respons®920

LDH 21 FS*

Order Information

Cat. No.	Kit size
1 4251 99 10 920	Σ 800 (4 x 200)

Intended Use

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

Summary

Lactate dehydrogenase (LDH) is an enzyme, consisting of five different isoenzymes, which catalyze the interconversion of L-lactate and pyruvate. LDH is present in the cytoplasm of all human tissues with higher concentrations in liver, heart and skeletal muscle and lower values in erythrocytes, pancreas, kidney and stomach. Increased LDH activities are found in a variety of pathological conditions such as myocardial infarction, cancer, diseases of liver, blood or muscle. However, because of the lack of organ specificity, determination of its isoenzymes or other enzymes such as alkaline phosphatase or ALAT/ASAT is necessary for differential diagnosis. [1,2]

Method

Optimized UV-test according to IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) [modified].

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

Reagents

Components and Concentrations

R1:	N-Methyl-D-Glucamine	pH 8.4	420 mmol/L
	L-Lactate		65 mmol/L
R2:	NAD^+		50 mmol/L

Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze reagents and protect them from light.

Warnings and Precautions

1. Reagent 1 contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. In very rare cases, samples of patients with gammopathy might give falsified results [3].
3. 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.
4. 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.
5. For professional use only.

Waste Management

Refer to local legal requirements.

Reagent Preparation

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

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Stability [4]:

7 days	at	20 – 25°C
4 days	at	4 – 8°C
6 weeks	at	–20°C

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. TruCal U calibrator values have been standardized against the original IFCC formulation. Use DiaSys TruLab N and P for internal quality control. 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

Exemplary data mentioned below may slightly differ in case of deviating measurement conditions.

Measuring range up to 1500 U/L. In case of higher activities re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	18 U/L
Onboard stability	12 weeks
Calibration stability	12 weeks

Interfering substance	**Interferences ≤ 10% up to**
Ascorbic acid	30 mg/dL
Bilirubin (conjugated)	60 mg/dL
Bilirubin (unconjugated)	50 mg/dL
Lipemia (triglycerides)	2000 mg/dL
Sulfapyridine	30 mg/dL
Sulfasalazine	30 mg/dL
Hemoglobin interferes at low concentrations.	
For further information on interfering substances refer to Young DS [5,6].	

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	107	243	977
CV [%]	1.87	1.24	2.15
Total precision CLSI (n=80)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	104	257	982
CV [%]	3.01	3.08	2.91

Method comparison (n=210)	
Test x	Competitor LDH
Test y	DiaSys LDH 21 FS
Slope	0.948
Intercept	0.799 U/L
Coefficient of correlation	0.9975

** according to CLSI document EP17-A2, Vol. 32, No. 8

Conversion Factor
LDH [U/L] x 0.0167 = LDH [µkat/L]

Reference Range

	Female		Male	
	[U/L]	[µkat/L]	[U/L]	[µkat/L]
Adults [7]	< 247	< 4.12	< 248	< 4.14
Children [8]				
1 – 30 day(s)	145 – 765	2.42 – 12.8	125 – 735	2.09 – 12.3
31 – 365 days	190 – 420	3.17 – 7.01	170 – 450	2.84 – 7.52
1 – 3 year(s)	165 – 395	2.76 – 6.60	155 – 345	2.59 – 5.76
4 – 6 years	135 – 345	2.25 – 5.76	155 – 345	2.59 – 5.76
7 – 9 years	140 – 280	2.34 – 4.68	145 – 300	2.42 – 5.01
10 – 12 years	120 – 260	2.00 – 4.34	120 – 325	2.00 – 5.43
13 – 15 years	100 – 275	1.67 – 4.59	120 – 290	2.00 – 4.84
16 – 18 years	105 – 230	1.75 – 3.84	105 – 235	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. Thomas L. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 89-94.
2. 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.
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4. Guder WG, da Fonseca-Wollheim F, Heil W, et al. The Quality of Diagnostic Samples. 3rd ed. Darmstadt: GIT Verlag; 2010. p. 52-3.
5. 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.
6. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, https://clinfx.wiley.com/aaccweb/aacc/, accessed in March 2021. Published by AACC Press and John Wiley and Sons, Inc.
7. 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.
8. Soldin SJ, Brugnara C, Wong EC. Pediatric reference ranges. 6th Edition. Washington: AACC Press:2007:140.

IVD CE

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany
www.diasys-diagnostics.com

* Fluid Stable

respons®920

LDH 21 FS

Application for serum and plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	LDH21				Auto Rerun		☐
Report Name	:	LDH 21 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	:	LDH21 R1
M1 Start	:	0	M1 End	:	0	Reagent R2	:	LDH21 R2
M2 Start	:	21	M2 End	:	33	**Consumables/Calibrators:**		
Sample Replicates	:	1	Standard Replicates	:	3	Blank/Level 0		0
Control Replicates	:	1	Control Interval	:	0	Calibrator 1		*
Reaction Direction	:	Increasing	React. Abs. Limit	:	1.20			
Prozone Limit %	:	0	Prozone Check	:	Lower			
Linearity Limit %	:	0	Delta Abs./Min.	:	0.00			
Technical Minimum	:	18.00	Technical Maximum	:	1500.00			
Y = aX + b a=	:	1.00	b=	:	0.00			

* Enter calibrator value.

Test Details			Test Volumes	Reference Ranges
Test	:	LDH21		
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	:	LDH21		
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