecholamine (CA) biosynthesis and catalyzes the conversion of L-tyrosine to L-DOPA. Tyrosine hydroxylase is reported to be expressed in all CA neurons. Despite the abundant data about the distribution of catecholaminergic neurons in a wide variety of species, data on their distribution in the human brain is less comprehensive. However, one such study has reported that tyrosine hydroxylase products in the substantia nigra were restricted to neural bodies, axons and dendrites. These in turn were restricted to the third decade of life and their number increased in this location with age. This finding may be related to ageing of melanin-pigmented neurons.

Tyrosine Hydroxylase is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

PRODUCT SPECIFIC INFORMATION

TH is reactive with tyrosine hydroxylase in human, mouse and rat brain tissue.

Utrophin



Human skeletal muscle: immunohistochemical staining for Utrophin. In control muscle the antibody labels blood vessels and neuromuscular junctions (A). Utrophin is expressed at the sarcolemma in individuals with mutations in the DMD gene (B). Utrophin: clone DRP3/20C5

DRP3/20C5

FORMAT	CODE	USAGE	US	EU	ROW*
Lyophilized 2.5 mL	NCL-DRP2	F	IVD	IVD	IVD

PATHOLOGY MENU

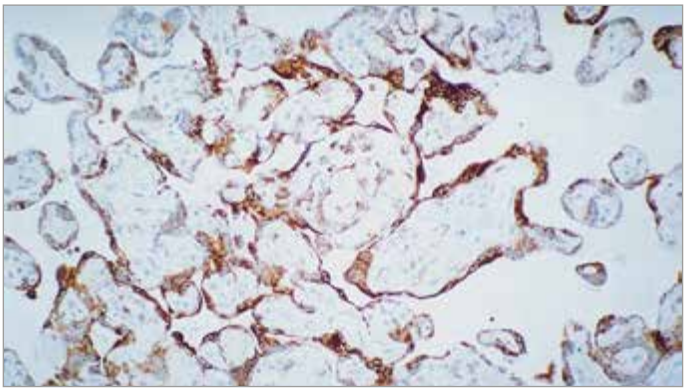
MUSCLE PATHOLOGY

ANTIGEN BACKGROUND

The utrophin gene is located on chromosome 6. The protein is a homologue of dystrophin and is known as dystrophin-related protein. In normal muscle, utrophin is restricted to neuromuscular junctions; however, in dystrophin-deficient muscle, utrophin expression may be upregulated and labeling appears around the periphery of most fibers. Immunohistochemical staining with DRP2 labels vessels and neuromuscular junctions and the upregulated form of utrophin, located around fiber membranes.

Utrophin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Vascular Endothelial Growth Factor Receptor-3



Human placenta: immunohistochemical staining for Vascular Endothelial Growth Factor Receptor-3: clone KLT9

KLT9

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-VEGFR-3	-	ASR	RUO	RUO

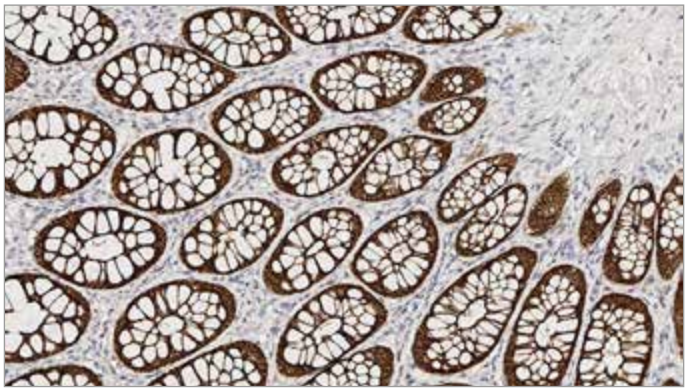
PATHOLOGY MENU

SPECIALIZED

ANALYTE SPECIFIC REAGENT

Analyte Specific Reagent. Analytical and performance characteristics are not established.

Villin



Human large bowel: immmunohistochemical staining for Villin. Note cytoplasmic staining of the epithelial cells. Villin: clone CWWB1

CWWB1

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-VILLIN	-	ASR	RUO	RUO

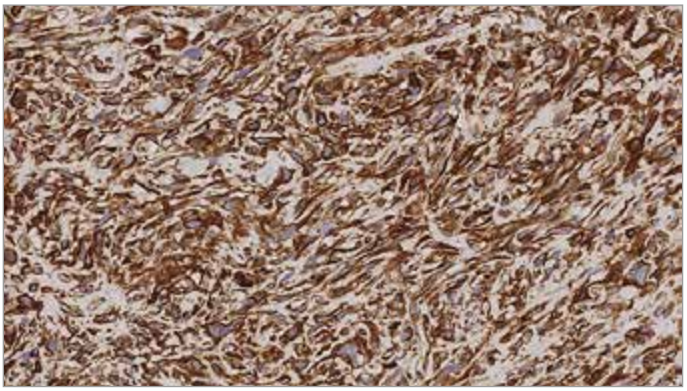
PATHOLOGY MENU

GASTROINTESTINAL PATHOLOGY

ANALYTE SPECIFIC REAGENT

Analyte Specific Reagent. Analytical and performance characteristics are not established.

Vimentin



Spindle cell carcinoma: immmunohistochemical staining for Vimentin. Vimentin: clone V9

V9

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0640	P(HIER)	IVD	IVD	IVD
Liquid 0.5 mL	NCL-L-VIM-V9	P(HIER)	IVD	IVD	IVD/RUO
Liquid 1 mL	NCL-L-VIM-V9	P(HIER)	IVD	IVD	IVD/RUO

SRL33

FORMAT	CODE	USAGE	US	EU	ROW*
Liquid 1 mL	NCL-L-VIM-572	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

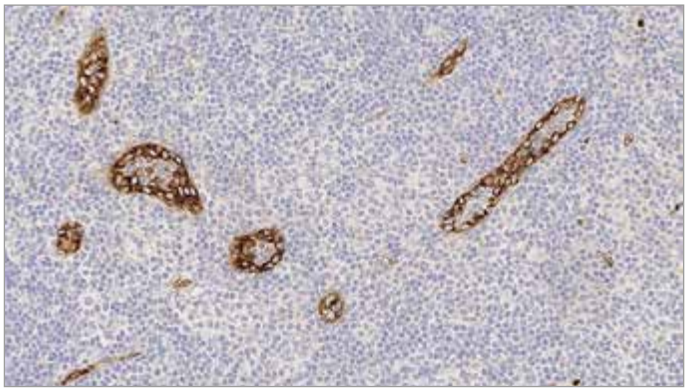
TUMOR DIFFERENTIATION

ANTIGEN BACKGROUND

Eukaryotic cells contain a number of types of cytoplasmic filamentous proteins, microtubule, microfilaments and intermediate-sized filaments (IF). Vimentin, a 57 kD protein that is an intermediate filament is reported to be expressed in most cells of mesenchymal origin, including fibroblasts, endothelial cells, smooth muscle, melanocytes as well as T and B lymphocytes.

Vimentin is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

von Willebrand Factor (Factor VIII-related antigen)



Human tonsil: immunohistochemical staining for von Willebrand Factor. Note cytoplasmic staining of endothelial cells. Von Willebrand Factor: clone 36B11

36B11

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0055	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-vWF	P(HIER)	IVD	IVD	IVD/RUO

PATHOLOGY MENU

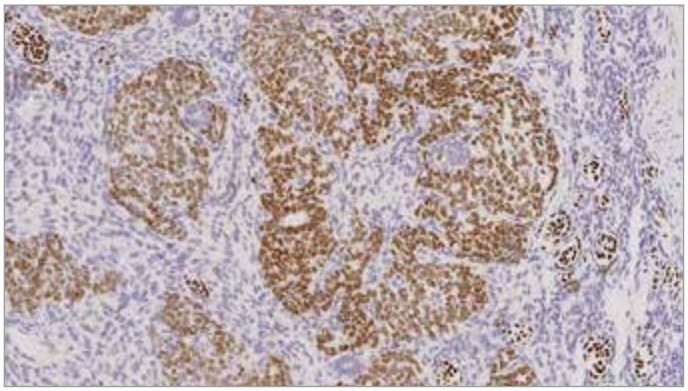
SOFT TISSUE PATHOLOGY

ANTIGEN BACKGROUND

Human von Willebrand factor (or factor VIII-related antigen) is a 270 kD multimeric plasma glycoprotein. It mediates platelet adhesion to injured vessel walls and serves as a carrier and stabilizer for coagulation factor VIII. The von Willebrand factor has functional binding domains to platelet glycoprotein Ib, glycoprotein Ib/IIIa, collagen and heparin. Von Willebrand factor is synthesized by endothelial cells and is reported to be expressed in a number of tumors of vascular origin.

von Willebrand Factor (Factor VIII-related antigen) is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

Wilms' Tumor



Human kidney: immunohistochemical staining for Wilms' tumor. Wilms' Tumor: clone WT49

WT49

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0562	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-WT1-562	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

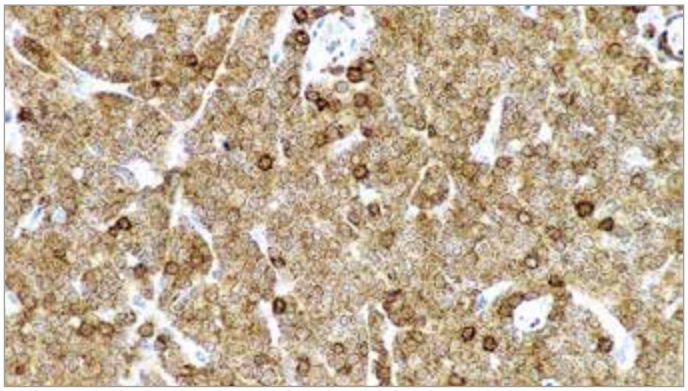
UROPATHOLOGY

ANTIGEN BACKGROUND

Wilms' tumor protein (WT1) has a role in transcriptional regulation and is expressed in the kidney and a subset of hematopoietic cells. Alteration of transcription factor function is a common mechanism in oncogenesis. The WT1 protein contains a DNA binding domain and any deletions or point mutations of the WT1 gene which destroy this activity result in the development of the childhood nephroblastoma Wilms' tumor and Denys-Drash syndrome. The description of WT1 involvement in nephroblastoma is not clear.

Wilms' Tumor is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

ZAP-70



Human B cell chronic lymphocytic leukemia: immunohistochemical staining for ZAP-70 antigen. ZAP-70: clone L453R

L453R

FORMAT	CODE	USAGE	US	EU	ROW*
BOND 7 mL	PA0998	P(HIER)	IVD	IVD	IVD
Liquid 1 mL	NCL-L-ZAP-70	P(HIER)	IVD	IVD	IVD

PATHOLOGY MENU

HEMATOPATHOLOGY

ANTIGEN BACKGROUND

ZAP-70 is a member of the syk family of proteins. It is expressed on T cells and NK cells and is required for the T cell receptor activation that triggers an immune response. CLL B cells that express the non-mutated immunoglobulin VH genes express levels of ZAP-70 protein that are comparable to those found in the blood T cells of healthy adults. Leukemic cells that express mutated Ig VH genes generally do not express detectable levels of ZAP-70 protein and this is correlated with the high level expression of CD38.

ZAP-70 is recommended for the detection of specific antigens of interest in normal and neoplastic tissues, as an adjunct to conventional histopathology using non-immunologic histochemical stains.

CELL MARQUE

BOND RTU FORMAT ANTIBODIES

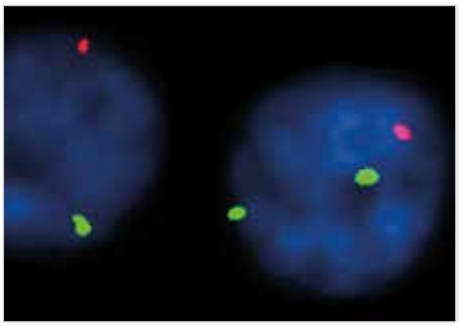
NAME	CLONE	FORMAT	CODE	USAGE	US	EU	ROW*	PRETREATEMENT
7 mL Arginase-1 (SP156 Rab) 'CM'	SP156	7 mL BRTU	PA0791	HIER	IVD	-	-	ER1 20
7 mL C4d (SP91 Rab) 'CM'	SP91	7 mL BRTU	PA0792	HIER	IVD	-	-	ER1 20
7 mL CD163 (MRQ-26 Mab) 'CM'	MRQ-26	7 mL BRTU	PA0794	HIER	IVD	-	-	ER2 20
7 mL Cytokeratin 5/6 (D5 & 16B4 Mab) 'CM'	D5 & 16B4	7 mL BRTU	PA0795	HIER	IVD	-	-	ER2 20
7 mL Podoplanin (D2-40 Mab) 'CM'	D2-40	7 mL BRTU	PA0796	HIER	IVD	-	-	ER1 30
7 mL Ep-CAM (MOC31 Mab) 'CM'	MOC31	7 mL BRTU	PA0797	EIER	IVD	-	-	ENZ 1 10
7 mL GATA3 (L50-823 Mab) 'CM'	L50-823	7 mL BRTU	PA0798	HIER	IVD	-	-	ER1 5
7 mL Glypican-3 (1G12 Mab) 'CM'	1G12	7 mL BRTU	PA0800	HIER	IVD	-	-	ER2 20
7 mL Hepatocyte Specific Antigen Hep-Par1	OCH1E5	7 mL BRTU	PA0801	HIER	IVD	-	-	ER2 30
7 mL Mammaglobin (31A5 Rab) 'CM'	31A5	7 mL BRTU	PA0802	HIER	IVD	-	-	ER1 30
7 mL Microphthalmia Transcription Factor	C5/D5	7 mL BRTU	PA0803	HIER	IVD	-	-	ER2 20
7 mL Napsin A (MRQ-60 Mab) 'CM'	MRQ-60 Mab	7 mL BRTU	PA0805	HIER	IVD	-	-	ER2 20
7 mL p120 Catenin (MRQ-5 Mab) 'CM'	MRQ-5 Mab	7 mL BRTU	PA0806	HIER	IVD	-	-	ER2 20
7 mL PAX8 (MRQ-50 Mab) 'CM'	MRQ-50 Mab	7 mL BRTU	PA0808	HIER	IVD	-	-	ER2 10
7 mL Renal Cell Carcinoma (PN-15 Mab) CM	PN-15 Mab	7 mL BRTU	PA0811	EIER	IVD	-	-	ENZ 1 10
7 mL SOX-10 (Polyclonal) 'CM'	Polyclonal	7 mL BRTU	PA0813	HIER	IVD	-	-	ER2 20
7 mL SOX-2 (SP76 Rab) 'CM'	SP76 Rab	7 mL BRTU	PA0815	HIER	IVD	-	-	ER2 20
7 mL SOX-11 (MRQ-58 Mab) 'CM'	MRQ-58 Mab	7 mL BRTU	PA0816	HIER	IVD	-	-	ER2 20
7 mL PHH3 (Polyclonal) 'CM'	Polyclonal	7 mL BRTU	PA0817	HIER	IVD	-	-	ER2 20
7 mL IgG4 (MRQ-44 Mab) 'CM'	MRQ-44 Mab	7 mL BRTU	PA0818	EIER	IVD	-	-	ENZ 1 10
7 mL (4C4.9 MAB) S100 Protein 'CM'	4C4.9 MAB	7 mL BRTU	PA0820	HIER	IVD	-	-	ER1 10

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent
F Frozen P Paraffin O Other Applications W Western blotting BOND BOND Ready-to-Use format Liquid Liquid Concentrate format

IVD PROBES

IVD PROBES

11q23 / DLEU1



11q23 / DLEU1 13q14 probe hybridized to MM patient material showing a 13q14 deletion (1R2G).

Image kindly provided by Prof. Jauch, Heidelberg.

11q23 / DLEU1 (13q14)

CODE	COLOR	FORMAT	STATUS
KBI-10502	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

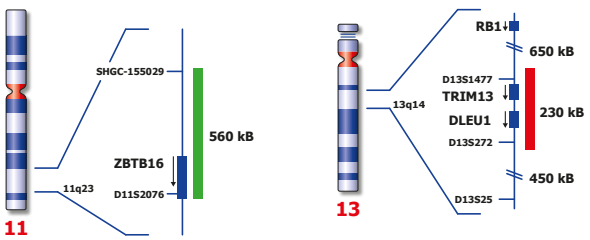
BACKGROUND

Hybridization results delineated 11q23 and 11q25 as the most frequently gained regions in Multiple Myeloma (MM) which supports a relevant pathogenetic role of genes in this region. Deletions of 13q14 are frequently detected by interphase FISH in patients with newly diagnosed MM, correlate with increased proliferative activity, and represent an independent adverse prognostic feature in MM.

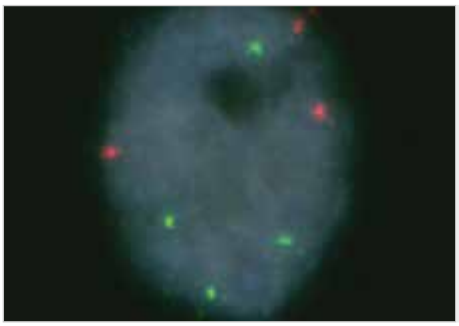
The 11q23 specific FISH probe is optimized to detect copy numbers at 11q23. The DLEU1 (13q14) specific DNA region is optimized to detect copy numbers of the DLEU1 (previously known as DLEU) gene region at 13q14.

REFERENCES

Gonzalez et al, 2004, Haematologica, 89; 1213-1218.
Cremer et al, 2005, Genes Chrom Cancer, 44; 194-203.



15q22 / 6q21



15q22 / 6q21 hybridized to MM patient material with gain of both critical regions 6q21 and 15q22.

Image kindly provided by Prof. Jauch, Heidelberg.

15q22 / 6q21

CODE	COLOR	FORMAT	STATUS
KBI-10504	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

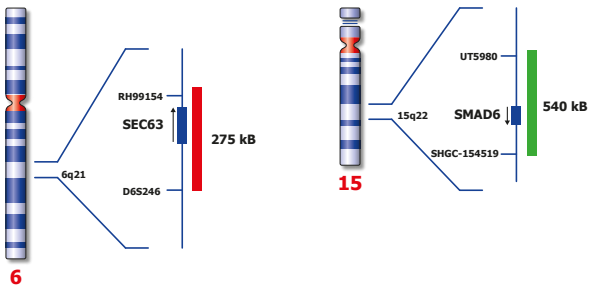
BACKGROUND

Chromosome 6q amplifications encompassing 6q21-22 have been observed in MM including the same region as in CLL. Amplification including band 15q22 has been reported in MM. The 15q22 specific FISH probe is optimized to detect copy numbers at 15q22.

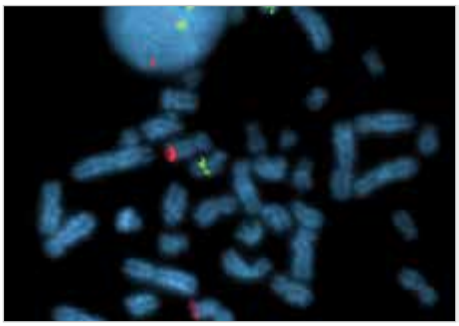
The 6q21 specific DNA region is optimized to detect copy numbers at 6q21.

REFERENCES

Cremer et al, 2005, Genes Chrom Cancer, 44; 194-203.



15q22 / 9q34



15q22 / 9q34 hybridized to a normal interphase/ metaphase (2R2G).

15q22 / 9q34

CODE	COLOR	FORMAT	STATUS
KBI-10508	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

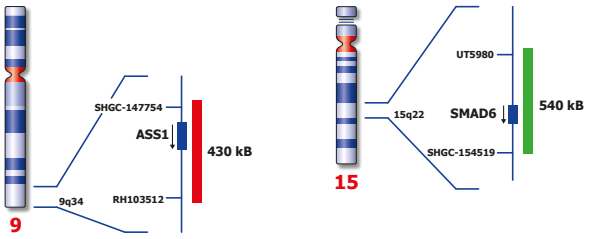
BACKGROUND

The hyperdiploid subtype in MM is defined by presence of multiple trisomic chromosomes. Combination of the chromosome 9q34 and 15q22 specific regions are important regions to detect the hyperdiploid subtype in MM which is usually associated with a low frequency of IGH translocations.

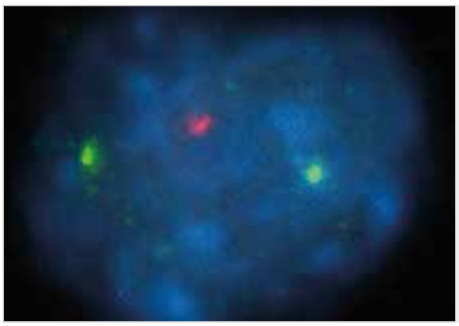
The 15q22 and 9q34 FISH probe is designed as a dual-color assay to detect amplifications at 15q22 and 9q34.

REFERENCES

Cremer et al, 2005, Genes Chrom Cancer, 44; 194-203.



19q13 / TP53



19q13 / TP53 (17p13) hybridized to patient material showing a TP53 (17p13) deletion (1R2G).

19q13 / TP53 (17p13)

CODE	COLOR	FORMAT	STATUS
KBI-10509	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

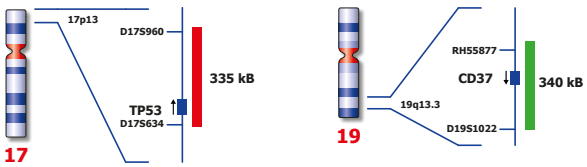
BACKGROUND

TP53 (previously known as p53) gene deletion, which can be identified by interphase FISH in almost a third of patients with newly diagnosed MM, is a prognostic factor predicting for short survival of MM patients treated with conventional-dose chemotherapy. Amplification of 19q13 has been reported in a variety of cancer. The 19q13 specific FISH probe is optimized to detect copy numbers at 19q13.

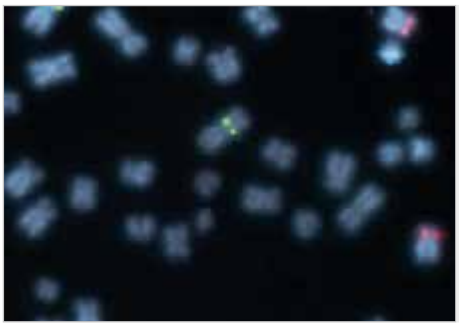
The TP53 (17p13) specific DNA region is optimized to detect copy numbers of the TP53 gene region at 17p13.

REFERENCES

Drach et al, 1998, Blood, 92; 802-809.
Cremer et al, 2005, Genes Chrom Cancer, 44; 194-203.



1q21 / 8p21



1q21 / 8p21 hybridized to a normal metaphase (2R2G).

1q21 / 8p21

CODE	COLOR	FORMAT	STATUS
KBI-10503	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

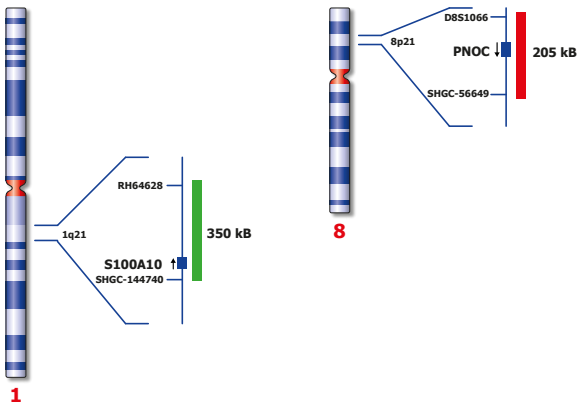
BACKGROUND

Amplifications of 1q21 are concurrent with dysregulated expression of MAF, MMSET / FGFR3, or Deletion 13 and represent an independent unfavorable prognostic factor. Allelic losses of the chromosome 8p21-22 have been reported as a frequent event in several cancers.

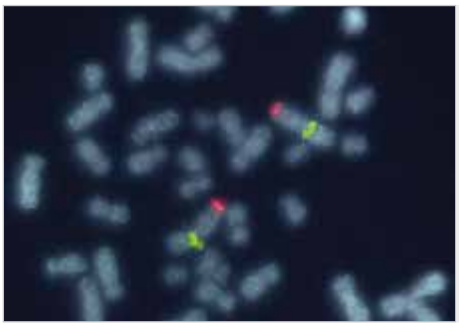
The 1q21 specific FISH probe is optimized to detect copy numbers at 1q21. The 8p21 specific DNA region is optimized to detect copy numbers at 8p21.

REFERENCES

Shaughnessy J., 2005, Hematology, 10 suppl, 1; 117-126.
Cremer et al, 2005, Genes Chrom Cancer, 44; 194-203.



1q21 / SRD



1q21 / SRD (1p36) hybridized to a normal metaphase (2R2G).

1q21 / SRD (1p36)

CODE	COLOR	FORMAT	STATUS
KBI-10507	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

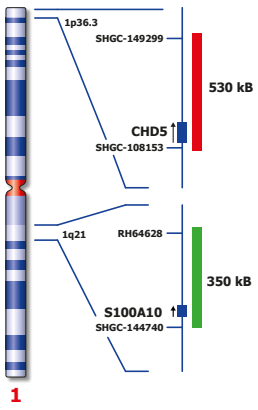
BACKGROUND

Frequent loss of heterozygosity (LOH) on the short arm of chromosome 1 (1p) has been reported in a series of human malignancies. The combination with the potentially amplified 1q21 region allows to detect deletions at 1p36 and gain of 1q21 in a single FISH assay.

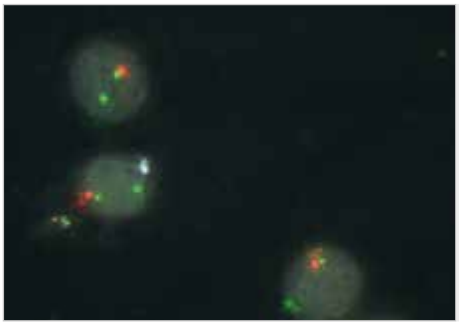
The 1q21 specific FISH probe is optimized to detect copy numbers at 1q21. The SRD 1p36 specific FISH probe is optimized to detect copy numbers of 1p at region 1p36 containing the markers D1S2795 and D1S253.

REFERENCES

Cremer et al, 2005, Genes Chrom Cancer, 44; 194-203.
Shaughnessy J., 2005, Hematology, 10 suppl, 1; 117-126..



20q-



20q- (20q12) / 20q11 probe hybridized to patient material showing 20q- deletion (1R2G).

Material kindly provided by Labdia Labordiagnostik, Vienna.

20q- (20q12) / 20q11

CODE	COLOR	FORMAT	STATUS
KBI-10203	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

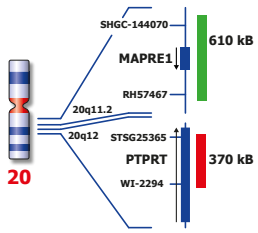
BACKGROUND

Acquired deletions of the long arm of chromosome 20 are found in several hematologic conditions and particularly in the myeloproliferative disorders (MPD) and myelodysplastic syndromes and acute myeloid leukemia (MDS / AML). A minimal critical region deleted in MPD and MDS has been identified at 20q12 which includes a protein tyrosine phosphatase receptor gene.

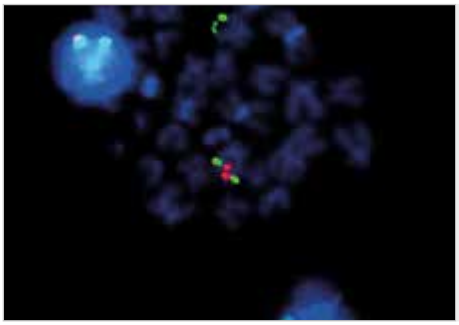
The 20q- (20q12) specific FISH probe is optimized to detect copy numbers of 20q at region 20q12. A 20q11 region specific probe is included to facilitate chromosome identification.

REFERENCES

Bench et al, 2000, Oncogene, 19; 3902-3913.
Asimakopoulos et al, 1994, Blood, 84; 3086-3094.



5q Dual-Color



5q- (5q31; 5q33) probe hybridized to patient material showing a 5q33 deletion (1R2G).

5q- (5q31; 5q33)

CODE	COLOR	FORMAT	STATUS
KBI-10209	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

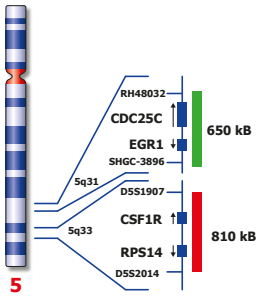
BACKGROUND

The presence of del(5q), either as the sole karyotypic abnormality or as part of a more complex karyotype, has distinct clinical implications for myelodysplastic syndromes (MDS) and acute myeloid leukemia. Interstitial 5q deletions are the most frequent chromosomal abnormalities in MDS and are present in 10% to 15% of MDS patients. Two different critical regions are described, one at 5q31-q33 containing the CSF1R and RPS14 gene regions, characteristic for the '5q-' syndrome, and a more proximal located region at 5q13-q31 containing the CDC25C and EGR1 gene regions.

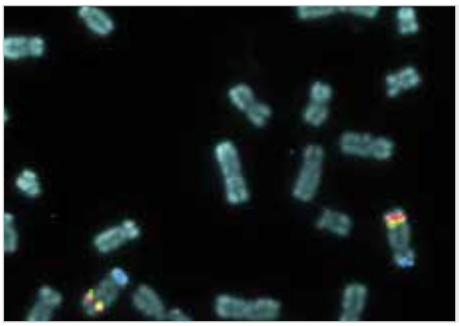
The 5q- specific FISH probe is optimized to detect copy numbers at the CDC25C / EGR1 gene region at 5q31 and the CSF1R / RPS14 gene region at 5q33 simultaneously in a dual-color assay.

REFERENCES

Boultwood J e.a., Blood 2002, 99; 4638-4641.
Zhao N e.a., PNAS 1997, 94; 6948-6953.
Wang e.a., Haematologica 2008, 93; 994-1000.
Ebert BL e.a., Nature 2008, 451; 335-339.
Mohamedali A and Mufti GJ, Brit J Haematol 2008, 144; 157-168.



5q- Triple-Color



5q- (5q31; 5q33) / TERT (5p15)Triple-Color probe hybridized to a normal metaphase (2R2G2B).

5q- (5q31; 5q33) / TERT (5p15) Triple-Color

CODE	COLOR	FORMAT	STATUS
KBI-10210	Green/Red/Blue	10 test	IVD

MENU

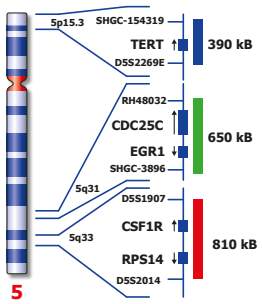
HEMATOPATHOLOGY

BACKGROUND

The 5q- specific FISH probe is optimized to detect copy numbers at the CDC25C / EGR1 gene region at 5q31 and the CSF1R / RPS14 gene region at 5q33 simultaneously in a dual-color assay. The triple-color probe provides in addition to the two critical regions a control in blue targeting the TERT (previously known as hTERT) gene region at 5p15.

REFERENCES

Boultwood J e.a., Blood 2002, 99; 4638-4641.
Zhao N e.a., PNAS 1997, 94; 6948-6953.
Wang e.a., Haematologica 2008, 93; 994-1000.
Ebert BL e.a., Nature 2008, 451; 335-339.
Mohamedali A and Mufti GJ, Brit J Haematol 2008, 144; 157-168.



6q21 / MYC

6q21 / MYC (8q24)

CODE	COLOR	FORMAT	STATUS
KBI-10117	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

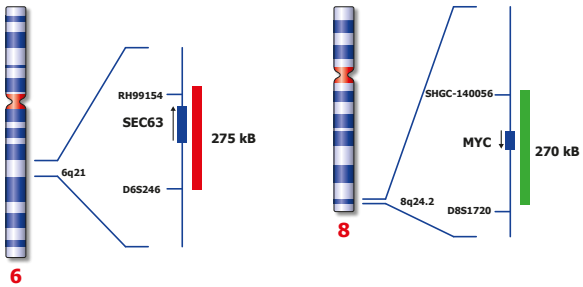
BACKGROUND

Deletions affecting the long arm of chromosome 6 (6q) involving band 6q21 are among the most commonly observed chromosomal aberrations in lymphoid malignancies and have been identified as adverse prognostic factor in subsets of tumors. Amplification of MYC (8q24) has been described in many types of solid tumors, such as breast, cervical and colon cancers, as well as in myeloma, non-Hodgkin's lymphoma, gastric adenocarcinomas and ovarian cancer.

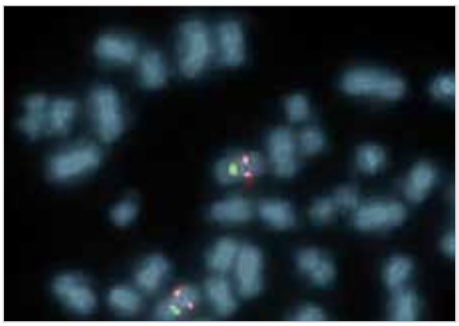
The 6q21 / MYC (8q24) FISH probe is designed as a dual-color assay to detect deletions and amplifications at 6q21 and 8q24.

REFERENCES

Zhang, Y, 2000, Genes, Chrom. And Canc. 27; 52-58.
Bentz, M et al, 1995, Blood, 85; 3610-3618.



6q21 / SE 6



6q21 / SE 6 probe hybridized to a normal metaphase (2R2G).

6q21 / SE 6

CODE	COLOR	FORMAT	STATUS
KBI-10105	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

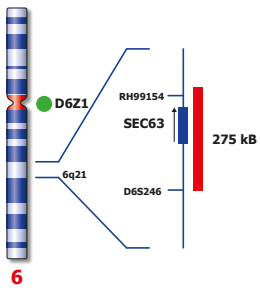
BACKGROUND

Deletions affecting the long arm of chromosome 6 (6q) are among the most commonly observed chromosomal aberrations in lymphoid malignancies and have been identified as an adverse prognostic factor in subsets of tumors including CLL. A minimal deletion region has been identified within a 2-megabase segment of 6q21, between D6S447 and D6S246. The SEC63 gene is located within this critical region.

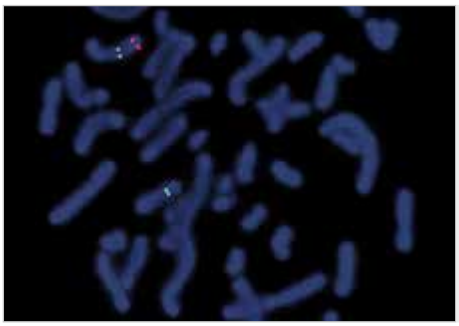
The 6q21 specific FISH probe is optimized to detect copy numbers of 6q at region 6q21.The chromosome 6 Satellite Enumeration FISH probe (SE 6) at D6Z1 is included to facilitate chromosome identification.

REFERENCES

Sherratt et al, 1997, Chromosome Res, 5; 118-124.
Zhang et al, 2000, Genes Chrom Cancer, 27; 52-58.



7q-



7q- (7q22; 7q36) hybridized to patient material showing a 7q36 deletion (1R2G).

Image kindly provided by Prof. Jauch, Heidelberg.

7q- (7q22; 7q36)

CODE	COLOR	FORMAT	STATUS
KBI-10202	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

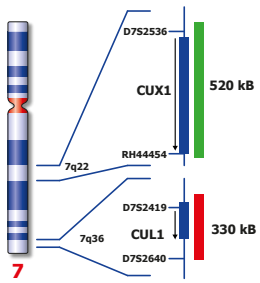
BACKGROUND

Loss of a whole chromosome 7 or a deletion of the long arm, del(7q), are recurring abnormalities in malignant myeloid diseases. Most deletions are interstitial and there are two distinct deleted segments of 7q. The majority of patients have proximal breakpoints in bands q11-22 and distal breakpoints in q31-36. The CCAAT displacement protein CUX1 gene region is located in the 7q22 critical region.

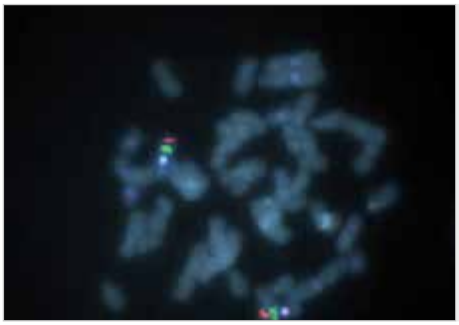
The 7q- specific FISH probe is optimized to detect copy number of 7q at 7q22 and at 7q36 simultaneously in a dual-color assay.

REFERENCES

LeBeau et al., 1996, Blood, 88; 1930-1935.
Doehner et al, 1998, Blood, 92; 4031-4035.



7q- Triple-Color



7q (7q22; 7q36) / SE 7 Triple-Color probe hybridized to a normal metaphase (2R2G2B).

7q- (7q22; 7q36) / SE7 Triple-Color

CODE	COLOR	FORMAT	STATUS
KBI-10207	Green/Red/Blue	10 test	IVD

MENU

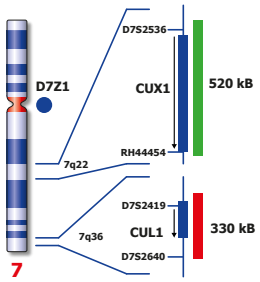
HEMATOPATHOLOGY

BACKGROUND

The 7q- specific FISH probe is optimized to detect copy number of 7q at 7q22 and at 7q36 simultaneously in a dual-color assay. The chromosome 7 Satellite Enumeration FISH probe (SE 7) at D7Z1 in blue is included to facilitate chromosome identification.

REFERENCES

LeBeau et al., 1996, Blood, 88; 1930-1935.
Doehner et al, 1998, Blood, 92; 4031-4035.



Acro-P-Arms

Acro-P-Arms NOR Blue

CODE	COLOR	FORMAT	STATUS
KBI-20033B	Blue	10 test	IVD
KBI-20033G	Green	10 test	IVD
KBI-20033R	Red	10 test	IVD

MENU

CONSTITUTIONAL

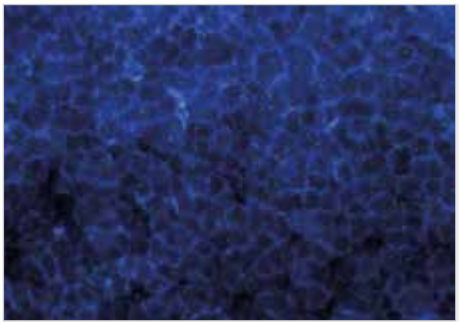
BACKGROUND

The NOR (Nucleolar Organizer Region) is located on every p-arm of the human acrocentric chromosomes. Enlargement of the acrocentric p-arms can be caused by an unusual variant or a translocation event. NOR stain of the p-arms is useful to detect such a p-arm variant. In the classification of small supernumerary marker chromosomes (SMCs) the Acro-P-Arms NOR FISH probe can detect the origin of DNA, in which about 80% will turn out to be derived from the acrocentric chromosomes. The Acro-P-Arms NOR FISH probe is optimized to detect the short (p) arm of all acrocentric human chromosomes. The probe is intended to be used on metaphase/interphase spreads.

REFERENCES

Starke H et al., 2003, Hum. Genet., 114; 51-67.
Starke H et al., 2005, J. Histochem Cytochem, 53; 359-360.

ALK / EML4



Hybridization of ALK EML4 fusion probe to a lung adenocarcinoma tissue section showing normal signal pattern (2R2G).

ALK (2p23) / EML4 t(2;2) inv (2) Fusion

CODE	COLOR	FORMAT	STATUS
KBI-10746	Green/Red	10 test	IVD

MENU

LUNG PATHOLOGY

BACKGROUND

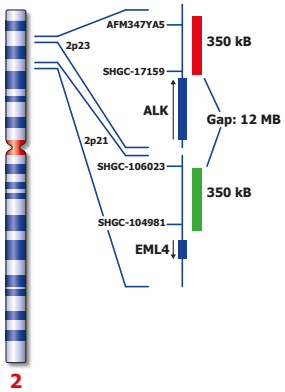
The inversion in 2p21 and 2p23 leading to a fusion of the kinase domain of ALK (anaplastic lymphoma kinase) and EML4 (echinoderm microtubule associated protein like 4) has been described in 5-7% of non-small cell lung cancer (NSCLC) cases.

Multiple tyrosine kinsae inhibitors (TKI's) specific for ALK have since been approved for first line treatment of NSCLC-patients carrying the fusion gene ALK-EML4. These ALK inhibitors include crizotinib (Xalkori), alectinib (Alecensa) and ceritinib (Zykadia).

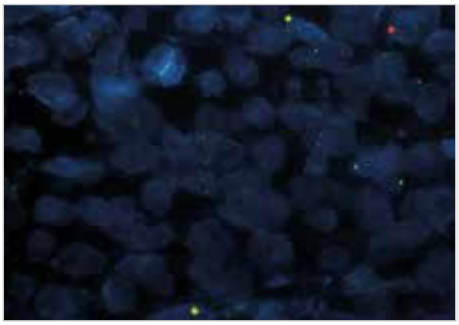
The ALK / EML4 t(2;2); inv(2) Fusion probe is designed as a dual-color assay to detect the fusion of the ALK gene with the EML4 gene by paracentric inversion with breakage and reunion occurring at bands 2p21 and 2p23.

REFERENCES

Soda et al, Nature, 2007, 448, 561-566.
Koivunen et al, Clin Cancer Res, 2008, 14, 4275-4283.



ALK Break



Hybridization of ALK break probe to a lung adenocarcinoma tissue section showing positive translocation signal (1RG1R1G).

ALK (2p23) Break

CODE	COLOR	FORMAT	STATUS
KBI-10747	Green/Red	10 test	IVD

MENU

LUNG PATHOLOGY

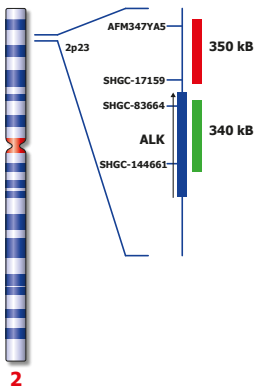
BACKGROUND

Translocations of the ALK (anaplastic lymphoma kinase) gene at 2p23 have originally been associated with anaplastic lymphomas, B-cell lymphomas, neuroblastomas and myofibroblastic tumors. At least 21 translocation partners have been described, however 80% of the translocations involves the NPM1 gene (5q35). ALK rearrangements have been described in non-small cell lung cancer (NSCLC) cases. Multiple tyrosine kinsae inhibitors (TKI's) specific for ALK have since been approved for first line treatment of NSCLC-patients carrying the fusion gene ALK-EML4. These ALK inhibitors include crizotinib (Xalkori), alectinib (Alecensa) and ceritinib (Zykadia).

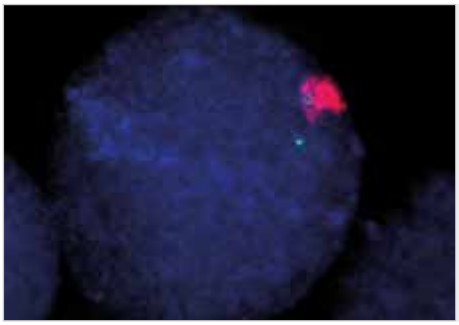
The ALK (2p23) Break probe is optimized to detect translocations involving the ALK gene region at 2p23.

REFERENCES

Soda et al, Nature, 2007, 448, 561-566.
Kwak et al, J Clin Oncol., 27(26):4247-53.
Koivunen et al, Clin Cancer Res, 2008, 14, 4275-4283.



AR / SE X



AR (Xq12) / SE X probe hybridized to VCaP prostate cancer cell showing highlevel AR gene amplification.

Image kindly provided by Prof. Trapman, Erasmus Medical Centre, Rotterdam.

AR (Xq12) / SE X

CODE	COLOR	FORMAT	STATUS
KBI-10720	Green/Red	10 test	IVD

MENU

UROPATHOLOGY

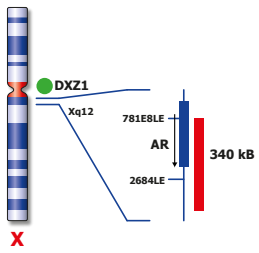
BACKGROUND

The androgen receptor (AR) gene has been identified as a target gene for the Xq12 amplification found in one-third of hormone-refractory prostate cancers. The findings suggest that AR gene amplification and overexpression is involved in the emergence of prostate cancer.

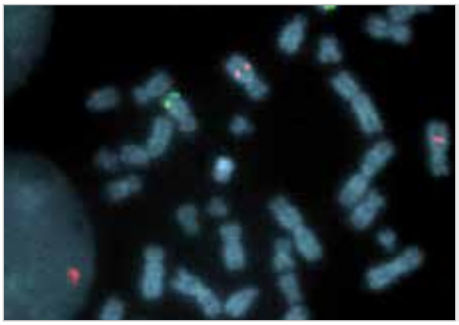
The AR (Xq12) FISH probe is optimized to detect copy numbers of the AR gene region at region Xq12. The chromosome X satellite enumeration probe (SE X) at DXZ1 is included to facilitate chromosome identification.

REFERENCES

Visakorpi T et al, 1995, Nat. Genet. 9; 401-406.
Koivisto P et al, 1997, Cancer Res. 57 ; 314-319.



ATM / GLI1



ATM (11q22) / GLI1 (12q13) hybridized to a normal metaphase (2R2G).

ATM (11q22) / GLI1 (12q13)

CODE	COLOR	FORMAT	STATUS
KBI-10108	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

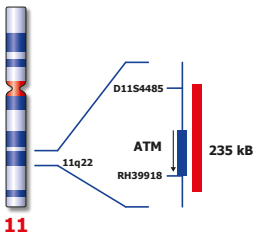
BACKGROUND

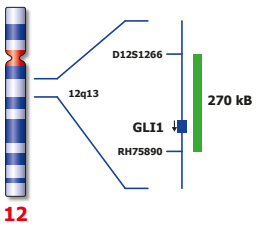
Deletion of ATM at 11q22-q23 indicates a rather poor prognosis, amplification of GLI1 (previously known as GLI) at 12q13 is associated with an intermediate prognosis. The ATM (11q22) specific FISH probe is optimized to detect copy numbers of the ATM gene region at 11q22.

The GLI1 (12q13) specific FISH probe is optimized to detect copy numbers of the GLI1 gene region at 12q13.

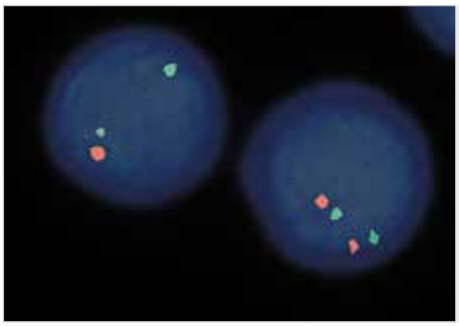
REFERENCES

Doehner H et al, 1997, Blood, 7; 2516-2522.
Boultwood J, 2001, J. Clin. Pathol., 54; 512-516.
Dierlamm J et al, 1998, Genes Chromosomes Cancer, 20; 155-166.
Doehner H at al, 1999, J. Molec. Med., 77; 266-281.





ATM / SE 11



ATM (11q22) / SE 11 hybridized to patient material showing a 11q22 deletion at the ATM gene region (1R2G).

Image kindly provided by Dr. Wenzel, Basel.

ATM (11q22) / SE 11

CODE	COLOR	FORMAT	STATUS
KBI-10103	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

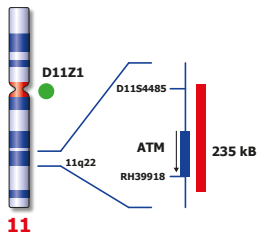
BACKGROUND

Chromosome 11q22.3-23.1 deletions involving the ataxia-teleangiectasia mutated (ATM) locus are detected at diagnosis in 15-20% of cases of B-cell chronic lymphocytic leukemia (CLL) and are associated with a relatively aggressive disease. Loss of the 11q22-23 region, where the ataxia-telangiectasia mutated (ATM) gene is located, is also one of the most frequent secondary chromosomal aberrations in mantle cell lymphoma.

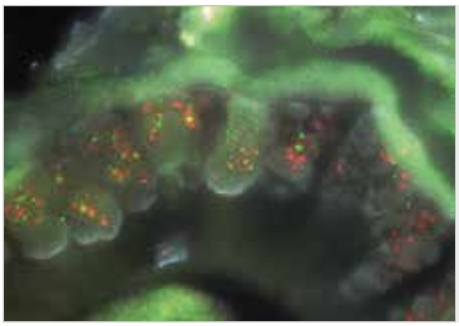
The ATM (11q22.3) specific FISH probe is optimized to detect copy numbers of the ATM gene region at region 11q22.3. The chromosome 11 Satellite Enumeration (SE 11) at D11Z1 FISH probe is included to facilitate chromosome identification.

REFERENCES

Doehner et al, 1997, Blood, 89; 2516-2522.
Bigoni et al, 1997, Leukemia, 11; 1933-1940.



AURKA



AURKA (20q13) / 20q11 probe hybridized to colorectal carcinoma material showing amplification of AURKA, gene region at 20q13.

Material kindly provided by Dr. Carvalho, Amsterdam.

AURKA (20q13) / 20q11

CODE	COLOR	FORMAT	STATUS
KBI-10721	Green/Red	10 test	IVD

MENU

UROPATHOLOGY

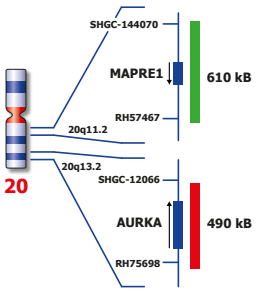
BACKGROUND

Aurora kinase A (AURKA) gene amplification has been detected in approximately 12% of primary breast tumors, as well as in bladder, ovarian, colon, prostate, neuroblastoma and cervical cancer cell lines. The AURKA (20q13) / 20q11 probe is designed to detect copy numbers of the AURKA gene region at region 20q13.

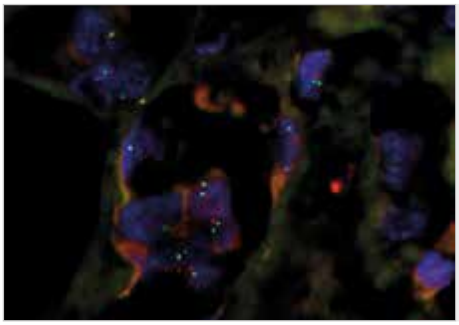
The AURKA (20q13) FISH probe is optimized to detect copy numbers of the AURKA gene region at region 20q13. The 20q11 specific DNA probe is included to facilitate chromosome identification.

REFERENCES

Uchida et al, 2010, Cancer Genet Cytogenet 203; 324-327.
Sen et al, 2002, J of Nat Canc Inst 94; 1320-1329.
Lassmann et al, 2007, Clin Cancer Res 13; 4083-4091.



AURKB



AURKB (17p13) / SE 17 probe hybridized to tumor tissue (2R2G).

AURKB (17p13) / SE 17

CODE	COLOR	FORMAT	STATUS
KBI-10722	Green/Red	10 test	IVD

MENU

TUMOR DIFFERENTIATION

BACKGROUND

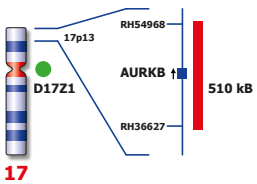
Aurora kinase B (AURKB) localizes to microtubules, and is a key regulator of the mitotic cell division and chromosome segregation processes. Gain of function of AURKB correlates with cell proliferation, induction of multinuclear cells, and chromosomal instability.

The significant interest of the gene in cancer diagnostics is related to the driving function of AURKB in tumor progression, histological differentiation, and metastasis. AURKB is predictive for the aggressive recurrence of many different types of tumors, including hepatocellular carcinoma and oral squamous cell carcinoma.

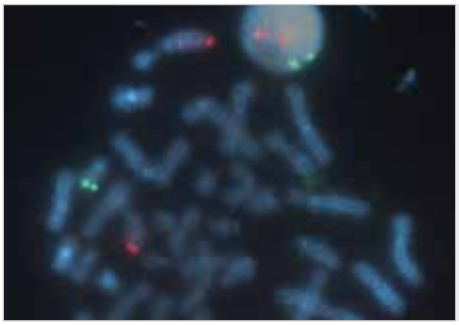
The AURKB (17p13) FISH probe is optimized to detect copy numbers of the AURKB gene region at region 17p13. The Chromosome 17 Satellite Enumeration (SE 17) probe at D17Z1 is included to facilitate chromosome identification.

REFERENCES

Smith et al, 2005, Br J Cancer, 93; 719-729.



BCL2 / IGH



BCL2 / IGH t(14;18) probe hybridized to a normal interphase/metaphase (2R2G).

BCL2 / IGH t(14;18) Fusion

CODE	COLOR	FORMAT	STATUS
KBI-10606	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

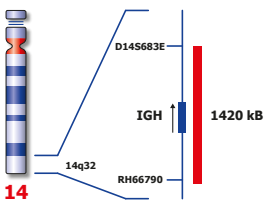
BACKGROUND

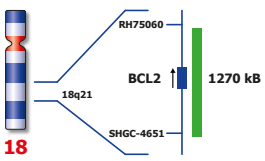
The t(14;18) chromosomal translocation is a common cytogenetic abnormality in human lymphoma and is observed in about 85% of follicular lymphoma (FL) and up to one-third of diffuse lymphomas (DL). Two breakpoint region clusters (brc) have been identified: a major breakpoint region (mbr) within the 3' untranslated region of the BCL2 proto-oncogene (approximately 60% of the cases) and a minor cluster region (mcr) 30 kb 3' of BCL2 (approximately 25%).

The BCL2 / IGH t(14;18)(q21;q32) specific FISH probe is optimized to detect the reciprocal translocation t(18;14), involving either of the two brc in the BCL2 gene in a dual-color, dual-fusion assay. Kreatech has optimized this FISH probe for the specific use on cell material (KBI-10606), or on tissue (KBI-10755).

REFERENCES

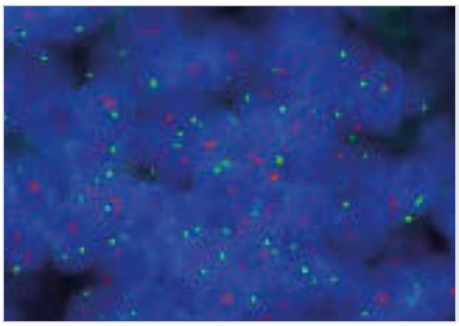
Poetsch et al, 1996, J Clin Oncol, 14; 963-969.
Vaandrager et al, 2000, Genes Chrom Cancer, 27; 85-94.





* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent

BCL2 / IGH (tissue)



BCL2/IGH t(14;20) Fusion Probe hybridized to paraffin embedded lymph node material (2R2G).

Image kindly provided by P. May, Imperial College, Hammersmith Hospital, London

BCL2 / IGH t(14;18) Fusion (tissue)

CODE	COLOR	FORMAT	STATUS
KBI-10755	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

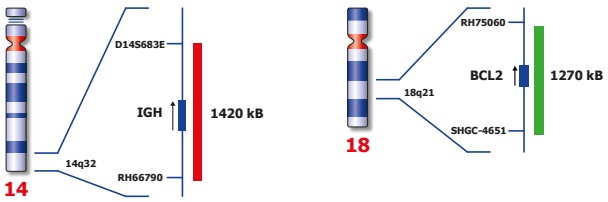
BACKGROUND

Follicular lymphoma is a mature B-Cell lymphoma, characterized by the presence of the t(14;18) translocation that juxtaposes the BCL2 locus on chromosome 18q21 to the immunoglobulin H (IGH) locus on chromosome 14q32, resulting in the overexpression of the antiapoptotic protein BCL2.

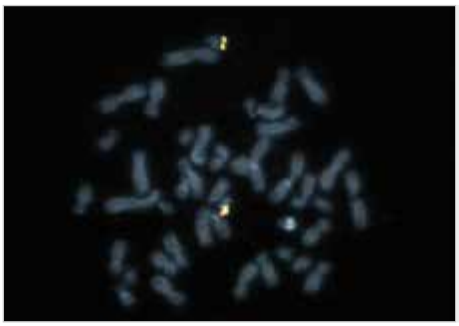
The BCL2 / IGH t(14;18) Fusion probe is optimized to detect the reciprocal translocation t(14;18) in a dual-color, dual-fusion assay on formalin fixed paraffin embedded tissue samples. In addition Kreatech has developed a probe for the specific use on cell material (KBI-10606).

REFERENCES

Taniwaki M et al, 1995, Blood, 86; 1481-1486.
Poetsch M et al, 1996, J Clin Oncol, 14; 963-969.



BCL2 Break



BCL2 (18q21) Break probe hybridized to a normal metaphase.

BCL2 (18q21) Break

CODE	COLOR	FORMAT	STATUS
KBI-10612	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

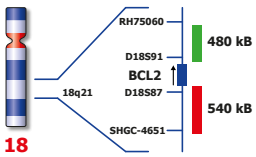
BACKGROUND

Follicular lymphoma is a mature B-cell lymphoma characterized by the presence of the t(14;18) translocation that juxtaposes the BCL2 locus on chromosome 18q21 to the immunoglobulin H (IGH) locus on chromosome 14q32, resulting in the overexpression of the anti-apoptotic protein BCL2. Next to IGH, other translocation partners to BCL2 are also known (e.g. IGK at 2p11.2 and IGL at 22q11). A break or split assay is therefore best suited to detect rearrangements of the BCL2 gene region at 18q21.

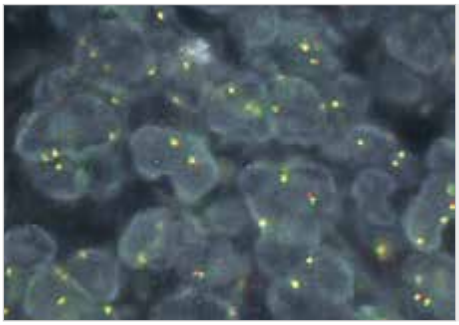
The BCL2 (18q21) Break FISH probe is optimized to detect translocations involving the BCL2 gene region at 18q21 in a dual-color, split assay on metaphase/ interphase spreads, bloodsmears and bone marrow cells.

REFERENCES

Taniwaki M et al, 1995, Blood, 86; 1481-1486.
Poetsch M et al, 1996, J Clin Oncol, 14; 963- 969.
Einerson R et al, 2005, Am J Clin Pathol, 124; 421-429.



BCL2 Break (tissue)



BCL2 (18q21) Break hybridized to paraffin embedded tissue (2RG).

BCL2 (18q21) Break (tissue)

CODE	COLOR	FORMAT	STATUS
KBI-10745	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

BACKGROUND

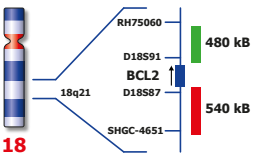
Follicular lymphoma is a mature B-cell lymphoma characterized by the presence of the t(14;18) translocation that juxtaposes the BCL2 locus on chromosome 18q21 to the immunoglobulin H (IGH) locus on chromosome 14q32, resulting in the overexpression of the anti-apoptotic protein BCL2. Besides IGH, additional translocation partners to BCL2 have been identified. A break or split assay is therefore best suited to detect rearrangements of the BCL2 gene region at 18q21.

The BCL2 (18q21) Break probe is optimized to detect translocations involving the BCL2 gene region at 18q21 in a dual-color, split assay on paraffin embedded tissue sections.

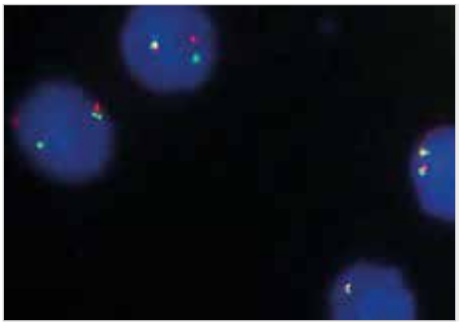
Kreatech has developed this probe for the specific use on cell material (KBI-10612), or on tissue (KBI-10745).

REFERENCES

Taniwaki M et al, 1995, Blood, 86; 1481-1486.
Poetsch M et al, 1996, J Clin Oncol, 14; 963- 969.
Einers R et al, 2005, Am J Clin Pathol, 124; 421-429.



BCL6 Break



BCL6 (3q27) Break probe hybridized to patient material (1RG1R1G).

Image kindly provided by Prof. Siebert, Kiel.

BCL6 (3q27) Break

CODE	COLOR	FORMAT	STATUS
KBI-10607	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

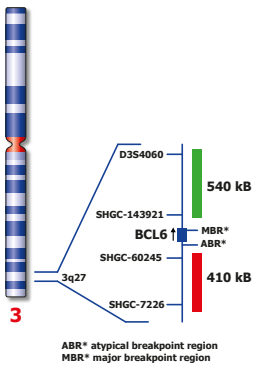
BACKGROUND

Chromosomal translocations involving band 3q27 with various different partner chromosomes represent a recurrent cytogenetic abnormality in B-cell non-Hodgkin's lymphoma. Kreatech has developed this probe for the specific use on cell material (KBI-10607), or on tissue (KBI-10730). Two different breakpoint regions have been identified; the major breakpoint region (MBR) is located within the 5' noncoding region of the BCL6 proto-oncogene, while the atypical breakpoint region (ABR) is located approximately 200 kb distal to the BCL6 gene.

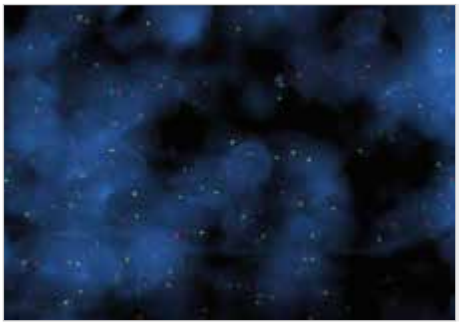
The BCL6 (3q27) Break FISH probe is designed in a way to flank both possible breakpoints, thereby providing clear split signals in either case.

REFERENCES

Butler et al, 2002, Cancer Res, 62; 4089-4094.
Sanchez-Izquierdo, 2001, Leukemia, 15; 1475-1484.



BCL6 Break (tissue)



Hybridization of BCL6 break probe to a tissue section showing aberrant pattern (1RG1R1G).

BCL6 (3q27) Break (tissue)

CODE	COLOR	FORMAT	STATUS
KBI-10730	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

BACKGROUND

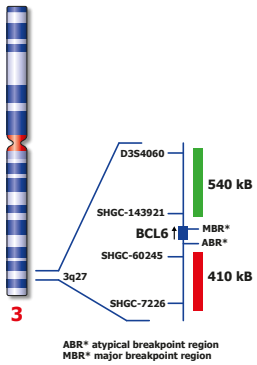
Chromosomal translocations involving band 3q27 with various different partner chromosomes represent a recurrent cytogenetic abnormality in B-cell non-Hodgkin's lymphoma. Kreatech has developed this probe for the specific use on cell material (KBI-10607), or on tissue (KBI-10730).

Two different breakpoint regions have been identified; the major breakpoint region (MBR) is located within the 5' noncoding region of the BCL6 proto-oncogene, while the atypical breakpoint region (ABR) is located approximately 200 kb distal to the BCL6 gene. The BCL6 (3q27) Break probe is designed to flank both possible breakpoints, thereby providing clear split signals.

The BCL6 (3q27) Break probe is optimized to detect translocations involving the BCL6 gene region at 3q27 in a dual-color, split assay on paraffin-embedded tissue sections.

REFERENCES

Butler et al, 2002, Cancer Res, 62; 4089-4094.
Sanchez-Izquierdo, 2001, Leukemia, 15; 1475-1484.



BCR / ABL1

BCR / ABL1 t(9;22) Fusion probe hybridized on patient material showing t(9;22) (q34;q11) reciprocal translocation (2RG1R1G).

Image kindly provided by Monika Conchon, São Paulo.

BCR / ABL1 t(9;22) Fusion

CODE	COLOR	FORMAT	STATUS
KBI-10005	Green/Red	10 test	IVD
KBI-12005	Green/Red	20 test	IVD

MENU

HEMATOPATHOLOGY

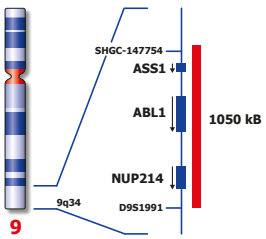
BACKGROUND

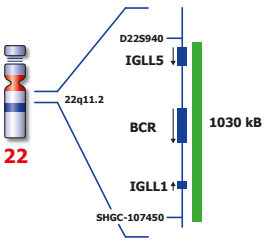
The BCR / ABL1 t(9;22) Fusion FISH probe is optimized to detect the t(9;22) (q34;q11) reciprocal translocation in a dual-color, dual-fusion assay on metaphase/ interphase spreads, blood smears and bone marrow cells.

This probe will also detect cryptic insertions of ABL1 (previously known as ABL) into the BCR region not detectable by karyotyping and therefore described as Ph-negative.

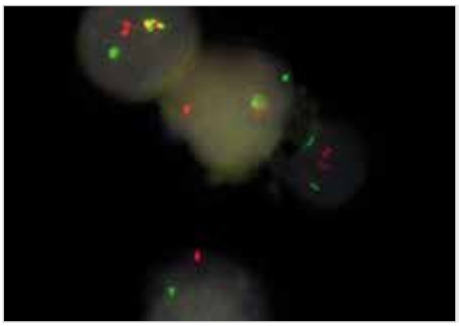
REFERENCES

Morris et al, 1990, Blood, 76; 1812-1818.
Dewald et al, 1998, Blood, 91; 3357-3365.
Kolomietz et al, 2001, Blood, 97; 3581-3588.
Huntly et al, 2003, Blood, 102; 1160-1168.
Tkachuk et al., 1990, Science, 250; 559-562.





BCR / ABL1 DC



BCR / ABL1 t(9;22), Dual-Color, Single-Fusion probe hybridized to patient material showing t(9;22) translocation (1RG1R1G).

Material kindly provided by Dr. Balogh, Budapest.

BCR / ABL1 t(9;22) Dual-Color, Single-Fusion

CODE	COLOR	FORMAT	STATUS
KBI-10009	Green/Red	10 test	IVD

MENU

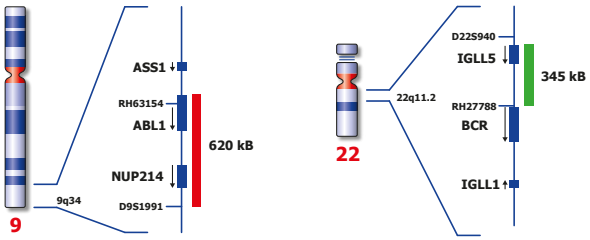
HEMATOPATHOLOGY

BACKGROUND

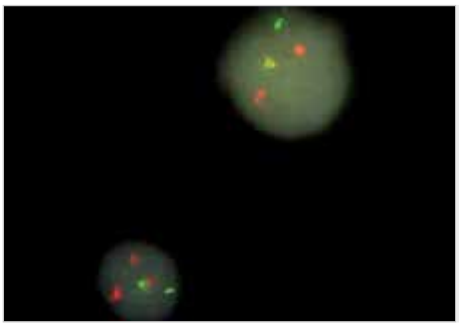
A simple dual-color, single-fusion assay is preferably used for the initial screening of CML and ALL patients. The Philadelphia chromosome, der(22q), is visualized by a fusion signal while the der(9q) shows no signal. The BCR / ABL1 t(9;22) FISH probe is optimized to detect the t(9;22)(q34;q11) reciprocal translocation in a dual-color, single-fusion assay on metaphase/interphase spreads, blood smears and bone marrow cells.

REFERENCES

Morris et al, 1990, Blood, 76; 1812-1818.
Dewald et al, 1998, Blood, 91; 3357-3365.
Kolomietz et al, 2001, Blood, 97; 3581-3588.
Huntly et al, 2003, Blood, 102; 1160-1168.
Tkachuk et al., 1990, Science, 250; 559-562.



BCR / ABL1 DC ES



BCR / ABL1 t(9;22), Dual-Color, Single-Fusion probe hybridized to patient material showing t(9;22) translocation (1RG1R1G).

Material kindly provided by Dr. Balogh, Budapest.

BCR / ABL1 t(9;22) Dual-Color, Single-Fusion, Extra Signal

CODE	COLOR	FORMAT	STATUS
KBI-10008	Green/Red	10 test	IVD

MENU

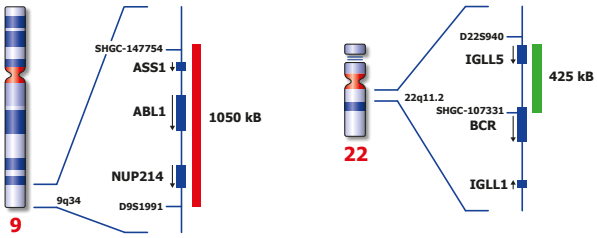
HEMATOPATHOLOGY

BACKGROUND

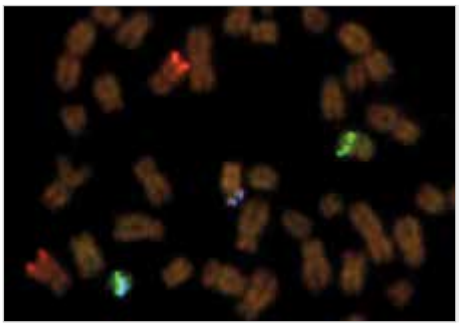
A simple dual-color, single-fusion assay is preferably used for the initial screening of CML and ALL patients. The Philadelphia chromosome, der(22q), is visualized by a fusion signal while the der(9q) shows no signal. The BCR / ABL1 t(9;22) FISH probe is optimized to detect the t(9;22)(q34;q11) reciprocal translocation in a dual-color, single-fusion, extra-signal assay on metaphase/interphase spreads, blood smears and bone marrow cells.

REFERENCES

Morris et al, 1990, Blood, 76; 1812-1818.
Dewald et al, 1998, Blood, 91; 3357-3365.
Kolomietz et al, 2001, Blood, 97; 3581-3588.
Huntly et al, 2003, Blood, 102; 1160-1168.
Tkachuk et al., 1990, Science, 250; 559-562.



BCR / ABL1 TC



BCR / ABL1 t(9;22),Triple-Color, Dual Fusion probe hybridized on patient material showing translocation of distal BCR (1BG1RB1R1G).

Image kindly provided by Prof. Siebert, Kiel.

BCR / ABL1 t(9;22) Triple-Color, Dual-Fusion

CODE	COLOR	FORMAT	STATUS
KBI-10006	Green/Red/Blue	10 test	IVD

MENU

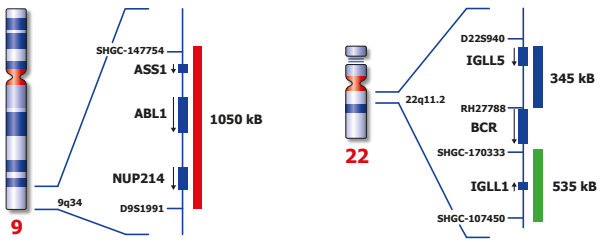
HEMATOPATHOLOGY

BACKGROUND

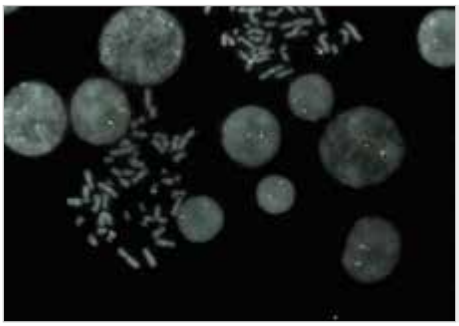
The BCR / ABL1 t(9;22) FISH probe is a triple-color, dual-fusion probe built from the same regions as the dual-color, dual-fusion probe, but the proximal BCR region is labeled in blue. Using the triple-color probe allows to distinguish between the derivative chromosome 22, the Philadelphia chromosome, which will be observed as purple (red/blue) color, while the derivative chromosome 9 will show a yellow (red/green) signal.

