Pariksha Biotech
A game changer in IVD

SGOT (AST) Estimation Kit

High-Q SGOT (AST)

IFCC Method

HIGH®
Command on Quality

Intented Use:
It for the quantitative determination of Aspartate aminotransferase (AST) in human serum and plasma.

Summary:
Aspartate aminotransferase (glutamate oxaloacetate transaminase) belongs to the transaminases, which catalyze the interconversion of amino acids and á-ketoacids by transfer of amino groups. Aspartate aminotransferase is commonly found in human tissue. Although heart muscle is found to have the most activity of the enzyme, significant activity has also been seen in the brain, liver, gastric mucosa, adipose tissue, skeletal muscle, and kidneys. AST is present in both the cytoplasm and mitochondria of cells. In cases involving mild tissue injury, the predominant form of AST is that from the cytoplasm, with a smaller amount coming from the mitochondria. Severe tissue damage results in more of the mitochondrial enzyme being Rele sed. Elevated levels of the transaminases can signal myocardial infarction, hepatic disease, muscular dystrophy, and organ damage. In 1955, Karmen et al described the first kinetic determination of AST activity in serum. The International Federation of Clinical Chemistry (IFCC) recommended in 1977 and 1980 standardized procedures for AST determination, including optimization of substrate concentrations, employment of TRIS* buffers, preincubation of combined buffer and serum to allow side reactions with NADH to occur, substrate start, and optional pyridoxal phosphate activation. This method is derived from the IFCC reterence method.
*TRIS = Tris(hydroxymethyl)-aminomethane

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

Principle

$$\text{L-Aspartate} + \text{2-Oxoglutarate} \xrightarrow{\text{ASAT}} \text{L-Glutamate} + \text{Oxaloacetate}$$

$$\text{Oxaloacetate} + \text{APADH (NADH Analogue)} + H^{+} \xrightarrow{\text{MDH}} \text{L-Malate} + \text{APAD (Oxidized NADH Analogue)}$$

Reagents

R1:	TRIS pH 7.65	100 mol/l
	L-Aspartate	250 mmol/l
	MDH (Malate Dehydrogenase)	≥550 U/l
	LDH (Lactate Dehydrogenase)	≥700 U/l
R2:	2-Oxoglutarate	10 mmol/l
	APADH (NADH Analogue)	0.20 mmol/l

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 and store.

Working reagent can be made at the time of testing as per the requirement.

Mix R1 and R2 (800 µl R1 + 200 µl 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 and grossly hemolyzed samples that are stored for longer period as they 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 60 Seconds incubation, measure the change in optical density per 60 seconds during 180 seconds against distilled water at 340 nm as follows.

Ao - Exactly after 60 Seconds
A1, A2, A3 - Exactly after every 60 seconds for 180seconds.

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

Activity of SGOT (AST) in IU/L

At 340 nm in IU/L = △Abs / min x 1975

System Parameters:

Reaction type	:	Kinetic
Reaction Direction	:	Decreasing
Wavelength	:	340 nm
Flow cell temp	:	37°C
Zero setting with	:	Distilled water
Delay	:	60 Sec
Measuring	:	180 Sec
Reagent volume	:	800 µl R1 + 200 µl R2
Sample Volume	:	100 µl
Factor	**:**	**1975**
Linearity	:	750
Units	:	IU/L
Low normal	:	0.00
High normal	:	40.0

Note : In some of the instruments the factor should be entered as - 1975 as the reaction direction is decreasing

Performance Characteristics:
Measuring range

The test has been developed to determine AST activities, which correspond to a maximal △A/min of 0.379 (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 SGOT concentration that can be distinguished from zero.

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Precision:

Intra-assay precision N=20	Mean (IU/L)	SD (IU/L)	CV (%)
Sample 1	43.5	2.05	4.71
sample 2	83.4	1.95	2.34
sample 3	127.0	2.92	2.30

Inter-assay precision N=20	Mean (IU/L)	SD (IU/L)	CV (%)
sample 1	39.8	1.13	2.83
sample 2	86.0	1.04	1.21
sample 3	135.0	1.51	1.12

Method Comparison
A comparison of the High-Q SGOT (AST) with a commercial obtainable assay (x) gave the following result with 58 samples:
y = 0.946 x + 1.385; r= 0.998

Reference range

Women	**< 30 (IU/L)**
Men	**< 40 (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 requirement.
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.
2. Bergmeyer HU, Herder M, Rej R. Approved recommendation (1985) on IFCC methods for the measurement of catalyticconcentration of enzymes. Part 2. IFCC Method for aspartate aminotransferase. J Clin Chem Clin Biochem 1986;24:49.
3. Glick MR, Ryder KW, Jackson SA. Graphical Comparisons of Interferences in Clinical Chemistry Instrumentation. Clin Chem 1986;32:470-474.
4. Greiling H, Gressner AM (Hrsg.). Lehrbuch der Klinischen Chemie und Pathobiochemie,3. Auflage. Stuttgart/New York: Schattauer Verlag, 1995

Order Information:

Ref./Cat. No.	Pack Size	Presentation
P-GOT(E) - 50	2 x 25 ml	2 x 20 ml (R1) + 2 x 5 ml (R2)
P-GOT(E) - 100	4 x 25 ml	4 x 20 ml (R1) + 4 x 5 ml (R2)
P-GOT(E) - 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).**
- **APADH (NADH Analogue) is used for better stability**
- **4 Minutes decreasing kinetic reaction (60 Sec Delay+ 180 Sec Measuring)**
- **Linearity - 750 IU/L**
- **Kinetic Factor: 1975**
- **Measuring Wavelength 340 nm**
- **Serum/ EDTA Plasma as specimens**
- **Available as multipurpose reagents and dedicated system packs**

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		

Pariksha Biotech
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eIFU Indicator

Pariksha's world inside
SCAN TO EXPLORE MORE

Manufactured in India by :
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AN ISO 13485 Certified Company

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