AST

Aspartate Aminotransferase
IFCC
RX SERIES

INTENDED USE

An AST test system is a device intended for the quantitative *in vitro* determination of aspartate aminotransferase (AST) activity in serum and plasma. This product is suitable for use on RX **series** instruments which includes the RX **daytona** and the RX **imola**.

Cat. No.

AS 3804	R1. Buffer/Enzyme	6 x 51 ml
	R2. α-oxoglutarate/Coenzyme	6 x 14 ml

GTIN: 05055273200478

UV METHOD

This is a modification of the optimized standard method according to the recommendations of the IFCC.

CLINICAL SIGNIFICANCE[1,2,3,4]

The aminotransferases are a group of enzymes that catalyse the inter conversions of amino acids and α-oxoacids by transfer of amino groups. AST (aspartate aminotransferase or glutamate oxaloacetate transaminase) has been found in the cytoplasm and the mitochondria of cells that have been studied. In cases of mild tissue damage e.g. liver, the predominant form of serum AST is that from the cytoplasm, with a smaller amount coming from the mitochondria. Severe tissue damage will result in more mitochondrial enzyme being released. Elevated levels of AST can signal myocardial infarction, hepatic disease, muscular dystrophy and organ damage.

Although heart muscle is found to have the most activity of the enzyme, significant activity has also been seen in the brain, liver, gastric mucosa, adipose tissue and kidneys of humans.

The IFCC has now recommended (1980)[1] standardized procedures for AST determinations including:-

1. Optimization of substrate concentrations.
2. Employment of Tris buffers (instead of phosphate, which has been shown to inhibit recombination of the apoenzyme with pyridoxal phosphate).
3. Preincubation of combined buffer and serum to allow side reactions with NADH to occur.
4. Substrate start (α-oxoglutarate).
5. Optional pyridoxal phosphate activation.
   This is an optimized standard method according to the recommendations of the IFCC.

PRINCIPLE

α-oxoglutarate reacts with L-aspartate in the presence of AST to form L-glutamate plus oxaloacetate. The indicator reaction utilizes the oxaloacetate for a kinetic determination of NADH consumption.

$$\alpha\text{-oxoglutarate} + \text{L-aspartate} \xrightarrow{\text{AST}} \text{L-glutamate} + \text{oxaloacetate}$$

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

SPECIMEN COLLECTION AND PREPARATION[5]

Serum:- Use serum free from haemolysis.

Plasma:- EDTA or heparin can be used as the anticoagulant. Plasma should be separated from cells within one hour after collection.
Specimens should be refrigerated if not used immediately.
Specimens stored longer than 3 days should be frozen at –20°C.

REAGENT COMPOSITION

Contents		Concentration in the Test
R1.	**Buffer/Enzyme**	
	Tris buffer	80 mmol/l, pH 7.5
	L-aspartate	240 mmol/l
	MDH	≥ 0.42 U/ml
	LD	≥ 0.60 U/ml
R2.	**α-oxoglutarate/Coenzyme**	
	α-oxoglutarate	12 mmol/l
	NADH	0.24 mmol/l

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Solutions R1 and R2 contain Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.

Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

Health and Safety Data Sheets are available on request.

The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.

STABILITY AND PREPARATION OF REAGENT

R1. Buffer/Enzyme
Contents ready for use as supplied. Stable up to the expiry date when stored at +2°C to +8°C.

R2. α-oxoglutarate/Coenzyme
Contents ready for use as supplied. Stable up to the expiry date when stored at +2°C to +8°C.

MATERIALS PROVIDED

Buffer/Enzyme
α-oxoglutarate/Coenzyme

MATERIALS REQUIRED BUT NOT PROVIDED

Randox Assayed Human Multisera Level 2 (Cat. No. HN 1530) and Level 3 (Cat. No. HE 1532)
Randox Calibration Serum Level 3 (Cat. No. CAL 2351)
RX **series** Saline (Cat. No. SA 3854)

PROCEDURE NOTES

This AST assay is susceptible to carryover between the following Randox assays, when run on the same system: LDH and Phosphate.
To avoid the potential for carryover, please refer to the RX Instrument Carryover Avoidance document - prior to sample analysis - to confirm the test running order and for details of recommended washes.

