

**DIAGNOSTIC KIT
FOR DETERMINATION OF
 α -HYDROXYBUTYRATE
DEHYDROGENASE ACTIVITY**



HC – HBDH

INTRODUCTION

Lactate dehydrogenase (LDH, LD) is a tetrameric molecule containing two possible forms of subunits (H and M). The result is five isoenzymes, one of which is hydroxybutyrate dehydrogenase (HBDH, LD-1) formed by four H subunits. HBDH is present mainly in heart muscle but occur also in kidney and erythrocytes. Normal serum contains mostly LD-2 with lesser amount of LD-1. Changes in the ratio of LD-1 to LD-2 indicate myocardial infarction or hemolysis.

METHOD PRINCIPLE

Kinetic method of Deutsche Gesellschaft für Klinische Chemie (DGKC).



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

REAGENTS**Package**

1-Reagent	6 x 79 ml
2-Reagent	6 x 20 ml

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

Concentrations in the test

phosphate buffer (pH 7.5)	50 mmol/l
2-oxybutyrate	3 mmol/l
NADH	0.25 mmol/l

Warnings and notes

- Product for in vitro diagnostic use only.
- The reagents contain < 0.1% sodium azide as a preservative. Avoid contact with skin and mucous membranes.

SPECIMEN

Serum.

Do not use hemolyzed blood because erythrocytes contain very high HBDH activity. Do not chill or freeze samples.

HBDH activity is unstable and is rapidly lost during storage. Specimens can be stored up to 6 hours at 15-25°C.

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:

- Delete previous version of application and calibrators assigned to it and restart the analyser.
- Enter codes of calibrators according to the attached list.
- Enter barcoded application and assign proper values to calibrators.
- 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.
- Put reagents on board the analyser – they will be assigned to relevant tests automatically. Perform also measurement of level of reagents inside the bottles.
- After calibration analyser is ready to use.

REFERENCE VALUES⁷

serum	37°C
adults	< 182 U/l (< 3.04 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 analysers systems the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) is recommended. **Calibrator and deionised water** should be used for calibration.

The calibration curve should be prepared 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:** 5 U/l (0.084 μ kat/l).
- Linearity:** up to 1200 U/l (20.04 μ kat/l).
If HBDH activity in tested sample exceeds or 1200 U/l dilute the sample 10-fold with 0.9% NaCl and repeat the assay. Multiply the result by 10.
- Specificity / Interferences**
Haemoglobin up to 2.5 g/dl, ascorbate up to 62 mg/l, bilirubin up to 20 mg/dl 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	160.36	1.22	0.76
level 2	444.25	2.93	0.66

Method comparison

A comparison between HBDH activity determined at Hitachi 912 (y) and at BS-400 (x) using 30 samples gave following results:

$$y = 1.0273 x + 6.3845 \text{ U/l};$$

$$R = 0.9980 \quad (R - \text{correlation coefficient})$$

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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