Cat. No 4-539

DIAGNOSTIC KIT FOR DETERMINATION OF LACTATE DEHYDROGENASE ACTIVITY

HC – 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 (H_4) through LD-5 (M_4). 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 Gesselschaft für Klinische Chemie (DGKC).

$$\text{Pyruvate} + \text{NADH} + H^+ \xleftrightarrow{\text{LDH}} \text{lactate} + NAD^+$$

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

REAGENTS

Package

1-Reagent	6 x 76 ml
2-Reagent	6 x 19.5 ml

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 11 weeks on board the analyser at 2-10°C. Protect from light and avoid contamination!

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 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 15-25ºC or 1-2 days at 2-8ºC.
Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

The reagents are ready to use.
These reagents may be used in automatic analyser Hitachi 911/912.
Application should be entered using handheld barcode scanner and attached barcodes sheet, according to procedure described below:

1. Delete previous version of application and calibrators assigned to it and restart the analyser.
2. Enter codes of calibrators according to the attached list.
3. Enter barcoded application and assign proper values to calibrators.
4. To activate entered application go to the tab UTILITY | APPLICATION | RANGE and change value of field DATA MODE from INACTIVE to ON BOARD. Confirm the change using UPDATE button.
5. Put reagents on board the analyser – they will be assigned to relevant tests automatically. Perform also measurement of level of reagents inside the bottles.
6. After calibration analyser is ready to use.

REFERENCE VALUES [4]

serum / plasma	37ºC	37ºC
adults	225 – 450 U/l	3.75 – 7.50 µkat/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 analysers systems the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) is recommended. **Calibrator and 0.9% NaCl** should be used for calibration.
The calibration curve should be prepared every 11 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 analyser Hitachi 912. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:** 12.9 U/l (0.22 µkat/l).
- **Linearity:** up to 2300 U/l (38.33 µkat/l).
  If LDH activity in tested sample exceeds 2300 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) n = 20	Mean [U/l]	SD [U/l]	CV [%]
level 1	319.08	1.71	0.54
level 2	813.35	3.61	0.44

Reproducibility (day to day) n = 80	Mean [U/l]	SD [U/l]	CV [%]
level 1	318.51	3.37	1.06
level 2	812.43	6.24	0.77

- **Method comparison**

A comparison between LDH values determined at Hitachi 912 (y) and at Cobas Integra 400 PLUS (x) using 80 samples gave following results:
y = 1.1119 x - 32.552 U/l;
R = 0.9906 (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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