REFERENCES

Morris et al, 1990, Blood, 76; 1812-1818.
Dewald et al, 1998, Blood, 91; 3357-3365.
Kolomietz et al, 2001, Blood, 97; 3581-3588.
Huntly et al, 2003, Blood, 102; 1160-1168.
Tkachuk et al., 1990, Science, 250; 559-562.



CBFB Break



Hybridization of CBFB break probe to a metaphase spread showing normal pattern (2RG).

CBFB t(16;16), inv(16) Break

CODE	COLOR	FORMAT	STATUS
KBI-10304	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

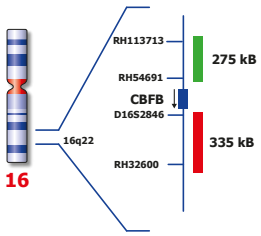
BACKGROUND

Inv(16)(p13;q22) and t(16;16)(p13;q22) are recurring chromosomal rearrangements in AML. In both the inversion and translocation, the critical genetic event is the fusion of the CBFB gene at 16q22 to the smooth muscle myosin heavy chain (MYH11) at 16p13. A deletion of between 150 and 350 kb centromeric to the p-arm inversion breakpoint cluster region can be observed in some patients containing the 5' portion of the myosin heavy chain (MYH11) gene.

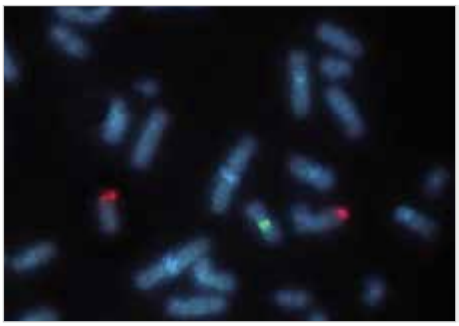
The CBFB t(16;16) inv(16) break FISH probe is optimized to detect the inversion of chromosome 16 involving the CBFB gene region at 16q22 in a dual-color, split assay.

REFERENCES

Dauwerse et al, 1993, Hum.Mol.Genet., 2; 1527-1534.
Marlton et al, 1995, Blood, 85; 772-779.



CCND1 / IGH Fusion



CCND1 / IGH t(11;14) Fusion probe hybridized to a normal interphase/metaphase (2R2G).

CCND1 / IGH t(11;14) Fusion

CODE	COLOR	FORMAT	STATUS
KBI-10604	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

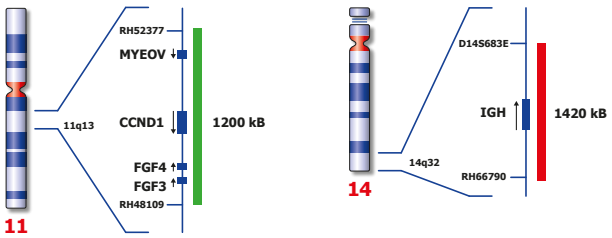
BACKGROUND

Mantle cell lymphoma is a subtype of non-Hodgkin lymphoma characterized by poor prognosis. Cytogenetically t(11;14) is associated with 75% of mantle cells lymphomas. The translocation breakpoints are scattered within the 120 kb region adjacent to CCND1 (previously known as BCL1). The translocation leads to overexpression of cyclin D1 due to juxtaposition of the Ig heavy chain gene enhancer on 14q32 to the cyclin D1 gene on 11q13.

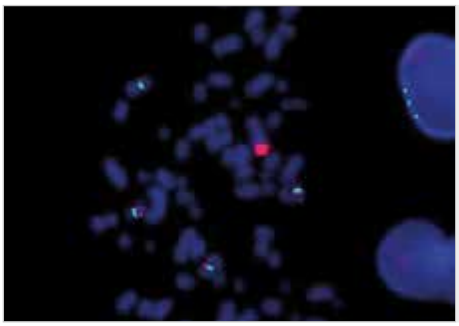
The CCND1 / IGH t(11;14)(q13;q32) specific FISH probe is optimized to detect the reciprocal translocation t(11;14) in a dual-color, dual-fusion assay.

REFERENCES

Vaandrager et al, 1996, Blood, 88; 1177-1182.



CCND1 /SE 11



CCDN1 (11q13) / SE 11 probe hybridized to patient interphases / metaphase showing CCDN1 (11q13) amplification with polyploidy for chromosome 11.

CCND1 (11q13) / SE 11

CODE	COLOR	FORMAT	STATUS
KBI-10734	Green/Red	10 test	IVD

MENU

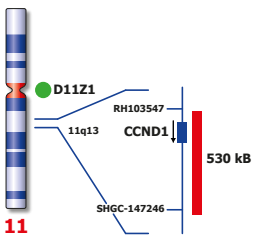
TUMOR DIFFERENTIATION

BACKGROUND

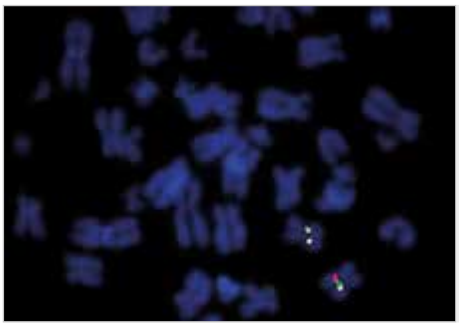
The binding of cyclin D1 (also named CCND1 or BCL1) to cyclin-dependent kinases (CDKs) leads to the phosphorylation of retinoblastoma protein (pRb), subsequently triggering the release of E2F transcription factors to allow G1 to S phase progression of the cell cycle. Consistent with this function, overexpression of cyclin D1 results in a more rapid progression from the G1 to S phase transition and in a reduced serum dependency in fibroblast cells, characteristics typically seen in cancer cells. The CCND1 (11q13) FISH probe is optimized to detect copy numbers of the CCND1 gene region at region 11q13. The Chromosome 11 Satellite Enumeration (SE 11) probe at D11Z1 is included to facilitate chromosome identification.

REFERENCES

Okami et al, 1999, Oncogene 18; 3541-3645.
Freier et al, 2003, Cancer Res; 1179-1182.



CCND1 Break



CCND1 (11q13) Break probe hybridized to a normal metaphase (2R2G).

CCND1 (11q13) Break

CODE	COLOR	FORMAT	STATUS
KBI-10609	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

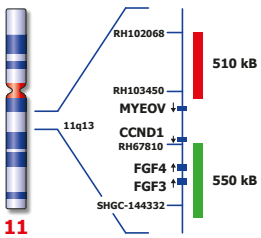
BACKGROUND

Overexpression of the Cyclin D1 gene caused by amplification or translocation is described for several types of cancer. A t(11;14) is the main characteristic aberration in mantle cell lymphoma (documented in 40-70% of the cases. In MM, the same translocation t(11;14)(q13:q32) is the most common, with a reported frequency of 15% to 20% of the cases.

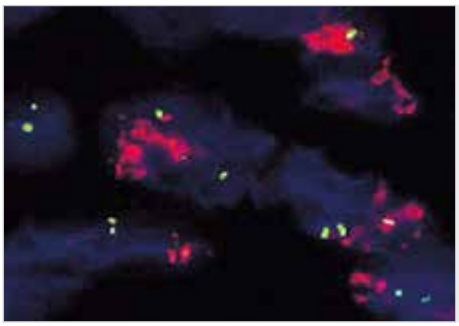
Kreatech has developed this probe to detect rearrangements of the CCND1 gene region at 11q13 (KBI-10609) or for the translocation t(11;14) in Mantle Cell Lymphoma (KBI-10604) and for MM (KBI-10605). The CCND1 (11q13) Break FISH probe is optimized to detect translocations involving the CCND1 gene region at 11q13 in a dual-color, split assay on metaphase/interphase spreads.

REFERENCES

Vaandrager et al, 1996, Blood, 88; 1177-1182.
Vaandrager et al, Blood, 89; 349-350.



CDK4 / SE 12



CDK4 (12q13) / SE 12 probe hybridized to liposarcoma tissue showing multiple amplification involving the CDK4 gene region at 12q13 (3+R2G).

Image kindly provided by Dr. Sapi, Hungary.

CDK4 (12q13) / SE 12

CODE	COLOR	FORMAT	STATUS
KBI-10725	Green/Red	10 test	IVD

MENU

SOFT TISSUE PATHOLOGY

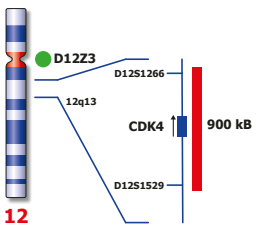
BACKGROUND

Amplification of the CDK4 gene region at 12q13-q15 has been observed in several types of cancer, especially in gliomas and sarcomas. CDK4 codes for a cyclin dependent kinase which is involved in controlling progression through the G1 phase of the cell cycle. The oncogenic potential of CDK4 activation has been related to the deregulation of the G1 phase by increasing the hyperphosphorylation of retinoblastoma tumor suppressor protein helping to cancel its growth-inhibitory effects.

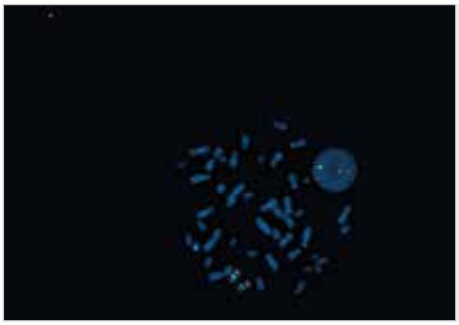
The CDK4 (12q13) FISH probe is optimized to detect copy numbers of the CDK4 gene region at 12q13. The chromosome 12 satellite enumeration probe (SE 12) at D12Z3 is included to facilitate chromosome identification.

REFERENCES

Kuhnen et al, 2002, Virchows Arch 441 ; 299-302.
Shimada et al, 2006, Hum Path 37(9) ; 1123-1129.



CDKN2A / 9q21



CDKN2A (9p21) / 9q21 hybridized to a metaphase spread showing a normal pattern (2R2G).

CDKN2A (9p21) / 9q21

CODE	COLOR	FORMAT	STATUS
KBI-10402	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

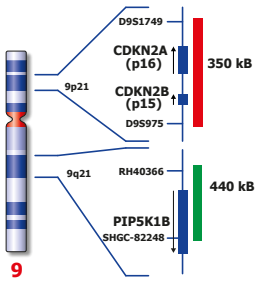
BACKGROUND

Hemizygous deletions and rearrangements of chromosome 9, band p21 are among the most frequent cytogenetic abnormalities detected in pediatric acute lymphoblastic leukemia (ALL). This deletion includes loss of the CDKN2A (previously known as p16, INK4A or MTS1) / CDKN2B (previously known as p15, INK4B or MTS2) genes, which are cell cycle kinase inhibitors and important in leukemogenesis.

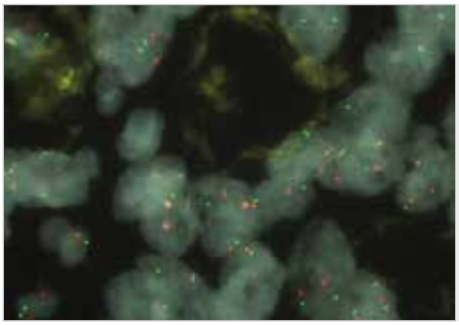
The CDKN2A (9p21) specific FISH probe is optimized to detect copy numbers of the CDKN2A gene region at region 9p21. The 9q21 region probe is included to facilitate chromosome identification.

REFERENCES

Dreyling et al, 1995, Blood, 86; 1931-1938.
Southgate et al, 1995, Br J Cancer, 72; 1214-1218.



CDKN2A / 9q21 (tissue)



CDKN2A (9p21) / 9q21 (tissue) probe hybridized to tissue (2R2G).

CDKN2A (9p21) / 9q21 (tissue)

CODE	COLOR	FORMAT	STATUS
KBI-10710	Green/Red	10 test	IVD

MENU

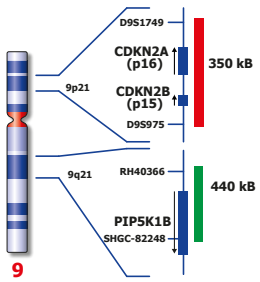
UROPATHOLOGY

BACKGROUND

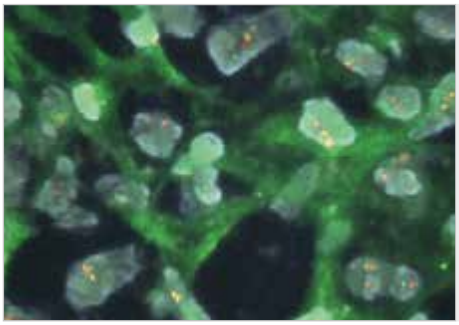
Homozygous and hemizygous deletions of 9p21 are the earliest and most common genetic alteration in bladder cancer. The CDKN2A (INK4A) gene has been identified as tumor suppressor gene in this region which is commonly deleted in bladder cancer. The loss of DNA sequences on chromosomal bands 9p21-22 has been documented also in a variety of malignancies including leukemias, gliomas, lung cancers, and melanomas. The CDKN2A (9p21) FISH probe is optimized to detect copy numbers of the CDKN2A gene region at region 9p21. The 9q21 region probe is included to facilitate chromosome identification.

REFERENCES

Stadler et al, 1994, Cancer Res, 54:2260-2063.
Williams et al, 1995, Hum Mol Genet; 4: 1569-1577.



COL1A1 / PDGFB



Interphase FISH result of COL1A1/PDGFB Fusion probe hybridized to dermatofibrosarcoma protuberans tumor tissue, showing co-localization and amplification of the fusion gene.

COL1A1 / PDGFB t(17;22) Dual-Color, Single-Fusion

CODE	COLOR	FORMAT	STATUS
KBI-10742	Green/Red	10 test	IVD

MENU

SOFT TISSUE PATHOLOGY

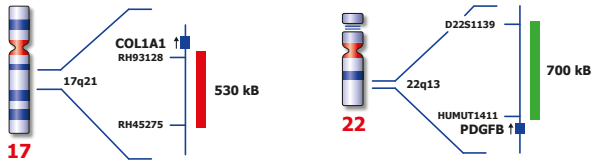
BACKGROUND

The diagnosis of primary soft tissue and bone tumors is often challenging as they are relatively rare. The misdiagnosis between dermatofibroma (DF) and dermatofibrosarcoma protuberans (DFSP) or giant cell fibroblastoma (GCF) might result in incorrect primary management. DFSP and GCF have in most cases diagnosed today a translocation involving the COL1A1 (collagen, type I, alpha 1) gene at 17q21 and the PDGFB (platelet-derived growth factor beta polypeptide) gene at 22q13. Also, a supernumerary ring chromosome derived from the translocation t(17;22) can be present.

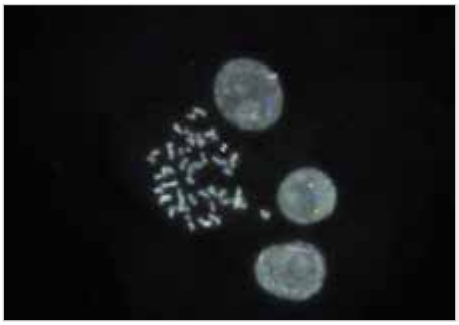
The COL1A1 / PDGFB t(17;22) Dual-Color Single-Fusion probe is optimized to detect the t(17;22)(q21;q13) involving the COL1A1 (17q21) and PDGFB (22q13) gene regions in dual-color, single-fusion assay on paraffin embedded tissue sections.

REFERENCES

Maire et al, 2007, Arch Dermatol, 143; 203-210.
Labropoulos et al, 2007, Biologics, 1; 347-353.
Patel et al, 2008, Hum Path, 39; 184-193.
Sandberg, 2003, Cancer Genet Cytogenet, 140; 1-12.



CRLF2 / IGH



Hybridization of CRLF2 break / IGH fusion probe to a metaphase spread showing normal pattern (2RG2B).

CRLF2 (Xp22 / Yp11) Break / IGH (14q32) Fusion, Triple-Color

CODE	COLOR	FORMAT	STATUS
KBI-10406	Green/Red/Blue	10 test	IVD

MENU

HEMATOPATHOLOGY

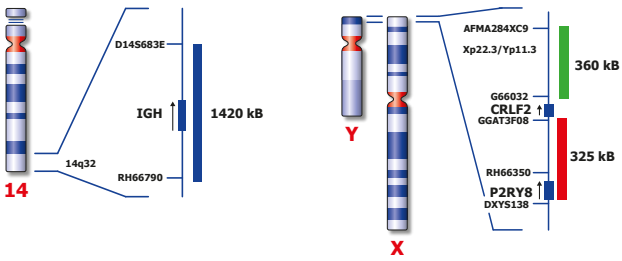
BACKGROUND

CRLF2-IGH fusions between Xp22-14q32 or Yp11-14q32 results in a deregulated expression of the cytokine receptor gene (CRLF2). This can also be the result of the fusion with the P2RY8 promoter on Xp22 or Yp11.

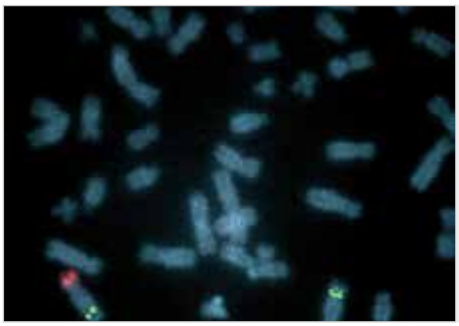
Gain of chromosome X has been observed in Down syndrome-associated ALL. The CRLF2 (Xp22 / Yp11) Break / IGH (14q32) Fusion Triple-Color FISH probe is optimized to detect translocations involving the CRLF2 gene at region Xp22 and Yp11. The probe shows a break between red and green in case of a translocation with CRLF2 and IGH involvement. In case of a fusion with the P2RY8 gene on Xp22 or Yp11, one red probe is deleted. For fusion confirmation to the IGH gene, a blue probe covering IGH is added.

REFERENCES

Mullighan et al., 2009, Nat. Genet. 41(11): 1243-1246.
Russell et al., 2009, Blood, 114(13): 2688-2698.



CTNND2



Cri-Du-Chat CTNND2 (5p15) / 5q31 probe hybridized to a normal metaphase 2RG).

Cri-Du-Chat CTNND2 (5p15) / 5q31

CODE	COLOR	FORMAT	STATUS
KBI-40106	Green/Red	10 test	IVD
KBI-45106	Green/Red	5 test	IVD

MENU

POSTNATAL

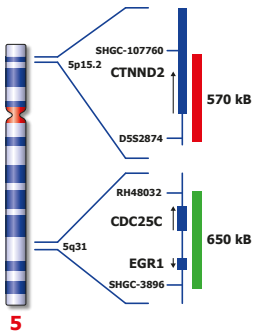
BACKGROUND

Cri-Du-Chat syndrome is an autosomal deletion syndrome caused by a partial deletion of chromosome 5p. It is characterized by a distinctive, high-pitched, catlike cry in infancy with growth failure, microcephaly, facial abnormalities, and mental retardation throughout life. Loss of a small region in band 5p15.2 (Cri-Du-Chat critical region) correlates with all the clinical features of the syndrome with the exception of the catlike cry, which maps to band 5p15.3 (catlike cry critical region).

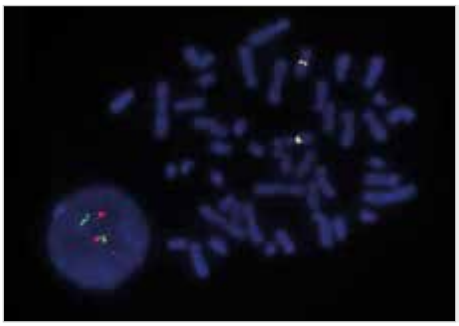
The Cri-Du-Chat region probe is optimized to detect copy numbers at the CTNND2 gene region in the Cri-Du-Chat critical region at 5p15.2. The 5q31 specific FISH probe is included as control probe.

REFERENCES

Overhauser et al, 1994, Hum. Mol. Genet., 3; 247-252.
Gersh et al, 1997, Cytogenet Cell Genet., 77; 246-251.



DDIT3 Break



DDIT3 (12q13) Break probe hybridized to a normal metaphase (2RG).

DDIT3 (12q13) Break

CODE	COLOR	FORMAT	STATUS
KBI-10714	Green/Red	10 test	IVD

MENU

SOFT TISSUE PATHOLOGY

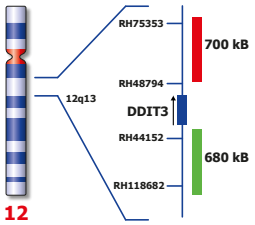
BACKGROUND

Liposarcoma is one of the most frequent sarcomas in adults, representing 10 to 16 percent of soft tissue sarcomas. Most patients with round cell/myxoid liposarcoma have an acquired t(12;16)(DDIT3-FUS) or t(12;22)(DDIT3-EWS) translocation, both of which involve the DDIT3 gene at 12q13. A break or split probe for DDIT3 is best used to analyze translocation of the DDIT3 (12q13) gene on formalin fixed paraffin embedded tissue for routine clinical diagnosis.

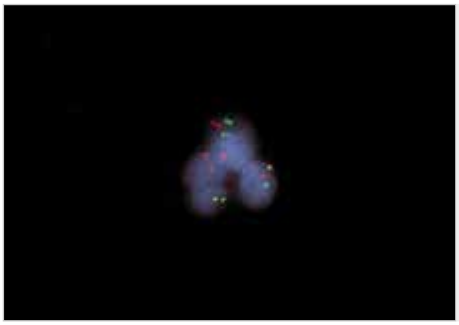
The DDIT3 (12q13) Break probe is optimized to detect translocations involving the DDIT3 gene region at 12q13 in a dual-color, break assay.

REFERENCES

Panagopoulos et al, 1994, Cancer Res, 54; 6500-6503.
Schoenmakers et al, 1994, Genomics, 20; 210-222.



DEK / NUP214



Hybridization of DEK/ NUP214 Fusion Probe to a positive cell line showing a fusion due to t(6;9).

DEK / NUP214 t(6;9) Fusion

CODE	COLOR	FORMAT	STATUS
KBI-10306	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

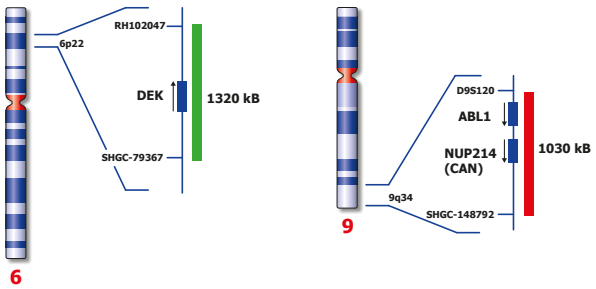
BACKGROUND

The chromosomal translocation t(6;9) (p22;q34) is associated with a specific subtype of acute myeloid leukemia (AML) and constitutes 0.5% to 4% of all AML cases. The translocation results in a fusion between the DEK oncogene (6p22) and the nucleoporin 214 kDa (NUP214 at 9q34; previously known as CAN). The exact mechanism by which the fusion protein DEK-NUP214 contributes to leukemia development has not been identified. Patients with t(6;9) AML have a very poor prognosis.

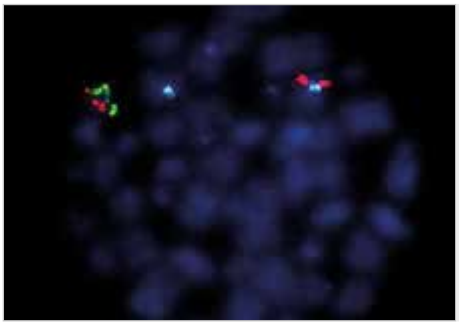
The DEK / NUP214 t(6;9) specific FISH probe has been optimized to detect the reciprocal translocation t(6;9) in a dual-color, dual-fusion assay on metaphase/ interphase spreads, blood smears and bone marrow cells.

REFERENCES

Von Lindern et al, 1992, Mol. Cell. Biol.,12; 1687-1697.
Ageberg et al, 2008, Gen. Chrom. Canc., 47; 276-287.
Chi et al, 2008, Arch. Pathol. Lab. Med., 132; 1835-1837.



dic(9;20)



dic(9;20) Triple-Color.

Image kindly provided by Dr. Ann Nordgren, Stockholm.

dic(9;20) Triple-Color

CODE	COLOR	FORMAT	STATUS
KBI-10405	Green/Red/Blue	10 test	IVD

MENU

HEMATOPATHOLOGY

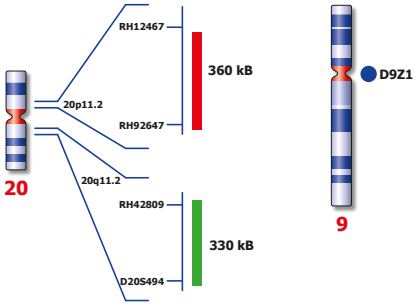
BACKGROUND

The dic(9;20)(p13.2;q11.2) is a recurrent chromosomal abnormality in pediatric Bcell precursor acute lymphoblastic leukemia (BCP-ALL), which occurs in ~2% of the cases. It is associated with an intermediate outcome with relapses being relatively frequent, compared to other common cytogenetic subgroups of BCP-ALL (e.g. high hyperploidy and t(12;21)). The dic(9;20) is an unbalanced rearrangement involving chromosomes 9 and 20, resulting in the co-localisation of the respective centromeres and concomitant loss of the chromosome arms 9p and 20q.

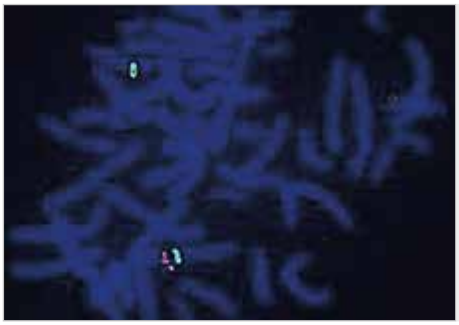
The dic(9;20) Triple-Color FISH probe is optimized to detect the dicentric (9;20) (p13.2;q11.2) in a triple-color assay on metaphase/interphase spreads, blood smears and bone marrow cells.

REFERENCES

Forestier et al., Genes Chromosome Cancer, 2008, 47; 149-158.
Pichler H et al., Br J Haematol, 2010, 149; 93-100.
Schmiegelow K et al., Leukemia, 2010, 24; 345-54.
Zachariadis V et al., Leukemia, 2011, 25; 22-628.
Zachariadis V et al., Br J Haematol, 2012, 159; 488-491.



DiGeorge II / SE 10



DiGeorge II(10p14) / SE 10 probe hybridized to DiGeorge II patient material showing a deletion of the DGSII region at 10p14 (1R2G).

Image kindly provided by Azzedine Aboura, Hôpital Robert Debré Paris.

DiGeorge II (10p14) / SE 10

CODE	COLOR	FORMAT	STATUS
KBI-40105	Green/Red	10 test	IVD
KBI-45105	Green/Red	5 test	IVD

MENU

POSTNATAL

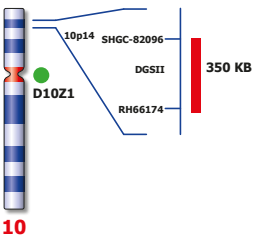
BACKGROUND

DiGeorge and VCFS present many clinical problems and are frequently associated with deletions within 22q11.2, but a number of cases have no detectable molecular defect of this region. A number of single case reports with deletions of 10p suggest genetic heterogeneity of DiGeorge syndrome. FISH analysis demonstrates that these patients have overlapping deletions at the 10p13 / 10p14 boundary. The shortest region of deletion overlap (SRO) has been identified in a 1 cM interval including makers D10S547 and D10S585.

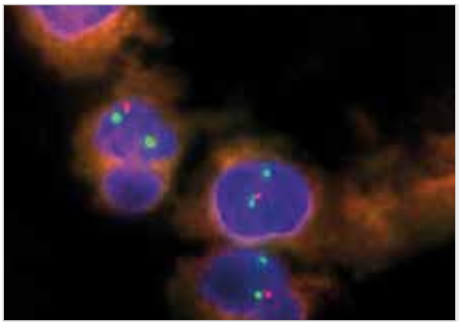
The DiGeorge II region probe is optimized to detect copy numbers of the DGSII at 10p14. The chromosome 10 satellite enumeration (SE 10) FISH probe at D10Z1 is included to facilitate chromosome identification.

REFERENCES

Monaco et al, 1991, Am. J. Med. Genet., 39; 215-216.
Schuffenhauer et al, 1998, Eur. J. Hum. Genet., 6; 213-225.



DLEU1 / 13qter



DLEU1 (13q14) / 13qter probe hybridized to patient material showing a 13q14 deletion (1R2G).

Image kindly provided by Dr. Dastugue, Toulouse.

DLEU1 (13q14) / 13qter

CODE	COLOR	FORMAT	STATUS
KBI-10102	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

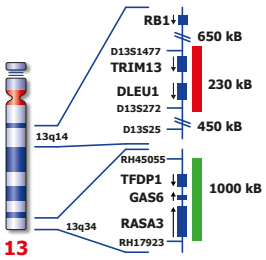
BACKGROUND

Deletions of chromosome 13q14 have been reported not only in CLL but in a variety of human tumors, including other types of lymphoid and myeloid tumors, as well as prostate, head and neck, and non-small cell lung cancers. The deletion of 13q may be limited to a single locus (13q14), or accompanied with the loss of a larger interstitial region of the long arm of chromosome 13. A minimal critical region of 400 kb has been described containing the DLEU1, DLEU2 and RFP2 genes.

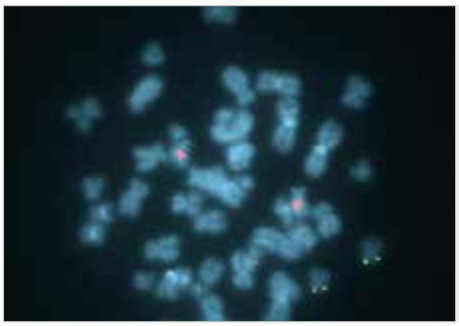
The DLEU1 (13q14) specific FISH probe is optimized to detect copy numbers of the DLEU1 (previously known as DLEU) gene region at 13q14. The 13qter (13q34) region is included to facilitate chromosome identification.

REFERENCES

Wolf et al, 2001, Hum Mol Genet, 10; 1275-1285.
Corcoran et al, 1998, Blood, 91; 1382-1390.



DLEU1 / TP53



DLEU1 (13q14) / TP53 (17p13) hybridized to a normal metaphase (2R2G).

DLEU1 (13q14) / TP53 (17p13)

CODE	COLOR	FORMAT	STATUS
KBI-10113	Green/Red	10 test	IVD

MENU

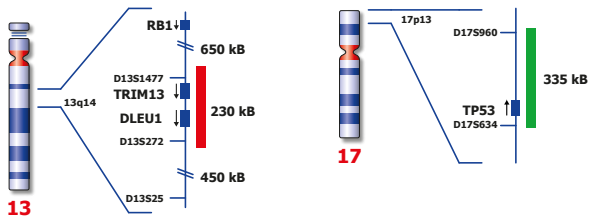
HEMATOPATHOLOGY

BACKGROUND

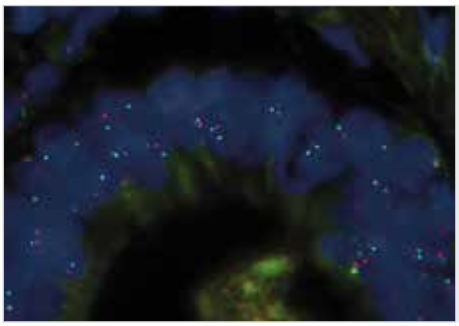
Deletion of DLEU1 (previously known as DLEU) at 13q14 indicates a rather good prognosis, deletion of TP53 (previously known as p53) at 17p13 is associated with poor prognosis. The DLEU1 (13q14) specific FISH probe is optimized to detect copy numbers at the DLEU1 gene region at 13q14. The TP53 (17p13) specific FISH probe is optimized to detect copy numbers of the TP53 gene region at 17p13

REFERENCES

Amiel A et al, 1997, Cancer Gener.Cytogenet, 97; 97-100.
Drach J et al, 1998, Blood, 92; 802-809.
Stilgenbauer S et al, 1998, Oncogene, 16; 1891 - 1897.
Wolf S et al, 2001, Hum. Molec. Genet., 10; 1275-1285.



EGFR / SE 7



EGFR (7p11) / SE 7 hybridized to colon tissue (2R2G).

EGFR (7p11) / SE 7

CODE	COLOR	FORMAT	STATUS
KBI-10702	Green/Red	10 test	IVD

MENU

LUNG PATHOLOGY

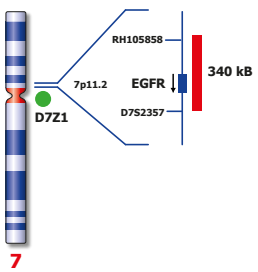
BACKGROUND

Epidermal growth factor receptor (EGFR) is a cell membrane protein, providing signal transduction and cell growth. It is a member of the Erb-B family of type I receptor tyrosine kinases and implicated in the development and progression of non-small cell lung carcinomas (NSCLC), breast, intestine, and other organs. EGFR has been found to act as a strong prognostic indicator in head and neck, ovarian, cervical, bladder and oesophageal cancers. In these cancers, increased EGFR expression was associated with reduced recurrence-free or overall survival.

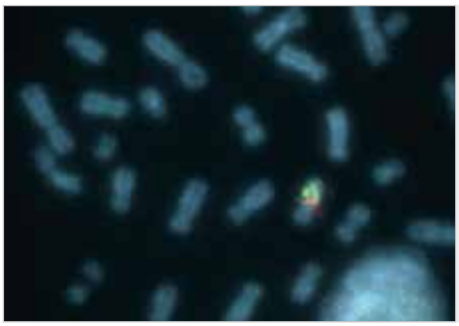
The EGFR (7p11) FISH probe is optimized to detect copy numbers of the EGFR gene region at region 7p11. The chromosome 7 satellite enumeration (SE 7) probe at D7Z1 is included to facilitate chromosome identification.

REFERENCES

Wang et al, 1993, Jpn J Hum Genet, 38: 399-406.
Nicholoset al, 2001, Eur J Cancer, 37: 9-15.



ELN / 7q22



Williams-Beuren ELN (7q11) / 7q22 probe hybridized to a normal metaphase (2RG).

Williams-Beuren ELN (7q11) / 7q22

CODE	COLOR	FORMAT	STATUS
KBI-40111	Green/Red	10 test	IVD
KBI-45111	Green/Red	5 test	IVD

MENU

POSTNATAL

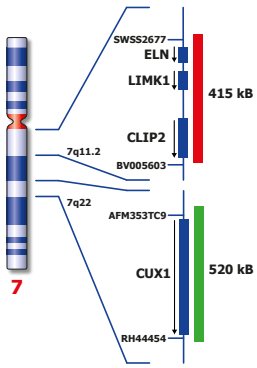
BACKGROUND

Williams-Beuren syndrome (WS) is characterized by cardiovascular disease, distinctive facial features, connective tissue abnormalities, mental retardation and endocrine abnormalities. Over 99% of individuals with the clinical diagnosis of WS have this contiguous gene deletion, that encompasses the elastin (ELN) gene region including ELN, LIMK1, and the D7S613 locus.

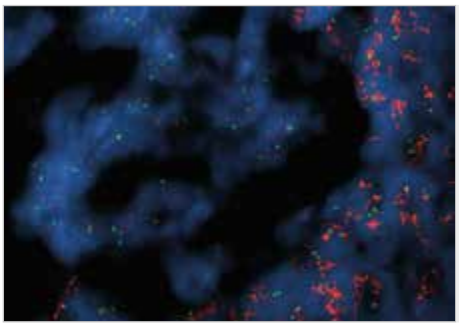
The Williams-Beuren region probe is optimized to detect copy numbers of the ELN gene region at 7q11. The 7q22 region specific FISH probe at 7q22 is included as control probe.

REFERENCES

Ewart, et al, 1993, Nat. Genet., 5; 11-16.
Botta et al, 1999, J. Med. Genet., 36; 478-480.



ERBB2 / SE 17



ERBB2 (17q12) / SE 17 probe hybridized to breast tumor tissue showing amplification of ERBB2 / SE 17.

ERBB2 (17q12) / SE 17

CODE	COLOR	FORMAT	STATUS
KBI-10701	Green/Red	10 test	IVD
KBI-14701	Green/Red	50 test	IVD

MENU

BREAST PATHOLOGY

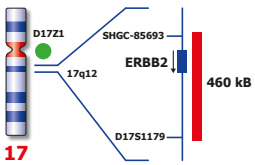
BACKGROUND

The ERBB2 (or HER2) gene encodes a receptor tyrosine kinase involved in growth factor signaling. Overexpression of this gene is seen in about 20% of invasive breast cancers. ERBB2 gene amplification is a permanent genetic change that results in this continuous overexpression of ERBB2. Trastuzumab (commonly known as Herceptin) has been developed to be effective against ERBB2-positive breast cancer. ERBB2 amplification is also observed in a variety of other tumors, such as gastric, prostate, lung, colon and ovary carcinoma.

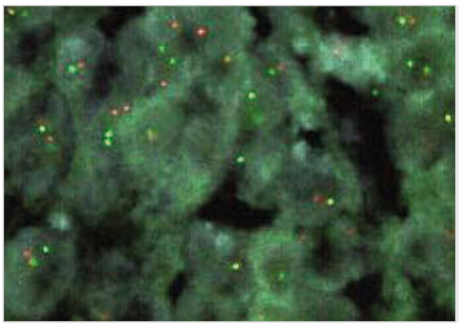
The ERBB2 (17q12) FISH probe is optimized to detect copy numbers of the ERBB2 gene region at region 17q12. The chromosome 17 satellite enumeration probe (SE 17) at D17Z1 is included to facilitate chromosome identification/enumeration.

REFERENCES

Pauletti et al, 1996, Oncogene, 13: 63-72.
Xing et al, 1996, Breast Cancer Res Treat, 39: 203-212.



ERCC1 / ZNF443



ERCC1 (19q13) / ZNF443 (19p13) probe hybridized to paraffin embedded tissue (2R2G).

ERCC1 (19q13) / ZNF443 (19p13)

CODE	COLOR	FORMAT	STATUS
KBI-10739	Green/Red	10 test	IVD

MENU

LUNG PATHOLOGY

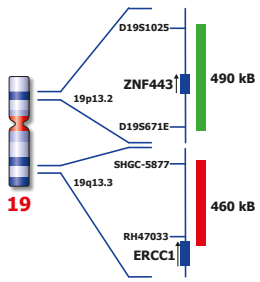
BACKGROUND

Excision repair cross-complementing rodent repair deficiency, complementation group 1 (ERCC1) is a critical gene in the Nucleotide excision repair pathway. A growing list of reports links cisplatin, carboplatin, and oxaliplatin based chemotherapy resistance to ERCC1 expression levels in several tumors. ERCC1 has been shown to be an important marker to predict responsiveness to cisplatin-based chemotherapy. Low ERCC1 gene expression correlates with prolonged survival after cisplatin-based chemotherapy.

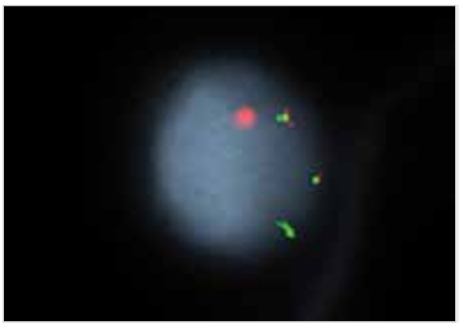
The ERCC1 (19q13) FISH probe has been optimized to detect copy numbers of the ERCC1 gene region at 19q13. The ZNF443 (19p13) probe is included to facilitate chromosome identification.

REFERENCES

Olaussen et al, 2006, N. Engl. J. Med. 335; 983-991.
Ceppi et al, 2006, Ann. Oncol. 17; 1818-1825.



ETV6 / RUNX1



ETV6 / RUNX1 t(12;21) Fusion probe hybridized to patient material showing t(12;21)translocation (2RG1R1G).

Material kindly provided by Dr. Balogh, Budapest.

ETV6 / RUNX1 t(12;21) Fusion

CODE	COLOR	FORMAT	STATUS
KBI-10401	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

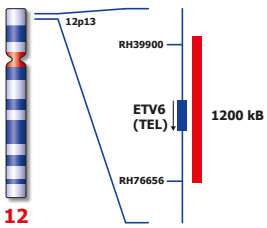
BACKGROUND

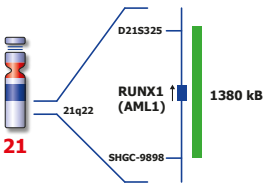
The t(12;21), a cryptic translocation rarely observed by conventional cytogenetics, was first identified by fluorescence in situ hybridization (FISH). In ALL blasts, this translocation fuses the 5' part of the ETV6 (previously known as TEL) gene with almost the entire RUNX1 (previously known as AML) (CBFA2) gene, producing the chimeric transcript ETV6-CBFA2. The t(12;21) (p13;q22) has also been identified as the most frequent chromosomal abnormality in childhood ALL, affecting 20% to 25% of B-lineage cases.

The ETV6 / RUNX1 t(12;21) specific FISH probe is optimized to detect the reciprocal translocation t(12;21) (p13;q22) in a dual-color, dual-fusion assay.

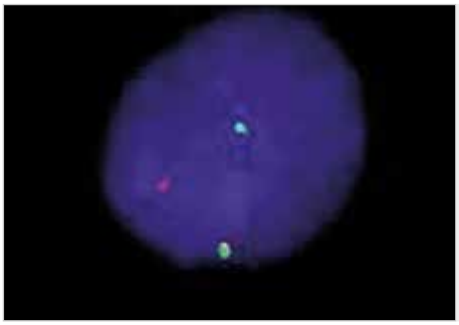
REFERENCES

Romana et al, 1995, Blood, 85; 3662-3670.





ETV6 Break



ETV6 (12p13) Break probe hybridized to patient material showing a translocation involving the ETV6 region at 12p13 (TRG1R1G).

Image kindly provided by Magret Ratjen, Kiel.

ETV6 (12p13) Break

CODE	COLOR	FORMAT	STATUS
KBI-10403	Green/Red	10 test	IVD

MENU

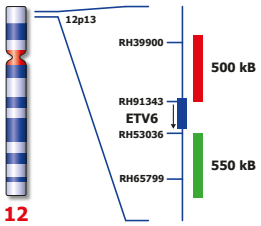
HEMATOPATHOLOGY

BACKGROUND

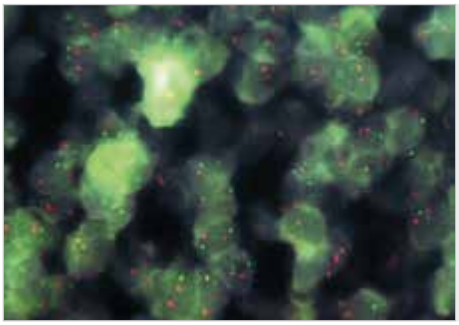
ETV6 (previously known as TEL) gene is the abbreviation for -ETS variant 6- gene. It encodes an ETS family factor which functions as a transcriptional repressor in hematopoiesis and in vascular development. The gene is located on chromosome 12p13, and is frequently rearranged in human leukemias of myeloid or lymphoid origins. Also systematic deletion of the normal ETV6 allele in patients with ETV6-RUNX1 fusions can be found. The ETV6 Break FISH probe is optimized to detect translocations involving the ETV6 region at 12p13 in a dual-color, split assay on metaphase/interphase spreads and bone marrow cells.

REFERENCES

Golub et al, 1995, PNAS 92; 4917-4921.
Ford et al, 2001, Blood 98; 558-564.



EWSR1 / NFATC



FISH result of the EWSR1/ NFATC2 t(20;22) DC, S-Fusion probe.

EWSR1 / NFATC2 t(20;22) Dual-Color, Single-Fusion

CODE	COLOR	FORMAT	STATUS
KBI-10751	Green/Red	10 test	IVD

MENU

SOFT TISSUE PATHOLOGY

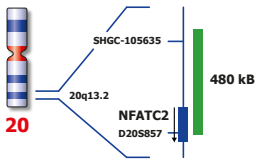
BACKGROUND

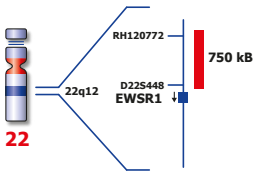
Ewing's sarcoma is the second most frequent primary bone cancer. In most cases a translocation involving the EWSR1 gene at 22q12 and the FLI1 gene at 11q24 is observed. Several other translocation partners of the ETS gene family can also be involved. The first non-ETS family translocation partner described is the NFATC2 gene (nuclear factor of activated T-cells, cyto-plasmic, calcineurin-dependent 2) at 20q13.

The EWSR1 / NFATC2 t(20;22) Dual-Color Single-Fusion probe is optimized to detect the t(20;22)(q13;q12) involving the NFATC2 (20q13) and EWSR1 (22q12) gene regions in a dual-color, single fusion assay on paraffin embedded tissue sections.

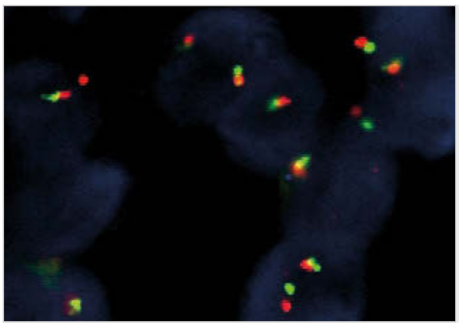
REFERENCES

Szuhai et al, 2009, Clin Cancer Res, 15; 2259-2268.
Zucman-Rossi et al, 1998, PNAS, 95; 11786-11791.
Bernstein et al, 2006, Oncologist, 11; 503-519.





EWSR1 Break



EWSR1 (22q12) break probe hybridized to a tissue section showing co-localized and split signals.

EWSR1 (22q12) Break

CODE	COLOR	FORMAT	STATUS
KBI-10750	Green/Red	10 test	IVD

MENU

SOFT TISSUE PATHOLOGY

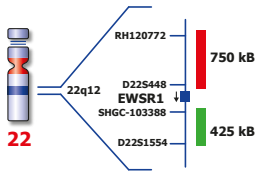
BACKGROUND

Ewing's sarcoma is the second most frequent primary bone cancer. In most cases a translocation involving the EWSR1 gene at 22q12 and the FLI1 gene at 11q24 are observed, but several other translocation partners (ERG, ETV1, FEV, and E1A3) can also be involved.

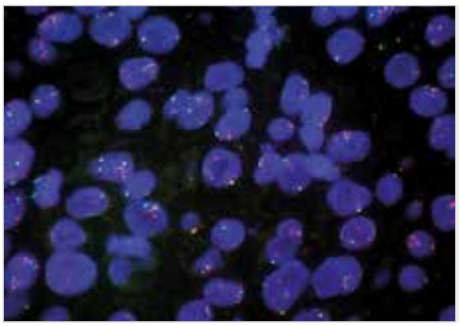
The EWSR1 (22q12) Break probe is optimized to detect translocations involving the EWSR1 gene region at 22q12 in a dual-color, split assay on paraffin embedded tissue sections.

REFERENCES

Zucman-Rossi, et al, 1998, PNAS, 95; 11786-11791.
Bernstein et al, 2006, Oncologist, 11; 503-519.



FGFR1 / SE 8



FGFR1 gene locus amplification in FFPE tissue showing an amplification of FGFR1 gene region at 8p11.

FGFR1 (8p11) / SE 8

CODE	COLOR	FORMAT	STATUS
KBI-12754	Green/Red	20 test	IVD

MENU

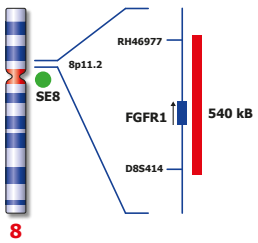
LUNG PATHOLOGY

BACKGROUND

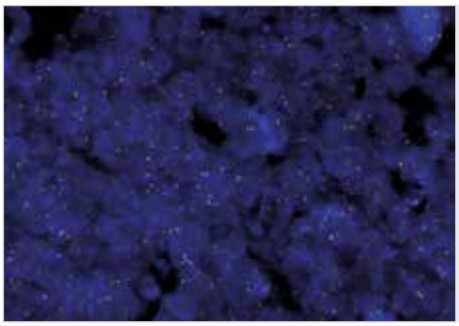
Amplification of the fibroblast growth factor receptor type 1 gene (FGFR1) has been observed in numerous cancer types including lung cancer (especially squamous cell carcinoma) and breast cancer. With the development of new therapeutic strategies, FGFR1 amplification could act as a valuable biomarker for R&D and provide an attractive tool for clinical stratification. The FGFR1 (8p11) / SE 8 FISH probe is optimized to detect amplification involving the FGFR1 gene region at 8p11 in a dual-color assay on paraffin embedded tissue sections. The chromosome 8 satellite enumeration probe (SE 8) at D8Z1 is included to facilitate chromosome identification.

REFERENCES

Weiss et al, 2010, Sci Transl. Med. 2(62); 62ra93.
Brooks et al, 2012, Clin. Cancer res. 18(7): 1855-62



FGFR1 Break



FGFR1 (8p11) Break probe hybridization to a tissue section showing a normal pattern.

FGFR1 (8p11) Break

CODE	COLOR	FORMAT	STATUS
KBI-10737	Green/Red	10 test	IVD

MENU

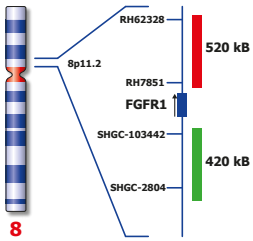
BREAST PATHOLOGY

BACKGROUND

FGFR1 has been implicated in the tumorigenesis of haematological malignancies, where it is frequently involved in balanced chromosomal translocations, including cases of chronic myeloid leukemia (BCR-FGFR1 fusion) and the 8p11 myeloproliferative syndrome/stem cell leukemia-lymphoma syndrome, which is characterized by myeloid hyperplasia and non-Hodgkin's lymphoma with chromosomal translocations fusing several genes, the most common being a fusion between ZNF198 and FGFR1. The FGFR1 (8p11) Break FISH probe is optimized to detect translocations involving the FGFR1 gene region at 8p11 in a dual-color assay on FFPE tissue sections.

REFERENCES

Smedley et al, 1998, Hum Mol Genet., 7; 627-642.
Sohal et al, 2001, Genes Chrom. Cancer, 32; 155-163.
Kwak et al, J Clin Oncol., 27(26); 4247-53.



FGFR2 / SE 10

FGFR2 (10q26) / SE 10

CODE	COLOR	FORMAT	STATUS
KBI-10757	Green/Red	10 test	IVD

MENU

LUNG PATHOLOGY

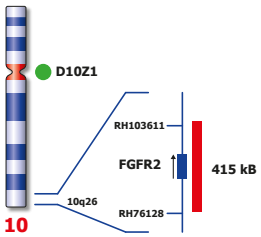
BACKGROUND

It is well documented that dysregulation of FGF-FGFR signaling via amplification, point mutation or translocations may have an important role in tumor development and progression. Alterations in FGFRs are associated with a number of human cancers, including lung, myeloma, breast, gastric, colon, bladder, pancreatic, and hepatocellular carcinomas. A growing body of preclinical data demonstrates that inhibition of FGFR signaling can result in antiproliferative and/or pro-apoptic effects, thus confirming the validity of the FGFR / FGFR axis as a potential therapeutic target.

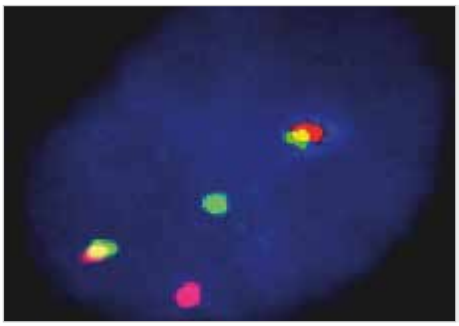
The FGFR2 (10q26) FISH probe is optimized to detect copy numbers of the FGFR2 gene region at region 10q26. The Chromosome 10 Satellite Enumeration (SE) probe is included to facilitate chromosome identification.

REFERENCES

Brooks et al, Clin Cancer Res. 2012; 18:1855.
Dutt et al, PLoS ONE 6: e2035.1
Kunii et al, Cancer Res. 2008; 68:2340-8.
Liang et al, Clin Cancer Res. 2013;19: 2572
Liao et al, Cancer Res. 2013;73:5195-205.
Weiss et al, Sci Transl Med. 2010; 2:62ra93.



FGFR3 / IGH



FGFR3 / IGH t(4;14) Fusion probe hybridized to MM patient material showing t(4;14) translocation (2RG1R1G).

Image kindly provided by Prof. Jauch, Heidelberg.

FGFR3 / IGH t(4;14) Fusion

CODE	COLOR	FORMAT	STATUS
KBI-10602	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

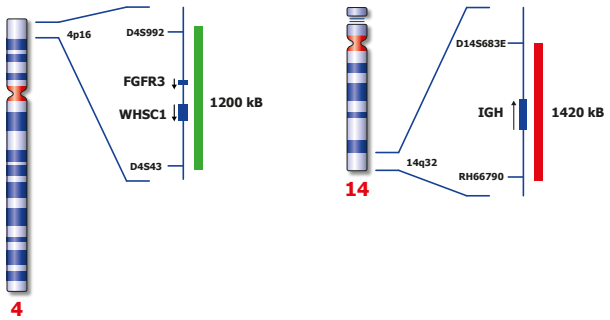
BACKGROUND

The t(4;14) translocation is undetectable by conventional cytogenetics. The breakpoints on chromosome 4 occur within an approximately 113-kb region located in small part of a conserved gene cluster including the transforming acidic coiled-coil protein 3 (TACC3), fibroblast growth factor receptor 3 (FGFR3), and multiple myeloma SET domain-containing protein (MMSET). The translocation is indicative for poor survival and poor response to chemotherapy.

The FGFR3 / IGH t(4;14)(p16;q32) Fusion specific FISH probe is optimized to detect the reciprocal translocation t(4;14) in a dual-color, dual-fusion assay.

REFERENCES

Chesi et al, 1997, Nat Genet, 16; 260-264.
Finelli et al, 1999, Blood, 94; 724-732.



FGFR4 / 5q11.2

FGFR4 (5q35) / 5q11.2

CODE	COLOR	FORMAT	STATUS
KBI-10756	Green/Red	10 test	IVD

MENU

LUNG PATHOLOGY

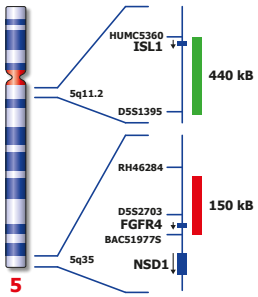
BACKGROUND

It is well documented that dysregulation of FGF-FGFR signaling via amplification, point mutation or translocations may have an important role in tumor development and progression. Alterations in FGFRs are associated with a number of human cancers, including lung, myeloma, breast, gastric, colon, bladder, pancreatic, and hepatocellular carcinomas. A growing body of preclinical data demonstrates that inhibition of FGFR signaling can result in antiproliferative and/or pro-apoptic effects, thus confirming the validity of the FGFR / FGFR axis as a potential therapeutic target.

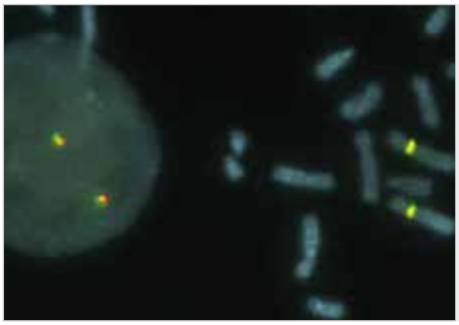
The FGFR4 (5q35) FISH probe is optimized to detect copy numbers of the FGFR4 gene region at region 5q35. The 5q11.2 probe is included to facilitate chromosome identification.

REFERENCES

Brooks et al, Clin Cancer Res. 2012; 18:1855.
Dutt et al, PLoS ONE 6: e2035.1
Kunii et al, Cancer Res. 2008; 68:2340-8.
Liang et al, Clin Cancer Res. 2013;19: 2572
Liao et al, Cancer Res. 2013; 73:5195-205.
Weiss et al, Sci Transl Med. 2010; 2:62ra93.



FIP1L1 / CHIC2 /PDGFRA Dual-Color



FIP1L1 / CHIC2 / PDGFRA (4q12) Deletion, Break probe hybridized to a normal interphase/metaphase (2RG).

FIP1L1 / CHIC2 / PDGFRA (4q12) Deletion, Break

CODE	COLOR	FORMAT	STATUS
KBI-10003	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

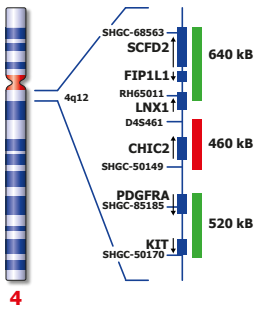
BACKGROUND

The deletion of the CHIC2 locus generates a fusion FIP1L1-PDGFRA gene giving raise to a novel tyrosine kinase. This deletion has been observed in patients with idiophatic hypereosinophilic syndrome (HES), chronic eosinophilic leukemia (CEL), systemic mast cell disease, and chronic myeloproiferative disorders (CMPD).

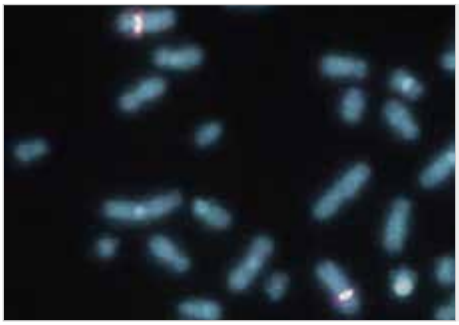
The FIP1L1 / CHIC2 / PDGFRA FISH probe is optimized to detect the CHIC2 deletion at 4q12 associated with the FIP1L1 / PDGFRA fusion in a Dual-Color, split assay. It also allows the detection of translocation involving the FIP1L1 and PDGFRA region. However, chromosome 4 polyploidy may provide additional signals not associated with a translocation involving 4q12.

REFERENCES

Cools et al, N Engl J Med, 2003, 348; 1201-1214.
Godlib et al, Blood, 2004, 103; 2879-2891.



FIP1L1 / CHIC2 /PDGFRA Triple-Color



FIP1L1 / CHIC2 / PDGFRA (4q12) Deletion, Break Triple-Color

FIP1L1 / CHIC2 / PDGFRA (4q12) Deletion, Break, Triple-Color

CODE	COLOR	FORMAT	STATUS
KBI-10007	Green/Red/Blue	10 test	IVD

MENU

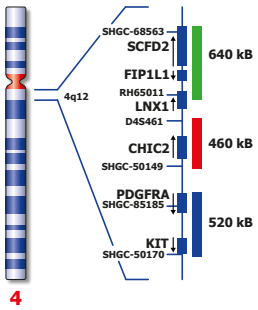
HEMATOPATHOLOGY

BACKGROUND

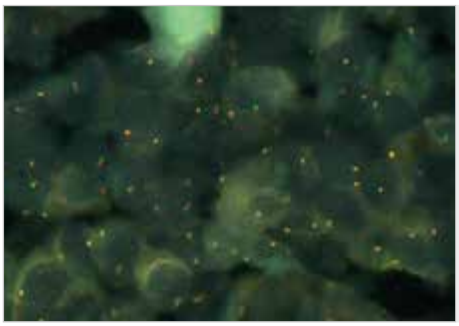
The FIP1L1 / CHIC2 / PDGFRA Triple-Color FISH probe is optimized to detect the CHIC2 deletion at 4q12 associated with the FIP1L1 / PDGFRA fusion in a triple-color, split assay. It also allows the detection of translocation involving the FIP1L1 and PDGFRA region.

REFERENCES

Cools et al, N Engl J Med, 2003, 348; 1201-1214.
Griffin et al, 2003, PNAS, 100;7830-7835.
Gotlib et al, 2004, Blood, 103;2879-2891



FOXO1 Break



FOXO1 (13q14) Break probe hybridized to patient material (2RG).

FOXO1 (13q14) Break

CODE	COLOR	FORMAT	STATUS
KBI-10716	Green/Red	10 test	IVD

MENU

SOFT TISSUE PATHOLOGY

BACKGROUND

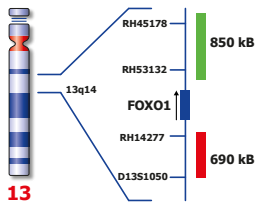
The t(2;13) is associated with alveolar rhabdomyo-sarcomas. This translocation results in the formation of a chimeric transcript consisting of the 5' portion of PAX3, including an intact DNA-binding domain fused to the FOXO1 gene on chromosome 13. The t(1;13)(p36;q14) also seen in alveolar rhabdomyosarcomas results in the fusion of another member of the PAX family, PAX7 to the FOXO1 gene on chromosome 13.

A break or split probe for FOXO1 is best used to analyze translocation of the FOXO1 (13q14) gene on formalin fixed paraffin embedded tissue for routine clinical diagnosis.

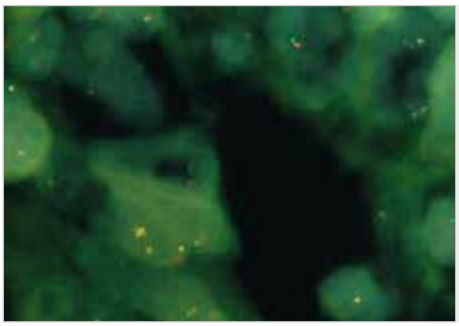
The FOXO1 (13q14) Break probe is optimized to detect translocations involving the FOXO1 gene region at 13q14 in a dual-color, split assay on metaphase/interphase spreads and paraffin embedded tissue sections.

REFERENCES

Barr et al, 1996, Hum. Mol. Genet., 5; 15-21.
Coignet et al, 1999, Genes Chrom. Cancer, 25; 222-229.



FUS Break



FUS (16p11) Break probe hybridized to liposarcoma material.

FUS (16p11) Break

CODE	COLOR	FORMAT	STATUS
KBI-10715	Green/Red	10 test	IVD

MENU

SOFT TISSUE PATHOLOGY

BACKGROUND

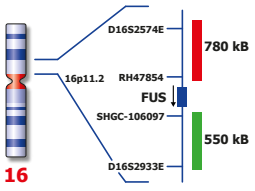
The fused in sarcoma (FUS) gene was originally shown to be rearranged in myxoid liposarcomas harboring a t(12;16)(q13;p11) translocation. FUS has also been shown to be involved in other recombinations: with ERG in acute myeloid leukemia carrying a t(16;21), with ATF1 in band 12q13 in angiomatoid fibrous histiocytoma, and with CREB3L2 in fibromyxoid sarcoma.

A break or split probe for FUS is best used to analyze translocation of the FUS (16p11) gene on formalin fixed paraffin embedded tissue for routine clinical diagnosis.

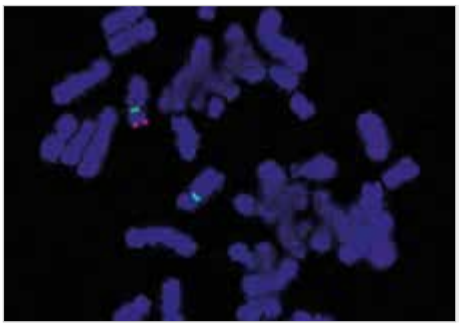
The FUS (16p11) Break probe is optimized to detect translocations involving the FUS gene region at 16p11 in a dual-color, split assay on metaphase/interphase spreads and paraffin embedded tissue sections.

REFERENCES

Shing et al, 2003, Cancer Res, 63: 4568-4576.
Storlazzi et al, 2003, Hum. Mol. Genet., 12: 2349-2358.



GATA4 / SE 8



GATA4 (8p23) / SE 8 probe hybridized to patient material showing a deletion of the GATA4 (8p23) region (1R2G).

GATA4 (8p23) / SE 8

CODE	COLOR	FORMAT	STATUS
KBI-40118	Green/Red	10 test	IVD
KBI-45118	Green/Red	5 test	IVD

MENU

POSTNATAL

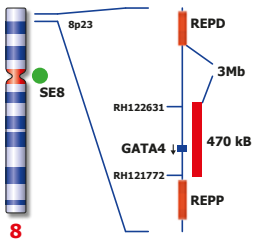
BACKGROUND

The deletion of GATA4 (8p23) is found in patients with congenital heart disease. Besides the deletion, duplications are found of the region flanked by low copy repeats 8p-OR-REPD (distal) and -REPP (proximal). These recurrent deletions are associated with a spectrum of anomalies, including developmental delay and neuropsychiatric findings. GATA4 is expressed in adult heart, epithelium and gonads. During fetal development, GATA4 is expressed in yolk sac endoderm and cells involved in heart formation.

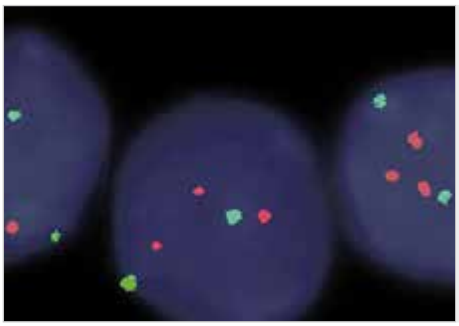
The GATA4 (8p23) / SE 8 FISH probe is optimized to detect deletions of the GATA4 gene region at 8p23 in a dual-color assay on metaphase/interphase spreads, blood smears and bone marrow cells. The Chromosome 8 Satellite Enumeration (SE) FISH probe is included to facilitate chromosome identification.

REFERENCES

Bhatia et al, 1999, Prenat Diagn., 19; 863-867.
Giorda et al, 2007, Hum. Mut., 28; 459-468.
Wat et al, 2009, Am. J. Med. Genet., Part A, 149A; 1661-1677.



GLI1 / SE 12



GLI1 (12q13) / SE 12 hybridized to patient material showing GLI (12q13) amplification (3R2G).

Image kindly provided by Dr. Wenzel, Basel.

GLI1 (12q13) / SE 12

CODE	COLOR	FORMAT	STATUS
KBI-10104	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

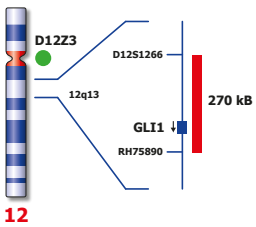
BACKGROUND

Trisomy 12 is the most common numerical chromosomal aberration in patients with B-cell chronic lymphocytic leukemia (B-CLL). Partial trisomy 12 of the long arm of chromosome 12 consistently includes a smaller region at 12q13-15 and has been observed in CLL and several other tumors. A number of loci located close to either MDM2 or CDK4 / SAS, including the genes GADD153, GLI1 (previously known as GLI), RAP1B, A2MR, and IFNG, were found to be coamplified.

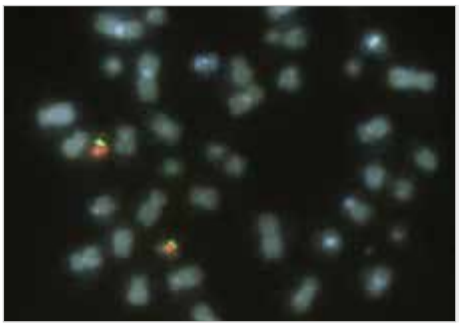
The GLI1 (12q13) specific FISH probe is optimized to detect copy numbers of the GLI1 gene region at region 12q13. The chromosome 12 Satellite Enumeration FISH probe (SE 12) D12Z3 is included to facilitate chromosome identification.

REFERENCES

Merup et al, 1997, Eur J Haematol, 58; 174-180.
Dierlamm et al., 1997, Genes Chrom Cancer, 20; 155-166.



HIRA / SHANK3



DiGeorge HIRA (22q11) / 22q13 (SHANK3) probe hybridized to a normal metaphase (2R2G).

DiGeorge HIRA (22q11) / 22q13 (SHANK3)

CODE	COLOR	FORMAT	STATUS
KBI-40103	Green/Red	10 test	IVD
KBI-45103	Green/Red	5 test	IVD

MENU

POSTNATAL

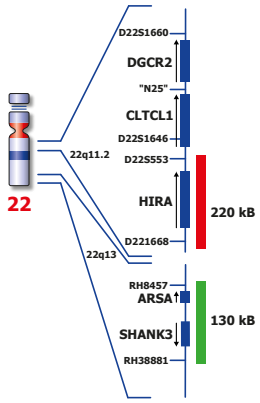
BACKGROUND

The DiGeorge HIRA (TUPLE) probe targets a putative transcriptional regulator (TUPLE1 or HIRA, HIR histone cell cycle regulation defective homolog A) which also has been identified to lie within the commonly deleted region DiGeorge syndrome. This probe is located distally to the "N25" probe.

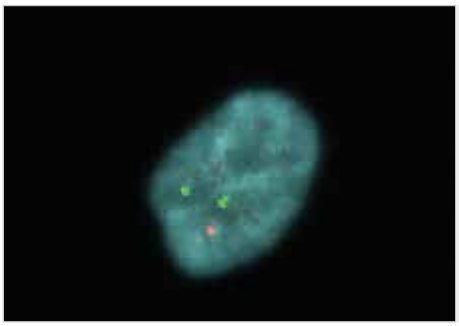
The DiGeorge HIRA region probe is optimized to detect copy numbers of the HIRA gene region at 22q11.2. The SHANK3 probe at 22q13 is serving as internal control.

REFERENCES

Lorain at al, 1996, Genome Res, 6; 43-50.



IGF1R / 15q11



IGF1R (15q26) / 15q11 probe hybridized to patient material showing a deletion of the IGF1R gene region at 15q26 (1R2G).

IGF1R (15q26) / 15q11

CODE	COLOR	FORMAT	STATUS
KBI-40116	Green/Red	10 test	IVD
KBI-45116	Green/Red	5 test	IVD

MENU

POSTNATAL

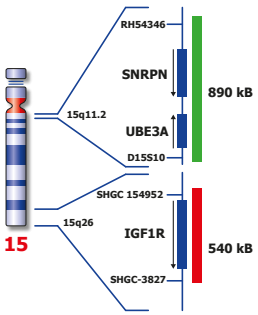
BACKGROUND

Congenital diaphragmatic hernia (CDH) is a severe, life-threatening, congenital anomaly characterized by variable defect in the diaphragm, pulmonary hypoplasia, and postnatal pulmonary hypertension. Deletion of the IGF1R (insulin-like growth factor 1 receptor) gene region at 15q25 is the most frequent anomaly found in CDH. The type 1 IGF receptor at 15q26 is required for normal embryonic and postnatal growth. Deletions, but also gain of an approximately 5 Mb region including the IGF1R gene has been found to have a profound effect on prenatal and early postnatal growth.

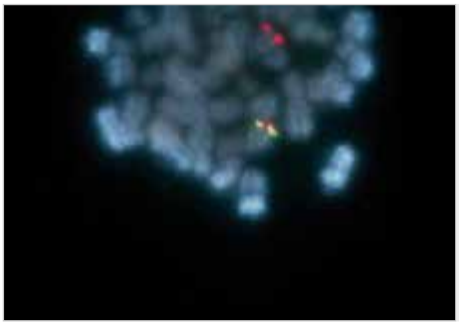
The IGF1R (15q26) specific FISH probe is optimized to detect copy numbers of the IGF1R gene region at region 15q26. The 15q11 (SNRPN / UBE3A) specific region probe is included to facilitate chromosome identification.

REFERENCES

Faivre et al, 2002, Eur, J, Hum, Genet., 10; 699-706.
Okubo et al, 2003, J. Clin. Endocrinol. Metab, 88; 5981-5988.



IGH Break



IGH (14q32) Break probe hybridized to patient material showing a partial deletion of 14q32 (1RG1R).

