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®910.

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. 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

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**	35 U/L
Onboard stability	8 weeks
Calibration stability	1 week

Interfering substance	**Interferences ≤ 10% up to**	**Analyte concentration [U/L]**
Ascorbic acid	30 mg/dL	183
	30 mg/dL	277
Bilirubin (conjugated)	60 mg/dL	172
	60 mg/dL	265
Bilirubin (unconjugated)	60 mg/dL	208
	60 mg/dL	265
Lipemia (triglycerides)	2000 mg/dL	183
	2000 mg/dL	265
Sulfapyridine	30 mg/dL	172
	30 mg/dL	271
Sulfasalazine	30 mg/dL	182
	30 mg/dL	269
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]	117	278	1016
CV [%]	3.14	1.97	0.964
Total precision CLSI (n=80)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	108	268	1021
CV [%]	4.25	4.11	2.84

Method comparison (n=211)	
Test x	Competitor LDH
Test y	DiaSys LDH 21 FS
Slope	0.993
Intercept	6.15 U/L
Coefficient of correlation	0.995

** 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.
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3. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanisms, detection and prevention. Clin Chem Lab med 2007; 45(9): 1240-1243.
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.

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* Fluid Stable

respons®910

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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:	LDH21
Shortcut:	
Reagent barcode reference:	074
Host reference:	

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:	1.000
1 st reading time [min:sec]	06:24
Last reading time [min:sec]	09:48
Reaction way:	Increasing
Linear Kinetics Substrate depletion: Absorbance li	0.6000
Linearity: Maximum deviation [%]	100
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	35
Concentration technical limits-Upper	1500
SERUM	
Normal volume [µL]	3
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	6
URIN	
Normal volume [µL]	3
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	3
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	3
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	6
Whole blood	
Normal volume [µL]	3
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	6

Results	
Decimals	1
Units	U/L
Correlation factor-Offset	0.000
Correlation factor-Slope	1.000

Range	
Gender	Male
Age	
SERUM	>= <=248
URINE	
PLASMA	>= <=248
CSF	
Whole blood	
Gender	Female
Age	
SERUM	>= <=247
URINE	
PLASMA	>= <=247
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 [%]	0.8

Calculations	
Model	X
Degree	1

* Enter calibrator value