SBio SGOT (ASAT) KIT

(Mod. IFCC Method)

(For invitro diagnostic use only)

REF	90730075	90752150
Pack Size	75 ml	2 x 150 ml

CE

8°C 2°C Store at 2-8°C	Manufacturer	IVD *In vitro* Diagnostic Medical Device	L2 Starter Reagent	Mod. IFCC Modified IFCC Method
Use by (Last day of stated month)	Consult Instructions for use	LOT Batch Number		
Date of Manufacture	REF Catalogue Number	L1 Enzyme Reagent	This way up	EC REP Authorised Representative in the European Community

INTENDED USE

SGOT (ASAT) Kit is used for the determination of SGOT (ASAT) activity in serum.

PRINCIPLE OF THE TEST

SGOT (ASAT) catalyzes the transfer of amino group between L-Aspartate and α Ketoglutarate to form Oxaloacetate and Glutamate. The Oxaloacetate formed reacts with NADH in the presence of Malate Dehydrogenase to form NAD. The rate of oxidation of NADH to NAD is measured as a decrease in absorbance which is proportional to the SGOT (ASAT) activity in the sample.

L-Aspartate + α Ketoglutarate —*SGOT*→ **Oxaloacetate + L-Glutamate**

Oxaloacetate + NADH + H^+ —*MDH*→ **Malate + NAD^+**

CLINICAL SIGNIFICANCE

SGOT is an enzyme found mainly in heart muscle, liver cells, skeletal muscle and kidneys. Injury to these tissues results in the release of the enzyme in blood. Elevated levels are found in myocardial infarction, Cardiac operations, Hepatitis, Cirrhosis, acute pancreatitis, acute renal diseases, primary muscle diseases. Decreased levels may be found in Pregnancy, Beri Beri and Diabetic ketoacidosis.

PRESENTATION	75 ml	2 x 150 ml
L1 : Enzyme Reagent	60 ml	2 x 120 ml
L2 : Starter Reagent	15 ml	2 x 30 ml

COMPOSITION

Tris Buffer 80 mM; pH 7.8; L Aspartate 200 mM; LDH≥1000 U/L; MDH≥ 600U/L; NADH 0.18 mM; Ketoglutarate 12 mM.; Non Reactive Stabilizers, Detergents and Preservatives.

STORAGE / STABILITY

Contents are stable at 2-8°C till the expiry mentioned on the labels.

SAMPLE REQUIRED

Serum. Free from hemolysis.

REAGENT PREPARATION

Reagents are ready to use.

Working reagent: For sample start assays a single reagent is required. Pour the contents of 1 bottle of L2 (Starter Reagent) into 1 bottle of L1 (Enzyme Reagent). This working reagent is stable for at least 3 weeks when stored at 2-8°C.

Alternatively for flexibility as much of working reagent may be made as and when desired by mixing together 4 parts of L1 (Enzyme Reagent) and 1 part of L2 (Starter Reagent). Alternatively 0.8 ml of L1 and 0.2 ml of L2 may also be used instead of 1 ml of the working reagent directly during the assay.

SAMPLE WASTE AND DISPOSAL

Do not reuse the reagent containers, bottles, caps or plugs due to the risks of contamination and the potential to compromise reagent performance.

This product requires the handling of human specimen. It is recommended that all human sourced material are considered potentially hazardous and are handled in accordance with the OSHA standard on blood borne pathogens.

Appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.

Handle specimen, solid and liquid waste and test components in accordance with local regulations and NCCLS guidelines M29, or other published biohazard safety guidelines.

PROCEDURE

Wavelength / filter : 340 nm
Temperature : 37°C / 30°C / 25°C
Light path : 1 cm

MATERIALS REQUIRED BUT NOT PROVIDED

General laboratory instrumentation like Spectrophotometer/Analyzer, Thermostatic Cuvette holder, Cuvettes, Micropipettes, Test tubes, Waterbath, Stopwatch/Timer.

