

Thermo Scientific Clinical LIMS: Delivering Lab-Centric Solutions for Patient-Centric Results

“One of the major goals of the translational research movement has been to bridge the gap from bench to bedside and any initiative to blend the LIS with the LIMS can be understood as an extension of this quest. The lesson from all of this is obvious. We now need to make an effort to understand the relative strengths of LIS and LIMS and proceed to develop new systems that capture the best features of each of them.”

Bruce A. Friedman, M.D.; Active Emeritus Professor of Pathology; Department of Pathology; University of Michigan Medical School

The Challenges

- Clinical diagnostics labs require distinct Laboratory Information System (LIS) and Laboratory Information Management System (LIMS) functionality in one cohesive system to meet the technical, integration and business needs of the emerging fields of translational and personalized medicine.
- Researchers and clinicians need lab processes that are responsive to physician and patient needs, while meeting the technical complexities of a medical research lab.
- Clinical labs need informatics solutions that can easily integrate with internal applications and laboratory instrumentation, as well as external partners and collaborators.
- Diagnostics labs need to deliver faster turnaround of results to physicians to enable more informed and personalized patient health care, while maintaining compliance with CLIA and HIPAA regulations.

Advancing Medicine Requires Next Generation Informatics Solutions

The improvements related to understanding the unique genetic makeup of both patients and disease have allowed physicians to utilize specialized diagnostic tests to diagnose and treat their patients. Due to the patient specific nature of the testing, labs must have in place all of the tools and compliant methodologies that are required to support CLIA and HIPAA regulations. Furthermore, labs also need to manage complex sample oriented workflows (including sophisticated instruments and automation) and support business processes. The new challenge for clinical testing labs responding to the increase in genetics testing is converging the functionality of informatics systems that manage patient information and those that manage lab and sample data.

The Solution

To meet these challenges Thermo Scientific Clinical LIMS delivers comprehensive laboratory and patient management functionality needed by researchers and technicians involved in clinical testing and molecular diagnostics. The first comprehensive solution to combine the sample-centric functionality of a LIMS with the patient-centric functionality inherent in a traditional LIS, Thermo Scientific Clinical LIMS bridges the gap between the two and delivers a complete and streamlined solution.

Thermo Scientific Clinical LIMS is developed on the proven, world class Thermo Scientific Informatics platform which offers unmatched flexibility and ease-of-use, increased automation and throughput of sample analysis for clinical laboratories that require sophisticated sample management, research tools and business enterprise integration. Built to support the laboratory's end-to-end clinical business process, Thermo Scientific Clinical LIMS enables bi-directional communication between physicians and the lab via a dedicated Lab Web Portal.

The Clinical LIMS also enables customer service follow-up and CRM interface, patient management, final report generation and automated delivery, benefits investigation, interface with a billing provider, and the ability to interface with multiple clinical vocabularies. The Clinical LIMS is designed to be fully compliant with key industry regulations; those related to protecting patient privacy (HIPAA) and those related to clinical testing (CLIA). Our solution also supports the most widely used ANSI-accredited standard for interoperability of health information technology (HL7) and enables laboratories to operate in compliance with GLP and 21 CFR Part 11.

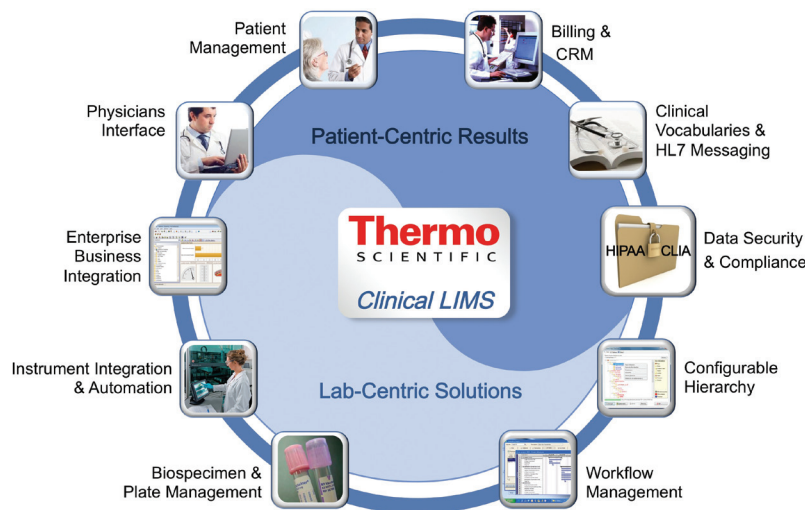


Figure 1. Thermo Scientific Clinical LIMS delivers lab-centric solutions for patient-centric results.

