# AST/GOT

| Cat. No. | Pack Name | Packaging (Content) |
|---|---|---|
| BLT00050 | AST/GOT 250 | R1: 4 x 50 ml, R2: 1 x 50 ml |
| BLT00051 | AST/GOT 500 | R1: 4 x 100 ml, R2: 1 x 100 ml |

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## INTENDED USE
Diagnostic reagent for quantitative *in vitro* determination of AST/GOT (Aspartate Aminotransferase) in human serum and plasma.

## CLINICAL SIGNIFICANCE
SGOT / ASAT 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 / ASAT.

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

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

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

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

1. SGOT / ASAT 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
**R1**

| | |
|---|---|
| Tris Buffer (pH 7.8) | 110 mmol/l |
| L-Aspartate | 340 mmol/l |
| LDH | ≥ 4000 U/l |
| MDH | ≥ 750 U/l |

**R2**

| | |
|---|---|
| CAPSO | 20 mmol/l |
| 2-Oxoglutarate | 85 mmol/l |
| NADH | 1.05 mmol/l |

## REAGENT PREPARATION
Reagents are liquid, ready to use.

## 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.

**Two reagents method – substrate start**

Reagents are ready to use. After the first opening the vials, reagents are stable for 30 days at 2–8 °C in the dark.

**Monoreagent method – sample start**

Mix 4 portion of reagent R1 with 1 portion of reagent R2.

Stability: 5 days at 20–25 °C in the dark
4 weeks at 2–8 °C in the dark

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## SPECIMEN COLLECTION AND HANDLING
Use unheamolytic serum or plasma (EDTA, heparin).
It is recommended to follow NCCLS procedures (or similar standardized conditions).

**Loss of activity:** within 3 days at 2–8 °C < 8 %
within 3 days at 15–25 °C < 10 %

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

## CALIBRATION
Calibration with the calibrator XL MULTICAL, Cat. No. XSYS0034 is recommended.

## QUALITY CONTROL
For quality control ERBA NORM, Cat. No. BLT00080 and ERBA PATH, Cat. No. BLT00081 are recommended.

## UNIT CONVERSION
U/l x 0.017 = µkat/l

## EXPECTED VALUES [4]
At 37°C
Men up to 35 U/l
Women up to 31 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 ERBA XL systems. Data obtained in your laboratory may differ from these values.

**Limit of quantification:** 3.84 U/l
**Linearity:** 390 U/l
**Measuring range:** 3.84 – 390 U/l

## PRECISION

| Intra-assay precision Within run (n=20) | Mean (U/l) | SD (U/l) | CV (%) |
|---|---|---|---|
| **Sample 1** | 103.2 | 0.60 | 0.54 |
| **Sample 2** | 313.2 | 1.68 | 0.54 |

| Inter-assay precision Run to run (n=20) | Mean (U/l) | SD (U/l) | CV (%) |
|---|---|---|---|
| **Sample 1** | 43.8 | 0.60 | 1.37 |
| **Sample 2** | 115.2 | 1.08 | 0.92 |

## COMPARISON
A comparison between XL-Systems AST/GOT (y) and a commercially available test (x) using 40 samples gave following results:
y = 0.941 x - 3.96 U/l
r = 0.996

## INTERFERENCES
Following substances do not interfere:
bilirubin up to 30 mg/dl, triglycerides up to 2000 mg/dl, haemolysis interferes due to ASAT activity from erythrocytes.

## WARNING AND PRECAUTIONS
For *in vitro* diagnostic use. To be handled by entitled and professionally educated person.
Reagent 1 of the kit is classified as irritating, it contains 1.1 % of sodium hydroxide which is classified as corrosive substance.

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Irritated

**Risk phrases (R):**
R 36/38 Irritating to eyes and skin.

**Safety phrases (S):**
S 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S 28 After contact with skin, wash immediately with plenty of water.
S 37/39 Wear suitable gloves and eye/face protection.
S 45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

## WASTE MANAGEMENT
Please refer to local legal requirements.

## ASSAY PROCEDURE
**Wavelength** 340 nm, Hg 334 nm, Hg 365 nm
**Cuvette** 1 cm

**Two reagents method – substrate start**

| | |
|---|---|
| Reagent 1 (buffer) | 1.000 ml |
| Sample | 0.100 ml |

Mix and incubate for 5 min. at 37°C. Then add:

| | |
|---|---|
| Reagent 2 (substrate) | 0.250 ml |

Mix, incubate 1 min. at 37°C and then measure the initial absorbance of calibrator and sample against reagent blank. Measure the absorbance change exactly after 1, 2 and 3 min. Calculate 1 minute absorbance change (ΔA/min).

**Monoreagent method – sample start**

| | |
|---|---|
| Working solution | 1.000 ml |
| Sample | 0.100 ml |

Mix, incubate 1 min. at 37°C and then measure the initial absorbance of calibrator and sample against reagent blank. Measure the absorbance change exactly after 1, 2 and 3 min. Calculate 1 minute absorbance change (ΔA/min).

## CALCULATION
**1.** AST/GOT (U/l) = $\frac{\Delta A_{sam}/min}{\Delta A_{cal}/min}$ x $C_{cal}$

$C_{cal}$ = calibrator concentration

**2.** Using factor:
AST/GOT = f x ΔA/min f = factor

| Factors: | Substrate Start: | 25° or 30°C | 37°C |
|---|---|---|---|
| | Factor at 340 nm | 1151 | 2143 |
| | Factor at 334 nm | 1173 | 2184 |
| | Factor at 365 nm | 2132 | 3971 |
| | **Sample Start:** | **25° or 30°C** | **37°C** |
| | Factor at 340 nm | 952 | 1745 |
| | Factor at 334 nm | 971 | 1780 |
| | Factor at 365 nm | 1765 | 3235 |

**Applications for automatic analysers are available on request.**

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**ASSAY PARAMETERS FOR PHOTOMETERS**

| | |
|---|---|
| Mode | Kinetic |
| Wavelength 1 (nm) | 340 |
| Sample Volume (µl) | 50/100 |
| Working Reagent Volume (µl) | 500/1000 |
| Lag time (sec.) | 60 |
| Kinetic interval (sec.) | 60 |
| No. of readings | 3 |
| Kinetic factor | 1745 |
| Reaction temperature (°C) | 37 |
| Reaction direction | Decreasing |
| Normal Low (U/l) | 0 |
| Normal High (U/l) | 31 |
| Linearity Low (U/l) | 3.84 |
| Linearity High (U/l) | 390 |
| Blank with | Water |
| Absorbance limit (max.) | 1.1 |
| Units | U/l |

**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: 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 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**

REF Catalogue Number

Manufacturer

See Instruction for Use

LOT Lot Number

CE Mark - Device comply with the Directive 98/79/EC

Storage Temperature

Expiry Date

IVD In Vitro Diagnostics

CONT Content

QUALITY SYSTEM CERTIFIED
**ISO 9001 ISO 13485**


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