SGOT Kit

CliniQuant - FSR

IFCC Method, Kinetic

Meril Diagnostics

For *in vitro* diagnostic use
Read this pack insert thoroughly before use

REF	Pack Size	R1 SGOT Reagent	R2 SGOT Reagent
GOTFSR-01	4 x 20 / 4 x 5ml	4 x 20ml	4 x 5ml
GOTFSR-02	4 x 100 / 2 x 50ml	4 x 100ml	2 x 50ml

INTENDED USE

This reagent is intended for quantitative determination of SGOT level in human serum.

CLINICAL SIGNIFICANCE

The aminotransferases (transaminases) are widely distributed in animal tissues. Both AST & ALT are normally present in human plasma, bile, cerebrospinal fluid, and saliva. Elevated AST levels are observed in viral hepatitis and other liver disease, cirrhosis, myocardial infarction.

PRINCIPLE OF THE METHOD

$$\text{L-Aspartate} + \text{2-Oxoglutarate} \xrightarrow{\text{AST}} \text{Oxoloacetate} + \text{L-Glutamate}$$

$$\text{Oxoloacetate} + \text{NADH} \xrightarrow{\text{MDH}} \text{Malate} + \text{NAD}$$

$$\text{Pyruvate} + \text{NADH} \xrightarrow{\text{LDH}} \text{L-Lactate} + \text{NAD}$$

AST: Aspartate aminotransferase
MDH: Malate dehydrogenase
LDH: Lactate dehydrogenase

KIT COMPONENTS

Composition

R1 - SGOT Reagent : Tris buffer 20 mmol/l pH 7.8, L-Asparatic acid 231 mmol/l, MDH > 0.2 KU/l, LDH > 4 KU/l, 2-oxoglutarate 17.17 mmol/l

R2 - SGOT Reagent : NADH 0.18 mmol/l, 2-oxoglutarate 15 mmol/l

MATERIALS REQUIRED BUT NOT PROVIDED

Laboratory instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi automated, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/ rack, heating bath, controls, saline.

REAGENT PREPARATION, STORAGE & STABILITY

Mix reagent 1 & reagent 2 in ratio 4:1. Keep away from direct light sources.

Stability: up to expiration date on labels at 2-8 °C.

Stability of working reagent: 30 days at 2-8 °C.

REAGENT DETERIORATION

Discard the working reagent if absorbance < 1.0 at 340 nm against distilled water.

WARNINGS AND PRECAUTIONS

1. Reagent may contain some non-reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
2. Specimens should be considered infectious and handled appropriately.
3. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

SPECIMEN

Use serum, plasma. SGOT is stable for 4 days at 2-8 °C or 1 month at -20°C.

Programme Parameter for MERILYZER CliniQuant

Procedure	Assay protocol1: Normal	Assay protocol2: High linearity
Reading Mode	Rate	Rate
Factor	1768	1768
Filter- 1(nm)	340	340
Temperature	37 °C	37 °C
Volume (µl)	450	450
Delay Time (Sec)	60	30
Read Time (Sec)	120	60
Unit	U/l	U/l
Reaction Direction	Decrease	Decrease
Reference Low	0	0
Reference High	45	45
Linearity Limit	450	1600

CE
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TEST PROCEDURE

Dispense in tube : working reagent	500 µl
Add Sample	50 µl
Assay Protocol1: Mix and incubate 60 seconds at 37°C, then record first reading of absorbance. Perform other 2 readings at 60 seconds intervals. Calculate the ΔA/min.	

Assay Protocol2: Mix and incubate 30 seconds at 37°C, then record first reading of absorbance. Perform other 2 readings at 30 seconds intervals. Calculate the ΔA/min.

RESULT CALCULATION

Perform calculations in units per litre, multiplying the ΔA/min by the factor.

Activity in U/l = ΔA/min x 1768

SI conversion factor: 1 U/l x 0.017= 1 µkat/l

EXPECTED VALUES

< 45 U/l at 37°C OR 0.8 µkat/l

It is recommended that each laboratory verifies this range or derives reference interval for the population it serves.

QUALITY CONTROL AND CALIBRATION

It is suggested to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and assure the accuracy of patient result.

When using the recommended Calibrator (BioCal), calibrate the assay:

a. When using a new reagent or lot

b. When QC values are out of range

PERFORMANCE CHARACTERISTICS

1. Linearity

As per assay protocol1: Linearity is up to 450 U/l or 7.7 µkat/l.

As per assay protocol2: Linearity is up to 1600 U/l or 27.2 µkat/l

2. Sensitivity/ Limit of detection (LOD)

The limit of detection is 1 U/l

The limit of quantification is 4 U/l.

3. Interferences

No interference has been observed for the following

Hemoglobin up to 70 mg/dl; Bilirubin up to 40 mg/dl

Triglyceride up to 1000 mg/dl

4. Precision

Intra-assay precision

	Mean	SD	CV
n = 20	U/l	U/l	%
sample 1	46.94	0.43	0.92
sample 2	137.49	0.78	0.57

Inter-assay precision

	Mean	SD	CV
n = 20	U/l	U/l	%
sample 1	49.86	2.41	4.84
sample 2	143.33	2.36	1.65

5. Methods Comparison

Comparison was done between reference AST (SGOT) Reagent and CliniQuant - FSR SGOT Reagent (test)

N = 36 $y = 0.967x + 6.082$

$r^2 = 0.946$

LIMITATIONS

Samples with values above 1600 U/l should be diluted with 0.9% saline, re-run and results multiplied by dilution factor

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for correct waste disposal.

REFERENCES

1. Burtis, C.A., Ashwood, E.R., editors. Tietz Textbook of Clinical Chemistry. 2nd ed. Philadelphia, W.B. Saunders Company, 1994, p. 790 - 795.

2. Data on file: Meril Diagnostics.

IFU/GOTFSR01/00

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Symbols used on Meril Diagnostics labels:

REF	Catalogue No.		Attention See Instruction for Use
LOT	Batch No.	IVD	*In vitro* Diagnostics
	Expiry Date		Consult Instruction for Use
	Manufacturer		Storage Temperature
	Keep Dry		Keep Away from Sunlight
	Manufacturing Date		Do not use if package is damaged

EC REP Authorized European Representative in the European Community