

LDH FS*

IFCC

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

Order Information

Cat. No.	Kit size					
1 4211 99 10 021	R1	5 x 20 mL	+	R2	1 x	25 mL
1 4211 99 10 704	R1	8 x 50 mL	+	R2	8 x	12.5 mL
1 4211 99 10 930	R1	4 x 20 mL	+	R2	2 x	10 mL
1 4211 99 90 305	R1	10 x 12 mL	+	R2	2 x	20 mL

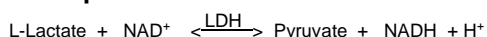
Summary [1,2]

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, liver diseases, blood diseases, and cancer or muscle diseases. 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.

Method

Optimized UV-test according to IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) and DGKC (German Society of Clinical Chemistry)

Principle



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 and contamination is avoided. Do not freeze the reagents!

Reagent 2 must be protected from light.

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

Substrate Start

The reagents are ready to use.

Sample Start

Mix 4 parts of R1 + 1 part of R2

(eg 20 mL R1 + 5 mL R2) = mono reagent

Stability:	12 hours	at	2 – 8°C
	2 hours	at	15 – 25°C

The mono reagent must be protected from light.

Materials required but not provided

NaCl solution 9 g/L

General laboratory equipment

Specimen

Serum, heparin plasma or EDTA plasma

Stability [4]:	4 days	at	20 – 25°C
	6 weeks	at	4 – 8°C

Discard contaminated specimens.

Assay Procedure

Application sheets for automated systems are available on request.

Wavelength	340 nm, Hg 365 nm, Hg 334 nm
Optical path	1 cm
Temperature	37°C
Measurement	Against reagent blank

Substrate start

	Blank	Sample
Sample or calibrator	-	20 µL
Dist. Water	20 µL	-
Reagent 1	1000 µL	1000 µL
Mix, incubate for approx. 1 – 5 min., then add:		
Reagent 2	250 µL	250 µL
Mix, read absorbance after 1 min. and start stopwatch.		
Read absorbance again after 1, 2 and 3 min.		

Sample start

	Blank	Sample
Sample or calibrator	-	20 µL
Dist. Water	20 µL	-
Mono reagent	1000 µL	1000 µL
Mix, read absorbance after 1 min. and start stopwatch.		
Read absorbance again after 1, 2 and 3 min.		

Calculation

With factor

From absorbance readings calculate $\Delta A/\text{min}$ and multiply by the corresponding factor from table below:

$\Delta A/\text{min} \times \text{factor} = \text{LDH activity [U/L]}$

Substrate Start

340 nm	10080
334 nm	10275
365 nm	18675

Sample Start

340 nm	8095
334 nm	8250
365 nm	15000

With calibrator

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

Conversion factor

$$\text{LDH [U/L]} \times 0.0167 = \text{LDH [\mu kat/L]}$$

Calibrators and Controls

For the calibration of automated photometric systems, DiaSys TruCal U calibrator is recommended. This method has been standardized against the original IFCC formulation. DiaSys TruLab N and P controls should be assayed 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

Measuring range

On automated systems the test is suitable for the determination of LDH activities up to 1200 U/L.

In case of a manual procedure, the test is suitable for LDH activities which correspond to a maximum of $\Delta A/\text{min}$ of 0.15 at 340 and 334 nm or 0.08 at 365 nm.

If these values are exceeded the sample should be diluted 1 + 10 with NaCl solution (9 g/L) and results multiplied by 11.

Specificity/Interferences

No interference was observed by ascorbic acid up to 30 mg/dL, bilirubin up to 40 mg/dL and lipemia up to 2000 mg/dL triglycerides. Hemolysis interferes because LDH is released by erythrocytes. For further information on interfering substances refer to Young DS [5].

Sensitivity/Limit of Detection

The lower limit of detection is 5 U/L.

Precision

Intra-assay precision n = 20	Mean [U/L]	SD [U/L]	CV [%]
Sample 1	178	2.00	1.12
Sample 2	187	2.12	1.14
Sample 3	566	2.27	0.40

Inter-assay precision n = 20	Mean [U/L]	SD [U/L]	CV [%]
Sample 1	170	1.62	0.95
Sample 2	176	2.48	1.41
Sample 3	566	3.61	0.64

Method Comparison

A comparison of DiaSys LDH FS IFCC (y) with the IFCC reference reagent (x) using 51 samples gave following results:
 $y = 0.949x + 8.451 \text{ U/L}$; $r = 0.998$.

A comparison with a commercially available test using 216 samples gave following results:

$$y = 0.988x + 0.504 \text{ U/L}; r = 0.999.$$

Reference Range

	Female [U/L]	Male [U/L]	Female [μkat/L]	Male [μkat/L]
Adults [6]	< 247	< 248	< 4.12	< 4.14
Children [7]				
1 – 30 day(s)	145 – 765	125 – 735	2.42 – 12.8	2.09 – 12.3
31 days – 1 year	190 – 420	170 – 450	3.17 – 7.01	2.84 – 7.52
1 – 3 year(s)	165 – 395	155 – 345	2.76 – 6.60	2.59 – 5.76
4 – 6 years	135 – 345	155 – 345	2.25 – 5.76	2.59 – 5.76
7 – 9 years	140 – 280	145 – 300	2.34 – 4.68	2.42 – 5.01
10 – 12 years	120 – 260	120 – 325	2.00 – 4.34	2.00 – 5.43
13 – 15 years	100 – 275	120 – 290	1.67 – 4.59	2.00 – 4.84
16 – 18 years	105 – 230	105 – 235	1.75 – 3.84	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. 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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6. Schumann G, Bonora R, Ceriotti F, Féraud 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.
7. Soldin JS, Hicks JM. Pediatric reference ranges. Washington: AACC Press:1995:95.
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



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