Key Words

- LIMS
- LIS
- Physicians' Interface
- Patient Management
- Billing & CRM
- Clinical Vocabularies & HL7 Messaging
- Data Security & Compliance
- Configurable Hierarchy
- Workflow Management
- Biospecimen & Plate Management
- Instrument Integration & Automation
- Enterprise Business Integration
- CLIA & HIPAA Compliance
- Electronic TRF
- PHI

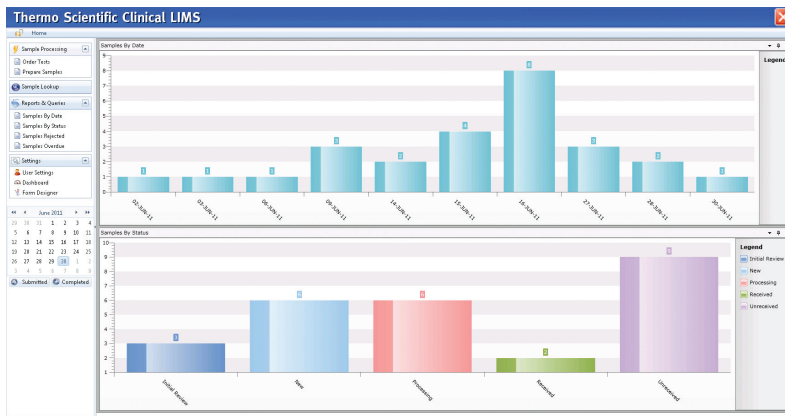


Figure 2. The Lab Web Portal cuts overall turnaround time (TAT) by employing electronic TRF submission and patient reporting, automated shipment tracking, and regular notifications to sender and receiver.

Figure 3. The electronic Test Request Form (TRF) mimics the paper form and offers built-in features like patient search, insurance lookup/update, consent management and 'hard stops' flagging logic.

Figure 4. Patient Demographics forms support various types of patient searches (Exact, Like, Soundex, Reverse) as well as blind patient entry for STD samples and flexible logic to configure Patient Comparison Algorithm.

Key Features and Benefits

- The Physicians' Interface** provides a secure web-based interface for submission of test requests to the lab, tracking sample progress, and access to published patient reports. The Lab Web Portal features an integrated dashboard with tailored KPI alerts, on-demand querying, and pre-packaged reports. The Lab Web Portal employs automated shipment tracking with regular updates to sender and receiver, allowing for improved capacity planning at the lab.
- Patient Management Functionality** facilitates comprehensive patient clinical record tracking including insurance information, consent information, family and medical history, clinical notes and testing results history. All Protected Health Information (PHI) is stored and managed in compliance with the privacy and security rules of the Health Insurance Portability and Accountability Act (HIPAA).
- Billing & CRM** is enabled via integration with existing business systems that manage accounting and customer information. Customer service can set up rules to automatically flag samples with known discrepancies or make manual observations. Sample follow-up is facilitated internally and/or via CRM interface. An integrated dashboard is used to organize the workload and send alerts. Automated clinical data delivery through HL7 communication provides accurate information to the billing partner to allow increased reimbursement in a timely fashion.
- Clinical Vocabularies and Health Level 7 (HL7) Messaging** supports CLIA mandated exchange of laboratory information between clinical laboratories and external partners. This interface facilitates sample accessioning, patient results reporting and secure patient billing. Thermo Scientific Clinical LIMS supports usage of standard clinical terminologies and interfaces with clinical vocabularies (ICD, CPT, LOINC, SNOMED, etc.).
- Complete Data Security and Audit Trail** capabilities address the needs of both the laboratory data and PHI. All patient information is stored in compliance with HIPAA privacy regula-

tions including software accessibility, PHI separation and data integrity, personnel HIPAA training, and the storage, retrieval and secure electronic transmission of lab test results. The auditing capabilities monitor all views and changes to any record in the system. The Clinical LIMS supports compliance with CLIA and 21 CFR Part 11. All patient reports are stored in a read-only format (PDF) and corrections or amendments to reports are handled in accordance with CLIA sec. 493.1291. All data is stored in a database and access is managed through privileges based on role, operator and group, ensuring data security and traceability.

