respons®920

LDH FS* IFCC

Diagnostic reagent for quantitative in vitro determination of lactate dehydrogenase (LDH) in serum or plasma on DiaSys respons®920

Order Information

Cat. No. 1 4211 99 10 920
4 twin containers for 200 determinations 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. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
2. In very rare cases, samples of patients with gammopathy might give falsified results [8].
3. 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.
4. 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

DiaSys TruCal U calibrator is recommended for calibration. 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**	6 U/L LDH
On-board stability	10 days
Calibration stability	5 days

Interferences < 10% by
Ascorbate up to 30 mg/dL
Bilirubin up to 60 mg/dL
Lipemia (triglycerides) up to 2000 mg/dL
Hemoglobin interferes at low concentrations; indicates destruction of erythrocytes and ,therefore, release of LDH
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]	135	248	377
Coefficient of variation [%]	2.30	1.18	1.46
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	138	235	378
Coefficient of variation [%]	3.84	4.85	2.13

Method comparison (n=110)	
Test x	DiaSys LDH FS (Hitachi 917)
Test y	DiaSys LDH FS (respons®920)
Slope	0.946
Intercept	–2.24 U/L
Coefficient of correlation	0.990

** lowest measurable activity which can be distinguished from zero mean + 3 SD (n=20) of an analyte free specimen

Conversion factor

LDH [U/L] x 0.0167= LDH [µkat/L]

Reference Range

	Weiblich [U/L]	Männlich [U/L]	Weiblich [µkat/L]	Männlich [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. ClinChemLabMed 2007;45(9):1240–1243.

Manufacturer

IVD CE

DiaSys Diagnostic Systems GmbH
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* fluid stable

respons®920

LDH FS IFCC

Application for serum and plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	LDH				Auto Rerun		☐
Report Name	:	LDH-IFCC				Online Calibration		☐
Unit	:	U/L	Decimal Places	:	1	Cuvette Wash		☐
Wavelength-Primary	:	340	Secondary	:	405	Total Reagents	:	2
Assay Type	:	RATE - A	Curve Type	:	Linear	Reagent R1	:	LDH R1
M1 Start	:	0	M1 End	:	0	Reagent R2	:	LDH R2
M2 Start	:	21	M2 End	:	33			
Sample Replicates	:	1	Standard Replicates	:	3	Consumables/Calibrators:		
Control Replicates	:	1	Control Interval	:	0	Blank/Level 0	:	*
Reaction Direction	:	Increasing	React. Abs. Limit	:	1.20	Calibrator 1	:	*
Prozone Limit %	:	0	Prozone Check	:	Lower			
Linearity Limit %	:	0	Delta Abs./Min.	:	0.00			
Technical Minimum	:	6.00	Technical Maximum	:	1200.00			
Y = aX + b a=	:	1.00	b=	:	0.00			

* Enter calibrator value.

Test Details			Test Volumes	Reference Ranges
Test	:	LDH		
Sample Type	:	Serum		

Sample Volumes

Normal	:	3.00	µL	Dilution Ratio	:	1	X
Increase	:	6.00	µL	Dilution Ratio	:	1	X
Decrease	:	2.00	µL	Dilution Ratio	:	1	X
Standard Volume	:	3.00	µL				

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	160	µL	R1 Stirrer Speed	: Medium
RGT-2 Volume	:	40	µL	R2 Stirrer Speed	: High

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	LDH		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (U/L)	Upper Limit (U/L)
Normal	:	0.00	248.00
Panic	:	0.00	0.00

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other