IGH (14q32) Break

CODE	COLOR	FORMAT	STATUS
KBI-10601	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

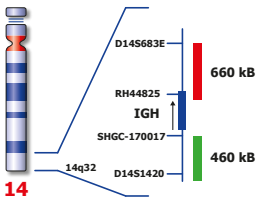
BACKGROUND

Multiple myeloma is characterized by complex rearrangements involving the IgH gene, particularly at the constant locus. The IgH rearrangement provides a useful marker of clonality in B-cell malignancies and amplification of this rearrangement is the method of choice to monitor the residual tumor cells in multiple myeloma.

The IGH (14q32) break probe is optimized to detect translocations involving the IGH gene region at 14q32 in a dual-color, split assay.

REFERENCES

Taniwaki et al, 1994, Blood, 83; 2962-1969.
Gozetti et al, 2002, Cancer Research, 62; 5523-5527.



IGH Break (tissue)

Hybridization of IGH break probe to a tissue section showing normal and aberrant pattern (2RG)(1RG1R1G)

IGH (14q32) Break (tissue)

CODE	COLOR	FORMAT	STATUS
KBI-10729	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

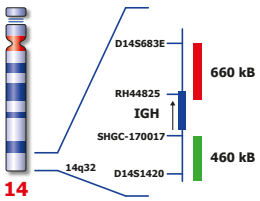
BACKGROUND

Chromosomal rearrangements involving the immunoglobulin heavy chain gene (IGH) at 14q32 are observed in 50% of patients with B-cell non-Hodgkin's lymphoma (NHL) and many other types of Lymphomas. More than 50 translocation partners with IGH have been described. In particular t(8;14) is associated with Burkitt's lymphoma, t(11;14) is associated with Mantle cell lymphoma, t(14;18) is observed in a high proportion of follicular lymphomas and t(3;14) is associated with Diffuse Large B-Cell Lymphoma.

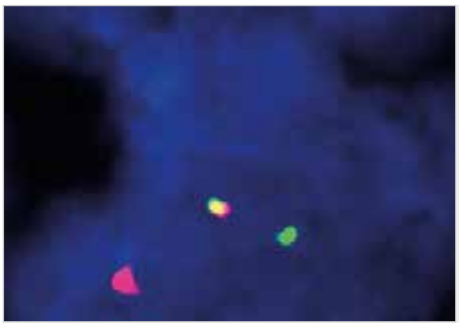
The IGH (14q32) Break probe is optimized to detect translocations involving the IGH gene region at 14q32 in a dual-color, split assay.

REFERENCES

Taniwaki et al, 1994, Blood, 83: 2962-1969.
Gozetti et al, 2002, Cancer Research, 62: 5523-5527.



IRF4 / DUSP22 Break



IRF4 / DUSP22 (6p25) Break.

Image kindly provided by Hopital Universitario Marqués de Valdecilla, Satander.

IRF4 / DUSP22 (6p25) Break

CODE	COLOR	FORMAT	STATUS
KBI-10613	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

BACKGROUND

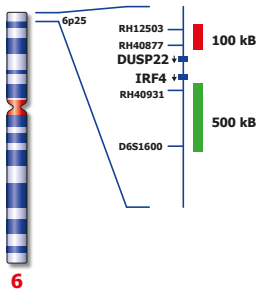
Rearrangements of the 6p25.3 locus define a subtype of CTCL. Genes rearranged at the 6p25.3 locus are IRF4 (also known as MUM1) and the DUSP22. Rearrangements of the 6p25.3 locus have also been described to occur in high and low grade B-cell lymphomas, myeloma and chronic B-cell lymphoid leukemia.

The IRF4 / DUSP22 (6p25) Break FISH probe detects both rearrangements involving IRF4 and DUSP22, but does not distinguish them from each other.

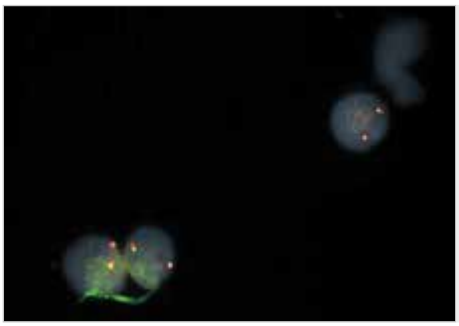
The IRF4 / DUSP22 (6p25) Break FISH probe is optimized to detect translocations involving the IRF4 / DUSP22 gene region at the 6p25.3 locus in a dual-color assay on metaphase/interphase spreads, blood smears, bone marrow cells and lymph node biopsies.

REFERENCES

Bisig et al., Best Pract Res Clin Haematol, 2012, 25; 13-28.
Feldman et al., Blood, 2011, 117; 915-919.
Karai et al., Am J Surg Pathol, 2013 [Epub ahead of print].
Pham-Ledard et al., J Invest Dermatol, 2010, 130; 816-825.
Salaverria et al., Blood, 2011, 118; 139-147.
Wada et al., Mod Pathol, 2011, 24; 596-605.



JAK2 Break



JAK2 (9p24) Break probe hybridized to bone marrow sample (2RG).

JAK2 (9p24) Break

CODE	COLOR	FORMAT	STATUS
KBI-10012	Green/Red	10 test	IVD

MENU

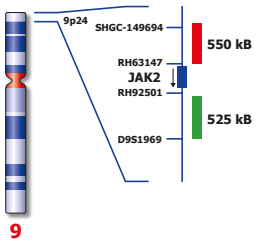
HEMATOPATHOLOGY

BACKGROUND

Janus Kinase 2 (JAK2) is a tyrosine kinase involved in cytokine signaling. Mutations and translocations involving the JAK2 gene region are observed in myeloproliferative neoplasms. The common JAK2617V>F point mutation and translocations results in constitutive activation of JAK2. Translocations are described with the following fusion partners: PCM1, BCR, ETV6 (TEL), SSBP2 and 3q21. Patients with the JAK2617V>F point mutation can also exhibit a numerical gain of the gene.

The JAK2 (9p24) Break FISH probe is optimized to detect translocations involving the JAK2 gene region at region 9p24 in a dual-color, split assay on metaphase/ interphase spreads. The JAK2 (9p24) Break FISH probe can not be used to detect point mutations, and it has not been optimized to detect gene amplifications.jfeld V et al, 2007, Exp Hematol, 35; 1668-1676.

Smith C et al, 2008, Hum Pathol, 39; 795-810.
Poitras J et al, 2008, Genes Chromosomes Cancer, 47; 884-889.



KMT2A / AFF1

KMT2A / AFF1 t(4;11) Fusion probe. Standard t(4;11) 2 Fusion, 1 Red, 1 Green (2F1R1G).

Image kindly provided by Dr. Christine Harrison, Newcastle.

KMT2A / AFF1 t(4;11) Fusion

CODE	COLOR	FORMAT	STATUS
KBI-10404	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

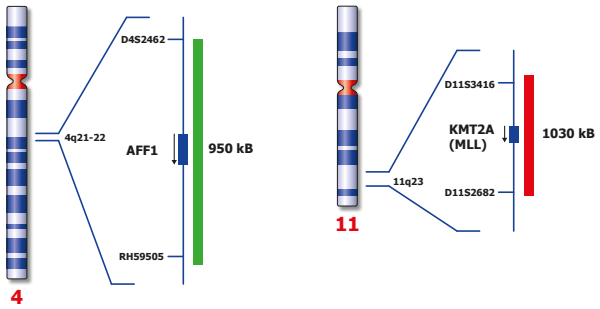
BACKGROUND

The t(4;11) KMT2A / AFF1 is the most frequently (approximately 66% according to Meyer et al.) observed translocation involving the KMT2A gene resulting in ALL. The KMT2A / AFF1 translocation results in the generation of fusion proteins KMT2A / AFF1 and AFF1 / KMT2A; both seem to have leukemogenic properties. Furthermore, MECOM (3q26) is one of the targets of the KMT2A oncoproteins, which increased expression correlates with unfavorable prognosis in Acute Myeloid Leukemia.

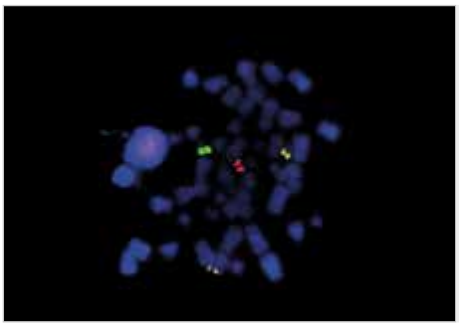
The KMT2A / AFF1 t(4;11) Fusion FISH probe is optimized to detect translocations involving the KMT2A (previously known as MLL) and AFF1 gene regions at 4q21-22 and 11q23 in a dual-color, fusion assay on metaphase/interphase spreads, blood smears and bone marrow cells.

REFERENCES

Harrison CJ et al, 2010, Br J Haem, 151; 132-142.
Arai S et al, 2011, Blood, 117; 6304-6314
Meyer C et al, 2009, Leukemia, 23; 1490-1499.



KMT2A / MLLT1



KMT2A / MLLT1 t(11;19) Fusion probe hybridized to patient material showing t(11;19) translocation (2RG1R1G).

KMT2A / MLLT1 t(11;19) Fusion

CODE	COLOR	FORMAT	STATUS
KBI-10307	Green/Red	10 test	IVD

MENU

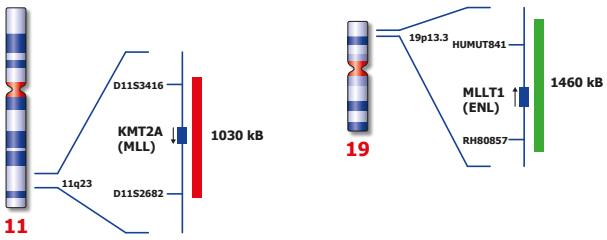
HEMATOPATHOLOGY

BACKGROUND

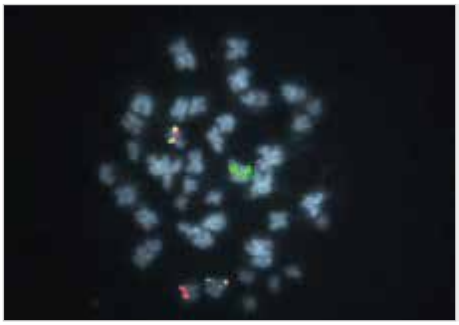
One of the relatively frequently observed translocations (around 10 %) in AML and ALL involves the genes KMT2A (previously known as MLL) and MLLT1 (aka ENL) at 11q23 and 19p13. The KMT2A / MLLT1 translocation results in the generation of fusion protein that retains the MLL N-terminus, including both an A-T hook domain and a region similar to mammalian DNA methyltransferase. There are several breakpoints within the MLLT1 gene described, without clear differences in clinicohematologic features. The KMT2A / MLLT1 Fusion probe is optimized to detect translocations involving the KMT2A and MLLT1 gene regions at 11q23 and 19p13 in a dual-color, fusion assay on metaphase/interphase spreads, blood smears and bone marrow cells in a dual-color, fusion assay.

REFERENCES

Mitterbauer-Hohdanner G et al, 2004, Eur J Clin Invest, 34; 12-24.
Meyer C et al, 2009, Leukemia, 23; 1490-1499.
Fu JF et al, 2007, Am J Clin Pathol, 127; 24-30.



KMT2A / MLLT3



KMT2A/MLLT3 t(9;11) Fusion probe hybridized to patient material showing t(9;11) translocation (2RG1R1G).

Image kindly provided by Dr. Mohr, Dresden.

KMT2A / MLLT3 t(9;11) Fusion

CODE	COLOR	FORMAT	STATUS
KBI-10308	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

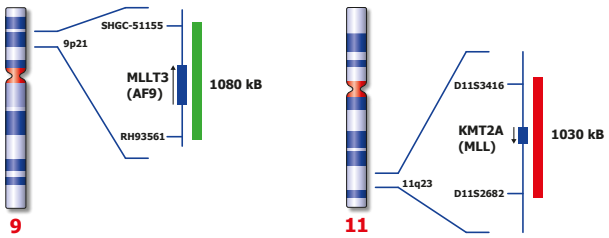
BACKGROUND

Chromosomal rearrangements involving the mixed lineage leukemia (MLL) gene at 11q23 are frequently observed in adult and childhood acute leukemia and are, in general, associated with poor prognosis. However, children with Acute Myeloid Leukemia (AML) carrying the t(9;11) KMT2A / MLLT3 (aka AF9) translocation have been described to be more sensitive to chemotherapy than patients with other 11q23 rearrangements.

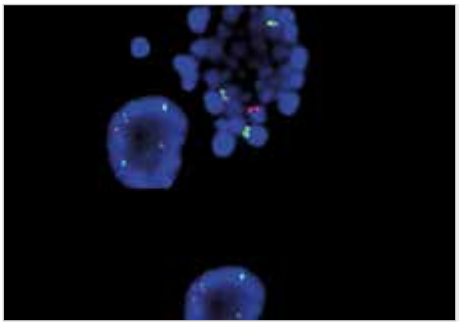
The KMT2A / MLLT3 Fusion FISH probe is optimized to detect translocations involving the KMT2A (previously known as MLL) and MLLT3 gene regions at 11q23 and 9p21 in a dual-color fusion assay on metaphase/interphase spreads, blood smears and bone marrow cells.

REFERENCES

Von Lindern et al, 1992, Mol. Cell. Biol.,12; 1687-1697.
Ageberg et al, 2008, Gen. Chrom. Canc., 47; 276-287.
Chi et al, 2008, Arch. Pathol. Lab. Med.,132; 1835-1837.



KMT2A / MLLT4



KMT2A / MLLT4 t(6;11) Fusion probe hybridized to patient material showing 47,XX,t(6;11)(q27;q23),+der(6)t(6;11)(q27;q23).

KMT2A / MLLT4 t(6;11) Fusion

CODE	COLOR	FORMAT	STATUS
KBI-10309	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

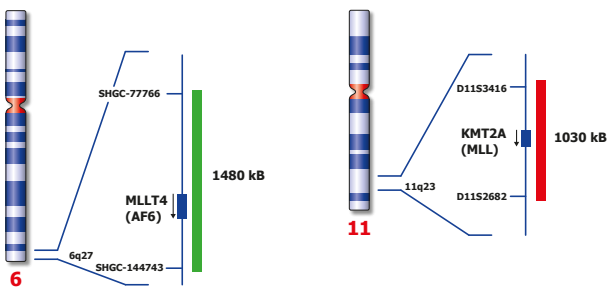
BACKGROUND

One of the relatively frequently observed translocations in AML involves the genes KMT2A and MLLT4 (previously known as AF6) at 11q23 and 6q27. The KMT2A / MLLT4 translocation results in the generation of fusion protein that retains the KMT2A N-terminus, including both an A-T hook domain and a region similar to mammalian DNA methyltransferase. The breakpoint region of the MLLT4 gene is located within intron 1 and downstream of the initiation codon.

The KMT2A / MLLT4 t(6;11) Fusion FISH probe is optimized to detect translocations involving the KMT2A (previously known as MLL) and MLLT4 gene regions at 11q23 and 6q27 in a dual-color, fusion assay on metaphase/interphase spreads, blood smears and bone marrow cells.

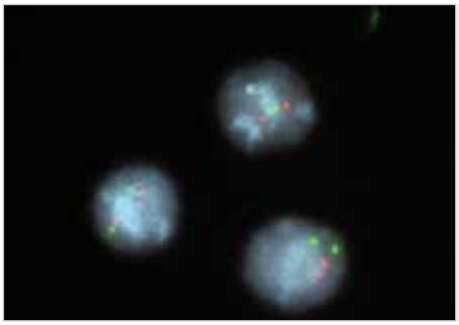
REFERENCES

Mitterbauer-Hohdanner G et al, 2004, Eur J Clin Invest, 34; 12-24.
Meyer C et al, 2009, Leukemia, 23; 1490-1499.



* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use RUO For Research Use Only. Not for use in diagnostic procedures ASR Analyte Specific Reagent GPR General Purpose Reagent

KMT2A / SE 11



KMT2A (11q23) / SE 11 hybridized to normal interphases (2R2G).

KMT2A (11q23) / SE 11

CODE	COLOR	FORMAT	STATUS
KBI-10711	Green/Red	10 test	IVD

MENU

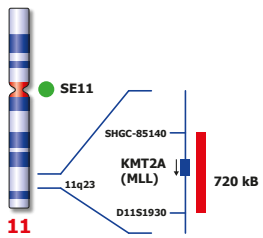
NEUROPATHOLOGY

BACKGROUND

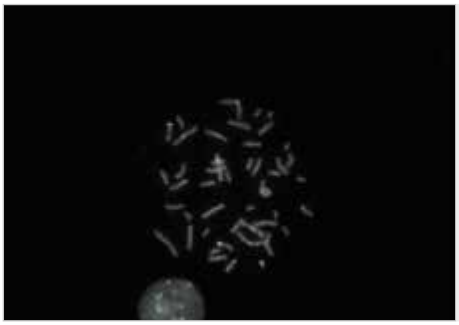
Deletions of the long arm of chromosome 11 (11q) have been noted in primary neuroblastomas. It is assumed that a tumor suppressor gene mapping within 11q23.3 is commonly inactivated during the malignant evolution of a large subset of neuroblastomas, especially those with unamplified MYCN. The KMT2A (11q23) FISH probe is optimized to detect amplification or deletion involving the KMT2A gene region at 11q23 in a dual-color assay. The Chromosome 11 Satellite Enumeration probe (SE 11) at D11Z1 is included to facilitate chromosome identification.

REFERENCES

Guo et al, 1999, Oncogene, 18: 4948-4957.
Maris et al, 2001, Med Pediatr Oncol, 36: 24-27.



KMT2A Break



Hybridization of KMT2A probe to a metaphase spread showing normal pattern (2F).

KMT2A (11q23) Break

CODE	COLOR	FORMAT	STATUS
KBI-10303	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

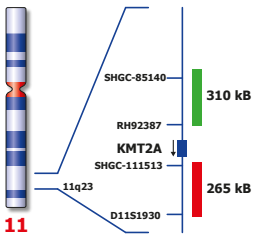
BACKGROUND

The human chromosome band 11q23 is associated with a high number of recurrent chromosomal abnormalities including translocations, insertions, and deletions. It is involved in over 20% of acute leukemias. The KMT2A (previously known as MLL) gene, named for its involvement in myeloid (usually monoblastic) and lymphoblastic leukemia, and less commonly in lymphoma, is located in the 11q23 breakpoint region. Leukemias involving the KMT2A gene usually have a poor prognosis.

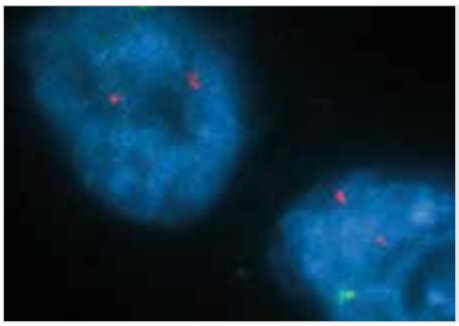
The KMT2A (11q23) Break FISH probe is optimized to detect translocations involving the KMT2A gene region at 11q23 in a dual-color split assay.

REFERENCES

Kobayashi et al, 1993, Blood, 81; 3027-3022
Martinez-Climent et al, 1995, Leukemia, 9; 1299-1304.



MAF/ IGH



MAF / IGH t(14;16) Fusion probe hybridized to patient material showing a deletion of the MAF gene region at 16q23 (2R1G).

MAF / IGH t(14;16) Fusion

CODE	COLOR	FORMAT	STATUS
KBI-10610	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

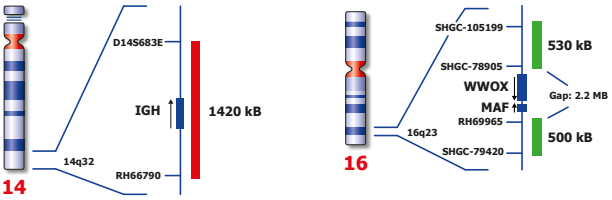
BACKGROUND

Abnormalities of 16q are important recurrent events in multiple myeloma (MM). The t(14;16)(q32;q23) is a karyotypically silent translocation that is associated with the ectopic expression and dysregulation of MAF mRNA. Translocations that bracket the MAF locus (dispersed over 500 kb) are estimated to be present in up to 25% of plasma cell myelomas.

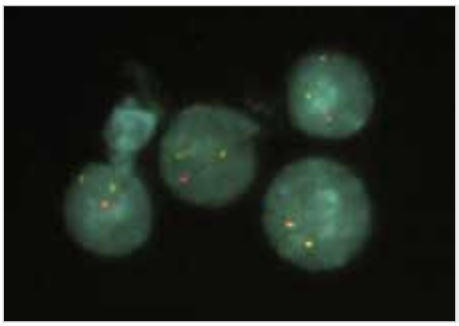
The MAF / IGH t(14;16) specific FISH probe is optimized to detect the reciprocal translocation t(14;16) in a dual-color, dual-fusion assay on metaphase/interphase spreads, blood smears and bone marrow cells.

REFERENCES

Chesi et at, 1998, Blood 91; 4457-4463.
Sawyer et al, 1998, Blood 92; 4269-4278.



MAFB /IGH



The MAFB / IGH t(14;20) Fusion FISH probe hybridized to patient material showing a complex pattern with a t(14;20) translocation.

Image kindly provided by Erasmus Medical Center, Rotterdam.

MAFB / IGH t(14;20) Fusion

CODE	COLOR	FORMAT	STATUS
KBI-10510	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

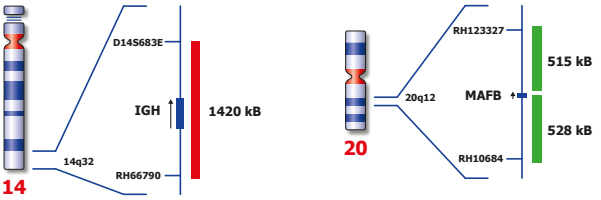
BACKGROUND

The immunoglobulin heavy chain (IGH) gene at 14q32 is an important cause of genetic deregulation in MM. Among the known fusion partners for the IGH (previously known as IGH@) gene, reciprocal translocation with the MAFB gene at 20q12 is relatively rare in MM (~2% occurrence). However, the MAFB / IGH t(14;20) translocation is associated with poor prognosis in multiple myeloma patients.

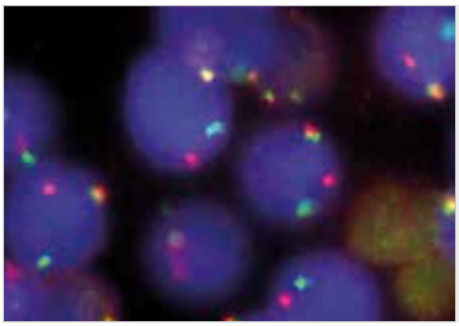
The MAFB / IGH t(14;20) Fusion FISH probe is optimized to detect the reciprocal translocation t(14;20) in a dual-color, dual-fusion assay on metaphase/interphase spreads and bone marrow cells.

REFERENCES

Boersma-Vreugdenhil GR et al, 2004, Br J Haematol, 126; 355-363.
Bergsagel PL et al, 2005, JCO, 23; 6333-6338.



MALT1 Break



MALT1 (18q21) Break probe hybridized to patient material showing a translocation at 18q21 (1RG1RG).

MALT1 (18q21) Break

CODE	COLOR	FORMAT	STATUS
KBI-10608	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

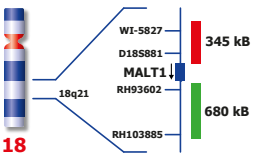
BACKGROUND

Low grade malignant lymphomas arising from mucosa associated lymphoid tissue (MALT) represent a distinct clinicopathological entity. The three major translocations seen in MALT lymphomas are t(11;18)(q21;q21) / API2-MALT1, t(14;18)(q32;q21) / IGH-MALT1 and t(1;14)(p22;q32) / IGH-BCL10. A break or split probe for MALT1 (18q21) is best used to analyze translocation of the MALT1 gene on formalin fixed paraffin embedded tissue for routine clinical diagnosis.

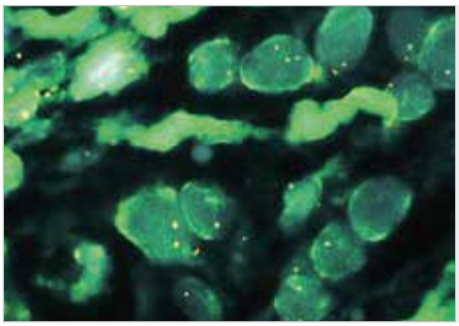
Kreatech has optimized this FISH probe for the specific use on cell material (KBI-10608), or for the use on tissue (KBI-10731).

REFERENCES

Morgan et al, 1999, Cancer Res, 59; 6205-6213.
Dierlamm et al, 2000, Blood, 96; 2215-2218.



MALT1 Break (tissue)



MALT1 (18q21) Break tissue probe hybridized to paraffin embedded material (2RG).

MALT1 (18q21) Break (tissue)

CODE	COLOR	FORMAT	STATUS
KBI-10731	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

BACKGROUND

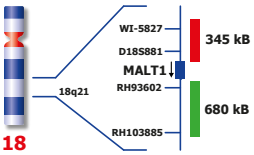
Low grade malignant lymphomas arising from mucosa associated lymphoid tissue (MALT) represent a distinct clinicopathological entity. The three major translocations seen in MALT lymphomas are t(11;18)(q21;q21) / API2-MALT1, t(14;18)(q32;q21) / IGH-MALT1 and t(1;14)(p22;q32) / IGH-BCL10. A break or split probe for MALT1 (18q21) is best used to analyze translocation of the MALT1 gene on formalin fixed paraffin embedded tissue for routine clinical diagnosis.

The MALT1 (18q21) Break probe is optimized to detect translocations involving the MALT1 gene region at 18q21 in a dual-color, split assay.

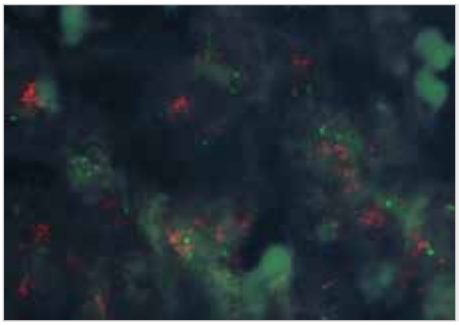
Kreatech has developed this probe for the specific use on cell material (KBI-10608), or for the use on tissue (KBI-10731).

REFERENCES

Morgan et al, 1999, Cancer Res, 59; 6205-6213.
Dierlamm et al, 2000, Blood, 96; 2215-2218.



MDM2 / SE 12



MDM2 (12q15) / SE 12 Amplification probe hybridized to patient material showing amplification of the MDM2 gene region at 12q15.

MDM2 (12q15) / SE 12

CODE	COLOR	FORMAT	STATUS
KBI-10717	Green/Red	10 test	IVD

MENU

SOFT TISSUE PATHOLOGY

BACKGROUND

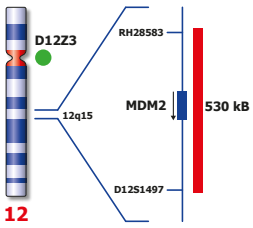
Well-differentiated liposarcoma/atypical lipomatous tumor and dedifferentiated liposarcoma are among the most common malignant soft tissue tumors presented in older adults. These tumors can be difficult to distinguish from benign lipomatous neoplasms and other high-grade sarcomas.

Amplification of the MDM2 gene has been identified in lipomatous neoplasms. The use of fluorescence in situ hybridization in identifying MDM2 amplification has made the MDM2 amplification probe a valuable diagnostic tool in well-differentiated liposarcomas/atypical lipomatous tumors. The MDM2 (12q15) FISH probe is optimized to detect copy numbers of the MDM2 gene region at region 12q15.

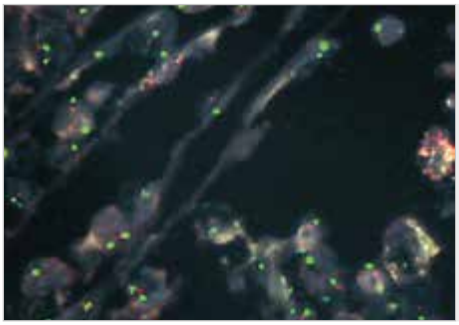
The chromosome 12 satellite enumeration probe (SE 12) at D12Z3 is included to facilitate chromosome identification.

REFERENCES

Uchida et al, 2010, Cancer Genet Cytogenet 203; 324-327.
Lucas et al, 2010, Am J Surg Pathol 34: 844-851.
Weaver et al, 2008, Mod Pathol 21: 943-949.
Mitchell et al, 1995, Chrom. Res., 3; 261-262.
Reifenberger et al, 1996, Cancer Res., 15; 5141-5145.



MDM4 / SE 1



MDM4 (1q32) / SE 1 probe hybridized to paraffin embedded tissue (2R2G).

MDM4 (1q32) / SE 1

CODE	COLOR	FORMAT	STATUS
KBI-10736	Green/Red	10 test	IVD

MENU

NEUROPATHOLOGY

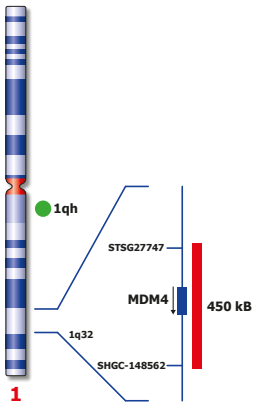
BACKGROUND

MDM4 (MDM4 p53 binding protein homolog (mouse), also known as MDMX, murine double minute gene) is a relative of MDM2 that was identified on the basis of its ability to physically interact with TP53. MDM4, like MDM2, acts as a key negative supressor of TP53 by interfering with its transcriptional activity. MDM4 amplification and/or overexpression occurs in several diverse tumors. Studies showed an increased MDM4 copy number in 65% of human retinoblastomas compared to other tumors, qualifying MDM4 as a specific chemotherapeutic target for treatment of this tumor.

The MDM4 (1q32) FISH probe is designed as a dual-color assay to detect amplification at 1q32. The chromosome 1 Satellite Enumeration (SE 1) probe at 1qh is included to facilitate chromosome identification.

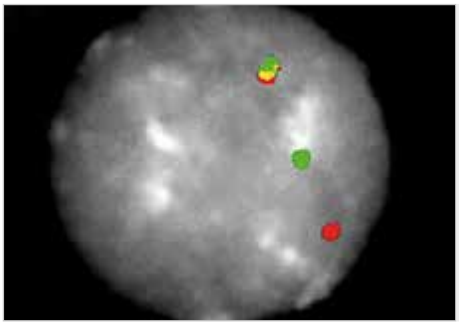
REFERENCES

Riemenschneider et al, 1999, Cancer Res. 59 ; 6091-6096.
Danovi et al, 2004, Mol.Cell.Biol. 24; 5835-5843.



* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use RUO For Research Use Only. Not for use in diagnostic procedures ASR Analyte Specific Reagent GPR General Purpose Reagent

MECOM Break



MECOM t(3;3);inv(3) (3q26) Break probe hybridized to patient material showing a rearrangement involving the MECOM gene region at 3q26 (1RG1R1G).

Image kindly provided by Dr. Reed, London.

MECOM t(3;3); inv(3) (3q26) Break

CODE	COLOR	FORMAT	STATUS
KBI-10204	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

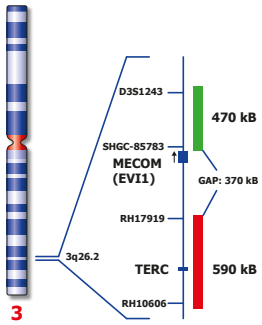
BACKGROUND

The inv(3)(q21;q26) is a recurrent cytogenetic aberration of myeloid malignancy associated with fusion of MECOM (EVI) and RPN1. Genomic breakpoints in 3q26 are usually located proximal to the MECOM locus, spanning a region of several hundred kilobases. Other recurrent and sporadic rearrangements of 3q26 also cause transcriptional activation of MECOM including the translocations t(3;3)(q21;q26) and t(3;21)(q26;q22). Breakpoints in the latter rearrangements span a wider genomic region of over 1 megabase encompassing sequences distal to MECOM and neighboring gene MDS1.

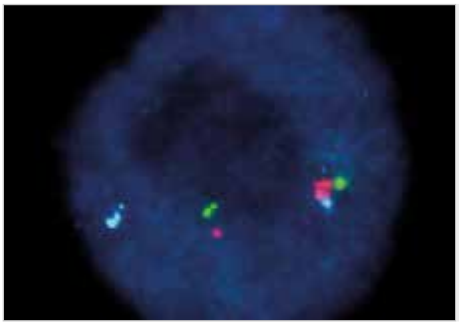
The MECOM t(3;3) inv(3) Break, dual-color FISH probe is optimized to detect the inversion of chromosome 3 involving the MECOM gene region at 3q26 in a dual-color, split assay on metaphase/interphase spreads, blood smears and bone marrow cells.

REFERENCES

De Braekeleer et al, 2011, Anticancer Res, 31; 3441-3448.
Shearer B. et al, 2010, Am J Hematol, 85:569-574.
Cui W. et al, 2011, Am J Clin Pathol, 136; 282-288.
De Melo V. et al, 2007, Leukemia aop, 13 Sep, 1-4.
Levy E. et al, 1994, Blood, 83; 1348-1354.
Wieser R et al, 2003, Haematologica, 88; 25-30.



MECOM Break Triple-Color



MECOM t(3;3);inv(3) (3q26) Break probe hybridized to patient material showing a rearrangement involving the MECOM gene region at 3q26 (1RG1R1G).

Image kindly provided by Dr. Reed, London.

MECOM t(3;3); inv(3) (3q26) Break, Triple-Color

CODE	COLOR	FORMAT	STATUS
KBI-10205	Green/Red/Blue	10 test	IVD

MENU

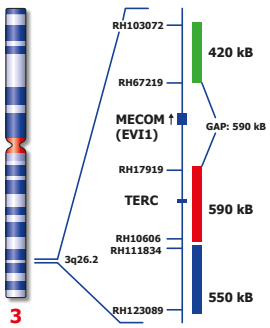
HEMATOPATHOLOGY

BACKGROUND

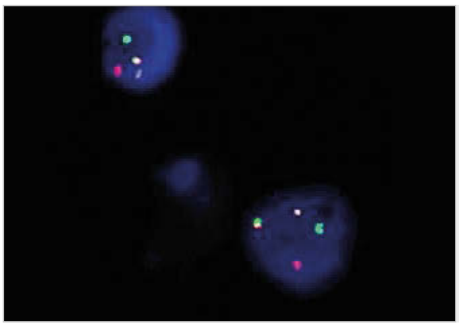
The MECOM t(3;3); inv(3)(3q26) Break Triple-Color FISH probe is optimized to detect the inversion of chromosome 3 involving the MECOM (previously known as EVI) gene region at 3q26 in a dual-color, split assay on metaphase/interphase spreads, blood smears and bone marrow cells. By using a third color breakpoint variations can also be easily observed.

REFERENCES

De Braekeleer et al, 2011, Anticancer Res, 31; 3441-3448;
Levy E. et al, 1994, Blood, 83; 1348-1354.
Cui W. et al, 2011, Am J Clin Pathol, 136; 282-288.
Wieser R et al, 2003, Haematologica, 88; 25-30.
De Melo V. et al, 2007, Leukemia aop, 13 Sep, 1-4.
Shearer B. et al, 2010, Am J Hematol, 85:569-574.



MECOM/RUNX1



MECOM / RUNX1 Fusion probe hybridized to patient material showing t(3;21) (2F1R1G).

Image kindly provided by Dr. Mohr, Dresden.

MECOM / RUNX1 t(3;21) Fusion

CODE	COLOR	FORMAT	STATUS
KBI-10310	Green/Red	10 test	IVD

MENU

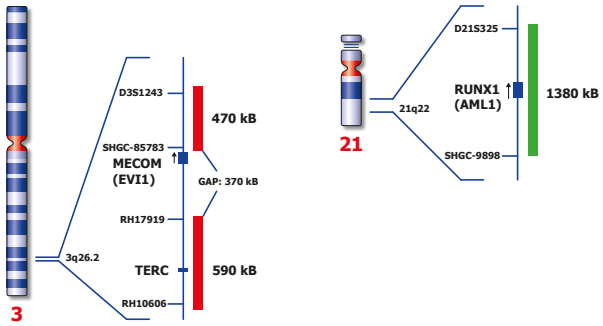
HEMATOPATHOLOGY

BACKGROUND

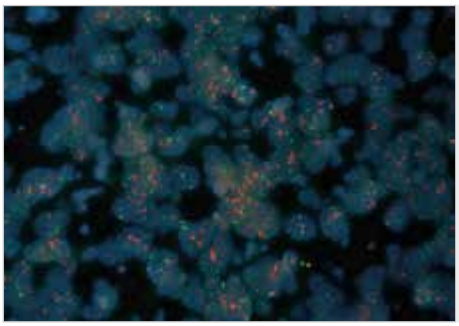
The MECOM (EVI1, 3q26) / RUNX1 (AML1, 21q22) translocation, t(3;21), is consistently found in blastic crisis of chronic myelocytic leukemia (CML) and myelodysplatic syndromederived leukemias. The translocation produces RUNX1 / MECOM chimeric transcription factor and is thought to play important roles in acute leukemic transformation of hemopoietic stem cells. The MECOM / RUNX1 t(3;21) Fusion specific FISH probe is optimized to detect the reciprocal translocation t(3;21) in a dual-color, dual-fusion assay on metaphase/interphase spreads, blood smears and bone marrow cells.

REFERENCES

Mitani et al., EMBO, 1994, Vol 13, 504-510.
Tanaka et al., Mol Cell Biol, 1995, 2383-2392.



MET / SE 7



Hybridization of MET Amplification probe to a tissue section showing MET amplification.

MET (7q31) / SE 7

CODE	COLOR	FORMAT	STATUS
KBI-10719	Green/Red	10 test	IVD

MENU

LUNG PATHOLOGY

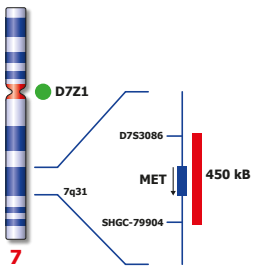
BACKGROUND

The MET proto-oncogene is a receptor-like tyrosine kinase that drives a physiological cellular program important for development, cell movement, cell repair and cellular growth. Aberrant execution of this program has been associated to neoplastic transformation, invasion and metastasis. Activation of MET has been reported in a significant percentage of human cancers including non-small cell lung cancer (NSCLC) and is amplified during the transition between primary tumors and metastasis.

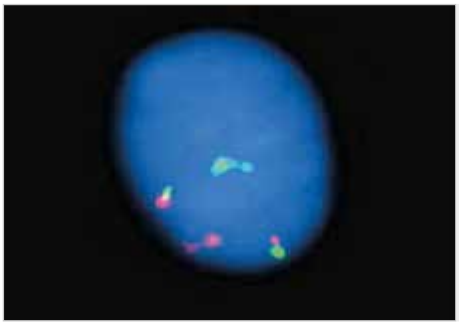
The MET (7q31) FISH probe is optimized to detect copy numbers of the MET gene region at region 7q31. The Chromosome 7 Satellite enumeration probe (SE 7) at D7Z1 is included to facilitate chromosome identification.

REFERENCES

Go et al, 2010, J Thorac Oncol 5: 305-313.
Hara et al, 1998, Lab Invest 78; 1143-1153.
Tsugawa et al, 1998, Oncology 55; 475-481.



Mm-BCR / ABL1



Mm-BCR / ABL1 probe hybridized to patient material showing t(9;22) with M-BCR (1F1r1R1G).

Mm-BCR / ABL1 t(9;22) Dual-Color, Single-Fusion, Extra Signal

CODE	COLOR	FORMAT	STATUS
KBI-10013	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

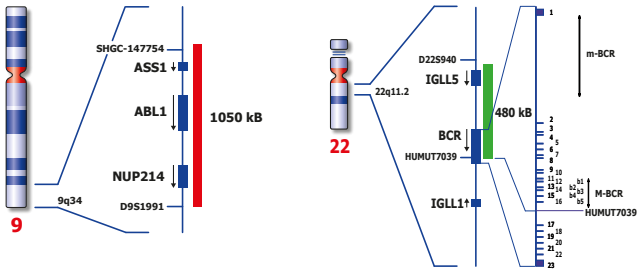
BACKGROUND

Breakpoints in the BCR gene region can occur in different regions, predominantely in a major breakpoint cluster region (M-BCR) but can also occur in a minor breakpoint cluster region (m-BCR) or micro breakpoint cluster region (µ-BCR). Further research has indicated that CML patients with different BCR-ABL1 transcripts respond differently to treatment with Gleevec.

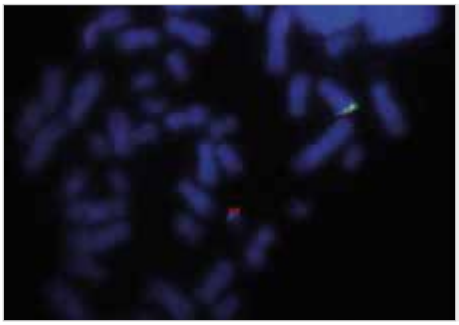
The Mm-BCR / ABL1 t(9;22), Dual-Color (DC), Single-Fusion (SF), Extra -Signal (ES) FISH probe is designed to differentiate between a M-BCR and m-BCR gene rearrangement by giving different signal patterns.

REFERENCES

Dewald et al., 1998, Blood, 91; 3357-3365.
Huntly et al., 2003, Blood, 102; 1160-1168.
Sharma et al., 2010, Ann Hematol, 89; 241-7.
Tkachuk et al., 1990, Science, 250; 559-56.
Kolomietz et al., 2001. Blood, 97; 3581-3588.



MYC (8q24) Break



MYC (8q24) Break probe hybridized to patient material showing a 8q24 proximal break (1GBR1G1BR).

Image kindly provided by Prof. Siebert, Kiel.

MYC (8q24), Triple-Color, Break

CODE	COLOR	FORMAT	STATUS
KBI-10611	Green/Red/Blue	10 test	IVD

MENU

HEMATOPATHOLOGY

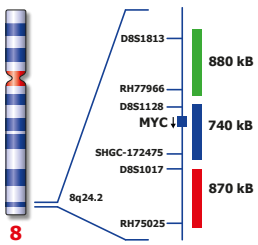
BACKGROUND

Rearrangements of the protooncogene MYC (C-MYC) have been consistently found in Burkitt's lymphoma tumor cells. In cases with the common t(8;14) chromosomal translocation, the MYC gene is translocated to chromosome 14 and rearranged with the immunoglobulin heavychain genes; the breakpoint occurs 5' to the MYC gene and may disrupt the gene itself. In Burkitt's lymphoma showing the variant t(2;8) or t(8;22) translocations, the genes coding for the k and l immunoglobulin light chain are translocated to chromosome 8. The rearrangement takes place 3' to the MYC gene.

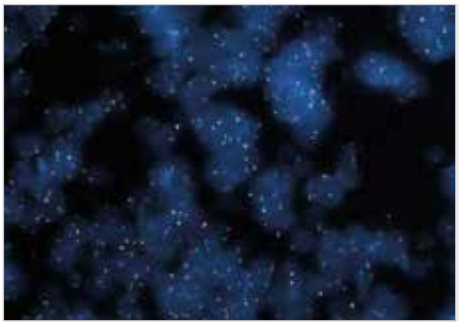
The MYC (8q24) Break probe is optimized to detect rearrangements involving the 8q24 locus in a triple-color, split assay on metaphase/interphase spreads, blood smears and bone marrow cells.

REFERENCES

Fabris et al, 2003, Genes Chromosomes Cancer, 37;261-269.
Hummel et al, 2006, N Engl J Med, 354; 2419-30.



MYC (8q24) Break (tissue)



Hybridization of MYC TC break probe to a tissue section showing abarrant pattern (1GBR1G1BR).

MYC (8q24) Triple-Color, Break (tissue)

CODE	COLOR	FORMAT	STATUS
KBI-10749	Green/Red/Blue	10 test	IVD

MENU

HEMATOPATHOLOGY

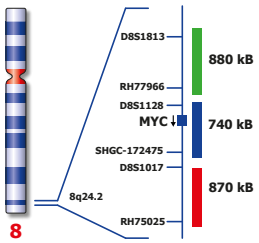
BACKGROUND

Rearrangements of the proto oncogene MYC c-myc) have been consistently found in Burkitt's lymphoma tumor cells . In cases with the common t(8;14) chromosomal translocation, the MYC gene is translocated to chromosome 14 and rearranged with the immunoglobulin heavy chain genes; the breakpoint occurs 5' to the MYC gene and may disrupt the gene itself. In Burkitt's lymphoma showing the variant t(2;8) or t(8;22) translocations, the genes coding for the k and l immunoglobulin light chain are translocated to v-myc avian myelocytomatosis viral oncogene homolog (MYC or c-myc) chromosome 8.

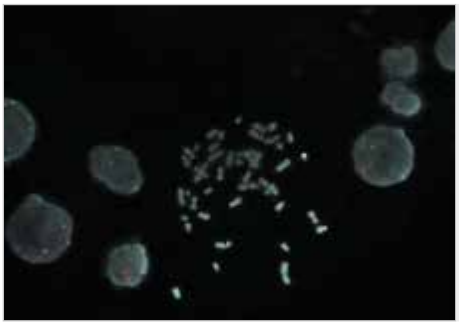
The MYC (8q24) Break probe is optimized to detect rearrangements involving the 8q24 locus in a triple-color, split assay on formalin fixed paraffin embedded tissue.

REFERENCES

Fabris et al, 2003, Genes Chromosomes Cancer, 37;261-269.
Hummel et al, 2006, N Engl J Med, 354; 2419-30.



MYC / SE 8



MYC (8q24) / SE 8 hybridized to a metaphase spread showing a normal pattern.

MYC (8q24) / SE 8

CODE	COLOR	FORMAT	STATUS
KBI-10106	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

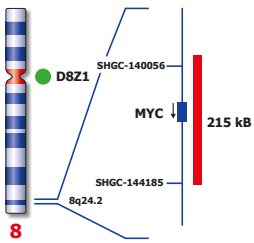
BACKGROUND

The MYC (previously known as C-MYC) gene produces an oncogenic transcription factor that affects diverse cellular processes involved in cell growth, cell proliferation, apoptosis and cellular metabolism. The MYC oncogene has been shown to be amplified in many types of human cancer such as bladder, breast and cervical. Amplification at 8q24 including MYC is also observed in 5% of CLL patients. MYC is also the prototype for oncogene activation by chromosomal translocation.

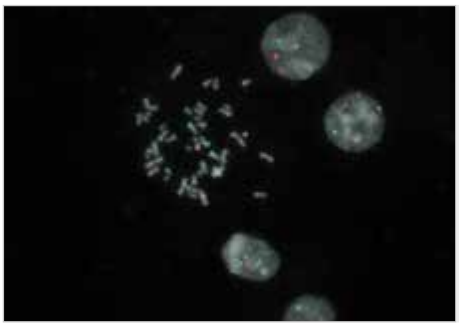
The MYC (8q24) specific FISH probe is optimized to detect copy numbers of the MYC gene region at 8q24. The chromosome 8 Satellite Enumeration FISH probe (SE 8) at D8Z1 is included to facilitate chromosome identification.

REFERENCES

Greil et al, 1991, Blood, 78; 180-191.



MYC / IGH t(8;14) Fusion



Hybridization of MYC/IGH fusion probe to a metaphase spread showing normal pattern (2R2G).

MYC / IGH t(8;14) Fusion

CODE	COLOR	FORMAT	STATUS
KBI-10603	Green/Red	10 test	IVD

MENU

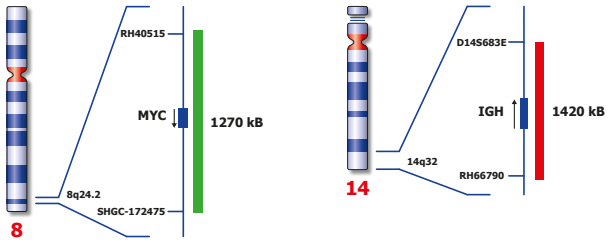
HEMATOPATHOLOGY

BACKGROUND

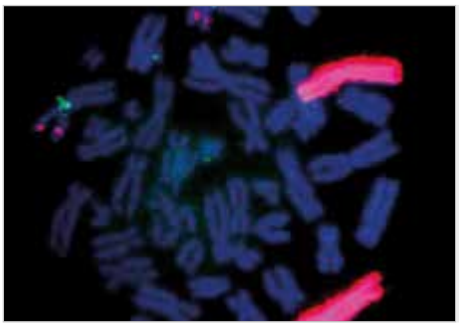
The translocation t(8;14)(q24;q32) is the characteristic chromosomal aberration of Burkitt's-type of lymphomas. This translocation fuses the MYC gene at 8q24 next to the IGH locus at 14q32, resulting in overexpression of the transcription factor MYC. Detection of the t(8;14) is aimed to help in the diagnostic process of patients with high-grade B-cell lymphomas because treatment strategies differ between Burkitt and other high-grade lymphomas. The MYC / IGH t(8;14)(q24;q32) specific FISH probe is optimized to detect the reciprocal translocation t(8;14) in a dual-color, dual-fusion assay.

REFERENCES

Veronese et al, 1995, Blood, 85;2132-2138.
Siebert et al, 1998, Blood, 91; 984-990.



MYCN / AFF3



MYCN (2p24) / AFF3 (2q11) hybridized to a cell line showing amplification of MYCN on chromosome 13 and 15.

Image kindly provided by Pasteur Workshop 2008, Paris.

MYCN (2p24) / AFF3 (2q11)

CODE	COLOR	FORMAT	STATUS
KBI-10706	Green/Red	10 test	IVD

MENU

NEUROPATHOLOGY

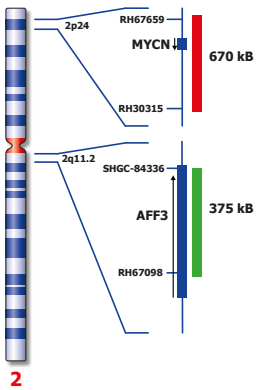
BACKGROUND

Amplification of the human protooncogene, v-myc avian myelocytomatosis viral oncogene neuroblastoma derived homolog (MYCN) is frequently seen either in extrachromosomal double minutes or in homogeneously staining regions of aggressively growing neuroblastomas. MYCN amplification has been defined by the INRG as > 4-fold MYCN signals compared to 2q reference probe signals.

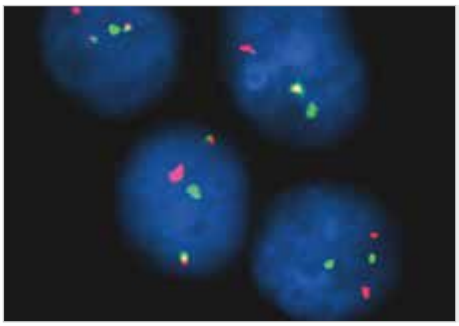
The MYCN (2p24) FISH probe is optimized to detect copy numbers of the MYCN gene region at 2p24. The AFF3 gene region probe at 2q11 is included to facilitate chromosome identification.

REFERENCES

Shapiro et al, 1993, Am J Pathol, 142: 1339-1346.
Corvi et al, 1994, PNAS, 91: 5523-5527.



MYEOV / IGH



MYEOV / IGH t(11;14) Fusion probe hybridized to MM patient material showing t(11;14) translocation (2RG1R1G).

Image kindly provided by Prof. Jauch, Heidelberg.

MYEOV / IGH t(11;14) Fusion

CODE	COLOR	FORMAT	STATUS
KBI-10605	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

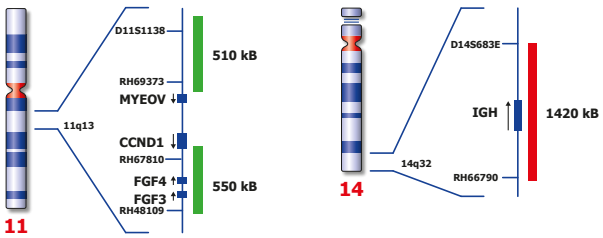
BACKGROUND

The most common chromosomal translocation in multiple myeloma (MM) is t(11;14), resulting in up-regulation of cyclin D1. In MM the breakpoints are scattered within a 360-kb region between CCND1 and MYEOV. This breakpoint is more proximal than the t(11;14) breakpoints observed in mantle cell lymphoma or other leukemias. Patients with MM who have t(11;14)(q13;q32) seem to have an aggressive clinical course.

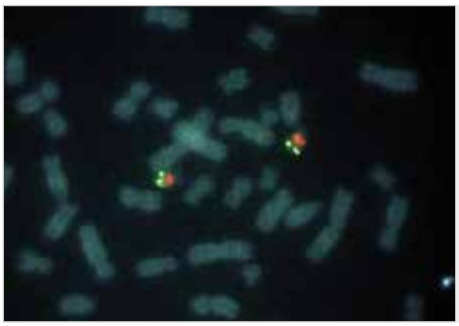
The MYEOV / IGH t(11;14)(q13;q32) Fusion specific FISH probe is optimized to detect the reciprocal translocation t(11;14) in a dual-color, dual-fusion assay.

REFERENCES

Janssen et al., 2000, Blood, 95; 2691-2698.
Fonseca et al, 2002, Blood, 99; 3735-3741.



"N25" / SHANK3



DiGeorge "N25" (22q11) / 22q13 (SHANK3) probe hybridized to a normal metaphase (2R2G).

DiGeorge "N25" (22q11) / 22q13 (SHANK3)

CODE	COLOR	FORMAT	STATUS
KBI-40102	Green/Red	10 test	IVD
KBI-45102	Green/Red	5 test	IVD

MENU

POSTNATAL

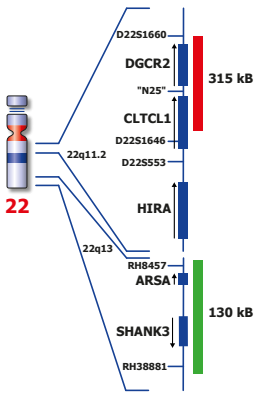
BACKGROUND

The DiGeorge "N25" FISH probe was the first commercial microdeletion probe for chromosome 22q and detects the locus D22S75. This marker is located between DGCR2 and CLTCL1 (Clathrin). Both genes have been extensively investigated and their role in DiGeorge syndrome is well established.

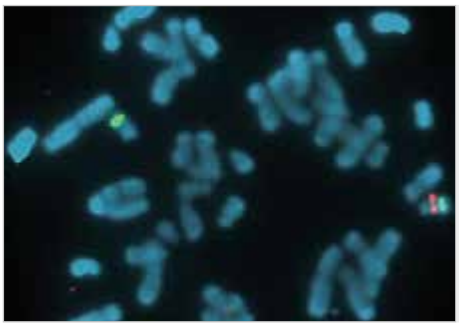
The DiGeorge "N25" region probe covers the marker "N25" (D22S75) and adjacent region of CLTCL1 (Clathrin gene region) and DGCR2 (DiGeorge critical region gene 2). The SHANK3 FISH probe at 22q13 is serving as internal control.

REFERENCES

Sirotkin et al, 1996, Hum. Mol. Genet., 5; 617-624.
Holmes et al, 1997, Hum. Mol. Genet., 6; 357-367.
Wilson, et al, 2003, J. Med. Genet., 40; 575-584.
Luciani, et al, 2003, J. Med. Genet., 40; 690-696.



NF1 / MPO



NF1 (17q11) / MPO (17q22) probe hybridized to patient material showing a deletion of NF1 gene region at 17q11 (1R2G).

NF1 (17q11) / MPO (17q22)

CODE	COLOR	FORMAT	STATUS
KBI-40114	Green/Red	10 test	IVD
KBI-45114	Green/Red	5 test	IVD

MENU

POSTNATAL

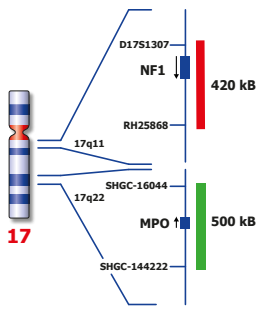
BACKGROUND

NF1, or Von Recklinghausen disease, is one of the most common hereditary neurocutaneous disorders in humans and one of the most common single gene syndromes. Clinically, NF1 is characterized by café-au-lait spots, freckling, skin neurofibroma, plexiform neurofibroma, bone defects, Lisch nodules and tumors of the central nervous system. The responsible gene, NF1 (neurofibromin), was identified on chromosome 17q11. Whole NF1 gene deletions occur in 4%-5% of individuals with NF1 and can be detected by FISH analysis.

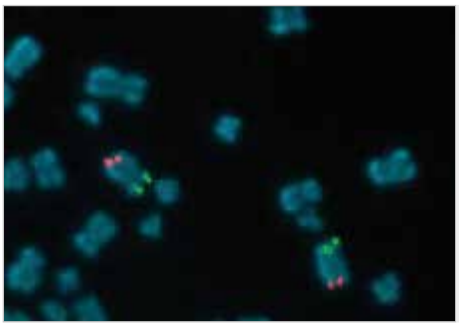
The NF1 (17q11) region probe is optimized to detect copy numbers of the NF1 gene region at 17q11.2. The MPO region specific FISH probe at 17q22 is included as control probe.

REFERENCES

Riva P et al, 2000, Am. J. Hum. Genet., 66; 100-109.
Dorschner et al, 2000, Hum. Mol. Genet., 9; 35-46.



NSD1 / TERT



NSD1 (5q35) / TERT (5p15) probe hybridized to a normal metaphase (2R2G).

NSD1 (5q35) / TERT (5p15)

CODE	COLOR	FORMAT	STATUS
KBI-40113	Green/Red	10 test	IVD
KBI-45113	Green/Red	5 test	IVD

MENU

POSTNATAL

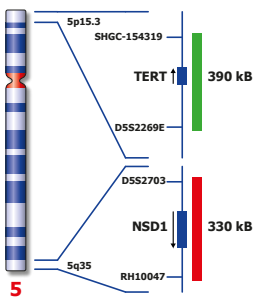
BACKGROUND

NSD1 microdeletions (chromosome 5q35) are the major cause of Sotos syndrome, and occur in some cases of Weaver syndrome. Sotos is a childhood overgrowth characterized by distinctive craniofacial features, advanced bone age, and mental retardation. Weaver syndrome is characterized by the same criteria but has its own specific facial characteristics. Sotos syndrome is inherited in an autosomal dominant manner. While 50% of Sotos patients in Asia are showing a chromosomal microdeletion, only 9% deletion cases are observed in the affected European population.

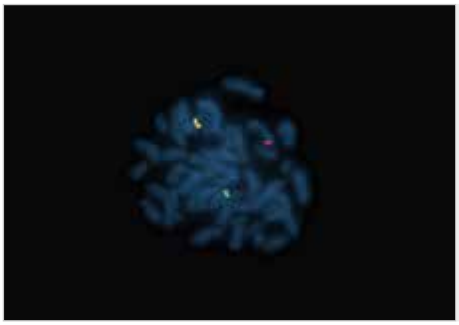
The NSD1 (5q35) region probe is optimized to detect copy numbers of the NSD1 gene region at 5q35.2. The TERT region specific FISH probe at 5p15 is included as control probe.

REFERENCES

Douglas et al, 2003, Am. J. Hum. Genet. 72; 132-143.
Rio et al, 2003, J. Med. Genet., 40; 436-440.



NUP98 Break



NUP98 (11p15) Break Probe hybridized to AML patient sample showing a rearrangement of 11p15 involving the NUP98 gene (1F1R1G).

Image kindly provided by Prof. Manuel R. Teixeira, Porto.

NUP98 (11p15) Break

CODE	COLOR	FORMAT	STATUS
KBI-10311	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

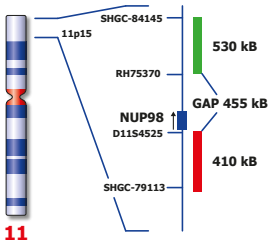
BACKGROUND

Nucleoporin 98kDa gene (NUP98) rearrangements have been identified in a wide range of hematologic malignancies, including acute myeloid leukemia (AML), acute lymphoblastic leukemia (ALL), chronic myeloid leukemia in blast crisis (CML-bc), myelodysplastic syndrome (MDS) and bilineage/biphenotypic leukemia. The NUP98 gene is highly promiscuous with regard to its recombination spectrum, as at least 28 different partner genes have been identified for NUP98 rearrangements, all forming in-frame fusion genes. Patients with NUP98 gene rearrangements have an aggressive clinical course and the outcome of treatment is disappointing.

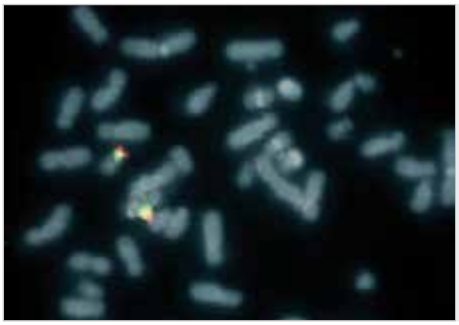
The NUP98 (11p15) Break FISH Probe is optimized to detect translocations involving the NUP98 gene region at 11p15 in a dual-color assay on metaphase/ interphase spreads, blood smears and bone marrow cells.

REFERENCES

Gough et al, 2011, Blood, 118; 62 47-6257.
Nebral et al, 2005, Haematologica, 90; 74 6-752.
Romana et al, 2006, Leukemia, 20; 696-70 6.



PAFAH1B1 / 17p11



Miller-Dieker PAFAH1B1 (17p13)/ Smith-Magenis RAI1 (17p11) probe hybridized to a normal metaphase (2RG).

Miller-Dieker PAFAH1B1 (17p13) / Smith-Magenis RAI1 (17p11)

CODE	COLOR	FORMAT	STATUS
KBI-40101	Green/Red	10 test	IVD
KBI-45101	Green/Red	5 test	IVD

MENU

POSTNATAL

BACKGROUND

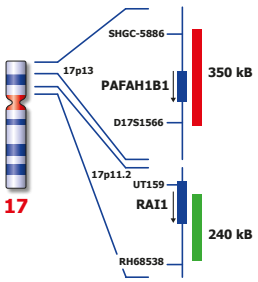
The Miller-Dieker lissencephaly syndrome appears to be caused by deletion of several genes on 17p including the PAFAH1B1 (previously known as LIS1) gene.

About 15% of patients with isolated lissencephaly and more than 90% of patients with Miller-Dieker syndrome have microdeletions in a critical 350-kb region at 17p13.3. Smith-Magenis is caused by a deletion of 17p11.2. The RAI1 (previously known as SMCR, KIAA1820 or SMS) gene region has been identified to be deleted in more than 90% of Smith-Magenis syndrome patients.

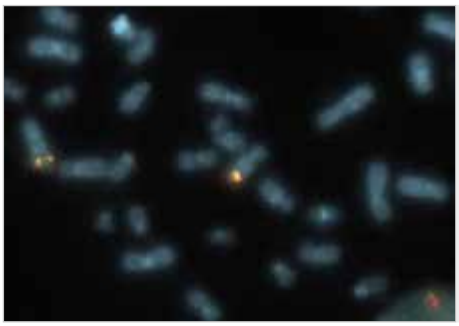
The Miller-Dieker PAFAH1B1 region probe is optimized to detect copy numbers of the PAFAH1B1 region at 17p13. The Smith-Magenis RAI1 region probe is optimized to detect copy numbers of the RAI1 gene region at 17p11.

REFERENCES

Kuwano et al, 1991, Am. J. Hum. Genet., 49; 707-714.
Cardoso et al, 2003, Am. J. Hum. Genet., 72; 918-930.
Smith et al, 1986, Am. J. Med. Genet., 24; 393-414.
Greenberg et al, 1991, Am. J. Med. Genet., 49; 1207-1218.
Vlangos et al, 2005, Am. J. Med. Genet., 132; 278-282.



PDGFRB Break



PDGFRB (5q32) Break probe hybridized to a normal metaphase (2RG).

PDGFRB (5q32) Break

CODE	COLOR	FORMAT	STATUS
KBI-10004	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

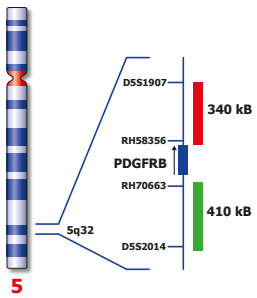
BACKGROUND

PDGFRB activation has been observed in patients with chronic myelomonocytic leukemia/atypical chronic myeloid leukemia and has been associated with over 50 translocation partners, the best known is the ETV6 gene on 12p13, causing a t(5;12) translocation. Cytogenetic responses are achieved with imatinib in patients with PDGFRB fusion positive, BCR / ABL1 negative CMPDs.

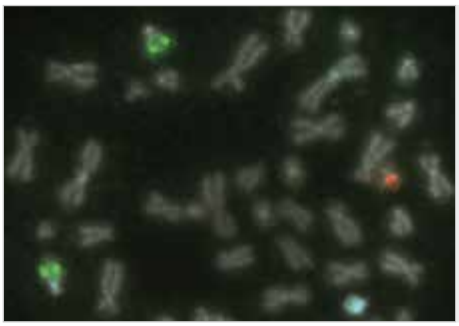
The PDGFRB (5q32) Break FISH probe is optimized to detect translocations involving the PDGFRB region at 5q32 in a dual-color, split assay.

REFERENCES

Wlodarska et al, 1997, Blood, 89; 1716-1722.
Wilkinson et al, 2003, Blood, 102; 4287-419.



PML / RARA



PML / RARA t(15;17) Fusion probe hybridized to a normal metaphase (2R2G).

PML / RARA t(15;17) Fusion

CODE	COLOR	FORMAT	STATUS
KBI-10302	Green/Red	10 test	IVD
KBI-12302	Green/Red	20 test	IVD

MENU

HEMATOPATHOLOGY

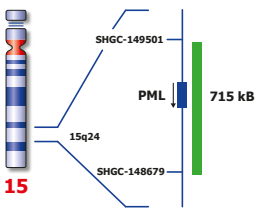
BACKGROUND

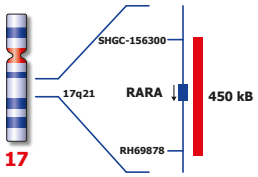
A structural rearrangement involving chromosomes 15 and 17 in acute promyelocytic leukemia (APL) was first recognized in 1977. The critical junction is located on the der(15) chromosome and consists of the 5' portion of PML fused to virtually all of the RARA gene. The PML / RARA fusion protein interacts with a complex of molecules known as nuclear co-repressors and histone deacetylase. This complex binds to the fusion protein and blocks the transcription of target genes. Other less common variant translocations fuse the RARA gene on 17q21 to the PLZF, NPM, NUMA, and STAT5b genes, respectively.

The PML / RARA t(15;17) Fusion specific FISH probe is optimized to detect the reciprocal translocation t(15;17) (q24;q21) in a dual-color, dual-fusion assay.

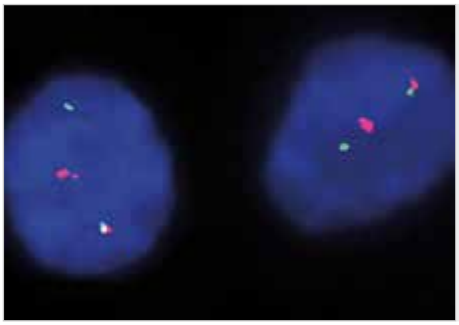
REFERENCES

Schad et al, 1994, Mayo Clin Proc, 69; 1047-1053.
Brockman et al, 2003, Cancer Genet Cytogenet, 145; 144-151.





PPARG Break



PPARG (3p25) Break probe hybridized to patient material showing a translocation at 3p25 (1RG1R1G).

Image kindly provided by Dr. Valent, Paris.

PPARG (3p25) Break

CODE	COLOR	FORMAT	STATUS
KBI-10707	Green/Red	10 test	IVD

MENU

HEAD, NECK AND ENDOCRINE PATHOLOGY

BACKGROUND

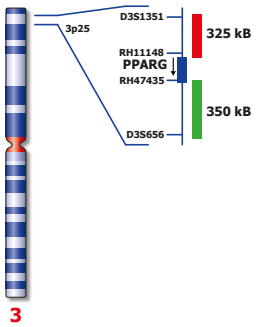
Follicular thyroid carcinoma is associated with the chromosomal translocation t(2;3)(q13;p25), fusing PAX8 (2q13) with the nuclear receptor, peroxisome proliferator-activated receptor _ (PPARG). PPARG is located in a breakpoint hot spot region, leading to recurrent alterations of this gene in thyroid tumors of follicular origin including carcinomas as well as adenomas with or without involvement of PAX8.

A break or split probe for PPARG is best used to analyze translocation of the PPARG (3p25) gene on formalin fixed paraffin embedded tissue for routine clinical diagnosis.

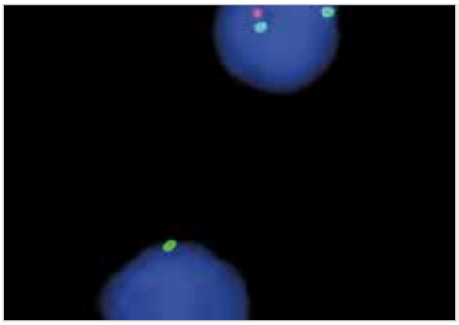
The PPARG (3p25) Break probe is optimized to detect translocations and amplification involving the PPARG gene region at 3p25 in a dual_color, split assay.

REFERENCES

French et al, 2003, Am J Pathol, 162; 1053-1060.
Drieschner et al, 2006, Thyroid, 16; 1091-1096.



PTEN / SE 10



PTEN (10q23) / SE 10 probe hybridized to prostate cancer material showing deletion of PTEN gene region at 10q23 (1R2G).

Image kindly provided by Portuguese Cancer Inst., Porto.

PTEN (10q23) / SE 10

CODE	COLOR	FORMAT	STATUS
KBI-10718	Green/Red	10 test	IVD

MENU

UROPATHOLOGY

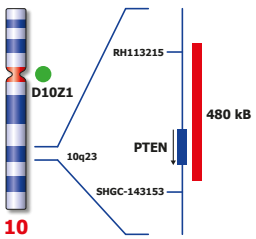
BACKGROUND

The gene 'phosphatase and tensin homolog' (PTEN), is a tumor suppressor located at chromosome region 10q23, that plays an essential role in the maintenance of chromosomal stability, cell survival and proliferation. Loss of PTEN has been found in a wide number of tumors, and its important role is demonstrated by the fact that it is the second most frequently mutated gene after TP53. Loss of PTEN significantly correlates with the advanced forms of gliomas, but also of prostate cancer and breast tumors.

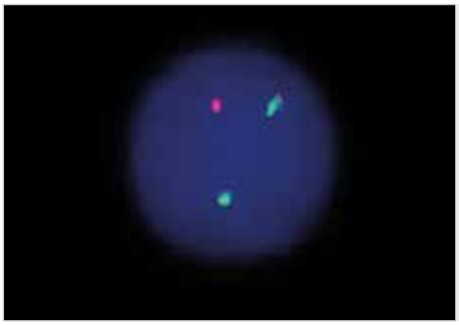
The PTEN (10q23) FISH probe is optimized to detect copy numbers of the PTEN gene region at region 10q23. The Chromosome 10 Satellite enumeration probe (SE 10) at D10Z1 is included to facilitate chromosome identification.

REFERENCES

Cairns et al, 1997, Cancer Res, 57 ; 4997-5000.
Hermans et al, 2004, Genes Chrom Cancer, 39; 171-184.



RARA Break



RARA (17q21) Break probe hybridized to patient material showing a translocation at 17q21 (1RG1R1G).

