



ALT- GPT LR liquid reagent

REF C3800650 1280 Test

CE C3800650A 1280 Test

IVD For in vitro medical device

Analytical Sensitivity

The test sensitivity in terms of detection limit is 2.5U/l.

"Intra-Assay" precision (within-Run)

Determined on 20 samples for each control (N-H) (Normal-High). Results:

MEAN (U/l) N = 41.15 H = 130.50

S.D. N = 1.53 H = 2.09

C.V.% N = 3.71 H = 1.60

"Inter-Assay" precision (between-run)

Determined on 20 samples for each control (N-H) Results:

MEAN (U/l) N = 41.55 H = 131.65

S.D. N = 1.40 H = 2.35

C.V.% N = 3.36 H = 1.78

Correlation

A study based comparing this method with a similar method on 20 samples has given a correlating factor $r = 0.99$

$$y = 0.9254x + 1.5293$$

Interferences

No interferences was observed by the presence of:

Bilirubin ≤ 30 mg/dl.

Triglycerides ≤ 1000 mg/dl.

Ascorbate acid ≤ 25 mg/dl.

Haemolysed specimens should not be used for analysis.

Quality Controls

It's necessary, each time the kit is used, to make the quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should establish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.

Bibliography

Wroblewski F, La Due JS.: Proc. Sec. Exp. Biol. and Med., 34, 381 (1956).

Bergmeyer HU, Horder M, Rej R.: International Federation of Clinical Chemistry (IFCC) Scientific Committee. J. Clin. Chem. Clin. Biochem., 24, 481 (1986).

Lorentz K, Röhle G, Siekmann L.: DG Klinische Chemie Mitteilungen, 26, 190 (1995).

Kaplan LA, Pesce AJ.: "Clinical Chemistry", Mosby Ed. (1996).

Symbols

CE CE Mark (98/79 CE regulation)

IVD in vitro medical device

LOT Batch Code

Hourglass Use by

Thermometer Storage temperature limits

Open book Read instruction for use

Factory Gesana Production srl

Use

Kit for measurement of alanine-aminotransferase in serum or plasma. Kinetic UV optimized method IFCC*

* International Federation of Clinical Chemistry and Laboratory Medicine

Summary

ALT measurements are used in the diagnosis and treatment of certain types of liver and heart disease.

Principle

The enzyme alanine-aminotransferase (ALT) (or glutamic-pyruvic transaminase/GPT) catalyzes reaction between alpha-ketoglutarate and L-alanine giving glutamate and pyruvic acid. In presence of lactate dehydrogenase (LDH), pyruvic acid reacts with NADH giving lactic acid and NAD+. The rate of decrease in absorbance due to the oxidation of NADH to NAD+ is directly proportional to sample Alt activity. In the reagent is contained also LDH to convert the endogenous pyruvate into lactate during the preincubation.

Reagents

R1 Goods buffer pH 7.5 80.0 mmol/l;

L-alanine 500.0 mmol/l;

LDH ≥ 1500 U/l;

R2 Goods buffer pH 7.5 80.0 mmol/l;

alpha-ketoglutarate 65.0 mmol/l;

NADH ≥ 1.18 mmol/l

Reagents Preparation

Reagents are liquid and ready to use. About using as monoreagent ("sample-starter" procedure) add the entire contents of one bottle of ALT R2 in the ALT R1 bottle and mix gently. For minor use add to every 4 ml of R1 reagent, 1 ml of R2 reagent. Keep out the reagents from refrigerator only for the use and recap them immediately.

Storage And Stability

- Store the kit at 2-8°C.

- After opening, the vials R1 and R2 are stable 90 days if recapped immediately and protected from contamination, evaporation, direct light, and stored at the correct temperature.

- Working solution stability (R1+ R2): 20 days at 2-8°C.

Precaution in Use

The product is not classified as dangerous (DLg. N. 285 art. 28 l. n. 128/1998).

However the reagent should be handled with care, according to good laboratory practice.

Caution: the reagents contain Sodium Azide (0.095%) as preservative. Avoid swallowing and contacting with skin, eyes and mucous membranes. In case of contact with eyes rinse immediately with plenty of water and seek medical advice.

Waste Management

Please refer to the local legal requirements.

Specimen Collection and Preparation

- Serum-heparinized plasma or EDTA plasma.

- Do not use samples with haemolysis because this one could cause wrongly positive results.

- The ALT activity tends to decrease ($< 10\%$) after 3 days at 2-8°C.

Note

- The kit, according to this method, must be used in manual procedures. About automatic using follow specific applications.

- Avoid direct light, contamination and evaporation.

- The volumes in the procedure can be changed proportionally.

- In case of complaint or quality control request, refer to the lot number on the package or the lot number on the singles vials.

Procedures

Wavelength λ : 340 (334-365) nm

Working temperature 37°C

Optical path 1 cm

Reaction kinetic (decreasing)

Bring the reagents at 15-25°C before using them.

Monoreagent Procedure "sample starter"

	BLANK	SAMPLE
Working Reagent	1000 μ l	1000 μ l
Distilled Water	100 μ l	--
Sample	--	100 μ l

Mix, then incubate for 1' a 37°C. Measure the absorbance of sample (EC) at time 0 and after 1, 2, 3 minutes. Then, calculate the absorbance variation $\Delta E/\text{min}$ obtained by performed readings.

Bireagent Procedure "substrate starter"

	BLANK	SAMPLE
Reagent R1	800 μ l	800 μ l
Distilled Water	100 μ l	--
Sample	--	100 μ l
Reagent R2	200 μ l	200 μ l

Mix, then incubate for 1' a 37°C. Then add: Mix, then incubate for 1' a 37°C. Measure the absorbance of sample (EC) at time 0 and after 1, 2, 3 minutes. Then, calculate the absorbance variation $\Delta E/\text{min}$ obtained by performed readings.

Calculation

$$\text{ALT [U/l]} = \Delta E/\text{min} \times 1746$$

The factor and the reagent performances are related to 37°C, 1 cm and 340 nm.

Reference Values to 37°C

Serum - plasma [U/l] 37°C

Women ≤ 31 U/L

Men ≤ 41 U/L

Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

ANALYTICAL PERFORMANCES

Linearity

Reaction is linear up to a concentration of 400 U/l. Samples with values exceeding this range must be diluted with saline solution. Then multiply the result for the diluting factor.

Alt-Gpt

Mod. 7.3.5 Rev. 0 of 2005-07

Gesana Production s.r.l.