To access the RX Instrument Carryover Avoidance document, please visit www.randox.com. Select **Support & Documentation**, followed by **Reagent Product Inserts**.
Please note: You will be required to create a user account if you do not already have one. To do this, please select **Request Access** and complete all the fields displayed.
Once logged in, please enter "Carryover" in the **Search** field, and the Carryover Avoidance document will be displayed.
Alternatively, please contact Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 9445 1070 or technical.services@randox.com.

The Chemistry parameters for Randox Dedicated RX **series** Assays are predefined on the hard drive of the analyser PC. The required programs should be downloaded to the analyser software. Please note that the predefined chemistry parameters use SI units. If alternative units are required, these can be edited by the user. In this case, the technical range should be edited in accordance with the users selected units. All necessary instructions are encoded on the bar code. If the barcode cannot be read by the analyser, enter manually the series of numbers given beneath the barcode. If problems continue, contact Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 9445 1070.

CALIBRATION

The use of Saline and Randox Calibration Serum Level 3 is recommended for calibration.

STANDARDISATION

Randox Calibration Serum Level 3 is traceable to AST reference material JSCC TS01.

QUALITY CONTROL

Randox Assayed Multisera, Level 2 and Level 3 are recommended for daily quality control. Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check cleanliness of all equipment in use.
3. Check water, contaminants i.e. bacterial growth may contribute to inaccurate results.
4. Check reaction temperature.
5. Check expiry date of kit and contents.
6. Contact Randox Laboratories Technical Services, Northern Ireland (028) 94451070.

Quality control requirements should be determined in conformance with government regulations or accreditation requirements.

SPECIFICITY/INTERFERENCE[6,7]

Gross haemolysis will produce falsely elevated test results. The effects of various drugs on AST activity should be taken into consideration in the case of patients receiving large doses of drugs.

The analytes below were tested up to the following levels and were found not to interfere:

Haemoglobin	250 mg/dl
Free Bilirubin	25 mg/dl
Conjugate Bilirubin	25 mg/dl
Triglycerides	1000 mg/dl
Intralipid®	200 mg/dl

A list of substances and conditions known to effect AST activity *in vivo* is given by both Young *et al* and Friedman *et al.* No representation is made by Randox Laboratories Ltd regarding the completeness of these lists and the accuracy of the information contained therein.

Physiological changes in serum or plasma analyte concentrations can be caused by a number of substances. Comprehensive discussion of possible interfering substances, their serum or plasma concentrations, and their possible physiological involvements is beyond the scope of this document. The listed reference contains specific details on known potential interfering substances [8]. The user must remain vigilant to the possible effect on results of unknown interferences from medications or endogenous substances. All patient results must be evaluated in light of the total clinical status of the patient.

NORMAL VALUES IN SERUM[9, 10]

	25°C	30°C	37°C
Men	up to 18 U/l	up to 25 U/l	up to 37 U/l
Women	up to 15 U/l	up to 21 U/l	up to 31 U/l

TEMPERATURE CONVERSION FACTORS[11]

30/25°C: 1.41 ± 0.07
37/25°C: 2.21 ± 0.15

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

SPECIFIC PERFORMANCE CHARACTERISTICS

The following performance characteristics were obtained using a RX **daytona** analyser at 37°C.

LINEARITY

The method is linear up to 657 U/l. In the event of a rerun, the linearity is extended to 2628 U/l. Alternatively, if the sample exceeds this value dilute sample 1 + 3 with 0.9% NaCl and reassay. Multiply the result by 4.

SENSITIVITY

The minimum detectable activity of aspartate aminotransferase (AST) with an acceptable level of precision was determined as 18.7 U/l.

PRECISION

Within run precision

	Level 1	Level 2	Level 3
Mean (U/l)	25.9	37.1	178
SD	1.09	1.37	2.96
CV(%)	4.21	3.66	1.66
n	20	20	20

Between run precision

	Level 1	Level 2	Level 3
Mean (U/l)	23.5	31.3	175
SD	1.02	1.29	3.20
CV(%)	4.34	4.11	1.82
n	20	20	20

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:

Y =1.10X - 2.21
and a correlation coefficient of r = 1.00.

40 patient samples were analysed spanning the range 10 to 225 U/l.

REFERENCES

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6. Young D S, *et al*: *Clin Chem* 1975, 21; No5.
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The presence of a vertical bar in the margin indicates a technical update from the previous revision.

EC REP

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