SGPT 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
BA230	SGPT System Pack	4x40 + 4x10 ml

INTENDED USE

Diagnostic reagent for quantitative *in vitro* determination of ALT/GPT (Alanine Aminotransferase) in human serum.

CLINICAL SIGNIFICANCE

ALT/GPT is present in high concentration in liver and to a lesser extent in kidney, heart, skeletal muscle, pancreas, spleen and lung. Increased levels of ALT/GPT however is generally a result of liver disease associated with some degree of hepatic necrosis such as cirrhosis, viral or toxic hepatitis and obstructive jaundice. Characteristically ALT/GPT is generally higher than AST/GOT in acute viral or toxic hepatitls, whereas for most patients with chronic hepatic disease, ALT/GPT levels are generally lower than AST/GOT levels. Elevated ALT/GPT levels have also been found in extensive trauma and muscle disease, circulatory failure with shock, hypoxia, myocardial infarction and haemolytic disease.

PRINCIPLE

This ALT/GPT reagent is based on the recommendations of the IFCC without pyridoxal phosphate. The series of reactions involved in the assay system is as follows:

$$\text{L-Alanine} + \text{2-oxoglutarate} \xrightarrow{\text{ALT / GPT}} \text{Pyruvate} + \text{L-Glutamate}$$

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

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

1. The amino group is enzymatically transferred by SGPT / ALT present in the sample from alanine to the carbon atom of 2-oxoglutarate yielding pyruvate and L-glutamate.
2. Pyruvate is reduced to lactate by LDH present in the reagent with the simultaneous oxidation of NADH to NAD. The reaction is monitored by measuring the rate of decrease in absorbance at 340nm due the oxidation of NADH.
3.Endogenous sample pyruvate is rapidly and completely reduced by LDH during initial incubation period to avoid interference during the assay.

REAGENT COMPOSITION

Reagent 1 : SGPT Enzyme Reagent

Tris Buffer	>100 mmol/L
Alanine	>500 mmol/L
LDH	>1500 U/L
2-Oxoglutarate	>10 mmol/L

Reagent 2 : SGPT 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 : 4.4 U/L
Linearity : 800 U/L
Measuring range : 4.4 - 800 U/L

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PRECISION

Intra-assay precision Within run (n=20)	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	125	2.96	2.37
Sample 2	95	2.30	2.42

Inter-assay precision Run to run (n=20)	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	38.7	1.175	3.04

COMPARISON

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

y = 0.942 x + 0.181 U/L

r= 0.992

INTERFERENCES

Following substances do not interfere:

haemoglobin up to 2.5 g/l, bilirubin up to 30 mg/dl, triglycerides up to 2000 mg/dl.

WARNING AND PRECAUTIONS

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

Reagents of the kit are not classified like dangerous but contain 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	SGPT
Full Name	SGPT
PRI Wave	340 nm
SEC Wave	630 nm
Assay/point	KINETIC
Start	21
End	31
Decimal	2
Unit	U/L
Linearity Range Low	4.40
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
Concentartion Std	Refer calibrator value sheet

NOTE

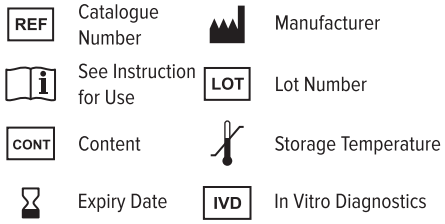
The program is made as per the in house testing, it can be modified as per requirements.

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: Thomas L, editor. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 55-65.
2. Moss DW, Henderson AR, Clinical enzymology. In: Burris 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 37 °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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JAS-ANZ BSCIC ISO 9001 : 2015 BSCIC ISO 13485:2016