GENESIS

Instructions For Use

GOT/AST (IFCC Method) (4+1)

Cat no.	size
1204 101	5*10
1204 102	10*10
1204 103	5*20
1204 104	10*20
1204 105	2*25

INTENDED USE

GOT/AST Reagent is intended for the in vitro Quantitative diagnostic determination of Aspartate Aminotransferase (AST) in human serum and plasma.

DIAGNOSTIC CHARACTERISTICS

The aminotransferases catalyze the formation of glutamic acid from 2-oxoglutarate by transfer of amino groups. AST is found in highest concentration in the liver and heart muscle but it is also abundant in skeletal muscle, kidney and pancreas.The serum concentration of AST is elevated in hepatitis and other forms of hepatic disease associated with necrosis: infectious mononucleosis, cholestasis, cirrhosis, metastasic carcinoma of the liver, delirium tremens, and after administration of various drugs Serum AST concentration is also elevated after myocardial infarction, in sketetal muscle disease (as progressive muscular distrophy), in acute pancreatitis or hemolytic disease and other. Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

PRINCIPLE OF THE METHOD

Aspartate aminotransferase (AST or GOT) catalyzes the transfer of the amino group from aspartate to 2-oxoglutarate, forming oxalacetate and glutamate.The catalytic concentration is determined from the rate of decrease of NADH, measured at 340 nm, by means of the malate dehydrogenase (MDH) .

Aspartate + 2 – Oxoglutarate $\xrightarrow{AST}$ Oxalacetate + Glutamate

Oxalacetate + NADH + H^+ $\xrightarrow{MDH}$ Malate + NAD^+

COMPOSITION

Reagent (R1)	Tris Buffer	121 mmol/L
	L-Aspartate	100 mmol/L
	Malate dehydrogenase	>460 U/L
Reagent (R2)	NADH	2.0 mmol/L
	2-oxoglutarate	75 mmol/L
	Sodium Azide	9.5 g/L

STORAGE

Store at 2 - 8°C

The reagent is stable until expiration date stated on vial label .

REAGENT PREPARATION

Working reagent: (4) Parts of(R1) are mixed with (1) part of (R2).

Working reagent is stable for 3 weeks at 2 - 8 °C .

ADDITIONAL EQUIPMENT

− Thermostatic water bath at 37ºC

− Analyzer, spectrophotometer able to read at 340 nm.

SPECIMEN.

1.Serum and plasma collected by standard procedures.

2.Aspartate aminotransferase in serum and plasma is stable for 7 days at 2-8ºC and stable for 24 hrs at 15-25°C .

3.Use heparin as anticoagulant.

Precautions and Warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Symbols in Product Labeling

EC REP	Authorized Representative		Expiration date
IVD	For in-vitro diagnostic use		CAUTION, consult instructions for use
REF	Catalogue number		
LOT	Lot number		Manufactured by
	Consult instructions for use		Temperature Limit

PROCEDURE

1. Bring the Reagent to room temperature.
2. Assay parameters:

Reaction……Kinetic
Wavelength. . . . . ……340 nm
Cuvette: ……1cm light path Constant temperature . ……. 37ºC
Delay time…… ……60sec
Measuring time……..…180sec

3. Adjust the instrument to zero with distilled water or air.
4. Pipette into a cuvette:

Working Reagent	1.0 mL
Sample	100 µL

5. Mix and incubate for 60 seconds.
6. Read initial absorbance (A) of the sample, start the stopwatch and read absorbance at 1 minute intervals thereafter for 3 minutes.
7. Calculate the difference between absorbance and the average absorbance differences per minute (ΔA/min).

CALCULATIONS

AST(U/l) = ΔA/min x 1746

REFERENCE VALUES

Females	up to 31 U/l (up to 0.52 mKat/L)
Males	up to 37 U/l (up to 0.62 mKat/L)

QUALITY CONTROL

It is recommended to use Control Serum level I and II to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control

METROLOGICAL CHARACTERISTICS

− Detection limit: 1.1 U/L = 0.018 µkat/L

− Linearity limit: 400 U/L = 13.3 µkat/L.

− For higher values dilute sample **1/5** with Physiological saline and repeat measurement.

− Repeatability (within run):

Mean Concentration	CV	n
38 U/L = 0.63 µkat/L	1.4 %	20
119 U/L = 1.98 µkat/L	1.5%	20

− Reproducibility (run to run):

Mean Concentration	CV	n
38 U/L = 0.63 µkat/L	5.9 %	25
119 U/L = 1.98 µkat/L	3.8%	25

− Interferences:

−Bilirubin (20 mg/dL) does not interfere.

− Lipemia (triglycerides 2 g/L) and hemolysis may affect the results.

− Other drugs and substances may interfere.

BIBLIOGRAPHY

1.IFCC primary reference procedures 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; 40:725-733.

2.IFCC reference procedures for measurement of catalytic concentrations of enzymes:corrigendum, notes and useful advice. Clin Chem Lab Med 2010; 48: 615-621.

GENESIS LAB FOR DIAGNOSTIC REAGENTS
1st industrial area, Obour City, Cairo, Egypt
(+202) 44891632 Fax : (+202) 44891632
www.genesis-egy.com
info@genesis-egy.com

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CE

EC REP CMC Medical device, C/ Horacio Lengo n18 C.P 29006, Málaga-Spain