TRUEchemie SGOT (AST) Test Kit (IFCC)

IVD 2°C 8°C

for the quantitative determination of Serum Glutamate Oxaloacetate Transaminase (SGOT) in human serum or plasma

INTENDED USE

The TRUEchemie SGOT (AST) Test Kit (IFCC) is used for the direct quantitative determination of Serum Glutamate Oxaloacetate Transaminase (SGOT) or Aspartate Aminotransferase (AST) in human serum or plasma.

INTRODUCTION

Serum Glutamic Oxaloacetate Transaminase (SGOT) also known as Aspartate Aminotransferase (AST) is a tissue enzy me that catalyzes the exchange of amino and keto groups between alpha-amino acids and alpha-keto acids. SGOT is widely distributed in tissue principally cardiac, hepatic, muscle and kidney. Injury to these tissues results in the release of the SGOT (AST) enzyme to general circulation. Following a myocardial infarction, serum levels of SGOT (AST) are elevated and reach a peak in 48 to 60 hours after onset. Hepatobiliary diseases, such as cirrhosis, metastatic carcinoma, and viral hepatitis also will increase serum SGOT levels.

The first kinetic assay of SGOT for diagnostic purposes was described by Karmen et al. in 1955, using a coupled reaction of malate dehydrogenase (MDH) and NADH. This assay system was critically evaluated and optimized in 1960 by Henry et al. In 1977 the International Federation of Clinical Chemistry (IFCC) recommended a reference procedure for the measurement of SGOT activity based upon Karmen's procedures. The SGOT reagent applies the formulation recommended by the IFCC.

PRINCIPLE

$$\text{L-Aspartate} + \text{2-Oxoglutarate} \xrightarrow{\text{SGOT (AST)}} \text{Oxaloacetate} + \text{L-Glutamate}$$

$$\text{Oxaloacetate} + \text{NADH} + \text{H}^+ \xrightarrow{\text{MDH}} \text{Malate} + \text{NAD}^+ + \text{H}_2\text{O}$$

AST catalyzes the transfer of an amino group between L-aspartate and 2-oxoglutarate. The oxaloacetate formed in the first reaction is then reacted with NADH in the presence of malate dehydrogenase (MDH) to form NAD. AST activity is determined by measuring the rate of oxidation of NADH at 340 nm. Lactate dehydrogenase is included in the reagent to convert endogenous pyruvate in the sample to lactate during the lag phase prior to measurement.

PACK SIZE

Kit size	**2 x 50 ml**
Cat no.	**ADX226**
Kit contents	
1) SGOT Reagent (R1)	2 x 40 ml
2) SGOT Reagent (R2)	2 x 10 ml

REAGENTS COMPOSITION

SGOT Reagent (R1) and (R2) comes in separate containers, and both reagents are clear,colorless liquid in ready to use format. After combining SGOT Reagent (R1) and SGOT Reagent (R2) the reagent composition:

Working reagent composition

L-Aspartate	: 240	mmol/L
MDH (porcine muscle)	: > 600	U/L
LDH (rabbit muscle)	: > 600	U/L
Tris buffer, pH 7.5	: 80	mmol/L
2 - Oxoglutarate	: 12	mmol/L
NADH	: 0.18	mmol/L

Stabilizers and Preservatives

REAGENT PREPARATION

Ready to use reagents.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Specimens should be considered infectious and handled appropriately.
3. Avoid ingestion. DO NOT PIPETTE BY MOUTH.
4. The disposal of the residues has to be done as per local legal regulations.

REAGENT STORAGE & STABILITY

The components of the kit, stored at 2 - 8°C, will remain stable until the expiry date stated on the label.

SPECIMEN COLLECTION AND STORAGE

SGOT is stable in non-hemolyzed serum or EDTA treated plasma or heparinized plasma for a minimum of 7 days at 2 - 8°C.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Pipettes to accurately measure required volumes.
2. Test tubes/rack
3. Timer
4. 37°C heating block or water bath
5. Photometer capable of accurately measuring absorbance at 340 nm

TEST PROCEDURE

Wavelength	:	340 nm
Temperature	:	37°C

Prewarm the reagent to reaction temperature.

	Blank (µL)	Test (µL)
Distilled water	1000	--
1) SGOT Reagent (R1)	--	800
2) SGOT Reagent (R2)	--	200
Sample	--	100

Reading & Calculations

Blank the Photometer with D.I Water.

