

GPT-ALT



For in vitro medical device
10122 – 10x20 ml
10123 – 6x50 ml

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

* International Federation of Clinical Chemistry and Laboratory Medicine

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 absorbance variation is proportional to the ALT activity. In the reagent is contained LDH to convert the endogenous pyruvate into lactate during the preincubation.

REAGENTS

R1 TRIS buffer pH 7.5 80.0 mmol/l; L-alanine 500.0 mmol/l;
alpha-ketoglutarate 15.0 mmol/l; preservatives and no reactive stabilizers.
R2 NADH 0.22 mmol/l; LDH ≥ 2000 U/l.

SAMPLE

- Serum-heparinized plasma or EDTA plasma.

Note

- Do not use samples with haemolysis because this one could cause wrongly overestimated results.
- The ALT activity tends to decrease (< 10%) after 3 days at 2-8°C.

REFERENCE VALUES

Serum - plasma [U/l]	37°C
Women	<36
Men	<46

References values are considered indicatives since each laboratory should establish references ranges for its own patient's population. The analytical results should be evaluated with other information coming from patient's clinical story.

PREPARATION OF REAGENTS

Dissolve the content of **R2** vial with:

vial 20 ml: 20 ml of **R1** solution
vial 50 ml: 50 ml of **R1** solution

Keep out the reagents from refrigerator only for the use and recap them immediately.

STORAGE AND STABILITY

- Store the kit at 2-8°C. Do not freeze the reagents.
- Reconstituted reagent stability: 21 days at 2-8°C.

NOTE

- The kit, according to this method, must be used in manual procedures. About automatic using follow specific applications.
- Evaluate carefully the results if working reagent absorbance is < 1.000 at 340 nm.
- 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.

AUXILIARY EQUIPMENT

Materials not included in the kit: diluent solutions, laboratory glassware, disposable tips, photometers and calibrators.

QUALITY CONTROLS

It's necessary, every 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.

Suggested serum:

REF 20350 Precise Norm **REF** 20360 Precise Path

PRECAUTION IN USE

The product is not classified as dangerous (DLg. N. 285 art. 28 l. n. 128/1998). The total concentration of components is lower than the limits reported by 67/548 and 88/379 CE Regulations (and following modifications) about classification, packaging and labelling of dangerous substances.
However the reagent should be handled with caution, 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.

WASTE MANAGEMENT

Please refer to the local legal requirements.

PROCEDURE

Wavelength λ: 340 nm
Working temperature 37°C
Optical path 1 cm
Reaction kinetic (decreasing)

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

	BLANK	SAMPLE
WORKING REAGENT	1000 µl.....	1000 µl
DISTILLED WATER	100 µl	---
SAMPLE	---	100 µl

Mix, then incubate for 1' a 37°C. Measure the initial absorbance and at 1 minute intervals thereafter for 3 minutes. Calculate the difference between consecutive absorbances, and the average absorbance difference per minute (ΔE/min)..

CALCULATION

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

ANALYTICAL PERFORMANCES

Interferences

Bilirubin does not interfere up to concentration of 40 mg/dl.
Triglycerides do not interfere up to concentration of 2000 mg/dl.
Hemoglobin does not interfere up to concentration of 400 mg/dl.
Ascorbate acid does not interfere up to concentration of 30 mg/dl.

Linearity

Reaction is linear up to a concentration of 350 U/l. Samples with values exceeding this range must be diluted with saline solution. Multiply, then, the result for diluting factor.

"Intra-Assay" precision (within-Run)

Determined on 30 samples for each control (L-N-H) (Low-Normal-High).

Results:

MEAN (U/l)	L = 25.93	N = 53.82	H = 118.53
S.D.	0.64	1.12	2.61
C.V.%	2.46	2.07	2.20

"Inter-Assay" precision (between-run)

Determined on 15 samples for each control (L-N-H) for 3 days.

Results:

MEAN (U/l)	L = 28.20	N = 57.18	H = 114.02
S.D.	0.71	1.28	2.57
C.V.%	2.52	2.24	2.25

Analytical sensitivity

The test sensitivity in terms of detection limit is 4 U/l.

Correlation

A study based comparing this method with a similar method on 21 samples has given a correlating factor **r = 0.90**

BIBLIOGRAPHY

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SYMBOLS



Read instruction for use



CE mark (requirement of 98/79 regulation)



Storing temperature limits



In vitro medical device



Producer