

**DIAGNOSTIC KIT
FOR DETERMINATION OF
LACTATE DEHYDROGENASE
ACTIVITY**



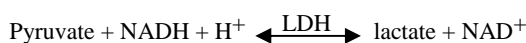
A-400 LDH

INTRODUCTION

Lactate dehydrogenase (LDH, LD) is intracellular enzyme occurred in all tissues. LDH catalyzes the reversible conversion of lactate to pyruvate using NAD⁺ as a cofactor. LD is a tetramer containing two possible forms of subunits: H and M. The result is five isoenzymes termed LD-1 (H₄) through LD-5 (M₄). The isoenzymes are present in different proportion in each tissue and have different electrophoresis mobility, what is very useful for diagnostic.

METHOD PRINCIPLE

Optimized kinetic method of Deutsche Gesellschaft für Klinische Chemie (DGKC).



The rate of absorbance changing at $\lambda=340$ nm is directly proportional to lactate dehydrogenase activity.

REAGENTS**Package**

1-Reagent	1 x 40 ml
2-Reagent	1 x 11 ml

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 12 weeks on board the analyser at 2-10°C.

Concentrations in the test

phosphate buffer (pH 7.5)	50 mmol/l
pyruvate	0.6 mmol/l
NADH	0.25 mmol/l

Warnings and notes

- Product for in vitro diagnostic use only.
- The reagents must be used only for the intended purpose, by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- Protect from light and avoid contamination!
- The reagents contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

SPECIMEN

Serum, heparinized plasma free from hemolysis.

Do not use hemolyzed blood or serum because erythrocytes contain 150 times more LDH activity than serum.

As an anticoagulant for plasma preparation use heparin lithium or ammonium salt.

LDH activity is unstable and is rapidly lost during storage.

Specimens can be stored up to 4 hours at 15-25°C or 1-2 days at 2-8°C. Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

These reagents may be used in automatic analysers BS-400 and BS-480.

1-Reagent and 2-Reagent are ready to use.

For reagent blank deionized water is recommended.

Actions required:**BS-400**

When performing assays at analyzer BS-400, there is a probability of cross-contamination affecting the tests results: ASAT - LDH, ALAT - LDH. To avoid this effect follow the recommendations contained in the advisory note "Carry-over – Preventive Actions".

REFERENCE VALUES⁴

serum / plasma	37°C	37°C
adults	225 – 450 U/l	3.75 – 7.50 μ kat/l

It is recommended for each laboratory to establish its own reference ranges for local population

QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY SERUM HN (Cat. No 5-172) and CORMAY SERUM HP (Cat. No 5-173) with each batch of samples.

For the calibration of automatic analyser system BS-400 the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) or LEVEL 2 (Cat. No 5-175; 5-177) is recommend. Deionised water should be used as a calibrator 0.

For the calibration of automatic analyser system BS-480 the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) and LEVEL 2 (Cat. No 5-175; 5-177) is recommended. Deionised water should be used as a calibrator 0.

The calibration curve should be prepared every 12 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using automatic analysers BS-400 and BS-480. Results may vary if a different instrument or a manual procedure is used.

- Sensitivity:**

11 U/l (0.183 μ kat/l) – BS-400
8.84 U/l (0.147 μ kat/l) – BS-480

- Linearity:**

up to 2100 U/l (35 μ kat/l) – BS-400
up to 2000 U/l (33.33 μ kat/l) – BS-480

If LDH activity in tested sample exceeds 2100 U/l dilute the sample with 0.9% NaCl in the ratio of 1 to 9 and repeat the assay, multiply the result by 10.

- Specificity / Interferences**

Haemoglobin up to 5 g/dl, bilirubin up to 20 mg/dl, ascorbate up to 62 mg/l and triglycerides up to 1000 mg/dl do not interfere with the test.

- Precision**

Repeatability (run to run)		Mean [U/l]	SD [U/l]	CV [%]
BS-400 (n = 10)	level 1	334.01	1.71	0.51
	level 2	829.60	3.07	0.37
BS-480 (n = 10)	level 1	331.79	3.83	1.15
	level 2	818.37	3.04	0.37
Reproducibility (day to day)		Mean [U/l]	SD [U/l]	CV [%]
BS-400 (n = 10)	level 1	343.07	3.16	0.92
	level 2	869.12	7.83	0.90
BS-480 (n = 10)	level 1	330.03	4.30	1.30
	level 2	809.51	9.21	1.14

- Method comparison**

A comparison between LDH values determined at BS-400 (y) and at Cobas Integra 400 Plus (x) using 26 samples gave following results:

$$y = 0.9597x + 16.961 \text{ U/l};$$

$$R = 0.994$$

(R – correlation coefficient)

A comparison between LDH values determined at BS-480 (y) and at Cobas Integra 400 Plus (x) using 35 samples gave following results:

$$y = 1.0353 x - 22.439 \text{ U/l;}$$

R = 0.999 (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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Date of issue: 10. 2017.

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10/17/10/17