Atlas Medical CE

GPT (ALT) TEST Kinetic

IVD *For In Vitro Diagnostic and professional Use Only.*

Store at 2-8°C

INTENDED USE

For the quantitative determination of alanine aminotransferse (ALT) concentration in human serum or plasma.

INTRODUCTION

Alanine aminotransferase (ALT) formerly called Glutamate pyruvate transaminase (GPT) is an enzyme found mostly in the cells of the liver and kidney. Much smaller amounts of it are also found in the heart and muscles. This test measures the level of ALT in the blood. Your body uses ALT to break down food into energy. Normally, ALT levels in the blood are low. If your liver is damaged, it will release more ALT into your blood and levels will rise.

PRINCIPLE OF THE METHOD

Alanine aminotranferase (ALT) or Glutamate pyruvate transaminase (GPT) catalyses the reversible transfer of an amino group from alanine to α-ketoglutarate forming glutamate and piruvate.

The piruvate produced is reduced to lactate by lactate dehydrogenase (LDH) and NADH:

Alanine + α-Ketoglutarate $\xrightarrow{ALT}$ Glutamate + Piruvate

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

The rate of decrease in concentration of NADH, measured photometrically, is proportional to the catalytic concentration of ALT present in the sample[1].

REAGENTS

R 1 Buffer	TRIS pH 7.8	100 mmol/L
	L-Alanine	500 mmol/L
R 2 Substrate	NAD	0.18mmol/L
	Lactate dehydrogenase (LDH)	1200 U/L
	α-Ketoglutarate	15 mmol/L

EQUIPMENTS NEEDED BUT NOT PROVIDED

- Spectrophotometer or colorimeter measuring at 340 nm.
- Thermostatic bath at 25°C, 30°C, 37° C (± 0.1°C).
- Matched cuvettes 1.0 cm light path.
- General laboratory equipment.

PREPARATION

Working reagent (WR):

- Dissolve one tablet of R2 Substrate in 2 mL of R1.cap and mix gently to dissolve contents.
- Stability: 21 days at 2-8°C or 72 hours at room temperature (15-25°C).

STORAGE AND STABILITY

- All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C, protected from light and contaminations prevented during their use.
- Do not use the tablets if appears broken.
- Do not use reagents over the expiration date.
- Signs of reagent deterioration:
  - Presence of particles and turbidity.
  - Blank absorbance (A) at 340 nm < 1.00.

SAMPLES

Serum or plasma[1]: Stability 7 days at 2-8°C.

PROCEDURE

1. Assay conditions:
   Wavelength: .....340 nm
   Cuvette :.....1 cm light path
   Constant temperature .....25°C / 30°C / 37°C
2. Adjust the instrument to zero with distilled water or air.
3. Pipette into a cuvette:

WR (mL)	1.0
Sample (µL)	100

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

CALCULATIONS

ΔA/min x 1750 = U/L of ALT

Units: One international unit (IU) is the amount of enzyme that transforms 1 µmol of substrate per minute, in standard conditions. The concentration is expressed in units per liter of sample (U/L).

Temperature conversion factors

To correct results to other temperatures multiply by:

Assay temperature	Conversion factor to		
	25°C	30°C	37°C
25°C	1.00	1.32	1.82
30°C	0.76	1.00	1.39
37°C	0.55	0.72	1.00

QUALITY CONTROL

- Control sera are recommended to monitor the performance of assay procedures.
- If control values are found outside the defined range, check the instrument, reagents and technique for problems.
- Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES

	25°C	30°C	37°C
Men	up to 22 U/L	29 U/L	40 U/L
Women	up to 18 U/L	22 U/L	32 U/L

Normal newborns have been reported to show a reference range of up to double the adult, attributed to the neonate's hepatocytes. These values decline to adult levels by approximately 3 months of age.

These values are for orientation purpose; each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

1. *Measuring range:*

From *detection limit* of 0 U/L to *linearity limit* of 400 U/L. If the results obtained were greater than linearity limit, dilute the sample 1/10 with NaCl 9 g/L and multiply the result by 10.

2. *Precision:*

	Intra-assay (n=20)		Inter-assay (n=20)	
MEAN U/L	42	112	41	111
SD	0.47	0.96	0.79	2.21
CV (%)	1.12	0.85	1.90	1.98

3. *Sensitivity:*

1 U/L = 0.000503 ΔA / min.

4. *Accuracy:*

Results obtained using ATLAS reagents (y) did not show systematic differences when compared with other

commercial reagents (x). The results obtained using 50 samples were the following:
Correlation coefficient $(r)^2$: 0.9869.
Regression equation: y= 1.0589x – 0.6075.
The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

Anticoagulants currently in use like heparin, EDTA, oxalate and fluoride do not affect the results. Hemolysis interferes with the assay.
A list of drugs and other interfering substances with ALT determination has been reported by Young.

REFERENCES

1. Murray R. Alanine aminotransferase. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984; 1088-1090.
2. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed *AACC* Press, 1995.
3. Young DS. Effects of disease on Clinical Lab. Tests, 4th ed *AACC* 2001.
4. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
5. Tietz N W et al. Clinical Guide to Laboratory Tests, 3rd ed *AACC* 1995.

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PPI1636A01
Rev A (02.09.2019)

REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry