ROBONIK®

CE

prietest™ ...Clinical Chemistry Reagents

GOT / AST

In vitro diagnostic test kit, for professional use only

INTENDED USE : Quantitative in vitro determination of activity of GOT/AST in serum or plasma on photometric systems.

ORDERING INFORMATION

Pack Size	Cat No.
1 X 25 ml	GOT 01 25
2 X 50 ml	GOT 02 50
4 X 50 ml	GOT 04 50
2 X 500 ml	GOT 02 500

CLINICAL SIGNIFICANCE : Glutamate Oxaloacetate Transaminase (GOT) also known as Aspartate aminotransferase (AST) is a transaminase. GOT catalyses the transfer of the aminogroup of L-aspartate to α-ketoglutarate to give L-glutamate. GOT is widely distributed in the body, but the highest levels are found in heart, liver, skeletal muscles and kidneys.

Damages to cells of these tissues induce GOT increase in serum. In case of viral hepatitis the enzyme level is elevated. In case of myocardial infarction, GOT activity increases and reaches a peak after 18-24 hours. The activity falls back to normal after 4-5 days, provided no new infarct has occurred.

The following pathological states are examples of disorders also resulting in an increase of enzyme activity : liver cell necrosis or injury of any cause (for example intake of alcohol, delirium tremens, and administration of drug induce moderate GOT elevation), alcoholic hepatitis, muscular dystrophy and gangrene, infectious mononucleosis, acute pancreatitis, myocarditis or pericarditis, pulmonary emboli. On the contrary, GOT serum level can decrease in case of vitamin B6 deficiency.

METHOD :

IFCC method without pyridoxal phosphate, Kinetic, UV.

PRINCIPLE :

Kinetic determination of the aspartate aminotransferase (GOT) activity :

$$\text{L-Aspartate} + \alpha\text{-Ketoglutarate} \xrightarrow{\text{GOT}} \text{Oxaloacetate} + \text{L-Glutamate}$$

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

REAGENTS :

COMPONENTS AND CONCENTRATIONS :

R 1:	Tris	:	80 mmol/l
	L - Aspartate	:	240 mmol/l
	Lactate Dehydrogenase	:	> 600U/l
	Malate Dehydrogenase	:	> 600U/l
R 2 :	α - Ketoglutarate	:	12 mmol/l
	NADH	:	0.18 mmol/l

STORAGE INSTRUCTIONS AND REAGENT STABILITY :

The reagents are stable up to the end of the indicated date of expiry on the vial label, if stored at 2 to 8°C, protected from light and contamination is avoided. Do not freeze the reagent ! Discard the Reagent if found turbid or in case the absorbance of Working Reagent is less than 1.0 AU at 340 nm against distilled water.

WARNINGS AND PRECAUTIONS :

Take the necessary precautions for the use of laboratory reagents.

WASTE MANAGEMENT :

Please refer to local regulation requirements.

REAGENT PREPARATION :

1) Two Reagent Procedure : The reagents are ready-to-use.

2) One Reagent Procedure : Mix four volumes of reagent R1 with one volume of reagent R2. Stability of working reagent solution : Four Weeks at 2 to 8°C

MATERIAL REQUIRED BUT NOT PROVIDED :

NaCl solution 9 g/l, General laboratory equipment, Analyser / Photometer, pipettes etc.

SPECIMEN :

Serum free from hemolysis, Heparinized or EDTA plasma.

Stability in serum/plasma : Sera are stable 24 hours at20 to 25°C, 28 days at 4°C.

Discard contaminated specimens.

ASSAY PROCEDURE 1: Two Reagent procedure

Application sheets for automated systems are available on request.

Wavelength	:	Hg 340 nm
Optical path	:	1 cm
Temperature	:	37°C
Mode	:	Kinetic

Bring all the contents of the kit to Room Temperature prior to use.

Read rate of change of absorbance of sample against distilled water or air

Label the test tube as sample, control and pipette into respective test tube the reagent, sample, control sample as per the table given below :

	Sample / Control
Reagent R1	800 µl
Reagent R2	200µl

Mix and Incubate at 37°C for 2 minutes then add

Sample / Control	100 µl

Mix and after a 60 seconds incubation at 37°C measure the change of absorbance per minute (ΔA/minute) during 180 seconds.

ASSAY PROCEDURE 2: One Reagent procedure

Label the test tube as sample, control and pipette into respective test tube the reagent, sample, control sample as per the table given below :

Prewarm working reagent at 37°C for two minutes prior to addition of sample.