- The **Configurable Hierarchy** manages data collected during the sample testing process and accommodates varying laboratory needs. Configurable hierarchy is integrated with chain-of-custody, location management, aliquot/derivative and pooled sample tracking. The disposition of a sample or aliquot is documented, ensuring that the Clinical LIMS stores its workflow history throughout the testing process.

- **Workflow Management** is designed to emulate laboratory processes via an intuitive graphical interface. The patented Workflow Manager expedites the mapping of static and dynamic processes without the need for custom programming, allowing users to organize data and manage tasks effectively.

- **Biospecimen and Plate Management** includes graphical workflows and plate editors, as well as built-in integration functionality that facilitates increased throughput and automation. The plate editor allows manual editing with user friendly functionality such as drag-and-drop. High throughput processes and plate based assays can be emulated using graphical workflows which include features such as replication, compositing, pooling, and cherry-picking.

- **Instrument Integration & Automation** includes robotics, next-generation sequencing, analyzers, etc., and facilitates standardization of processes and simplifies operations across the clinical network. This results in fewer transcription errors, improved data quality and cost savings.

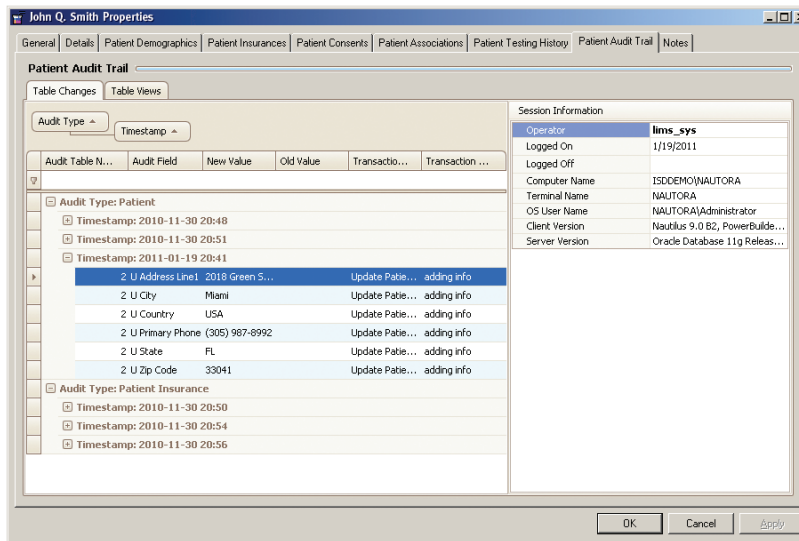


Figure 5. Patient Management includes Demographics, Insurance, Consent, Family, Medical and Testing Results History information per patient. Full PHI audit trail, clinical notes and attachments are recorded and stored.

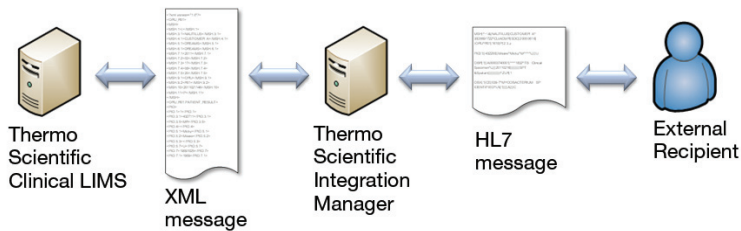


Figure 6. HL7 communication between the Clinical LIMS and external collaborators is facilitated by Thermo Scientific Integration Manager.

