

FOR FULL PRODUCT DETAILS, PLEASE REFER TO THE KIT INSERT.

INTENDED USE

For the quantitative *in vitro* determination of Glutamate Dehydrogenase (GLDH) in Serum. This product is suitable for use on the Hitachi 917 and Hitachi P Module analysers.

Cat. No.

GL 441	R1a. Buffer/Substrate	1 x 70 ml
8 x 33 t	R1b. Reagent	8 x 6 ml
	R2. α -oxoglutarate	2 x 10 ml

GL442	R1a. Buffer/Substrate	5 x 100 ml
5 x 555 t	R1b. Enzyme/Coenzyme	5 x 100 ml
	R2. α -oxoglutarate	2 x 20 ml

This is an optimised standard method according to the recommendations of the Deutsche Gesellschaft für Klinische Chemie.

SAMPLE

Serum.
Haemolytic and lipaemic sera interfere with the assay.

STABILITY AND PREPARATION OF REAGENTS

R1a. Buffer/Substrate

Contents stable as supplied up to the expiry date when stored at +2 to +8°C or 7 days at +15 to +25°C.

R1b. Enzyme/Coenzymes

Cat. No. GL 441

Reconstitute the contents of one vial of Enzyme/Coenzyme R1b with 6 ml of Buffer/Substrate R1a. Stable for 1 week at +2 to +8°C.

Cat. No. GL 442

Reconstitute the contents of one vial of Enzyme/Coenzyme R1b with a portion of Buffer/Substrate R1a and then transfer the entire contents to bottle R1a rinsing vial R1b several times. Stable for 1 week at +2 to +8°C.

R2. α -oxoglutarate

Reconstitute the contents of one vial of α -oxoglutarate (R2) with the appropriate volume of redistilled water:

50 ml for the 8 x 6 ml kit (GL 441)

100 ml for the 5 x 100 ml kit (GL 442)

Stable for 8 weeks at +2 to +8°C or 7 days at +15 to +25°C.

R1 = Buffer/Substrate/Enzyme/Coenzyme

R3 = α -oxoglutarate

MATERIALS PROVIDED

Buffer/Substrate
Enzyme/Coenzyme
 α -oxoglutarate

MATERIALS REQUIRED BUT NOT PROVIDED

Randox Assayed Multi-sera Level 2 (Cat. No. HN 1530) and Level 3 (Cat. No. HE 1532)
Randox Calibration Serum Level 3 (Cat. No. CAL 2351)

INSTRUMENT SETTINGS FOR HITACHI 917

ANALYZE

CH-Test-Type	* - GLDH - Ser
Assay	Rate A - 10
Point	21 - 34 - 0 - 0
Wave (Sub-Main)	415 - 340
S. VOL (NORMAL)	15 - 0 - 0
(DEC)	2 - 0 - 0
(INC)	30 - 0 - 0
Diluent	Detergent 1
Reagent Vol. R1	180 - 0 - * - 7
Reagent Vol. R2	0 - 0 - * - 0
Reagent Vol. R3	36 - 0 - * - 7
Reagent Vol. R4	0 - 0 - * - 0
ABS Limit	8000 - Decrease
Prozone Limit	0 - Lower
Cell Det.	Detergent 1

CALIBRATOR

Calib. Type	Linear
Point	2 - 2
Weight	0
Auto Calibration	
Blank	24
Span	0
2 Point	0
Full	0
SD Limit	0.1
Duplicate Limit	5 % - 10 Abs
Sensitivity Lim.	-99999 - 99999
S1 ABS Limit	-32000 - 32000

RANGE

Test	GLDH
Unit	U / l
Report Name	GLDH
Data Mode	On Board
Control Interval	*
Inst. Factor	1.0 - 0.0
Technical Limit	0 - 70 U / l
Expected value	
(Male)	* - *
(Female)	* - *

STANDARD CONC.

(1)	0
(2)	*

(3)	
(4)	
(5)	
(6)	

K- FACTOR

* Data entered by operator

INSTRUMENT SETTINGS FOR P MODULE

ANALYZE

CH/Test/Type */GLDH/SER
 Assay/Time RATE A/10
 Point 21/34/0/0
 Wave (2nd/Primary) 415/340
 Sample Volume
 Normal 15/0/0
 Decrease 2/0/0
 Increase 30/0/0
 Diluent
 ○ Water
 ● Diluent
 Reagent Volume
 R1 180/0/*/7
 R2 0/0/*/0
 R3 36/0/*/7
 R4 0/0/*/0
 Reagent Dummy Volume
 ○ Type 1
 ● Type 2
 ABS Limit 8000/DECREASE
 Prozone Limit 0/0/0/0/LOWER
 Cell Detergent DETERGENT 1
 Twin Test CANCEL

CALIBRATION

Calibration Type LINEAR
 Point 2
 Span 2
 Weight 0
 Isozyme Q CANCEL
 SD Limit 0.1
 Duplicate Limit 5%/10
 Sensitivity Lim. -99999/99999
 S1 ABS Limit -32000/32000

RANGE

Unit U/l
 Report Name GLDH
 Data Mode ON BOARD
 Technical Limit 0/70
 Repeat Limit */*
 Expected value
 (Male) */*
 (Female) */*

OTHERS

Standards	(1)	(2)	(3)	(4)	(5)	(6)
Calibrator Code	*	*	0	0	0	0
Concentration	0.0	*	0	0	0	0
Rack. No.	S001-1	*	0	0	0	0
Sample Volume	15	15	0	0	0	0
Diluted S Volume	0	0	0	0	0	0
Diluent Volume	0	0	0	0	0	0

* Data entered by operator

CALIBRATION

When setting up this method, it is essential that a factor is established with a calibrator. We recommend Randox Calibration Serum Level 3.

QUALITY CONTROL

Randox Assayed Multi-sera, Level 2 and Level 3 are recommended for daily quality control. Two levels of controls should be assayed at least once a day. Values obtained outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check cleanliness of all equipment in use.
3. Check water, contaminants i.e. bacterial growth may contribute to inaccurate results.
4. Check reaction temperature.
5. Check expiry date of kit and contents.
6. Contact Randox Laboratories Customer Technical Support, Northern Ireland (028) 94422413.

LINEARITY

The method is linear up to 50 U/l. In the event of a rerun, the linearity is extended to 525 U/l (Hitachi 917) or 420 U/l (Modular P).

Revised 14 Oct 10 bm