BioMajesty

LDH FS* IFCC

Diagnostic reagent for quantitative in vitro determination of lactate dehydrogenase (LDH) in serum or plasma on BioMajesty JCA-BM6010/C

Order Information

Cat. No. 1 4211 99 10 964
R1: 6 x 150 tests
R2: 6 x 150 tests

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. Do not freeze the reagents!

Warnings and Precautions

1. In very rare cases, samples of patients with gammopathy might give falsified results [8].
2. 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.
3. 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 trays.

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

For calibration DiaSys TruCal U calibrator is recommended. 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 (20 µkat/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 (0.1 µkat/L) LDH
On-board stability	4 weeks
Calibration stability	2 weeks

Interferences < 10% by
Ascorbate up to 30 mg/dL
Conjugated bilirubin up to 55 mg/dL
Unconjugated bilirubin up to 40 mg/dL
Lipemia (triglycerides) up to 1800 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 [7].

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	122	183	416
Mean [µkat/L]	2.04	3.04	6.94
Coefficient of variation [%]	2.05	0.95	0.89
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	175	356	393
Mean [µkat/L]	2.92	5.93	6.55
Coefficient of variation [%]	1.88	1.33	1.88

Method comparison (n=100)	
Test x	Competitor LDH
Test y	DiaSys LDH FS IFCC
Slope	1.03
Intercept	–17.0 U/L (–0.284 µkat/L)
Coefficient of correlation	r = 0.998

** 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

	Female	**Male**
Adults [2]	< 247 U/L	< 248 U/L
Children [3]		
1 – 30 day(s)	145 – 765 U/L	125 – 735 U/L
31 days – 1 year	190 – 420 U/L	170 – 450 U/L
1 – 3 year(s)	165 – 395 U/L	155 – 345 U/L
4 – 6 years	135 – 345 U/L	155 – 345 U/L
7 – 9 years	140 – 280 U/L	145 – 300 U/L
10 – 12 years	120 – 260 U/L	120 – 325 U/L
13 – 15 years	100 – 275 U/L	120 – 290 U/L
16 – 18 years	105 – 230 U/L	105 – 235 U/L

	Female	**Male**
Adults [2]	< 4.12 µkat/L	< 4.14 µkat/L
Children [3]		
1 – 30 day(s)	2.42 – 12.8 µkat/L	2.09 – 12.3 µkat/L
31 days – 1 year	3.17 – 7.01 µkat/L	2.84 – 7.52 µkat/L
1 – 3 year(s)	2.76 – 6.60 µkat/L	2.59 – 5.76 µkat/L
4 – 6 years	2.25 – 5.76 µkat/L	2.59 – 5.76 µkat/L
7 – 9 years	2.34 – 4.68 µkat/L	2.42 – 5.01 µkat/L
10 – 12 years	2.00 – 4.34 µkat/L	2.00 – 5.43 µkat/L
13 – 15 years	1.67 – 4.59 µkat/L	2.00 – 4.84 µkat/L
16 – 18 years	1.75 – 3.84 µkat/L	1.75 – 3.92 µkat/L

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

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Literature

1. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 36-7.
2. 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.
3. Soldin JS, Hicks JM. Pediatric reference ranges. Washington: AACC Press. 1995: p. 95.
4. 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.
5. Thomas L. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 89-94.
6. 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.
7. 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.
8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanisms, detection and prevention. Clin Chem Lab med 2007; 45(9): 1240–1243.

Manufacturer

IVD CE

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Chemistry code 10 421

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	LDH
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