

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

EN

CE IVD

INTENDED USE

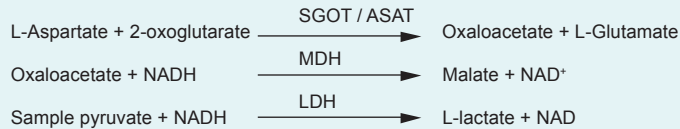
Diagnostic reagent for quantitative *in vitro* determination of AST/GOT (Aspartate Aminotransferase) in human serum and plasma.

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:



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

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 *

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:

$$y = 0.941 x - 3.96 \text{ U/l}$$

$$r = 0.996$$

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.

Xi



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
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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

$$1. \text{AST/GOT (U/l)} = \frac{\Delta A_{\text{sam}}/\text{min}}{\Delta A_{\text{cal}}/\text{min}} \times C_{\text{cal}}$$

C_{cal} = calibrator concentration

2. Using factor:

$$\text{AST/GOT} = f \times \Delta A/\text{min} \quad f = \text{factor}$$

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, Féraud 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



Catalogue Number



Manufacturer



See Instruction for Use



Lot Number



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



Storage Temperature



Expiry Date



In Vitro Diagnostics



Content

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485



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