SGOT SYSTEM PACK

(IFCC METHOD)

B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem 200 , Beaconic chem 200,Beaconic B200,Beaconic analyzer 120, Bonavera chem 100(Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
BA229	SGOT System Pack	4x40 + 4x10 ml

INTENDED USE

Diagnostic reagent for quantitative *in vitro* determination of AST/GOT (Aspartate Aminotransferase) in human serum.

CLINICAL SIGNIFICANCE

SGOT / AST is widely distributed with high concentrations in the heart, liver, skeletal muscle, kidney and erythrocytes. Damage or disease to any of these tissues such as myocardial infarction, viral hepatitis, liver necrosis, cirrhosis and muscular dystrophy may result in raised levels of SGOT/AST.

PRINCIPLE

This reagent is based on IFCC recommendations, without pyridoxal phosphate. The series of reactions involved in the assay system is as follow:

$$\text{L-Aspartate} + \text{2-oxoglutarate} \xrightarrow{\text{SGOT / AST}} \text{Oxaloacetate} + \text{L-Glutamate}$$

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

$$\text{Sample pyruvate} + \text{NADH} \xrightarrow{\text{LDH}} \text{L-lactate} + \text{NAD}$$

1. SGOT/AST present in the sample catalyses the transfer of the amino group from L-aspartate to 2-oxoglutarate forming oxaloacetate and L-glutamate.

2. Oxaloacetate in the presence of NADH and Malate dehydrogenase (MDH) is reduced to L-malate. In this reaction NADH is oxidized to NAD. The reaction is monitored by measuring the rate of decrease in absorbance at 340 nm due to the oxidation of NADH to NAD.

3. Addition of Lactate dehydrogenase (LDH) to the reagent is necessary to achieve rapid and complete reduction of endogenous pyruvate so that it does not interfere with the assay.

REAGENT COMPOSITION

Reagent 1 : SGOT Enzyme Reagent

Tris Buffer (pH 7.8)	>100 mmol/L
L-Aspartate	>200 mmol/L
LDH	>2000 U/L
MDH	>750 U/L

Reagent 2 : SGOT Substrate Reagent

NADH	>1.05 mmol/L

STABILITY AND STORAGE

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at +2 - +8°C.

On board stability: Min. 30 days if refrigerated (+8 - +14°) and not contaminated.

REAGENT PREPARATION

Ready to use

SPECIMEN COLLECTION AND HANDLING

Use unheamolytic serum.
It is recommended to follow NCCLS procedures (or similar standardized conditions).

STABILITY

At least 3 months at -20°C.
Discard contaminated specimens.

CALIBRATION

Calibration with the Beacon Multicalibrator is recommended.

QUALITY CONTROL

Its recommended to run normal and abnormal control sera to validate reagent performance.

UNIT CONVERSION

U/l x 0.017 = µkat/l

EXPECTED VALUES

At +37°C
Serum < 40 U/L

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

PERFORMANCE DATA

Data contained within this section is representative of performance on Beacon systems. Data obtained in your laboratory may differ from these values.

Limit of quantification :	3.84 U/L
Linearity :	800 U/L
Measuring range :	3.84 - 800 U/L

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PRECISION

Intra-assay precision Within run (n=20)	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	37	0.67	1.81
Sample 2	150	3.20	2.13

Inter-assay precision Run to run (n=20)	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	58.3	2.02	3.47

COMPARISON

A comparison between SGOT System Pack (y) and commercially available test (x) using 20 samples gave following results:

y = 0.967 x + 1.31 U/L

r = 0.998

INTERFERENCES

Following substances do not interfere:

bilirubin up to 30 mg/dl, triglycerides up to 2000 mg/dl, haemolysis interferes due to AST activity from erythrocytes.

WARNING AND PRECAUTIONS

For *in vitro* diagnostic use. To be handles by entitled and professionally educated person.

Reagents of the kit are not classified like dangerous but contains less than 0.1% sodium azide - classified as very toxic and dangerous substance for the environment. MSDS will be provided on request.

WASTE MANAGEMENT

Please refer to local legal requirements.

Parameter For B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem200 , Beaconic chem 200,Beaconic B200,Beaconic analyzer 120,Bonavera chem 100
(Fully Auto Biochemistry Analyzer)

Test Name	SGOT
Full Name	SGOT
PRI Wave	340 nm
SEC Wave	630 nm
Assay/Point	KINETIC
Start	21
End	31
Decimal	2
Unit	U/L
Linearity Range Low	3.84
Linearity Range High	800
Sample Volume	15 µl
Reagent 1 (R1) Volume	120 µl
Reagent 1 (R2) Volume	30 µl
Substrate Depleted/Abs.limit	0.8
Linearity	800 U/L
Out Of Linearity Range	-
Calibration Type	2 Point linear
Points	2

Blank Type	Reagent
Concentration Blank	0.00
Concentration Std	Refer calibrator value sheet

NOTE

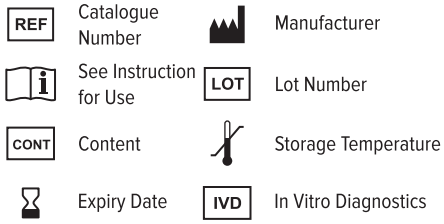
The program is made as per the in house testing, it can be modified as per requirements.

Clinical diagnosis should not be made on findings of a single test results, but both clinical and laboratory data.

REFERENCES

1. Thomas L. Alanine aminotransferase (ALT) Aspartate aminotransferase (AST). In : homas L, editor. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 55-65.
2. Moss DW, Henderson AR, Clinical enzymology. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 617-721.
3. Schumann G, Bonora R, Ceriotti F, Férard G et al. IFCC primary reference procedure for the measurement of catalytic activity concentrations of enzymes. at 7 °C. Part 5: Reference procedure for the measurement of catalytic concentration of aspartate aminotransferase. Clin Chem Lab Med 2002:40:725 - 33.4.Tietz Textbook of Clinical Chemistry. Burtis CA and Ashwood ER, Fifth Edition, 2012.

Symbols Used On Labels



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