Substrate Start Assay

Pipette into a clean dry test tube labeled as Test (T):

Addition Sequence	(T) 25°C / 30°C	(T) 37°C
Enzyme Reagent (L1)	0.8 ml	0.8 ml
Sample	0.2 ml	0.1 ml
Incubate at the assay temperature for 1 minute and add		
Starter Reagent (L2)	0.2 ml	0.2 ml

Mix well and read the initial absorbance A_0 after 1 min. & repeat the absorbance reading after every 1, 2, & 3 minutes. Calculate the mean absorbance change per minute (ΔA/min.).

Sample Start Assay:

Pipette into a clean dry test tube labelled as Test (T) :

Addition Sequence	(T) 25°C / 30°C	(T) 37°C
Working Reagent	1.0 ml	1.0 ml
Incubate at the assay temperature for 1 minute and add		
Sample	0.2 ml	0.1 ml

Mix well and read the initial absorbance A_0 after 1 minute & repeat the absorbance reading after every 1, 2, & 3 minutes. Calculate the mean absorbance change per minute (ΔA/ min.)

CALCULATIONS

Substrate/ Sample start

SGOT (ASAT) Activity in U/L 25°C / 30°C = ΔA min. x 952
37°C = ΔA min. x 1746

QUALITY CONTROL

The following process is recommended for QC during the assay of SGOT (ASAT). *Define and establish acceptable range for your laboratory.

1. Two levels of control (Normal and Abnormal) are to be run on a daily basis.
2. If QC results fall outside acceptance criteria, recalibration may be necessary.
3. Review QC results and run acceptance criteria following a change of reagent lot.

SPECIFIC PERFORMANCE CHARACTERISTICS

Linearity:

The procedure is linear upto 500 U/L at 37°C, If the absorbance change (Δ A min.) exceeds 0.250, use only the value of the first two minutes to calculate the result, or dilute the sample 1+ 9 with normal saline (NaCl 0.9%) and repeat the assay (Results x 10).

Limit of detection:

The limit of detection for SGOT (ASAT) is 3.5 U/L.

Interferences:

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Precision:

Precision studies were performed with two controls using NCCLS protocol EP5-A. The results of the precision studies are shown below:

Sample	Within-run		Between-run		Total	
	Mean	CV%	Mean	CV%	Mean	CV%
Control 1	42.8	5.26	43.51	5.37	86.31	10.63
Control 2	132.2	2.73	132.37	1.80	264.57	4.53

Method comparison:

Comparative studies were done to compare our reagent with another commercial SGOT (ASAT) Assay. No significant differences were observed. Details of the comparative studies are available on request.

TEMPERATURE CONVERSION FACTORS

Assay Temperature	Desired Reporting Temperature 25°C	30°C	37°C
25°C	1.00	1.37	2.08
30°C	0.73	1.00	1.54
37°C	0.48	0.65	1.00

REFERENCE RANGE

Serum (males) : upto 37 U/L at 37°C
(Females) : upto 31 U/L at 37°C

It is recommended that each laboratory establish its own normal range representing its patient population*.

NOTE

SGOT (ASAT) is reported to be stable in serum for 3 days at 2-8°C. Samples having a very high activity show a very low initial absorbance as most of the NADH is consumed prior to the start of measurement. If this is suspected then dilute the sample and repeat the assay.

The working reagent or the combined reagent should have an absorbance above 1.000 against distilled water at 340 nm. Discard the reagent if the absorbance is below 1.000. The reagent may be used in several automated analyzers. Instructions are available on request. Do not use turbid, deteriorated or leaking reagents.

REFERENCES

1. IFCC methods for the measurement of catalytic concentrations of enzymes, J. Clin. Chem. Clin Biochem. (1986) 24: 497.
2. Wallnofer H. E. Schmidt and F. W. Schmidt, eds (1974). Synopsis Der Leberkrankheiten. Georg Theme Veriag Stuttgart Thefeld W. et. al. (1974) Dtsh. Med. Wschr. 99:343.

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EC REP

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