Mix well, read the initial absorbance after 1 min. and repeat the absorbance reading after every 1st, 2nd and 3rd min.

Calculations:

ΔE = Initial absorbance - Absorbance after 1st / 2nd / 3rd min.

Calculations determine the ΔE/min. for every reading and find the mean value.

ΔA = (Avg ΔE/min.) x 1768 = U/L of SGOT

QUALITY CONTROL

Quality Controls are recommended to monitor the performance of automated assay procedures. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

EXPECTED VALUE

Normal range: 8 - 33 U/L (37°C)

It is strongly recommended that each laboratory establish its own normal range

PERFORMANCE CHARACTERISTICS

Sensitivity: 2.65 U/L.

Linearity: Up to 500 U/L under the described assay conditions. If the concentration is greater than linearity (500 U/L), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor. The linearity limit depends on the sample / reagent ratio, as well as the analyzers used.

PRECISION:

Intra-assay precision within run (n=10)	**Mean (U/L)**	**SD (U/L)**	**CV (%)**
Control Level - 1	41.2	0.4	1.1
Control Level - 2	199.8	0.5	0.2

Inter-assay precision run to run (n=12)	**Mean (U/L)**	**SD (U/L)**	**CV (%)**
Control Level - 1	39.7	0.2	0.5
Control Level - 2	202.4	0.6	0.3

The reagent was tested for 12 days, using two different SGOT(AST) concentrations. The coefficient of variation was <5%.

AUTOMATED PROCEDURE

Appropriate program sheet is available for different analyzers upon request.

METHOD COMPARISON

Results obtained using TRUEchemie SGOT(AST) reagent (y) did not show systematic differences when compared with another commercial reagent (x) with similar characteristics. The results obtained is below: The correlation coefficient (r^2) was 0.997 and the regression equation is y=1.038x-0.426. The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

1. Hemolysis must be avoided as the concentration of AST in red cells is roughly 10 times that of serum.
2. Bilirubin levels up to 40 mg/dL does not interfere.
3. Triglyceride levels up to 2000 mg/dL does not interfere.
4. Certain drugs and other substances are known to affect AST values.

WASTE MANAGEMENT

Please refer to local regulation requirements.

SYSTEMS PARAMETERS

Mode	:	Kinetic
Factor	:	1768
Wave length	:	340 nm
Units	:	U/L
Flow cell temp	:	37°C
Blank	:	Distilled water
Reagent volume	:	800 µL (R1) + 200 µL (R2)
Sample volume	:	100 µL
Lag time / Delay time	:	60 sec. (1 min.)
Read time	:	180 sec. (3 min.)
Low normal	:	8
High normal	:	33
Sensitivity	:	2.65
Linearity	:	Up to 500
Reaction slope	:	Decreasing

REFERENCES

1. Henry, J.B.: Clinical Diagnosis and Management by Laboratory Methods, W.B. Saunders and Co., Philadelphia, PA. p 361 (1974).
2. Karmen A: A note on the spectrophotometric assay of glutamicoxolacetic transaminase in human blood. J Clin Invest 34:131, 1955.
3. Henry, R.J., et al.: Am. J. Clin. Path, 34:381 (1960). The Committee on Enzymes of the Scandinavian Society for 4. Clinical Chemistry and Clinical Physiology. Scand. J. Clin. Lab.Invest32:291(1974).
4. Demetriou, JA et al. In Clinical Chemistry - Principles and Techniques 2nd ed. RJ Henry et al. Eds. Harper & Row, Hagerstown MD, (1974), p 873.
5. International Federation of Clinical Chemistry. Provisional Recommendations on IFCC Methods for the Measurement of Catalytic Concentrations of Enzymes. Clin Chem 23: 887, 1977.
6. Young D.S. Effects of drugs on clinical laboratory tests. AACC Press, Washington D.C., 1990.
7. Henry JB. Clinical Diagnosis and Management by Laboratory Methods, 17th ed. WB Saunders Co., 1984, p 1437.
8. ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

Index of Symbols

Consult instructions for use	REF Catalogue number	Caution
IVD *In vitro* diagnostic medical device	LOT Batch code	Non-sterile
2°C 8°C Temperature limit 2-8 °C	Do not re-use	Use-by date
Manufacturer	Date of manufacture	Keep dry
Do not use if package is damaged	Keep away from sunlight	

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