In-vitro Diagnostic reagent kit for quantitative determination of Glutamic Oxaloacetic Transaminase/ Aspartate Transaminase (GOT/ASAT) in serum/plasma sample on Photometric System.

ORDER INFORMATION

Cat no. Kit Configuration LG119-100 Reagent R1 - 2 x 40mL

Reagent R2 - 2 x 10mL

LG119-500 Reagent R1 -1 x 400ml Reagent R2 - 1 x 100mL

LG119-1000

Reagent R2 - 2 x 100ml

REAGENT

Reagent 1: Enzyme Solution Reagent 2: Buffer Solution

SUMMARY

Aspartate aminotransferase (ASAT) is an enzyme found primarily in the liver and kidney. It was originally referred to as serum glutamic oxaloacetic transaminase (SGOT). Normally, a low level of ASAT exists in the serum. ASAT is increased with liver damage and is used to screen for and/or monitor liver disease. Aspartate aminotransferase (ASAT) is usually measured concurrently with ALAT as part of a liver function panel to determine the source of organ damage

PRINCIPLE

The rate of NADH consumption is measured photometrically and is directly proportional to the ASAT concentration in the sample.

L-Aspartate + 2-Oxoglutarate + ASAT + Oxaloacetate Oxaloacetate + NADH* + H* MDH L - Malate + NAD*

REAGENTS STORAGE INSTRUCTIONS AND STABILITY

Reagents are stable up to the end of the indicated month of expiry, if stored - 8°C, protected from light and contamination is avoided. Do not freeze the reagents!

COMPOSITION

TRIS buffer pH 7.8 25.2 g/L, L – Aspartate 24. g/L, MDH (Malate dehydrogenase) \geq 600 U/L, LDH (lactate dehydrogenase) \geq 1200 U/L, 2-Keto glutaric acid 7.9 g/L, NADH 1.1 g/L

WASTE MANAGEMENT

Please refer to local legal requirements.

REAGENT PREPARATION

Mix, 4 parts of reagent 1 and 1 part of reagent 2 = working reagent. The stability of the working reagent is 5 days at 15°-25°C. 4 weeks at 2° - 8°C. Protect the reaction solution from light.

MATERIALS REQUIRED BUT NOT PROVIDED

NaCl solution 9 g/L. General laboratory equipment

SPECIMEN

Serum, heparin, plasma or EDTA plasma separate at the latest 1h after blood collection from cellular contents.

7 days 30 days at -20°C

Only freeze once! Discard contaminated specimens.

ASSAY PROCEDURE

Wavelength: 340 nm Optical Path: 10 mm Temperature: 37°C

Working Reagent	1000 μL	
Sample	100 μL	

Mix and incubate for 1 min. and read absorbance after every 1 min. for 3

CALCULATION

 $\Delta A/min$ and multiply by the corresponding factor from table below: ASAT activity $U/L = \Delta A/\min x factor (1745)$

QUALITY CONTROLS

For internal quality control any normal and abnormal controls should be assayed with each batch of samples.

Each laboratory should establish corrective action in case of deviations in

WARNINGS AND PRECAUTIONS

- Keep out of reach of children. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- Take off immediately all contaminated clothing
- The reagents contain sodium azide (0.95 g/L) as preservative. Do not $swallow. \, Avoid \, contact \, with \, skin \, and \, mucous \, membranes. \,$
- For professional use only!

PERFORMANCE CHARACTERISTICS **MEASURING RANGE**

The test has been developed determine GOT/ASAT activities within a measuring range from 5 - 800 U/L. If such value is exceeded the sample should be diluted 1 + 9 with NaCl solution (9 g/L) and results multiplied by

LINEARITY/LIMIT OF **MAXIMUM DETECTION**

Linearity of detection is 800 U/L

SENSITIVITY/LIMIT OF DETECTION

The lower limit of detection is 5 U/L.

SPECIFICITY/INTERFERENCES

No interference was observed by, Ascorbic acid upto 30 mg/dL, Bilirubin upto 40 mg/dL and Triglycerides upto 2000 mg/dL.

PRECISION

Intra assay n=20	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	35.72	0.49	1.38
Sample 2	46.41	0.44	0.94
Sample 3	168.10	0.67	0.40

Inter assay n=20	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	36.36	0.33	0.90
Sample 2	47.17	0.41	0.87
Sample 3	172.43	1.12	0.65

METHOD COMPARISON

A comparison of precision biomed GOT/ASAT (v) with a commercially available test (x) using 15 samples gave following results: y=1.024x-1.406; r2=0.997

ASSAY PARAMETERS

Mode	Kinetic	
Reaction slop	Decreasing	
Wavelength	340 nm	
Path length	10 mm	
Temperature	37°C	
Working reagent	4 part Reagent 1	
	1 Part Reagent 2	
Working reagent Volume	1000 μL	
Sample volume	100 μL	
Delay	60 sec	
Rate	60 sec	
No. of readings	3	
Factor	1745	
Normal range	Male: < 37 U/L	
	Female: < 31 U/L	
Linearity	800 U/L	
Sensitivity	5 U/L	

REFERENCE RANGE

Adults		
Men	< 37 U/L	
Women	< 31 U/L	

Note: It is recommended that each laboratory should establish its own reference range based on the patient population.

LITERATURE

- 1st ed. Frankurt: TH-Books Verlagsgesellschaft: 1998.p.55-65.
- Tietz Textbook of clinical chemistry. 3rd ed.
- Philadelphia: W.B saunders company; 1999.p.617-72 . 4. Clin Chem Lab Med 2002; 40:718-24.
- Association for Clinical Biochemistry and Laboratory Medicine Retrieved 7 October 2013.
- Central Pollution Control Board (CPCB) Guidelines for Management of healthcare waste as per Biomedical Waste Management rules, 2016.

INDEX OF SYMBOLS

ISO 13485	International Organization or Standardization	*	Keep out of Sunlight
ш	Manufacturer	IVD	For invitro diagnostic use only
8	Expiry date	Ωį	Read product insert before use.
LOT	Lot (batch) number	®	Do not use if package is damaged
2°C 8°C	Store between 2-8°c	*	Keep Away From Moisture
ART/IFU/PRC-119-01			

Manufactured by:

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