LDH 21 FS*

Order Information

Cat. No.	Kit size				
1 4251 99 10 021	R1	5 x 20 mL	+	R2	1 x 25 mL
1 4251 99 10 704	R1	8 x 50 mL	+	R2	8 x 12.5 mL
1 4251 99 10 930	R1	4 x 20 mL	+	R2	2 x 10 mL

Intended Use

Diagnostic reagent for quantitative in vitro determination of lactate dehydrogenase (LDH) in human serum or heparin plasma on automated photometric systems.

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.

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Stability [4]:

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

Discard contaminated specimens.

Assay Procedure

Basic settings for BioMajesty® JCA-BM6010/C

Wavelength	340/410 nm (bichromatic)
Temperature	37°C
Measurement	Linear kinetics
Sample/calibrator	1.5 µL
Reagent 1	80 µL
Reagent 2	20 µL
Addition reagent 2	Cycle 19 (286 s)
Absorbance 1	Cycle 25 (367 s)
Absorbance 2	Cycle 40 (527 s)
Calibration	Linear

Calculation

With calibrator

$$\text{LDH [U/L]} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Cal}} \times \text{Conc. Cal [U/L]}$$

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

Data evaluated on BioMajesty® JCA-BM6010/C

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

Measuring range from 43 U/L up to 1500 U/L. When values exceed this range, samples should be diluted 1 + 10 with NaCl solution (9 g/L) and the result multiplied by 11.	
Limit of detection**	15 U/L

Interfering substance	**Interferences ≤ 10% up to**
Ascorbic acid	60 mg/dL
Bilirubin (conjugated)	60 mg/dL
Bilirubin (unconjugated)	60 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]	106	265	990
CV [%]	1.85	0.824	1.89
Total Precision CLSI (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
Test y	Competitor LDH
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

	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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4. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 36-7.
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8. Soldin JS, Hicks JM. Pediatric reference ranges. Washington: AACC Press:1995:95.

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* Fluid Stable