BioMajesty®

LDH 21 FS*

Order Information

Cat. No.
1 4251 99 10 964

Kit size
900 (R1: 6 x 150, R2: 6 x 150)

Intended Use

Diagnostic reagent for quantitative in vitro determination of lactate dehydrogenase activity in human serum or heparin plasma on automated BioMajesty® JCA-BM6010/C.

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].

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

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 43 U/L up to 1500 U/L, linearity is given within ± 10%.
In case of higher activities re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.

Limit of detection**	15 U/L
Limit of quantitation**	15 U/L
Onboard stability	12 weeks
Calibration stability	9 weeks

Interference by	**Interferences ≤ 10% up to**	**Analyte concentration [U/L]**
Ascorbic acid	60 mg/dL	172
	60 mg/dL	251
Bilirubin (conjugated)	60 mg/dL	166
	60 mg/dL	250
Bilirubin (unconjugated)	60 mg/dL	161
	60 mg/dL	247
Lipemia (triglycerides)	2000 mg/dL	171
	2000 mg/dL	244
Sulfapyridine	30 mg/dL	162
	30 mg/dL	249
Sulfasalazine	30 mg/dL	177
	30 mg/dL	266

Hemoglobin interferes at low concentrations.

For further information on interfering substances, refer to the literature [5-7].

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Precision			
Repeatability (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	106	265	990
CV [%]	1.85	0.824	1.89
Within-laboratory (n=80)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	104	254	978
CV [%]	2.16	1.70	1.87

Method comparison (n=216)	
Test x	DiaSys LDH 21 FS (BioMajesty® JCA-BM6010/C)
Test y	Competitor LDH (cobas c 501)
Slope	0.998
Intercept	-0.628 U/L
Coefficient of correlation	0.999

** 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.
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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.

IVD CE

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* Fluid Stable

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LDH 21 FS

Chemistry code 10 425

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.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	20
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	1.5
Sample vol (U)	1.5
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Sub-analy. Conditions	
Name	LDH21
Digits	2
M-wave L.	340
S-wave.L	410
Analy.mthd.	RRA
Calc.mthd.	STD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	1.5	1.5
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

entered by user

Endpoint method	
Re.absorb (u)	9.999
Re. Absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	21
M-DET.P.m	25
M-DET.P.n	40
S-DET.P.p	0
S-DET.P.r	0
Check D.P.I.	21
Limit value	0.003
Variance	10
Reac.type	Inc

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	1.0
Sample (d)	-9.999

Standards Setting	
FV	#
BLK H	9.999
BLK L	-9.999
STD H	9.999
STD L	-9.999