AST (GOT) IFCC (2-8°C)

CATALOGUE NUMBER	KIT SIZE (mL)
MPRAST3	4x60ml / 2x30ml

Intended Use:
For *In Vitro* diagnostic use by trained professionals only.
This reagent is intended for the quantitative determination of AST in human serum and plasma.

Clinical Significance:
AST belongs to the transaminases which catalyse the interconversion of amino acids and α-ketoacids by transfer of amino groups. AST is commonly found in human tissue, and although the heart muscle is found to have highest activity, significant amounts are also seen in the brain, liver, gastric mucosa, adipose tissue, skeletal muscle and kidneys.
Elevated levels of transaminases can signal myocardial infarction, hepatic disease, muscular dystrophy and organ damage.

Test Principle:
2-oxoglutarate + L-aspartate $\xrightarrow{AST}$ L-glutamate + oxalacetate

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

The rate of formation of NAD from NADH is directly proportional to the AST concentration in the sample. This can be measured at 340nm.

Reagent Composition

REAGENT	COMPONENT	CONCENTRATION
Reagent R1	Tris Buffer pH 7.8	80 mmol/l
	L-Aspartate	200 mmol/l
	LDH	800 U/l
	MDH	600 U/l
Reagent R2	NADH	0.18 mmol/l
	Oxoglutarate	12 mmol/l

Reagent Preparation and Stability:
R1: Liquid, ready for use
R2: Liquid, ready for use
R1 and R2 are stable to the stated expiry date when stored unopened at 2 - 8°C. Protect reagents from light. Once opened the R1 is stable for a period of 1 month and R2 is stable for a period of 1 month at 2 - 8°C, when stored without contamination.
Dispose of reagents carefully in line with local guidelines.

Sample / Sample Preparation / Sample Stability:
Collect serum and Heparin or EDTA plasma by standard venepuncture technique. Stability: 24 hours at +20 – 25°C, 3 days at 2 - 8°C. Separate serum / plasma from clot/cells within 8 hours at room temperature or 48 hours at 2 - 8°C.

Assay Procedure: Serum start
Prepare a working reagent by adding 1 volume of R2 to 4 volumes of R1. This working reagent will be stable for a period of 21 days at 2 - 8°C or 3 days at room temperature.

WAVELENGTH	340nm
TEMPERATURE	37°C
CUVETTE	1cm Path Length
BLANK	Against air

	Sample
Sample	100 µl
Working Reagent	1000 µl
Mix and incubate for 1 minute then start timer and read the absorbance after exactly 1,2 & 3 minutes.	

Calculation:
Calculate the ΔAbs/min of the sample
Concentration = ΔAbs/min x 1746

Performance Characteristics:
Measuring range:
Up to 467 U/l
Dilute samples with higher concentrations using Normal saline 1+9 and rerun the assay. Multiply the result by the dilution factor (for 1+9 dilution, the dilution factor is 10)

Analytical Sensitivity: (Lowest detection limit):
1 U/l = 0.00053 ΔAbs/min

Imprecision
Intra-Assay Precision:

Sample	Mean (U/l)	SD (U/l)	CV %
Pool 1	48.1	0.56	1.16
Pool 2	159	0.57	0.36

Inter-Assay Precision:

Sample	Mean (U/l)	SD (U/l)	CV %
Pool 1	47.4	1.42	3.00
Pool 2	156	4.35	2.97

Method Comparison:
Prestige Diagnostics AST reagent (y) was compared with another commercially available reagent (x) and gave the following results:

y = 1.042 x - 0.342, r = 0.99

Interferences:
Haemolysis interferes with the assay. Anticoagulants commonly used in laboratories do not interfere.

Limitations:
The AST result from this test should not be used as the sole criteria for the diagnosis of liver disorders, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Reference Range:

Male	Female
Up to 38 U/l	Up to 31 U/l

Each laboratory should establish its own mean reference range according to the population.

Automated systems:
Contact Prestige Diagnostics Technical Department for applications on a wide range of automated analysers.
For automation we recommend the use of a serum based calibrator.

Quality Control and Calibration Material:
Calibration Serum: **QCCCAL1 / QCCCAL2**
Human Assayed Control Normal: **QCCHAN1 / QCCHAN2**
Human Assayed Control Elevated: **QCCHAE1 / QCCHAE2**

References:

1. Murray R. Alanine Aminotransferase Kaplan A et al Clin Chem The CV. Mosby Co St Louis. Toronto. Princeton, 1984;783-790.
2. Young DS Effects of drugs on Clinical Laboratory Tests. 4th ed AACC Press 1995.
3. Young DS Effects of disease on Clinical Laboratory Tests. 4th ed AACC Press 2001.
4. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
5. Tietz NW et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.

REF	Catalogue number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by Date
	Manufacturer		Keep away from sunlight

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