	Sample / Control
Working Reagent	1000 µl
Sample / Control	100 µl

Mix and after a 60 seconds incubation at 37°C measure the change of absorbance per minute (ΔA/minute) during 180 seconds.

CALCULATION :

At 340 nm with one reagent procedure and two reagent procedure for 1 cm path light cuvette

Activity of Sample (U/L) = Δ A/Min X 1746

TEMPERATURE CONVERSION FACTORS :

To correct result to other temperatures multiply by factor shown in table

Assay Temperature	Conversion Factor to		
	25°C	30°C	37°C
25°C	1.00	1.37	2.08
30°C	0.73	1.00	1.54
37°C	0.48	0.65	1.00

CALIBRATION :

For the calibration of automated photometric systems use of the commercially available calibrator is recommended.

QUALITY CONTROL :

To ensure adequate quality, use of the commercially available control sera is recommended.

PERFORMANCE CHARACTERISTICS :

MEASURING RANGE :

The test has been developed to determine GOT/AST Activity within a measuring range from 5 to 400 U/L. When values exceed higher limit of the range, such samples should be diluted 1 + 1 with NaCl solution (9 g/l) and the result multiplied by 2.

SPECIFICITY / INTERFERENCE :

No interference was observed by Ascorbic Acid up to 30 mg/dl (1703.4µmol /L), Bilirubin up to 15 mg/dl (256.5µmol/L), Glucose up to 500 mg/dl (27.75mmol/L) and lipemia up to 600 mg/dl (6.84mmol/L) Triglycerides. A list of drugs and other interfering substances with GOT/AST determination has been reported by Young et al.

SENSITIVITY / LIMIT OF DETECTION :

The lower limit of detection is 5 U/L.

PRECISION :

Intra-assay precision n = 20	Mean [U/L]	SD [U/L]	CV [%]
Sample 1	26.7	0.2	0.74
Sample 2	46.2	0.4	0.86
Sample 3	187	1.4	0.74

Inter-assay precision n = 20	Mean [U/L]	SD [U/L]	CV [%]
Sample 1	42	0.4	0.95
Sample 2	146	1.0	0.68
Sample 3	179	1.2	0.67

METHOD COMPARISON :

A comparison between Robonik prietest GOT/AST (y) and a commercially available test (x) using 20 samples gave following results:

Linear Regression : y = 1.2543x - 8.6117 U/L

Correlation Coefficient : r = 0.9913

REFERENCE RANGE :

Men : 0 to 38 U/L **Women** : 0 to 31 U/L

It is recommended that each laboratory should assign its own reference range.

LITERATURE :

1. Henderson, A.R., Moss, D.W., Enzymes, Tietz Fundamentals of Clinical Chemistry, 5th Ed., Burtis, C.A. & Ashwood, E.R. (W.B. Saunders eds. Philadelphia USA), 2001, 352.
2. Tietz, N.W., Clinical guide to laboratory tests, 3rd Ed., (W.B. Saunders eds. Philadelphia USA), (1995), 76.
3. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed. AACC Press, 1995

INSTRUMENT APPLICATION
prietest TOUCH

Name : GOT , Mod : KIN
Pri.: 340 , Sec.: 0
Temp: 37C , KF : 1.000
Vol : 500ul , Unit : U/L
Lag : 60 , Read : 180
Blk : N, QC : Y, Norm : Y
Std : N , Factor : 1746
Normal HI = 38
Normal LO = 0
QCNH : *
QCNL : *
QCABH = *
QCABL = *
Init. OD : = 1.0 L
Max Delta/Min : = 0.229
Rgnt. Linearity : 400

NOTE :
* Indicates user definable parameter.
NA Implies Not Applicable

PARAMETERS FOR INSTRUMENT SETTING

TEST NAME	GOT
Reaction	Kinetic
Reaction Slope	Decreasing
Wavelength 1	340 nm
Temperature	37°C
Zero Setting	Distilled Water
Factor	1746
Units	U/L
Sample Volume	100 µl
Reagent Volume	1000 µl
Lag Time	60 Seconds
Read Time	180 Seconds
Reference Range	0 to 38
Reagent Linearity	400
Max Delta/Min	0.229
Initial OD	> 1.0

ROBONIK®

An ISO 9001 : 2008 Certified Company
An ISO 13485 : 2012 Certified Company

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