

Intended Use

The reagents are used for the quantitative determination of Aspartate aminotransferase (AST) in serum or plasma. For in-vitro diagnostic use only.

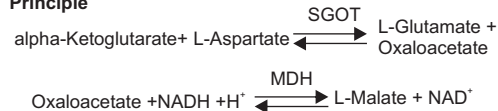
Introduction

Aspartate aminotransferase (AST) also referred to as serum glutamate oxaloacetate transferase (SGOT) is an enzyme involved in amino acid metabolism. AST is widely distributed in liver, red blood cells, heart, muscles tissues, pancreas and kidney. Low levels of AST in blood is observed in recent or severe liver disease, myocardial infarction, heart attack or heart failure, kidney disease or lung disease.

Method

IFCC - UV Kinetic Method.

Principle



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

Reagent Composition

Reagent 1:

L-Aspartate	> 200 mmol/l
Malate Dehydrogenase	> 2000 IU/L

Reagent 2:

Alpha-Ketoglutarate	>35 mmol/l
NADH	1.05 mmol/l

Precautions

Following precautions should be taken:

- Avoid ingestion, do not pipette by mouth.
- Avoid contact with skin and eyes. If spilled, thoroughly wash affected area with water.

•Do not swallow or inhale vapor, it may cause irritation to mouth, throat and stomach.

•Flush with plenty of water while disposing.

Reagent Storage and Stability

Unopened Reagents are stable till expiry mentioned on the label when stored at 2-8°C.

Reagent Preparation

- 1) Two Reagents Procedure: The reagents are ready for use.
- 2) One Reagent Procedure (Working solution) : Mix four volumes of Reagent R1 with one volume of Reagent R2. The working solution is stable for four weeks at 2 to 8°C.

Reagent Deterioration

Reagents should be clear. Turbidity and/or precipitation may be because of reagent deterioration.

Specimen Collection and Storage

Serum or heparinized plasma can be used for the testing. Anti-coagulants like EDTA, oxalates and citrates cannot be used, as they inhibit AST activity.

Serum samples can be stored for 3 days at 2-8°C . Freezing of sample causes loss of enzyme activity, hence not recommended.

General Assay Parameters

Mode	Kinetic
Wavelength 1 (nm)	340
Wavelength 2 (nm)	-
Blank with	Air or Water
Sample Volume (µl)	50/100
Working Reagent (µl)	500/1000
Delay Time (sec)	60
Read Time (sec)	60
No. of readings	3
Incubation Temperature(°C)	37
Normal Level (IU/L)	Upto 40
Linearity (IU/L)	Upto 250
Factor	1746
Units	IU/L

PROCEDURE

Two Reagent Procedure:

Pipette into test tubes as per table given below:

Particulars	Sample Volume
Reagent R1	800 µl
Reagent R2	200 µl
Mix and incubate at 37°C for 2 minutes then add	
Sample	100 µl

One Reagent Procedure:

Pre-warm working reagent at 37°C for two minutes prior to addition of sample.

Particulars	Sample volume
Working Reagent	1000 µl
Sample	100 µl

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

Calculation

AST concentration in the sample can be calculated using the following formula:

ΔA = Rate of change of absorbance/minute

AST = ΔAbs/min X Factor (1746)

If the AST concentration exceeds 250 IU/L, dilute the sample with normal saline and repeat the assay. The reportable results in this case shall be calculated by multiplying the results obtained with dilution factor.

Reference value

Serum

Adult Male : upto 40 IU/L

Adult Female : upto 31 IU/L

Reference range varies from population to population; therefore, each laboratory should establish its own normal range.

Limitations

1. The reagent and sample volumes can be altered proportionately so that the sample:reagent ratio remains same.
2. Temperature has to be maintained constant throughout the reaction as the rate of color development is highly temperature sensitive.

Quality Control

The patient results obtained for each batch can be validated by using normal and abnormal control sera with assayed values for aspartate amino transferase.

Performance

Linearity Limit: 250 IU/L

Precision:

Within run

Control	Control 1	Control 2
No. of samples	20	20
Mean (IU/L)	41.23	185.25
S.D.	1.21	1.12
C.V. %	2.93	0.60

Between run

Control	Control 1	Control 2
No. of samples	60	60
Mean (IU/L)	41.19	185.43
S.D.	0.99	1.22
C.V. %	2.40	0.66

References

1. Gaze DC (2007). "The role of existing and novel cardiac biomarkers for cardioprotection". Curr.Opin. Invest. Drugs 8 (9): 711–717. PMID 17729182.
2. National Committee for Clinical Laboratory Standards. User evaluation of Precision Performance of Clinical Chemistry Devices. NCCLS; 1984, NCCLS Publication. http://www.thermo.com/eThermo/CMA/PDFs/Product/productPDF_50918.pdf

3. Young, D. S., Effects of Preanalytical Variables on Clinical Laboratory Tests, AACC Press, Washington, DC. (1993). http://www.beckman.com/customersupport/IFU/cis/389714/ADEN_AST.pdf

Pack Presentation

Product Code/ Catalogue No.	Pack Size*	Reagent 1	Reagent 2
KGAST102.3.1	5x20ml	4x20ml	1x20ml
KGAST102.3.2	5x50ml	4x50ml	1x50ml











*Pack size may vary on market demand.

Revision No: (Ver: KGAST102.3/1)

Date of Issue: 1st April 2010

Symbols

Following symbols are used in the labeling of KEE GAD kits:

	Catalogue No.		Batch No.
	CE Mark		Read instructions
	In Vitro Diagnostics		Storage temperature
	Expiry Date		Content
	Product Name		Manufactured By



Manufactured by:

KEE GAD Biogen Pvt. Ltd.

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