Name	Component	Property	Time	Sample Type	Scale	Method	Short Name	Version	Version Status
Component: INFLUENZA VIRUS A AB									
322851	INFLUENZA VIRUS A AB	TITR	PT	SER	QN		FLUA-Ab Tit Ser	1	Authorized
179124	INFLUENZA VIRUS A AB	ACNC	PT	CSF	QN		FLUA-Ab CSF+Qnc	1	Authorized
356368	INFLUENZA VIRUS A AB	ACNC	PT	SER	QN	CF	FLUA-Ab Ser CF+Qnc	1	Authorized
341537	INFLUENZA VIRUS A AB	ACNC	PT	XXX	QN		FLUA-Ab XXX+Qnc	1	Authorized
52290	INFLUENZA VIRUS A AB	TITR	PT	SER	QN	CF	FLUA-Ab Tit Ser CF	1	Authorized
Component: JC VIRUS DNA									
332957	JC VIRUS DNA	ACNC	PT	CSF	ORD	PROBE AMP.TAR	JCVJ DNA CSF QI PCR	1	Authorized
322634	JC VIRUS DNA	ACNC	PT	SER	ORD	PROBE AMP.TAR	JCVJ DNA Ser QI PCR	1	Authorized
348868	JC VIRUS DNA	ACNC	PT	TIS5	ORD	PROBE AMP.TAR	JCVJ DNA Tis QI PCR	1	Authorized
356618	JC VIRUS DNA	ACNC	PT	UR	ORD	PROBE AMP.TAR	JCVJ DNA Ur QI PCR	1	Authorized
429217	JC VIRUS DNA	ACNC	PT	XXX	ORD	PROBE AMP.TAR	JCVJ DNA XXX QI PCR	1	Authorized
Component: MICROORGANISM IDENTIFIED									
804-9	MICROORGANISM IDENTIF.	PRID	PT	BRO	NOM	AEROBIC CULTURE	Bro Aerobic Cult	1	Authorized
805-6	MICROORGANISM IDENTIF.	PRID	PT	CNL	NOM	AEROBIC CULTURE	Cnl Aerobic Cult	1	Authorized
806-4	MICROORGANISM IDENTIF.	PRID	PT	CSF	NOM	STERILE BODY FLUID CULTURE	CSF BFD Cult	1	Authorized
807-2	MICROORGANISM IDENTIF.	PRID	PT	DRN	NOM	AEROBIC CULTURE	Drn Aerobic Cult	1	Authorized
808-0	MICROORGANISM IDENTIF.	PRID	PT	EAR	NOM	AEROBIC CULTURE	Ear Aerobic Cult	1	Authorized
809-8	MICROORGANISM IDENTIF.	PRID	PT	EYE	NOM	AEROBIC CULTURE	Eye Aerobic Cult	1	Authorized
810-6	MICROORGANISM IDENTIF.	PRID	PT	FLU	NOM	AEROBIC CULTURE	Flu Aerobic Cult	1	Authorized

Figure 7. Support for clinical vocabularies - universal LOINC identifiers are used for HL7 messaging.

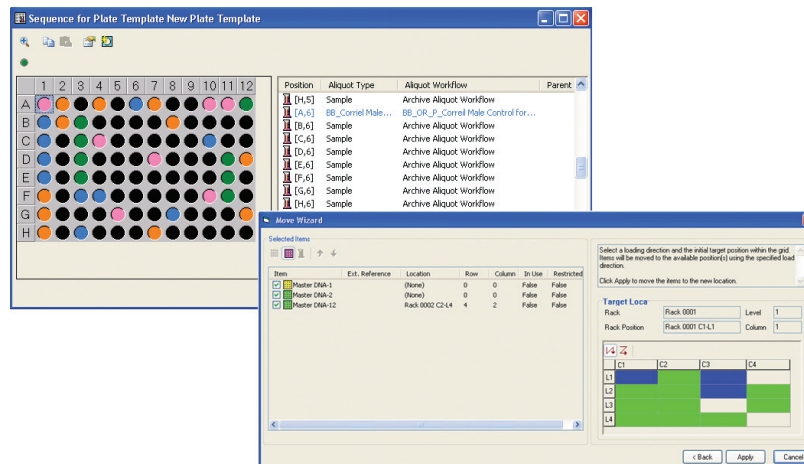


Figure 8. Biospecimen and Plate Management includes graphical workflows and plate editors.

- **Enterprise Business Integration** facilitates enterprise level information exchange by integrating the Clinical LIMS with other systems like EMR, CRM, ERP, billing via HL7 messaging, web services and application interfaces. Process metrics such as turnaround time, failure rates and statistical quality

control enable efficient, streamlined operations by uncovering bottlenecks and improving processes. The integration of these systems allows for optimized data correlation and collaboration, end-to-end data tracking, secure data exchange, and maximizes the organization's investment in its information technology.

Delivering Lab-Centric Solutions for Patient-Centric Results

The emerging fields of translational and personalized medicine have been the catalyst for a more symbiotic relationship between patient-centric processes and the sample-centric lab environment. The ultimate goal of this new symbiosis is a streamlined end-to-end information flow following the patient from the point of care, to molecular testing and results analysis, to diagnosis and treatment.

Thermo Scientific Clinical LIMS satisfies this critical need by delivering a comprehensive sample and patient management solution which enables physicians and healthcare staff to have pertinent data readily available to optimize patient care. This unique solution standardizes ordering and reporting practices and improves patient laboratory and healthcare documentation, allowing laboratories to manage healthcare information more efficiently and improve compliance with laws governing medical records management.

