

GPT (ALT)

NADH Kinetic UV IFCC Liquid

IVD For *in-vitro* diagnostic and professional

use only



Store at 2-8°C



CLINICAL SIGNIFICANCE

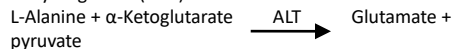
Alanine transaminase (ALT) is a transaminase enzyme. It is also known as alanine aminotransferase (ALAT) and was formerly known as serum glutamate-pyruvate transaminase (SGPT) or serum glutamic-pyruvic transaminase (SGPT). ALT is found in plasma and in various body tissues, but is most common in the liver. It catalyzes the two parts of the alanine cycle. Serum ALT level, serum AST (aspartate transaminase) level, and their ratio (AST/ALT ratio) are commonly measured clinically as biomarkers for liver health. The tests are part of blood panels.

ALT is commonly measured clinically as part of liver function tests and is a component of the AST/ALT ratio. When used in diagnostics, it is almost always measured in international units/liter (IU/L) or μkat . While sources vary on specific reference range values for patients, 0-40 IU/L is the standard reference range for experimental studies.

PRINCIPLE OF THE METHOD

Alanine aminotransferase (ALT) or Glutamate pyruvate transaminase (GPT) catalyses the reversible transfer of an amino group from alanine to α ketoglutarate forming glutamate and pyruvate. The pyruvate produced is reduced to lactate by lactate

dehydrogenase (LDH) and NADH:



This test has been formulated according to the standardized method described by IFCC.

REAGENTS

R 1 Buffer	TRIS buffer pH7.8	100 mmol/L
	Lactate dehydrogenase(LDH)	1200 U/L
	L-Alanine	500 mmol/L
R2 Substrate	NADH	0.18 mmol/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 ($\pm 0.1^\circ\text{C}$).
- Matched cuvettes 1.0 cm light path.
- General laboratory equipment.

PREPARATION

- Working reagent (WR):
Mix: 4 vol. (R1) Buffer + 1 vol. (R2) Substrate.
- Stability: 4 weeks at 2-8°C. Protect from light.

STORAGE AND STABILITY

- All components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C.
- Do not use reagents over the expiration date.
- Signs of reagent deterioration:
 - Presence of particles and turbidity.
 - Blank absorbance (A) at 340 nm < 1.000 in 1cm cuvette.

SAMPLES

Serum EDTA or heparinized plasma free of hemolysis. ALT is stable in serum or plasma for 24 hours at room temperature and for 1 week at 2-8°C.

PROCEDURE

- Assay conditions:
Wavelength :340 nm
Cuvette : 1 cm. light path
Constant temperature25°C /30°C / 37°C
- Adjust the instrument to zero either with distilled water or an empty cuvette.
- Pipette into a cuvette:

WR (mL)	1.0
Sample (μL)	100

- Mix sample and working reagent, start stop watch.
- Incubate reaction mix at one of the 3 temperatures mentioned in point 1.
- Read absorbance (A) at 1 minute intervals thereafter for 4 minutes.
- Calculate delta absorbance (ΔA) between each two successive minutes.
- Calculate the average of absorbance differences per minute ($\Delta A/\text{min}$).

CALCULATIONS

$\text{U/L} = \Delta A/\text{min} \times 1750$

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 litre 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

REFERENCE VALUES

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

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

INTERFERENCES

- Lipemia (intralipid >15 g/L) does not interfere.
- Bilirubin (>30 mg/dL) does not interfere.
- Hemoglobin (>10g/dL) does not interfere.
- Other drugs and substances may interfere.

QUALITY CONTROL

- 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.

ANALYTICAL PERFORMANCE

1. **Detection Limit:** 7.95 U/L.
2. **Linearity:** Up to 500 U/L.
3. **Precision:**

	Within-run		Between-run	
Mean (U/L)	32.4	140.8	32.4	140.8
SD	0.79	1.41	0.97	2.77
CV (%)	2.43	1.00	3.49	1.97
N	10	10	10	10

4. **Sensitivity:** 0.280 mA/min/U/L GPT.
5. **Correlation:** this assay (y) was compared with a similar commercial method (x).

The results were:

$$N=50 \quad (R)^2=0.99 \quad y=1.041x + 1.447$$

The analytical performances have been generated using an automatic instrument. Results may vary depending on the instrument.

Notes

1. The method may be used with different instruments .Applying method to another instrument require validation .Therefore, it is recommended to validate instrument periodically. Contact the distributor for any question on the application of method.
2. Clinical diagnosis should not be based on findings of a single test result. But should integrate both clinical and laboratory data.

















REFERENCES

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2. International Federation of clinical Chemistry (IFCC). Clin Chem Lab 1998;36:185.
3. Young DS. Effect of drugs on clinical laboratory tests. 5th ed . AACC Press,2000.
4. Tietz. Textbook of Clinical Chemistry, 2 edition. Burtis CA, Ashwood ER.W.B.Saunders Co. 1994.

 **ATLAS MEDICAL**
Ludwig-Erhard Ring 3
15827 Blankenfelde-Mahlow
Germany
Tel: +49 - 33708 – 3550 30
Email: Info@atlas-medical.com
Website: www.atlas-medical.com

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 REF	Catalogue Number		Temperature limit
 IVD	<i>In Vitro</i> 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