RARA (17q21) Break

CODE	COLOR	FORMAT	STATUS
KBI-10305	Green/Red	10 test	IVD

MENU

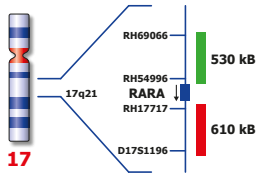
HEMATOPATHOLOGY

BACKGROUND

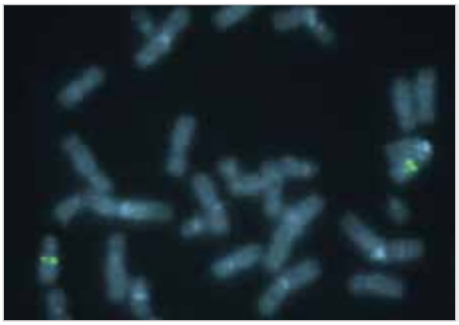
This break apart probe can detect the numerous types of recurrent rearrangement of the RAR_ (Retinoid acid receptor, alpha) gene with various gene partners (e.g., PML, NPM, MLL, FIP1L1, NuMA1, PLZF, amongst the others), leading to the formation of different reciprocal fusion proteins. The importance of retinoid metabolism in acute promyelocytic leukemia (APL) is highlighted by the numerous recent studies, but the different leukemogenic functions of the RAR_ fusion proteins in the neoplastic myeloid development still has to be defined, as well as the distinct clinical outcome of the patients with the variant forms of APL.

REFERENCES

Grimwade et al, 2000, Blood 96; 1297-1308.



RB1



RB1 (13q14) probe hybridized to a normal metaphase (2G).

RB1 (13q14)

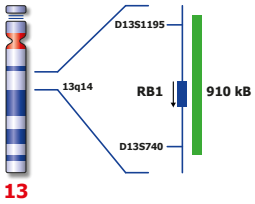
CODE	COLOR	FORMAT	STATUS
KBI-40001	Green	10 test	IVD

MENU

PRENATAL

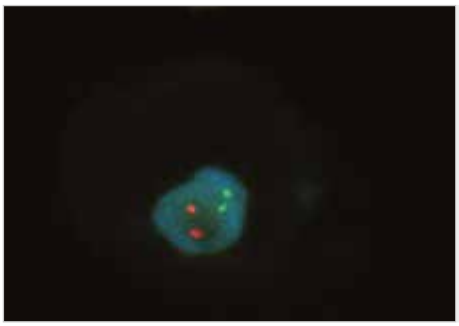
BACKGROUND

The chromosome 13 specific region probe is optimized to detect copy numbers of chromosome 13 at 13q14.2 on uncultered amniotic cells. In all PN combinations the 13q14 specific FISH probe is direct-labeled in green with PlatinumBright 495.



* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use RUO For Research Use Only. Not for use in diagnostic procedures ASR Analyte Specific Reagent GPR General Purpose Reagent

RB1 / RCAN1



RB1 (13q14)/RCAN1 (21q22) probe hybridized to a normal interphase (2R2G).

RB1 (13q14) / RCAN1 (21q22)

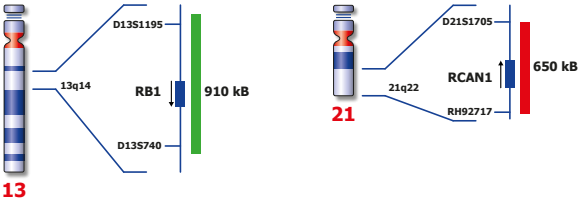
CODE	COLOR	FORMAT	STATUS
KBI-40003	Green/Red	10 test	IVD

MENU

PRENATAL

BACKGROUND

Trisomy 21 is one of the most common chromosomal abnormalities in live born children and causes Down syndrome. Molecular analysis has revealed that the 21q22.1-q22.3 region appears to contain the gene(s) responsible for the congenital heart disease observed in Down syndrome. Trisomy 13, also called Patau syndrome, is a chromosomal condition that is associated with severe mental retardation and certain physical abnormalities. The critical region has been reported to include 13q14-13q32 with variable expression, gene interactions,or interchromosomal effects. The RCAN1 (21q22) specific FISH probe is optimized to detect copy numbers of chromosome 21 at 21q22 on uncultured amniotic cells. The RB1 (13q14) specific FISH probe is optimized to detect copy numbers of chromosome 13 at 13q14 on uncultured amniotic cells.



RB1 / RCAN1, SE X/SE Y/ SE 18

RB1 (13q14) / RCAN1 (21q22), SE X (DXZ1) / SE Y (DYZ3) / SE 18 (D18Z1)

CODE	COLOR	FORMAT	STATUS
KBI-40005	Green/Red/Blue	10 test	IVD
KBI-40006	Green/Red/Blue	30 test	IVD
KBI-40007	Green/Red/Blue	50 test	IVD

MENU

PRENATAL

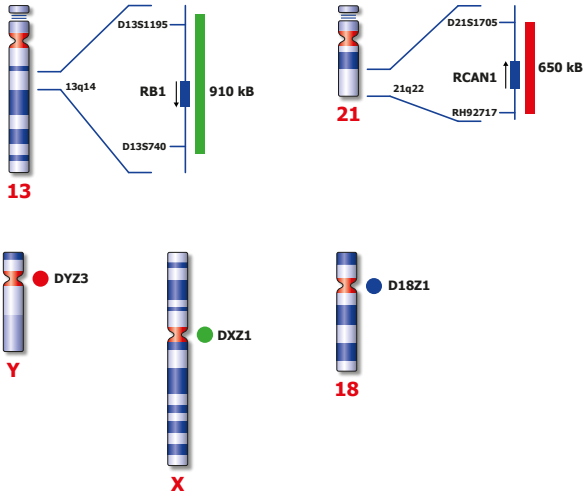
BACKGROUND

Trisomy 21 is one of the most common chromosomal abnormalities in live born children and causes Down syndrome.

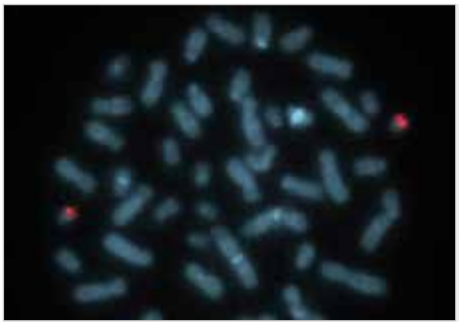
Trisomy 13, also called Patau syndrome, is a chromosomal condition that is associated with severe mental retardation and certain physical abnormalities. Trisomy 18 causing Edwards syndrome is the second most common autosomal trisomy after trisomy 21. The disorder/condition is characterized by severe symptoms. Turner syndrome occurs when females inherit only one X chromosome; their genotype is X0. Metafemales or triple-X females, inherit three X of more chromosomes. Klinefelter syndrome males inherit one or more extra X chromosomes; XYY syndrome males inherit an extra Y chromosome.

REFERENCES

Uchida et al, 2010, Cancer Genet Cytogenet, 203; 324-327.
Sen et al, 2002, J of Nat Canc Inst, 94; 1320-1329.
Lassmann et al, 2007, Clin Cancer Res, 13; 4083-4091.



RCAN1



RCAN1 (21q22) probe hybridized to a normal metaphase (2R).

RCAN1 (21q22)

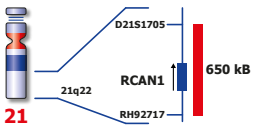
CODE	COLOR	FORMAT	STATUS
KBI-40002	Red	10 test	IVD

MENU

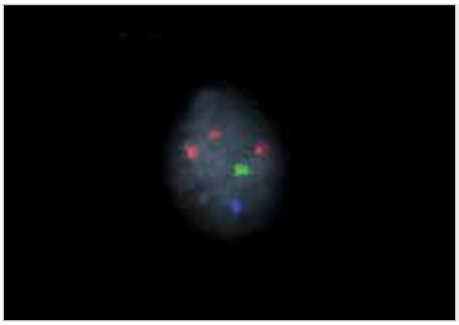
PRENATAL

BACKGROUND

The chromosome 21 specific region probe is optimized to detect copy numbers of chromosome 21 at 21q22.1 on uncultured amniotic cells. In all PN combinations the 21q specific FISH probe is direct-labeled in red with PlatinumBright 550.



RCAN1 / SE X / SE Y



Hybridization of the RCAN1 (21q22), SE X, SE Y probe to a male metaphase spread showing normal pattern (2R1G1B)

RCAN1 (21q22), SE X, SE Y

CODE	COLOR	FORMAT	STATUS
KBI-40008	Green/Red/Blue	20 test	IVD
KBI-45008	Green/Red/Blue	5 test	IVD

MENU

PRENATAL

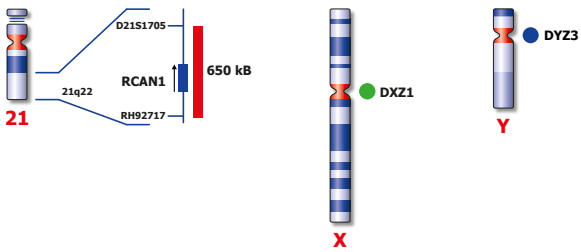
BACKGROUND

Chromosomal abnormalities involving the X and Y chromosome (sex chromosomes) are slightly less common than autosomal abnormalities and are usually much less severe in their effects. The high frequency of people with sex chromosome aberrations is partly due to the fact that they are rarely lethal conditions.

- Turner syndrome occurs when females inherit only one X chromosome - their genotype is X0.

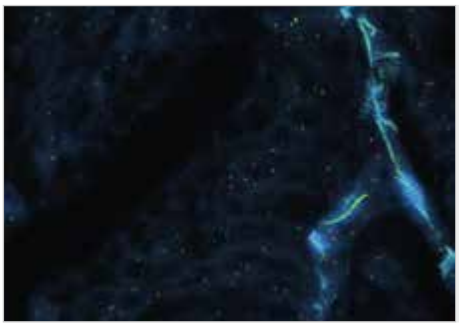
- Metafemales or triple-X females, inherit three X chromosomes - their genotype is XXX or more rarely XXXX or XXXXX.

- Klinefelter syndrome males inherit one or more extra X chromosomes - their genotype is XXY or more rarely XXXY, XXXXY, or XY / XXY mosaic.



* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use RUO For Research Use Only. Not for use in diagnostic procedures ASR Analyte Specific Reagent GPR General Purpose Reagent

RET Break



Hybridization of RET break probe to a tissue section showing abarrant pattern (1RG1R1G).

RET (10q11) Break

CODE	COLOR	FORMAT	STATUS
KBI-10753	Green/Red	10 test	IVD

MENU

LUNG PATHOLOGY

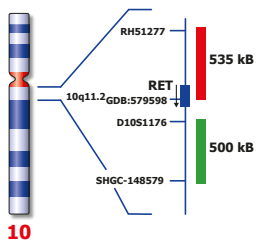
BACKGROUND

Pericentric inversion of chromosome 10 involving the RET (ret proto-oncogene) gene at chromosome 10q11 is known to increase expression of the RET gene by fusion with KIF5B (10p11). Translocations with other fusion partners have also been described. Elevated expression of RET is observed in non-small cell lung cancer (NSCLC), in which the function of tyrosine kinase-based therapeutics is based on the inhibition of such fusion proteins. Translocations involving RET have also been described in thyroid carcinomas.

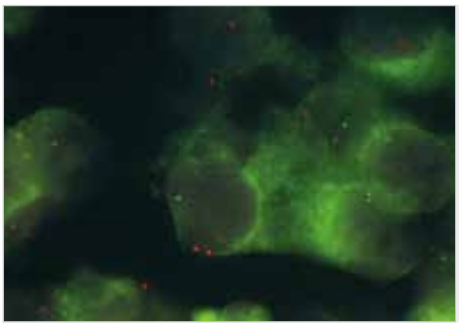
The RET (10q11) Break probe is optimized to detect translocations involving the RET gene region at 10q11.

REFERENCES

Chen et al, Cancer Genet Cytogenet, 2007, 178: 128-134.
Kohno et al, Nat Med, 2012, 18: 375-377.
Takeuchi et al, Nat Med, 2012, 18: 378-381.



ROS1 Break



Hybridization of ROS1 (6q22) Break Probe (KBI-10752) to a tissue section harboring a ROS1 rearrangement.

ROS1 (6q22) Break

CODE	COLOR	FORMAT	STATUS
KBI-10752	Green/Red	10 test	IVD

MENU

LUNG PATHOLOGY

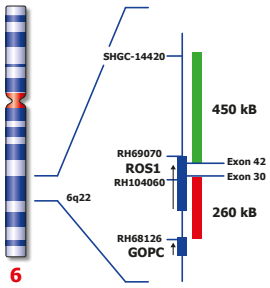
BACKGROUND

Translocations involving the ROS1 gene at chromosome 6q22 can increase expression of the gene by fusion with SLC34A2 (4p15), but also with other fusion partners. Elevated expression is observed in non-small cell lung cancer (NSCLC), where the success of tyrosine kinase-based therapeutics like Crizotinib (Xalkori) is based on inhibiting the activity of these fusion genes. The fusion of ROS1 to the GOPC (FIG) gene, by deletion of a 240 kb DNA fragment, also results in activation of a fusion gene.

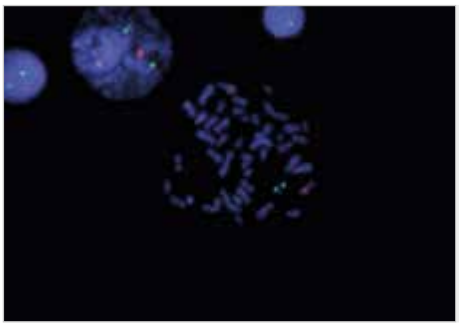
The ROS1 (6q22) Break probe is optimized to detect translocations involving the ROS1 gene region at the 6q22 locus, as well as the 240 kb deletion forming the ROS1-GOPC fusion gene, in a dual-color assay on formalin- fixed paraffin-embedded tissue samples.

REFERENCES

Charest et al, Genes Chromosomes Cancer, 2003, 37: 58-71.
Rikova et al, Cell, 2007, 131: 1190-120.
Rimkunas et al, Clin. Can. Res., 2012, 18: 4449-4457.
Takeuchi et al, Nat. Med., 2012, 18: 378-381.
Gu et al, PLoS, 2011, 6: e15640.



RUNX1 / RUNX1T1



Hybridization of RUNX1/ RUNX1T1 fusion probe to a metaphase spread showing normal pattern (2R2G).

RUNX1 / RUNX1T1 t(8;21) Fusion

CODE	COLOR	FORMAT	STATUS
KBI-10301	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

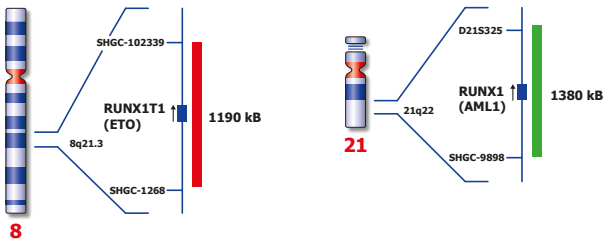
BACKGROUND

t(8;21)(q21;q22) is the most frequently observed karyotypic abnormality associated with acute myeloid leukemia (AML), especially in FAB M2. As a consequence of the translocation the RUNX1 (previously known as AML) (CBFA2) gene in the 21q22 region is fused to the RUNX1T1 (previously known as ETO) (MTG8) gene in the 8q21 region, resulting in one transcriptionally active gene on the 8q-derivative chromosome.

The RUNX1 / RUNX1T1 t(8;21)(q21;q22) specific FISH probe is optimized to detect the reciprocal translocation t(8;21) in a dual-color, dual-fusion assay.

REFERENCES

Sacchi et al, 1995, Genes Chrom Cancer, 79; 97-103.
Hagemeijer et al, 1998, Leukemia, 12; 96-101.



SE 18 (D18Z1)

SE 18 (D18Z1)

CODE	COLOR	FORMAT	STATUS
KBI-20018B	Blue	10 test	IVD

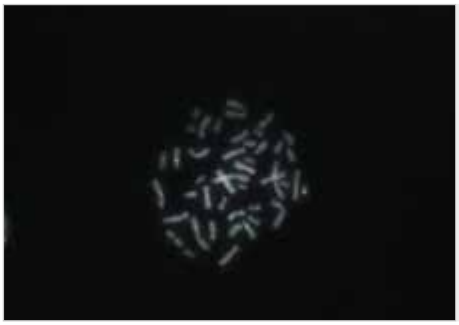
MENU

CONSTITUTIONAL

BACKGROUND

The chromosome 18 specific Satellite Enumeration (SE 18) FISH probe (D18Z1) is optimized to detect copy numbers of chromosome 18 at 18p11-18q11 on uncultured amniotic cells. In all PN combinations the 18 SE centromeric FISH probe is offered direct-labeld in blue with PlatinumBright415.

SE 7 / SE 8



Hybridization of SE 7 / SE 8 probe to a metaphase spread showing normal pattern (2R2G).

SE 7 (D7Z1) / SE 8 (D8Z1)

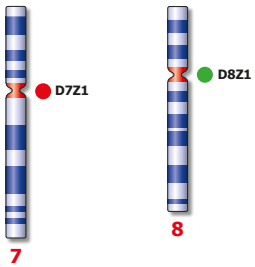
CODE	COLOR	FORMAT	STATUS
KBI-20031	Green/Red	10 test	IVD

MENU

CONSTITUTIONAL

BACKGROUND

Trisomy 8 is found as one of the genetic changes in CML, while loss of chromosome 7 is found in AML. The SE 7 (D7Z1) / SE 8 (D8Z1) FISH probes are optimized to detect repetitive sequences located in the pericentric heterochromatin of chromosome 7 and 8.



SE X / SE Y

Hybridization of SE X / SE Y probe to a male metaphase spread showing normal pattern (1R1G).

SE X (DXZ1) / SE Y (DYZ3)

CODE	COLOR	FORMAT	STATUS
KBI-20030	Green/Red	10 test	IVD

MENU

CONSTITUTIONAL

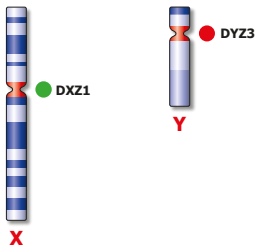
BACKGROUND

Chromosomal abnormalities involving the X and Y chromosome (sex chromosomes) are slightly less common than autosomal abnormalities and are usually much less severe in their effects. The high frequency of people with sex chromosome aberrations is partly due to the fact that they are rarely lethal conditions.

- Turner syndrome occurs when females inherit only one X chromosome - their genotype is X0.

- Metafemales or triple-X females, inherit three X chromosomes - their genotype is XXX or more rarely XXXX or XXXXX.

- Klinefelter syndrome males inherit one or more extra X chromosomes - their genotype is XXY or more rarely XXXY, XXXXY, or XY / XXY mosaic.



SE X / SE Y / SE 18

Hybridization of SE X / SE Y / SE 18 probe to a metaphase spread showing normal pattern (1R1G2B).

SE X (DXZ1) / SE Y (DYZ3) / SE 18 (D18Z1)

CODE	COLOR	FORMAT	STATUS
KBI-20032	Green/Red/Blue	10 test	IVD

MENU

CONSTITUTIONAL

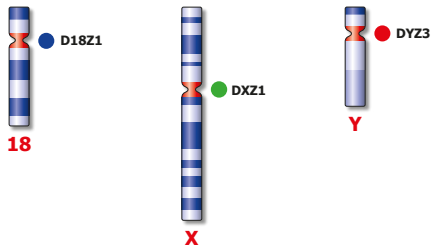
BACKGROUND

Chromosomal abnormalities involving the X and Y chromosome (sex chromosomes) are slightly less common than autosomal abnormalities and are usually much less severe in their effects. The high frequency of people with sex chromosome aberrations is partly due to the fact that they are rarely lethal conditions.

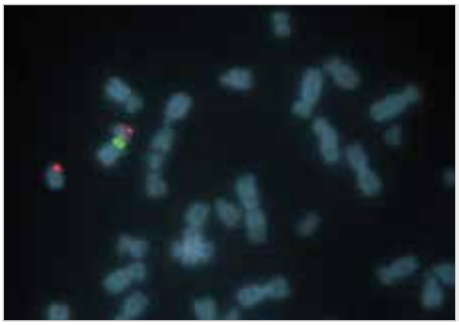
- Turner syndrome occurs when females inherit only one X chromosome - their genotype is X0.

- Metafemales or triple-X females, inherit three X chromosomes - their genotype is XXX or more rarely XXXX or XXXXX.

- Klinefelter syndrome males inherit one or more extra X chromosomes - their genotype is XXY or more rarely XXXY, XXXXY, or XY / XXY mosaic.



SHOX / SE X



Short Stature SHOX (Xp22) / SE X probe hybridized to a male metaphase (2R1G).

Short Stature SHOX (Xp22) / SE X

CODE	COLOR	FORMAT	STATUS
KBI-40112	Green/Red	10 test	IVD
KBI-45112	Green/Red	5 test	IVD

MENU

POSTNATAL

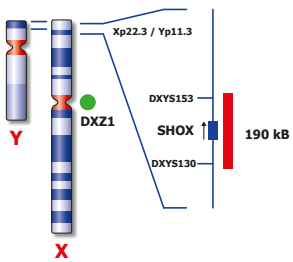
BACKGROUND

Individuals with SHOX-related short stature have disproportionate short stature and/or wrist abnormalities consistent with those described in Madelung deformity. The SHOX genes located on the pseudoautosomal regions of the X and Y chromosomes are the only genes known to be associated with SHOX-related haploinsufficiency.

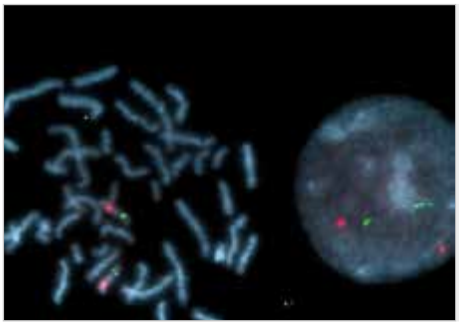
The SHOX region probe is optimized to detect copy numbers of the SHOX gene region at Xp22. The chromosome X Satellite Enumeration (SE X) FISH probe at DXZ1 is added to facilitate chromosome identification.

REFERENCES

Rao et al, 1997, Hum. Genet., 100; 236-239.
Morizio et al, 2003, Am. J. Med. Genet., 119; 293-296.



SNRPN / PML



Prader-Willi SNRPN (15q11) / PML (15q24) probe hybridized to a normal interphase/metaphase (2R2G).

Prader-Willi SNRPN (15q11) / PML (15q24)

CODE	COLOR	FORMAT	STATUS
KBI-40109	Green/Red	10 test	IVD
KBI-45109	Green/Red	5 test	IVD

MENU

POSTNATAL

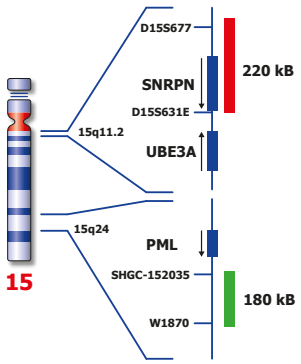
BACKGROUND

Prader-Willi Syndrome (PWS) is a clinically distinct disorder including diminished fetal activity, obesity, hypotonia, mental retardation, short stature, hypogonadotropic hypogonadism, strabismus, and small hands and feet.

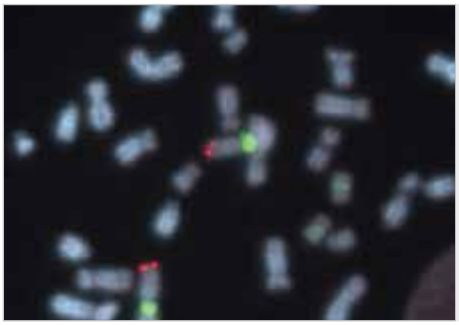
Approximately 70% of cases of PWS arise from paternal deletion of the 15q11-q13 region including the gene SNRPN (small nuclear ribonucleoprotein polypeptide N). The PWS SNRPN region probe is optimized to detect copy numbers of the SNRPN gene region at 15q11. The PML (promyelocytic leukemia) gene specific FISH probe at 15q24 is included as control probe.

REFERENCES

Knoll et al, 1989, Am. J. Med. Genet., 32; 285-290.
Ozcelik et al, 1992, Nat. Genet., 2; 265-269.



SRD / SE 1



SRD (1p36) / SE 1 probe hybridized to a normal metaphase (2R2G).

SRD (1p36) / SE 1 (1qh)

CODE	COLOR	FORMAT	STATUS
KBI-10712	Green/Red	10 test	IVD

MENU

NEUROPATHOLOGY

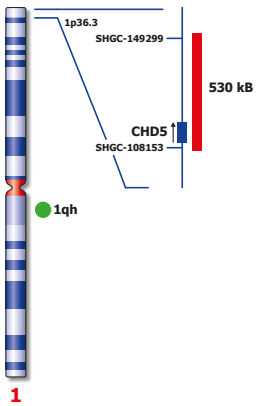
BACKGROUND

Neuroblastomas frequently have deletions of chromosome 1p and amplification of the MYCN oncogene. These deletions tend to be large and extend to the telomere, but a common region within sub-band 1p36.3 is consistently lost in these deletions. Inactivation of a tumor suppressor gene within 1p36.3 is believed to be associated with an increased risk for disease relapse.

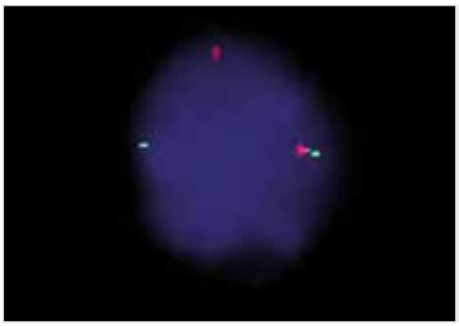
The SRD (1p36) FISH probe is optimized to detect copy numbers of the 1p36 region on chromosome 1. The chromosome 1 satellite enumeration probe (SE 1) at 1qh is included to facilitate chromosome identification.

REFERENCES

Caron et al, 1993, Nat Genet, 4: 187-190.
Cheng et al, 1995, Oncogene, 10: 291-297.
White et al, 2005, Oncogene, 24: 2684-2694.



SS18 Break



SS18 (18q11) Break probe hybridized to patient material showing translocation of the SYT (SS18) gene region at 18q11 (1RG1R1G).

SS18 (18q11) Break

CODE	COLOR	FORMAT	STATUS
KBI-10713	Green/Red	10 test	IVD

MENU

SOFT TISSUE PATHOLOGY

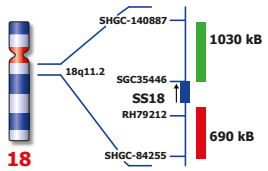
BACKGROUND

The characteristic chromosomal abnormality in Synovial Sarcoma t(X;18) (p11.2;q11.2) is present in 90% of the patients. This translocation results in the fusion of the synovial sarcoma translocation, chromosome 18 (SS18) gene to either of two distinct genes, SSX1 or SSX2, located on the X chromosome.

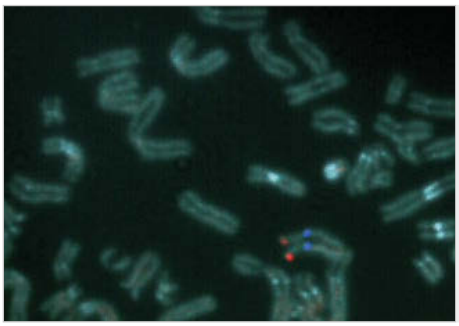
The SS18 (18q11) Break probe is optimized to detect translocations involving the SS18 gene region at 18q11 in a dual-color, split assay on paraffin embedded tissue sections.

REFERENCES

Kawai et al, 1998, NEJM, 338; 153-160.
Surace et al, 2004, LabInvest., 84; 1185-1192.



STS / KAL1 / SE X



STS (Xp22) / KAL1 (Xp22) / SE X Triple-Color probe hybridized to male patient material showing a deletion of the STS gene region (1R1B).

Material kindly provided by Necker hospital, Paris.

STS (Xp22) / KAL1 (Xp22) / SE X Triple-Color

CODE	COLOR	FORMAT	STATUS
KBI-40115	Green/Red/Blue	10 test	IVD
KBI-45115	Green/Red/Blue	5 test	IVD

MENU

POSTNATAL

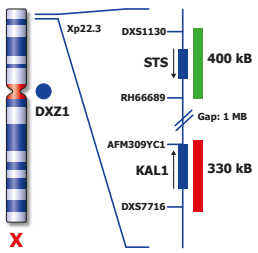
BACKGROUND

STS (Steroid Sulfatase) disease is a chromosome X-linked disorder associated with a microdeletion of the gene within the Xp22.3 region. Deletion of the steroid sulfatase gene has been detected in individuals with recessive X-linked ichtyosis, the disease been considered one of the most frequent human enzyme deficient disorders. KAL1 (Kallmann syndrome interval gene-1) maps to the Kallmann syndrome critical region on the distal short arm of the human X chromosome. Individuals with Kallmann syndrome suffers of hypogonadotropic hypogonadism and anosmia, with clinical features of variable phenotype. It affects approximately 1 in 8000 males and 1 in 40000 females.

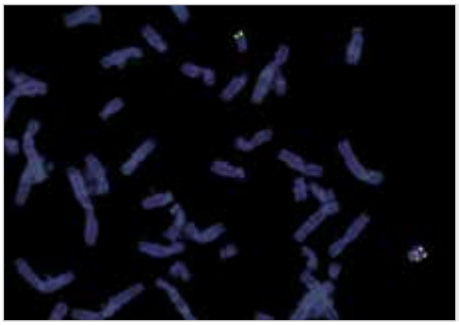
The STS (Xp22) region probe is optimized to detect copy numbers of the STS gene region at Xp22. The KAL1 (Xp 22) region probe is optimized to detect copy numbers of the KAL1 gene region at Xp22. The Chromosome X Satellite Enumeration (SE X) FISH probe at DXZ1 is included to facilitate chromosome identification.

REFERENCES

Alper in et al, 1997, J. Biol. Chem., 272; 20756-20763.
Meroni et al, 1996, Hum. Mol. Genet., 5; 423-431.



TBX1 / SHANK3



DiGeorge TBX1 (22q11) / 22q13 (SHANK3) probe hybridized to DiGeorge patient material showing a deletion of the TBX1 gene region at 22q11 (1R2G).

Image kindly provided by Dr. F. Girard- Lemaire Service de Cytogénétique (Dr. Flori), CHU Strasbourg.

DiGeorge TBX1 (22q11) / 22q13 (SHANK3)

CODE	COLOR	FORMAT	STATUS
KBI-40104	Green/Red	10 test	IVD
KBI-45104	Green/Red	5 test	IVD

MENU

POSTNATAL

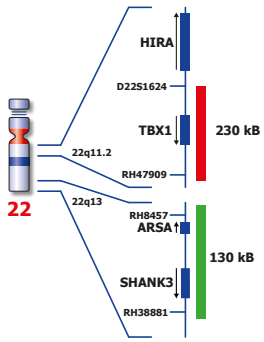
BACKGROUND

The 22q11 deletion in DiGeorge syndrome/VCFS is characterized by defects in the derivatives of the pharyngeal apparatus. TBX1, a member of the T-box transcription factor family, is required for normal development of the pharyngeal arch arteries. Haploinsufficiency of TBX1 has been demonstrated to be sufficient to generate at least one important component of the DiGeorge syndrome phenotype in mice. The TBX1 is also located within the minimal critical DiGeorge region in humans.

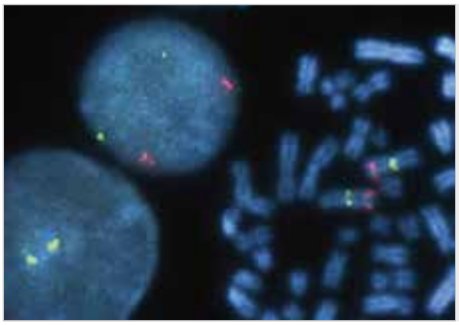
The DiGeorge TBX1 region probe is optimized to detect copy numbers of the TBX1 gene region at 22q11.2. The subtelomeric (ST) 22qter FISH probe is included as control probe. The SHANK3 FISH probe at 22q13 is serving as internal control.

REFERENCES

Lindsay et al, 2001, Nature, 410; 97-101.
Merscher et al, 2001, Cell, 104; 619-629.
Paylor et al, 2006, PNAS, 103; 7729-7734.



TERC / 3q11



TERC (3q26) / 3q11 probe hybridized to a normal interphase/metaphase (2R2G).

TERC (3q26) / 3q11

CODE	COLOR	FORMAT	STATUS
KBI-10110	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

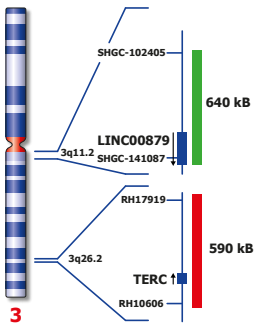
BACKGROUND

Amplification of the 3q26-q27 has a high prevalence in cervical, prostate, lung, and squamous cell carcinoma. This amplification can also be found to a lesser extent in CLL patients. The minimal region of amplification was refined to a 1- to 2-Mb genomic segment containing several potential cancer genes including TERC, the human telomerase RNA gene.

The TERC (3q26) specific FISH probe is optimized to detect copy numbers of the TERC (previously known as hTERC) gene region at region 3q26. The 3q11 region probe is included to facilitate chromosome identification.

REFERENCES

Arnold et al, 1996, Genes Chrom Cancer, 16; 46-54.
Soder et al, 1997, Oncogene, 14; 1013-1021.



TERC / MYC / SE 7

TERC (3q26) / MYC (8q24) / SE 7 Triple-Color probe hybridized to a PAP smear (destained) showing 3q26 and 8q24 amplification. The SE 7 control probe indicates a non-triploid karyotype (2B).

Image kindly provided by Dr. Weimer, Kiel.

TERC (3q26) / MYC (8q24) / SE 7 Triple-Color

CODE	COLOR	FORMAT	STATUS
KBI-10704	Green/Red/Blue	10 test	IVD

MENU

GYNEPATHOLOGY

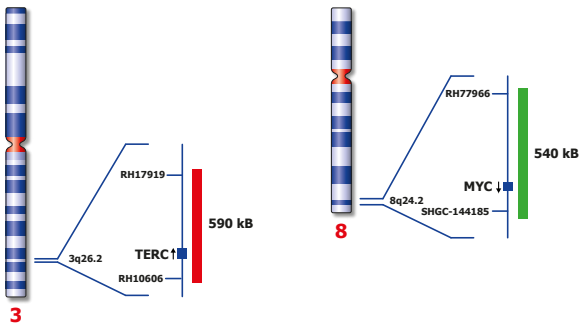
BACKGROUND

The most consistent chromosomal gain in aneuploid tumors of cervical squamous cell carcinoma mapped to chromosome arm 3q, including the human telomerase gene locus (TERC) at 3q26. Highlevel copy number increases were also mapped to chromosome 8. Integration of HPV (Human Papilloma Virus) DNA sequences into MYC chromosomal regions have been repeatedly observed in cases of invasive genital carcinomas and in cervical cancers.

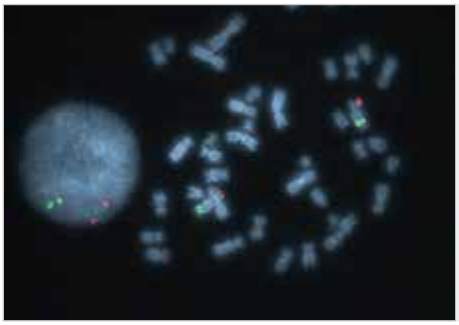
The TERC (3q26) FISH probe is optimized to detect copy numbers of the TERC gene region at region 3q26. The MYC (8q24) FISH probe is optimized to detect copy numbers of the MYC gene region at 8q24. The chromosome 7 satellite enumeration probe (SE 7) at D7Z1 is included as ploidy control.

REFERENCES

Xie et al, 2008, Geburtshilfe Frauenheilkunde, 68: 573.
Heselmeyer et al, 1996, PNAS, 93: 479-484.
Herrick et al, 2005, Cancer Res, 65: 1174-1179.



TERT / 5q31



TERT (5p15) / 5q31 probe hybridized to a normal interphase/metaphase (2R2G).

Image kindly provided by Dr. Mohr, Dresden.

TERT (5p15) / 5q31

CODE	COLOR	FORMAT	STATUS
KBI-10208	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

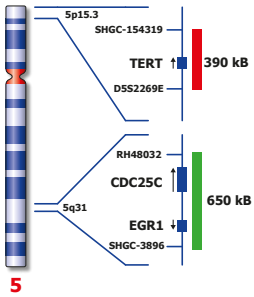
BACKGROUND

The TERT / 5q31 dual-color FISH probe can be used to detect deletions involving band 5q31 in MDS and RUNX1.

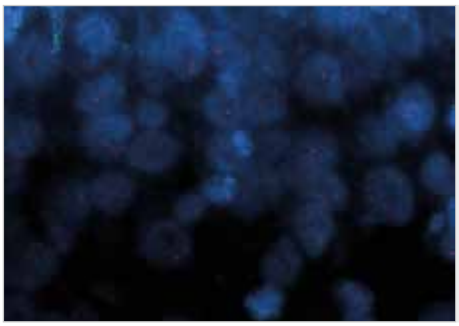
The 5q- specific FISH probe is optimized to detect copy numbers at the CDC25C / EGR1 gene region at 5q31. The TERT (previously known as hTERT) gene region at 5p15 is included to facilitate chromosome identification.

REFERENCES

Zhao et al, 1997, PNAS, 94; 6948-6053.
Horrigan et al, 2000, Blood, 95; 2372-2377.



TERT / 5q31 (tissue)



Hybridization of TERT / 5q31 Probe to a tissue section showing gain of the TERT region.

TERT (5p15) / 5q31 (tissue)

CODE	COLOR	FORMAT	STATUS
KBI-10709	Green/Red	10 test	IVD

MENU

LUNG PATHOLOGY

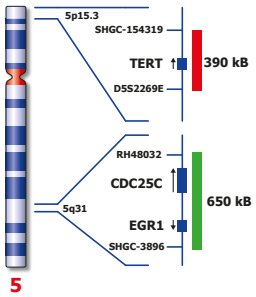
BACKGROUND

Amplifications of the TERT gene at 5p15 has been observed in a variety of cancers, particularly lung cancer, cervical tumors, and breast carcinomas. Several studies have revealed a high frequency of TERT gene amplification in human tumors, which indicates that the TERT gene may be a target for amplification during the transformation of human malignancies and that this genetic event probably contributes to a dysregulation of TERT / telomerase occurring in a subset of human tumors.

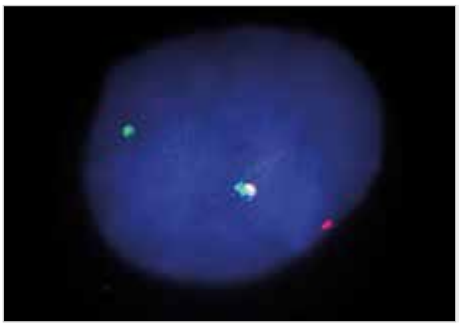
The TERT (5p15) FISH probe is designed as a dual-color assay to detect amplification at 5p15. The CDC25C / EGR1 (5q31) gene region probe is included as internal control.

REFERENCES

Bryce et al, 2000, Neoplasia, 2;197-201.
Zhang et al, 2000, Cancer Res, 60;6230-6235



TFE3 Break



TFE3 (Xp11) Break probe hybridized to renal cell carcinoma showing a translocation at Xp11 (1RG1R1G).

Image kindly provided by Dr. Desangles, Paris.

TFE3 (Xp11) Break

CODE	COLOR	FORMAT	STATUS
KBI-10741	Green/Red	10 test	IVD

MENU

HEAD, NECK AND ENDOCRINE PATHOLOGY

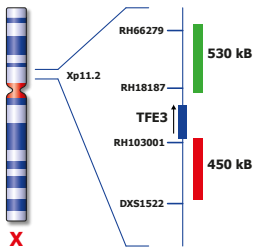
BACKGROUND

Abnormalities of Xp11.2 region have often been observed in papillary renal cell carcinomas and are sometimes the sole cytogenetic abnormality present. The transcription factor binding to IGHM enhancer 3 (TFE3) gene, which encodes a member of the helix-loop-helix family of transcription factors, is located in this critical region and can be fused to various other chromosomal regions by translocation. Known fusion partners are NONO (Xq12), PRCC (1q21), SFPQ (1p34), CLTC (17q23) and ASPSCR1 (17q25).

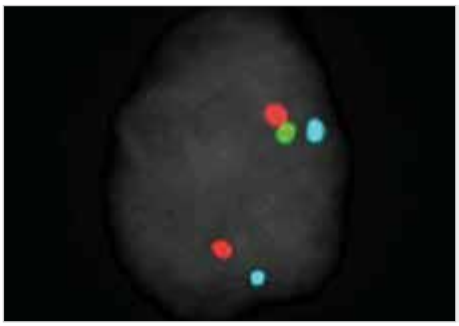
The TFE3 (Xp11) Break probe is optimized to detect translocations involving the TFE3 gene region at Xp11.2 in a dual-color, break assay.

REFERENCES

Sidhar et al, 1996, Hum Mol Genet, 5; 1333-1338.
Weterman et al, 1996, Proc Natl, Acad Sci, 93; 15294-15298.



TMPRSS2-ERG



TMPRSS2-ERG (21q22) rearrangement probe hybridized to prostate carcinoma tissue showing a deletion of the TMPRSS2 (21q22) gene region associated with TMPRSS2-ERG fusion (1RGB 1RB).

Image kindly provided by Dr. Teixeira, Porto.

TMPRSS2-ERG (21q22) Deletion, Break, Triple-Color

CODE	COLOR	FORMAT	STATUS
KBI-10726	Green/Red/Blue	10 test	IVD

MENU

UROPATHOLOGY

BACKGROUND

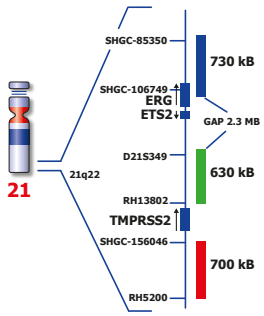
The transmembrane protease serine 2 gene (TMPRSS2) is involved in gene fusions with ERG, ETV1 or ETV4 in prostate cancer. It has been reported that the expression of the TMPRSS2-ERG fusion gene is a strong prognostic factor for the risk of prostate cancer recurrence in prostate cancer patients treated by surgery.

The TMPRSS2-ERG rearrangement probe is optimized to detect the deletion between TMPRSS2 and ERG at 21q22 associated with the TMPRSS2-ERG fusion in a triple-color deletion assay.

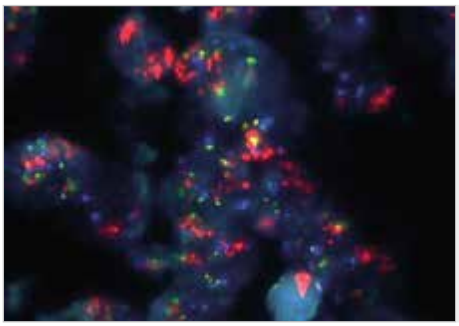
It also detects translocations involving the TMPRSS2 region such as ETV1 t(7;21), or ETV4 t(17;21).

REFERENCES

Perner et al, 2006 Cancer Res 66; 8337-8341.
Hermans et al, 2006, Cancer Res 66; 10658-10663.
Attard et al, 2008, Oncogene 27; 253-263.



TOP2A / ERBB2 / SE 17



TOP2A (17q21) / ERBB2 (17q12) / SE 17 TC probe hybridized to breast tumor tissue showing amplification of TOP2A / ERBB2.

TOP2A (17q21) / ERBB2 (17q12) / SE 17, Triple-Color

CODE	COLOR	FORMAT	STATUS
KBI-10735	Green/Red/Blue	10 test	IVD

MENU

BREAST PATHOLOGY

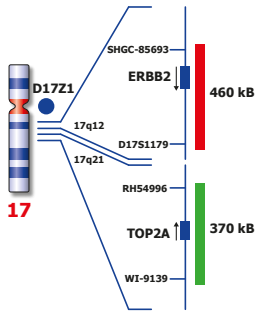
BACKGROUND

The presence of both TOP2A amplification and deletion in advanced cancer are associated with decreased survival, and occur frequently and concurrently with ERBB2 gene amplification (commonly refered to as HER2).

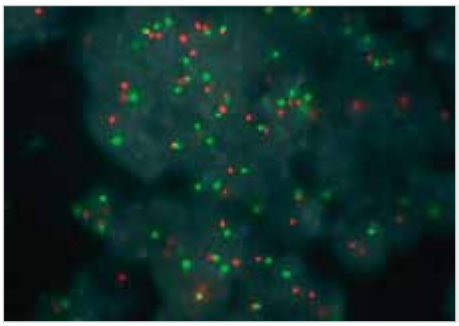
The TOP2A (17q21) / ERBB2 (17q12) / SE 17 probe is designed as a triple-color assay to detect amplification at 17q12 as well as amplifications or deletions at 17q21. The chromosome 17 satellite enumeration probe (SE 17) at D17Z1 in blue is included to facilitate chromosome identification/enumeration.

REFERENCES

Järvinen et al, 1999, Genes Chromosomes Cancer 26; 142-150.
Järvinen et al, 2000, Am. J. Pathology 156; 639-647.



TOP2A / SE 17



TOP2A (17q21) / SE 17 probe hybridized to breast tissue (2R2G).

TOP2A (17q21) / SE 17

CODE	COLOR	FORMAT	STATUS
KBI-10724	Green/Red	10 test	IVD

MENU

BREAST PATHOLOGY

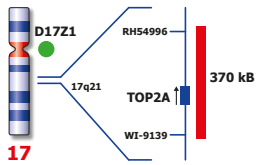
BACKGROUND

The Topoisomerase2A (TOP2A) enzyme, which is vital for the cell because of its role in cell replication and repair, catalyzes the relaxation of supercoiled DNA molecules to create a reversible double-strand DNA break. This enzyme is also the target of a number of cytotoxic agents, namely TOP2A inhibitors (anthracyclines, etoposide, teniposide).

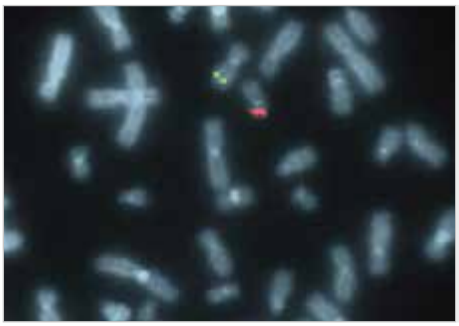
The TOP2A (17q21) / SE 17 FISH probe is optimized to detect amplifications (copy numbers) or deletions of the TOP2A gene region at the 17q21. The chromosome 17 satellite enumeration probe (SE 17) at D17Z1 is included to facilitate chromosome identification.

REFERENCES

Järvinen et al, 1999, Genes Chromosomes Cancer 26; 142-150.
Järvinen et al, 2000, Am. J. Pathology 156; 639-647.



TP53 / ATM



TP53 (17p13) / ATM (11q22) hybridized to a normal metaphase (2R2G).

TP53 (17p13) / ATM (11q22)

CODE	COLOR	FORMAT	STATUS
KBI-10114	Green/Red	10 test	IVD

MENU

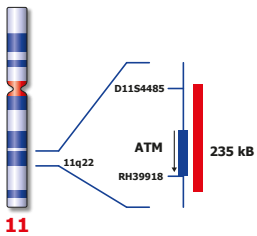
HEMATOPATHOLOGY

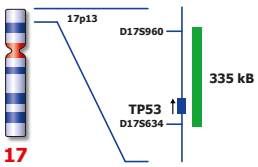
BACKGROUND

Deletion of TP53 (previously known as p53) and ATM are both indicating poor prognosis in CLL. Alterations of the TP53 (17p13) gene occur not only as somatic mutations in human malignancies, but also as germline mutations in some cancer-prone families with Li-Fraumeni syndrome. Deletions of TP53 are frequent in CLL and MM, usually associated with unfavorable prognosis. Deletions of the long arm of chromosome 11 (11q) are one of the most frequent structural chromosome aberrations in various types of lymphoproliferative disorders. A critical genomic region located in bands 11q22.3-q23.1 has been identified and contains among other genes the ATM (ataxia telangiectasia mutated) gene.

REFERENCES

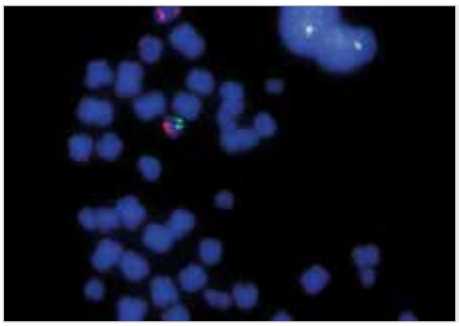
Boultwood J, 2001, J. Clin. Pathol., 54; 512-516.
Amiel A et al, 1997, Cancer Gener.Cytogenet,, 97; 97-100.
Drach J et al, 1998, Blood, 92; 802-809.
Doehner H et al, 1997, Blood, 7; 2516-2522.





* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use RUO For Research Use Only. Not for use in diagnostic procedures ASR Analyte Specific Reagent GPR General Purpose Reagent

TP53 / MPO



TP53 (17p13) / MPO (17q22) "ISO 17q" probe hybridized to peripheral blood of a CLL patient with an isochromosome 17 (3R1G).

Image kindly provided by Dr. Lana Harder, Kiel.

TP53 (17p13) / MPO (17q22) "ISO 17q"

CODE	COLOR	FORMAT	STATUS
KBI-10011	Green/Red	10 test	IVD

MENU

HEMATOPATHOLOGY

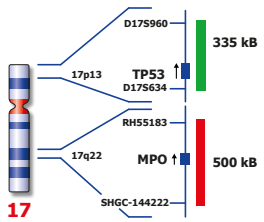
BACKGROUND

Isochromosome 17q is the most common isochromosome in cancer. It plays an important role in tumor development and progression. Hematologic malignancies such as chronic myeloid leukemia (CML) with isochromosome 17q carry a poor prognosis. Isochromosome 17q is the most common chromosome abnormality in primitive neuroectodermal tumors and medulloblastoma. Isochromosome 17q is, by convention, symbolized as i(17q).

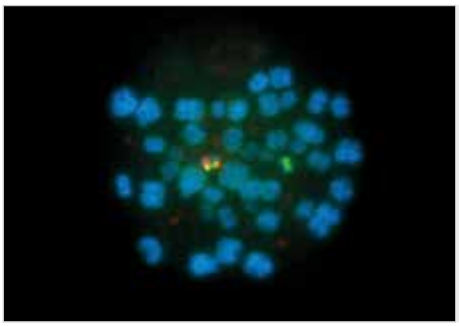
The TP53 (17p13) / MPO (17q22) "ISO 17q" FISH probe is optimized to detect copy numbers of the TP53 gene region at 17p13 and MPO gene region at 17q22. In case of i(17q) a signal pattern of three red signals for MPO (17q22) and one signal for TP53 at 17p13 is expected.

REFERENCES

Becher et al, 1990, Blood, 75; 1679-1683.
Fioretos et al, 1999, Blood, 94; 225-232.



TP53 / SE 17



TP53 (17p13) / SE 17 probe hybridized to patient material showing a 17p13 deletion at the TP53 gene region (1R2G).

TP53 (17p13) / SE 17

CODE	COLOR	FORMAT	STATUS
KBI-10112	Green/Red	10 test	IVD
KBI-12112	Green/Red	20 test	IVD

MENU

HEMATOPATHOLOGY

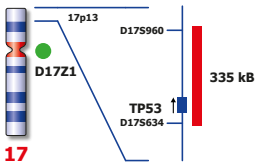
BACKGROUND

The TP53 tumor suppressor gene at 17p13, has been shown to be implicated in the control of normal cellular proliferation, differentiation, and apoptosis. Allelic loss, usually by deletion, and inactivation of TP53 have been reported in numerous tumor types and are associated with poor prognosis in CLL.

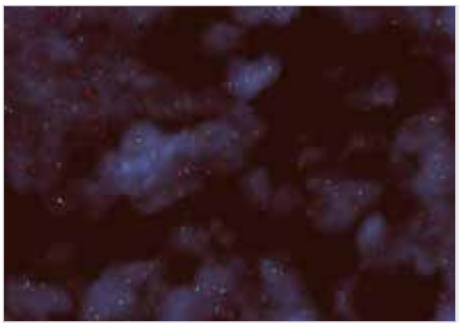
The TP53 (17p13) FISH probe is optimized to detect copy numbers of the TP53 gene region at 17p13. The chromosome 17 satellite enumeration probe (SE 17) at D17Z1 is included to facilitate chromosome identification. Kreatech has developed this probe for the specific use on cell material (KBI-10112 / KBI-12112), or for the use on tissue (KBI-10738).

REFERENCES

Amiel A et al, 1997, Cancer Gener. Cytogenet, 97; 97-100.
Drach J et al, 1998, Blood, 92; 802-809.



TP53 / SE 17 (tissue)



Hybridization of TP53 probe to a tissue section showing normal pattern (2R2G).

TP53 (17p13) / SE 17 (tissue)

CODE	COLOR	FORMAT	STATUS
KBI-10738	Green/Red	10 test	IVD

MENU

TUMOR DIFFERENTIATION

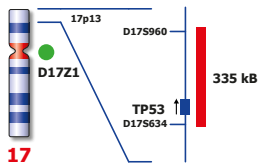
BACKGROUND

The TP53 tumor suppressor gene at 17p13, has been shown to be implicated in the control of normal cellular proliferation, differentiation, and apoptosis. Allelic loss, usually by deletion, and inactivation of TP53 have been reported in numerous tumor types and are associated with poor prognosis in CLL.

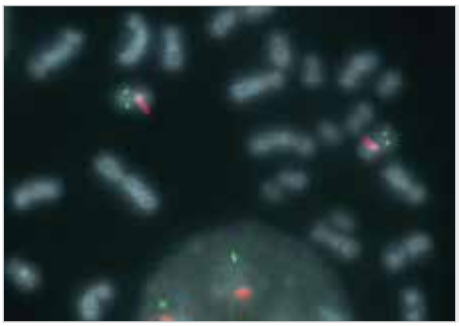
The TP53 (17p13) FISH probe is optimized to detect copy numbers of the TP53 gene region at 17p13. The chromosome 17 satellite enumeration probe (SE 17) at D17Z1 is included to facilitate chromosome identification. Kreatech has developed this probe for the specific use on cell material (KBI-10112 / KBI-12112), or for the use on tissue (KBI-10738).

REFERENCES

Amiel A et al, 1997, Cancer Gener.Cytogenet,, 97; 97-100.
Drach J et al, 1998, Blood, 92; 802-809.



UBE3A / PML



Angelman UBE3A (15q11) / PML (15q24) probe hybridized to a normal interphase/metaphase (2R2G).

Angelman UBE3A (15q11) / PML (15q24)

CODE	COLOR	FORMAT	STATUS
KBI-40110	Green/Red	10 test	IVD
KBI-45110	Green/Red	5 test	IVD

MENU

POSTNATAL

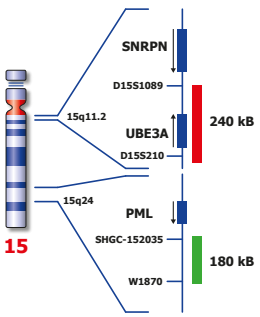
BACKGROUND

Angelman syndrome (AS) is characterized by severe developmental delay or mental retardation, severe speech impairment, gait ataxia and/or tremulousness of the limbs, and an unique behavior with an inappropriate happy demeanor that includes frequent laughing, smiling, and excitability. In addition, microcephaly and seizures are common. AS is caused by absence of a maternal contribution to the imprinted region on chromosome 15q11-q13 including the UBE3A gene.

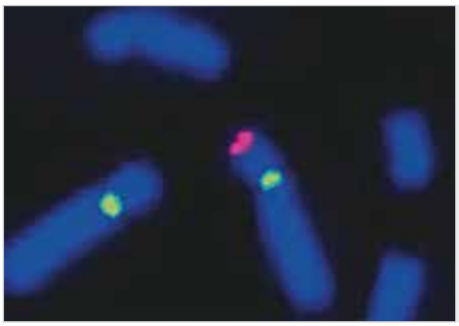
The AS UBE3A region probe is optimized to detect copy numbers of the UBE3A gene region at 15q11. The PML (promyelocytic leukemia) gene specific FISH probe at 15q24 is included as control probe.

REFERENCES

Matsuura et al, 1997, Nat. Genet., 15; 74-77.
Burger et al, 2002, Am. J. Med. Genet., 111; 233-237.



WHSC1 / SE 4



Wolf-Hirschhorn WHSC1 (4p16) / SE 4 probe hybridized to Wolf-Hirschhorn patient material showing a deletion of the WHSC1 gene region at 4p16 (1R2G).

Image kindly provided by Prof. Zollino, Rome.

Wolf-Hirschhorn WHSC1 (4p16) / SE 4

CODE	COLOR	FORMAT	STATUS
KBI-40107	Green/Red	10 test	IVD
KBI-45107	Green/Red	5 test	IVD

MENU

POSTNATAL

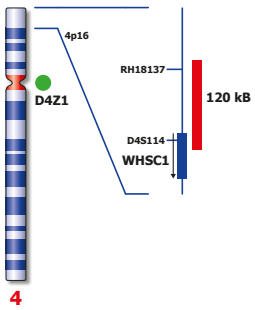
BACKGROUND

Wolf-Hirschhorn Syndrome (WHS) affected individuals have prenatal-onset growth deficiency followed by postnatal growth retardation and hypotonia with muscle under-development. Developmental delay/mental retardation of variable degree is present in all. FISH analysis using a WHSC1 specific FISH probe for chromosomal locus 4p16.3 detects more than 95% of deletions in WHS.

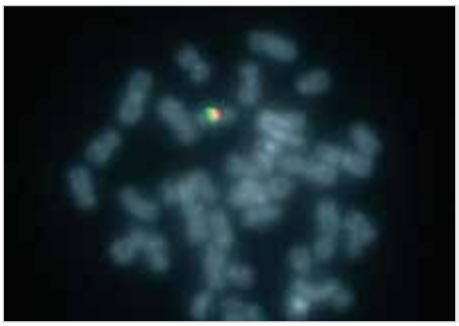
The Wolf-Hirschhorn region probe is optimized to detect copy numbers of the Wolf-Hirschhorn critical region at 4p16. The chromosome 4 Satellite Enumeration (SE 4) FISH probe at D4Z1 is included to facilitate chromosome identification.

REFERENCES

Gandelman et al, 1992, Am. J. Hum. Genet., 51; 571-578.
Wright et al, 1997, Hum. Mol. Genet., 6; 317-324.



XIST / SE X



X-Inactivation XIST (Xq13) / SE X probe hybridized to a male metaphase (1R1G).

X-Inactivation XIST (Xq13) / SE X

CODE	COLOR	FORMAT	STATUS
KBI-40108	Green/Red	10 test	IVD
KBI-45108	Green/Red	5 test	IVD

MENU

POSTNATAL

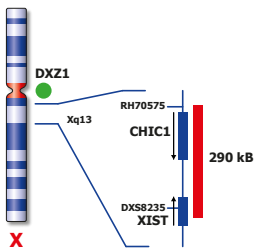
BACKGROUND

The XIST locus is expressed only from the inactive X chromosome, resides at the putative X inactivation center, and is considered a prime player in the initiation of mammalian X dosage compensation. The severe phenotype of human females whose karyotype includes tiny ring X chromosomes has been attributed to the inability of the small ring X chromosome to inactivate. Many of the ring chromosomes lack the XIST locus, consistent with XIST being necessary for cis inactivation.

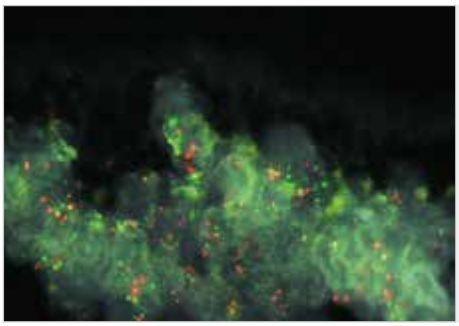
The XIST specific FISH probe is optimized to detect copy numbers of the XIST region at Xq13. The chromosome X Satellite Enumeration (SE X) FISH probe at DXZ1 is added to facilitate chromosome identification.

REFERENCES

Migeon et al, 1993, PNAS, 90; 12025-12029.
Jani et al, 1995, Genomics, 27; 182-188.



ZNF217 / 20q11



ZNF217 (20q13) / 20q11 probe hybridized to tissue (2R2G).

ZNF217 (20q13) / 20q11

CODE	COLOR	FORMAT	STATUS
KBI-10733	Green/Red	10 test	IVD

MENU

BREAST PATHOLOGY

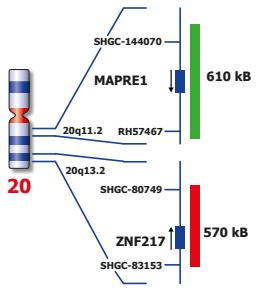
BACKGROUND

Zinc-finger protein 217 (ZNF217) is a Kruppel-like zinc-finger protein located at 20q13.2, within a region of recurrent maximal amplification in a variety of tumor types, and especially breast cancer cell lines and primary breast tumors. Copy number gains at 20q13 are also found in more than 25% of cancers of the ovary, colon, head and neck, brain, and pancreas. ZNF217 is considered a strong candidate oncogene that may have profound effects on cancer progression, which is transcribed in multiple normal tissues, and overexpressed in almost all cell lines and tumors in which it is amplified.

The ZNF217 (20q13) FISH probe is optimized to detect copy numbers of 20q at 20q13. The 20q11 probe is included to facilitate chromosome identification.

REFERENCES

Tanner M et al, 2000, Clin Cancer Res, 6; 1833-1839.
Ginestier C et al, 2006, Clin Cancer Res, 12; 4533-4544.



Product Name	Product code	Color	Content	Conc
SE 1 (1qh) Blue	KBI-20001B	Blue	10 test	5x
SE 1 (1qh) Green	KBI-20001G	Green	10 test	5x
SE 1 (1qh) Red	KBI-20001R	Red	10 test	5x
SE 2 (D2Z) Blue	KBI-20002B	Blue	10 test	5x
SE 2 (D2Z) Green	KBI-20002G	Green	10 test	5x
SE 2 (D2Z) Red	KBI-20002R	Red	10 test	5x
SE 3 (D3Z1) Blue	KBI-20003B	Blue	10 test	5x
SE 3 (D3Z1) Green	KBI-20003G	Green	10 test	5x
SE 3 (D3Z1) Red	KBI-20003R	Red	10 test	5x
SE 4 (D4Z1) Blue	KBI-20004B	Blue	10 test	5x
SE 4 (D4Z1) Green	KBI-20004G	Green	10 test	5x
SE 4 (D4Z1) Red	KBI-20004R	Red	10 test	5x
SE 6 (D6Z1) Blue	KBI-20006B	Blue	10 test	5x
SE 6 (D6Z1) Green	KBI-20006G	Green	10 test	5x
SE 6 (D6Z1) Red	KBI-20006R	Red	10 test	5x
SE 7 (D7Z1) Blue	KBI-20007B	Blue	10 test	5x
SE 7 (D7Z1) Green	KBI-20007G	Green	10 test	5x
SE 7 (D7Z1) Red	KBI-20007R	Blue	10 test	5x
SE 8 (D8Z1) Blue	KBI-20008B	Green	10 test	5x
SE 8 (D8Z1) Green	KBI-20008G	Red	10 test	5x
SE 8 (D8Z1) Red	KBI-20008R	Blue	10 test	5x
SE 9 (classical) Blue	KBI-20009B	Green	10 test	5x
SE 9 (classical) Green	KBI-20009G	Red	10 test	5x
SE 9 (classical) Red	KBI-20009R	Blue	10 test	5x
SE 10 (D10Z1) Blue	KBI-20010B	Green	10 test	5x
SE 10 (D10Z1) Green	KBI-20010G	Red	10 test	5x
SE 10 (D10Z1) Red	KBI-20010R	Blue	10 test	5x
SE 11 (D11Z1) Blue	KBI-20011B	Green	10 test	5x
SE 11 (D11Z1) Green	KBI-20011G	Red	10 test	5x
SE 11 (D11Z1) Red	KBI-20011R	Blue	10 test	5x
SE 12 (D12Z3) Blue	KBI-20012B	Green	10 test	5x
SE 12 (D12Z3) Green	KBI-20012G	Red	10 test	5x
SE 12 (D12Z3) Red	KBI-20012R	Blue	10 test	5x

Product Name	Product code	Color	Content	Conc
SE 15 (D15Z) Blue	KBI-20015B	Green	10 test	5x
SE 15 (D15Z) Green	KBI-20015G	Blue	10 test	5x
SE 15 (D15Z) Red	KBI-20015R	Green	10 test	5x
SE 16 (D16Z2) Blue	KBI-20016B	Red	10 test	5x
SE 16 (D16Z2) Green	KBI-20016G	Blue	10 test	5x
SE 16 (D16Z2) Red	KBI-20016R	Green	10 test	5x
SE 17 (D17Z1) Blue	KBI-20017B	Red	10 test	5x
SE 17 (D17Z1) Green	KBI-20017G	Blue	10 test	5x
SE 17 (D17Z1) Red	KBI-20017R	Green	10 test	5x
SE 18 (D18Z1) Blue	KBI-20018B	Red	10 test	5x
SE 18 (D18Z1) Green	KBI-20018G	Blue	10 test	5x
SE 18 (D18Z1) Red	KBI-20018R	Green	10 test	5x
SE 20 (D20Z1) Blue	KBI-20020B	Red	10 test	5x
SE 20 (D20Z1) Green	KBI-20020G	Blue	10 test	5x
SE 20 (D20Z1) Red	KBI-20020R	Green	10 test	5x
SE X (DXZ1) Blue	KBI-20023B	Red	10 test	5x
SE X (DXZ1) Green	KBI-20023G	Blue	10 test	5x
SE X (DXZ1) Red	KBI-20023R	Green	10 test	5x
SE Y (DYZ3) Blue	KBI-20024B	Blue	10 test	5x
SE Y (DYZ3) Green	KBI-20024G	Green	10 test	5x
SE Y (DYZ3) Red	KBI-20024R	Red	10 test	5x
SE Y class. q arm Blue	KBI-20025B	Blue	10 test	5x
SE Y class. q arm Green	KBI-20025G	Green	10 test	5x
SE Y class. q arm Red	KBI-20025R	Red	10 test	5x
SE 1/5/19 Blue	KBI-20026B	Blue	10 test	5x
SE 1/5/19 Green	KBI-20026G	Green	10 test	5x
SE 1/5/19 Red	KBI-20026R	Red	10 test	5x
SE 13/21 Blue	KBI-20027B	Blue	10 test	5x
SE 13/21 Green	KBI-20027G	Green	10 test	5x
SE 13/21 Red	KBI-20027R	Red	10 test	5x
SE 14/22 Blue	KBI-20028B	Blue	10 test	5x
SE 14/22 Green	KBI-20028G	Green	10 test	5x
SE 14/22 Red	KBI-20028R	Red	10 test	5x

Product Name	Product code	Color	Content	Conc
Whole Chromosome 1 Blue	KBI-30001B	Blue	5 test	5x
Whole Chromosome 1 Green	KBI-30001G	Green	5 test	5x
Whole Chromosome 1 Red	KBI-30001R	Red	5 test	5x
Whole Chromosome 2 Blue	KBI-30002B	Blue	5 test	5x
Whole Chromosome 2 Green	KBI-30002G	Green	5 test	5x
Whole Chromosome 2 Red	KBI-30002R	Red	5 test	5x
Whole Chromosome 3 Blue	KBI-30003B	Blue	5 test	5x
Whole Chromosome 3 Green	KBI-30003G	Green	5 test	5x
Whole Chromosome 3 Red	KBI-30003R	Red	5 test	5x
Whole Chromosome 4 Blue	KBI-30004B	Blue	5 test	5x
Whole Chromosome 4 Green	KBI-30004G	Green	5 test	5x
Whole Chromosome 4 Red	KBI-30004R	Red	5 test	5x
Whole Chromosome 5 Blue	KBI-30005B	Blue	5 test	5x
Whole Chromosome 5 Green	KBI-30005G	Green	5 test	5x
Whole Chromosome 5 Red	KBI-30005R	Red	5 test	5x
Whole Chromosome 6 Blue	KBI-30006B	Blue	5 test	5x
Whole Chromosome 6 Green	KBI-30006G	Green	5 test	5x
Whole Chromosome 6 Red	KBI-30006R	Red	5 test	5x
Whole Chromosome 7 Blue	KBI-30007B	Blue	5 test	5x
Whole Chromosome 7 Green	KBI-30007G	Green	5 test	5x
Whole Chromosome 7 Red	KBI-30007R	Red	5 test	5x
Whole Chromosome 8 Blue	KBI-30008B	Blue	5 test	5x
Whole Chromosome 8 Green	KBI-30008G	Green	5 test	5x
Whole Chromosome 8 Red	KBI-30008R	Red	5 test	5x
Whole Chromosome 9 Blue	KBI-30009B	Blue	5 test	5x
Whole Chromosome 9 Green	KBI-30009G	Green	5 test	5x
Whole Chromosome 9 Red	KBI-30009R	Red	5 test	5x
Whole Chromosome 10 Blue	KBI-30010B	Blue	5 test	5x
Whole Chromosome 10 Green	KBI-30010G	Green	5 test	5x
Whole Chromosome 10 Red	KBI-30010R	Red	5 test	5x
Whole Chromosome 11 Blue	KBI-30011B	Blue	5 test	5x
Whole Chromosome 11 Green	KBI-30011G	Green	5 test	5x
Whole Chromosome 11 Red	KBI-30011R	Red	5 test	5x
Whole Chromosome 12 Blue	KBI-30012B	Blue	5 test	5x
Whole Chromosome 12 Green	KBI-30012G	Green	5 test	5x
Whole Chromosome 12 Red	KBI-30012R	Red	5 test	5x

Product Name	Product code	Color	Content	Conc
Whole Chromosome 13 Blue	KBI-30013B	Blue	5 test	5x
Whole Chromosome 13 Green	KBI-30013G	Green	5 test	5x
Whole Chromosome 13 Red	KBI-30013R	Red	5 test	5x
Whole Chromosome 14 Blue	KBI-30014B	Blue	5 test	5x
Whole Chromosome 14 Green	KBI-30014G	Green	5 test	5x
Whole Chromosome 14 Red	KBI-30014R	Red	5 test	5x
Whole Chromosome 15 Blue	KBI-30015B	Blue	5 test	5x
Whole Chromosome 15 Green	KBI-30015G	Green	5 test	5x
Whole Chromosome 15 Red	KBI-30015R	Red	5 test	5x
Whole Chromosome 16 Blue	KBI-30016B	Blue	5 test	5x
Whole Chromosome 16 Green	KBI-30016G	Green	5 test	5x
Whole Chromosome 16 Red	KBI-30016R	Red	5 test	5x
Whole Chromosome 17 Blue	KBI-30017B	Blue	5 test	5x
Whole Chromosome 17 Green	KBI-30017G	Green	5 test	5x
Whole Chromosome 17 Red	KBI-30017R	Red	5 test	5x
Whole Chromosome 18 Blue	KBI-30018B	Blue	5 test	5x
Whole Chromosome 18 Green	KBI-30018G	Green	5 test	5x
Whole Chromosome 18 Red	KBI-30018R	Red	5 test	5x
Whole Chromosome 19 Blue	KBI-30019B	Blue	5 test	5x
Whole Chromosome 19 Green	KBI-30019G	Green	5 test	5x
Whole Chromosome 19 Red	KBI-30019R	Red	5 test	5x
Whole Chromosome 20 Blue	KBI-30020B	Blue	5 test	5x
Whole Chromosome 20 Green	KBI-30020G	Green	5 test	5x
Whole Chromosome 20 Red	KBI-30020R	Red	5 test	5x
Whole Chromosome 21 Blue	KBI-30021B	Blue	5 test	5x
Whole Chromosome 21 Green	KBI-30021G	Green	5 test	5x
Whole Chromosome 21 Red	KBI-30021R	Red	5 test	5x
Whole Chromosome 22 Blue	KBI-30022B	Blue	5 test	5x
Whole Chromosome 22 Green	KBI-30022G	Green	5 test	5x
Whole Chromosome 22 Red	KBI-30022R	Red	5 test	5x
Whole Chromosome X Blue	KBI-30023B	Blue	5 test	5x
Whole Chromosome X Green	KBI-30023G	Green	5 test	5x
Whole Chromosome X Red	KBI-30023R	Red	5 test	5x
Whole Chromosome Y Blue	KBI-30024B	Blue	5 test	5x
Whole Chromosome Y Green	KBI-30024G	Green	5 test	5x
Whole Chromosome Y Red	KBI-30024R	Red	5 test	5x

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent

Product Name	Product code	Color	Content	Conc
Sub Telomere 1pter Blue	KBI-40201B	Blue	5 test	5x
Sub Telomere 1pter Green	KBI-40201G	Green	5 test	5x
Sub Telomere 1pter Red	KBI-40201R	Red	5 test	5x
Sub Telomere 1qter Blue	KBI-40202B	Blue	5 test	5x
Sub Telomere 1qter Green	KBI-40202G	Green	5 test	5x
Sub Telomere 1qter Red	KBI-40202R	Red	5 test	5x
Sub Telomere 2pter Blue	KBI-40203B	Blue	5 test	5x
Sub Telomere 2pter Green	KBI-40203G	Green	5 test	5x
Sub Telomere 2pter Red	KBI-40203R	Red	5 test	5x
Sub Telomere 2qter Blue	KBI-40204B	Blue	5 test	5x
Sub Telomere 2qter Green	KBI-40204G	Green	5 test	5x
Sub Telomere 2qter Red	KBI-40204R	Red	5 test	5x
Sub Telomere 3pter Blue	KBI-40205B	Blue	5 test	5x
Sub Telomere 3pter Green	KBI-40205G	Green	5 test	5x
Sub Telomere 3pter Red	KBI-40205R	Red	5 test	5x
Sub Telomere 3qter Blue	KBI-40206B	Blue	5 test	5x
Sub Telomere 3qter Green	KBI-40206G	Green	5 test	5x
Sub Telomere 3qter Red	KBI-40206R	Red	5 test	5x
Sub Telomere 4pter Blue	KBI-40207B	Blue	5 test	5x
Sub Telomere 4pter Green	KBI-40207G	Green	5 test	5x
Sub Telomere 4pter Red	KBI-40207R	Red	5 test	5x
Sub Telomere 4qter Blue	KBI-40208B	Blue	5 test	5x
Sub Telomere 4qter Green	KBI-40208G	Green	5 test	5x
Sub Telomere 4qter Red	KBI-40208R	Red	5 test	5x
Sub Telomere 5pter Blue	KBI-40209B	Blue	5 test	5x
Sub Telomere 5pter Green	KBI-40209G	Green	5 test	5x
Sub Telomere 5pter Red	KBI-40209R	Red	5 test	5x
Sub Telomere 5qter Blue	KBI-40210B	Blue	5 test	5x
Sub Telomere 5qter Green	KBI-40210G	Green	5 test	5x
Sub Telomere 5qter Red	KBI-40210R	Red	5 test	5x
Sub Telomere 6pter Blue	KBI-40211B	Blue	5 test	5x
Sub Telomere 6pter Green	KBI-40211G	Green	5 test	5x
Sub Telomere 6pter Red	KBI-40211R	Red	5 test	5x
Sub Telomere 6qter Blue	KBI-40212B	Blue	5 test	5x
Sub Telomere 6qter Green	KBI-40212G	Green	5 test	5x
Sub Telomere 6qter Red	KBI-40212R	Red	5 test	5x
Sub Telomere 7pter Blue	KBI-40213B	Blue	5 test	5x
Sub Telomere 7pter Green	KBI-40213G	Green	5 test	5x
Sub Telomere 7pter Red	KBI-40213R	Red	5 test	5x
Sub Telomere 7qter Blue	KBI-40214B	Blue	5 test	5x
Sub Telomere 7qter Green	KBI-40214G	Green	5 test	5x
Sub Telomere 7qter Red	KBI-40214R	Red	5 test	5x
Sub Telomere 8pter Blue	KBI-40215B	Blue	5 test	5x
Sub Telomere 8pter Green	KBI-40215G	Green	5 test	5x
Sub Telomere 8pter Red	KBI-40215R	Red	5 test	5x
Sub Telomere 8qter Blue	KBI-40216B	Blue	5 test	5x
Sub Telomere 8qter Green	KBI-40216G	Green	5 test	5x
Sub Telomere 8qter Red	KBI-40216R	Red	5 test	5x
Sub Telomere 9pter Blue	KBI-40217B	Blue	5 test	5x
Sub Telomere 9pter Green	KBI-40217G	Green	5 test	5x
Sub Telomere 9pter Red	KBI-40217R	Red	5 test	5x
Sub Telomere 9qter Blue	KBI-40218B	Blue	5 test	5x
Sub Telomere 9qter Green	KBI-40218G	Green	5 test	5x
Sub Telomere 9qter Red	KBI-40218R	Red	5 test	5x
Sub Telomere 10pter Blue	KBI-40219B	Blue	5 test	5x
Sub Telomere 10pter Green	KBI-40219G	Green	5 test	5x
Sub Telomere 10pter Red	KBI-40219R	Red	5 test	5x
Sub Telomere 10qter Blue	KBI-40220B	Blue	5 test	5x
Sub Telomere 10qter Green	KBI-40220G	Green	5 test	5x
Sub Telomere 10qter Red	KBI-40220R	Red	5 test	5x
Sub Telomere 11pter Blue	KBI-40221B	Blue	5 test	5x
Sub Telomere 11pter Green	KBI-40221G	Green	5 test	5x
Sub Telomere 11pter Red	KBI-40221R	Red	5 test	5x
Sub Telomere 11qter Blue	KBI-40222B	Blue	5 test	5x
Sub Telomere 11qter Green	KBI-40222G	Green	5 test	5x
Sub Telomere 11qter Red	KBI-40222R	Red	5 test	5x
Sub Telomere 12pter Blue	KBI-40223B	Blue	5 test	5x
Sub Telomere 12pter Green	KBI-40223G	Green	5 test	5x
Sub Telomere 12pter Red	KBI-40223R	Red	5 test	5x
Sub Telomere 12qter Blue	KBI-40224B	Blue	5 test	5x
Sub Telomere 12qter Green	KBI-40224G	Green	5 test	5x
Sub Telomere 12qter Red	KBI-40224R	Red	5 test	5x
Sub Telomere 13qter Blue	KBI-40225B	Blue	5 test	5x
Sub Telomere 13qter Green	KBI-40225G	Green	5 test	5x
Sub Telomere 13qter Red	KBI-40225R	Red	5 test	5x
Sub Telomere 14qter Blue	KBI-40226B	Blue	5 test	5x
Sub Telomere 14qter Green	KBI-40226G	Green	5 test	5x
Sub Telomere 14qter Red	KBI-40226R	Red	5 test	5x
Sub Telomere 15qter Blue	KBI-40227B	Blue	5 test	5x
Sub Telomere 15qter Green	KBI-40227G	Green	5 test	5x
Sub Telomere 15qter Red	KBI-40227R	Red	5 test	5x
Sub Telomere 16pter Blue	KBI-40228B	Blue	5 test	5x
Sub Telomere 16pter Green	KBI-40228G	Green	5 test	5x
Sub Telomere 16pter Red	KBI-40228R	Red	5 test	5x
Sub Telomere 16qter Blue	KBI-40229B	Blue	5 test	5x
Sub Telomere 16qter Green	KBI-40229G	Green	5 test	5x
Sub Telomere 16qter Red	KBI-40229R	Red	5 test	5x
Sub Telomere 17pter Blue	KBI-40230B	Blue	5 test	5x
Sub Telomere 17pter Green	KBI-40230G	Green	5 test	5x
Sub Telomere 17pter Red	KBI-40230R	Red	5 test	5x
Sub Telomere 17qter Blue	KBI-40231B	Blue	5 test	5x
Sub Telomere 17qter Green	KBI-40231G	Green	5 test	5x
Sub Telomere 17qter Red	KBI-40231R	Red	5 test	5x
Sub Telomere 18pter Blue	KBI-40232B	Blue	5 test	5x
Sub Telomere 18pter Green	KBI-40232G	Green	5 test	5x
Sub Telomere 18pter Red	KBI-40232R	Red	5 test	5x
Sub Telomere 18qter Blue	KBI-40233B	Blue	5 test	5x
Sub Telomere 18qter Green	KBI-40233G	Green	5 test	5x

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent

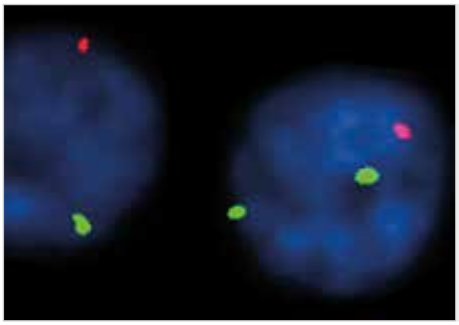
Product Name	Product code	Color	Content	Conc
Sub Telomere 18qter Red	KBI-40233R	Red	5 test	5x
Sub Telomere 19pter Blue	KBI-40234B	Blue	5 test	5x
Sub Telomere 19pter Green	KBI-40234G	Green	5 test	5x
Sub Telomere 19pter Red	KBI-40234R	Red	5 test	5x
Sub Telomere 19qter Blue	KBI-40235B	Blue	5 test	5x
Sub Telomere 19qter Green	KBI-40235G	Green	5 test	5x
Sub Telomere 19qter Red	KBI-40235R	Red	5 test	5x
Sub Telomere 20pter Blue	KBI-40236B	Blue	5 test	5x
Sub Telomere 20pter Green	KBI-40236G	Green	5 test	5x
Sub Telomere 20pter Red	KBI-40236R	Red	5 test	5x
Sub Telomere 20qter Blue	KBI-40237B	Blue	5 test	5x
Sub Telomere 20qter Green	KBI-40237G	Green	5 test	5x
Sub Telomere 20qter Red	KBI-40237R	Red	5 test	5x

Product Name	Product code	Color	Content	Conc
Sub Telomere 21qter Blue	KBI-40238B	Blue	5 test	5x
Sub Telomere 21qter Green	KBI-40238G	Green	5 test	5x
Sub Telomere 21qter Red	KBI-40238R	Red	5 test	5x
Sub Telomere 22qter Blue	KBI-40239B	Blue	5 test	5x
Sub Telomere 22qter Green	KBI-40239G	Green	5 test	5x
Sub Telomere 22qter Red	KBI-40239R	Red	5 test	5x
Sub Telomere XYpter Blue	KBI-40240B	Blue	5 test	5x
Sub Telomere XYpter Green	KBI-40240G	Green	5 test	5x
Sub Telomere XYpter Red	KBI-40240R	Red	5 test	5x
Sub Telomere XYqter Blue	KBI-40241B	Blue	5 test	5x
Sub Telomere XYqter Green	KBI-40241G	Green	5 test	5x
Sub Telomere XYqter Red	KBI-40241R	Red	5 test	5x

RUO PROBES

RUO PROBES

11q23 / DLEU1



11q23 / DLEU1 13q14 probe hybridized to MM patient material showing a 13q14 deletion (1R2G).

Image kindly provided by Prof. Jauch, Heidelberg.

11q23 / DLEU1 (13q14)

CODE	COLOR	FORMAT	STATUS
KI-10502	Green/Red	100 µL	RUO

MENU

RESEARCH

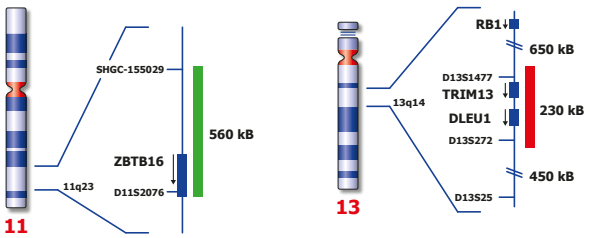
BACKGROUND

Hybridization results delineated 11q23 and 11q25 as the most frequently gained regions in Multiple Myeloma (MM) which supports a relevant pathogenetic role of genes in this region. Deletions of 13q14 are frequently detected by interphase FISH in patients with newly diagnosed MM, correlate with increased proliferative activity, and represent an independent adverse prognostic feature in MM.

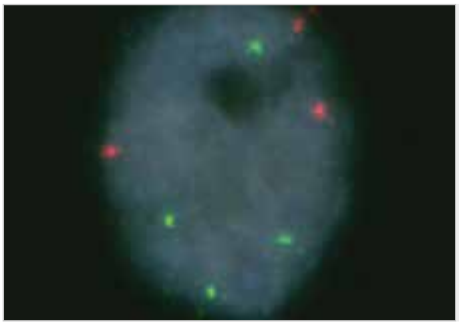
The 11q23 specific FISH probe is optimized to detect copy numbers at 11q23. The DLEU1 (13q14) specific DNA region is optimized to detect copy numbers of the DLEU1 (previously known as DLEU) gene region at 13q14.

REFERENCES

Gonzalez et al, 2004, Haematologica, 89; 1213-1218.
Cremer et al, 2005, Genes Chrom Cancer, 44; 194-203.



15q22 / 6q21



15q22 / 6q21 hybridized to MM patient material with gain of both critical regions 6q21 and 15q22.

Image kindly provided by Prof. Jauch, Heidelberg.

15q22 / 6q21

CODE	COLOR	FORMAT	STATUS
KI-10504	Green/Red	100 µL	RUO

MENU

RESEARCH

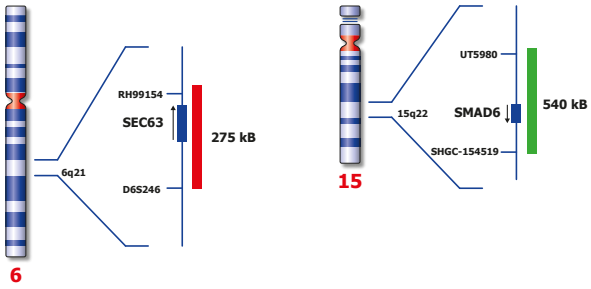
BACKGROUND

Chromosome 6q amplifications encompassing 6q21-22 have been observed in MM including the same region as in CLL. Amplification including band 15q22 has been reported in MM. The 15q22 specific FISH probe is optimized to detect copy numbers at 15q22.

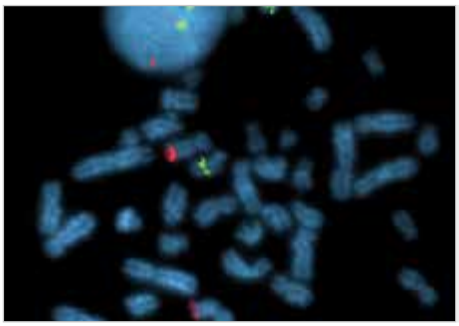
The 6q21 specific DNA region is optimized to detect copy numbers at 6q21.

REFERENCES

Cremer et al, 2005, Genes Chrom Cancer, 44; 194-203.



15q22 / 9q34



15q22 / 9q34 hybridized to a normal interphase/ metaphase (2R2G).

15q22 / 9q34

CODE	COLOR	FORMAT	STATUS
KI-10508	Green/Red	100 µL	RUO

MENU

RESEARCH

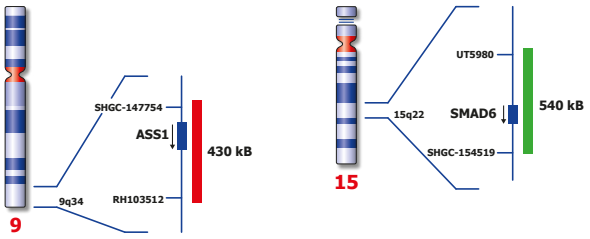
BACKGROUND

The hyperdiploid subtype in MM is defined by presence of multiple trisomic chromosomes. Combination of the chromosome 9q34 and 15q22 specific regions are important regions to detect the hyperdiploid subtype in MM which is usually associated with a low frequency of IGH translocations.

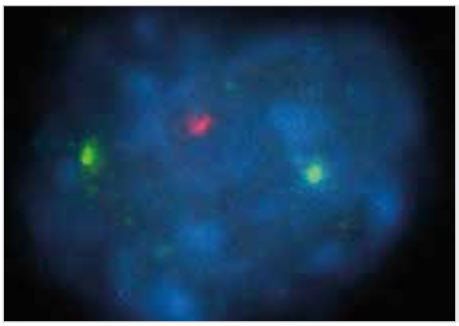
The 15q22 and 9q34 FISH probe is designed as a dual-color assay to detect amplifications at 15q22 and 9q34.

REFERENCES

Cremer et al, 2005, Genes Chrom Cancer, 44; 194-203.



19q13 / TP53



19q13 / TP53 (17p13) hybridized to patient material showing a TP53 (17p13) deletion (1R2G).

19q13 / TP53 (17p13)

CODE	COLOR	FORMAT	STATUS
KI-10509	Green/Red	100 µL	RUO

MENU

RESEARCH

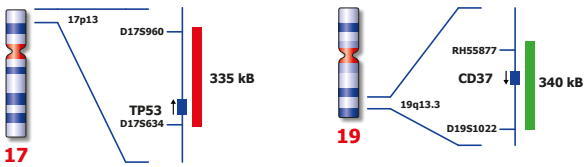
BACKGROUND

TP53 (previously known as p53) gene deletion, which can be identified by interphase FISH in almost a third of patients with newly diagnosed MM, is a prognostic factor predicting for short survival of MM patients treated with conventional-dose chemotherapy. Amplification of 19q13 has been reported in a variety of cancer. The 19q13 specific FISH probe is optimized to detect copy numbers at 19q13.

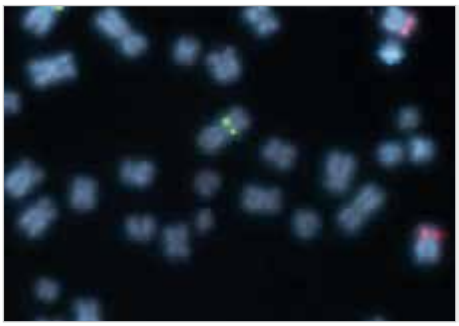
The TP53 (17p13) specific DNA region is optimized to detect copy numbers of the TP53 gene region at 17p13.

REFERENCES

Drach et al, 1998, Blood, 92; 802-809.
Cremer et al, 2005, Genes Chrom Cancer, 44; 194-203.



1q21 / 8p21



1q21 / 8p21 hybridized to a normal metaphase (2R2G).

1q21 / 8p21

CODE	COLOR	FORMAT	STATUS
KI-10503	Green/Red	100 µL	RUO

MENU

RESEARCH

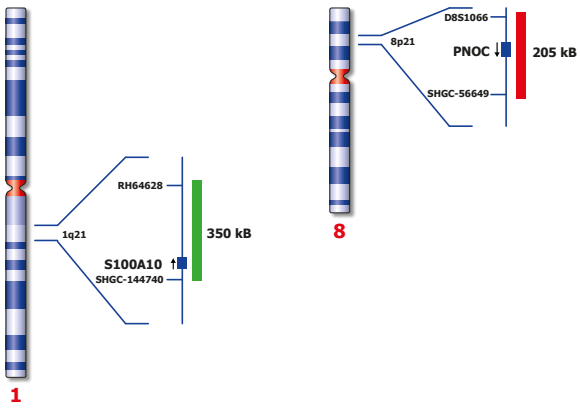
BACKGROUND

Amplifications of 1q21 are concurrent with dysregulated expression of MAF, MMSET / FGFR3, or Deletion 13 and represent an independent unfavorable prognostic factor. Allelic losses of the chromosome 8p21-22 have been reported as a frequent event in several cancers.

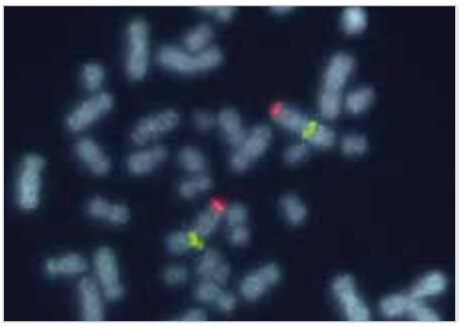
The 1q21 specific FISH probe is optimized to detect copy numbers at 1q21. The 8p21 specific DNA region is optimized to detect copy numbers at 8p21.

REFERENCES

Shaughnessy J., 2005, Hematology, 10 suppl, 1; 117-126.
Cremer et al, 2005, Genes Chrom Cancer, 44; 194-203.



1q21 / SRD



1q21 / SRD (1p36) hybridized to a normal metaphase (2R2G).

1q21 / SRD (1p36)

CODE	COLOR	FORMAT	STATUS
KI-10507	Green/Red	100 µL	RUO

MENU

RESEARCH

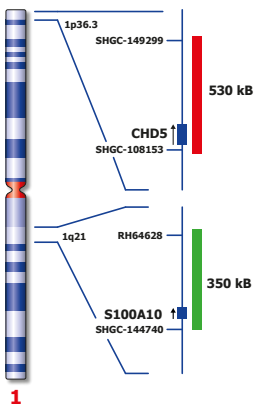
BACKGROUND

Frequent loss of heterozygosity (LOH) on the short arm of chromosome 1 (1p) has been reported in a series of human malignancies. The combination with the potentially amplified 1q21 region allows to detect deletions at 1p36 and gain of 1q21 in a single FISH assay.

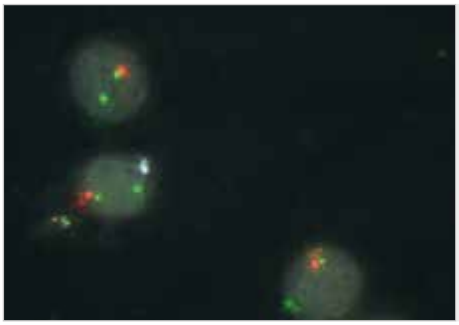
The 1q21 specific FISH probe is optimized to detect copy numbers at 1q21. The SRD 1p36 specific FISH probe is optimized to detect copy numbers of 1p at region 1p36 containing the markers D1S2795 and D1S253.

REFERENCES

Cremer et al, 2005, Genes Chrom Cancer, 44; 194-203.
Shaughnessy J., 2005, Hematology, 10 suppl, 1; 117-126.



20q-



20q- (20q12) / 20q11 probe hybridized to patient material showing 20q- deletion (1R2G).

Material kindly provided by Labdia Labordiagnostik, Vienna.

20q- (20q12) / 20q11

CODE	COLOR	FORMAT	STATUS
KI-10203	Green/Red	100 µL	RUO

MENU

RESEARCH

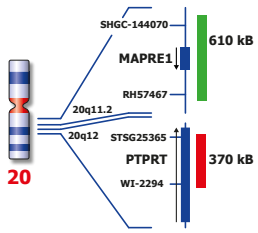
BACKGROUND

Acquired deletions of the long arm of chromosome 20 are found in several hematologic conditions and particularly in the myeloproliferative disorders (MPD) and myelodysplastic syndromes and acute myeloid leukemia (MDS / AML). A minimal critical region deleted in MPD and MDS has been identified at 20q12 which includes a protein tyrosine phosphatase receptor gene.

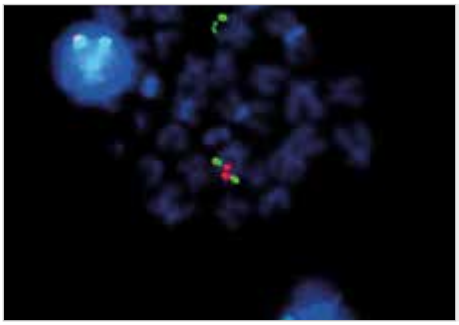
The 20q- (20q12) specific FISH probe is optimized to detect copy numbers of 20q at region 20q12. A 20q11 region specific probe is included to facilitate chromosome identification.

REFERENCES

Bench et al, 2000, Oncogene, 19; 3902-3913.
Asimakopoulos et al, 1994, Blood, 84; 3086-3094.



5q Dual-Color



5q- (5q31; 5q33) probe hybridized to patient material showing a 5q33 deletion (1R2G).

5q- (5q31; 5q33)

CODE	COLOR	FORMAT	STATUS
KI-10209	Green/Red	100 µL	RUO

MENU

RESEARCH

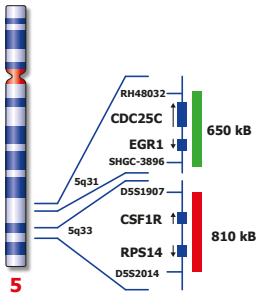
BACKGROUND

The presence of del(5q), either as the sole karyotypic abnormality or as part of a more complex karyotype, has distinct clinical implications for myelodysplastic syndromes (MDS) and acute myeloid leukemia. Interstitial 5q deletions are the most frequent chromosomal abnormalities in MDS and are present in 10% to 15% of MDS patients. Two different critical regions are described, one at 5q31-q33 containing the CSF1R and RPS14 gene regions, characteristic for the '5q-' syndrome, and a more proximal located region at 5q13-q31 containing the CDC25C and EGR1 gene regions.

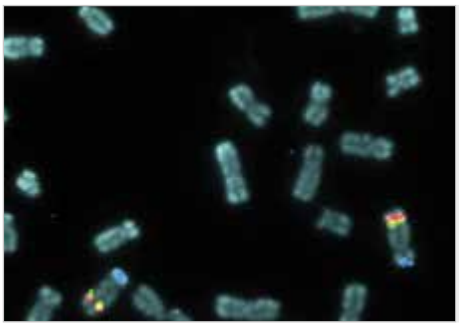
The 5q- specific FISH probe is optimized to detect copy numbers at the CDC25C / EGR1 gene region at 5q31 and the CSF1R"/ RPS14 gene region at 5q33 simultaneously in a dual-color assay.

REFERENCES

Boultwood J e.a., Blood 2002, 99; 4638-4641.
Zhao N e.a., PNAS 1997, 94; 6948-6953.
Wang e.a., Haematologica 2008, 93; 994-1000.
Ebert BL e.a., Nature 2008, 451; 335-339.
Mohamedali A and Mufti GJ, Brit J Haematol 2008, 144; 157-168.



5q- Triple-Color



5q- (5q31; 5q33) / TERT (5p15)Triple-Color probe hybridized to a normal metaphase (2R2G2B).

5q- (5q31; 5q33) / TERT (5p15) Triple-Color

CODE	COLOR	FORMAT	STATUS
KI-10210	Green/Red/Blue	100 µL	RUO

MENU

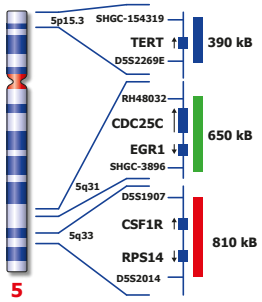
RESEARCH

BACKGROUND

The 5q- specific FISH probe is optimized to detect copy numbers at the CDC25C / EGR1 gene region at 5q31 and the CSF1R / RPS14 gene region at 5q33 simultaneously in a dual-color assay. The triple-color probe provides in addition to the two critical regions a control in blue targeting the TERT (previously known as hTERT) gene region at 5p15.

REFERENCES

Boultwood J e.a., Blood 2002, 99; 4638-4641.
Zhao N e.a., PNAS 1997, 94; 6948-6953.
Wang e.a., Haematologica 2008, 93; 994-1000.
Ebert BL e.a., Nature 2008, 451; 335-339.
Mohamedali A and Mufti GJ, Brit J Haematol 2008, 144; 157-168.



6q21 / MYC

6q21 / MYC (8q24)

CODE	COLOR	FORMAT	STATUS
KI-10117	Green/Red	100 µL	RUO

MENU

RESEARCH

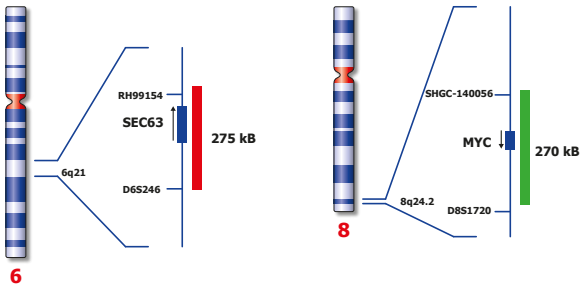
BACKGROUND

Deletions affecting the long arm of chromosome 6 (6q) involving band 6q21 are among the most commonly observed chromosomal aberrations in lymphoid malignancies and have been identified as adverse prognostic factor in subsets of tumors. Amplification of MYC (8q24) has been described in many types of solid tumors, such as breast, cervical and colon cancers, as well as in myeloma, non-Hodgkin's lymphoma, gastric adenocarcinomas and ovarian cancer.

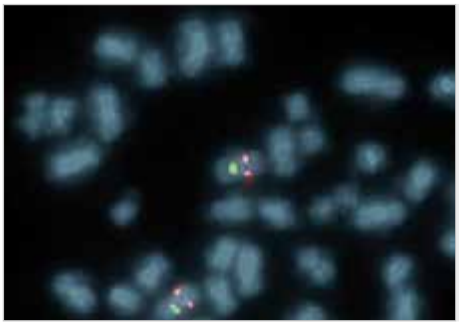
The 6q21 / MYC (8q24) FISH probe is designed as a dual-color assay to detect deletions and amplifications at 6q21 and 8q24.

REFERENCES

Zhang, Y, 2000, Genes, Chrom. And Canc. 27; 52-58
Bentz, M et al, 1995, Blood, 85; 3610-3618



6q21 / SE 6



6q21 / SE 6 probe hybridized to a normal metaphase (2R2G).

6q21 / SE 6

CODE	COLOR	FORMAT	STATUS
KI-10105	Green/Red	100 µL	RUO

MENU

RESEARCH

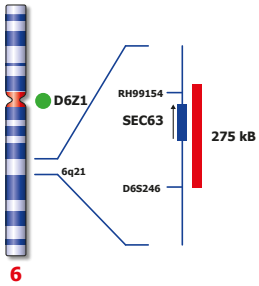
BACKGROUND

Deletions affecting the long arm of chromosome 6 (6q) are among the most commonly observed chromosomal aberrations in lymphoid malignancies and have been identified as an adverse prognostic factor in subsets of tumors including CLL. A minimal deletion region has been identified within a 2-megabase segment of 6q21, between D6S447 and D6S246. The SEC63 gene is located within this critical region.

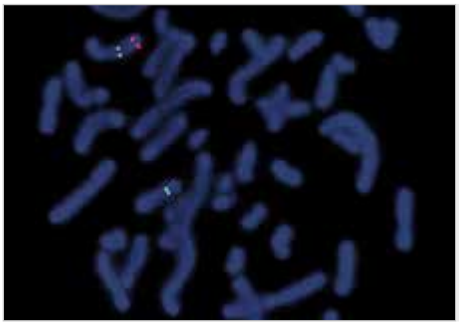
The 6q21 specific FISH probe is optimized to detect copy numbers of 6q at region 6q21.The chromosome 6 Satellite Enumeration FISH probe (SE 6) at D6Z1 is included to facilitate chromosome identification.

REFERENCES

Sherratt et al, 1997, Chromosome Res, 5; 118-124.
Zhang et al, 2000, Genes Chrom Cancer, 27; 52-58.



7q-



7q- (7q22; 7q36) hybridized to patient material showing a 7q36 deletion (1R2G).

Image kindly provided by Prof. Jauch, Heidelberg.

7q- (7q22; 7q36)

CODE	COLOR	FORMAT	STATUS
KI-10202	Green/Red	100 µL	RUO

MENU

RESEARCH

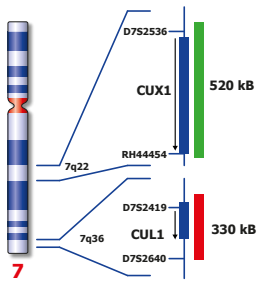
BACKGROUND

Loss of a whole chromosome 7 or a deletion of the long arm, del(7q), are recurring abnormalities in malignant myeloid diseases. Most deletions are interstitial and there are two distinct deleted segments of 7q. The majority of patients have proximal breakpoints in bands q11-22 and distal breakpoints in q31-36. The CCAAT displacement protein CUX1 gene region is located in the 7q22 critical region.

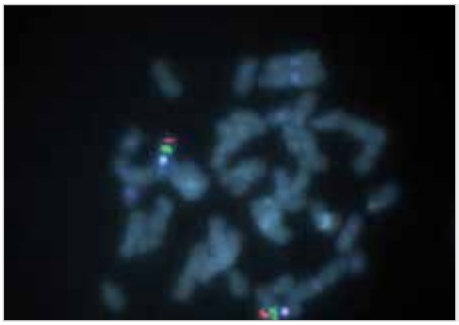
The 7q- specific FISH probe is optimized to detect copy number of 7q at 7q22 and at 7q36 simultaneously in a dual-color assay.

REFERENCES

LeBeau et al., 1996, Blood, 88; 1930-1935.
Doehner et al, 1998, Blood, 92; 4031-4035.



7q- Triple-Color



7q (7q22; 7q36) / SE 7 Triple-Color probe hybridized to a normal metaphase (2R2G2B).

7q- (7q22; 7q36) / SE7 Triple-Color

CODE	COLOR	FORMAT	STATUS
KI-10207	Green/Red/Blue	100 µL	RUO

MENU

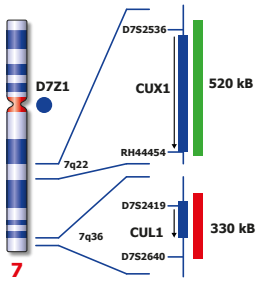
RESEARCH

BACKGROUND

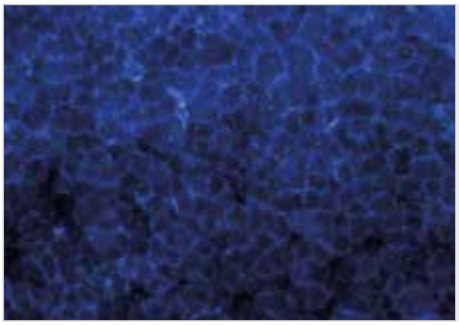
The 7q- specific FISH probe is optimized to detect copy number of 7q at 7q22 and at 7q36 simultaneously in a dual-color assay. The chromosome 7 Satellite Enumeration FISH probe (SE 7) at D7Z1 in blue is included to facilitate chromosome identification.

REFERENCES

LeBeau et al., 1996, Blood, 88; 1930-1935.
Doehner et al, 1998, Blood, 92; 4031-4035.



ALK / EML4



Hybridization of ALK EML4 fusion probe to a lung adenocarcinoma tissue section showing normal signal pattern (2R2G).

ALK (2p23) / EML4 t(2;2) inv (2) Fusion

CODE	COLOR	FORMAT	STATUS
KI-10746	Green/Red	100 µL	RUO

MENU

RESEARCH

BACKGROUND

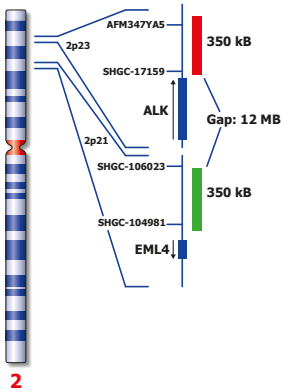
The inversion in 2p21 and 2p23 leading to a fusion of the kinase domain of ALK (anaplastic lymphoma kinase) and EML4 (echinoderm microtubule associated protein like 4) has been described in 5-7% of non-small cell lung cancer (NSCLC) cases.

Multiple tyrosine kinsae inhibitors (TKI's) specific for ALK have since been approved for first line treatment of NSCLC-patients carrying the fusion gene ALK-EML4. These ALK inhibitors include crizotinib (Xalkori), alectinib (Alecensa) and ceritinib (Zykadia).

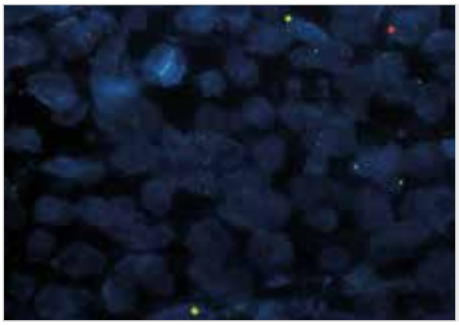
The ALK / EML4 t(2;2); inv(2) Fusion probe is designed as a dual-color assay to detect the fusion of the ALK gene with the EML4 gene by paracentric inversion with breakage and reunion occurring at bands 2p21 and 2p23.

REFERENCES

Soda et al, Nature, 2007, 448, 561-566.
Koivunen et al, Clin Cancer Res, 2008, 14, 4275-4283.



ALK Break



Hybridization of ALK break probe to a lung adenocarcinoma tissue section showing"positive translocation signal (1RG1R1G).

ALK (2p23) Break

CODE	COLOR	FORMAT	STATUS
KI-10747	Green/Red	100 µL	RUO

MENU

RESEARCH

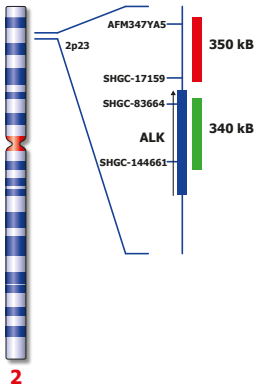
BACKGROUND

Translocations of the ALK (anaplastic lymphoma kinase) gene at 2p23 have originally been associated with anaplastic lymphomas, B-cell lymphomas, neuroblastomas and myofibroblastic tumors. At least 21 translocation partners have been described, however 80% of the translocations involves the NPM1 gene (5q35). ALK rearrangements have been described in non-small cell lung cancer (NSCLC) cases. Multiple tyrosine kinsae inhibitors (TKI's) specific for ALK have since been approved for first line treatment of NSCLC-patients carrying the fusion gene ALK-EML4. These ALK inhibitors include"crizotinib (Xalkori), alectinib (Alecensa) and ceritinib (Zykadia).

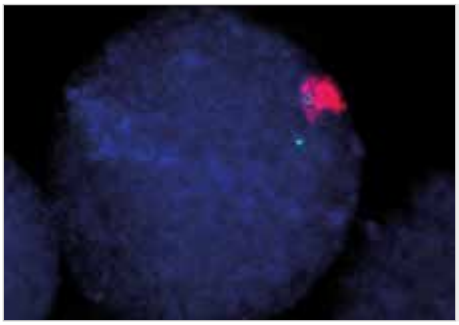
The ALK (2p23) Break probe is optimized to detect translocations involving the ALK gene region at 2p23.

REFERENCES

Soda et al, Nature, 2007, 448, 561-566.
Kwak et al, J Clin Oncol., 27(26):4247-53.
Koivunen et al, Clin Cancer Res, 2008, 14, 4275-4283.



AR / SE X



AR (Xq12) / SE X probe hybridized to VCaP prostate cancer cell showing highlevel AR gene amplification.

Image kindly provided by Prof. Trapman, Erasmus Medical Centre, Rotterdam.

AR (Xq12) / SE X

CODE	COLOR	FORMAT	STATUS
KI-10720	Green/Red	100 µL	RUO

MENU

RESEARCH

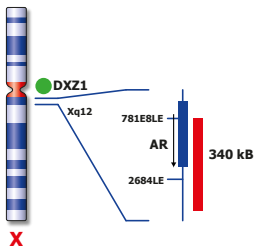
BACKGROUND

The androgen receptor (AR) gene has been identified as a target gene for the Xq12 amplification found in one-third of hormone-refractory prostate cancers. The findings suggest that AR gene amplification and overexpression is involved in the emergence of prostate cancer.

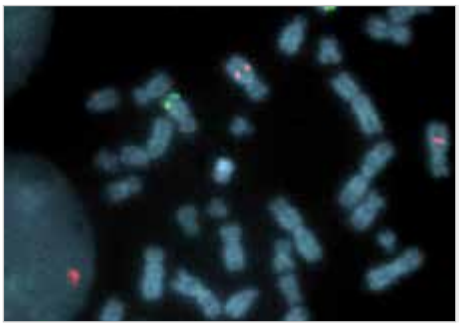
The AR (Xq12) FISH probe is optimized to detect copy numbers of the AR gene region at region Xq12. The chromosome X satellite enumeration probe (SE X) at DXZ1 is included to facilitate chromosome identification.

REFERENCES

Visakorpi T et al, 1995, Nat. Genet. 9; 401-406.
Koivisto P et al, 1997, Cancer Res. 57"; 314-319.



ATM / GLI1



ATM (11q22) / GLI1 (12q13) hybridized to a normal metaphase (2R2G).

ATM (11q22) / GLI1 (12q13)

CODE	COLOR	FORMAT	STATUS
KI-10108	Green/Red	100 µL	RUO

MENU

RESEARCH

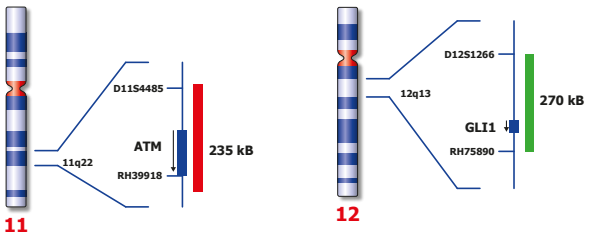
BACKGROUND

Deletion of ATM at 11q22-q23 indicates a rather poor prognosis, amplification of GLI1 (previously known as GLI) at 12q13 is associated with an intermediate prognosis. The ATM (11q22) specific FISH probe is optimized to detect copy numbers of the ATM gene region at 11q22.

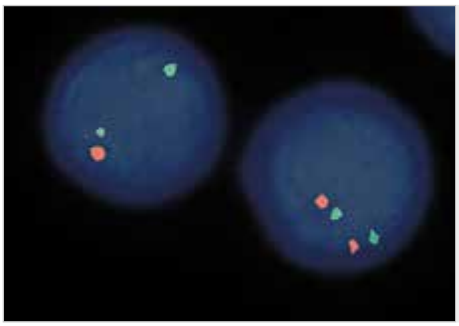
The GLI1 (12q13) specific FISH probe is optimized to detect copy numbers of the GLI1 gene region at 12q13.

REFERENCES

Doehner H et al, 1997, Blood, 7; 2516-2522.
Boultwood J, 2001, J. Clin. Pathol., 54; 512-516.
Dierlamm J et al, 1998, Genes Chromosomes Cancer, 20; 155-166.
Doehner H at al, 1999, J. Molec. Med., 77; 266-281.



ATM / SE 11



ATM (11q22) / SE 11 hybridized to patient material showing a 11q22 deletion at the ATM gene region (1R2G).

Image kindly provided by Dr. Wenzel, Basel.

ATM (11q22) / SE 11

CODE	COLOR	FORMAT	STATUS
KI-10103	Green/Red	100 µL	RUO

MENU

RESEARCH

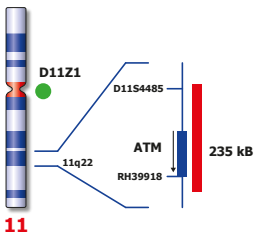
BACKGROUND

Chromosome 11q22.3-23.1 deletions involving the ataxia-teleangiectasia mutated (ATM) locus are detected at diagnosis in 15-20% of cases of B-cell chronic lymphocytic leukemia (CLL) and are associated with a relatively aggressive disease. Loss of the 11q22-23 region, where the ataxia-telangiectasia mutated (ATM) gene is located, is also one of the most frequent secondary chromosomal aberrations in mantle cell lymphoma.

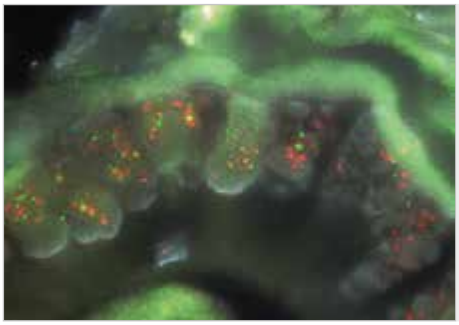
The ATM (11q22.3) specific FISH probe is optimized to detect copy numbers of the ATM gene region at region 11q22.3. The chromosome 11 Satellite Enumeration (SE 11) at D11Z1 FISH probe is included to facilitate chromosome identification.

REFERENCES

Doehner et al, 1997, Blood, 89; 2516-2522.
Bigoni et al, 1997, Leukemia, 11; 1933-1940.



AURKA



AURKA (20q13) / 20q11 probe hybridized to colorectal carcinoma material showing amplification of AURKA, gene region at 20q13.

Material kindly provided by Dr. Carvalho, Amsterdam.

AURKA (20q13) / 20q11

CODE	COLOR	FORMAT	STATUS
KI-10721	Green/Red	100 µL	RUO

MENU

RESEARCH

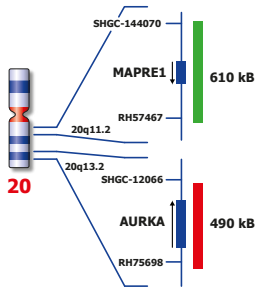
BACKGROUND

Aurora kinase A (AURKA) gene amplification has been detected in approximately 12% of primary breast tumors, as well as in bladder, ovarian, colon, prostate, neuroblastoma and cervical cancer cell lines. The AURKA (20q13) / 20q11 probe is designed to detect copy numbers of the AURKA gene region at region 20q13.

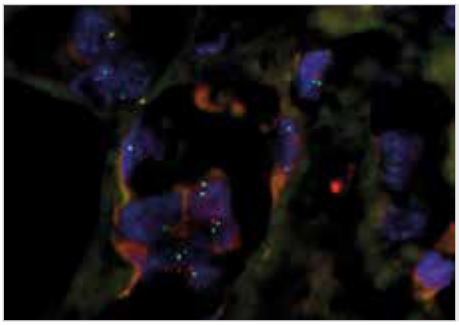
The AURKA (20q13) FISH probe is optimized to detect copy numbers of the AURKA gene region at region 20q13. The 20q11 specific DNA probe is included to facilitate chromosome identification.

REFERENCES

Uchida et al, 2010, Cancer Genet Cytogenet 203; 324-327.
Sen et al, 2002, J of Nat Canc Inst 94; 1320-1329.
Lassmann et al, 2007, Clin Cancer Res 13; 4083-4091.



AURKB



AURKB (17p13) / SE 17 probe hybridized to tumor tissue (2R2G).

AURKB (17p13) / SE 17

CODE	COLOR	FORMAT	STATUS
KI-10722	Green/Red	100 µL	RUO

MENU

RESEARCH

BACKGROUND

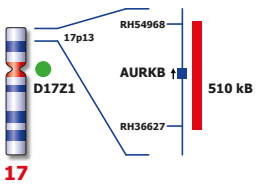
Aurora kinase B (AURKB) localizes to microtubules, and is a key regulator of the mitotic cell division and chromosome segregation processes. Gain of function of AURKB correlates with cell proliferation, induction of multinuclear cells, and chromosomal instability.

The significant interest of the gene in cancer diagnostics is related to the driving function of AURKB in tumor progression, histological differentiation, and metastasis. AURKB is predictive for the aggressive recurrence of many different types of tumors, including hepatocellular carcinoma and oral squamous cell carcinoma.

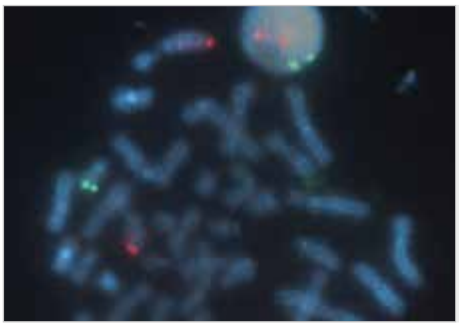
The AURKB (17p13) FISH probe is optimized to detect copy numbers of the AURKB gene region at region 17p13. The Chromosome 17 Satellite Enumeration (SE 17) probe at D17Z1 is included to facilitate chromosome identification.

REFERENCES

Smith et al, 2005, Br J Cancer, 93; 719-729.



BCL2 / IGH



BCL2 / IGH t(14;18) probe hybridized to a normal interphase/metaphase (2R2G).

BCL2 / IGH t(14;18) Fusion

CODE	COLOR	FORMAT	STATUS
KI-10606	Green/Red	100 µL	RUO

MENU

RESEARCH

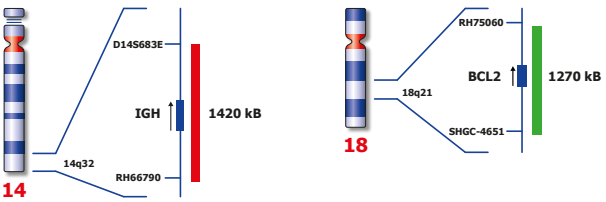
BACKGROUND

The t(14;18) chromosomal translocation is a common cytogenetic abnormality in human lymphoma and is observed in about 85% of follicular lymphoma (FL) and up to one-third of diffuse lymphomas (DL). Two breakpoint region clusters (brc) have been identified: a major breakpoint region (mbr) within the 3' untranslated region of the BCL2 proto-oncogene (approximately 60% of the cases) and a minor cluster region (mcr) 30 kb 3' of BCL2 (approximately 25%).

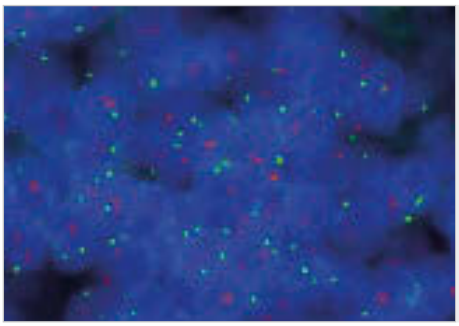
The BCL2 / IGH t(14;18)(q21;q32) specific FISH probe is optimized to detect the reciprocal translocation t(18;14), involving either of the two brc in the BCL2 gene in a dual-color, dual-fusion assay. Kreatech has optimized this FISH probe for the specific use on cell material (KBI-10606), or on tissue (KBI-10755).

REFERENCES

Poetsch et al, 1996, J Clin Oncol, 14; 963-969.
Vaandrager et al, 2000, Genes Chrom Cancer, 27; 85-94.



BCL2 / IGH (tissue)



BCL2 / IGH t(14;20) Fusion Probe hybridized to paraffin embedded lymph node material (2R2G).

Image kindly provided by P. May, Imperial College, Hammersmith Hospital, London

BCL2 / IGH t(14;18) Fusion (tissue)

CODE	COLOR	FORMAT	STATUS
KI-10755	Green/Red	100 µL	RUO

MENU

RESEARCH

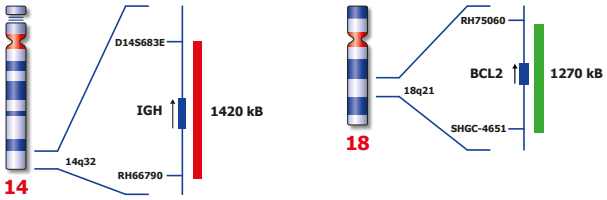
BACKGROUND

Follicular lymphoma is a mature B-Cell lymphoma, characterized by the presence of the t(14;18) translocation that juxtaposes the BCL2 locus on chromosome 18q21 to the immunoglobulin H (IGH) locus on chromosome 14q32, resulting in the overexpression of the antiapoptotic protein BCL2.

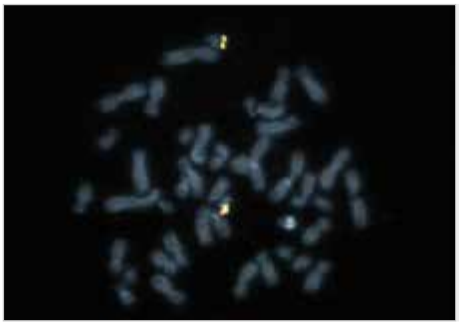
The BCL2 / IGH t(14;18) Fusion probe is optimized to detect the reciprocal translocation t(14;18) in a dual-color, dual-fusion assay on formalin fixed paraffin embedded tissue samples. In addition Kreatech has developed a probe for the specific use on cell material (KBI-10606).

REFERENCES

Taniwaki M et al, 1995, Blood, 86; 1481-1486.
Poetsch M et al, 1996, J Clin Oncol, 14; 963-969.



BCL2 Break



BCL2 (18q21) Break probe hybridized to a normal metaphase.

BCL2 (18q21) Break

CODE	COLOR	FORMAT	STATUS
KI-10612	Green/Red	100 µL	RUO

MENU

RESEARCH

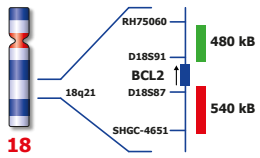
BACKGROUND

Follicular lymphoma is a mature B-cell lymphoma characterized by the presence of the t(14;18) translocation that juxtaposes the BCL2 locus on chromosome 18q21 to the immunoglobulin H (IGH) locus on chromosome 14q32, resulting in the overexpression of the anti-apoptotic protein BCL2. Next to IGH, other translocation partners to BCL2 are also known (e.g. IGK at 2p11.2 and IGL at 22q11). A break or split assay is therefore best suited to detect rearrangements of the BCL2 gene region at 18q21.

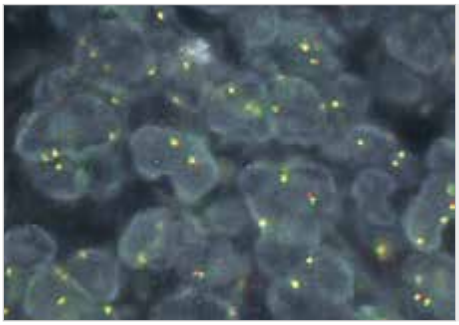
The BCL2 (18q21) Break FISH probe is optimized to detect translocations involving the BCL2 gene region at 18q21 in a dual-color, split assay on metaphase/ interphase spreads, bloodsmears and bone marrow cells.

REFERENCES

Taniwaki M et al, 1995, Blood, 86; 1481-1486.
Poetsch M et al, 1996, J Clin Oncol, 14; 963- 969.
Einerson R et al, 2005, Am J Clin Pathol, 124; 421-429.



BCL2 Break (tissue)



BCL2 (18q21) Break hybridized to paraffin embedded tissue (2RG).

BCL2 (18q21) Break (tissue)

CODE	COLOR	FORMAT	STATUS
KI-10745	Green/Red	100 µL	RUO

MENU

RESEARCH

BACKGROUND

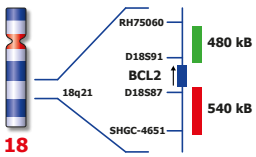
Follicular lymphoma is a mature B-cell lymphoma characterized by the presence of the t(14;18) translocation that juxtaposes the BCL2 locus on chromosome 18q21 to the immunoglobulin H (IGH) locus on chromosome 14q32, resulting in the overexpression of the anti-apoptotic protein BCL2. Besides IGH, additional translocation partners to BCL2 have been identified. A break or split assay is therefore best suited to detect rearrangements of the BCL2 gene region at 18q21.

The BCL2 (18q21) Break probe is optimized to detect translocations involving the BCL2 gene region at 18q21 in a dual-color, split assay on paraffin embedded tissue sections.

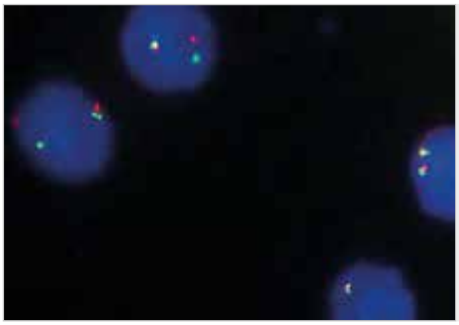
Kreatech has developed this probe for the specific use on cell material (KBI-10612), or on tissue (KBI-10745).

REFERENCES

Taniwaki M et al, 1995, Blood, 86; 1481-1486.
Poetsch M et al, 1996, J Clin Oncol, 14; 963- 969.
Einers R et al, 2005, Am J Clin Pathol, 124; 421-429.



BCL6 Break



BCL6 (3q27) Break probe hybridized to patient material (1RG1R1G).

Image kindly provided by Prof. Siebert, Kiel.

BCL6 (3q27) Break

CODE	COLOR	FORMAT	STATUS
KI-10607	Green/Red	100 µL	RUO

MENU

RESEARCH

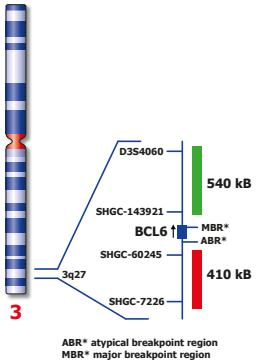
BACKGROUND

Chromosomal translocations involving band 3q27 with various different partner chromosomes represent a recurrent cytogenetic abnormality in B-cell non-Hodgkin's lymphoma. Kreatech has developed this probe for the specific use on cell material (KBI-10607), or on tissue (KBI-10730). Two different breakpoint regions have been identified; the major breakpoint region (MBR) is located within the 5' noncoding region of the BCL6 proto-oncogene, while the atypical breakpoint region (ABR) is located approximately 200 kb distal to the BCL6 gene.

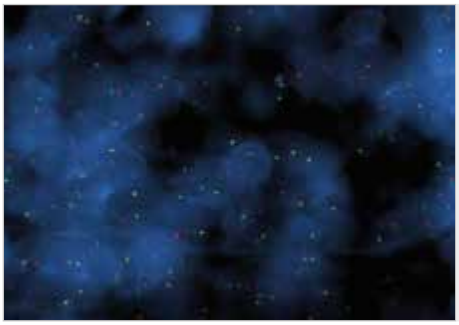
The BCL6 (3q27) Break FISH probe is designed in a way to flank both possible breakpoints, thereby providing clear split signals in either case.

REFERENCES

Butler et al, 2002, Cancer Res, 62; 4089-4094.
Sanchez-Izquierdo, 2001, Leukemia, 15; 1475-1484.



BCL6 Break (tissue)



Hybridization of BCL6 break probe to a tissue section showing aberrant pattern (1RG1R1G).

BCL6 (3q27) Break (tissue)

CODE	COLOR	FORMAT	STATUS
KI-10730	Green/Red	100 µL	RUO

MENU

RESEARCH

BACKGROUND

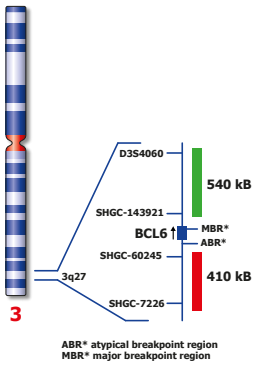
Chromosomal translocations involving band 3q27 with various different partner chromosomes represent a recurrent cytogenetic abnormality in B-cell non-Hodgkin's lymphoma. Kreatech has developed this probe for the specific use on cell material (KBI-10607), or on tissue (KBI-10730).

Two different breakpoint regions have been identified; the major breakpoint region (MBR) is located within the 5' noncoding region of the BCL6 proto-oncogene, while the atypical breakpoint region (ABR) is located approximately 200 kb distal to the BCL6 gene. The BCL6 (3q27) Break probe is designed to flank both possible breakpoints, thereby providing clear split signals.

The BCL6 (3q27) Break probe is optimized to detect translocations involving the BCL6 gene region at 3q27 in a dual-color, split assay on paraffin-embedded tissue sections.

REFERENCES

Butler et al, 2002, Cancer Res, 62; 4089-4094.
Sanchez-Izquierdo, 2001, Leukemia, 15; 1475-1484.



BCR / ABL1

BCR / ABL1 t(9;22) Fusion probe hybridized on patient material showing t(9;22)(q34;q11) reciprocal translocation (2RG1R1G).

Image kindly provided by Monika Conchon, São Paulo.

BCR / ABL1 t(9;22) Fusion

CODE	COLOR	FORMAT	STATUS
KI-10005	Green/Red	100 µL	RUO
KI-12005	Green/Red	200 µL	RUO

MENU

RESEARCH

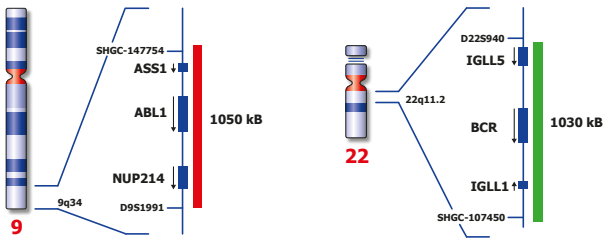
BACKGROUND

The BCR / ABL1 t(9;22) Fusion FISH probe is optimized to detect the t(9;22)(q34;q11) reciprocal translocation in a dual-color, dual-fusion assay on metaphase/interphase spreads, blood smears and bone marrow cells.

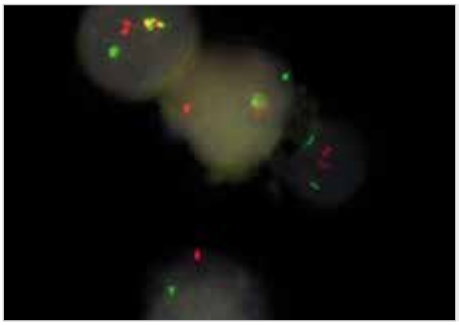
This probe will also detect cryptic insertions of ABL1 (previously known as ABL) into the BCR region not detectable by karyotyping and therefore described as Ph-negative.

REFERENCES

Morris et al, 1990, Blood, 76; 1812-1818.
Dewald et al, 1998, Blood, 91; 3357-3365.
Kolomietz et al, 2001, Blood, 97; 3581-3588.
Huntly et al, 2003, Blood, 102; 1160-1168.
Tkachuk et al., 1990, Science, 250; 559-562.



BCR / ABL1 DC



BCR / ABL1 t(9;22), Dual-Color, Single-Fusion probe hybridized to patient material showing t(9;22) translocation (1RG1R1G).

Material kindly provided by Dr. Balogh, Budapest.

BCR / ABL1 t(9;22) Dual-Color, Single-Fusion

CODE	COLOR	FORMAT	STATUS
KI-10009	Green/Red	100 µL	RUO

MENU

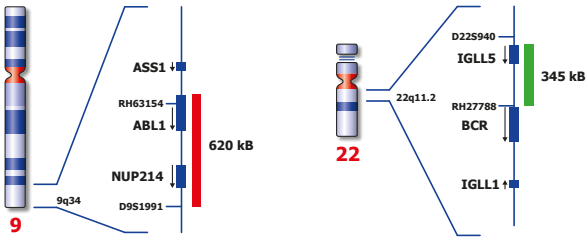
RESEARCH

BACKGROUND

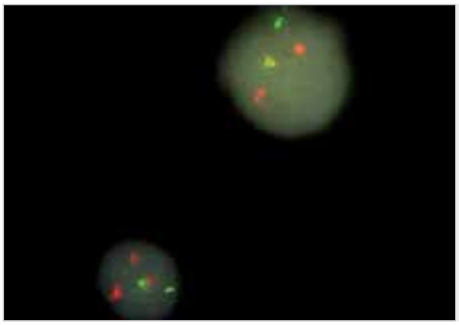
A simple dual-color, single-fusion assay is preferably used for the initial screening of CML and ALL patients. The Philadelphia chromosome, der(22q), is visualized by a fusion signal while the der(9q) shows no signal. The BCR / ABL1 t(9;22) FISH probe is optimized to detect the t(9;22)(q34;q11) reciprocal translocation in a dual-color, single-fusion assay on metaphase/interphase spreads, blood smears and bone marrow cells.

REFERENCES

Morris et al, 1990, Blood, 76; 1812-1818.
Dewald et al, 1998, Blood, 91; 3357-3365.
Kolomietz et al, 2001, Blood, 97; 3581-3588.
Huntly et al, 2003, Blood, 102; 1160-1168.
Tkachuk et al., 1990, Science, 250; 559-562.



BCR / ABL1 DC ES



BCR / ABL1 t(9;22), Dual-Color, Single-Fusion probe hybridized to patient material showing t(9;22) translocation (1RG1R1G).

Material kindly provided by Dr. Balogh, Budapest.

BCR / ABL1 t(9;22) Dual-Color, Single-Fusion, Extra Signal

CODE	COLOR	FORMAT	STATUS
KI-10008	Green/Red	100 µL	RUO

MENU

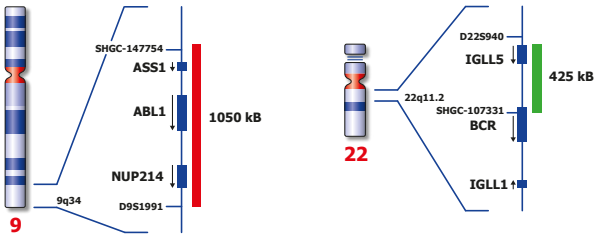
RESEARCH

BACKGROUND

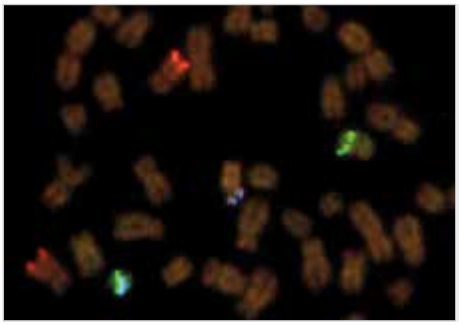
A simple dual-color, single-fusion assay is preferably used for the initial screening of CML and ALL patients. The Philadelphia chromosome, der(22q), is visualized by a fusion signal while the der(9q) shows no signal. The BCR / ABL1 t(9;22) FISH probe is optimized to detect the t(9;22)(q34;q11) reciprocal translocation in a dual-color, single-fusion, extra-signal assay on metaphase/interphase spreads, blood smears and bone marrow cells.

REFERENCES

Morris et al, 1990, Blood, 76; 1812-1818.
Dewald et al, 1998, Blood, 91; 3357-3365.
Kolomietz et al, 2001, Blood, 97; 3581-3588.
Huntly et al, 2003, Blood, 102; 1160-1168.
Tkachuk et al., 1990, Science, 250; 559-562.



BCR / ABL1 TC



BCR / ABL1 t(9;22),Triple-Color, Dual Fusion probe hybridized on patient material showing translocation of distal BCR (1BG1RB1R1G).

Image kindly provided by Prof. Siebert, Kiel.

BCR / ABL1 t(9;22) Triple-Color, Dual-Fusion

CODE	COLOR	FORMAT	STATUS
KI-10006	Green/Red/Blue	100 µL	RUO

MENU

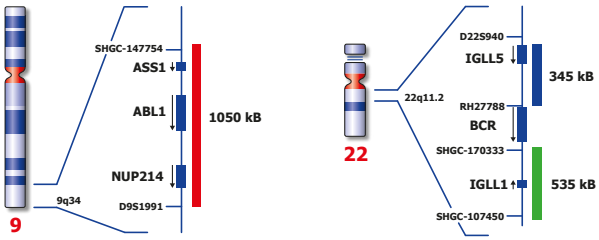
RESEARCH

BACKGROUND

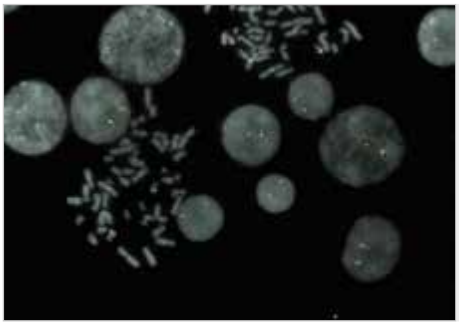
The BCR / ABL1 t(9;22) FISH probe is a triple-color, dual-fusion probe built from the same regions as the dual-color, dual-fusion probe, but the proximal BCR region is labeled in blue. Using the triple-color probe allows to distinguish between the derivative chromosome 22, the Philadelphia chromosome, which will be observed as purple (red/blue) color, while the derivative chromosome 9 will show a yellow (red/green) signal.

REFERENCES

Morris et al, 1990, Blood, 76; 1812-1818.
Dewald et al, 1998, Blood, 91; 3357-3365.
Kolomietz et al, 2001, Blood, 97; 3581-3588.
Huntly et al, 2003, Blood, 102; 1160-1168.
Tkachuk et al., 1990, Science, 250; 559-562.



CBFB Break



Hybridization of CBFB break probe to a metaphase spread showing normal pattern (2RG).

CBFB t(16;16), inv(16) Break

CODE	COLOR	FORMAT	STATUS
KI-10304	Green/Red	100 µL	RUO

MENU

RESEARCH

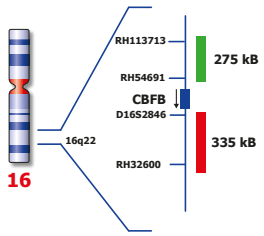
BACKGROUND

Inv(16)(p13;q22) and t(16;16)(p13;q22) are recurring chromosomal rearrangements in AML. In both the inversion and translocation, the critical genetic event is the fusion of the CBFB gene at 16q22 to the smooth muscle myosin heavy chain (MYH11) at 16p13. A deletion of between 150 and 350 kb centromeric to the p-arm inversion breakpoint cluster region can be observed in some patients containing the 5' portion of the myosin heavy chain (MYH11) gene.

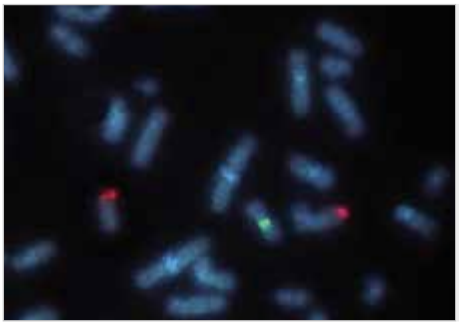
The CBFB t(16;16) inv(16) break FISH probe is optimized to detect the inversion of chromosome 16 involving the CBFB gene region at 16q22 in a dual-color, split assay.

REFERENCES

Dauwerse et al, 1993, Hum.Mol.Genet., 2; 1527-1534.
Marlton et al, 1995, Blood, 85; 772-779.



CCND1 / IGH Fusion



CCND1 / IGH t(11;14) Fusion probe hybridized to a normal interphase/metaphase (2R2G).

CCND1 / IGH t(11;14) Fusion

CODE	COLOR	FORMAT	STATUS
KI-10604	Green/Red	100 µL	RUO

MENU

RESEARCH

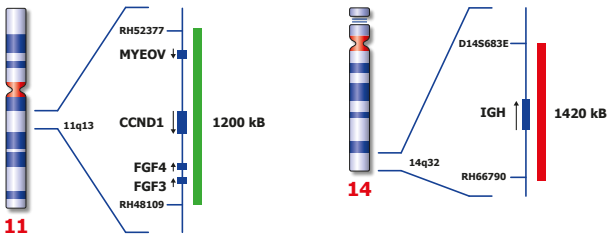
BACKGROUND

Mantle cell lymphoma is a subtype of non-Hodgkin lymphoma characterized by poor prognosis. Cytogenetically t(11;14) is associated with 75% of mantle cells lymphomas. The translocation breakpoints are scattered within the 120 kb region adjacent to CCND1 (previously known as BCL1). The translocation leads to overexpression of cyclin D1 due to juxtaposition of the Ig heavy chain gene enhancer on 14q32 to the cyclin D1 gene on 11q13.

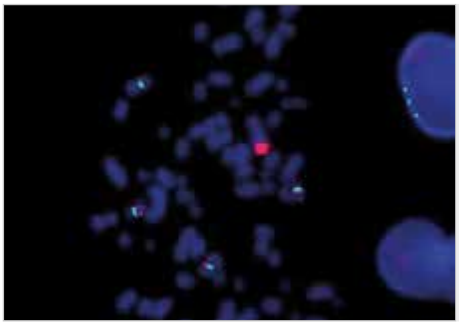
The CCND1 / IGH t(11;14)(q13;q32) specific FISH probe is optimized to detect the reciprocal translocation t(11;14) in a dual-color, dual-fusion assay.

REFERENCES

Vaandrager et al, 1996, Blood, 88; 1177-1182.



