

SGPT (IFCC MODIFIED) WITHOUT PYRIDOXAL-5-PHOSPHATE

Invitro Diagnostic reagent kit for quantitative determination of Glutamate Pyruvate Transaminase / Alanine Transaminase (GPT/ALAT) in human serum/plasma sample on Photometric System.

ORDER INFORMATION		
Cat no.	Kit Configuration	Pack
LG120-100	Reagent R1: 2 X 40 mL Reagent R2: 2 X 10 mL	100ML
LG120-500	Reagent R1: 1 X 400 mL Reagent R2: 1 X 100 mL	500ML
LG120-1000	Reagent R1: 2 X 400 mL Reagent R2: 2 X 100 mL	1000ML

SUMMARY

Alanine aminotransferase (ALAT) is an enzyme found primarily in the liver and kidney. It was originally referred to as serum glutamic pyruvic transaminase (SGPT). Normally, a low level of ALAT exists in the serum. ALAT is increased with liver damage and is used to screen for and/or monitor liver disease. Alanine aminotransferase (ALAT) is usually measured concurrently with ASAT as part of a liver function panel to determine the source of organ damage.

REAGENT

Reagent 1: Enzyme Solution, Reagent 2: Buffer Solution

PRINCIPLE



The rate of NADH consumption is measured photometrically and is directly proportional to the ALAT concentration in the sample.

STORAGE INSTRUCTIONS AND REAGENT STABILITY

Reagent are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze the reagents!

COMPOSITION AND CONCENTRATIONS

TRIS buffer 12.1 g/L, L – Alanine 24.1 g/L, LDH (lactate dehydrogenase) ≥ 1200 U/L, 2-Keto glutaric acid 7.9 g/L, NADH 1.1 g/L
For professional use only!

WASTE MANAGEMENT

Please refer to latest Biological Medical Waste (BMW) guidelines and local legal requirements.

REAGENT PREPARATION

Mix, 4 parts of reagent 1 and 1 part of reagent 2 = working reagent. The stability of the working reagent is
5 days at 15°-25°C.
4 weeks at 2°- 8°C.
Protect the reaction solution from light.

MATERIALS REQUIRED BUT NOT PROVIDED

NaCl solution 9 g/L
General laboratory equipment

SPECIMEN

Serum, heparin, plasma or EDTA plasma separate at the latest 1h after blood collection from cellular contents.
7 days at 2° – 8°C
30 days at 20°C
Only freeze once! Discard contaminated specimens.

ASSAY PROCEDURE

Wavelength 340 nm
Optical Path 10 mm
Temperature 37°C

Sample	100 µL
Working reagent	1000 µL

Mix incubate for 1 min. and read absorbance after every 1 min. for 3 min.

CALCULATION

ΔA/min and multiply by the corresponding factor from table below:
ALAT activity U/L = ΔA/min x factor (1745)

QUALITY CONTROLS

For internal quality control any normal and abnormal controls should be assayed with each batch of samples.
Each laboratory should establish corrective action in case of deviations in control recovery.

WARNINGS AND PRECAUTIONS

- Keep out of reach of children. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- Take off immediately all contaminated clothing.
- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For professional use only!

PERFORMANCE CHARACTERISTICS

MEASURING RANGE

The test has been developed determine GPT/ALAT activities within a measuring range from 5 - 800 U/L. If such value is exceeded the sample should be diluted 1 + 4 with NaCl solution (9 g/L) and results multiplied by 5.

LINEARITY/LIMIT OF MAXIMUM DETECTION

The Linearity of detection is 800 U/L.

SENSITIVITY/LIMIT OF DETECTION

The lower limit of detection is 5 U/L

INTERFERENCES

No interference was observed by, Ascorbic acid up to 30 mg/dL, Bilirubin up to 40 mg/dL and Triglycerides up to 2000 mg/dL.

PRECISION

Intra assay n=20	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	34.62	0.29	0.84
Sample 2	82.22	0.31	0.38
Sample 3	191.37	0.66	0.35

Inter assay n=20	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	35.20	0.29	0.83
Sample 2	85.22	0.47	0.55
Sample 3	188.15	0.97	0.52

METHOD COMPARISON

A comparison of Precision Biomed GPT/ALAT (y) with a commercially available test (x) using 15 samples gave following results:
y = 1.037x-1.154; r2 = 0.993.

ASSAY PARAMETERS

Parameter	GPT / ALAT
Mode	Kinetic
Reaction slope	Decreasing
Wavelength	340 nm
Path length	10 mm
Temperature	37°C
Working reagent	4 part Reagent 1 1 Part Reagent 2
Working reagent Volume	1000 µL
Sample volume	100 µL
Delay	60 sec
Rate	60 sec
No. of readings	3
Factor	1745
Normal range	Male : < 41 U/L
Incubation Time	Female : < 31 U/L
Linearity	800 U/L
Sensitivity	5 U/L



REFERENCE RANGE

Women	< 31 U/L
Men	< 41 U/L

Note: It is recommended that each laboratory should establish its own reference range based on the patient population.

LITERATURE

- 1st ed. Frankurt: TH-Books Verlagsgesellschaft; 1998.p.55
- Tietz Textbook of clinical chemistry.3rded.
- Philadelphia: W.B saunders company; 1999.p.617-721.
- Clin Chem Lab Med 2002; 40:718-24.
- Association for Clinical Biochemistry and Laboratory Medicine
- Retrieved 7 October 2013.
- Central Pollution Control Board (CPCB) Guidelines for Management of healthcare waste as per Biomedical Waste Management rules, 2016.

INDEX OF SYMBOLS

ISO 13485	International Organization or Standardization	Keep out of Sunlight
	Manufacturer	For invitro diagnostic use only
	Expiry date	Read product insert before use.
	Lot (batch) number	Do not use if package is damaged
2-8°C	Store between 2-8°C	Keep Away From Moisture
ART/IFU/PRC-120-01		

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“Thinks for you”