BioMed-GOT

(ASAT/AST/GOT) -Kinetic

REF: GOT111060 (10 x 6 ml)
GOT111090 (5 x 18 ml)
GOT111120 (2 x 60 ml)

INTENDED FOR USE

For the determination of AST/GOT in serum

PRINCIPLE :

Present Kinetic method for determination of aspartate amino transferase without perodoxal-phosphate is optimized in accordance with I.F.C.C. recommendations.

Aspartate amino transferase (AST/GOT) catalyzes the following reaction:

$$\alpha\text{-ketoglutarate} + \text{L-aspartate} \xrightarrow{\text{AST/GOT}} \text{L –glutamate} + \text{oxaloacetate}$$

By the coupled reaction of Malate –hydrogenase (MDH) and the relative co enzyme (NADH), oxaloacetate is reduced to Malate with the co enzyme oxidation

$$\text{oxaloacetate} + \text{NADH} + H^+ \xrightarrow{\text{MDH}} \text{L-Malate} + NAD^+ + H_2O$$

The reduced co enzyme consumption, observed as decrease of the per time extinction, is proportional to AST/GOT activity in the sample.

SPECIMEN COLLECTION:

Non hemolized serum or plasma .
Common anticoagulants can be used.
(Heparin, EDTA, oxalates, and fluorides).
AST/GOT in serum or plasma is reported stable up to 4 days at +15-25°C., 10 days at +2-8 °C and 3 weeks if frozen at -20°C.
Shake and bring the samples at room temperature (+15-25°C) before using.

REAGENTS COMPOSITION :

R1	***Buffer/Substrate (Liquid)***	
	Phosphate buffer	80 mmol/l
	L-Aspartate	200 mmol/l
R2	***Enzymes/coenzyme (liquid)***	
	LDH	≥ 1.2 U/ml
	MDH	≥ 0.6 U/ml
	NADH	≥ 0.18 mmol/l
	α - Oxoglutarate	12 mmol/l

PACKAGE : Collection & Storage .

Store at +2-8°C .
Stable until the expiration date reported upon the package.
After the unsealing and the taking of the reagent , it is advised to close up the bottle immediately in order to avoid evaporation , direct light exposure and bacterial contamination .

PRECAUTIONS & WARNING:

Avoid pipette by mouth.
The preparation, according to current regulation, is classified as not dangerous. The total concentration of non active components (preservatives, detergents, and stabilizers) is below the minimum required for citation. Anyway handle with care, avoid ingestion, avoid contact with eyes, skin and mucous membranes **.** The samples must be handle as potentially infected from HIV or Hepatitis

REAGENT PREPARATION & STABILITY :

Liquid reagents must be at room temperature (+15-25°C) before using .
Reagent (R1) is limpid/ colorless; Reagent (R2) is from colorless to pale yellow.
Add 4 parts of Reagent (R1) to 1 part of Reagent (R2).
Reagent (R1+R2) is reported stable up to 2 days at room temperature and 4 weeks if stored in refrigerator.

REQUIRED MATERIALS NOT PROVIDED :

General Laboratory Equipment and instrumentations .

PROCEDURE :

Wavelength	340,334 or 365 nm
Optical path	1 cm
Incubation temperature	25,30 or 37°C
Zero adjustment	Against air

Pipette into cuvette

	Macro	**Semi-micro**
Specimen	200 µl	100 µl
Working solution	2.0 ml	1.0 ml

Mix, read initial absorbance after 60 sec. and start timer simultaneously. Read again after 1, 2 and 3 minutes. Determine the mean absorbance change per minute (ΔA/min).

CALCULATION :

To calculate the AST /GOT activity use the following formula

U/l = 1780 x ΔA 334 nm / min
U/l = 1746 x ΔA 340 nm / min
U/l = 3235 x ΔA 365 nm / min

EXPECTED VALUES :

	25°C	30°C	37°C
Female	Up to 15 U/l	Up to 21 U/l	Up to 31 U/l
Male	Up to 18 U/l	Up to 25 U/l	Up to 37 U/l

The above mentioned values are to be considered as a reference. It is strongly recommended that each laboratory establish its own normal range.

WASTE DISPOSAL :

The disposal of the product must be in accordance with local regulation concerning waste disposal .

QUALITY CONTROL :

It is recommended to execute the quality control at every kit utilization to verify that values are within the reference range indicated by the methodology.

PERFORMANCE :

MEASURE INTERVAL :	0-500 U/L
MEASURABLE LIMIT :	3 U/L
SENSITIVITY :	1 U/L= 0.0017 ΔE/min.

PRECISION WITHIN SERIES: n=20

LOW LEVEL	M= 31U/L	C.V.=2.9%
HIGH LEVEL	M= 156U/L	C.V.=2.1%

PRECISION AMONG SERIES: n=20

LOW LEVEL	M= 31U/L	C.V.=3.1%
HIGH LEVEL	M= 160U/L	C.V.=3.8%
CORRELATION	r = 0.998	n=50
LIN. REGRESSION	y = 0.96x + 1.33	n=50

INTERFERENCE:

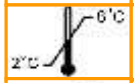
Interferences are negligible up to :			
Bilirubin	18 mg/dL	Triglycerides	500 mg/dL
Hemoglobin	300 mg/dL	Glucose	500 mg/dL

METHOD LIMITATIONS:

For concentration higher than 500 U/L, repeat the measure on a sample diluted 1:2 with physiological solution and multiply the results by 2.Hemolyzed sample may provide elevated readings due to AST presence in erythrocytes.
Individuals lacking B6 vitamin may present low AST level, probably due to pirid-oxalic-phosphate absence.
For a through evaluation of the interfering substances , consult : Young, D.S.,et al.,Clin.Chem. 21:1D (1975).

REFERENCES :

1. Tietz, N.W. (ed) Fundamentals of Clinical Chemistry W.B. Saunders Co., Philadelphia, 1976.
2. Henry, R.J. Clinical Chemistry, Principles and Technics. Harper and Row Publishers. New York, 1964.
3. Provisional Recommendations on IFCC methods for the measurement of catalytic concentrations of enzymes. Clin chem. 23(887), 1977.

	Consult Instructions for Use
	Caution, Consult accompanying Documents
IVD	In Vitro Diagnostic Medical Device
	Temperature Limitation
	Manufacturer
EC REP	Authorized Representative in the European Community
REF	Catalogue Number
LOT	Batch Code
	Use by

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