Spectrum For Diagnostic Industries

Aspartate aminotransferase (AST/GOT) - *Ultimate Single Reagent*

IVD

REF.	Pack size
175 02 020	40 T
175 06 020	120 T

Intended Use

SDI AST reagent is intended for the in-vitro quantitative, diagnostic determination of AST in human serum on both automated and manual systems.

Background

The enzyme aspartate aminotransferase (AST) is widely distributed in erythrocytes and tissues, principally heart, liver, muscle, and kidney. Elevated serum levels are found in diseases involving these tissues such as myocardial infarction,viral hepatitis and muscular dystrophy. Following myocardial infarction, serum AST is elevated and reaches a peak two days after onset. Two isoenzymes of AST have been detected, cytoplasmic and mitochondrial. Only the cytoplasmic isoenzyme occurs in normal serum, while the mitochondrial, together with the cytoplasmic isoenzyme, has been detected in the sera of patients with coronary and hepatobiliary diseases.

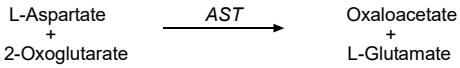
Method

Kinetic method according to the International Federation of ClinicalChemistry (IFCC) .

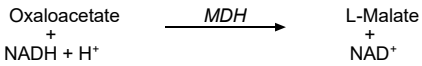
Assay Principle

The series of the reaction involved in the assay system is as follows:

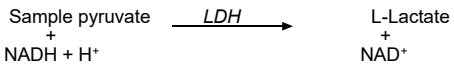
1. The amino group is enzymatically transferred by AST present in the sample from L-aspartate to the carbon atom of 2-oxoglutarate yielding oxaloacetate and L-glutamate.



2. Oxaloacetate in presence of NADH and malate dehyrogenase (MDH), is reduced to L-malate. In this reaction NADH is oxidized to NAD. The reaction is monitored by measuring the rate of decrease in absorbance at 340 nm due to oxidation of NADH to NAD.



3. Addition of lactate dehydrogenase (LDH) to the reagent is necessary to achieve rapid and complete reduction of endogenous pyruvate so that it does not interfere with the assay.



Reagent (R)

Tris buffer (pH 7.7)	80 mmol/L
L- Aspartate	240 mmol/L
MDH	> 450 U/L
LDH	> 1200 U/L
Sodium Hydroxide	220 mmol/L
Sodium Azide	8 mmol/L
NADH	> 0.18 mmol/L
2 - Oxoglutarate	18 mmol/L

Irritant (Xi): R36/38: Irritating to eyes and skin. S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S37/39: Wear suitable gloves and eye/face protection.

The reagent also contains additives required to maintain NADH in its reduced forrm.

For further information, refer to the Aspartate aminotransferase reagent material safety data sheet.

Precautions and Warnings

Do not ingest or inhalate. 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.

The Reagent (R) contain sodium azide which may react with copper or lead plumbing.

Reagent Preparation, Storage and Stability

SDI AST reagent is supplied ready-to-use and stable up to the expiry date labeled on the bottles
Once opened, the reagent vial is stable for 1 month at the specified temperature.

Deterioration

Do not use SDI AST reagent if it is turbid or if the absorbance of the working reagent is less than 0.9 at 340 nm. Failure to recover control values within the assigned range may be an indication of reagent deterioration.

Specimen Collection and Preservation

Use nonhemolyzed serum. Heparin and EDTA are the only acceptable anticoagulants. The biological half-life of AST in serum is 17 hours.
Stability: 1 day at 15 – 25 °C; 7 days at 4 - 8°C;
12 weeks at -20 °C

System Parameters

Wavelength	340 nm (334 – 365 nm)
Optical path	1 cm
Assay type	Kinetic
Direction	decrease
Sample : Reagent Ratio	1 : 10
e.g.: Reagent volume	1 ml
Sample volume	100 µl
Temperature	37 °C or 30 °C
Equilibration time	60 seconds.
Read time	180 seconds
Zero adjustment	Against air
Reagent Blank Limits	Low 0.9 AU
	High 2.5 AU
Sensitivity	5 U/L
Linearity	400 U/L

Procedure

	Macro	Semi-Micro
Reagent (**R**)	1.0 ml	500 µl
Specimen	100 µl	50 µl

Mix, read initial absorbance after 60 seconds. and start timer simultaneously. Read again after 60, 120 and 180 seconds. Determine the mean absorbance change per minute (ΔA/min).

Calculation

To calculate the AST/GOT activity use the following formulae:

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

Quality Control

Normal and abnormal control serum of known concentrations should be analyzed with each run.

Performance Characterstics

Precision
Within run (Repeatability

	Level 1	Level 2
n	20	20
Mean (U/L)	32.6	133
SD	1.3	1.3
CV%	4.08	0.97

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (U/L)	33.1	135.5
SD	1.5	1.42
CV%	4.25	1.13

Methods Comparison

A comparison between Spectrum Diagnostics AST reagent and a commercial reagent of the same methodology was performed on 20 human serum.A correlation of 0.991 was obtained.

Sensitivity

When run as recommended, the minimum detection limit of this assay is 5.0 U/L.

Linearity

The reaction is linear up to AST concentration of 400 U/L; specimens showing higher concentration should be diluted 1+5 with physiological saline and repeat the assay (result×6).

Interfering Substances

Hemolysis
Erythrocyte contamination elevates results, since AST activities in erythrocytes are 15 times higher than those in normal sera.

Icterus
No significant interference.

Lipemia
Lipemic specimens may cause high absorbance flagging. Diluted sample is recommended.

Anticoagulants
Citrate and fluoride inhibit the enzyme activity.

Drugs
Calcium dobesilate and doxycycline HCL cause artificially low AST values at the tested drug level.

Expected values

37 °C	Females	up to 31 U/l	(up to 0.52 µKat/L)
	Males	up to 37 U/l	(up to 0.62 µKat/L)
30 °C	Females	up to 21 U/l	(up to 0.35 µKat/L)
	Males	up to 25 U/l	(up to 0.42 µKat/L)

Temperature conversion factor is 1.37 (25 - 30 °C) and 2.04 (25-37 °C).

Analytical Range

5 – 400 U/L.

Waste Disposal

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment. refer to special instructions/safety data sheets.

References

1. Breuer J, Report on the symposium "drug effects in clinicalchemistry methods". Eur J Clin Chem Clin Biochem. 1996;34:385-386.
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3. IFCC expert panel on enzymes part 3. J Clin Chem Clin Biochem 1986;24:481-95.
4. Henry RJ, et al. Am j Clin Path 1960 :34:381
5. Sherwin JE. Liver function. In:kaplan LA, PESCE AJ, eds.Clinical chemistry, theory, analysis, and correlation. Stlouis:mosby;1984:420-438.
6. Young DS. Effects of drugs on clinical laboratory tests.Third edition. 1990 :3:6-12.
7. Zilva JF, pannall PR : Plasma enzymes in diagnosis inclinical chemistry in diagnosis and treatment lioyd- luke london 1979:chap 17: 338.

SYMBOLS IN PRODUCT LABELLING

IVD For in-vitro diagnostic use
LOT Batch Code/Lot number
REF Catalogue Number
Consult instructions for use
Temperature Limitation
Use by/Expiration Date
CAUTION. Consult instructions for use
Manufactured by

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Ismailia Free Zone Industerial Area, Block 5 .
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