# SGOT SYSTEM PACK

Unicorn 480, Bonavera Chem 480 & Bonavera Chem 400

(Fully Auto Biochemistry Analyzer)

**BEACON**

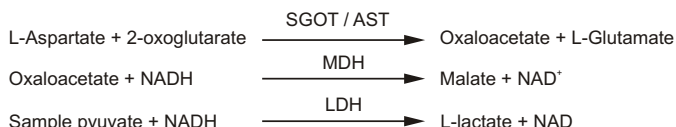| Code | Product Name | Pack Size |
|---|---|---|
| UNI29 | SGOT System Pack | 4x40 + 4x10 ml |

## 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:

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

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

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

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 (2-10°) 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
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

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

y = 0.967x + 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.

## WASTE MANAGEMENT
Please refer to local legal requirements.

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**BEACON DIAGNOSTICS PVT. LTD.** *424, NEW GIDC, KABILPORE, NAVSARI - 396 424. INDIA*

Parameter for Unicorn 480, Bonavera Chem 480 &

Bonavera chem 400 (Fully Auto Biochemistry Analyzer)

| TEST NAME | SGOT |
|---|---|
| FULL NAME | SGOT |
| PRI WAVE | 340 nm |
| SEC WAVE | 630 nm |
| ASSAY/POINT | KINETIC |
| START | 16 |
| END | 33 |
| DECIMAL | 0 |
| 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 |
| SUBSATRATE DEPLETED | - |
| 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. |
| SAMPLE VOLUME | 15 µl |

**NOTE**

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

**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**

| Symbol | Meaning |
|---|---|
| REF | Catalogue Number |
| | Manufacturer |
| i | See Instruction for Use |
| LOT | Lot Number |
| CONT | Content |
| | Storage Temperature |
| | Expiry Date |
| IVD | In Vitro Diagnostics |

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