CCND1 /SE 11



CCDN1 (11q13) / SE 11 probe hybridized to patient interphases / metaphase showing CCDN1 (11q13) amplification with polyploidy for chromosome 11.

CCND1 (11q13) / SE 11

CODE	COLOR	FORMAT	STATUS
KI-10734	Green/Red	100 µL	RUO

MENU

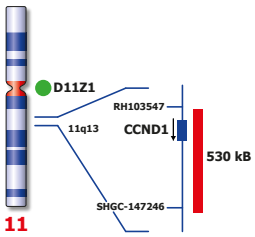
RESEARCH

BACKGROUND

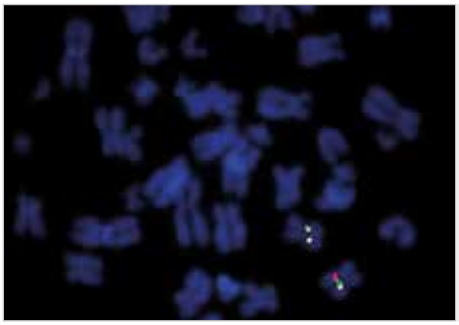
The binding of cyclin D1 (also named CCND1 or BCL1) to cyclin-dependent kinases (CDKs) leads to the phosphorylation of retinoblastoma protein (pRb), subsequently triggering the release of E2F transcription factors to allow G1 to S phase progression of the cell cycle. Consistent with this function, overexpression of cyclin D1 results in a more rapid progression from the G1 to S phase transition and in a reduced serum dependency in fibroblast cells, characteristics typically seen in cancer cells. The CCND1 (11q13) FISH probe is optimized to detect copy numbers of the CCND1 gene region at region 11q13. The Chromosome 11 Satellite Enumeration (SE 11) probe at D11Z1 is included to facilitate chromosome identification.

REFERENCES

Okami et al, 1999, Oncogene 18; 3541-3645.
Freier et al, 2003, Cancer Res; 1179-1182.



CCND1 Break



CCND1 (11q13) Break probe hybridized to a normal metaphase (2R2G).

CCND1 (11q13) Break

CODE	COLOR	FORMAT	STATUS
KI-10609	Green/Red	100 µL	RUO

MENU

RESEARCH

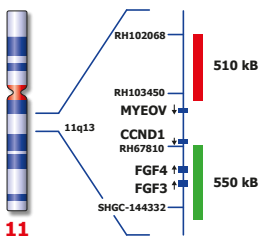
BACKGROUND

Overexpression of the Cyclin D1 gene caused by amplification or translocation is described for several types of cancer. A t(11;14) is the main characteristic aberration in mantle cell lymphoma (documented in 40-70% of the cases. In MM, the same translocation t(11;14)(q13:q32) is the most common, with a reported frequency of 15% to 20% of the cases.

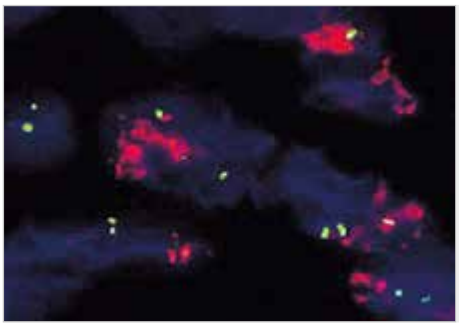
Kreatech has developed this probe to detect rearrangements of the CCND1 gene region at 11q13 (KBI-10609) or for the translocation t(11;14) in Mantle Cell Lymphoma (KBI-10604) and for MM (KBI-10605). The CCND1 (11q13) Break FISH probe is optimized to detect translocations involving the CCND1 gene region at 11q13 in a dual-color, split assay on metaphase/interphase spreads.

REFERENCES

Vaandrager et al, 1996, Blood, 88; 1177-1182.
Vaandrager et al, Blood, 89; 349-350.



CDK4 / SE 12



CDK4 (12q13) / SE 12 probe hybridized to liposarcoma tissue showing multiple amplification involving the CDK4 gene region at 12q13 (3+R2G).

Image kindly provided by Dr. Sapi, Hungary.

CDK4 (12q13) / SE 12

CODE	COLOR	FORMAT	STATUS
KI-10725	Green/Red	100 µL	RUO

MENU

RESEARCH

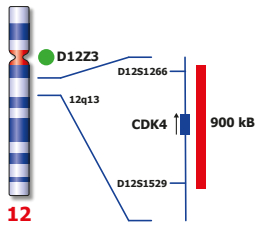
BACKGROUND

Amplification of the CDK4 gene region at 12q13-q15 has been observed in several types of cancer, especially in gliomas and sarcomas. CDK4 codes for a cyclin dependent kinase which is involved in controlling progression through the G1 phase of the cell cycle. The oncogenic potential of CDK4 activation has been related to the deregulation of the G1 phase by increasing the hyperphosphorylation of retinoblastoma tumor suppressor protein helping to cancel its growth-inhibitory effects.

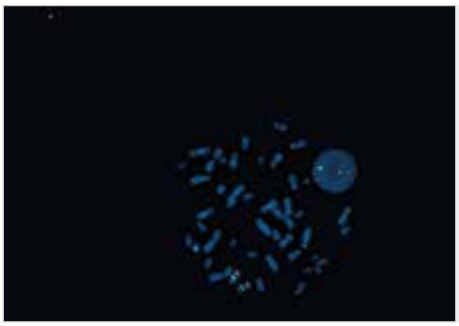
The CDK4 (12q13) FISH probe is optimized to detect copy numbers of the CDK4 gene region at 12q13. The chromosome 12 satellite enumeration probe (SE 12) at D12Z3 is included to facilitate chromosome identification.

REFERENCES

Kuhnen et al, 2002, Virchows Arch 441"; 299-302.
Shimada et al, 2006, Hum Path 37(9)"; 1123-1129.



CDKN2A / 9q21



CDKN2A (9p21) / 9q21 hybridized to a metaphase spread showing a normal pattern (2R2G).

CDKN2A (9p21) / 9q21

CODE	COLOR	FORMAT	STATUS
KI-10402	Green/Red	100 µL	RUO

MENU

RESEARCH

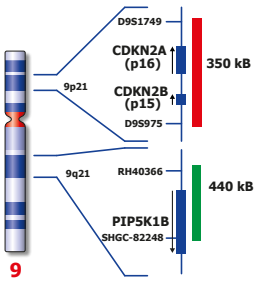
BACKGROUND

Hemizygous deletions and rearrangements of chromosome 9, band p21 are among the most frequent cytogenetic abnormalities detected in pediatric acute lymphoblastic leukemia (ALL). This deletion includes loss of the CDKN2A (previously known as p16, INK4A or MTS1) / CDKN2B (previously known as p15, INK4B or MTS2) genes, which are cell cycle kinase inhibitors and important in leukemogenesis.

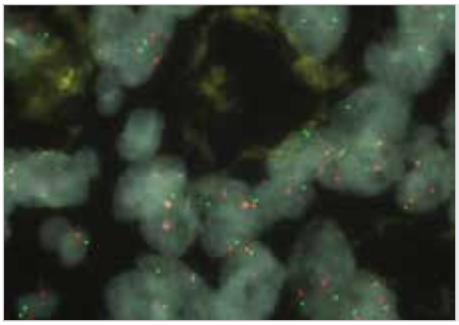
The CDKN2A (9p21) specific FISH probe is optimized to detect copy numbers of the CDKN2A gene region at region 9p21. The 9q21 region probe is included to facilitate chromosome identification.

REFERENCES

Dreyling et al, 1995, Blood, 86; 1931-1938.
Southgate et al, 1995, Br J Cancer, 72; 1214-1218.



CDKN2A / 9q21 (tissue)



CDKN2A (9p21) / 9q21 (tissue) probe hybridized to tissue (2R2G).

CDKN2A (9p21) / 9q21 (tissue)

CODE	COLOR	FORMAT	STATUS
KI-10710	Green/Red	100 µL	RUO

MENU

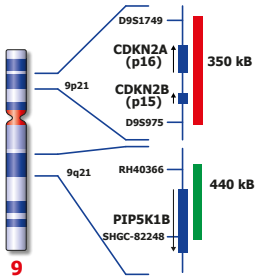
RESEARCH

BACKGROUND

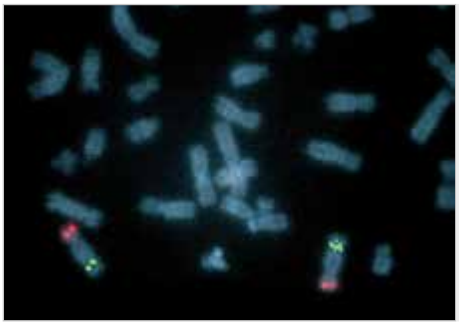
Homozygous and hemizygous deletions of 9p21 are the earliest and most common genetic alteration in bladder cancer. The CDKN2A (INK4A) gene has been identified as tumor suppressor gene in this region which is commonly deleted in bladder cancer. The loss of DNA sequences on chromosomal bands 9p21-22 has been documented also in a variety of malignancies including leukemias, gliomas, lung cancers, and melanomas. The CDKN2A (9p21) FISH probe is optimized to detect copy numbers of the CDKN2A gene region at region 9p21. The 9q21 region probe is included to facilitate chromosome identification.

REFERENCES

Stadler et al, 1994, Cancer Res, 54:2260-2063.
Williams et al, 1995, Hum Mol Genet; 4: 1569-1577.



CTNND2



Cri-Du-Chat CTNND2 (5p15) / 5q31 probe hybridized to a normal metaphase (2RG).

CTNND2 (5p15) / 5q31

CODE	COLOR	FORMAT	STATUS
KI-40106	Green/Red	100 µL	RUO

MENU

RESEARCH

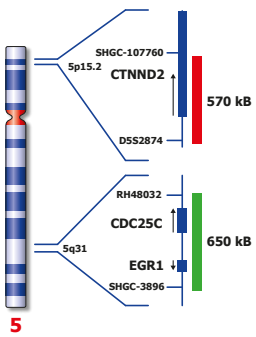
BACKGROUND

Cri-Du-Chat syndrome is an autosomal deletion syndrome caused by a partial deletion of chromosome 5p. It is characterized by a distinctive, high-pitched, catlike cry in infancy with growth failure, microcephaly, facial abnormalities, and mental retardation throughout life. Loss of a small region in band 5p15.2 (Cri-Du-Chat critical region) correlates with all the clinical features of the syndrome with the exception of the catlike cry, which maps to band 5p15.3 (catlike cry critical region).

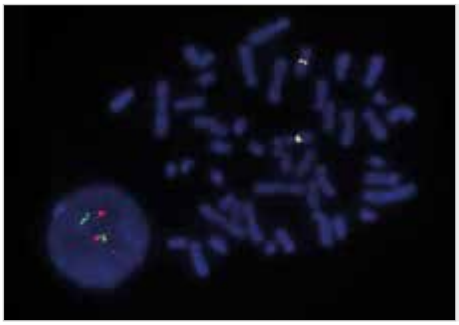
The Cri-Du-Chat region probe is optimized to detect copy numbers at the CTNND2 gene region in the Cri-Du-Chat critical region at 5p15.2. The 5q31 specific FISH probe is included as control probe.

REFERENCES

Overhauser et al, 1994, Hum. Mol. Genet., 3; 247-252.
Gersh et al, 1997, Cytogenet Cell Genet., 77; 246-251.



DDIT3 Break



DDIT3 (12q13) Break probe hybridized to a normal metaphase (2RG).

DDIT3 (12q13) Break

CODE	COLOR	FORMAT	STATUS
KI-10714	Green/Red	100 µL	RUO

MENU

RESEARCH

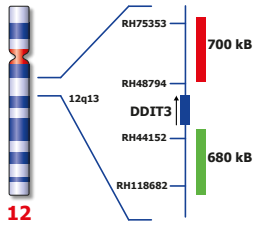
BACKGROUND

Liposarcoma is one of the most frequent sarcomas in adults, representing 10 to 16 percent of soft tissue sarcomas. Most patients with round cell / myxoid liposarcoma have an acquired t(12;16)(DDIT3-FUS) or t(12;22)(DDIT3-EWS) translocation, both of which involve the DDIT3 gene at 12q13. A break or split probe for DDIT3 is best used to analyze translocation of the DDIT3 (12q13) gene on formalin fixed paraffin embedded tissue for routine clinical diagnosis.

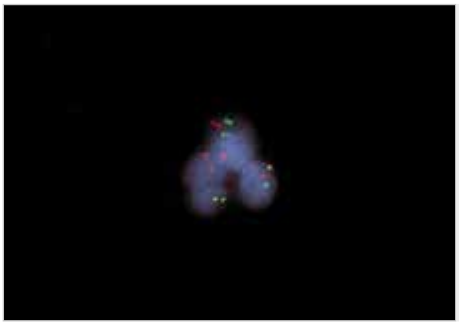
The DDIT3 (12q13) Break probe is optimized to detect translocations involving the DDIT3 gene region at 12q13 in a dual-color, break assay.

REFERENCES

Panagopoulos et al, 1994, Cancer Res, 54; 6500-6503.
Schoenmakers et al, 1994, Genomics, 20; 210-222.



DEK / NUP214



Hybridization of DEK/ NUP214 Fusion Probe to a positive cell line showing a fusion due to t(6;9).

DEK / NUP214 t(6;9) Fusion

CODE	COLOR	FORMAT	STATUS
KI-10306	Green/Red	100 µL	RUO

MENU

RESEARCH

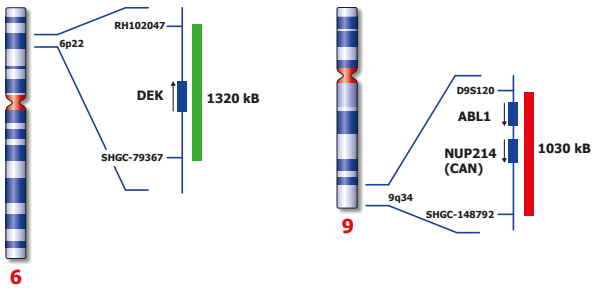
BACKGROUND

The chromosomal translocation t(6;9) (p22;q34) is associated with a specific subtype of acute myeloid leukemia (AML) and constitutes 0.5% to 4% of all AML cases. The translocation results in a fusion between the DEK oncogene (6p22) and the nucleoporin 214 kDa (NUP214 at 9q34; previously known as CAN). The exact mechanism by which the fusion protein DEK-NUP214 contributes to leukemia development has not been identified. Patients with t(6;9) AML have a very poor prognosis.

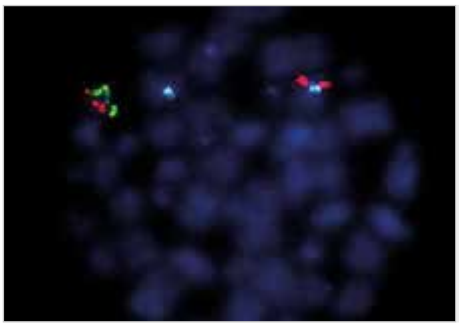
The DEK / NUP214 t(6;9) specific FISH probe has been optimized to detect the reciprocal translocation t(6;9) in a dual-color, dual-fusion assay on metaphase/ interphase spreads, blood smears and bone marrow cells.

REFERENCES

Von Lindern et al, 1992, Mol. Cell. Biol.,12; 1687-1697.
Ageberg et al, 2008, Gen. Chrom. Canc., 47; 276-287.
Chi et al, 2008, Arch. Pathol. Lab. Med., 132; 1835-1837.



dic(9;20)



dic(9;20) Triple-Color.

Image kindly provided by Dr. Ann Nordgren, Stockholm.

dic(9;20) Triple-Color

CODE	COLOR	FORMAT	STATUS
KI-10405	Green/Red/Blue	100 µL	RUO

MENU

RESEARCH

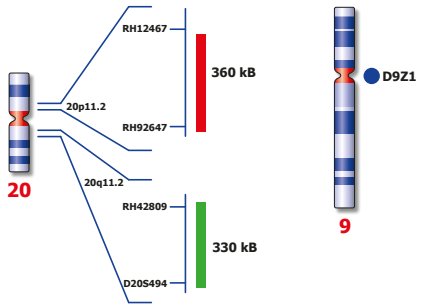
BACKGROUND

The dic(9;20)(p13.2;q11.2) is a recurrent chromosomal abnormality in pediatric Bcell precursor acute lymphoblastic leukemia (BCP-ALL), which occurs in ~2% of the cases. It is associated with an intermediate outcome with relapses being relatively frequent, compared to other common cytogenetic subgroups of BCP-ALL (e.g. high hyperploidy and t(12;21)). The dic(9;20) is an unbalanced rearrangement involving chromosomes 9 and 20, resulting in the co-localisation of the respective centromeres and concomitant loss of the chromosome arms 9p and 20q.

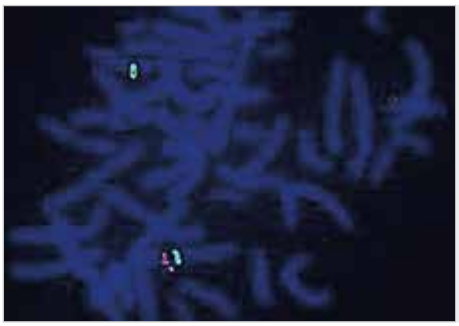
The dic(9;20) Triple-Color FISH probe is optimized to detect the dicentric (9;20)(p13.2;q11.2) in a triple-color assay on metaphase/interphase spreads, blood smears and bone marrow cells.

REFERENCES

Forestier et al., Genes Chromosome Cancer, 2008, 47; 149-158.
Pichler H et al., Br J Haematol, 2010, 149; 93-100.
Schmiegelow K et al., Leukemia, 2010, 24; 345-54.
Zachariadis V et al., Leukemia, 2011, 25; 22-628.
Zachariadis V et al., Br J Haematol, 2012, 159; 488-491.



DiGeorge II / SE 10



DiGeorge II(10p14) / SE 10 probe hybridized to DiGeorge II patient material showing a deletion of the DGSII region at 10p14 (1R2G).

Image kindly provided by Azzedine Aboura, Hôpital Robert Debré Paris.

DiGeorge II (10p14) / SE 10

CODE	COLOR	FORMAT	STATUS
KI-40105	Green/Red	100 µL	RUO

MENU

RESEARCH

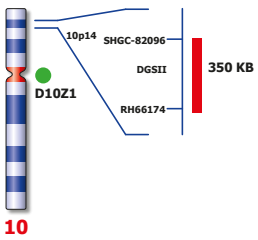
BACKGROUND

DiGeorge and VCFS present many clinical problems and are frequently associated with deletions within 22q11.2, but a number of cases have no detectable molecular defect of this region. A number of single case reports with deletions of 10p suggest genetic heterogeneity of DiGeorge syndrome. FISH analysis demonstrates that these patients have overlapping deletions at the 10p13 / 10p14 boundary. The shortest region of deletion overlap (SRO) has been identified in a 1 cM interval including makers D10S547 and D10S585.

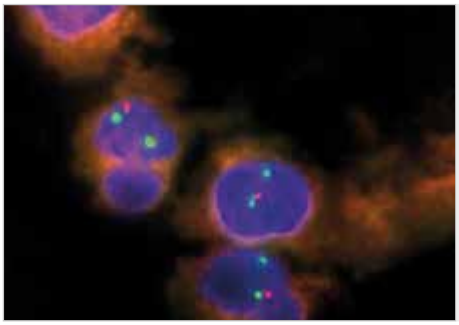
The DiGeorge II region probe is optimized to detect copy numbers of the DGSII at 10p14. The chromosome 10 satellite enumeration (SE 10) FISH probe at D10Z1 is included to facilitate chromosome identification.

REFERENCES

Monaco et al, 1991, Am. J. Med. Genet., 39; 215-216.
Schuffenhauer et al, 1998, Eur. J. Hum. Genet., 6; 213-225.



DLEU1 / 13qter



DLEU1 (13q14) / 13qter probe hybridized to patient material showing a 13q14 deletion (1R2G).

Image kindly provided by Dr. Dastugue, Toulouse.

DLEU1 (13q14) / 13qter

CODE	COLOR	FORMAT	STATUS
KI-10102	Green/Red	100 µL	RUO

MENU

RESEARCH

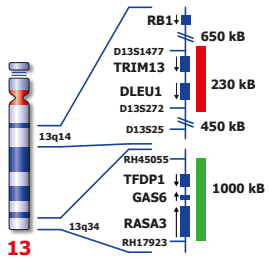
BACKGROUND

Deletions of chromosome 13q14 have been reported not only in CLL but in a variety of human tumors, including other types of lymphoid and myeloid tumors, as well as prostate, head and neck, and non-small cell lung cancers. The deletion of 13q may be limited to a single locus (13q14), or accompanied with the loss of a larger interstitial region of the long arm of chromosome 13. A minimal critical region of 400 kb has been described containing the DLEU1, DLEU2 and RFP2 genes.

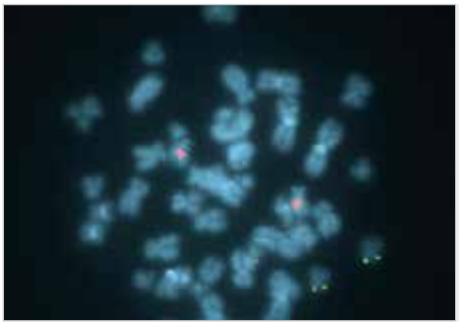
The DLEU1 (13q14) specific FISH probe is optimized to detect copy numbers of the DLEU1 (previously known as DLEU) gene region at 13q14. The 13qter (13q34) region is included to facilitate chromosome identification.

REFERENCES

Wolf et al, 2001, Hum Mol Genet, 10; 1275-1285.
Corcoran et al, 1998, Blood, 91; 1382-1390.



DLEU1 / TP53



DLEU1 (13q14) / TP53 (17p13) hybridized to a normal metaphase (2R2G).

DLEU1 (13q14) / TP53 (17p13)

CODE	COLOR	FORMAT	STATUS
KI-10113	Green/Red	100 µL	RUO

MENU

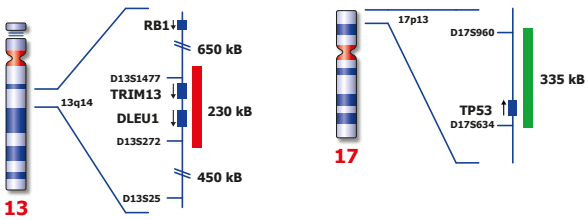
RESEARCH

BACKGROUND

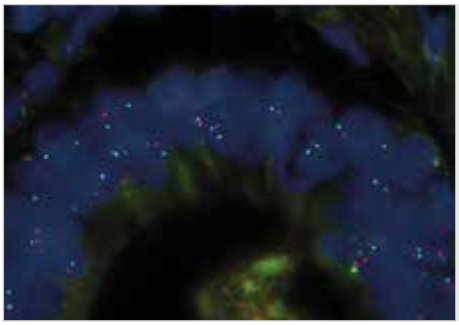
Deletion of DLEU1 (previously known as DLEU) at 13q14 indicates a rather good prognosis, deletion of TP53 (previously known as p53) at 17p13 is associated with poor prognosis. The DLEU1 (13q14) specific FISH probe is optimized to detect copy numbers at the DLEU1 gene region at 13q14. The TP53 (17p13) specific FISH probe is optimized to detect copy numbers of the TP53 gene region at 17p13

REFERENCES

Amiel A et al, 1997, Cancer Gener.Cytogenet, 97; 97-100.
Drach J et al, 1998, Blood, 92; 802-809.
Stilgenbauer S et al, 1998, Oncogene, 16; 1891 - 1897.
Wolf S et al, 2001, Hum. Molec. Genet., 10; 1275-1285.



EGFR / SE 7



EGFR (7p11) / SE 7 hybridized to colon tissue (2R2G).

EGFR (7p11) / SE 7

CODE	COLOR	FORMAT	STATUS
KI-10702	Green/Red	100 µL	RUO

MENU

RESEARCH

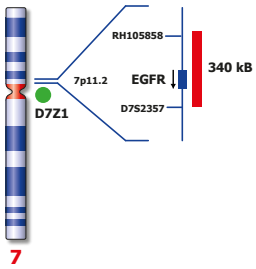
BACKGROUND

Epidermal growth factor receptor (EGFR) is a cell membrane protein, providing signal transduction and cell growth. It is a member of the Erb-B family of type I receptor tyrosine kinases and implicated in the development and progression of non-small cell lung carcinomas (NSCLC), breast, intestine, and other organs. EGFR has been found to act as a strong prognostic indicator in head and neck, ovarian, cervical, bladder and oesophageal cancers. In these cancers, increased EGFR expression was associated with reduced recurrence-free or overall survival.

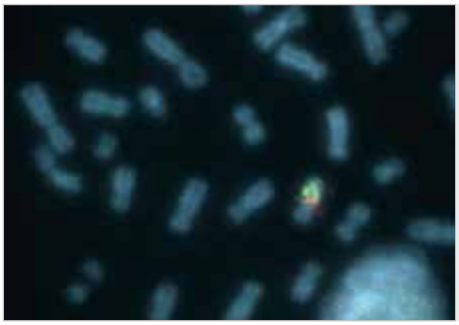
The EGFR (7p11) FISH probe is optimized to detect copy numbers of the EGFR gene region at region 7p11. The chromosome 7 satellite enumeration (SE 7) probe at D7Z1 is included to facilitate chromosome identification.

REFERENCES

Wang et al, 1993, Jpn J Hum Genet, 38: 399-406.
Nicholoset al, 2001, Eur J Cancer, 37: 9-15.



ELN / 7q22



Williams-Beuren ELN (7q11) / 7q22 probe hybridized to a normal metaphase (2RG).

ELN (7q11) / 7q22

CODE	COLOR	FORMAT	STATUS
KI-40111	Green/Red	100 µL	RUO

MENU

RESEARCH

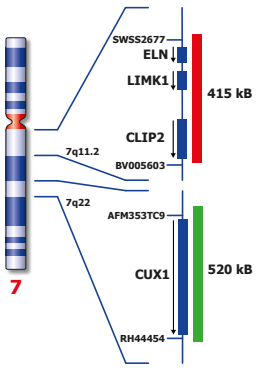
BACKGROUND

Williams-Beuren syndrome (WS) is characterized by cardiovascular disease, distinctive facial features, connective tissue abnormalities, mental retardation and endocrine abnormalities. Over 99% of individuals with the clinical diagnosis of WS have this contiguous gene deletion, that encompasses the elastin (ELN) gene region including ELN, LIMK1, and the D7S613 locus.

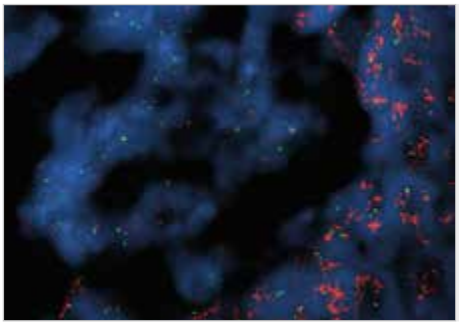
The Williams-Beuren region probe is optimized to detect copy numbers of the ELN gene region at 7q11. The 7q22 region specific FISH probe at 7q22 is included as control probe.

REFERENCES

Ewart, et al, 1993, Nat. Genet., 5; 11-16.
Botta et al, 1999, J. Med. Genet., 36; 478-480.



ERBB2 / SE 17



ERBB2 (17q12) / SE 17 probe hybridized to breast tumor tissue showing amplification of ERBB2 / SE 17.

ERBB2 (17q12) / SE 17

CODE	COLOR	FORMAT	STATUS
KI-10701	Green/Red	100 µL	RUO
KI-14701	Green/Red	500 µL	RUO

MENU

RESEARCH

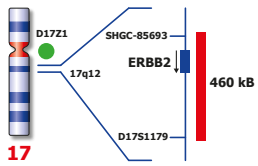
BACKGROUND

The ERBB2 (or HER2) gene encodes a receptor tyrosine kinase involved in growth factor signaling. Overexpression of this gene is seen in about 20% of invasive breast cancers. ERBB2 gene amplification is a permanent genetic change that results in this continuous overexpression of ERBB2. Trastuzumab (commonly known as Herceptin) has been developed to be effective against ERBB2-positive breast cancer. ERBB2 amplification is also observed in a variety of other tumors, such as gastric, prostate, lung, colon and ovary carcinoma.

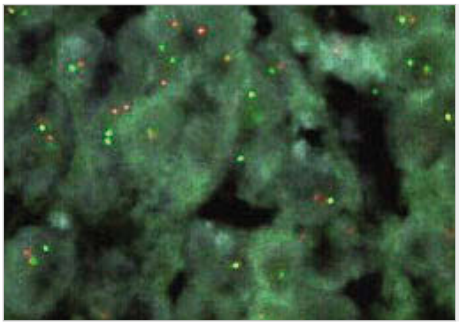
The ERBB2 (17q12) FISH probe is optimized to detect copy numbers of the ERBB2 gene region at region 17q12. The chromosome 17 satellite enumeration probe (SE 17) at D17Z1 is included to facilitate chromosome identification/enumeration.

REFERENCES

Pauletti et al, 1996, Oncogene, 13: 63-72.
Xing et al, 1996, Breast Cancer Res Treat, 39: 203-212.



ERCC1 / ZNF443



ERCC1 (19q13) / ZNF443 (19p13) probe hybridized to paraffin embedded tissue (2R2G).

ERCC1 (19q13) / ZNF443 (19p13)

CODE	COLOR	FORMAT	STATUS
KI-10739	Green/Red	100 µL	RUO

MENU

RESEARCH

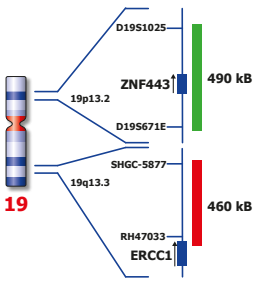
BACKGROUND

Excision repair cross-complementing rodent repair deficiency, complementation group 1 (ERCC1) is a critical gene in the Nucleotide excision repair pathway. A growing list of reports links cisplatin, carboplatin, and oxaliplatin based chemotherapy resistance to ERCC1 expression levels in several tumors. ERCC1 has been shown to be an important marker to predict responsiveness to cisplatin-based chemotherapy. Low ERCC1 gene expression correlates with prolonged survival after cisplatin-based chemotherapy.

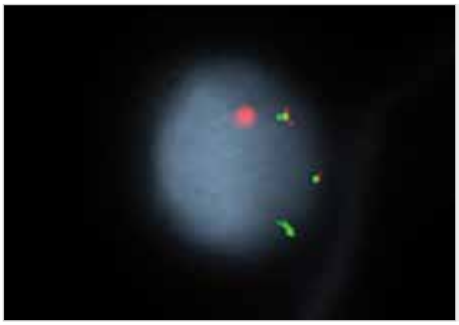
The ERCC1 (19q13) FISH probe has been optimized to detect copy numbers of the ERCC1 gene region at 19q13. The ZNF443 (19p13) probe is included to facilitate chromosome identification.

REFERENCES

Olaussen et al, 2006, N. Engl. J. Med. 335; 983-991.
Ceppi et al, 2006, Ann. Oncol. 17; 1818-1825.



ETV6 / RUNX1



ETV6 / RUNX1 t(12;21) Fusion probe hybridized to patient material showing t(12;21) translocation (2RG1R1G).

Material kindly provided by Dr. Balogh, Budapest.

ETV6 / RUNX1 t(12;21) Fusion

CODE	COLOR	FORMAT	STATUS
KI-10401	Green/Red	100 µL	RUO

MENU

RESEARCH

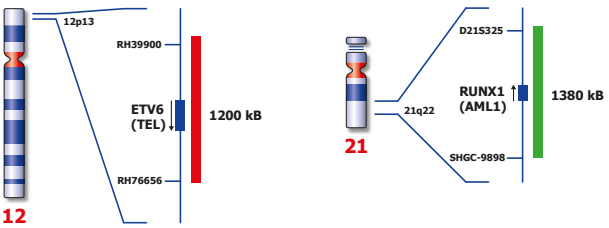
BACKGROUND

The t(12;21), a cryptic translocation rarely observed by conventional cytogenetics, was first identified by fluorescence in situ hybridization (FISH). In ALL blasts, this translocation fuses the 5' part of the ETV6 (previously known as TEL) gene with almost the entire RUNX1 (previously known as AML) (CBFA2) gene, producing the chimeric transcript ETV6-CBFA2. The t(12;21) (p13;q22) has also been identified as the most frequent chromosomal abnormality in childhood ALL, affecting 20% to 25% of B-lineage cases.

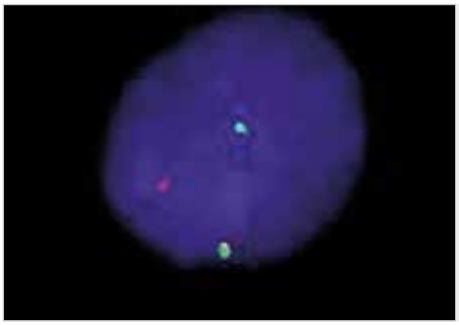
The ETV6 / RUNX1 t(12;21) specific FISH probe is optimized to detect the reciprocal translocation t(12;21) (p13;q22) in a dual-color, dual-fusion assay.

REFERENCES

Romana et al, 1995, Blood, 85; 3662-3670.



ETV6 Break



ETV6 (12p13) Break probe hybridized to patient material showing a translocation involving the ETV6 region at 12p13 (1RG1R1G).

Image kindly provided by Magret Ratjen, Kiel.

ETV6 (12p13) Break

CODE	COLOR	FORMAT	STATUS
KI-10403	Green/Red	100 µL	RUO

MENU

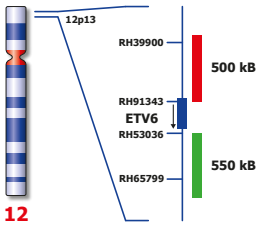
RESEARCH

BACKGROUND

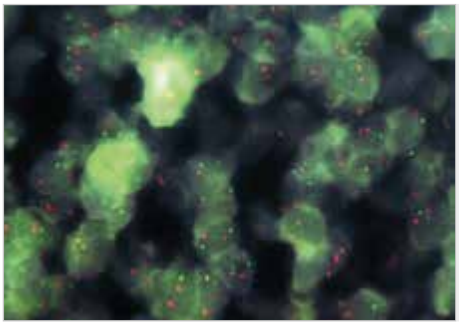
ETV6 (previously known as TEL) gene is the abbreviation for -ETS variant 6- gene. It encodes an ETS family factor which functions as a transcriptional repressor in hematopoiesis and in vascular development. The gene is located on chromosome 12p13, and is frequently rearranged in human leukemias of myeloid or lymphoid origins. Also systematic deletion of the normal ETV6 allele in patients with ETV6-RUNX1 fusions can be found. The ETV6 Break FISH probe is optimized to detect translocations involving the ETV6 region at 12p13 in a dual-color, split assay on metaphase/interphase spreads and bone marrow cells.

REFERENCES

Golub et al, 1995, PNAS 92; 4917-4921.
Ford et al, 2001, Blood 98; 558-564.



EWSR1 / NFATC



FISH result of the EWSR1/ NFATC2 t(20;22) DC, S-Fusion probe.

EWSR1 / NFATC2 t(20;22) Dual-Color, Single-Fusion

CODE	COLOR	FORMAT	STATUS
KI-10751	Green/Red	100 µL	RUO

MENU

RESEARCH

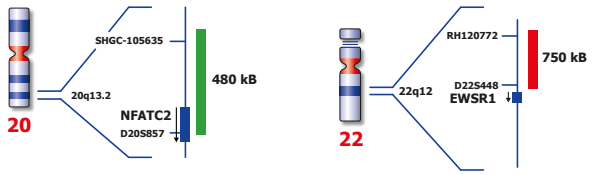
BACKGROUND

Ewing's sarcoma is the second most frequent primary bone cancer. In most cases a translocation involving the EWSR1 gene at 22q12 and the FLI1 gene at 11q24 is observed. Several other translocation partners of the ETS gene family can also be involved. The first non-ETS family translocation partner described is the NFATC2 gene (nuclear factor of activated T-cells, cyto-plasmic, calcineurin-dependent 2) at 20q13.

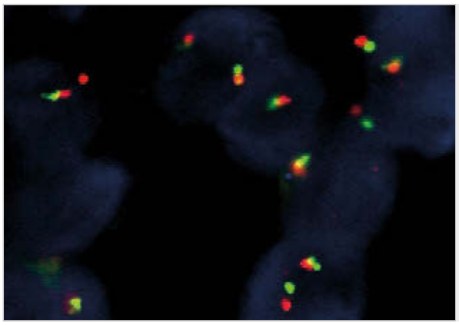
The EWSR1 / NFATC2 t(20;22) Dual-Color Single-Fusion probe is optimized to detect the t(20;22)(q13;q12) involving the NFATC2 (20q13) and EWSR1 (22q12) gene regions in a dual-color, single fusion assay on paraffin embedded tissue sections.

REFERENCES

Szuhai et al, 2009, Clin Cancer Res, 15; 2259-2268.
Zucman-Rossi et al, 1998, PNAS, 95; 11786-11791.
Bernstein et al, 2006, Oncologist, 11; 503-519.



EWSR1 Break



EWSR1 (22q12) break probe hybridized to a tissue section showing co-localized and split signals.

EWSR1 (22q12) Break

CODE	COLOR	FORMAT	STATUS
KI-10750	Green/Red	100 µL	RUO

MENU

RESEARCH

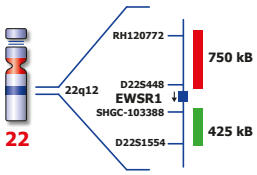
BACKGROUND

Ewing's sarcoma is the second most frequent primary bone cancer. In most cases a translocation involving the EWSR1 gene at 22q12 and the FLI1 gene at 11q24 are observed, but several other translocation partners (ERG, ETV1, FEV, and E1A3) can also be involved.

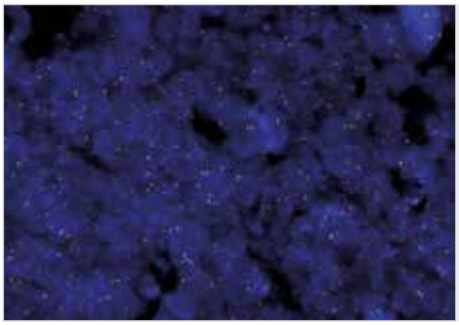
The EWSR1 (22q12) Break probe is optimized to detect translocations involving the EWSR1 gene region at 22q12 in a dual-color, split assay on paraffin embedded tissue sections.

REFERENCES

Zucman-Rossi, et al, 1998, PNAS, 95; 11786-11791.
Bernstein et al, 2006, Oncologist, 11; 503-519.



FGFR1 Break



FGFR1 (8p11) Break probe hybridization to a tissue section showing a normal pattern.

FGFR1 (8p11) Break

CODE	COLOR	FORMAT	STATUS
KI-10737	Green/Red	100 µL	RUO

MENU

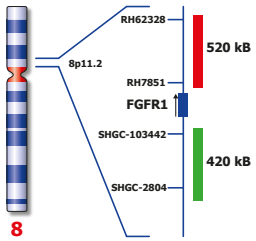
RESEARCH

BACKGROUND

FGFR1 has been implicated in the tumorigenesis of haematological malignancies, where it is frequently involved in balanced chromosomal translocations, including cases of chronic myeloid leukemia (BCR-FGFR1 fusion) and the 8p11 myeloproliferative syndrome/stem cell leukemia-lymphoma syndrome, which is characterized by myeloid hyperplasia and non-Hodgkin's lymphoma with chromosomal translocations fusing several genes, the most common being a fusion between ZNF198 and FGFR1."The FGFR1 (8p11) Break FISH probe is optimized to detect translocations involving the FGFR1 gene region at 8p11 in a dual-color assay on FFPE tissue sections.

REFERENCES

Smedley et al, 1998, Hum Mol Genet., 7; 627-642.
Sohal et al, 2001, Genes Chrom. Cancer, 32; 155-163.
Kwak et al, J Clin Oncol., 27(26); 4247-53.



FGFR2 / SE 10

FGFR2 (10q26) / SE 10

CODE	COLOR	FORMAT	STATUS
KI-10757	Green/Red	100 µL	RUO

MENU

RESEARCH

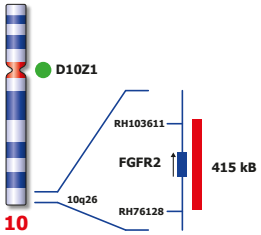
BACKGROUND

It is well documented that dysregulation of FGF-FGFR signaling via amplification, point mutation or translocations may have an important role in tumor development and progression. Alterations in FGFRs are associated with a number of human cancers, including lung, myeloma, breast, gastric, colon, bladder, pancreatic, and hepatocellular carcinomas. A growing body of preclinical data demonstrates that inhibition of FGFR signaling can result in antiproliferative and/or pro-apoptic effects, thus confirming the validity of the FGFR / FGFR axis as a potential therapeutic target.

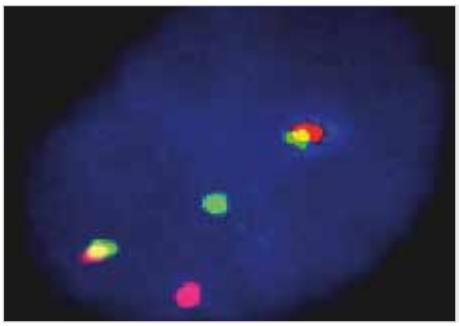
The FGFR2 (10q26) FISH probe is optimized to detect copy numbers of the FGFR2 gene region at region 10q26. The Chromosome 10 Satellite Enumeration (SE) probe is included to facilitate chromosome identification.

REFERENCES

Brooks et al, Clin Cancer Res. 2012; 18:1855.
Dutt et al, PLoS ONE 6: e2035.1
Kunii et al, Cancer Res. 2008; 68:2340-8.
Liang et al, Clin Cancer Res. 2013;19: 2572
Liao et al, Cancer Res. 2013;73:5195-205.
Weiss et al, Sci Transl Med. 2010; 2:62ra93.



FGFR3 / IGH



FGFR3 / IGH t(4;14) Fusion probe hybridized to MM patient material showing t(4;14) translocation (2RG1R1G).

Image kindly provided by Prof. Jauch, Heidelberg.

FGFR3 / IGH t(4;14) Fusion

CODE	COLOR	FORMAT	STATUS
KI-10602	Green/Red	100 µL	RUO

MENU

RESEARCH

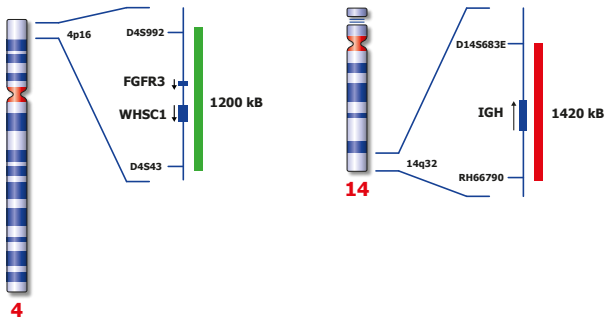
BACKGROUND

The t(4;14) translocation is undetectable by conventional cytogenetics. The breakpoints on chromosome 4 occur within an approximately 113-kb region located in small part of a conserved gene cluster including the transforming acidic coiled-coil protein 3 (TACC3), fibroblast growth factor receptor 3 (FGFR3), and multiple myeloma SET domain-containing protein (MMSET). The translocation is indicative for poor survival and poor response to chemotherapy.

The FGFR3 / IGH t(4;14)(p16;q32) Fusion specific FISH probe is optimized to detect the reciprocal translocation t(4;14) in a dual-color, dual-fusion assay.

REFERENCES

Chesi et al, 1997, Nat Genet, 16; 260-264.
Finelli et al, 1999, Blood, 94; 724-732.



FGFR4 / 5q11.2

FGFR4 (5q35) / 5q11.2

CODE	COLOR	FORMAT	STATUS
KI-10756	Green/Red	100 µL	RUO

MENU

RESEARCH

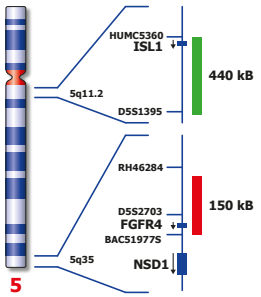
BACKGROUND

It is well documented that dysregulation of FGF-FGFR signaling via amplification, point mutation or translocations may have an important role in tumor development and progression. Alterations in FGFRs are associated with a number of human cancers, including lung, myeloma, breast, gastric, colon, bladder, pancreatic, and hepatocellular carcinomas. A growing body of preclinical data demonstrates that inhibition of FGFR signaling can result in antiproliferative and/or pro-apoptic effects, thus confirming the validity of the FGFR / FGFR axis as a potential therapeutic target.

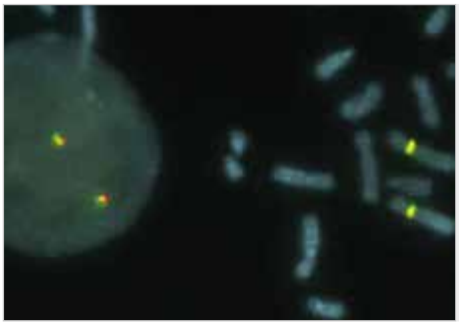
The FGFR4 (5q35) FISH probe is optimized to detect copy numbers of the FGFR4 gene region at region 5q35. The 5q11.2 probe is included to facilitate chromosome identification.

REFERENCES

Brooks et al, Clin Cancer Res. 2012; 18:1855.
Dutt et al, PLoS ONE 6: e2035.1
Kunii et al, Cancer Res. 2008; 68:2340-8.
Liang et al, Clin Cancer Res. 2013;19: 2572
Liao et al, Cancer Res. 2013; 73:5195-205.
Weiss et al, Sci Transl Med. 2010; 2:62ra93.



FIP1L1 / CHIC2 /PDGFRA Dual-Color



FIP1L1 / CHIC2 / PDGFRA (4q12) Deletion, Break probe hybridized to a normal interphase/metaphase (2RG).

FIP1L1 / CHIC2 / PDGFRA (4q12) Deletion, Break

CODE	COLOR	FORMAT	STATUS
KI-10003	Green/Red	100 µL	RUO

MENU

RESEARCH

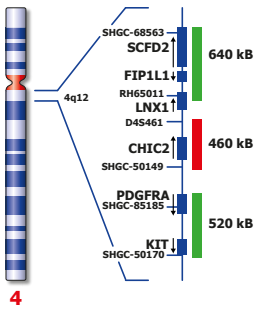
BACKGROUND

The deletion of the CHIC2 locus generates a fusion FIP1L1-PDGFRA gene giving raise to a novel tyrosine kinase. This deletion has been observed in patients with idiophatic hypereosinophilic syndrome (HES), chronic eosinophilic leukemia (CEL), systemic mast cell disease, and chronic myeloproiferative disorders (CMPD).

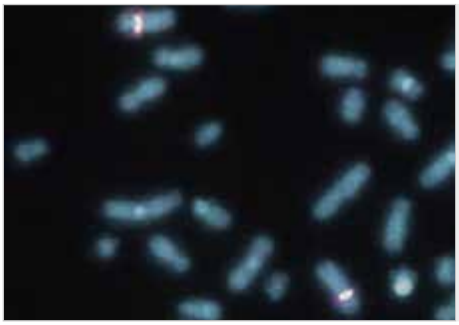
The FIP1L1 / CHIC2 / PDGFRA FISH probe is optimized to detect the CHIC2 deletion at 4q12 associated with the FIP1L1 / PDGFRA fusion in a Dual-Color, split assay. It also allows the detection of translocation involving the FIP1L1 and PDGFRA region. However, chromosome 4 polyploidy may provide additional signals not associated with a translocation involving 4q12.

REFERENCES

Cools et al, N Engl J Med, 2003, 348; 1201-1214.
Godlib et al, Blood, 2004, 103; 2879-2891.



FIP1L1 / CHIC2 /PDGFRA Triple-Color



FIP1L1 / CHIC2 / PDGFRA (4q12) Deletion, Break Triple-Color.

FIP1L1 / CHIC2 / PDGFRA (4q12) Deletion, Break, Triple-Color

CODE	COLOR	FORMAT	STATUS
KI-10007	Green/Red/Blue	100 µL	RUO

MENU

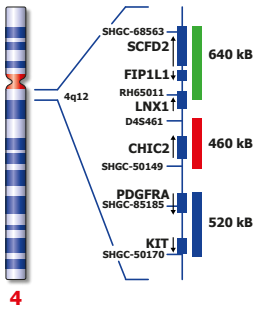
RESEARCH

BACKGROUND

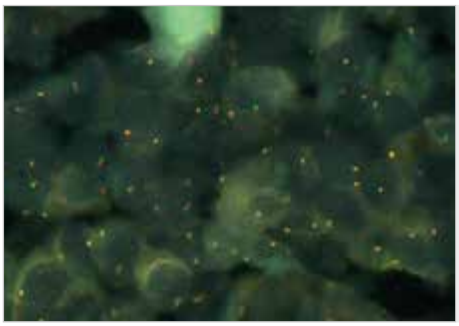
The FIP1L1 / CHIC2 / PDGFRA Triple-Color FISH probe is optimized to detect the CHIC2 deletion at 4q12 associated with the FIP1L1 / PDGFRA fusion in a triple-color, split assay. It also allows the detection of translocation involving the FIP1L1 and PDGFRA region.

REFERENCES

Cools et al, N Engl J Med, 2003, 348; 1201-1214.
Griffin et al, 2003, PNAS, 100;7830-7835.
Gotlib et al, 2004, Blood, 103;2879-2891



FOXO1 Break



FOXO1 (13q14) Break probe hybridized to patient material (2RG).

FOXO1 (13q14) Break

CODE	COLOR	FORMAT	STATUS
KI-10716	Green/Red	100 µL	RUO

MENU

RESEARCH

BACKGROUND

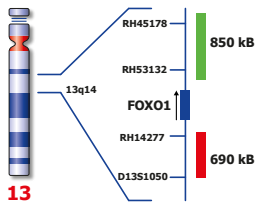
The t(2;13) is associated with alveolar rhabdomyo-sarcomas. This translocation results in the formation of a chimeric transcript consisting of the 5' portion of PAX3, including an intact DNA-binding domain fused to the FOXO1 gene on chromosome 13. The t(1;13)(p36;q14) also seen in alveolar rhabdomyosarcomas results in the fusion of another member of the PAX family, PAX7 to the FOXO1 gene on chromosome 13.

A break or split probe for FOXO1 is best used to analyze translocation of the FOXO1 (13q14) gene on formalin fixed paraffin embedded tissue for routine clinical diagnosis.

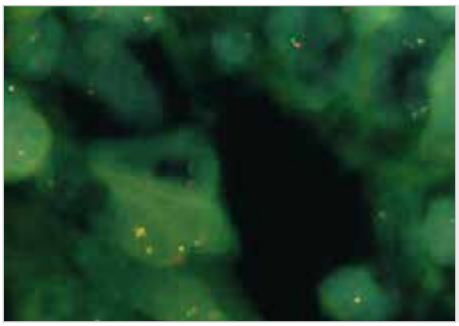
The FOXO1 (13q14) Break probe is optimized to detect translocations involving the FOXO1 gene region at 13q14 in a dual-color, split assay on metaphase/interphase spreads and paraffin embedded tissue sections.

REFERENCES

Barr et al, 1996, Hum. Mol. Genet., 5; 15-21.
Coignet et al, 1999, Genes Chrom. Cancer, 25; 222-229.



FUS Break



FUS (16p11) Break probe hybridized to liposarcoma material.

FUS (16p11) Break

CODE	COLOR	FORMAT	STATUS
KI-10715	Green/Red	100 µL	RUO

MENU

RESEARCH

BACKGROUND

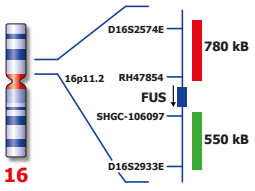
The fused in sarcoma (FUS) gene was originally shown to be rearranged in myxoid liposarcomas harboring a t(12;16)(q13;p11) translocation. FUS has also been shown to be involved in other recombinations: with ERG in acute myeloid leukemia carrying a t(16;21), with ATF1 in band 12q13 in angiomatoid fibrous histiocytoma, and with CREB3L2 in fibromyxoid sarcoma.

A break or split probe for FUS is best used to analyze translocation of the FUS (16p11) gene on formalin fixed paraffin embedded tissue for routine clinical diagnosis.

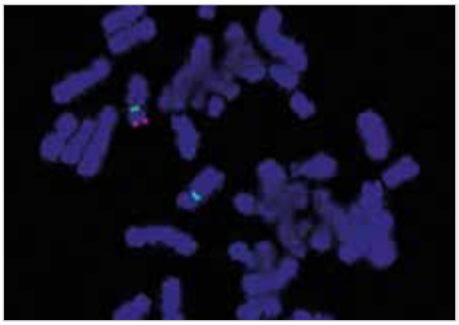
The FUS (16p11) Break probe is optimized to detect translocations involving the FUS gene region at 16p11 in a dual-color, split assay on metaphase/interphase spreads and paraffin embedded tissue sections.

REFERENCES

Shing et al, 2003, Cancer Res, 63: 4568-4576.
Storlazzi et al, 2003, Hum. Mol. Genet., 12: 2349-2358.



GATA4 / SE 8



GATA4 (8p23) / SE 8 probe hybridized to patient material showing a deletion of the GATA4 (8p23) region (1R2G).

GATA4 (8p23) / SE 8

CODE	COLOR	FORMAT	STATUS
KI-40118	Green/Red	100 µL	RUO

MENU

RESEARCH

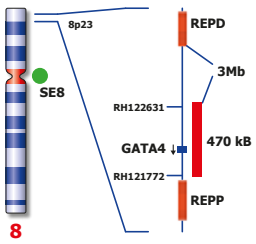
BACKGROUND

The deletion of GATA4 (8p23) is found in patients with congenital heart disease. Besides the deletion, duplications are found of the region flanked by low copy repeats 8p-OR-REPD (distal) and -REPP (proximal). These recurrent deletions are associated with a spectrum of anomalies, including developmental delay and neuropsychiatric findings. GATA4 is expressed in adult heart, epithelium and gonads. During fetal development, GATA4 is expressed in yolk sac endoderm and cells involved in heart formation.

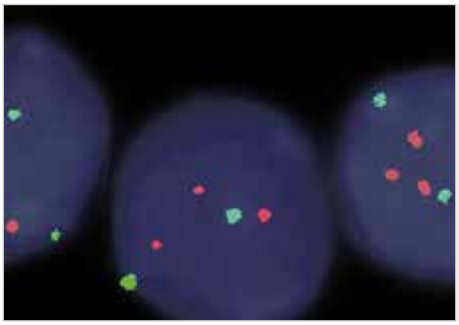
The GATA4 (8p23) / SE 8 FISH probe is optimized to detect deletions of the GATA4 gene region at 8p23 in a dual-color assay on metaphase/interphase spreads, blood smears and bone marrow cells. The Chromosome 8 Satellite Enumeration (SE) FISH probe is included to facilitate chromosome identification.

REFERENCES

Bhatia et al, 1999, Prenat Diagn., 19; 863-867.
Giorda et al, 2007, Hum. Mut., 28; 459-468.
Wat et al, 2009, Am. J. Med. Genet., Part A, 149A; 1661-1677.



GLI1 / SE 12



GLI1 (12q13) / SE 12 hybridized to patient material showing GLI (12q13) amplification (3R2G).

Image kindly provided by Dr. Wenzel, Basel.

GLI1 (12q13) / SE 12

CODE	COLOR	FORMAT	STATUS
KI-10104	Green/Red	100 µL	RUO

MENU

RESEARCH

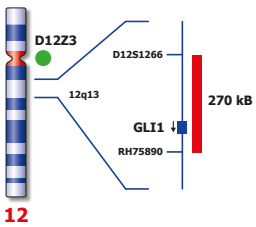
BACKGROUND

Trisomy 12 is the most common numerical chromosomal aberration in patients with B-cell chronic lymphocytic leukemia (B-CLL). Partial trisomy 12 of the long arm of chromosome 12 consistently includes a smaller region at 12q13-15 and has been observed in CLL and several other tumors. A number of loci located close to either MDM2 or CDK4 / SAS, including the genes GADD153, GLI1 (previously known as GLI), RAP1B, A2MR, and IFNG, were found to be coamplified.

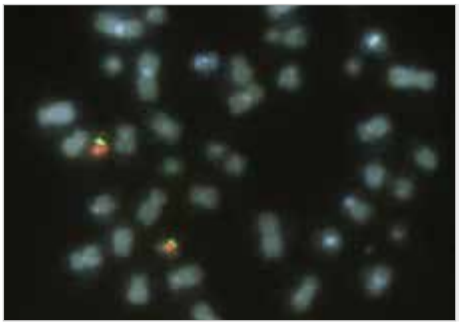
The GLI1 (12q13) specific FISH probe is optimized to detect copy numbers of the GLI1 gene region at region 12q13. The chromosome 12 Satellite Enumeration FISH probe (SE 12) D12Z3 is included to facilitate chromosome identification.

REFERENCES

Merup et al, 1997, Eur J Haematol, 58; 174-180.
Dierlamm et al., 1997, Genes Chrom Cancer, 20; 155-166.



HIRA / SHANK3



DiGeorge HIRA (22q11) / 22q13 (SHANK3) probe hybridized to a normal metaphase (2R2G).

HIRA (22q11) / 22q13 (SHANK3)

CODE	COLOR	FORMAT	STATUS
KI-40103	Green/Red	100 µL	RUO

MENU

RESEARCH

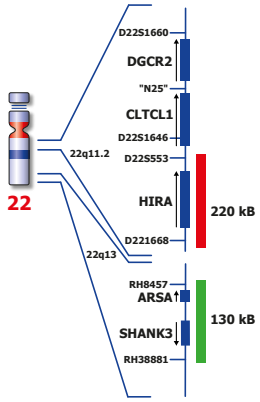
BACKGROUND

The DiGeorge HIRA (TUPLE) probe targets a putative transcriptional regulator (TUPLE1 or HIRA, HIR histone cell cycle regulation defective homolog A) which also has been identified to lie within the commonly deleted region DiGeorge syndrome. This probe is located distally to the “N25” probe.

The DiGeorge HIRA region probe is optimized to detect copy numbers of the HIRA gene region at 22q11.2. The SHANK3 probe at 22q13 is serving as internal control.

REFERENCES

Lorain at al, 1996, Genome Res, 6; 43-50.



Human Centromere

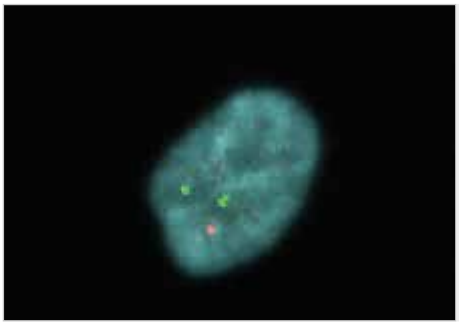
All Human Centromere Green

CODE	COLOR	FORMAT	STATUS
KBI-20000G	Green	10 test	RUO
KBI-20000R	Red	10 test	RUO
KI-20000G	Green	100 µL	RUO
KI-20000R	Red	100 µL	RUO

MENU

RESEARCH

IGF1R / 15q11



IGF1R (15q26) / 15q11 probe hybridized to patient material showing a deletion of the IGF1R gene region at 15q26 (1R2G).

IGF1R (15q26) / 15q11

CODE	COLOR	FORMAT	STATUS
KI-40116	Green/Red	100 µL	RUO

MENU

RESEARCH

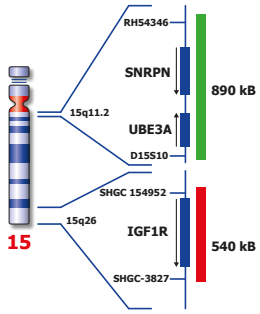
BACKGROUND

Congenital diaphragmatic hernia (CDH) is a severe, life-threatening, congenital anomaly characterized by variable defect in the diaphragm, pulmonary hypoplasia, and postnatal pulmonary hypertension. Deletion of the IGF1R (insulin-like growth factor 1 receptor) gene region at 15q25 is the most frequent anomaly found in CDH. The type 1 IGF receptor at 15q26 is required for normal embryonic and postnatal growth. Deletions, but also gain of an approximately 5 Mb region including the IGF1R gene has been found to have a profound effect on prenatal and early postnatal growth.

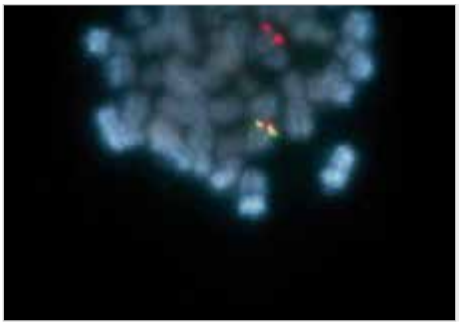
The IGF1R (15q26) specific FISH probe is optimized to detect copy numbers of the IGF1R gene region at region 15q26. The 15q11 (SNRPN / UBE3A) specific region probe is included to facilitate chromosome identification.

REFERENCES

Faivre et al, 2002, Eur, J, Hum, Genet., 10; 699-706.
Okubo et al, 2003, J. Clin. Endocrinol. Metab, 88; 5981-5988.



IGH Break



IGH (14q32) Break probe hybridized to patient material showing a partial deletion of 14q32 (1RG1R).

IGH (14q32) Break

CODE	COLOR	FORMAT	STATUS
KI-10601	Green/Red	100 µL	RUO

MENU

RESEARCH

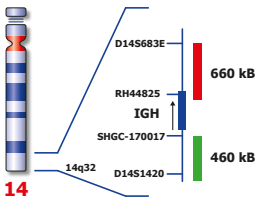
BACKGROUND

Multiple myeloma is characterized by complex rearrangements involving the IgH gene, particularly at the constant locus. The IgH rearrangement provides a useful marker of clonality in B-cell malignancies and amplification of this rearrangement is the method of choice to monitor the residual tumor cells in multiple myeloma.

The IGH (14q32) break probe is optimized to detect translocations involving the IGH gene region at 14q32 in a dual-color, split assay.

REFERENCES

Taniwaki et al, 1994, Blood, 83; 2962-1969.
Gozetti et al, 2002, Cancer Research, 62; 5523-5527.



IGH Break (tissue)

Hybridization of IGH break probe to a tissue section showing"normal and aberrant pattern (2RG) (1RG1R1G).

IGH (14q32) Break (tissue)

CODE	COLOR	FORMAT	STATUS
KI-10729	Green/Red	100 µL	RUO

MENU

RESEARCH

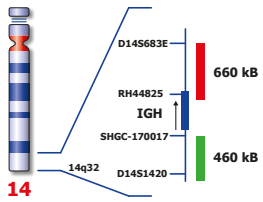
BACKGROUND

Chromosomal rearrangements involving the immunoglobulin heavy chain gene (IGH) at 14q32 are observed in 50% of patients with B-cell non-Hodgkin's lymphoma (NHL) and many other types of Lymphomas. More than 50 translocation partners with IGH have been described. In particular t(8;14) is associated with Burkitt's lymphoma, t(11;14) is associated with Mantle cell lymphoma, t(14;18) is observed in a high proportion of follicular lymphomas and t(3;14) is associated with Diffuse Large B-Cell Lymphoma.

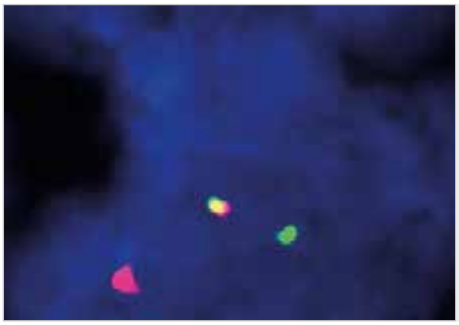
The IGH (14q32) Break probe is optimized to detect translocations involving the IGH gene region at 14q32 in a dual-color, split assay.

REFERENCES

Taniwaki et al, 1994, Blood, 83: 2962-1969.
Gozetti et al, 2002, Cancer Research, 62: 5523-5527.



IRF4 / DUSP22 Break



IRF4 / DUSP22 (6p25) Break.

Image kindly provided by Hopital Universitario Marqués de Valdecilla, Satander.

IRF4 / DUSP22 (6p25) Break

CODE	COLOR	FORMAT	STATUS
KI-10613	Green/Red	100 µL	RUO

MENU

RESEARCH

BACKGROUND

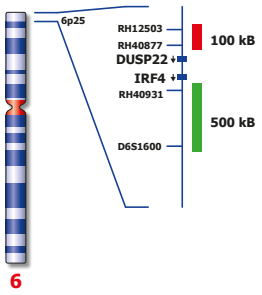
Rearrangements of the 6p25.3 locus define a subtype of CTCL. Genes rearranged at the 6p25.3 locus are IRF4 (also known as MUM1) and the DUSP22. Rearrangements of the 6p25.3 locus have also been described to occur in high and low grade B-cell lymphomas, myeloma and chronic B-cell lymphoid leukemia.

The IRF4 / DUSP22 (6p25) Break FISH probe detects both rearrangements involving IRF4 and DUSP22, but does not distinguish them from each other.

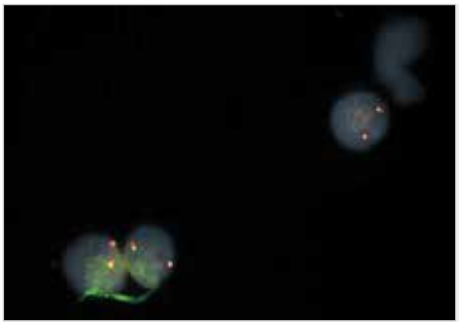
The IRF4 / DUSP22 (6p25) Break FISH probe is optimized to detect translocations involving the IRF4 / DUSP22 gene region at the 6p25.3 locus in a dual-color assay on metaphase/interphase spreads, blood smears, bone marrow cells and lymph node biopsies.

REFERENCES

Bisig et al., Best Pract Res Clin Haematol, 2012, 25; 13-28.
Feldman et al., Blood, 2011, 117; 915-919.
Karai et al., Am J Surg Pathol, 2013 [Epub ahead of print].
Pham-Ledard et al., J Invest Dermatol, 2010, 130; 816-825.
Salaverria et al., Blood, 2011, 118; 139-147.
Wada et al., Mod Pathol, 2011, 24; 596-605.



JAK2 Break



JAK2 (9p24) Break probe hybridized to bone marrow sample (2RG).

JAK2 (9p24) Break

CODE	COLOR	FORMAT	STATUS
KI-10012	Green/Red	100 µL	RUO

MENU

RESEARCH

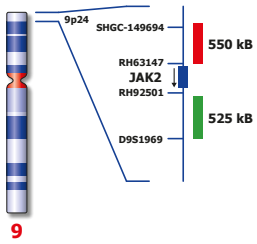
BACKGROUND

Janus Kinase 2 (JAK2) is a tyrosine kinase involved in cytokine signaling. Mutations and translocations involving the JAK2 gene region are observed in myeloproliferative neoplasms. The common JAK2617V>F point mutation and translocations results in constitutive activation of JAK2. Translocations are described with the following fusion partners: PCM1, BCR, ETV6 (TEL), SSBP2 and 3q21. Patients with the JAK2617V>F point mutation can also exhibit a numerical gain of the gene.

The JAK2 (9p24) Break FISH probe is optimized to detect translocations involving the JAK2 gene region at region 9p24 in a dual-color, split assay on metaphase/interphase spreads. The JAK2 (9p24) Break FISH probe can not be used to detect point mutations, and it has not been optimized to detect gene amplifications.jfeld V et al, 2007, Exp Hematol, 35; 1668-1676.

REFERENCES

Smith C et al, 2008, Hum Pathol, 39; 795-810.
Poitras J et al, 2008, Genes Chromosomes Cancer, 47; 884-889.



KMT2A / AFF1

KMT2A / AFF1 t(4;11) Fusion probe. Standard t(4;11) 2 Fusion, 1 Red, 1 Green (2F1R1G).

Image kindly provided by Dr. Christine Harrison, Newcastle.

KMT2A / AFF1 t(4;11) Fusion

CODE	COLOR	FORMAT	STATUS
KI-10404	Green/Red	100 µL	RUO

MENU

RESEARCH

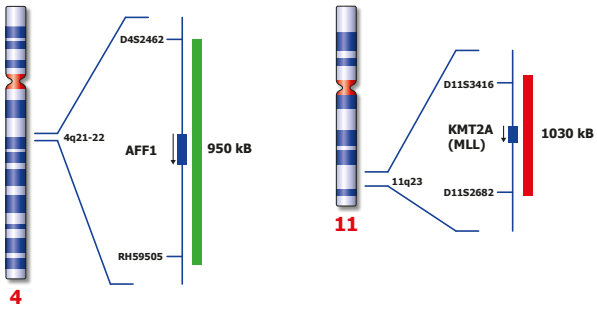
BACKGROUND

The t(4;11) KMT2A / AFF1 is the most frequently (approximately 66% according to Meyer et al.) observed translocation involving the KMT2A gene resulting in ALL. The KMT2A / AFF1 translocation results in the generation of fusion proteins KMT2A / AFF1 and AFF1 / KMT2A; both seem to have leukemogenic properties. Furthermore, MECOM (3q26) is one of the targets of the KMT2A oncoproteins, which increased expression correlates with unfavorable prognosis in Acute Myeloid Leukemia.

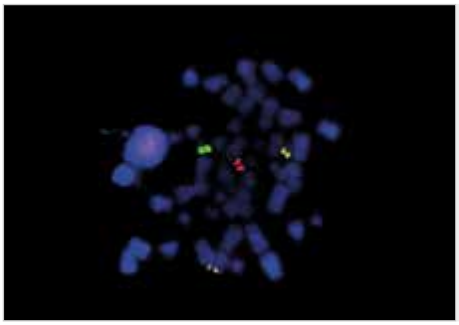
The KMT2A / AFF1 t(4;11) Fusion FISH probe is optimized to detect translocations involving the KMT2A (previously known as MLL) and AFF1 gene regions at 4q21-22 and 11q23 in a dual-color, fusion assay on metaphase/interphase spreads, blood smears and bone marrow cells.

REFERENCES

Harrison CJ et al, 2010, Br J Haem, 151; 132-142.
Arai S et al, 2011, Blood, 117; 6304-6314
Meyer C et al, 2009, Leukemia, 23; 1490-1499.



KMT2A / MLLT1



KMT2A / MLLT1 t(11;19) Fusion probe hybridized to patient material showing t(11;19) translocation (2RG1R1G).

KMT2A / MLLT1 t(11;19) Fusion

CODE	COLOR	FORMAT	STATUS
KI-10307	Green/Red	100 µL	RUO

MENU

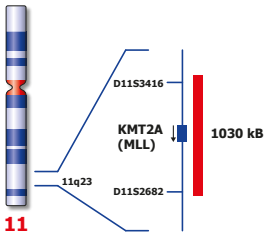
RESEARCH

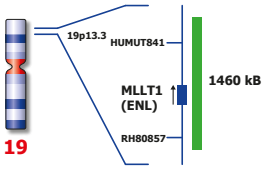
BACKGROUND

One of the relatively frequently observed translocations (around 10 %) in AML and ALL involves the genes KMT2A (previously known as MLL) and MLLT1 (aka ENL) at 11q23 and 19p13. The KMT2A / MLLT1 translocation results in the generation of fusion protein that retains the MLL N-terminus, including both an A-T hook domain and a region similar to mammalian DNA methyltransferase. There are several breakpoints within the MLLT1 gene described, without clear differences in clinicohematologic features. The KMT2A / MLLT1 Fusion probe is optimized to detect translocations involving the KMT2A and MLLT1 gene regions at 11q23 and 19p13 in a dual-color, fusion assay on metaphase/interphase spreads, blood smears and bone marrow cells in a dual-color, fusion assay.

