

BioMed-GPT



(ALAT/ALT/GPT) - Kinetic

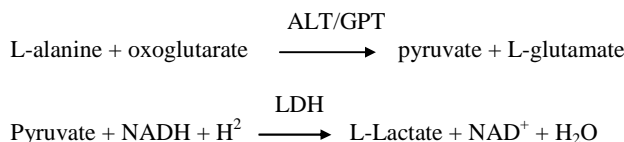
REF: GPT113100 (10 x10 ml)
GPT1131001 (2 x50 ml)

INTENDED FOR USE

For the quantitative determination of ALT/GPT in serum and plasma .

PRINCIPLE :

Present Kinetic method for determination of alanine amino transferase (GPT) without perod-oxalic-phosphate is optimized in accordance with I .F .C .C recommendations.



The reduced co enzyme consumption , observed as decrease of the per time extinction , is proportional to ALT/GPT activity in the sample.

SPECIMEN COLLECTION:

Non hemolyzed serum or plasma .

Notes :

Common anticoagulants can be used.

(Heparin , EDTA , oxalates , and fluorides) .

Shake and bring the samples at room temperature (+15-25°C) before using .

REAGENTS COMPOSITON :

R1	Good's Buffer	88 mmol/L
	L-Alanine	560 mmolL
	LDH	≥1500U/L
R2	NADH	0.24mmol/L
	oxoglutarate	16 mmol/L

PACKAGE : Collection & Storage .

Store at +2-8°C .

Stable until the expiration date reported upon the package.

After the unsealing and the taking of the reagent, it is advised to close up the bottle immediately in order to avoid evaporation, direct light exposure and bacteria contamination.

PRECAUTION & WARNING

Avoid pipetting by mouth .

The preparation , according to current regulation . is classified as not dangerous.

The total concentration of non active components (preservatives , detergents ,stabilizers) is below the minimum required for citation .

Anyway handle with care , avoid ingestion , avoid contact with eyes , skin and mucous membranes
The samples must be handle as potentially infected from HIV or Hepatitis .

REAGENT PREPARATION AND STABILITY :

Liquid reagents must be at room temperature (+15-25°C) before using .

Reagent(R1) is limpид/colorless .

Add 4 parts of Reagent (R1) to 1 part of Reagent(R2) .

Reagent (R1+R2) is reported stable up to 3 days at room temperature and 4 weeks if stored in refrigerator (2-8°C).

Ready to use liquid reagents.

REQUIRED MATERIALS NOT PROVIDED :

General Laboratory Equipment and instrumentations .

PROCEDURE :

Wavelength 334,340 or 365 nm
Optical path 1 cm
Incubation temperature 25,30 or 37°C
Zero adjustment Against air

Pipette into cuvette	Macro	Semi-micro
Specimen	200 µl	100 µl
Working solution	2.0 ml	1.0 ml
Mix, read initial absorbance after 60 sec. and start timer simultaneously. Read again after 1, 2 and 3 minutes. Determine the mean absorbance change per minute (A/min).		

CALCULATION :

340 nm AST/GPT (U/L) = ΔE/min Sample × 1746

334 nm AST/GPT (U/L) = ΔE/min Sample × 1780

365 nm AST/GPT (U/L) = ΔE/min Sample × 3235

EXPECTED VALUES :

	Women	Men
25°C	18 U/L	22 U/L
30°C	22 U/L	29 U/L
37°C	31 U/L	40 U/L

The above mentioned values are to be considered as a reference.

It is strongly recommended that each laboratory establish its own normal range according to its geographic area, according to IFCC protocol.

WASTE DISPOSAL :

The disposal of the product must be in accordance with local regulation concerning waste disposal.

QUALITY CONTROL :

It is recommended to execute the quality control at every kit utilization to verify that values are within the reference range indicated by the methodology.

PERFORMANCE :

MEASURE INTERVAL :	3-500 U/L
MEASURABLE LIMIT :	3 U/L
SENSITIVITY :	1 U/L= 0.0021 Δ E/min.

PRECISION WITH SERIES : n=20

LOW LEVEL	M = 34.9 U/L	C.V = 3.04%
HIGH LEVEL	M = 118 U/L	C.V = 0.99%

PRECISION AMONG SERIES : n=20

LOW LEVEL	M = 34 U/L	C.V = 3.1%
HIGH LEVEL	M = 118.3 U/L	C.V = 1.29%
CORRELATION	r = 0.998	n=50
LIN. REGRESSION	y= 0.98 x + 1.38	n=50

INTERFERENCE:

Interferences are negligible up to :			
Bilirubin	30 mg/dL	Triglycerides	500 mg/dL
Hemoglobin	400 mg/dL	Glucose	500 mg/dL

METHOD LIMITATIONS:










For concentration higher than 500 U/L for turbid and/or icteric specimens , repeat the measure on a sample diluted 1:10 with physiological saline and multiply the results by 10 .

Hemolyzed sample may provide elevated readings due to ALT presence in erythrocytes .

For through evaluation of the interfering substances ,consult : Young , D. S ,et al , Clin , Chem , 21:1 D (1975) .

REFERENCES :

1. Tietz, N.W. (ed) Fundamentals of Clinical Chemistry W.B.Saunders Co., Philadelphia, 1976.
2. Henry, R.J., Clinical Chemistry, Principles and Techniques. Harper and Row Publishers. New York, 1964.
3. Provisional Recommendations on IFCC methods for the measurement of catalytic concentrations of enzymes. Clin chem. 23(887), 1977.

	Consult Instructions for Use
	Caution, Consult accompanying
	In Vitro Diagnostic Medical
	Temperature Limitation
	Manufacturer
	Authorized Representative in the European Community
	Catalogue Number
	Batch Code
	Use by

 EGY- CHEM for lab technology Badr City, Industrial Area Piece 170 250 Fadan In East of Elrubaki, EGYPT Office Tel: +202 26236727 / +202 26236598 Factory Tel: +202 23108170 / +202 23108171 Fax: +202 26240986 www.egy-chem.com	  MDSS GmbH Schiffgraben 41 30175 Hannover, Germany
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