By unifying the distinct laboratory and patient management functionality needed by researchers and technicians involved in clinical testing and molecular diagnostics, Thermo Scientific Clinical LIMS delivers what no other stand-alone LIMS or LIS can: lab-centric solutions for patient-centric results.

In addition to these offices, Thermo Fisher Scientific maintains a network of representative organizations throughout the world.

Australia/Asia Pacific

+61 8 8208 8200

China

+86 800 810 5118

France

+33 160924800

Germany/Eastern Europe

+49 6103 408 1110

India

+91 22 6742 94 94

Latin America and the Caribbean

+1 781 933 4689

Netherlands/Benelux

+31 76 579 5555

Spain/Portugal

+34 914 845 965

United Kingdom

+44 1619423000

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+1 800 395 5467

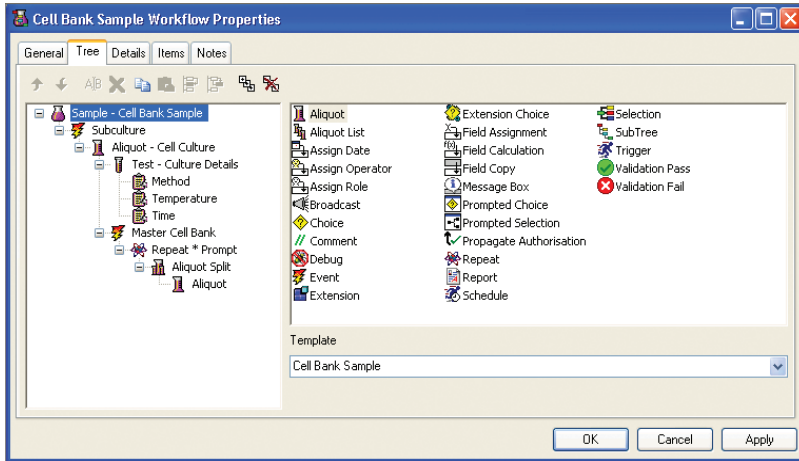


Figure 9. Patented Workflow Management is designed to emulate laboratory processes via an intuitive graphical interface.

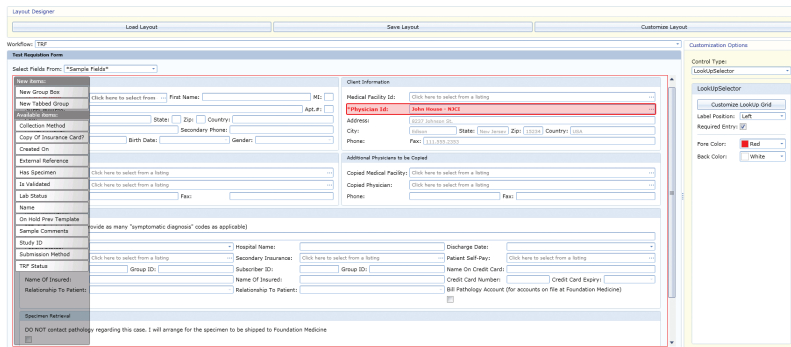


Figure 10. Lab users can design their own electronic forms without any programming experience by using built-in Form Designer.

For More Information

about Thermo Scientific solutions for clinical diagnostics, visit www.thermoscientific.com/clinicallms Or you can email us at marketing.informatics@thermofisher.com

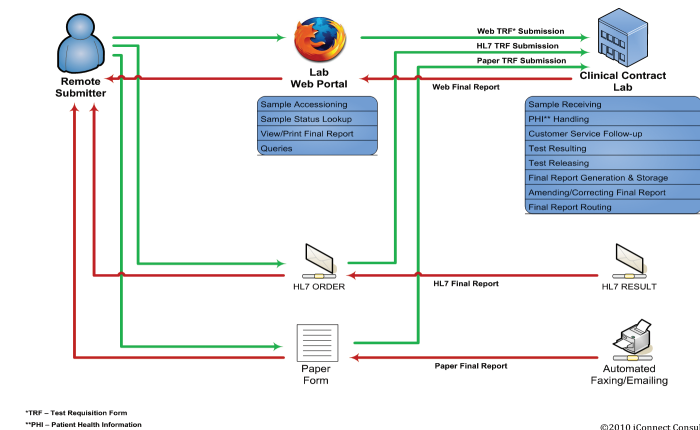


Figure 11. Patient reports can be transmitted through secure electronic fax, email, and HL7 transmission.

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