Pariksha Biotech
A game changer in IVD

SGPT (ALT) Estimation Kit

High-Q SGPT (ALT)

IFCC Method

HIGH®
Command on Quality

Intented Use:
Kit for the quantitative determination of Alanine aminotransferase (ALT) in human serum and plasma.

Clinical Significance:
Alanine Aminotransferase (glutamate-pyruvate-transaminase) belongs to the group of transaminases which catalyze the conversion of amino acids to the corresponding á-keto acids via the transfer of amino groups; they also catalyze the reverse process. Although higher activities exist in the liver, minor activity can also be detected in the kidneys, heart, skeletal muscle, pancreas, spleen, and lungs. Elevated levels of transaminases are indicative of myocardial infarction, hepatopathies, muscular dystrophy, and damage to internal organs. Increased ALT activity in the serum, however, is a rather specific indicator of damage to the liver parenchyma, while AST is not necessarily a liver-specific parameter. In 1956, Wroblewski and LaDue described the first kinetic determination of ALT in serum. In 1977 and 1980, the International Federation of Clinical Chemistry (IFCC) recommended standardized methods for the determination of ALT with optimized substrate concentrations. The method described here is derived from the IFCC reference method.

Method:
Optimized UV-test according to IFCC (International Federation of Clinical Chemistry and Laboratory Medicine)

Principle

$$\text{L-Alanine} + \text{2-Oxoglutarate} \xrightleftharpoons{\text{ALAT}} \text{L-Glutamate} + \text{Pyruvate}$$

$$\text{Pyruvate} + \text{APADPH (NADH Analogue)} + H^{+} \xrightarrow{\text{LDH}} \text{D-Lactate} + \text{APADP (Oxidized NADH Analogue)}$$

Active ingredients in the reagents:

R1:	TRIS	pH 7.5	250mmol/l
	L-Alanine		500mmol/l
	LDH (Lactate Dehydrogenase)		> 5000 U/l
R2:	2-Oxoglutarate		20 mmol/l
	APADPH (NADH Analogue)		0.25 mmol/l
	Azide		0.1 %

Reagent Stability:

Both Reagent 1 (R1) and Reagent 2 (R2) are available as ready to use reagents and are stable till the expiry date mentioned on the labels.

It is not suggested to make the working reagent when NADH Anlaogues are used as the reagents are configured as R1 and R2 systems to be used separately.

Do not make the working reagent.

Mix R1 and R2 (800 R1 + 200 R2) along with sample at the time of testing

Specimen

1. Unhemolysed freshly collected serum/EDTA plasma (Morning samples are preferred).
2. Do not use the old samples that are stored for longer period as the internal pyruvate might give falsely elevated results.
3. Samples are stable for a week at 2-8°C and for a month when frozen at -10°C. Samples should be brought to room temperature prior to use.

Test Procedure:

Take the following in to clean glass test tube

R1	800 µl
Serum / Plasma	100 µl
R2	200 µl

Mix well and immediately aspirate in to the analyzer. After 10 Seconds incubation (Delay) , measure the change in optical density per 60 seconds during 240 seconds (Measuring) against distilled water at 340 nm as follows.

Ao - Exactly after 10 Seconds
A1, A2, A3, A4 - Exactly after every 60 seconds for 240 seconds.

Calculations:
Calculate the average change in absorbance per minute (△ Abs/min).

Activity of SGPT (ALT) in IU/L

At 340 nm in IU/L = △Abs / min x 2225

System Parameters:

Reaction type	:	Kinetic
Reaction Direction	:	Decreasing
Wavelength	:	340 nm
Flow cell temp	:	37°C
Zero setting with	:	Distilled water
Delay	:	10 Sec
Measuring	:	240 Sec
Reagent volume	:	1ml
Sample Volume	:	100 µl
Factor	**:**	**2225**
Linearity	:	750
Units	:	IU/L
Low normal	:	0.00
High normal	:	48.0

Note : In some of the instruments the factor should be entered as - 2225 as the reaction direction is decreasing

Performance Characteristics:
Measuring range
The test has been developed to determine ALAT activities, which correspond to a maximal △A/min of 0.337 (Equivalent to 750 IU/ml) at 340 nm. If such value is exceeded the sample should be diluted 1+9 with NaCl solution (9 g/l) and results be multiplied by 10.

Specificity/Interferences
No interference was observed by ascorbic acid up to 32 mg/dl, bilirubin up to 43 mg/dl, hemoglobin up to 500 mg/dl and lipemia up to 2200 mg/dl.

Analytical sensitivity (lower detection limit)
Detection limit: 4 U/l). The lower detection limit represents the lowest measurable SGPT concentration that can be distinguished from zero.

Precision:

Intra-assay precision N=20	**Mean** (IU/L)	**SD** (IU/L)	**CV** (%)
sample 1	30.6	0.59	1.92
sample 2	79.5	1.28	1.61
sample 3	119.0	1.08	0.91

Inter-assay precision N=20	Mean (IU/L)	SD (IU/L)	CV (%)
sample 1	33.1	0.78	2.37
sample 2	93.3	1.25	1.34
sample 3	137.0	2.20	1.61

Method Comparison:
A comparison of the High-Q SGPT (y) with a commercial obtainable assay (x) gave with 20 samples the following result y = 1.062 x + 0.261; r= 0.997

Reference range

Pariksha Biotech
A game changer in IVD

SGPT (ALT) Estimation Kit

High-Q SGPT (ALT)

IFCC Method

HIGH®
Command on Quality

Women	**< 30 (IU/L)**
Men	**< 48 (IU/L)**

Notes:

1. Do not leave the working reagent at room temperature when not in use. Take only the required amount of the reagent and keep the reagent back at 2-8°C immediately.
2. The reagent and sample volumes may be altered proportionally to accommodate into different analyzer requirements.
3. Using hemolysed sample is strictly restricted and the same may interfere with the original result.

Reference:

1. Bablok W et al. A General Regression Procedure for Method Transformation. J Clin Chem Clin Biochem 1988;26:783-790.

Order Information:

Ref./Cat. No.	Pack Size	Presentation
P-GPT - 50	2 x 25 ml	2 x 20 ml (R1) + 2 x 5 ml (R2)
P-GPT- 100	4 x 25 ml	4 x 20 ml (R1) + 4 x 5 ml (R2)
P-GPT- 250	10 x25 ml	10 x 20 ml (R1) + 10 x 5ml (R2)

Product Features

- **Liquid stable, ready to use two Reagents (4 parts R1 + 1 part R2).**
- **APADPH (NADH Analogue) is used for better stability**
- **4 Minutes decreasing kinetic reaction (10 Sec Delay+ 240 Sec Measuring)**
- **Linearity: 750 IU/L**
- **Kinetic Factor 2225**
- **Measuring Wavelength 340 nm**
- **Serum/ EDTA Plasma as specimens**
- **Available as multipurpose reagents and dedicated system packs**

Pariksha Biotech
A game changer in IVD

Symbols used with IVD devices

	Date of manufacture		Manufactured by
IVD	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)	R	Reagent
CAL	Calibrator Material	LOT	Batch code
2°C 8°C	Temperature limitation (store at)	CONTROL	Control
	Consult instructions for use		Keep dry Keep away from rain
REF	Catalog Number		

eIFU Indicator

Pariksha's world inside
SCAN TO EXPLORE MORE

Manufactured in India by :
Pariksha Biotech Pvt Ltd,
Plot no.1/B-14, SVICE,
Balanagar,
Hyderabad-500037
Telangana State

+91 7075706709 info@parikshabio.com www.parikshabio.com

AN ISO 13485 Certified Company

Rev # 2