

**DIAGNOSTIC KIT
FOR DETERMINATION OF
ALANINE AMINOTRANSFERASE
ACTIVITY**



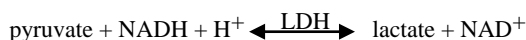
HC – ALAT

INTRODUCTION

Alanine aminotransferase (ALAT, ALT, GPT) is an enzyme participated in amino acids metabolism. ALAT is present in all tissues but the highest level is found in liver and kidney cells. Damage of hepatocytes or kidney cells causes significant release of ALAT into the circulation. Measurement of ALT activity in serum is valuable in the diagnosis of liver diseases: jaundice, mononucleosis or hepatic cirrhosis.

METHOD PRINCIPLE

Optimized, modified method according to International Federation of Clinical Chemistry (IFCC), without pyridoxal phosphate.



The rate of absorbance changing at $\lambda=340$ nm is directly proportional to alanine aminotransferase 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 12 weeks on board the analyser at 2-10°C. Protect from light and avoid contamination!

Concentrations in the test

Tris (pH 7.5)	100 mmol/l
L-alanine	500 mmol/l
LDH	> 36.7 $\mu\text{kat/l}$
2-oxoglutarate	15 mmol/l
NADH	0.18 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, heparinized or EDTA plasma free from hemolysis. Hemolysis should be avoided, since ALAT activity in erythrocytes is 3 to 5 times higher than in normal serum. Do not freeze the samples. ALAT activity remains stable in specimen up to 3 days at 15-25°C or up to 7 days at 2-8°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 VALUES ⁶

serum / plasma	37°C	
women	up to 31 U/l	up to 0.517 $\mu\text{kat/l}$
men	up to 41 U/l	up to 0.683 $\mu\text{kat/l}$

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 0.9% NaCl** should be used for calibration.

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 the automatic analyser Hitachi 912. Results may vary if a different instrument or a manual procedure is used.

- Sensitivity:** 3.09 U/l (0.052 $\mu\text{kat/l}$).
- Linearity:** up to 600 U/l (10.02 $\mu\text{kat/l}$).
- Specificity / Interferences**
Haemoglobin up to 0.16 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	34.72	0.75	2.17
level 2	99.58	0.81	0.81

Reproducibility (day to day) n = 80	Mean [U/l]	SD [U/l]	CV [%]
level 1	33.60	0.79	2.35
level 2	103.19	1.97	1.91

- Method comparison**

A comparison between ALAT values determined at Hitachi 912 (y) and at Cobas Integra 400 PLUS (x) using 100 samples gave following results:

$$y = 0.9582x - 0.0071 \text{ U/l};$$

$$R = 0.9978 \quad (R - \text{correlation coefficient})$$

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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