respons®910

LDH FS* IFCC

Diagnostic reagent for quantitative in vitro determination of lactate dehydrogenase (LDH) in serum or plasma on DiaSys respons®910

Order Information

Cat. No. 1 4211 99 10 920
4 twin containers for 200 tests each

Method

Optimized UV-test according to IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) and DGKC (German Society of Clinical Chemistry)

Principle

L-Lactate + NAD^+ $\xleftrightarrow{LDH}$ Pyruvate + NADH + H^+

Reagents

Components and Concentrations

R1:	N-Methyl-D-Glucamine	pH 9.40	420 mmol/L
	L-Lactate		65 mmol/L
R2:	NAD^+		50 mmol/L

Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. DiaSys respons containers provide protection from light. Do not freeze the reagents!

Warnings and Precautions

1. In very rare cases, samples of patients with gammopathy might give falsified results [8].
2. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
3. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent rotor.

Specimen

Serum, heparin plasma or EDTA plasma

Stability [1]:
4 days at 20 – 25°C
6 weeks at 4 – 8°C
Discard contaminated specimens.

Calibrators and Controls

For calibration, DiaSys TruCal U calibrator is recommended. This method has been standardized against the original IFCC formulation. For internal quality control DiaSys TruLab N and P controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal U	5 9100 99 10 063	20 x 3 mL
	5 9100 99 10 064	6 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL

Performance Characteristics

Measuring range up to 1200 U/L LDH (in case of higher activities re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).

Limit of detection**	5 U/L LDH
On-board stability	5 Wochen
Calibration stability	4 Tage

Interfering substance	Interferences < 10%	LDH [U/L]
Ascorbate	up to 30 mg/dL	224
Hemoglobin	interferes at low concentrations; indicates destruction of erythrocytes and therefore release of LDH.	
Bilirubin, conjugated	up to 60 mg/dL	203
	up to 60 mg/dL	611
Bilirubin, unconjugated	up to 50 mg/dL	219
	up to 80 mg/dL	465
Lipemia (triglycerides)	up to 1900 mg/dL	240
	up to 1900 mg/dL	658
For further information on interfering substances refer to Young DS [2].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	127	210	388
Coefficient of variation [%]	1.81	1.81	1.87
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	138	209	389
Coefficient of variation [%]	2.99	1.95	2.80

Method comparison (n=125)	
Test x	DiaSys LDH FS (Hitachi 911)
Test y	DiaSys LDH FS (respons®910)
Slope	0.987
Intercept	6.85 U/L
Coefficient of correlation	0.9997

** according to NCCLS document EP17-A, vol. 24, no. 34

Conversion factor

LDH [U/L] x 0.0167 = LDH [µkat/L]

Reference Range

	Female [U/L]	Male [U/L]	Female [µkat/L]	Male [µkat/L]
Adults [3]	< 247	< 248	< 4.12	< 4.14
Children [4]				
1 – 30 day(s)	145 – 765	125 – 735	2.42 – 12.8	2.09 – 12.3
31 days – 1 year	190 – 420	170 – 450	3.17 – 7.01	2.84 – 7.52
1 – 3 year(s)	165 – 395	155 – 345	2.76 – 6.60	2.59 – 5.76
4 – 6 years	135 – 345	155 – 345	2.25 – 5.76	2.59 – 5.76
7 – 9 years	140 – 280	145 – 300	2.34 – 4.68	2.42 – 5.01
10 – 12 years	120 – 260	120 – 325	2.00 – 4.34	2.00 – 5.43
13 – 15 years	100 – 275	120 – 290	1.67 – 4.59	2.00 – 4.84
16 – 18 years	105 – 230	105 – 235	1.75 – 3.84	1.75 – 3.92

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 36-7.
2. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th. ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press, 2000.
3. Schumann G, Bonora R, Ceriotti F, Férard G et al. IFCC primary reference procedure for the measurement of catalytic activity concentrations of enzymes at 37 °C. Part 3: Reference procedure for the measurement of catalytic concentration of lactate dehydrogenase. Clin Chem Lab Med 2002; 40: 643-48.
4. Soldin JS, Hicks JM. Pediatric reference ranges. Washington: AACC Press. 1995: p. 95.
5. Deutsche Gesellschaft für Klinische Chemie. (German Society for Clinical Chemistry). Recommendation for the determinaion of the catalytic concentration of lactate dehydrogenase at 37 °C. Eur J Clin Chem Clin Biochem 1993; 31: 897-9.
6. Thomas L. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 89-94.
7. Moss DW, Henderson AR. Clinical enzymology In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. 617-721.
8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanisms, detection and prevention. Clin Chem Lab med 2007; 45(9): 1240–1243.

Manufacturer

IVD CE
DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

respons®910

LDH FS IFCC

Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	LDH
Shortcut:	
Reagent barcode reference:	045
Host reference:	045

Technic	
Type:	Linear Kinetic
First reagent:[µL]	160
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	40
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	340
Secondary wavelength:[nm]	405
Polychromatic factor:	1.0000
1 st reading time [min:sec]	06:24
Last reading time [min:sec]	09:48
Reaction way:	Increasing
Linear Kinetics Substrate depletion: Absorbance limit	0.6000
Linearity: Maximum deviation [%]	100.0000
Fixed Time Kinetics Substrate depletion: Absorbance limit	
Endpoint Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	5.0000
Concentration technical limits-Upper	1200.0000
SERUM	
Normal volume [µL]	3.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	1
Above normal volume [µL]	3.0
Above normal dilution (factor)	6
URINE	
Normal volume [µL]	3.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	1
Above normal volume [µL]	3.0
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	3.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	1
Above normal volume [µL]	3.0
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	3.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	1
Above normal volume [µL]	3.0
Above normal dilution (factor)	6
Whole blood	
Normal volume [µL]	3.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	1
Above normal volume [µL]	3.0
Above normal dilution (factor)	6

Results	
Decimals	1
Units	U/L
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	Male
Age	
SERUM	>= <=248.0
URINE	
PLASMA	>= <=248.0
CSF	
Whole blood	
Gender	Female
Age	
SERUM	>= <=247.0
URINE	
PLASMA	>= <=247.0
CSF	
Whole blood	

Contaminants
Please refer to r910 Carryover Pair Table

Calibrators details	
Calibrator list	**Concentration**
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
	Max delta abs.
Cal. 1	0.002
Cal. 2	0.004
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.80

Calculations	
Model	X
Degree	1

* Enter calibrator value