Instructions For Use

GENESIS

GPT/ALT (IFCC Method) (4+1)

Cat no.	size
1205 101	5*10
1205 102	10*10
1205 103	5*20
1205 104	10*20
1205 105	2*25

INTENDED USE

GPT/ALT Reagent is intended for the in vitro Quantitative diagnostic determination of Alanine Aminotransferase (ALT) in human serum and plasma.

DIAGNOSTIC CHARACTERISTICS

The aminotransferase catalyze the formation of glutamic acid from 2-oxoglutarate by transfer of amino groups. ALT is normally present in various tissues but its higher concentrations are found in liver and kidney.

The serum concentration of ALT is elevated in hepatitis and other forms of hepatic disease associated with necrosis: infectious mononucleosis, cholestasis, cirrhosis, metastasic carcinoma of the liver, delirium tremens, and after administration of various drugs, such as opiates, salycilates or ampicillin. Serum ALT concentration can also be elevated in skeletal or cardiac muscle disease.

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

PRINCIPLE OF THE METHOD

Alanine aminotransferase (ALT or GPT) catalyzes the transfer of the amino group from alanine to 2-oxoglutarate, forming pyruvate and glutamate. The catalytic concentration is determined from the rate of decrease of NADH, measured at 340 nm, by means of the lactate Dehydrogenase (LDH).

Alanine + 2 – Oxoglutarate $\xrightarrow{ALT}$ Pyruvate + Glutamate

Pyruvate + NADH + H^+ $\xrightarrow{LDH}$ Lactate+ NAD^+

COMPOSITION

Reagent (R1)	Tris buffer	121 mmol/L
	L-Alanine	100 mmol/L
	Lactate dehydrogenase	>300 U/L
Reagent (R2)	NADH	2.0 mmol/L
	2-oxoglutarate	75 mmol/L
	Sodium Azide	9.5 g/L

STORAGE

Store at 2 - 8°C

The reagent is stable until expiration date stated on vial label.

REAGENT PREPARATION

Working reagent: (4) Parts of (R1) are mixed with (1) part of (R2).

Working reagent is stable for 3 weeks at 2 - 8 °C .

ADDITIONAL EQUIPMENT

− Thermostatic water bath at 37ºC.

− Analyzer, spectrophotometer able to read at 340nm.

SPECIMEN.

1. Serum and plasma collected by standard procedures.
2. Alanine aminotransferase in serum and plasma is stable for 7 days at 2-8ºC.
3. Use heparin as anticoagulant.

Precautions and Warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Symbols in Product Labeling

EC REP	Authorized Representative		Expiration date
IVD	For in-vitro diagnostic use		CAUTION, consult instructions for use
REF	Catalogue number		
LOT	Lot number		Manufactured by
	Consult instructions for use		Temperature Limit

PROCEDURE

1. Bring the Reagent to room temperature.
2. Assay parameters:

Mode:	Kinetic
Wavelength:	340 nm
Cuvette:	1 cm light path
Constant temperature :	37ºC
Delay Time:	60 sec
Measuring Time	180 sec

3. Adjust the instrument to zero with distilled water or air.
4. Pipette into a cuvette:

Working reagent	1.0 ml
sample	100 µL

5. Mix and incubate for 60 seconds**.**
6. Read initial absorbance (A) of the sample, start the stopwatch and read absorbance at 1 minute intervals thereafter for 3 minutes.
7. Calculate the difference between absorbance and the average absorbance differences per minute (ΔA/min).

CALCULATIONS

ALT(U/l) = Δ A/min x 1746

REFERENCE VALUES

Females	up to 31 U/l (up to 0.52 mKat/L)
Males	up to 41 U/l (up to 0.68 mKat/L**)**

QUALITY CONTROL

It is recommended to use the Control Serum level I and II to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control

METROLOGICAL CHARACTERISTICS

− Detection limit: 1.6 U/L = 0.027 µkat/L

− Linearity limit: 400 U/L = 13.3 µkat/L.

− For higher values dilute sample **1/5** with physiological saline and repeat measurement.

− Repeatability (within run):

Mean Concentration	CV	n
43 U/L = 0.72 µkat/L	1.8 %	20
192 U/L = 3.2 µkat/L	2.8%	20

− Reproducibility (run to run):

Mean Concentration	CV	n
43 U/L = 0.72 µkat/L	5.3 %	25
192 U/L = 3.2 µkat/L	2.7%	25

− INTERFERENCES:

−Bilirubin (20 mg/dL) does not interfere. Lipemia (triglycerides 2 g/L) and hemolysis may affect the results.

Other drugs and substances may interfere.

BIBLIOGRAPHY

1.IFCC primary reference procedures for the measurement of catalytic activity concentrations of enzymes at 37 ˚C. Part 4. Reference procedure for the measurement of catalytic concentration of alanine aminotransferase. Clin Chem Lab Med 2002; 40: 718-724.

2. IFCC reference procedures for measurement of catalytic concentrations of enzymes: corrigendum, notes and useful advice. Clin Chem Lab Med 2010; 48: 615-621.

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CE

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