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CE CORMAY

Liquick Cor - ALAT

Kit name	**(EN) Cat. No**
Liquick Cor-ALAT mini	1-289
Liquick Cor-ALAT 30	1-221
Liquick Cor-ALAT 60	1-216
Liquick Cor-ALAT 120	1-217
Liquick Cor-ALAT 500	1-312

INTENDED USE

Diagnostic kit for determination of alanine aminotransferase activity intended to use for manual assay (Sample Start and Reagent Start method) and in several automatic analysers.
The reagents must be used only for *in vitro* diagnostic, by suitably qualified laboratory personnel, only for the intended purpose, under appropriate laboratory conditions.

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.

$$\text{L-alanine} + \text{2-oxoglutarate} \xleftrightarrow{\text{ALAT}} \text{pyruvate} + \text{L-glutamate}$$

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

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

REAGENTS

Package

	Liquick Cor - ALAT mini	**Liquick Cor - ALAT 30**	**Liquick Cor - ALAT 60**
1-ALAT	2 x 24 ml	5 x 24 ml	5 x 48 ml
2-ALAT	1 x 12 ml	1 x 30 ml	1 x 60 ml

	Liquick Cor - ALAT 120	**Liquick Cor - ALAT 500**
1-ALAT	5 x 96 ml	3 x 400 ml
2-ALAT	1 x 120 ml	1 x 300 ml

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents stored on board of the analyzer at 2-10°C are stable for 12 weeks (Biolis 24i Premium).

Working reagent preparation and stability

Assay can be performed with use of separate 1-ALAT and 2-ALAT reagents or with use of working reagent. For working reagent preparation mix gently 4 parts of 1-ALAT with 1 part of 2-ALAT. Avoid foaming!

Stability of working reagent: 2 weeks at 2-8°C
5 days at 15-25°C

Concentrations in the test

1-Reagent

Tris (pH 7.4)	≤ 150 mmol/l
L-alanine	≤ 750 mmol/l
LDH	≤ 4 U/ml
stabilzer, preservative	

2-Reagent

2-oxoglutarate	≤ 74 mmol/l
NADH	≤ 1.7 mmol/l
buffer	
preservatives	

Warnings and notes

- Protect from direct sunlight and avoid contamination!
- The reagents are usable when the absorbance of the working reagent is higher than 1.400 (read against distilled water, wavelength λ=340 nm, cuvette l = 1cm, at temp. 25°C).
- Please refer to the MSDS for detailed information concerning safe storage and use of the product.

ADDITIONAL EQUIPMENT

- automatic analyzer or photometer able to read at 340 nm (Hg 334 nm, 365 nm);
- thermostat at 37ºC;
- general laboratory equipment;

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 15-25ºC or up to 7 days at 2-8ºC.
Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

Applications for analysers are available on request.

Manual procedure

wavelength	340 nm (Hg 334 nm, 365 nm)
temperature	37°C
cuvette	1 cm

Sample Start method

Pipette into the cuvette:

working reagent	1000 µl

Bring up to the temperature of determination 37°C for 10 minutes. Then add:

sample	100 µl

Mix and incubate at adequate temperature. After about 1 min. read the absorbance against air or water. Repeat the reading after exactly 1, 2 and 3 minutes. Calculate the mean absorbance change per minute (ΔA/min.).

Calculation

ALAT activity [U/l] = ΔA/min. x F

F value depends on the used wavelength:

λ	334 nm	340 nm	365 nm
F	1963	1973	4893

Reagent Start method

The determination can be also performed with use of separate 1-ALAT and 2-ALAT reagents.

Pipette into the cuvette:

1-ALAT	1000 µl

Bring up to the temperature of determination. Then add:

sample	100 µl

Mix well, incubate for 5 min. Then add:

2-ALAT	250 µl

Mix well; perform measurement as described for Sample Start method.

Calculation

ALAT activity [U/l] = ΔA/min. x F

F value depends on the used wavelength:

λ	334 nm	340 nm	365 nm
F	2435	2471	5778

REFERENCE VALUES [6]

serum / plasma	37ºC	
women	up to 31 U/l	up to 0.517 µkat/l
men	up to 41 U/l	up to 0.683 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 with each batch of samples the CORMAY SERUM HN (Cat. No 5-172) and CORMAY SERUM HP (Cat. No 5-173).
For the calibration of manual assay the CORMAY MULTICALIBRATOR LEVEL 2 (Cat. No 5-175; 5-177) is recommended.
For the calibration of automatic analysers systems the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) and LEVEL 2 (Cat. No 5-175; 5-177) are recommended. Deionised water should be used as a calibrator 0.
The calibration curve should be prepared every 12weeks (Biolis 24i Premium), with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

The following results have been obtained using Multi+ for manual assay and automatic analyser Biolis 24i Premium. Results may vary if a different instrument is used.

- **Limit of quantitation (LOQ):**
  7 U/l (0.12 µkat/l) – Multi+
  8 U/l (0.13 µkat/l) – Biolis 24i Premium.

- **Linearity:**
  up to 600 U/l (10 µkat/l) – Multi+
  up to 675 U/l (11.25 µkat/l) – Biolis 24i Premium

- **Specificity / Interferences**

Haemoglobin up to 0.31 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 (Biolis 24i Premium)**

Repeatability (run to run) n = 20	Mean [U/l]	SD [U/l]	CV [%]
level 1	32.0	1.4	4.4
level 2	98.03	2.2	2.2
Reproducibility (day to day) n = 80	Mean [U/l]	SD [U/l]	CV [%]
level 1	32.4	1.35	4.2
level 2	106	2.1	1.9

- **Method comparison**

A comparison between ALAT values determined at **Multi+** (y) and at **Beckman Coulter AU680** (x) using 22 serum samples gave following results:

Sample Start method

y = 0.9605x + 2.4819 U/l;
R = 1.000 (R – correlation coefficient)

Reagent Start method

y = 0.9369x + 2.3318 U/l;
R = 1.000 (R – correlation coefficient)

A comparison between ALAT values determined at **Biolis 24i Premium** (y) and at **Cobas 6000** (x) using 128 serum samples gave following results:
y = 1,0404 x + 1,4875 U/l;
R = 0.999 (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Wallhofer H., Schmidt E., Schmidt U.F. W.: Synopsis Der Leberkrankheiten. G. Thieme Verlag, Stuttgart (1974).
2. Thefeld W., et al: Dtsch. Med. Wschr. 99, 343 (1974).
3. Bergmeyer H.U., Horder M., Rej R.: J. Clin. Chem. Clin. Biochem. 24, 481-495 (1986).
4. Henry R.J. Cannon D.C. Winkerman J. W.: Clinical Chemistry Principles and Technics, 2nd ed. Hagerstown MD: Harper and Row, 815, 888 (1974).
5. Burtis C.A., Ashwood E.R., ed. Tietz Textbook of Clinical Chemistry, 3rd ed. Philadelphia, PA: Moss D. W., Henderson A. R., 652 (1999).
6. Dembińska-Kieć A., Naskalski J.W.: Diagnostyka laboratoryjna z elementami biochemii klinicznej, Volumed, 776, (1998).

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