

ALT/GPT SL

Kinetic method UV - IFCC
Liquid Reagents ready to use

REF 12004160 R1 8X20mL
REF 11201040 R2 8X5mL

IVD

PRODUCT CODE: ALT-8D25

INTENDED USE

Quantitative determination of alanine amino transferase (ALT/GPT) in serum and plasma according to IFCC recommendations.

PRINCIPLE

In presence of α -ketoglutarate, alanine is transformed into pyruvate and glutamate by ALT/GPT in the sample. In presence of NADH and lactate dehydrogenase, pyruvate is converted into lactate and NAD. NADH oxidation in time unit, measured at 340 nm, is proportional to ALT/GPT concentration in the sample.

SAMPLE

Serum, plasma with heparin or EDTA. Do not use hemolyzed samples. ALT/GPT activity in serum is stable 3 days at 2-8°C.

KIT COMPONENTS

Reagent (A) ALT Volume = 40/80 ml	Tris buffer pH 7.8 L-alanine LDH	100 mmol/l 500 mmol/l 1000 U/l
Reagent (B) ALT Volume = 10/40/80 ml	NADH α -ketoglutarate	0.18 mmol/l 15 mmol/l

The reagents are stable until the expiration date indicated on the label if stored at 2-8°C and protected from light. Do not use over expiry date. Once opened reagents are stable for 2 months at 2-8°C if contamination is avoided. Do not freeze.

Keep bottles closed when not in use.

REAGENT PREPARATION

Liquid reagents, bring to room temperature (15-25°C) before use. For use as monoreagent: add 1 part of Reagent (B) to 4 parts of Reagent (A).

The working solution (A+B) is stable 2 weeks at 2-8°C.

PRECAUTIONS AND WARNINGS

EC Regulation 1272/2008 (CLP):

Reagent (A):

EUH210 Safety data sheet available on request.

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow. Use the normal precautions required in the laboratory. Dispose of waste according to local laws.

PROCEDURE

Wavelength:	340 nm
Lightpath:	1 cm
Temperature:	37°C
Reading:	against distilled water
Method:	decreasing kinetic

Use as monoreagent:

pipette:	
Working solution (A+B)	300 μ l
sample	30 μ l

Mix, incubate at 37°C for 1 minute, read initial absorbance against water. Make 3 readings at a distance of 60 seconds. Calculate the average value of the absorbance variations per minute. ($\Delta A/min$).

Use as bireagent:

pipette:	
Reagent (A)	240 μ l
Sample	30 μ l
mix and after 30 seconds add:	
Reagent (B)	60 μ l



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Mix, incubate at 37°C for 1 minute, read initial absorbance against water. Make 3 readings at a distance of 60 seconds. Calculate the average value of the absorbance variations per minute. ($\Delta A/min$).

RESULTS CALCULATION

Perform calculation in Units per litre, multiplying the $\Delta A/min$ by the factor as it is indicated:

$$\text{Activity in U/L: } \Delta A/min \times 1750 (*)$$

(*) Factor calculated in our laboratories. We recommend the use of SicuroBio calibrator Acucal (Ref. SB-8327) to verify that this factor is correct for your test system.

EXPECTED VALUES

Men: ≤ 40 U/L

Women: ≤ 32 U/L

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL

You must perform the controls at each kit's use and verify that the values obtained are within the reference range reported in the operating instructions. For this purpose we recommend the use of SicuroBio control sera: ACUTROL 1 (REF. SB-8334) and ACUTROL 2 (REF. SB-8335).

PERFORMANCE

Sensitivity: the sensitivity of the method is: 4 U/L

Linearity: the method is linear up to 450 U/L. For higher values, dilute the sample 1:10 and multiply the result by 10.

Precision intra-assay:

	Level 1	Level 2	Level 3
Mean (U/l)	27.80	60.90	122.9
SD	0.632	1.197	0.876
CV %	2.28	1.97	0.71

Precision inter-assay:

	Level 1	Level 2	Level 3
Mean (U/l)	27.70	68.00	131.2
SD	0.675	1.247	1.317
CV %	2.44	1.83	1.00

Interferences: the bilirubin does not interfere up to 40 mg/dl. Hemolysis presence in the sample causes falsely positive results. Anticoagulants currently in use like heparin, EDTA, oxalate, fluoride do not affect the results.

Correlation against a reference method:

$$Y = 1.0356x + 0.4362 \quad r = 0.9975$$

REFERENCES

1. Tietz N. W. et al. Clin. Guide to Laboratory tests, (1995), 76.
2. Young, D.S., Effects of drugs on Clinical Lab. Tests, AACC Press, 1995.
3. Young, D.S., Effects of disease on Clinical Lab. Tests, AACC, 2001.
4. Burtis A. et al. Tietz Textbook of Clin. Chemistry, AACC, 1999.