

LACTATE DEHYDROGENASE (LDH)

Determination of lactate dehydrogenase in serum and plasma based on recommendations of DGKC

TEST SUMMARY

Lactate dehydrogenase (LDH) catalyses the conversion of Pyruvate to L-Lactate, in presence of NADH, which is converted to NAD⁺, monitored at 340 nm the rate of conversion from NADH to NAD⁺.

SAMPLES

Serum, plasma heparinate or EDTA.
Stability: 3 days at 2-8°C.

REAGENTS

Reagent A: Buffer phosphate pH 7.50 50 mM, pyruvate 0.60 mM.

Reagent B: NADH 0.18 mM.

MATERIALS REQUIRED BUT NOT SUPPLIED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Saline solutions.

PRECAUTIONS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow. Perform the test according to the general "Good Laboratory Practice" (GPL) guidelines.

REAGENTS PREPARATION

PROCEDURE STARTER SAMPLE

Add 10 ml of Reagent B to a vial of reagent A. Reagent of work is stable 30 days at 2-8°C away from light sources.

PROCEDURE STARTER REAGENT

Use reagents separately. Stability: until expiration date on label away from light sources.
Stability after first opening: ≥ 60 days.

PROCEDURE (STARTER SAMPLE)

Kind of analysis: Kinetics (decreasing)
Reading time: 1,2,3 minutes
Delay: 60 sec.
Wavelength: 340 nm
Temperature: 37°C
Lightpath: 1 cm
Zero: Distilled water

REAGENTS	CUVETTE
Work's reagent	1 ml
Preincubate at 37 °C at least for 5 minutes.	
Sample	10 µl

PROCEDURE (STARTER REAGENT)

Kind of analysis: Kinetics (decreasing)
Reading time: 1,2,3 minutes
Delay: 60 sec.
Wavelength: 340 nm
Temperature: 37°C
Lightpath: 1 cm
Zero: Distilled water

REAGENTS	CUVETTE
Reagent A	1 ml
Sample	10 µl
Preincubate at 37 °C at least for 5 minutes	
Reagent B	250 µl

CALCULATION

Activity in U/l: $\Delta A/\text{min} \times 16030$ (starter sample)

Activity in U/l: $\Delta A/\text{min} \times 20080$ (starter reagent)

Activity in µkat/l: $U/l \times 0.0167$

EXPECTED VALUES

225 – 450 U/l (3.75 – 7.51 µkat/l)

Each laboratory should establish appropriate reference intervals related to its population.

NOTE

- If the results are incompatible with clinical presentation, they have to be evaluated within a total clinical study.
- Only for IVD use.

CALIBRATION/QUALITY CONTROL

It is suggested to perform an internal quality control. For this purpose the following control sera on human base are available on request:

QN 0050 CH 10 x 5 ml

Control Sera normal values

QP 0050 CH 10 x 5 ml

Control Sera pathological values

TEST PERFORMANCE

Precision

Intra-assay (n = 20)	Mean (U/l)	SD (U/l)	CV%
Sample 1	309.7	0.8645	0.28
Sample 2	504.5	1.192	0.24

Inter-assay (n = 20)	Mean (U/l)	SD (U/l)	CV%
Sample 1	309.95	1.276	0.41
Sample 2	505.75	2.173	0.43

Sensitivity/limit of detection

The method is able to discriminate until 2 U/l.

Linearity

The method is linear up to 4000 U/l.

If $\Delta A/\text{min}$ is exceeded at 0.100, is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the results by 10.

Methods comparison

A comparison with a commercial available product gave the following results in a comparison on 30 samples:

LDH LTA = x

LDH competitor = y

n = 30

$y = 0,44045 + 0,99772x$ $r = 0,99972$

Interferences

No interference was observed by the presence of:
hemoglobin ≤ 500 mg/dl
bilirubin ≤ 40 mg/dl
lipids ≤ 1000 mg/dl

WASTE DISPOSAL

Product is intended for professional laboratories. Waste products must be handled as per relevant security cards and local regulations.

PACKAGING

CODE CC02000 (200 TESTS)

Reagent A 4 x 40 ml (liquid)

Reagent B 1 x 40 ml (liquid)

REFERENCES

HU Bergmeyer – Methods of enzymatic analysis, Vol. III (1987).

DGKC – Eur.J.Clin.Chem.Biochem., 31 (1993).









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Young D.S., et al. – Clin. Chem. 21 ID, 432D (1975).

MANUFACTURER

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SYMBOLS

-  Only for IVD use
-  Lot of manufacturing
-  Code number
-  Storage temperature interval
-  Expiration date (year, month)
-  Warning, read enclosed documents
-  Read the directions
-  Biological risk

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