

LDH 21 FS*

Order Information

Cat. No.

1 4251 99 10 920

Kit size



800 (4 x 200)

Intended Use

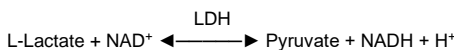
Diagnostic reagent for quantitative in vitro determination of lactate dehydrogenase activity in human serum or heparin plasma on automated responS®910.

Summary

Lactate dehydrogenase (LDH) is an enzyme, consisting of five different isoenzymes, which catalyze the interconversion of L-lactate and pyruvate with concomitant interconversion of NADH and NAD⁺. LDH is present in the cytoplasm of all human tissues with higher concentrations in liver, heart and skeletal muscle and kidney and lower values in erythrocytes [1]. Increased LDH activities are found in a variety of pathological conditions such as myocardial infarction, cancer, diseases of liver, blood or muscle [1,2]. 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].



One unit of LDH is the amount of enzyme required to produce 1.0 μmol of pyruvate per minute under enzyme specific conditions.

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 and protect from light.

The open-vial stability of the reagent is 24 months until expiry date.

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. Reagent 1 contains material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
3. In very rare cases, samples of patients with gammopathy might give falsified results [3].
4. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
5. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
6. Please refer to the safety data sheets (SDS) 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.
7. For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

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

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

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. Calibrator values have been standardized against the original IFCC formulation. Use DiaSys TruLab N and P for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. 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 from 35 U/L up to 1500 U/L. Linearity < 15 U/L is given with ± 5.4 U/L, between 15 U/L to 30 U/L within ± 10%, at > 30 U/L within ± 5%.	
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
Limit of quantitation**	35 U/L
Onboard stability	8 weeks
Calibration stability	1 week

Interference by	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 the literature [5-7].

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	117	278	1016
CV [%]	3.14	1.97	0.964
Within-laboratory (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 (cobas c 501)
Test y	DiaSys LDH 21 FS (respons [®] 910)
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 [1]

	U/L	µkat/L
Children		
0 – 1 year	196 – 438	3.27 – 7.3
1 – 3 year(s)	105 – 338	1.75 – 5.6
4 – 6 years	107 – 314	1.78 – 5.2
7 – 11 years	112 – 307	1.87 – 5.1
13 – 17 years	115 – 287	1.94 – 4.8
Adults		
Female	< 247	< 4.12
Male	< 248	< 4.13

Consensus for upper reference limits for adults: < 250 U/L
(4.20 µkat/L)

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 [Internet]. Prof. Lothar Thomas; 2024 [cited 2024 June 10]. Available from: <https://www.clinical-laboratory-diagnostics.com/>
2. Moss DW, Henderson AR. Clinical enzymology In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 4th ed. St. Louis Missouri: Elsevier Saunders Company;2006. 601-604.
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, Schmitt Y, Töpfer G, Wisser H, Zawta B. Quality of Diagnostic Samples. 3rd edition; 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. Sonntag O, Scholer A. Drug interference in clinical chemistry: recommendation of drugs and their concentrations to be used in drug interference studies. Ann Clin Biochem. 2001 Jul;38:376-85.

Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.



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* Fluid Stable

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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:[μ L]	160
Blank reagent	Yes
Sensitive to light	
Second reagent:[μ L]	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 [μ L]	0 (no hemolysis)
Cleaner	
Sample [μ L]	0
Technical limits	
Concentration technical limits-Lower	35
Concentration technical limits-Upper	1500
SERUM	
Normal volume [μ L]	3
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	3
Above normal dilution (factor)	6
URIN	
Normal volume [μ L]	3
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	3
Above normal dilution (factor)	6
PLASMA	
Normal volume [μ L]	3
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	3
Above normal dilution (factor)	6
CSF	
Normal volume [μ L]	3
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	3
Above normal dilution (factor)	6
Whole blood	
Normal volume [μ L]	3
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	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