



Instructions For Use

GENESIS

GOT (Single Reagent) (IFCC Method)

Cat no.	Size
1208 101	2*25
1208 102	4*25

INTENDED USE

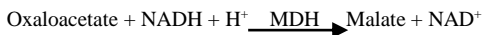
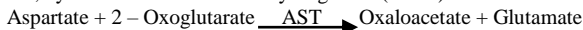
GOT Single Reagent is intended for the in vitro Quantitative diagnostic determination of Aspartate Aminotransferase (AST) in human serum and plasma.

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, metastatic carcinoma of the liver, delirium tremens, and after administration of various drugs Serum AST concentration is also elevated after myocardial infarction, in skeletal muscle disease (as progressive muscular dystrophy), 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 oxaloacetate 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).



COMPOSITION

GOT (Single Reagent)		
	Tris Buffer	121 mmol/L
	L-Aspartate	100 mmol/L
	Malate dehydrogenase	>460 U/L
	NADH	2.0 mmol/L
	2-oxoglutarate	75 mmol/L
	Sodium Azide	1.5 g/L

STORAGE

Store at 2 - 8°C

The reagent is stable until expiration date stated on vial label when stored tightly closed and if contaminations are prevented during their use.

REAGENT PREPARATION

Reagent provided ready to use.

ADDITIONAL EQUIPMENT

- Thermostatic water bath at 37°C
- 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 2-8°C
3. Use heparin as anticoagulant.

Precautions and Warnings

Do not ingest or inhale. 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			
	Authorized Representative		Expiration date
	For in-vitro diagnostic use		CAUTION, consult instructions for use
	Catalogue number		Manufactured by
	Lot number		Temperature Limit
	Consult instructions for use		

PROCEDURE

1. Bring the Reagent to room temperature.
2. Assay parameters:
Reaction.....Kinetic
Wavelength.....340 nm
Cuvette:1cm light path
Constant temperature.....37°C
Delay time.....60sec
Measuring time.....180sec
3. Adjust the instrument to zero with distilled water or air.

4. Pipette into a cuvette:

GOT(Single 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 ($\Delta A/\text{min}$).

CALCULATIONS

$$\text{AST (U/l)} = \Delta A/\text{min} \times 1746$$

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.