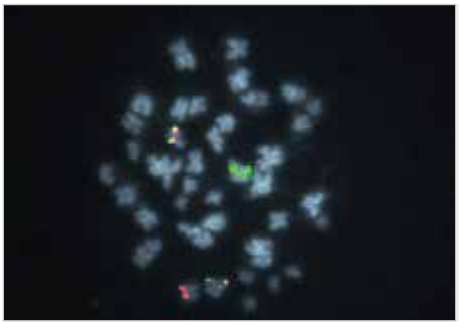
REFERENCES

Mitterbauer-Hohdanner G et al, 2004, Eur J Clin Invest, 34; 12-24.
Meyer C et al, 2009, Leukemia, 23; 1490-1499.
Fu JF et al, 2007, Am J Clin Pathol, 127; 24-30.





KMT2A / MLLT3



KMT2A/MLLT3 t(9;11) Fusion probe hybridized to patient material showing t(9;11) translocation (2RG1R1G).

Image kindly provided by Dr. Mohr, Dresden.

KMT2A / MLLT3 t(9;11) Fusion

CODE	COLOR	FORMAT	STATUS
KI-10308	Green/Red	100 µL	RUO

MENU

RESEARCH

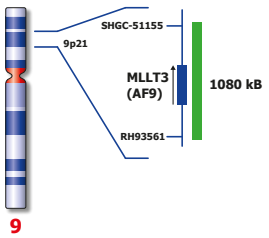
BACKGROUND

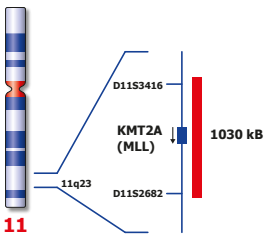
Chromosomal rearrangements involving the mixed lineage leukemia (MLL) gene at 11q23 are frequently observed in adult and childhood acute leukemia and are, in general, associated with poor prognosis. However, children with Acute Myeloid Leukemia (AML) carrying the t(9;11) KMT2A / MLLT3 (aka AF9) translocation have been described to be more sensitive to chemotherapy than patients with other 11q23 rearrangements.

The KMT2A / MLLT3 Fusion FISH probe is optimized to detect translocations involving the KMT2A (previously known as MLL) and MLLT3 gene regions at 11q23 and 9p21 in a dual-color fusion assay on metaphase/interphase spreads, blood smears and bone marrow cells.

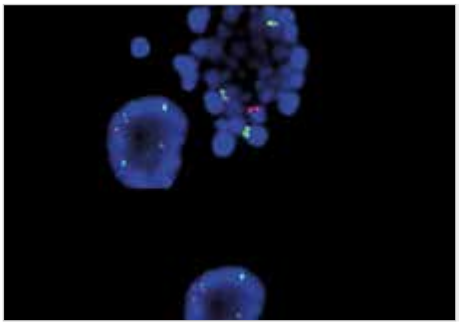
REFERENCES

Von Lindern et al, 1992, Mol. Cell. Biol.,12; 1687-1697.
Ageberg et al, 2008, Gen. Chrom. Canc., 47; 276-287.
Chi et al, 2008, Arch. Pathol. Lab. Med.,132; 1835-1837.





KMT2A / MLLT4



KMT2A / MLLT4 t(6;11) Fusion probe hybridized to patient material showing 47,XX,t(6;11)(q27;q23),+der(6)t(6;11)(q27;q23).

KMT2A / MLLT4 t(6;11) Fusion

CODE	COLOR	FORMAT	STATUS
KI-10309	Green/Red	100 µL	RUO

MENU

RESEARCH

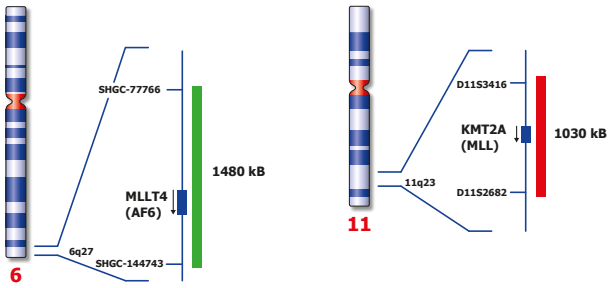
BACKGROUND

One of the relatively frequently observed translocations in AML involves the genes KMT2A and MLLT4 (previously known as AF6) at 11q23 and 6q27. The KMT2A / MLLT4 translocation results in the generation of fusion protein that retains the KMT2A N-terminus, including both an A-T hook domain and a region similar to mammalian DNA methyltransferase. The breakpoint region of the MLLT4 gene is located within intron 1 and downstream of the initiation codon.

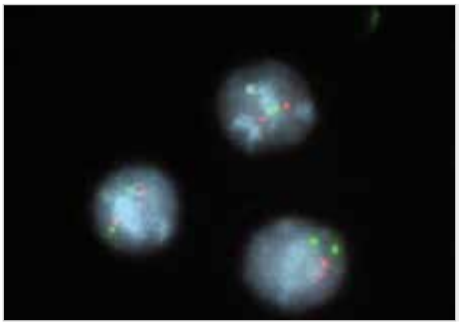
The KMT2A / MLLT4 t(6;11) Fusion FISH probe is optimized to detect translocations involving the KMT2A (previously known as MLL) and MLLT4 gene regions at 11q23 and 6q27 in a dual-color, fusion assay on metaphase/interphase spreads, blood smears and bone marrow cells.

REFERENCES

Mitterbauer-Hohdanner G et al, 2004, Eur J Clin Invest, 34; 12-24.
Meyer C et al, 2009, Leukemia, 23; 1490-1499.



KMT2A / SE 11



KMT2A (11q23) / SE 11 hybridized to normal interphases (2R2G).

KMT2A (11q23) / SE 11

CODE	COLOR	FORMAT	STATUS
KI-10711	Green/Red	100 µL	RUO

MENU

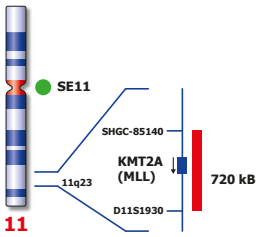
RESEARCH

BACKGROUND

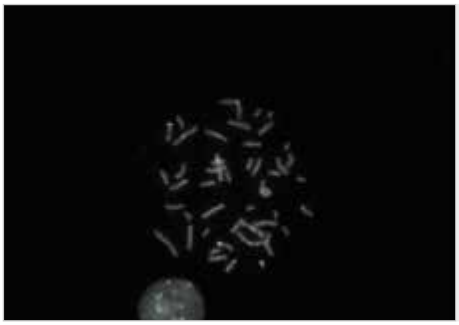
Deletions of the long arm of chromosome 11 (11q) have been noted in primary neuroblastomas. It is assumed that a tumor suppressor gene mapping within 11q23.3 is commonly inactivated during the malignant evolution of a large subset of neuroblastomas, especially those with unamplified MYCN. The KMT2A (11q23) FISH probe is optimized to detect amplification or deletion involving the KMT2A gene region at 11q23 in a dual-color assay. The Chromosome 11 Satellite Enumeration probe (SE 11) at D11Z1 is included to facilitate chromosome identification.

REFERENCES

Guo et al, 1999, Oncogene, 18: 4948-4957.
Maris et al, 2001, Med Pediatr Oncol, 36: 24-27.



KMT2A Break



Hybridization of KMT2A probe to a metaphase spread showing normal pattern (2F).

KMT2A (11q23) Break

CODE	COLOR	FORMAT	STATUS
KI-10303	Green/Red	100 µL	RUO

MENU

RESEARCH

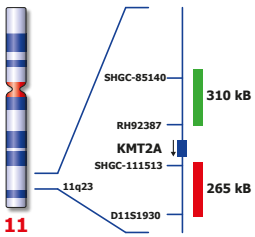
BACKGROUND

The human chromosome band 11q23 is associated with a high number of recurrent chromosomal abnormalities including translocations, insertions, and deletions. It is involved in over 20% of acute leukemias. The KMT2A (previously known as MLL) gene, named for its involvement in myeloid (usually monoblastic) and lymphoblastic leukemia, and less commonly in lymphoma, is located in the 11q23 breakpoint region. Leukemias involving the KMT2A gene usually have a poor prognosis.

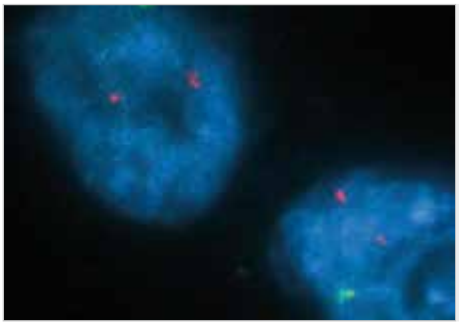
The KMT2A (11q23) Break FISH probe is optimized to detect translocations involving the KMT2A gene region at 11q23 in a dual-color split assay.

REFERENCES

Kobayashi et al, 1993, Blood, 81; 3027-3022
Martinez-Climent et al, 1995, Leukemia, 9; 1299-1304.



MAF/ IGH



MAF / IGH t(14;16) Fusion probe hybridized to patient material showing a deletion of the MAF gene region at 16q23 (2R1G).

MAF / IGH t(14;16) Fusion

CODE	COLOR	FORMAT	STATUS
KI-10610	Green/Red	100 µL	RUO

MENU

RESEARCH

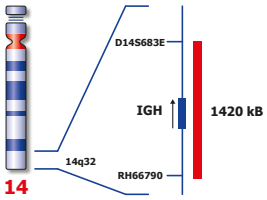
BACKGROUND

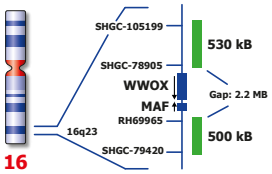
Abnormalities of 16q are important recurrent events in multiple myeloma (MM). The t(14;16)(q32;q23) is a karyotypically silent translocation that is associated with the ectopic expression and dysregulation of MAF mRNA. Translocations that bracket the MAF locus (dispersed over 500 kb) are estimated to be present in up to 25% of plasma cell myelomas.

The MAF / IGH t(14;16) specific FISH probe is optimized to detect the reciprocal translocation t(14;16) in a dual-color, dual-fusion assay on metaphase/interphase spreads, blood smears and bone marrow cells.

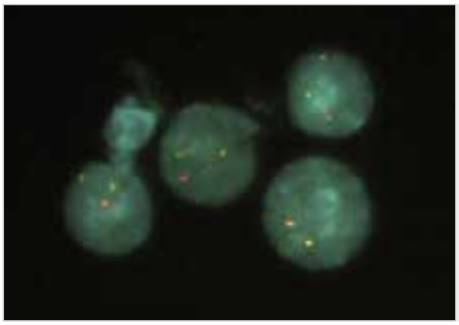
REFERENCES

Chesi et at, 1998, Blood 91; 4457-4463.
Sawyer et al, 1998, Blood 92; 4269-4278.





MAFB /IGH



The MAFB / IGH t(14;20) Fusion FISH probe hybridized to patient material showing a complex pattern with a t(14;20) translocation.

Image kindly provided by Erasmus Medical Center, Rotterdam.

MAFB / IGH t(14;20) Fusion

CODE	COLOR	FORMAT	STATUS
KI-10510	Green/Red	100 µL	RUO

MENU

RESEARCH

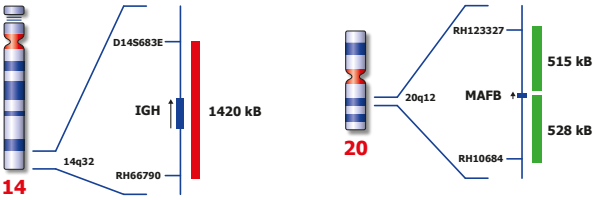
BACKGROUND

The immunoglobulin heavy chain (IGH) gene at 14q32 is an important cause of genetic deregulation in MM. Among the known fusion partners for the IGH (previously known as IGH@) gene, reciprocal translocation with the MAFB gene at 20q12 is relatively rare in MM (~2% occurrence). However, the MAFB / IGH t(14;20) translocation is associated with poor prognosis in multiple myeloma patients.

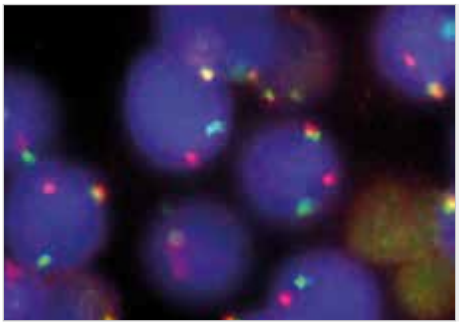
The MAFB / IGH t(14;20) Fusion FISH probe is optimized to detect the reciprocal translocation t(14;20) in a dual-color, dual-fusion assay on metaphase/interphase spreads and bone marrow cells.

REFERENCES

Boersma-Vreugdenhil GR et al, 2004, Br J Haematol, 126; 355-363.
Bergsagel PL et al, 2005, JCO, 23; 6333-6338.



MALT1 Break



MALT1 (18q21) Break probe hybridized to patient material showing a translocation at 18q21 (1RG1RG).

MALT1 (18q21) Break

CODE	COLOR	FORMAT	STATUS
KI-10608	Green/Red	100 µL	RUO

MENU

RESEARCH

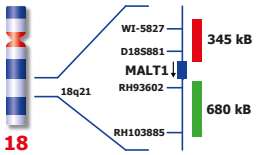
BACKGROUND

Low grade malignant lymphomas arising from mucosa associated lymphoid tissue (MALT) represent a distinct clinicopathological entity. The three major translocations seen in MALT lymphomas are t(11;18)(q21;q21) / API2-MALT1, t(14;18)(q32;q21) / IGH-MALT1 and t(1;14)(p22;q32) / IGH-BCL10. A break or split probe for MALT1 (18q21) is best used to analyze translocation of the MALT1 gene on formalin fixed paraffin embedded tissue for routine clinical diagnosis.

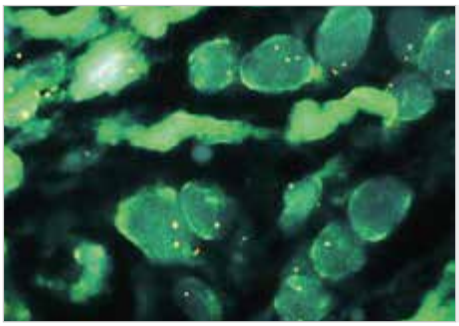
Kreatech has optimized this FISH probe for the specific use on cell material (KBI-10608), or for the use on tissue (KBI-10731).

REFERENCES

Morgan et al, 1999, Cancer Res, 59; 6205-6213.
Dierlamm et al, 2000, Blood, 96; 2215-2218.



MALT1 Break (tissue)



MALT1 (18q21) Break tissue probe hybridized to paraffin embedded material (2RG).

MALT1 (18q21) Break (tissue)

CODE	COLOR	FORMAT	STATUS
KI-10731	Green/Red	100 µL	RUO

MENU

RESEARCH

BACKGROUND

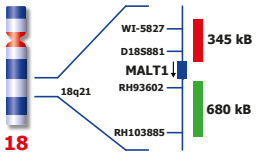
Low grade malignant lymphomas arising from mucosa associated lymphoid tissue (MALT) represent a distinct clinicopathological entity. The three major translocations seen in MALT lymphomas are t(11;18)(q21;q21) / API2-MALT1, t(14;18)(q32;q21) / IGH-MALT1 and t(1;14)(p22;q32) / IGH-BCL10. A break or split probe for MALT1 (18q21) is best used to analyze translocation of the MALT1 gene on formalin fixed paraffin embedded tissue for routine clinical diagnosis.

The MALT1 (18q21) Break probe is optimized to detect translocations involving the MALT1 gene region at 18q21 in a dual-color, split assay.

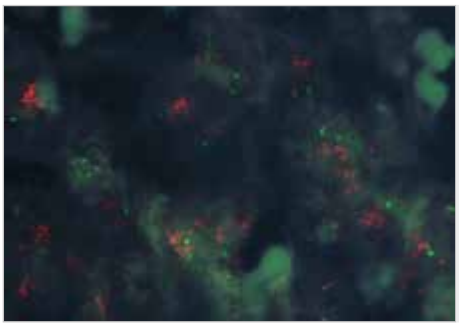
Kreatech has developed this probe for the specific use on cell material (KBI-10608), or for the use on tissue (KBI-10731).

REFERENCES

Morgan et al, 1999, Cancer Res, 59; 6205-6213.
Dierlamm et al, 2000, Blood, 96; 2215-2218.



MDM2 / SE 12



MDM2 (12q15) / SE 12 Amplification probe hybridized to patient material showing amplification of the MDM2 gene region at 12q15.

MDM2 (12q15) / SE 12

CODE	COLOR	FORMAT	STATUS
KI-10717	Green/Red	100 µL	RUO

MENU

RESEARCH

BACKGROUND

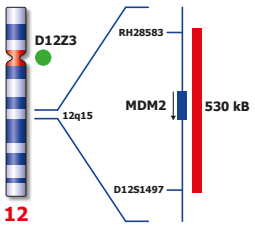
Well-differentiated liposarcoma/atypical lipomatous tumor and dedifferentiated liposarcoma are among the most common malignant soft tissue tumors presented in older adults. These tumors can be difficult to distinguish from benign lipomatous neoplasms and other high-grade sarcomas.

Amplification of the MDM2 gene has been identified in lipomatous neoplasms. The use of fluorescence in situ hybridization in identifying MDM2 amplification has made the MDM2 amplification probe a valuable diagnostic tool in well-differentiated liposarcomas/atypical lipomatous tumors. The MDM2 (12q15) FISH probe is optimized to detect copy numbers of the MDM2 gene region at region 12q15.

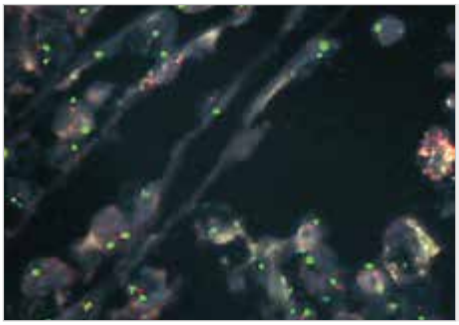
The chromosome 12 satellite enumeration probe (SE 12) at D12Z3 is included to facilitate chromosome identification.

REFERENCES

Uchida et al, 2010, Cancer Genet Cytogenet 203; 324-327.
Lucas et al, 2010, Am J Surg Pathol 34: 844-851.
Weaver et al, 2008, Mod Pathol 21: 943-949.
Mitchell et al, 1995, Chrom. Res., 3; 261-262.
Reifenberger et al, 1996, Cancer Res., 15; 5141-5145.



MDM4 / SE 1



MDM4 (1q32) / SE 1 probe hybridized to paraffin embedded tissue (2R2G).

MDM4 (1q32) / SE 1

CODE	COLOR	FORMAT	STATUS
KI-10736	Green/Red	100 µL	RUO

MENU

RESEARCH

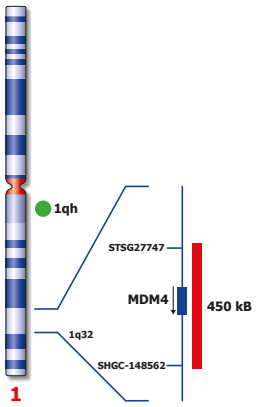
BACKGROUND

MDM4 (MDM4 p53 binding protein homolog (mouse), also known as MDMX, murine double minute gene) is a relative of MDM2 that was identified on the basis of its ability to physically interact with TP53. MDM4, like MDM2, acts as a key negative supressor of TP53 by interfering with its transcriptional activity. MDM4 amplification and/or overexpression occurs in several diverse tumors. Studies showed an increased MDM4 copy number in 65% of human retinoblastomas compared to other tumors, qualifying MDM4 as a specific chemotherapeutic target for treatment of this tumor.

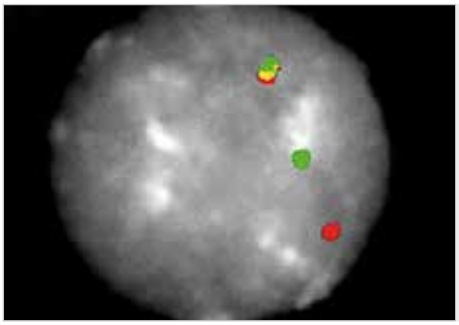
The MDM4 (1q32) FISH probe is designed as a dual-color assay to detect amplification at 1q32. The chromosome 1 Satellite Enumeration (SE 1) probe at 1qh is included to facilitate chromosome identification.

REFERENCES

Riemenschneider et al, 1999, Cancer Res. 59"; 6091-6096.
Danovi et al, 2004, Mol.Cell.Biol. 24; 5835-5843.



MECOM Break



MECOM t(3;3);inv(3) (3q26) Break probe hybridized to patient material showing a rearrangement involving the MECOM gene region at 3q26 (1RG1R1G).

Image kindly provided by Dr. Reed, London.

MECOM t(3;3); inv(3) (3q26) Break

CODE	COLOR	FORMAT	STATUS
KI-10204	Green/Red	100 µL	RUO

MENU

RESEARCH

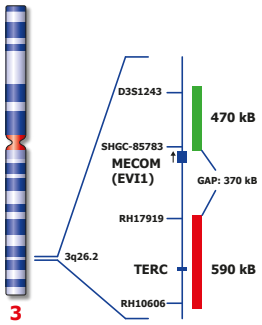
BACKGROUND

The inv(3)(q21;q26) is a recurrent cytogenetic aberration of myeloid malignancy associated with fusion of MECOM (EVI) and RPN1. Genomic breakpoints in 3q26 are usually located proximal to the MECOM locus, spanning a region of several hundred kilobases. Other recurrent and sporadic rearrangements of 3q26 also cause transcriptional activation of MECOM including the translocations t(3;3)(q21;q26) and t(3;21)(q26;q22). Breakpoints in the latter rearrangements span a wider genomic region of over 1 megabase encompassing sequences distal to MECOM and neighboring gene MDS1.

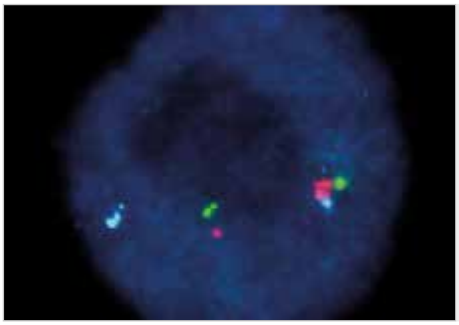
The MECOM t(3;3) inv(3) Break, dual-color FISH probe is optimized to detect the inversion of chromosome 3 involving the MECOM gene region at 3q26 in a dual-color, split assay on metaphase/interphase spreads, blood smears and bone marrow cells.

REFERENCES

De Braekeleer et al, 2011, Anticancer Res, 31; 3441-3448
Shearer B. et al, 2010, Am J Hematol, 85:569-574
Cui W. et al, 2011, Am J Clin Pathol, 136; 282-288
De Melo V. et al, 2007, Leukemia aop, 13 Sep, 1-4
Levy E. et al, 1994, Blood, 83; 1348-1354
Wieser R et al, 2003, Haematologica, 88; 25-30



MECOM Break Triple-Color



MECOM t(3;3);inv(3) (3q26) Break probe hybridized to patient material showing a rearrangement involving the MECOM gene region at 3q26 (1RG1R1G).

Image kindly provided by Dr. Reed, London.

MECOM t(3;3); inv(3) (3q26) Break, Triple-Color

CODE	COLOR	FORMAT	STATUS
KI-10205	Green/Red/Blue	100 µL	RUO

MENU

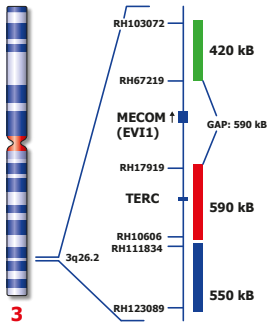
RESEARCH

BACKGROUND

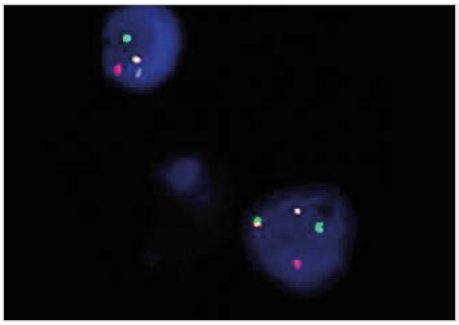
The MECOM t(3;3); inv(3)(3q26) Break Triple-Color FISH probe is optimized to detect the inversion of chromosome 3 involving the MECOM (previously known as EVI) gene region at 3q26 in a dual-color, split assay on metaphase/interphase spreads, blood smears and bone marrow cells. By using a third color breakpoint variations can also be easily observed.

REFERENCES

De Braekeleer et al, 2011, Anticancer Res, 31; 3441-3448;
Levy E. et al, 1994, Blood, 83; 1348-1354
Cui W. et al, 2011, Am J Clin Pathol, 136; 282-288
Wieser R et al, 2003, Haematologica, 88; 25-30
De Melo V. et al, 2007, Leukemia aop, 13 Sep, 1-4
Shearer B. et al, 2010, Am J Hematol, 85:569-574



MECOM / RUNX1



MECOM / RUNX1 Fusion probe hybridized to patient material showing t(3;21) (2F1R1G).

Image kindly provided by Dr. Mohr, Dresden.

MECOM / RUNX1 t(3;21) Fusion

CODE	COLOR	FORMAT	STATUS
KI-10310	Green/Red	100 µL	RUO

MENU

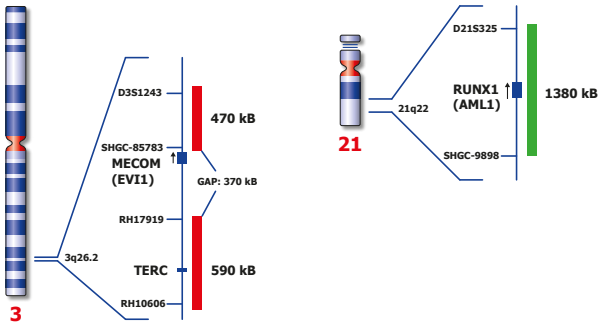
RESEARCH

BACKGROUND

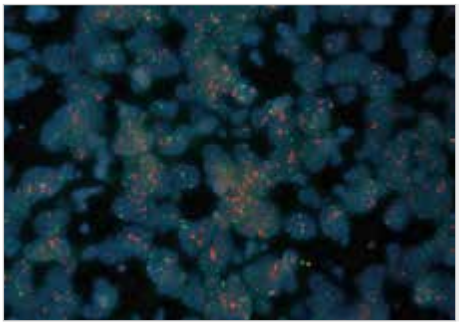
The MECOM (EVI1, 3q26) / RUNX1 (AML1, 21q22) translocation, t(3;21), is consistently found in blastic crisis of chronic myelocytic leukemia (CML) and myelodysplatic syndromederived leukemias. The translocation produces RUNX1 / MECOM chimeric transcription factor and is thought to play important roles in acute leukemic transformation of hemopoietic stem cells. The MECOM / RUNX1 t(3;21) Fusion specific FISH probe is optimized to detect the reciprocal translocation t(3;21) in a dual-color, dual-fusion assay on metaphase/interphase spreads, blood smears and bone marrow cells.

REFERENCES

Mitani et al., EMBO, 1994, Vol 13, 504-510
Tanaka et al., Mol Cell Biol, 1995, 2383-2392



MET / SE 7



Hybridization of MET Amplification probe to a tissue section showing MET amplification.

MET (7q31) / SE 7

CODE	COLOR	FORMAT	STATUS
KI-10719	Green/Red	100 µL	RUO

MENU

RESEARCH

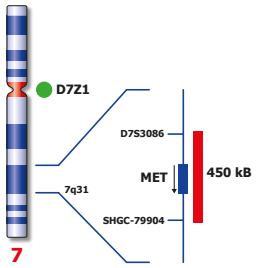
BACKGROUND

The MET proto-oncogene is a receptor-like tyrosine kinase that drives a physiological cellular program important for development, cell movement, cell repair and cellular growth. Aberrant execution of this program has been associated to neoplastic transformation, invasion and metastasis. Activation of MET has been reported in a significant percentage of human cancers including non-small cell lung cancer (NSCLC) and is amplified during the transition between primary tumors and metastasis.

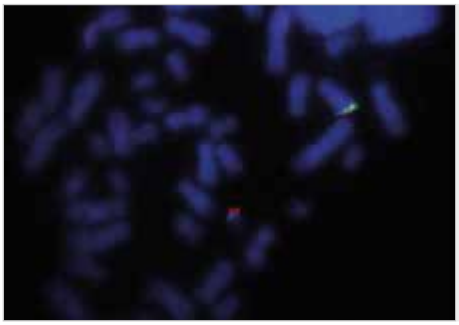
The MET (7q31) FISH probe is optimized to detect copy numbers of the MET gene region at region 7q31. The Chromosome 7 Satellite enumeration probe (SE 7) at D7Z1 is included to facilitate chromosome identification.

REFERENCES

Go et al, 2010, J Thorac Oncol 5: 305-313.
Hara et al, 1998, Lab Invest 78; 1143-1153.
Tsugawa et al, 1998, Oncology 55; 475-481.



MYC (8q24) Break



MYC (8q24) Break probe hybridized to patient material showing a 8q24 proximal break (1GBR1G1BR).

Image kindly provided by Prof. Siebert, Kiel.

MYC (8q24), Triple-Color, Break

CODE	COLOR	FORMAT	STATUS
KI-10611	Green/Red/Blue	100 µL	RUO

MENU

RESEARCH

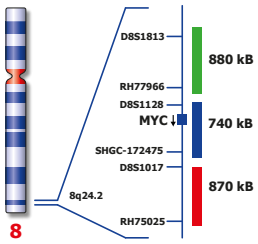
BACKGROUND

Rearrangements of the protooncogene MYC (C-MYC) have been consistently found in Burkitt's lymphoma tumor cells. In cases with the common t(8;14) chromosomal translocation, the MYC gene is translocated to chromosome 14 and rearranged with the immunoglobulin heavychain genes; the breakpoint occurs 5' to the MYC gene and may disrupt the gene itself. In Burkitt's lymphoma showing the variant t(2;8) or t(8;22) translocations, the genes coding for the k and l immunoglobulin light chain are translocated to chromosome 8. The rearrangement takes place 3' to the MYC gene.

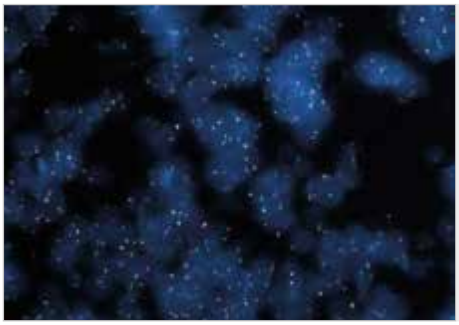
The MYC (8q24) Break probe is optimized to detect rearrangements involving the 8q24 locus in a triple-color, split assay on metaphase/ interphase spreads, blood smears and bone marrow cells.

REFERENCES

Fabris et al, 2003, Genes Chromosomes Cancer, 37;261-269.
Hummel et al, 2006, N Engl J Med, 354; 2419-30.



MYC (8q24) Break (tissue)



Hybridization of MYC TC break probe to a tissue section showing"abarrant pattern (1GBR1G1BR).

MYC (8q24) Triple-Color, Break (tissue)

CODE	COLOR	FORMAT	STATUS
KI-10749	Green/Red/Blue	100 µL	RUO

MENU

RESEARCH

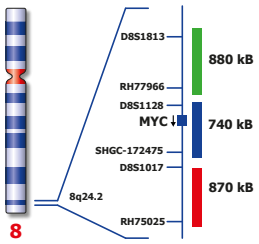
BACKGROUND

Rearrangements of the proto oncogene MYC c-myc) have been consistently found in Burkitt's lymphoma tumor cells . In cases with the common t(8;14) chromosomal translocation, the MYC gene is translocated to chromosome 14 and rearranged with the immunoglobulin heavy chain genes; the breakpoint occurs 5' to the MYC gene and may disrupt the gene itself. In Burkitt's lymphoma showing the variant t(2;8) or t(8;22) translocations, the genes coding for the k and l immunoglobulin light chain are translocated to v-myc avian myelocytomatosis viral oncogene homolog (MYC or c-myc) chromosome 8.

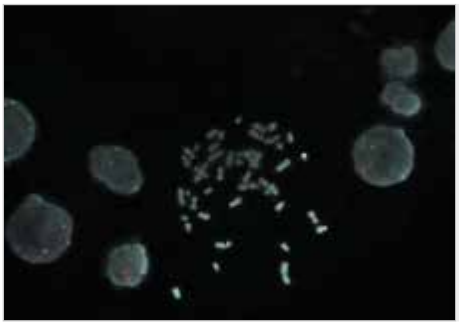
The MYC (8q24) Break probe is optimized to detect rearrangements involving the 8q24 locus in a triple-color, split assay on formalin fixed paraffin embedded tissue.

REFERENCES

Fabris et al, 2003, Genes Chromosomes Cancer, 37;261-269.
Hummel et al, 2006, N Engl J Med, 354; 2419-30.



MYC / SE 8



MYC (8q24) / SE 8 hybridized to a metaphase spread showing a normal pattern.

MYC (8q24) / SE 8

CODE	COLOR	FORMAT	STATUS
KI-10106	Green/Red	100 µL	RUO

MENU

RESEARCH

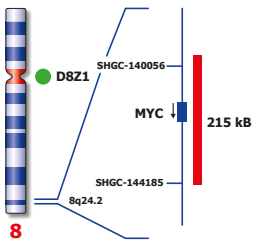
BACKGROUND

The MYC (previously known as C-MYC) gene produces an oncogenic transcription factor that affects diverse cellular processes involved in cell growth, cell proliferation, apoptosis and cellular metabolism. The MYC oncogene has been shown to be amplified in many types of human cancer such as bladder, breast and cervical. Amplification at 8q24 including MYC is also observed in 5% of CLL patients. MYC is also the prototype for oncogene activation by chromosomal translocation.

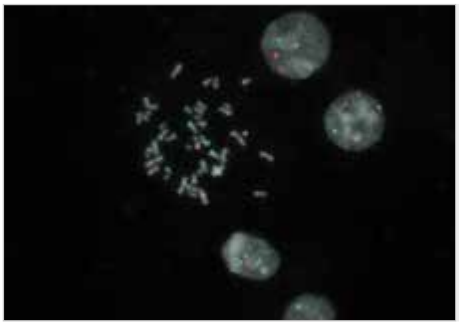
The MYC (8q24) specific FISH probe is optimized to detect copy numbers of the MYC gene region at 8q24. The chromosome 8 Satellite Enumeration FISH probe (SE 8) at D8Z1 is included to facilitate chromosome identification.

REFERENCES

Greil et al, 1991, Blood, 78; 180-191.



MYC / IGH t(8;14) Fusion



Hybridization of MYC/IGH fusion probe to a metaphase spread showing normal pattern (2R2G).

MYC / IGH t(8;14) Fusion

CODE	COLOR	FORMAT	STATUS
KI-10603	Green/Red	100 µL	RUO

MENU

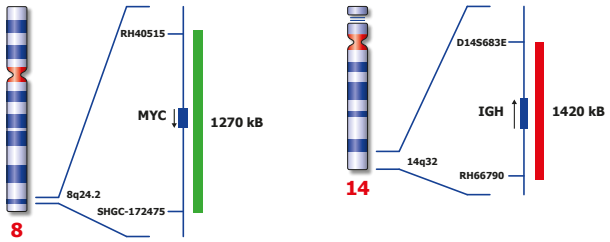
RESEARCH

BACKGROUND

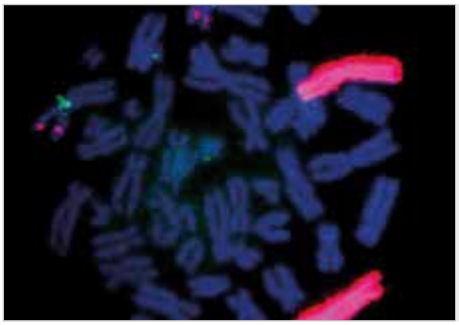
The translocation t(8;14)(q24;q32) is the characteristic chromosomal aberration of Burkitt's-type of lymphomas. This translocation fuses the MYC gene at 8q24 next to the IGH locus at 14q32, resulting in overexpression of the transcription factor MYC. Detection of the t(8;14) is aimed to help in the diagnostic process of patients with high-grade B-cell lymphomas because treatment strategies differ between Burkitt and other high-grade lymphomas. The MYC / IGH t(8;14)(q24;q32) specific FISH probe is optimized to detect the reciprocal translocation t(8;14) in a dual-color, dual-fusion assay.

REFERENCES

Veronese et al, 1995, Blood, 85;2132-2138.
Siebert et al, 1998, Blood, 91; 984-990.



MYCN / AFF3



MYCN (2p24) / AFF3 (2q11) hybridized to a cell line showing amplification of MYCN on chromosome 13 and 15.

Image kindly provided by Pasteur Workshop 2008, Paris.

MYCN (2p24) / AFF3 (2q11)

CODE	COLOR	FORMAT	STATUS
KI-10706	Green/Red	100 µL	RUO

MENU

RESEARCH

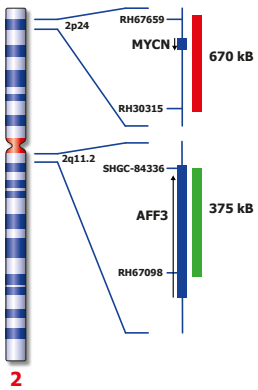
BACKGROUND

Amplification of the human protooncogene, v-myc avian myelocytomatosis viral oncogene neuroblastoma derived homolog (MYCN) is frequently seen either in extrachromosomal double minutes or in homogeneously staining regions of aggressively growing neuroblastomas. MYCN amplification has been defined by the INRG as > 4-fold MYCN signals compared to 2q reference probe signals.

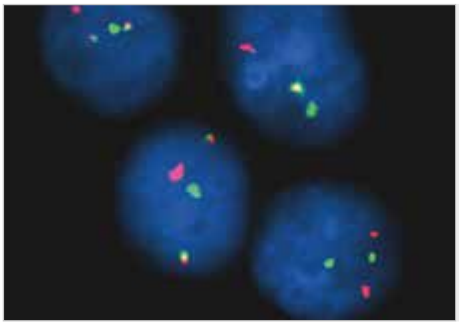
The MYCN (2p24) FISH probe is optimized to detect copy numbers of the MYCN gene region at 2p24. The AFF3 gene region probe at 2q11 is included to facilitate chromosome identification.

REFERENCES

Shapiro et al, 1993, Am J Pathol, 142: 1339-1346.
Corvi et al, 1994, PNAS, 91: 5523-5527.



MYEOV / IGH



MYEOV / IGH t(11;14) Fusion probe hybridized to MM patient material showing t(11;14) translocation (2RG1R1G).

Image kindly provided by Prof. Jauch, Heidelberg.

MYEOV / IGH t(11;14) Fusion

CODE	COLOR	FORMAT	STATUS
KI-10605	Green/Red	100 µL	RUO

MENU

RESEARCH

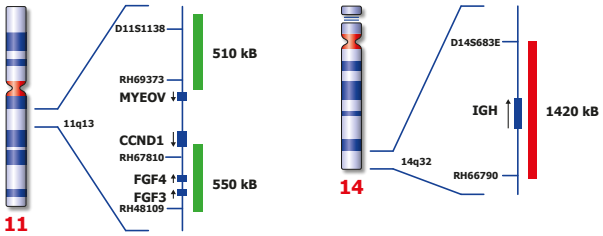
BACKGROUND

The most common chromosomal translocation in multiple myeloma (MM) is t(11;14), resulting in up-regulation of cyclin D1. In MM the breakpoints are scattered within a 360-kb region between CCND1 and MYEOV. This breakpoint is more proximal than the t(11;14) breakpoints observed in mantle cell lymphoma or other leukemias. Patients with MM who have t(11;14)(q13;q32) seem to have an aggressive clinical course.

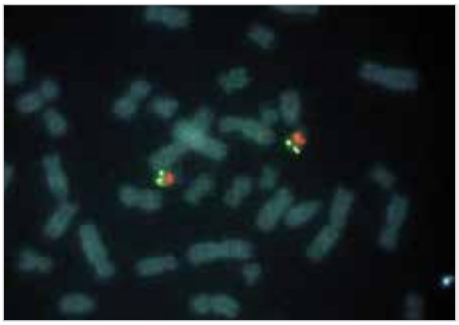
The MYEOV / IGH t(11;14)(q13;q32) Fusion specific FISH probe is optimized to detect the reciprocal translocation t(11;14) in a dual-color, dual-fusion assay.

REFERENCES

Janssen et al., 2000, Blood, 95; 2691-2698.
Fonseca et al, 2002, Blood, 99; 3735-3741.



"N25" / SHANK3



DiGeorge "N25" (22q11) / 22q13 (SHANK3) probe hybridized to a normal metaphase (2R2G).

"N25" (22q11) / 22q13 (SHANK3)

CODE	COLOR	FORMAT	STATUS
KI-40102	Green/Red	100 µL	RUO

MENU

RESEARCH

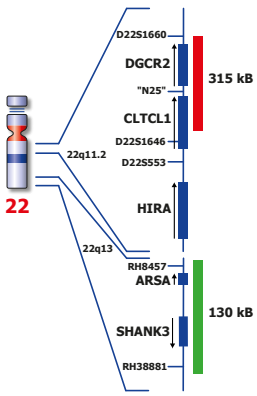
BACKGROUND

The DiGeorge "N25" FISH probe was the first commercial microdeletion probe for chromosome 22q and detects the locus D22S75. This marker is located between DGCR2 and CLTCL1 (Clathrin). Both genes have been extensively investigated and their role in DiGeorge syndrome is well established.

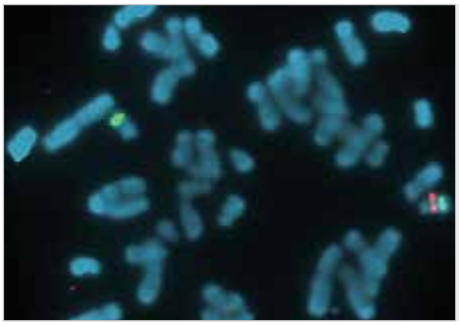
The DiGeorge "N25" region probe covers the marker "N25" (D22S75) and adjacent region of CLTCL1 (Clathrin gene region) and DGCR2 (DiGeorge critical region gene 2). The SHANK3 FISH probe at 22q13 is serving as internal control.

REFERENCES

Sirotkin et al, 1996, Hum. Mol. Genet., 5; 617-624.
Holmes et al, 1997, Hum. Mol. Genet., 6; 357-367.
Wilson, et al, 2003, J. Med. Genet., 40; 575-584.
Luciani, et al, 2003, J. Med. Genet., 40; 690-696.



NF1 / MPO



NF1 (17q11) / MPO (17q22) probe hybridized to patient material showing a deletion of NF1 gene region at 17q11 (1R2G).

NF1 (17q11) / MPO (17q22)

CODE	COLOR	FORMAT	STATUS
KI-40114	Green/Red	100 µL	RUO

MENU

RESEARCH

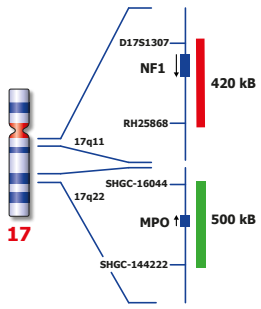
BACKGROUND

NF1, or Von Recklinghausen disease, is one of the most common hereditary neurocutaneous disorders in humans and one of the most common single gene syndromes. Clinically, NF1 is characterized by café-au-lait spots, freckling, skin neurofibroma, plexiform neurofibroma, bone defects, Lisch nodules and tumors of the central nervous system. The responsible gene, NF1 (neurofibromin), was identified on chromosome 17q11. Whole NF1 gene deletions occur in 4%-5% of individuals with NF1 and can be detected by FISH analysis.

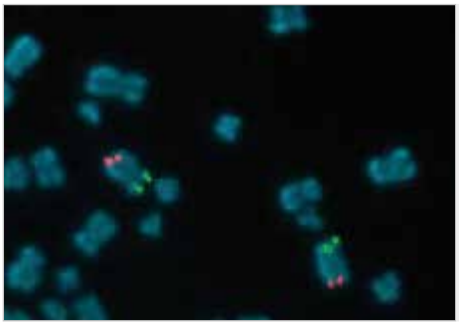
The NF1 (17q11) region probe is optimized to detect copy numbers of the NF1 gene region at 17q11.2. The MPO region specific FISH probe at 17q22 is included as control probe.

REFERENCES

Riva P et al, 2000, Am. J. Hum. Genet., 66; 100-109.
Dorschner et al, 2000, Hum. Mol. Genet., 9; 35-46.



NSD1 / TERT



NSD1 (5q35) / TERT (5p15) probe hybridized to a normal metaphase (2R2G).

NSD1 (5q35) / TERT (5p15)

CODE	COLOR	FORMAT	STATUS
KI-40113	Green/Red	100 µL	RUO

MENU

RESEARCH

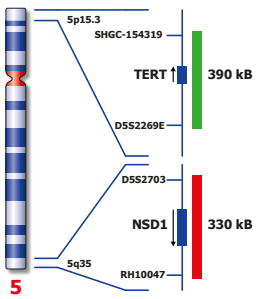
BACKGROUND

NSD1 microdeletions (chromosome 5q35) are the major cause of Sotos syndrome, and occur in some cases of Weaver syndrome. Sotos is a childhood overgrowth characterized by distinctive craniofacial features, advanced bone age, and mental retardation. Weaver syndrome is characterized by the same criteria but has its own specific facial characteristics. Sotos syndrome is inherited in an autosomal dominant manner. While 50% of Sotos patients in Asia are showing a chromosomal microdeletion, only 9% deletion cases are observed in the affected European population.

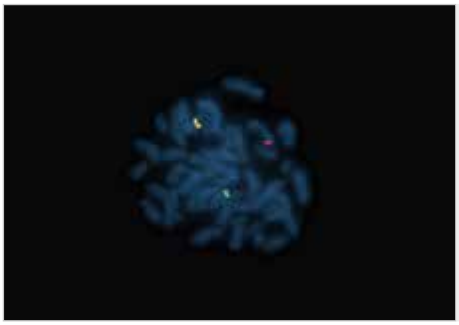
The NSD1 (5q35) region probe is optimized to detect copy numbers of the NSD1 gene region at 5q35.2. The TERT region specific FISH probe at 5p15 is included as control probe.

REFERENCES

Douglas et al, 2003, Am. J. Hum. Genet. 72; 132-143.
Rio et al, 2003, J. Med. Genet., 40; 436-440.



NUP98 Break



NUP98 (11p15) Break Probe hybridized to AML patient sample showing a rearrangement of 11p15 involving the NUP98 gene (1F1R1G).

Image kindly provided by Prof. Manuel R. Teixeira, Porto.

NUP98 (11p15) Break

CODE	COLOR	FORMAT	STATUS
KI-10311	Green/Red	100 µL	RUO

MENU

RESEARCH

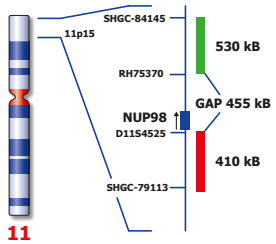
BACKGROUND

Nucleoporin 98kDa gene (NUP98) rearrangements have been identified in a wide range of hematologic malignancies, including acute myeloid leukemia (AML), acute lymphoblastic leukemia (ALL), chronic myeloid leukemia in blast crisis (CML-bc), myelodysplastic syndrome (MDS) and bilineage/biphenotypic leukemia. The NUP98 gene is highly promiscuous with regard to its recombination spectrum, as at least 28 different partner genes have been identified for NUP98 rearrangements, all forming in-frame fusion genes. Patients with NUP98 gene rearrangements have an aggressive clinical course and the outcome of treatment is disappointing.

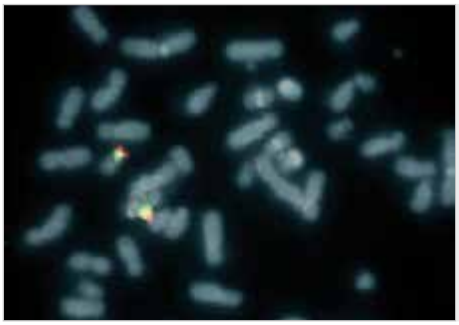
The NUP98 (11p15) Break FISH Probe is optimized to detect translocations involving the NUP98 gene region at 11p15 in a dual-color assay on metaphase/ interphase spreads, blood smears and bone marrow cells.

REFERENCES

Gough et al, 2011, Blood, 118; 62 47-6257.
Nebral et al, 2005, Haematologica, 90; 74 6-752.
Romana et al, 2006, Leukemia, 20; 696-70 6.



PAFAH1B1 / 17p11



Miller-Dieker PAFAH1B1 (17p13)/ Smith-Magenis RAI1 (17p11) probe hybridized to a normal metaphase (2RG).

PAFAH1B1 (17p13) / RAI1 (17p11)

CODE	COLOR	FORMAT	STATUS
KI-40101	Green/Red	100 µL	RUO

MENU

RESEARCH

BACKGROUND

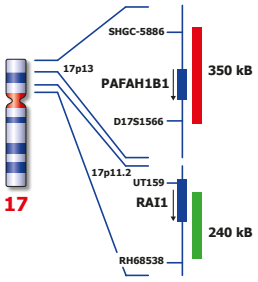
The Miller-Dieker lissencephaly syndrome appears to be caused by deletion of several genes on 17p including the PAFAH1B1 (previously known as LIS1) gene.

About 15% of patients with isolated lissencephaly and more than 90% of patients with Miller-Dieker syndrome have microdeletions in a critical 350-kb region at 17p13.3. Smith-Magenis is caused by a deletion of 17p11.2. The RAI1 (previously known as SMCR, KIAA1820 or SMS) gene region has been identified to be deleted in more than 90% of Smith-Magenis syndrome patients.

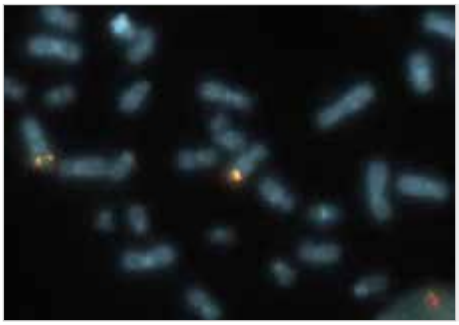
The Miller-Dieker PAFAH1B1 region probe is optimized to detect copy numbers of the PAFAH1B1 region at 17p13. The Smith-Magenis RAI1 region probe is optimized to detect copy numbers of the RAI1 gene region at 17p11.

REFERENCES

Kuwano et al, 1991, Am. J. Hum. Genet., 49; 707-714.
Cardoso et al, 2003, Am. J. Hum. Genet., 72; 918-930.
Smith et al, 1986, Am. J. Med. Genet., 24; 393-414.
Greenberg et al, 1991, Am. J. Med. Genet., 49; 1207-1218.
Vlangos et al, 2005, Am. J. Med. Genet., 132; 278-282.



PDGFRB Break



PDGFRB (5q32) Break probe hybridized to a normal metaphase (2RG).

PDGFRB (5q32) Break

CODE	COLOR	FORMAT	STATUS
KI-10004	Green/Red	100 µL	RUO

MENU

RESEARCH

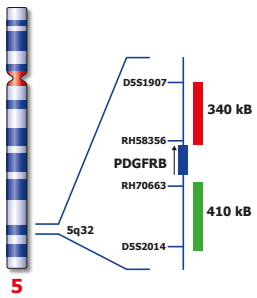
BACKGROUND

PDGFRB activation has been observed in patients with chronic myelomonocytic leukemia/atypical chronic myeloid leukemia and has been associated with over 50"translocation partners, the best known is the ETV6 gene on 12p13, causing a t(5;12) translocation. Cytogenetic responses are achieved with imatinib in patients with PDGFRB fusion positive, BCR / ABL1 negative CMPDs.

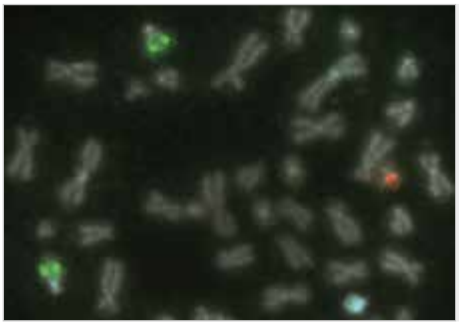
The PDGFRB (5q32) Break FISH probe is optimized to detect translocations involving the PDGFRB region at 5q32 in a dual-color, split assay.

REFERENCES

Wlodarska et al, 1997, Blood, 89; 1716-1722.
Wilkinson et al, 2003, Blood, 102; 4287-419.



PML / RARA



PML / RARA t(15;17) Fusion probe hybridized to a normal metaphase (2R2G).

PML / RARA t(15;17) Fusion

CODE	COLOR	FORMAT	STATUS
KI-10302	Green/Red	100 µL	RUO
KI-12302	Green/Red	200 µL	RUO

MENU

RESEARCH

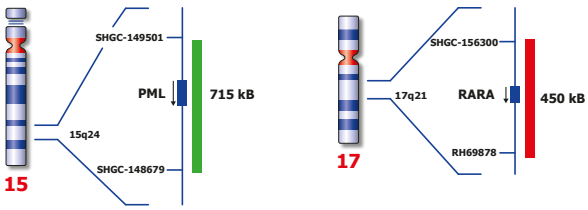
BACKGROUND

A structural rearrangement involving chromosomes 15 and 17 in acute promyelocytic leukemia (APL) was first recognized in 1977. The critical junction is located on the der(15) chromosome and consists of the 5' portion of PML fused to virtually all of the RARA gene. The PML / RARA fusion protein interacts with a complex of molecules known as nuclear co-repressors and histone deacetylase. This complex binds to the fusion protein and blocks the transcription of target genes. Other less common variant translocations fuse the RARA gene on 17q21 to the PLZF, NPM, NUMA, and STAT5b genes, respectively.

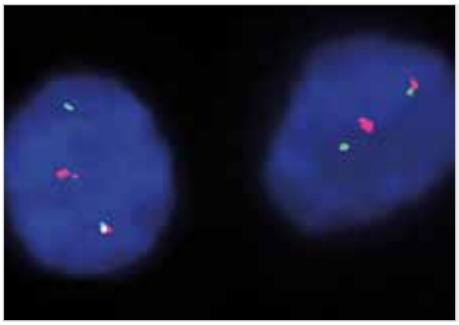
The PML / RARA t(15;17) Fusion specific FISH probe is optimized to detect the reciprocal translocation t(15;17) (q24;q21) in a dual-color, dual-fusion assay.

REFERENCES

Schad et al, 1994, Mayo Clin Proc, 69; 1047-1053.
Brockman et al, 2003, Cancer Genet Cytogenet, 145; 144-151.



PPARG Break



PPARG (3p25) Break probe hybridized to patient material showing a translocation at 3p25 (1RG1R1G).

Image kindly provided by Dr. Valent, Paris.

PPARG (3p25) Break

CODE	COLOR	FORMAT	STATUS
KI-10707	Green/Red	100 µL	RUO

MENU

RESEARCH

BACKGROUND

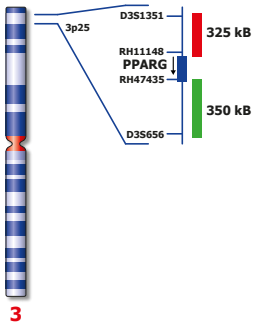
Follicular thyroid carcinoma is associated with the chromosomal translocation t(2;3)(q13;p25), fusing PAX8 (2q13) with the nuclear receptor, peroxisome proliferator-activated receptor Γ (PPARG). PPARG is located in a breakpoint hot spot region, leading to recurrent alterations of this gene in thyroid tumors of follicular origin including carcinomas as well as adenomas with or without involvement of PAX8.

A break or split probe for PPARG is best used to analyze translocation of the PPARG (3p25) gene on formalin fixed paraffin embedded tissue for routine clinical diagnosis.

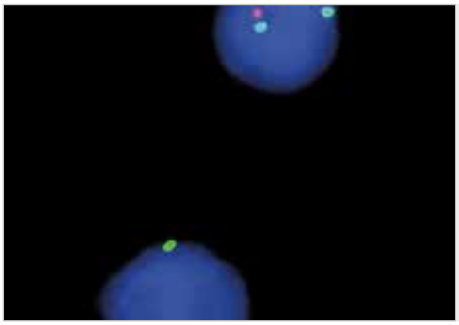
The PPARG (3p25) Break probe is optimized to detect translocations and amplification involving the PPARG gene region at 3p25 in a dual_color, split assay.

REFERENCES

French et al, 2003, Am J Pathol, 162; 1053-1060.
Drieschner et al, 2006, Thyroid, 16; 1091-1096.



PTEN / SE 10



PTEN (10q23) / SE 10 probe hybridized to prostate cancer material showing deletion of PTEN gene region at 10q23 (1R2G).

Image kindly provided by Portuguese Cancer Inst., Porto.

PTEN (10q23) / SE 10

CODE	COLOR	FORMAT	STATUS
KI-10718	Green/Red	100 µL	RUO

MENU

RESEARCH

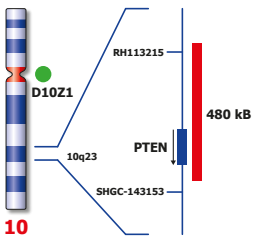
BACKGROUND

The gene 'phosphatase and tensin homolog' (PTEN), is a tumor suppressor located at chromosome region 10q23, that plays an essential role in the maintenance of chromosomal stability, cell survival and proliferation. Loss of PTEN has been found in a wide number of tumors, and its important role is demonstrated by the fact that it is the second most frequently mutated gene after TP53. Loss of PTEN significantly correlates with the advanced forms of gliomas, but also of prostate cancer and breast tumors.

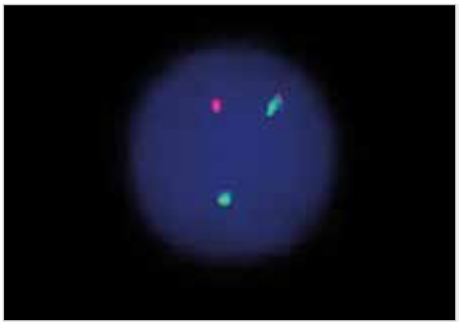
The PTEN (10q23) FISH probe is optimized to detect copy numbers of the PTEN gene region at region 10q23. The Chromosome 10 Satellite enumeration probe (SE 10) at D10Z1 is included to facilitate chromosome identification.

REFERENCES

Cairns et al, 1997, Cancer Res, 57 ; 4997-5000.
Hermans et al, 2004, Genes Chrom Cancer, 39; 171-184.



RARA Break



RARA (17q21) Break probe hybridized to patient material showing a translocation at 17q21 (1RG1R1G).

RARA (17q21) Break

CODE	COLOR	FORMAT	STATUS
KI-10305	Green/Red	100 µL	RUO

MENU

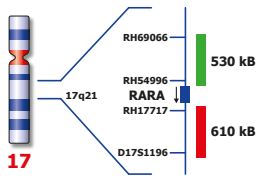
RESEARCH

BACKGROUND

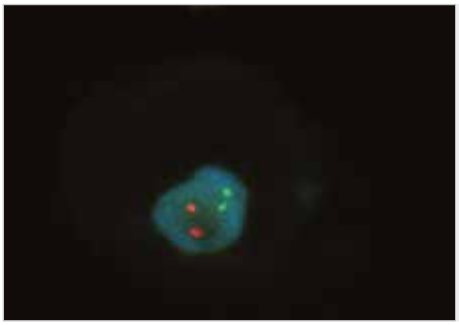
This break apart probe can detect the numerous types of recurrent rearrangement of the RAR_ (Retinoid acid receptor, alpha) gene with various gene partners (e.g., PML, NPM, MLL, FIP1L1, NuMA1, PLZF, amongst the others), leading to the formation of different reciprocal fusion proteins. The importance of retinoid metabolism in acute promyelocytic leukemia (APL) is highlighted by the numerous recent studies, but the different leukemogenic functions of the RARA fusion proteins in the neoplastic myeloid development still has to be defined, as well as the distinct clinical outcome of the patients with the variant forms of APL.

REFERENCES

Grimwade et al, 2000, Blood 96; 1297-1308



RB1 / RCAN1



RB1 (13q14)/RCAN1 (21q22) probe hybridized to a normal interphase (2R2G).

RB1 (13q14) / RCAN1 (21q22)

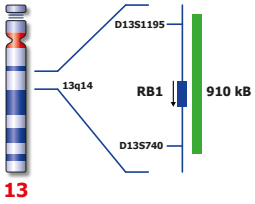
CODE	COLOR	FORMAT	STATUS
KI-40003	Green/Red	100 µL	RUO

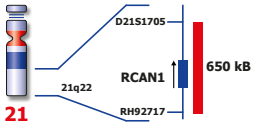
MENU

RESEARCH

BACKGROUND

Trisomy 21 is one of the most common chromosomal abnormalities in live born children and causes Down syndrome. Molecular analysis has revealed that the 21q22.1-q22.3 region appears to contain the gene(s) responsible for the congenital heart disease observed in Down syndrome. Trisomy 13, also called Patau syndrome, is a chromosomal condition that is associated with severe mental retardation and certain physical abnormalities. The critical region has been reported to include 13q14-13q32 with variable expression, gene interactions,or interchromosomal effects. The RCAN1 (21q22) specific FISH probe is optimized to detect copy numbers of chromosome 21 at 21q22 on uncultured amniotic cells. The RB1 (13q14) specific FISH probe is optimized to detect copy numbers of chromosome 13 at 13q14 on uncultured amniotic cells.





RB1 / RCAN1, SE X/SE Y/ SE 18

RB1 (13q14) / RCAN1 (21q22), SE X (DXZ1) / SE Y (DYZ3) / SE 18 (D18Z1)

CODE	COLOR	FORMAT	STATUS
KI-40005	Green/Red/Blue	100 µL	RUO
KI-40006	Green/Red/Blue	300 µL	RUO
KI-40007	Green/Red/Blue	500 µL	RUO

MENU

RESEARCH

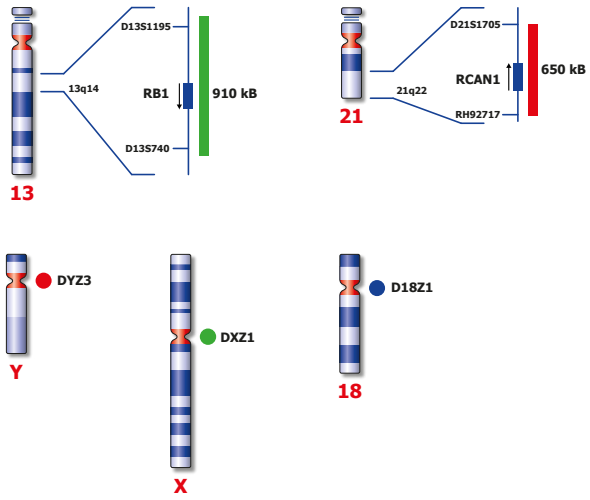
BACKGROUND

Trisomy 21 is one of the most common chromosomal abnormalities in live born children and causes Down syndrome.

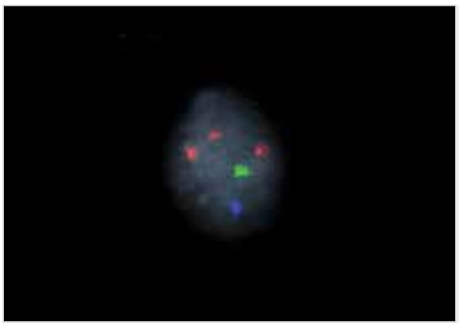
Trisomy 13, also called Patau syndrome, is a chromosomal condition that is associated with severe mental retardation and certain physical abnormalities. Trisomy 18 causing Edwards syndrome is the second most common autosomal trisomy after trisomy 21. The disorder/condition is characterized by severe symptoms. Turner syndrome occurs when females inherit only one X chromosome; their genotype is X0. Metafemales or triple-X females, inherit three X of more chromosomes. Klinefelter syndrome males inherit one or more extra X chromosomes; XYY syndrome males inherit an extra Y chromosome.

REFERENCES

Uchida et al, 2010, Cancer Genet Cytogenet, 203; 324-327.
Sen et al, 2002, J of Nat Canc Inst, 94; 1320-1329.
Lassmann et al, 2007, Clin Cancer Res, 13; 4083-4091.



RCAN1 / SE X / SE Y



Hybridization of the RCAN1 (21q22), SE X, SE Y probe to a male metaphase spread showing"normal pattern (2R1G1B).

-

RCAN1 (21q22), SE X, Y

CODE	COLOR	FORMAT	STATUS
KI-40008	Green/Red/Blue	200 µL	RUO

MENU

RESEARCH

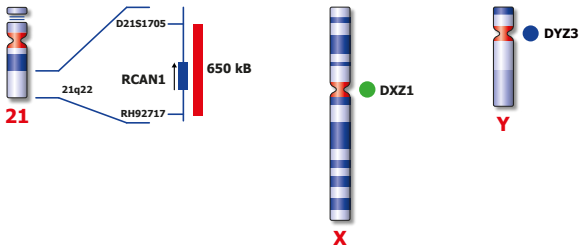
BACKGROUND

Chromosomal abnormalities involving the X and Y chromosome (sex chromosomes) are slightly less common than autosomal abnormalities and are usually much less severe in their effects. The high frequency of people with sex chromosome aberrations is partly due to the fact that they are rarely lethal conditions.

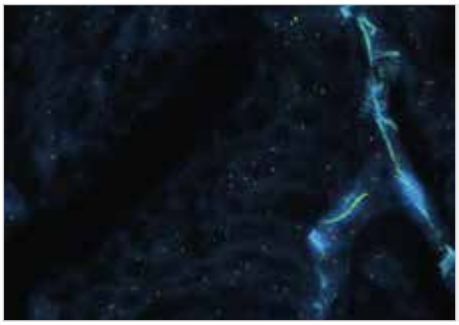
- Turner syndrome occurs when females inherit only one X chromosome - their genotype is X0.

- Metafemales or triple-X females, inherit three X chromosomes - their genotype is XXX or more rarely XXXX or XXXXX.

- Klinefelter syndrome males inherit one or more extra X chromosomes - their genotype is XXY or more rarely XXXY, XXXXY, or XY / XXY mosaic.



RET Break



Hybridization of RET break probe to a tissue section showing"abarrant pattern (1RG1R1G).

RET (10q11) Break

CODE	COLOR	FORMAT	STATUS
KI-10753	Green/Red	100 µL	RUO

MENU

RESEARCH

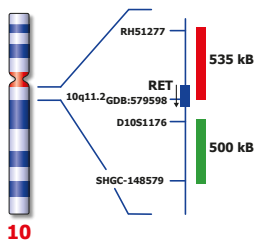
BACKGROUND

Pericentric inversion of chromosome 10 involving the RET (ret proto-oncogene) gene at chromosome 10q11 is known to increase expression of the RET gene by fusion with KIF5B (10p11). Translocations with other fusion partners have also been described. Elevated expression of RET is observed in non-small cell lung cancer (NSCLC), in which the function of tyrosine kinase-based therapeutics is based on the inhibition of such fusion proteins. Translocations involving RET have also been described in thyroid carcinomas.

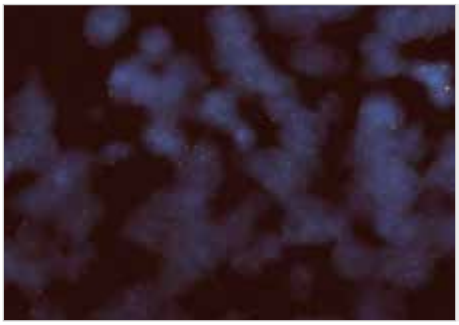
The RET (10q11) Break probe is optimized to detect translocations involving the RET gene region at 10q11.

REFERENCES

Chen et al, Cancer Genet Cytogenet, 2007, 178: 128-134.
Kohno et al, Nat Med, 2012, 18: 375-377.
Takeuchi et al, Nat Med, 2012, 18: 378-381.



ROS1 Break



Hybridization of ROS1 (6q22) Break Probe (KBI-10752) to a tissue section harboring a ROS1 rearrangement.

ROS1 (6q22) Break

CODE	COLOR	FORMAT	STATUS
KI-10752	Green/Red	100 µL	RUO

MENU

RESEARCH

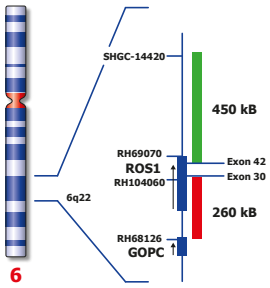
BACKGROUND

Translocations involving the ROS1 gene at chromosome 6q22 can increase expression of the gene by fusion with SLC34A2 (4p15), but also with other fusion partners. Elevated expression is observed in non-small cell lung cancer (NSCLC), where the success of tyrosine kinase-based therapeutics like"Crizotinib (Xalkori) is based on inhibiting the activity of these fusion genes. The fusion of ROS1 to the GOPC (FIG) gene, by deletion of a 240 kb DNA fragment, also results in activation of a fusion gene.

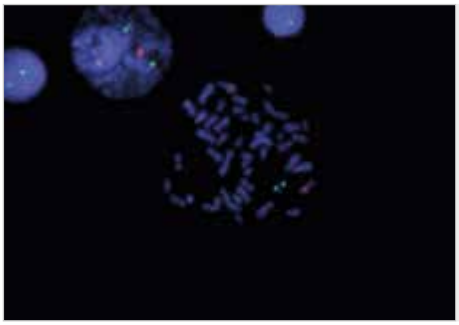
The ROS1 (6q22) Break probe is optimized to detect translocations involving the ROS1 gene region at the 6q22 locus, as well as the 240 kb deletion forming the ROS1-GOPC fusion gene, in a dual-color assay on formalin- fixed paraffin-embedded tissue samples.

REFERENCES

Charest et al, Genes Chromosomes Cancer, 2003, 37: 58-71.
Rikova et al, Cell, 2007, 131: 1190-120.
Rimkunas et al, Clin. Can. Res., 2012, 18: 4449-4457.
Takeuchi et al, Nat. Med., 2012, 18: 378-381.
Gu et al, PLoS, 2011, 6: e15640.



RUNX1 / RUNX1T1



Hybridization of RUNX1/ RUNX1T1 fusion probe to a metaphase spread showing normal pattern (2R2G).

RUNX1 / RUNX1T1 t(8;21) Fusion

CODE	COLOR	FORMAT	STATUS
KI-10301	Green/Red	100 µL	RUO

MENU

RESEARCH

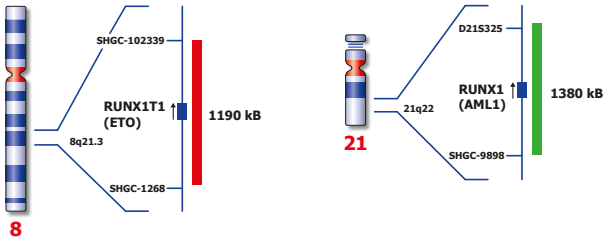
BACKGROUND

t(8;21)(q21;q22) is the most frequently observed karyotypic abnormality associated with acute myeloid leukemia (AML), especially in FAB M2. As a consequence of the translocation the RUNX1 (previously known as AML) (CBFA2) gene in the 21q22 region is fused to the RUNX1T1 (previously known as ETO) (MTG8) gene in the 8q21 region, resulting in one transcriptionally active gene on the 8q-derivative chromosome.

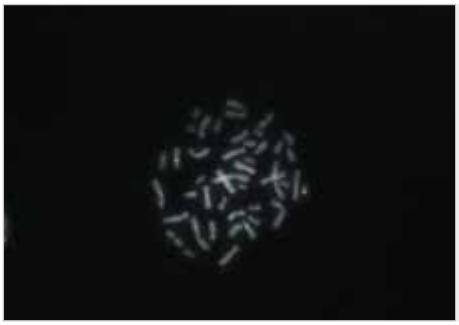
The RUNX1 / RUNX1T1 t(8;21)(q21;q22) specific FISH probe is optimized to detect the reciprocal translocation t(8;21) in a dual-color, dual-fusion assay.

REFERENCES

Sacchi et al, 1995, Genes Chrom Cancer, 79; 97-103.
Hagemeijer et al, 1998, Leukemia, 12; 96-101.



SE 7 / SE 8



Hybridization of SE 7 / SE 8 probe to a metaphase spread showing normal pattern (2R2G).

SE 7 (D7Z1) / SE 8 (D8Z1)

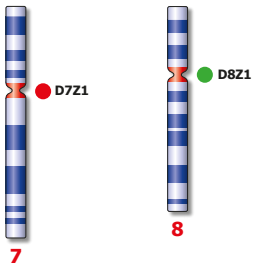
CODE	COLOR	FORMAT	STATUS
KI-20031	Green/Red	100 µL	RUO

MENU

RESEARCH

BACKGROUND

Trisomy 8 is found as one of the genetic changes in CML, while loss of chromosome 7 is found in AML. The SE 7 (D7Z1) / SE 8 (D8Z1) FISH probes are optimized to detect repetitive sequences located in the pericentric heterochromatin of chromosome 7 and 8.



SE X / SE Y

Hybridization of SE X / SE Y probe to a male metaphase spread showing"normal pattern (1R1G).

SE X (DXZ1) / SE Y (DYZ3)

CODE	COLOR	FORMAT	STATUS
KI-20030	Green/Red	100 µL	RUO

MENU

RESEARCH

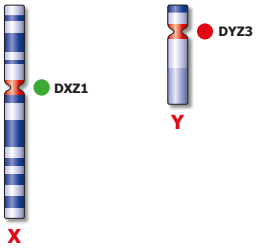
BACKGROUND

Chromosomal abnormalities involving the X and Y chromosome (sex chromosomes) are slightly less common than autosomal abnormalities and are usually much less severe in their effects. The high frequency of people with sex chromosome aberrations is partly due to the fact that they are rarely lethal conditions.

- Turner syndrome occurs when females inherit only one X chromosome - their genotype is X0.

- Metafemales or triple-X females, inherit three X chromosomes - their genotype is XXX or more rarely XXXX or XXXXX.

- Klinefelter syndrome males inherit one or more extra X chromosomes - their genotype is XXY or more rarely XXXY, XXXXY, or XY / XXY mosaic.



SE X / SE Y / SE 18

Hybridization of SE X / SE Y / SE 18 probe to a metaphase spread showing"normal pattern (1R1G2B).

SE X (DXZ1) / SE Y (DYZ3) / SE 18 (D18Z1)

CODE	COLOR	FORMAT	STATUS
KI-20032	Green/Red/Blue	100 µL	RUO

MENU

RESEARCH

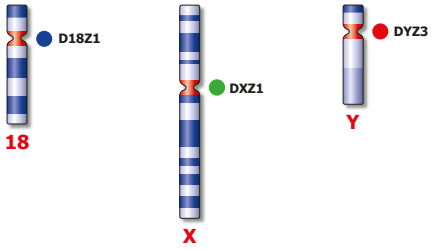
BACKGROUND

Chromosomal abnormalities involving the X and Y chromosome (sex chromosomes) are slightly less common than autosomal abnormalities and are usually much less severe in their effects. The high frequency of people with sex chromosome aberrations is partly due to the fact that they are rarely lethal conditions.

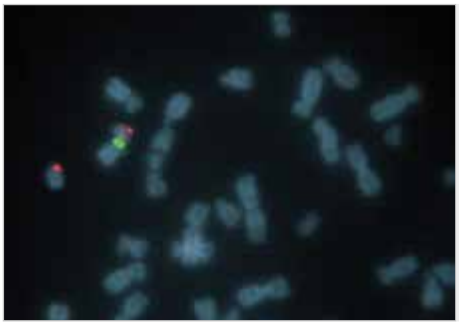
- Turner syndrome occurs when females inherit only one X chromosome - their genotype is X0.

- Metafemales or triple-X females, inherit three X chromosomes - their genotype is XXX or more rarely XXXX or XXXXX.

- Klinefelter syndrome males inherit one or more extra X chromosomes - their genotype is XXY or more rarely XXXY, XXXXY, or XY / XXY mosaic.



SHOX / SE X



Short Stature SHOX (Xp22) / SE X probe hybridized to a male metaphase (2R1G).

SHOX (Xp22) / SE X

CODE	COLOR	FORMAT	STATUS
KI-40112	Green/Red	100 µL	RUO

MENU

RESEARCH

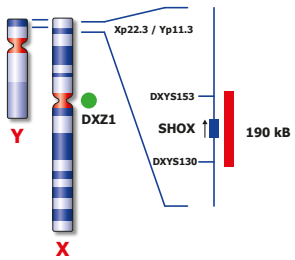
BACKGROUND

Individuals with SHOX-related short stature have disproportionate short stature and/or wrist abnormalities consistent with those described in Madelung deformity. The SHOX genes located on the pseudoautosomal regions of the X and Y chromosomes are the only genes known to be associated with SHOX-related haploinsufficiency.

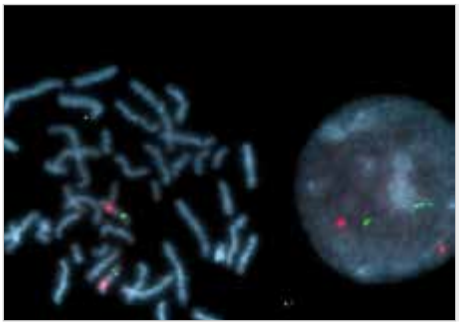
The SHOX region probe is optimized to detect copy numbers of the SHOX gene region at Xp22. The chromosome X Satellite Enumeration (SE X) FISH probe at DXZ1 is added to facilitate chromosome identification.

REFERENCES

Rao et al, 1997, Hum. Genet., 100; 236-239.
Morizio et al, 2003, Am. J. Med. Genet., 119; 293-296.



SNRPN / PML



Prader-Willi SNRPN (15q11) / PML (15q24) probe hybridized to a normal interphase/metaphase (2R2G).

SNRPN (15q11) / PML (15q24)

CODE	COLOR	FORMAT	STATUS
KI-40109	Green/Red	100 µL	RUO

MENU

RESEARCH

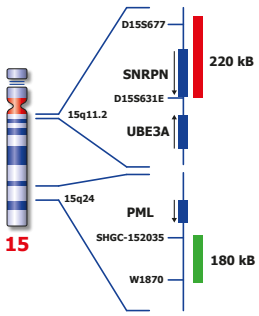
BACKGROUND

Prader-Willi Syndrome (PWS) is a clinically distinct disorder including diminished fetal activity, obesity, hypotonia, mental retardation, short stature, hypogonadotropic hypogonadism, strabismus, and small hands and feet.

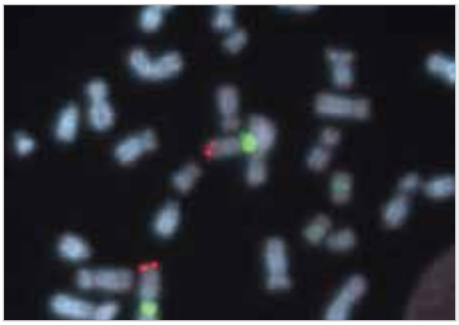
Approximately 70% of cases of PWS arise from paternal deletion of the 15q11-q13 region including the gene SNRPN (small nuclear ribonucleoprotein polypeptide N). The PWS SNRPN region probe is optimized to detect copy numbers of the SNRPN gene region at 15q11. The PML (promyelocytic leukemia) gene specific FISH probe at 15q24 is included as control probe.

REFERENCES

Knoll et al, 1989, Am. J. Med. Genet., 32; 285-290.
Ozcelik et al, 1992, Nat. Genet., 2; 265-269.



SRD / SE 1



SRD (1p36) / SE 1 probe hybridized to a normal metaphase (2R2G).

SRD (1p36) / SE 1 (1qh)

CODE	COLOR	FORMAT	STATUS
KI-10712	Green/Red	100 µL	RUO

MENU

RESEARCH

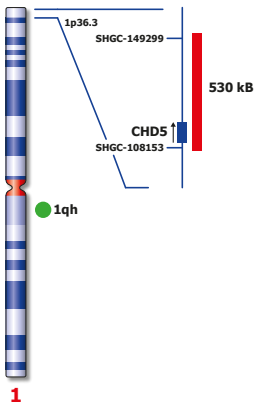
BACKGROUND

Neuroblastomas frequently have deletions of chromosome 1p and amplification of the MYCN oncogene. These deletions tend to be large and extend to the telomere, but a common region within sub-band 1p36.3 is consistently lost in these deletions. Inactivation of a tumor suppressor gene within 1p36.3 is believed to be associated with an increased risk for disease relapse.

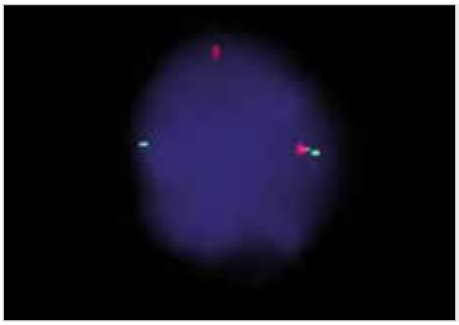
The SRD (1p36) FISH probe is optimized to detect copy numbers of the 1p36 region on chromosome 1. The chromosome 1 satellite enumeration probe (SE 1) at 1qh is included to facilitate chromosome identification.

REFERENCES

Caron et al, 1993, Nat Genet, 4: 187-190.
Cheng et al, 1995, Oncogene, 10: 291-297.
White et al, 2005, Oncogene, 24: 2684-2694.



SS18 Break



SS18 (18q11) Break probe hybridized to patient material showing translocation of the SYT (SS18) gene region at 18q11 (1RG1R1G).

SS18 (18q11) Break

CODE	COLOR	FORMAT	STATUS
KI-10713	Green/Red	100 µL	RUO

MENU

RESEARCH

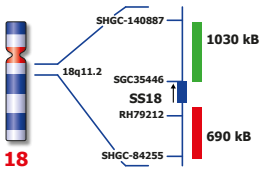
BACKGROUND

The characteristic chromosomal abnormality in Synovial Sarcoma t(X;18) (p11.2;q11.2) is present in 90% of the patients. This translocation results in the fusion of the synovial sarcoma translocation, chromosome 18 (SS18) gene to either of two distinct genes, SSX1 or SSX2, located on the X chromosome.

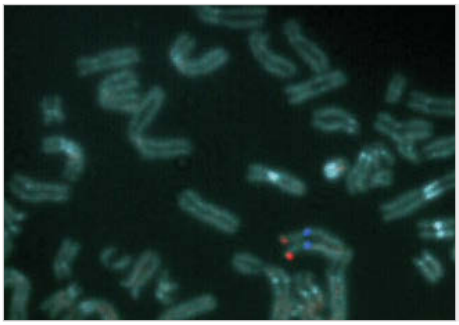
The SS18 (18q11) Break probe is optimized to detect translocations involving the SS18 gene region at 18q11 in a dual-color, split assay on paraffin embedded tissue sections.

REFERENCES

Kawai et al, 1998, NEJM, 338; 153-160.
Surace et al, 2004, LabInvest., 84; 1185-1192.



STS / KAL1 / SE X



STS (Xp22) / KAL1 (Xp22) / SE X Triple-Color probe hybridized to male patient material showing a deletion of the STS gene region (1R1B).

Material kindly provided by Necker hospital, Paris.

STS (Xp22) / KAL1 (Xp22) / SE X Triple-Color

CODE	COLOR	FORMAT	STATUS
KI-40115	Green/Red/Blue	100 µL	RUO

MENU

RESEARCH

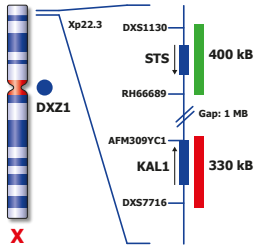
BACKGROUND

STS (Steroid Sulfatase) disease is a chromosome X-linked disorder associated with a microdeletion of the gene within the Xp22.3 region. Deletion of the steroid sulfatase gene has been detected in individuals with recessive X-linked ichtyosis, the disease been considered one of the most frequent human enzyme deficient disorders. KAL1 (Kallmann syndrome interval gene-1) maps to the Kallmann syndrome critical region on the distal short arm of the human X chromosome. Individuals with Kallmann syndrome suffers of hypogonadotropic hypogonadism and anosmia, with clinical features of variable phenotype. It affects approximately 1 in 8000 males and 1 in 40000 females.

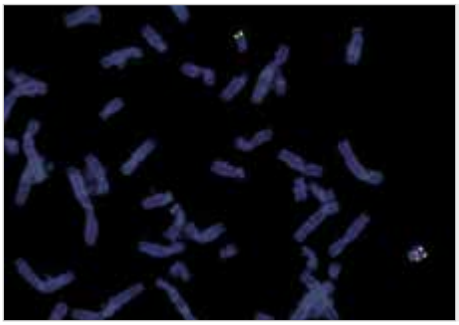
The STS (Xp22) region probe is optimized to detect copy numbers of the STS gene region at Xp22. The KAL1 (Xp 22) region probe is optimized to detect copy numbers of the KAL1 gene region at Xp22. The Chromosome X Satellite Enumeration (SE X) FISH probe at DXZ1 is included to facilitate chromosome identification.

REFERENCES

Alper in et al, 1997, J. Biol. Chem., 272; 20756-20763.
Meroni et al, 1996, Hum. Mol. Genet., 5; 423-431.



TBX1 / SHANK3



DiGeorge TBX1 (22q11) / 22q13 (SHANK3) probe hybridized to DiGeorge patient material showing a deletion of the TBX1 gene region at 22q11 (1R2G).

Image kindly provided by Dr. F. Girard- Lemaire Service de Cytogénétique (Dr. Flori), CHU Strasbourg.

TBX1 (22q11) / 22q13 (SHANK3)

CODE	COLOR	FORMAT	STATUS
KI-40104	Green/Red	100 µL	RUO

MENU

RESEARCH

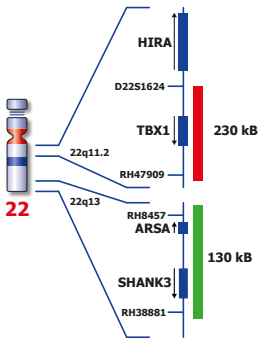
BACKGROUND

The 22q11 deletion in DiGeorge syndrome/VCFS is characterized by defects in the derivatives of the pharyngeal apparatus. TBX1, a member of the T-box transcription factor family, is required for normal development of the pharyngeal arch arteries. Haploinsufficiency of TBX1 has been demonstrated to be sufficient to generate at least one important component of the DiGeorge syndrome phenotype in mice. The TBX1 is also located within the minimal critical DiGeorge region in humans.

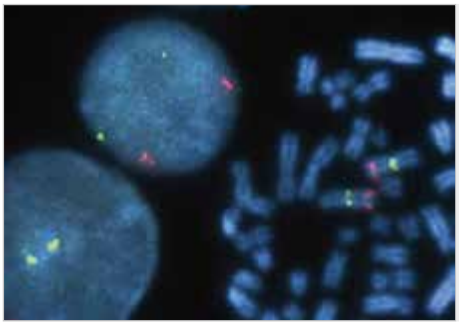
The DiGeorge TBX1 region probe is optimized to detect copy numbers of the TBX1 gene region at 22q11.2. The subtelomeric (ST) 22qter FISH probe is included as control probe. The SHANK3 FISH probe at 22q13 is serving as internal control.

REFERENCES

Lindsay et al, 2001, Nature, 410; 97-101.
Merscher et al, 2001, Cell, 104; 619-629.
Paylor et al, 2006, PNAS, 103; 7729-7734.



TERC / 3q11



TERC (3q26) / 3q11 probe hybridized to a normal interphase/metaphase (2R2G).

TERC (3q26) / 3q11

CODE	COLOR	FORMAT	STATUS
KI-10110	Green/Red	100 µL	RUO

MENU

RESEARCH

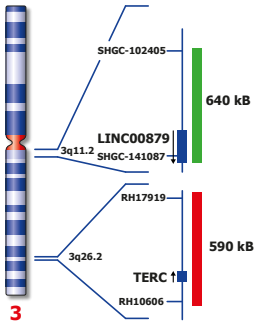
BACKGROUND

Amplification of the 3q26-q27 has a high prevalence in cervical, prostate, lung, and squamous cell carcinoma. This amplification can also be found to a lesser extent in CLL patients. The minimal region of amplification was refined to a 1- to 2-Mb genomic segment containing several potential cancer genes including TERC, the human telomerase RNA gene.

The TERC (3q26) specific FISH probe is optimized to detect copy numbers of the TERC (previously known as hTERC) gene region at region 3q26. The 3q11 region probe is included to facilitate chromosome identification.

REFERENCES

Arnold et al, 1996, Genes Chrom Cancer, 16; 46-54.
Soder et al, 1997, Oncogene, 14; 1013-1021.



TERC / MYC / SE 7

TERC (3q26) / MYC (8q24) / SE 7 Triple-Color probe hybridized to a PAP smear (destained) showing 3q26 and 8q24 amplification. The SE 7 control probe indicates a non-triploid karyotype (2B).

Image kindly provided by Dr. Weimer, Kiel.

TERC (3q26) / MYC (8q24) / SE 7 Triple-Color

CODE	COLOR	FORMAT	STATUS
KI-10704	Green/Red/Blue	100 µL	RUO

MENU

RESEARCH

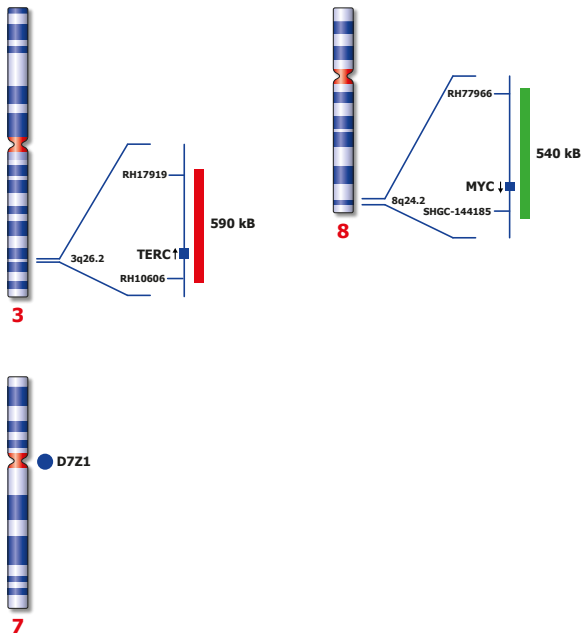
BACKGROUND

The most consistent chromosomal gain in aneuploid tumors of cervical squamous cell carcinoma mapped to chromosome arm 3q, including the human telomerase gene locus (TERC) at 3q26. Highlevel copy number increases were also mapped to chromosome 8. Integration of HPV (Human Papilloma Virus) DNA sequences into MYC chromosomal regions have been repeatedly observed in cases of invasive genital carcinomas and in cervical cancers.

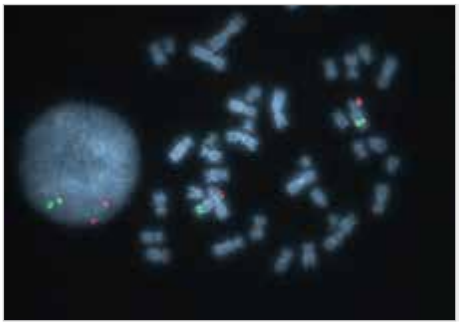
The TERC (3q26) FISH probe is optimized to detect copy numbers of the TERC gene region at region 3q26. The MYC (8q24) FISH probe is optimized to detect copy numbers of the MYC gene region at 8q24. The chromosome 7 satellite enumeration probe (SE 7) at D7Z1 is included as ploidy control.

REFERENCES

Xie et al, 2008, Geburtshilfe Frauenheilkunde, 68: 573.
Heselmeyer et al, 1996, PNAS, 93: 479-484.
Herrick et al, 2005, Cancer Res, 65: 1174-1179.



TERT / 5q31



TERT (5p15) / 5q31 probe hybridized to a normal interphase/metaphase (2R2G).

Image kindly provided by Dr. Mohr, Dresden.

TERT (5p15) / 5q31

CODE	COLOR	FORMAT	STATUS
KI-10208	Green/Red	100 µL	RUO

MENU

RESEARCH

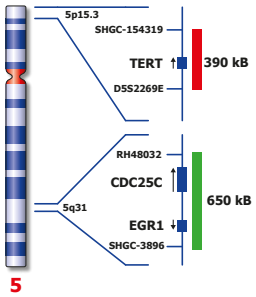
BACKGROUND

The TERT / 5q31 dual-color FISH probe can be used to detect deletions involving band 5q31 in MDS and RUNX1.

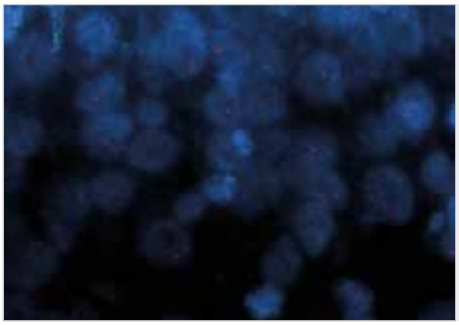
The 5q- specific FISH probe is optimized to detect copy numbers at the CDC25C / EGR1 gene region at 5q31. The TERT (previously known as hTERT) gene region at 5p15 is included to facilitate chromosome identification.

REFERENCES

Zhao et al, 1997, PNAS, 94; 6948-6053.
Horrigan et al, 2000, Blood, 95; 2372-2377.



TERT / 5q31 (tissue)



Hybridization of TERT / 5q31 Probe to a tissue section showing"gain of the TERT region.

TERT (5p15) / 5q31 (tissue)

CODE	COLOR	FORMAT	STATUS
KI-10709	Green/Red	100 µL	RUO

MENU

RESEARCH

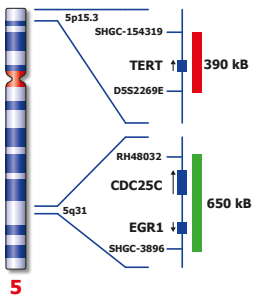
BACKGROUND

Amplifications of the TERT gene at 5p15 has been observed in a variety of cancers, particularly lung cancer, cervical tumors, and breast carcinomas. Several studies have revealed a high frequency of TERT gene amplification in human tumors, which indicates that the TERT gene may be a target for amplification during the transformation of human malignancies and that this genetic event probably contributes to a dysregulation of TERT/ telomerase occurring in a subset of human tumors.

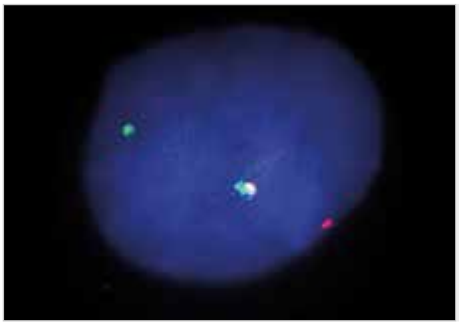
The TERT (5p15) FISH probe is designed as a dual-color assay to detect amplification at 5p15. The CDC25C / EGR1 (5q31) gene region probe is included as internal control.

REFERENCES

Bryce et al, 2000, Neoplasia, 2;197-201.
Zhang et al, 2000, Cancer Res, 60;6230-6235



TFE3 Break



TFE3 (Xp11) Break probe hybridized to renal cell carcinoma showing a translocation at Xp11 (1RG1R1G).

Image kindly provided by Dr. Desangles, Paris.

TFE3 (Xp11) Break

CODE	COLOR	FORMAT	STATUS
KI-10741	Green/Red	100 µL	RUO

MENU

RESEARCH

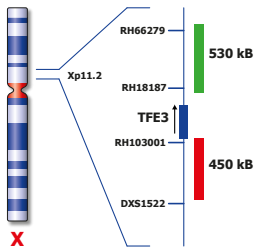
BACKGROUND

Abnormalities of Xp11.2 region have often been observed in papillary renal cell carcinomas and are sometimes the sole cytogenetic abnormality present. The transcription factor binding to IGHM enhancer 3 (TFE3) gene, which encodes a member of the helix-loop-helix family of transcription factors, is located in this critical region and can be fused to various other chromosomal regions by translocation. Known fusion partners are NONO (Xq12), PRCC (1q21), SFPQ (1p34), CLTC (17q23) and ASPSCR1 (17q25).

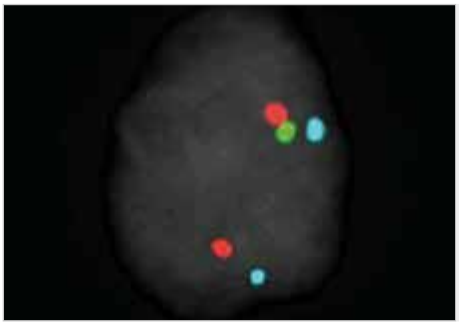
The TFE3 (Xp11) Break probe is optimized to detect translocations involving the TFE3 gene region at Xp11.2 in a dual-color, break assay.

REFERENCES

Sidhar et al, 1996, Hum Mol Genet, 5; 1333-1338.
Weterman et al, 1996, Proc Natl, Acad Sci, 93; 15294-15298.



TMPRSS2-ERG



TMPRSS2-ERG (21q22) rearrangement probe hybridized to prostate carcinoma tissue showing a deletion of the TMPRSS2 (21q22) gene region associated with TMPRSS2-ERG fusion (1RGB 1RB).

Image kindly provided by Dr. Teixeira, Porto.

TMPRSS2-ERG (21q22) Deletion, Break, Triple-Color

CODE	COLOR	FORMAT	STATUS
KI-10726	Green/Red/Blue	100 µL	RUO

MENU

RESEARCH

BACKGROUND

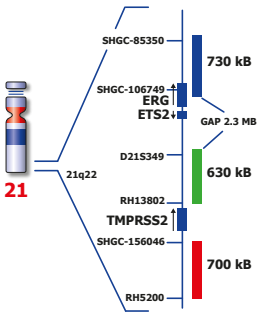
The transmembrane protease serine 2 gene (TMPRSS2) is involved in gene fusions with ERG, ETV1 or ETV4 in prostate cancer. It has been reported that the expression of the TMPRSS2-ERG fusion gene is a strong prognostic factor for the risk of prostate cancer recurrence in prostate cancer patients treated by surgery.

The TMPRSS2-ERG rearrangement probe is optimized to detect the deletion between TMPRSS2 and ERG at 21q22 associated with the TMPRSS2-ERG fusion in a triple-color deletion assay.

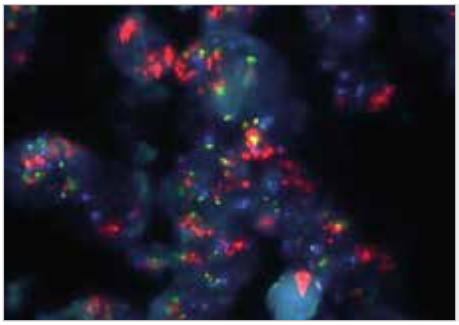
It also detects translocations involving the TMPRSS2 region such as ETV1 t(7;21), or ETV4 t(17;21).

REFERENCES

Perner et al, 2006 Cancer Res 66; 8337-8341.
Hermans et al, 2006, Cancer Res 66; 10658-10663.
Attard et al, 2008, Oncogene 27; 253-263.



TOP2A / ERBB2 / SE 17



TOP2A (17q21) / ERBB2 (17q12) / SE 17 TC probe hybridized to breast tumor tissue showing amplification of TOP2A / ERBB2.

TOP2A (17q21) / ERBB2 (17q12) / SE 17, Triple-Color

CODE	COLOR	FORMAT	STATUS
KI-10735	Green/Red/Blue	100 µL	RUO

MENU

RESEARCH

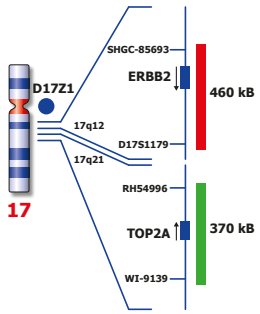
BACKGROUND

The presence of both TOP2A amplification and deletion in advanced cancer are associated with decreased survival, and occur frequently and concurrently with ERBB2 gene amplification (commonly refered to as HER2).

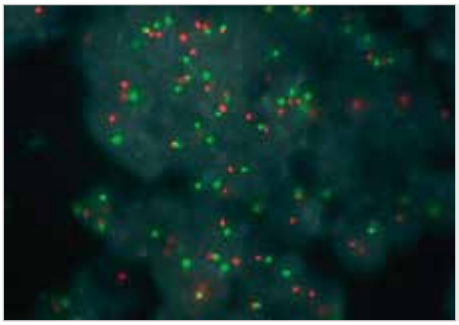
The TOP2A (17q21) / ERBB2 (17q12) / SE 17 probe is designed as a triple-color assay to detect amplification at 17q12 as well as amplifications or deletions at 17q21. The chromosome 17 satellite enumeration probe (SE 17) at D17Z1 in blue is included to facilitate chromosome identification/enumeration.

REFERENCES

Järvinen et al, 1999, Genes Chromosomes Cancer 26; 142-150.
Järvinen et al, 2000, Am. J. Pathology 156; 639-647.



TOP2A / SE 17



TOP2A (17q21) / SE 17 probe hybridized to breast tissue (2R2G).

TOP2A (17q21) / SE 17

CODE	COLOR	FORMAT	STATUS
KI-10724	Green/Red	100 µL	RUO

MENU

RESEARCH

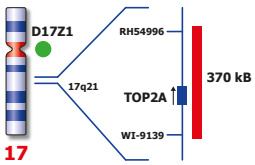
BACKGROUND

The Topoisomerase2A (TOP2A) enzyme, which is vital for the cell because of its role in cell replication and repair, catalyzes the relaxation of supercoiled DNA molecules to create a reversible double-strand DNA break. This enzyme is also the target of a number of cytotoxic agents, namely TOP2A inhibitors (anthracyclines, etoposide, teniposide).

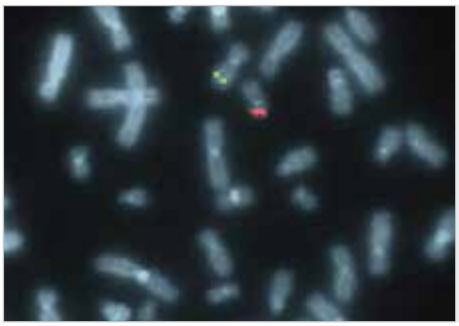
The TOP2A (17q21) / SE 17 FISH probe is optimized to detect amplifications (copy numbers) or deletions of the TOP2A gene region at the 17q21. The chromosome 17 satellite enumeration probe (SE 17) at D17Z1 is included to facilitate chromosome identification.

REFERENCES

Järvinen et al, 1999, Genes Chromosomes Cancer 26; 142-150.
Järvinen et al, 2000, Am. J. Pathology 156; 639-647.



TP53 / ATM



TP53 (17p13) / ATM (11q22) hybridized to a normal metaphase (2R2G).

TP53 (17p13) / ATM (11q22)

CODE	COLOR	FORMAT	STATUS
KI-10114	Green/Red	100 µL	RUO

MENU

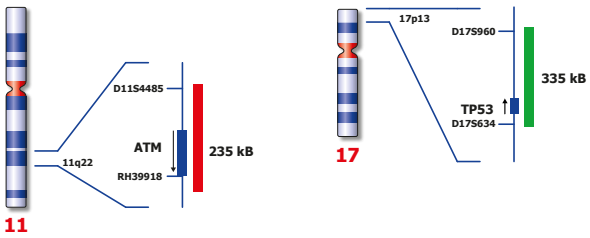
RESEARCH

BACKGROUND

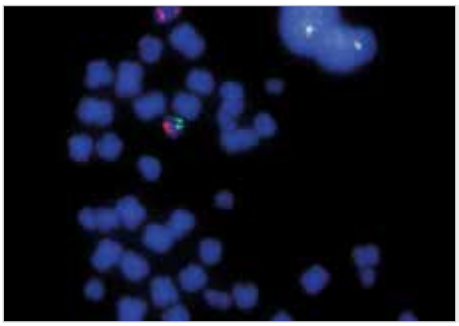
Deletion of TP53 (previously known as p53) and ATM are both indicating poor prognosis in CLL. Alterations of the TP53 (17p13) gene occur not only as somatic mutations in human malignancies, but also as germline mutations in some cancer-prone families with Li-Fraumeni syndrome. Deletions of TP53 are frequent in CLL and MM, usually associated with unfavorable prognosis. Deletions of the long arm of chromosome 11 (11q) are one of the most frequent structural chromosome aberrations in various types of lymphoproliferative disorders. A critical genomic region located in bands 11q22.3-q23.1 has been identified and contains among other genes the ATM (ataxia telangiectasia mutated) gene.

REFERENCES

Boultwood J, 2001, J. Clin. Pathol., 54; 512-516
Amiel A et al, 1997, Cancer Gener.Cytogenet,, 97; 97-100
Drach J et al, 1998, Blood, 92; 802-809
Doehner H et al, 1997, Blood, 7; 2516-2522



TP53 / MPO



TP53 (17p13) / MPO (17q22) "ISO 17q" probe hybridized to peripheral blood of a CLL patient with an isochromosome 17 (3R1G).

Image kindly provided by Dr. Lana Harder, Kiel.

TP53 (17p13) / MPO (17q22) "ISO 17q"

CODE	COLOR	FORMAT	STATUS
KI-10011	Green/Red	100 µL	RUO

MENU

RESEARCH

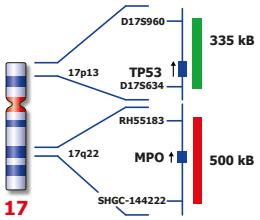
BACKGROUND

Isochromosome 17q is the most common isochromosome in cancer. It plays an important role in tumor development and progression. Hematologic malignancies such as chronic myeloid leukemia (CML) with isochromosome 17q carry a poor prognosis. Isochromosome 17q is the most common chromosome abnormality in primitive neuroectodermal tumors and medulloblastoma. Isochromosome 17q is, by convention, symbolized as i(17q).

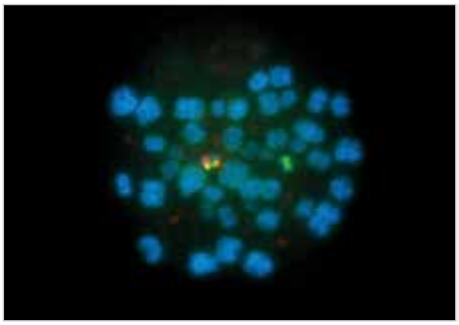
The TP53 (17p13) / MPO (17q22) "ISO 17q" FISH probe is optimized to detect copy numbers of the TP53 gene region at 17p13 and MPO gene region at 17q22. In case of i(17q) a signal pattern of three red signals for MPO (17q22) and one signal for TP53 at 17p13 is expected.

REFERENCES

Becher et al, 1990, Blood, 75; 1679-1683.
Fioretos et al, 1999, Blood, 94; 225-232.



TP53 / SE 17



TP53 (17p13) / SE 17 probe hybridized to patient material showing a 17p13 deletion at the TP53 gene region (1R2G).

TP53 (17p13) / SE 17

CODE	COLOR	FORMAT	STATUS
KI-10112	Green/Red	100 µL	RUO
KI-12112	Green/Red	200 µL	RUO

MENU

RESEARCH

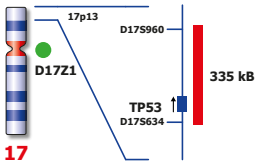
BACKGROUND

The TP53 tumor suppressor gene at 17p13, has been shown to be implicated in the control of normal cellular proliferation, differentiation, and apoptosis. Allelic loss, usually by deletion, and inactivation of TP53 have been reported in numerous tumor types and are associated with poor prognosis in CLL.

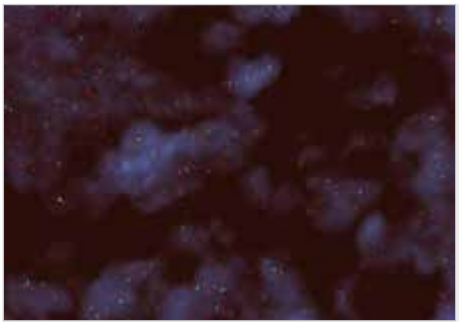
The TP53 (17p13) FISH probe is optimized to detect copy numbers of the TP53 gene region at 17p13. The chromosome 17 satellite enumeration probe (SE 17) at D17Z1 is included to facilitate chromosome identification. Kreatech has developed this probe for the specific use on cell material (KBI-10112 / KBI-12112), or for the use on tissue (KBI-10738).

REFERENCES

Amiel A et al, 1997, Cancer Gener. Cytogenet, 97; 97-100.
Drach J et al, 1998, Blood, 92; 802-809.



TP53 / SE 17 (tissue)



Hybridization of TP53 probe to a tissue section showing"normal pattern (2R2G).

TP53 (17p13) / SE 17 (tissue)

CODE	COLOR	FORMAT	STATUS
KI-10738	Green/Red	100 µL	RUO

MENU

RESEARCH

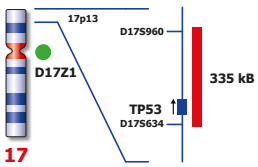
BACKGROUND

The TP53 tumor suppressor gene at 17p13, has been shown to be implicated in the control of normal cellular proliferation, differentiation, and apoptosis. Allelic loss, usually by deletion, and inactivation of TP53 have been reported in numerous tumor types and are associated with poor prognosis in CLL.

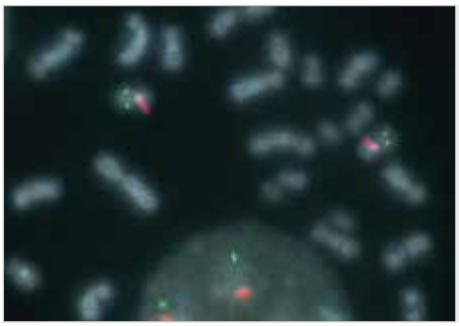
The TP53 (17p13) FISH probe is optimized to detect copy numbers of the TP53 gene region at 17p13. The chromosome 17 satellite enumeration probe (SE 17) at D17Z1 is included to facilitate chromosome identification. Kreatech has developed this probe for the specific use on cell material (KBI-10112 / KBI-12112), or for the use on tissue (KBI-10738).

REFERENCES

Amiel A et al, 1997, Cancer Gener.Cytogenet,, 97; 97-100.
Drach J et al, 1998, Blood, 92; 802-809.



UBE3A / PML



Angelman UBE3A (15q11) / PML (15q24) probe hybridized to a normal interphase/metaphase (2R2G).

UBE3A (15q11) / PML (15q24)

CODE	COLOR	FORMAT	STATUS
KI-40110	Green/Red	100 µL	RUO

MENU

RESEARCH

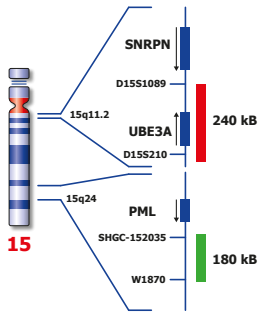
BACKGROUND

Angelman syndrome (AS) is characterized by severe developmental delay or mental retardation, severe speech impairment, gait ataxia and/or tremulousness of the limbs, and an unique behavior with an inappropriate happy demeanor that includes frequent laughing, smiling, and excitability. In addition, microcephaly and seizures are common. AS is caused by absence of a maternal contribution to the imprinted region on chromosome 15q11-q13 including the UBE3A gene.

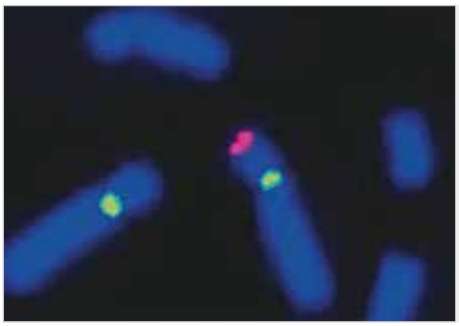
The AS UBE3A region probe is optimized to detect copy numbers of the UBE3A gene region at 15q11. The PML (promyelocytic leukemia) gene specific FISH probe at 15q24 is included as control probe.

REFERENCES

Matsuura et al, 1997, Nat. Genet., 15; 74-77.
Burger et al, 2002, Am. J. Med. Genet., 111; 233-237.



WHSC1 / SE 4



Wolf-Hirschhorn WHSC1 (4p16) / SE 4 probe hybridized to Wolf-Hirschhorn patient material showing a deletion of the WHSC1 gene region at 4p16 (1R2G).

Image kindly provided by Prof. Zollino, Rome.

WHSC1 (4p16) / SE 4

CODE	COLOR	FORMAT	STATUS
KI-40107	Green/Red	100 µL	RUO

MENU

RESEARCH

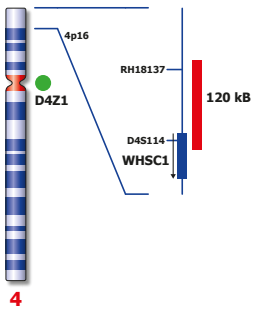
BACKGROUND

Wolf-Hirschhorn Syndrome (WHS) affected individuals have prenatal-onset growth deficiency followed by postnatal growth retardation and hypotonia with muscle under-development. Developmental delay/mental retardation of variable degree is present in all. FISH analysis using a WHSC1 specific FISH probe for chromosomal locus 4p16.3 detects more than 95% of deletions in WHS.

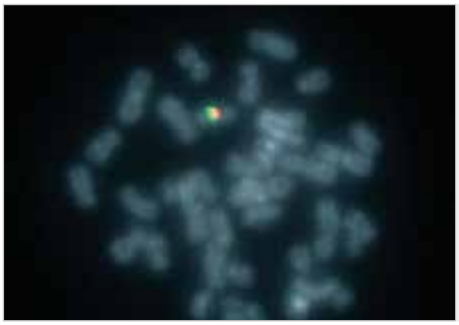
The Wolf-Hirschhorn region probe is optimized to detect copy numbers of the Wolf-Hirschhorn critical region at 4p16. The chromosome 4 Satellite Enumeration (SE 4) FISH probe at D4Z1 is included to facilitate chromosome identification.

REFERENCES

Gandelman et al, 1992, Am. J. Hum. Genet., 51; 571-578.
Wright et al, 1997, Hum. Mol. Genet., 6; 317-324.



XIST / SE X



X-Inactivation XIST (Xq13) / SE X probe hybridized to a male metaphase (1R1G).

XIST (Xq13) / SE X

CODE	COLOR	FORMAT	STATUS
KI-40108	Green/Red	100 µL	RUO

MENU

RESEARCH

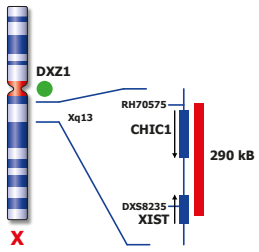
BACKGROUND

The XIST locus is expressed only from the inactive X chromosome, resides at the putative X inactivation center, and is considered a prime player in the initiation of mammalian X dosage compensation. The severe phenotype of human females whose karyotype includes tiny ring X chromosomes has been attributed to the inability of the small ring X chromosome to inactivate. Many of the ring chromosomes lack the XIST locus, consistent with XIST being necessary for cis inactivation.

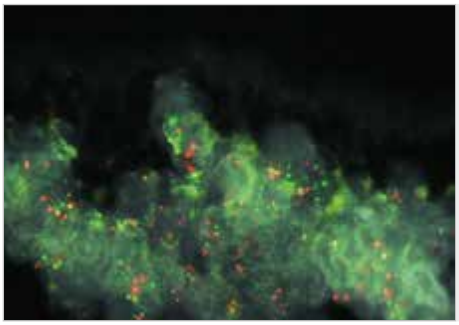
The XIST specific FISH probe is optimized to detect copy numbers of the XIST region at Xq13. The chromosome X Satellite Enumeration (SE X) FISH probe at DXZ1 is added to facilitate chromosome identification.

REFERENCES

Migeon et al, 1993, PNAS, 90; 12025-12029.
Jani et al, 1995, Genomics, 27; 182-188.



ZNF217 / 20q11



ZNF217 (20q13) / 20q11 probe hybridized to tissue (2R2G).

ZNF217 (20q13) / 20q11

CODE	COLOR	FORMAT	STATUS
KI-10733	Green/Red	100 µL	RUO

MENU

RESEARCH

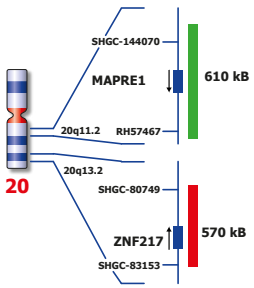
BACKGROUND

Zinc-finger protein 217 (ZNF217) is a Kruppel-like zinc-finger protein located at 20q13.2, within a region of recurrent maximal amplification in a variety of tumor types, and especially breast cancer cell lines and primary breast tumors. Copy number gains at 20q13 are also found in more than 25% of cancers of the ovary, colon, head and neck, brain, and pancreas. ZNF217 is considered a strong candidate oncogene that may have profound effects on cancer progression, which is transcribed in multiple normal tissues, and overexpressed in almost all cell lines and tumors in which it is amplified.

The ZNF217 (20q13) FISH probe is optimized to detect copy numbers of 20q at 20q13. The 20q11 probe is included to facilitate chromosome identification.

REFERENCES

Tanner M et al, 2000, Clin Cancer Res, 6; 1833-1839.
Ginestier C et al, 2006, Clin Cancer Res, 12; 4533-4544.



Product Name	Product code	Color	Content	Conc
13q34	13Q002B495	Green	50 µL	2x
13q34	13Q002C415	Blue	33 µL	3x
13q34	13Q002C495	Green	33 µL	3x
13q34	13Q002I495	Green	250 µL	2x
13q34	13Q002J415	Blue	166 µL	3x
3q11	03Q002B495	Green	50 µL	2x
5q11.2 (ISL1)	05Q006B495	Green	50 µL	2x
6q21	06Q001A550	Red	100 µL	RtU
ABL1 (9q34)	09Q001C415	Blue	33 µL	3x
ALK (2p23) Distal	02P002B550	Red	50 µL	2x
ALK (2p23) Distal-HS	02P006B550	Red	50 µL	2x
ALK (2p23) Proximal	02P001B495	Green	50 µL	2x
ALK (2p23) Proximal-HS	02P005B495	Green	50 µL	2x
ATM (11q22)	11Q001B495	Green	50 µL	2x
ATM (11q22)	11Q001I495	Green	250 µL	2x
CCND1 (11q13)	11Q002B495	Green	50 µL	2x
CCND1 (11q13)	11Q002I495	Green	250 µL	2x
CCND3 (6p21)	06P003B495	Green	50 µL	2x
CHIC2 (4q12)	04Q003C550	Red	33 µL	3x
CKS1B (1q21)	01Q001B495	Green	50 µL	2x
CKS1B (1q21)	01Q001B550	Red	50 µL	2x
CKS1B (1q21)	01Q001I550	Red	250 µL	2x
CKS1B (1q21)	01Q001N550	Red	50 µL	10x
CRLF2 (Xp22/Yp11)	23P004C550	Red	33 µL	3x
CRLF2 (Xp22/Yp11) Distal	23P003C495	Green	33 µL	3x
CRLF2 (Xp22/Yp11) Proximal	23P002C550	Red	33 µL	3x
DLEU1 (13q14)	13Q001B550	Red	50 µL	2x
DLEU1 (13q14)	13Q001C415	Blue	33 µL	3x
DLEU1 (13q14)	13Q001C550	Red	33 µL	3x
DLEU1 (13q14)	13Q001I550	Red	250 µL	2x
DLEU1 (13q14)-SV	13Q003C550	Red	33 µL	3x
DLEU1 (13q14)-SV	13Q003J550	Red	166 µL	3x
EGFR (7p11)	07P001B550	Red	50 µL	2x
EGFR (7p11)	07P001C495	Green	33 µL	3x
ERBB2 (17q12)	17Q002B550	Red	50 µL	2x
FGFR1 (8p11)	08P003B550	Red	50 µL	2x
FGFR1 (8p11) Distal	08P002B550	Red	50 µL	2x
FGFR1 (8p11) Proximal	08P001B495	Green	50 µL	2x
FGFR2 (10q26)	10Q003B550	Red	50 µL	2x
FGFR2 (10q26) Distal	10Q004B550	Red	50 µL	2x
FGFR2 (10q26) Proximal	10Q005B495	Green	50 µL	2x
FGFR3 (4p16)	04P001B495	Green	50 µL	2x
FGFR3 (4p16)	04P001I495	Green	250 µL	2x
FGFR3 (4p16) Distal	04P003B495	Green	50 µL	2x
FGFR3 (4p16) Proximal	04P002B550	Red	50 µL	2x
FGFR4 (5q35)	05Q005B550	Red	50 µL	2x
FIP1L1 (4q12)	04Q002C495	Green	33 µL	3x
IGH (14q32)	14Q001B550	Red	50 µL	2x
IGH (14q32)	14Q001I550	Red	250 µL	2x

Product Name	Product code	Color	Content	Conc
IGH (14q32)-002	14Q002B550	Red	50 µL	2x
JAK2 (9p24) Distal	09P004B550	Red	50 µL	2x
JAK2 (9p24) Proximal	09P003B495	Green	50 µL	2x
MAF (16q23)	16Q001B495	Green	50 µL	2x
MAF (16q23)	16Q001I495	Green	250 µL	2x
MAFB (20q12)	20Q002B495	Green	50 µL	2x
MECOM (3q26) Distal-004	03Q004B550	Red	50 µL	2x
MECOM (3q26) Distal-004	03Q004C550	Red	33 µL	3x
MECOM (3q26) Distal-006	03Q006C415	Blue	33 µL	3x
MECOM (3q26) Proximal	03Q003B495	Green	50 µL	2x
MECOM (3q26) Proximal-005	03Q005C495	Green	33 µL	3x
MET (7q31)	07Q001B550	Red	50 µL	2x
PDGFRA (4q12)	04Q001B550	Red	50 µL	2x
PDGFRA (4q12)-004	04Q004C415	Blue	33 µL	3x
PDGFRB (5q32) Distal	05Q001B495	Green	50 µL	2x
PDGFRB (5q32) Proximal	05Q002B550	Red	50 µL	2x
PTEN (10q23)	10Q006B550	Red	50 µL	2x
RET (10q11) Distal	10Q001B495	Green	50 µL	2x
RET (10q11) Proximal	10Q002B550	Red	50 µL	2x
ROS1 (6q22) Distal	06Q002B495	Green	50 µL	2x
ROS1 (6q22) Distal-SV	06Q005B550	Red	50 µL	2x
ROS1 (6q22) Proximal	06Q003B495	Green	50 µL	2x
ROS1 (6q22) Proximal	06Q003B550	Red	50 µL	2x
RREB1 (6p24)	06P001D590	Red	25 µL	4x
SE 10 (D10Z1)	10C001B495	Green	50 µL	2x
SE 10 (D10Z1)	10C001N495	Green	50 µL	10x
SE 12 (D12Z3)	12C001C495	Green	33 µL	3x
SE 12 (D12Z3)	12C001J495	Green	166 µL	3x
SE 17 (D17Z1)-006	17C006B495	Green	50 µL	2x
SE 3 (D3Z1)	03C001C550	Red	33 µL	3x
SE 3 (D3Z1)	03C001N415	Blue	50 µL	10x
SE 4 (D4Z1)	04C001B495	Green	50 µL	2x
SE 6 (D6Z1)	06C001D415	Blue	25 µL	4x
SE 7 (D7Z1)	07C001B495	Green	50 µL	2x
SE 7 (D7Z1)	07C001C495	Green	33 µL	3x
SE 7 (D7Z1)-002	07C002B495	Green	50 µL	2x
SE 8 (D8Z1)	08C001B495	Green	50 µL	2x
SE 8 (D8Z1)-002	08C002B495	Green	50 µL	2x
SE X (DXZ1)	23C001B495	Green	50 µL	2x
SE X (DXZ1)	23C002J495	Green	166 µL	3x
SHOX (Xp22)	23P001B550	Red	50 µL	2x
SRD (1p36)	01P001B495	Green	50 µL	2x
SRD (1p36)	01P001I495	Green	250 µL	2x
SRD (1p36)	01P001N495	Green	50 µL	10x
TERC (3q26)	03Q001B550	Red	50 µL	2x
TOP2A (17q21)	17Q003B550	Red	50 µL	2x
TP53 (17p13)	17P001B550	Red	50 µL	2x
TP53 (17p13)	17P001C550	Red	33 µL	3x
TP53 (17p13)	17P001I550	Red	250 µL	2x

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent

Product Name	Product code	Color	Content	Conc
ALK (2p23) Proximal - XL	02P008V495	Green	1 mL	10x
ALK (2p23) Distal - XL	02P009V550	Red	1 mL	10x
BCL6 (3q27) Proximal - XL	03Q009V495	Green	1 mL	10x
BCL6 (3q27) Distal - XL	03Q010V550	Red	1 mL	10x
ROS1 (6q22) Proximal - XL	06Q006V495	Green	1 mL	10x
ROS1(6q22) Distal - XL	06Q007V550	Red	1 mL	10x
SE 7 (D7Z1)-006 - XL	07C006V495	Green	1 mL	10x
MET (7q31) - XL	07Q002V550	Red	1 mL	10x
SE 8 (D8Z1)-003 - XL	08C003V495	Green	1 mL	10x
FGFR1 (8p11) - XL	08P004V550	Red	1 mL	10x
MYC (8q24) Proximal - XL	08Q007V495	Green	1 mL	10x
MYC (8q24) Distal - XL	08Q008V550	Red	1 mL	10x
RET (10q11) Distal - XL	10Q007V495	Green	1 mL	10x
RET (10q11) Proximal - XL	10Q008V550	Red	1 mL	10x
IGH (14q32) Proximal - XL	14Q004V550	Red	1 mL	10x
IGH (14q32) Distal - XL	14Q005V495	Green	1 mL	10x
TP53 (17p13) - XL	17P002V550	Red	1 mL	10x
BCL2 (18q21) Proximal - XL	18Q003V495	Green	1 mL	10x
BCL2 (18q21) Distal - XL	18Q004V550	Red	1 mL	10x
ERBB2 (17q12) - XL	17Q004V550	Red	1 mL	10x
SE 17 (D17Z1)-007 - XL	17C007V495	Green	1 mL	10x

Product Name	Product code	Color	Content	Conc
SE 1 (1qh) Blue	KI-20001B	Blue	20 µL	5x
SE 1 (1qh) Green	KI-20001G	Green	20 µL	5x
SE 1 (1qh) Red	KI-20001R	Red	20 µL	5x
SE 2 (D2Z) Blue	KI-20002B	Blue	20 µL	5x
SE 2 (D2Z) Green	KI-20002G	Green	20 µL	5x
SE 2 (D2Z) Red	KI-20002R	Red	20 µL	5x
SE 3 (D3Z1) Blue	KI-20003B	Blue	20 µL	5x
SE 3 (D3Z1) Green	KI-20003G	Green	20 µL	5x
SE 3 (D3Z1) Red	KI-20003R	Red	20 µL	5x
SE 4 (D4Z1) Blue	KI-20004B	Blue	20 µL	5x
SE 4 (D4Z1) Green	KI-20004G	Green	20 µL	5x
SE 4 (D4Z1) Red	KI-20004R	Red	20 µL	5x
SE 6 (D6Z1) Blue	KI-20006B	Blue	20 µL	5x
SE 6 (D6Z1) Green	KI-20006G	Green	20 µL	5x
SE 6 (D6Z1) Red	KI-20006R	Red	20 µL	5x
SE 7 (D7Z1) Blue	KI-20007B	Blue	20 µL	5x
SE 7 (D7Z1) Green	KI-20007G	Green	20 µL	5x
SE 7 (D7Z1) Red	KI-20007R	Red	20 µL	5x
SE 8 (D8Z1) Blue	KI-20008B	Blue	20 µL	5x
SE 8 (D8Z1) Green	KI-20008G	Green	20 µL	5x
SE 8 (D8Z1) Red	KI-20008R	Red	20 µL	5x
SE 9 (classical) Blue	KI-20009B	Blue	20 µL	5x
SE 9 (classical) Green	KI-20009G	Green	20 µL	5x
SE 9 (classical) Red	KI-20009R	Red	20 µL	5x
SE 10 (D10Z1) Blue	KI-20010B	Blue	20 µL	5x
SE 10 (D10Z1) Green	KI-20010G	Green	20 µL	5x
SE 10 (D10Z1) Red	KI-20010R	Red	20 µL	5x
SE 11 (D11Z1) Blue	KI-20011B	Blue	20 µL	5x
SE 11 (D11Z1) Green	KI-20011G	Green	20 µL	5x

Product Name	Product code	Color	Content	Conc
SE 11 (D11Z1) Red	KI-20011R	Red	20 µL	5x
SE 12 (D12Z3) Blue	KI-20012B	Blue	20 µL	5x
SE 12 (D12Z3) Green	KI-20012G	Green	20 µL	5x
SE 12 (D12Z3) Red	KI-20012R	Red	20 µL	5x
SE 15 (D15Z) Blue	KI-20015B	Blue	20 µL	5x
SE 15 (D15Z) Green	KI-20015G	Green	20 µL	5x
SE 15 (D15Z) Red	KI-20015R	Red	20 µL	5x
SE 16 (D16Z2) Blue	KI-20016B	Blue	20 µL	5x
SE 16 (D16Z2) Green	KI-20016G	Green	20 µL	5x
SE 16 (D16Z2) Red	KI-20016R	Red	20 µL	5x
SE 17 (D17Z1) Blue	KI-20017B	Blue	20 µL	5x
SE 17 (D17Z1) Green	KI-20017G	Green	20 µL	5x
SE 17 (D17Z1) Red	KI-20017R	Red	20 µL	5x
SE 18 (D18Z1) Blue	KI-20018B	Blue	20 µL	5x
SE 18 (D18Z1) Green	KI-20018G	Green	20 µL	5x
SE 18 (D18Z1) Red	KI-20018R	Red	20 µL	5x
SE 20 (D20Z1) Blue	KI-20020B	Blue	20 µL	5x
SE 20 (D20Z1) Green	KI-20020G	Green	20 µL	5x
SE 20 (D20Z1) Red	KI-20020R	Red	20 µL	5x
SE X (DXZ1) Blue	KI-20023B	Blue	20 µL	5x
SE X (DXZ1) Green	KI-20023G	Green	20 µL	5x
SE X (DXZ1) Red	KI-20023R	Red	20 µL	5x
SE Y (DYZ3) Blue	KI-20024B	Blue	20 µL	5x
SE Y (DYZ3) Green	KI-20024G	Green	20 µL	5x
SE Y (DYZ3) Red	KI-20024R	Red	20 µL	5x
SE Y class. q arm Blue	KI-20025B	Blue	20 µL	5x
SE Y class. q arm Green	KI-20025G	Green	20 µL	5x
SE Y class. q arm Red	KI-20025R	Red	20 µL	5x

WHOLE CHROMOSOME FISH PROBES (ASR)

Product Name	Product code	Color	Content	Conc
Whole Chromosome 1 Red	KI-30001R	Red	10 µL	5x
Whole Chromosome 4 Red	KI-30004R	Red	10 µL	5x
Whole Chromosome 7 Green	KI-30007G	Green	10 µL	5x
Whole Chromosome 8 Green	KI-30008G	Green	10 µL	5x
Whole Chromosome 18 Green	KI-30018G	Green	10 µL	5x
Whole Chromosome 21 Green	KI-30021G	Green	10 µL	5x

DNA PROBES (ASR)

Product Name	Product code	Color	Content	Conc
Human Satellite DNA	40V000V000		1 mL	10x
Human Satellite DNA, Flu labeled	40V000V495	Green	1 mL	10x
PapV-06, Flu labeled	40V006V495	Green	1 mL	10x
PapV-11, Flu labeled	40V011V495	Green	1 mL	10x
PapV-16, Flu labeled	40V016V495	Green	1 mL	10x
PapV-18, Flu labeled	40V018V495	Green	1 mL	10x
PapV-31, Flu labeled	40V031V495	Green	1 mL	10x
PapV-33, Flu labeled	40V033V495	Green	1 mL	10x

RNA PROBES (ASR)

Product Name	Product code	Content
EBER Probe	ISH5687-A	7 mL
CMV Probe	ISH5719-A	7 mL
Kappa Probe	ISH5748-A	7 mL
Lambda Probe	ISH5770-A	7 mL
RNA Positive Controle Probe	ISH5894-A	7 mL
RNA Negative Controle Probe	ISH5950-A	7 mL

ACD RNA PROBES (RUO)

Product Name	Product code	Content
CMV Probe	RS7750	14 mL
EBV Probe	RS7751	14 mL
Albumin Probe	RS7752	14 mL
TTF-1 Probe	RS7753	14 mL
Napsin A Probe	RS7754	14 mL
PPIB (Positive Control)	RS7755	14 mL
dapB (Negative Control)	RS7756	14 mL

PRODUCT NAME	PRODUCT CODE	CONTENT	CONCENTRATION	CLASSIFICATION
Tissue Digestion Kit II	KBI-60004	Kit		IVD
Tissue Digestion Kit II	KI-60004	Kit		RUO
FISH Reagent Kit	KBI-60005	Kit		IVD
FISH Reagent Kit	KI-60005	Kit		RUO
FISH Digestion Kit	KBI-60006	Kit		IVD
FISH Digestion Kit	KI-60006	Kit		RUO
Tissue Digestion Kit I	KBI-60007	Kit		IVD
Tissue Digestion Kit I	KI-60007	Kit		RUO
KREAvital Prenatal Medium (Basal)	KBI-90010	90 mL	RTU	IVD
KREAvital Prenatal Medium (Supplement)	KBI-90011	10 mL	RTU	IVD
KREAvital Prenatal Medium (Complete)	KBI-90012	100 mL	RTU	IVD
KREAvital Prenatal Medium PLUS (Complete)	KBI-90013	100 mL	RTU	IVD
KREAvital Lymphocyte Karyotyping Medium (without PHA)	KBI-90020	100 mL	RTU	IVD
KREAvital Lymphocyte Karyotyping Medium (including PHA)	KBI-90021	5 mL	RTU	IVD
KREAvital Bone Marrow Karyotyping Medium	KBI-90030	100 mL	RTU	IVD
KREAvital Myeloid Cell Medium	KBI-90031	100 mL	RTU	IVD
Colchicine Solution (10µg/ml, in PBS)	KBI-90050	25 mL	RTU	IVD
Colcemid Solution (10µg/ml, in PBS)	KBI-90051	10 mL	RTU	IVD
Potassium Chloride (0.075M)	KBI-90052	100 mL	RTU	IVD
Sodium Citrate Solution (0.8%)	KBI-90054	500 mL	RTU	IVD
Phytohaemagglutinin liquid	KBI-90056	5 mL	RTU	IVD
KREAvital Prenatal Medium (Complete)	KBI-92012	500 mL	RTU	IVD
KREAvital Lymphocyte Karyotyping Medium (without PHA)	KBI-92020	500 mL	RTU	IVD
Trypsin EDTA 10X (EDTA 0.2%, Trypsin 0.5%, in saline solution)	KBI-92055	100 mL	RTU	IVD
FISH Hybridization Buffer (FHB)	KBI-FHB	10 test	RTU	GPR
FISH Hybridization Buffer (FHB)	KI-FHB	10 test	RTU	GPR
Paraffin Tissue Buffer (PTB)	KBI-PTB	10 test	RTU	GPR
Whole Chromosome Buffer (WCB)	KBI-WCB	10 test	RTU	GPR
Whole Chromosome Buffer (WCB)	KI-WCB	10 test	RTU	GPR
20 x SSC	LK-061A	100 mL	RTU	GPR
Fixogum Rubber Cement	LK-071A	125 gr	RTU	GPR
DAPI Counterstain (0.1 µg/ml)	LK-095A	1 mL	RTU	GPR
DAPI Counterstain (1 µg/ml)	LK-096A	1 mL	RTU	GPR
Counterstain Diluent	LK-097A	1 mL	RTU	GPR
Pretreatment Solution B	LK-100C	1L	RTU	GPR
Pepsin Solution	LK-101A	2,5 mL	RTU	GPR
Wash Buffer I	LK-102A	100 mL	RTU	GPR
Wash Buffer II	LK-103A	100 mL	RTU	GPR
Pretreatment Solution A	LK-110C	1 L	RTU	GPR
Wash Buffer V (10x)	LK-141B	250 mL	10x	GPR
Wash Buffer V (10x)	LK-141C	1 L	10x	GPR

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use RUO For Research Use Only. Not for use in diagnostic procedures ASR Analyte Specific Reagent GPR General Purpose Reagent

CHROMOSOME POSITION	PREVIOUS KREATECH NAME	NEW KREATECH HUGO NAME
1p36	CHD5	CHD5
1p34	MYCL	MYCL
1q21	S100A10	S100A10
1q21	CKS1B	CKS1B
1q32	MDM4	MDM4
2p24	MYCN, NMYC	MYCN
2p23	ALK	ALK
2p21	EML4	EML4
2q11	LAF	AFF3
3p25	PPARy	PPARG
3q26	hTERC	TERC
3q26	EVI	MECOM
3q27	BCL6	BCL6
4p16	FGFR3	FGFR3
4p16	WHSC1, MMSET	WHSC1
4q12	FIP1L1	FIP1L1
4q12	CHIC2	CHIC2
4q12	PDGFRA	PDGFRA
4q21-22	AFF1, MLLT2	AFF1
5p15	hTERT	TERT
5p15	CTNND	CTNND2
5q31	CDC25C	CDC25C
5q31	EGR1	EGR1
5q33	PDGFRB	PDGFRB
5q33	CSF1R	CSF1R
5q33	RPS14	RPS14
5q35	NSD1	NSD1
5q35	FGFR4	FGFR4
6p25	DUSP22	DUSP22
6p25	IRF4	IRF4
6p24	RREB1	RREB1
6p23	MYB	MYB
6p22	DEK	DEK
6p21	CCND3	CCND3
6q21	SEC63	SEC63
6q22	ROS1	ROS1
6q27	MLLT4, AF6	MLLT4
7p11	EGFR, Her1	EGFR
7q11	ELN	ELN
7q11	LIMK1	LIMK1
7q22	CUTL1	CUX1
7q31	C-MET	MET
7q31	MDFIC	MDFIC
8p23	GATA4	GATA4
8p21	PNOC	PNOC
8p11	FGFR1	FGFR1
8q21	ETO	RUNX1T

CHROMOSOME POSITION	PREVIOUS KREATECH NAME	NEW KREATECH HUGO NAME
8q24	C-MYC	MYC
9p24	JAK2	JAK2
9p21	MLLT3, AF9	MLLT3
9p21	p16	CDKN2A
9q34	ABL	ABL1
9q34	ASS	ASS1
9q34	NUP214, CAN	NUP214
10q11	RET	RET
10q23	PTEN	PTEN
10q26	FGFR2	FGFR2
11p15	NUP98	NUP98
11q13	BCL1	CCND1
11q13	MYEOV	MYEOV
11q22	ATM	ATM
11q23	MLL	KMT2A
11q23	PLZF	ZBTB16
12p13	TEL	ETV6
12q13	CDK4	CDK4
12q13	CHOP	DDIT3
12q13	GLI	GLI1
12q15	MDM2	MDM2
13q14	DLEU	DLEU1
13q14	FKHR	FOXO1
14q32	IGH@	IGH
15q11	SNRPN	SNRPN
15q11	UBE3A	UBE3A
15q22	SMAD6	SMAD6
15q24	PML	PML
15q26	IGF1R	IGF1R
16p11	FUS	FUS
16q22	CBFB	CBFB
16q23	MAF	MAF
17p13	AURKB	AURKB
17p13	LIS	PAFAH1B1
17p13	p53	TP53
17p11	RAI1	RAI1
17q11	NF1	NF1
17q12	ERBB2, HER2	ERBB2
17q21	COL1A1	COL1A1
17q21	RARA	RARA
17q21	TOP2A	TOP2A
17q22	MPO	MPO
18q11	SYT	SS18
18q21	MALT	MALT1
18q21	BCL2	BCL2
19p13	MLLT1, ENL	MLLT1
19p13	ZNF443	ZNF443

CHROMOSOME POSITION	PREVIOUS KREATECH NAME	NEW KREATECH HUGO NAME
19q13	CD37	CD37
19q13	ERCC1	ERCC1
20p11	NINL	NINL
20q11	MAPRE1	MAPRE1
20q12	MAFB	MAFB
20q12	PTPRT	PTPRT
20q13	AURKA	AURKA
20q13	NFATC2	NFATC2
20q13	ZNF217	ZNF217
21q22	AML	RUNX1
21q22	DSCR1	RCAN1
21q22	ERG	ERG
21q22	TMPRSS2	TMPRSS2
22q11	BCR	BCR

CHROMOSOME POSITION	PREVIOUS KREATECH NAME	NEW KREATECH HUGO NAME
22q11	CLH22	CLTCL1
22q11	DGCR2	DGCR2
22q11	TBX1	TBX1
22q11	TUPLE	HIRA
22q12	EWSR1	EWSR1
22q13	ARSA	ARSA
22q13	PDGFB	PDGFB
22q13	SHANK3	SHANK3
Xp22	KAL	KAL1
Xp22	SHOX	SHOX
Xp22	STS	STS
Xp11	TFE3	TFE3
Xq12	AR	AR
Xq13	XIST	XIST

INDEX

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent

INDEX

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent

INDEX

INDEX

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent

INDEX

INDEX

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent

INDEX

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent

INDEX

* Products in this catalog are subject to regulatory approval. Please consult your Leica Biosystems Sales Representative for availability in your region.
IVD In Vitro Diagnostic Use **RUO** For Research Use Only. Not for use in diagnostic procedures **ASR** Analyte Specific Reagent **GPR** General Purpose Reagent

LeicaBiosystems.com

NOVOCASTRA PRIMARY ANTIBODIES

Spanning 14 pathology menus, Leica Biosystems offers laboratories a comprehensive range of clinically relevant antibodies for the most demanding workload.

NOVOCASTRA HD ANTIBODIES

Each antibody in the Novocastra HD range has been independently evaluated[1] by an external QA scheme, in comparison with two market leading vendors. Each antibody within the HD portfolio has been optimized to deliver high quality staining, for results you can trust.

NOVOCASTRA BOND RTU

BOND Ready-to-Use antibodies are optimized to deliver high quality staining results on BOND systems. This format eliminates variability that can occur with manual antibody dilutions and also reduces preparation time. Pre-optimized reagents and automated protocols deliver consistent results you can depend on.

NOVOCASTRA LIQUID CONCENTRATES

The Novocastra liquid concentrated antibody range is an extensive collection of primary antibodies for IHC testing. Concentrated antibodies afford workflow flexibility, enabling users to optimize their protocols according to their pre-analytical conditions[2].

Leica Biosystems is an international company with a strong network of worldwide customer services. For detailed contact information on your nearest sales office or distributor please visit our website: LeicaBiosystems.com

Leica Biosystems is a global leader in workflow solutions and automation. As the only company to own the workflow from biopsy to diagnosis, we are uniquely positioned to break down the barriers between each of these steps. Our mission of "Advancing Cancer Diagnostics, Improving Lives" is at the heart of our corporate culture. Our easy-to-use and consistently reliable offerings help improve workflow efficiency and diagnostic confidence. The company is represented in over 100 countries. It has manufacturing facilities in 9 countries, sales and service organizations in 19 countries, and an international network of dealers. The company is headquartered in Nussloch, Germany. Visit LeicaBiosystems.com for more information.

1 Independent analysis commissioned by Leica Biosystems and conducted by NordiQC according to the manufacturers' instructions for use and on the corresponding staining platform.
2 For recommended protocols see instructions for use. Any deviation from recommended conditions must be validated by the user.

190642 Rev B · 09/2020