ASO (Anti-Streptolysin O) (2-8°C)

(TURBIDIMETRY)

CATALOGUE NUMBER	KIT SIZE (ml)
MPRASO1	1x40ml/1x10ml/1x1ml

Intended Use:
For *In Vitro* diagnostic use by trained professionals only.
ASO Turbidimetry is intended to be used for quantitative measurement of ASO in human serum.

Clinical Significance:
Streptolysin O is a toxic immunogenic exoenzyme produced by beta haemolytic streptococci of groups A, C and G. Measuring Anti-SO antibody is useful for the diagnosis of rheumatoid fever, an inflammatory disease affecting connective tissue in several parts of human body including skin, heart and joints, acute glomerulonephritis (renal infection) and streptococcal infections.

Test Principle:
Latex particles coated with streptolysin O (SLO) are agglutinated when mixed with samples containing ASO antibody. The agglutination causes a change in absorbance, which is proportional to the ASO concentration in the patient sample that can be quantified by comparison with a calibrator of known ASO concentration.

Reagent Composition:

REAGENT	COMPONENT	CONCENTRATION
R1 – Buffer	Tris Buffer	20 mmol/l (pH 8.2)
	Preservative	
R2 – Latex Reagent	Latex particles coated with SLO, preservative	pH 10.0
ASO Calibrator	Human serum base containing ASO	Concentration stated on vial label. (NIBSC 97/662)

Precautions:
Components of human origin have been tested and found to be negative for the presence of HBsAg and antibody to HCV and HIV (1/2). However, handle as though potentially infectious.

Reagent Preparation and Stability:
R1: Liquid, ready to use.
R2: Liquid suspension, ready to use.
R1 and R2 are stable to the expiry date stated when stored unopened at 2 - 8°C. Once opened store tightly capped without contamination at 2 - 8°C. Do not use the reagents after the expiry date.
Exercise the normal precautions associated with the handling of laboratory reagents and dispose of carefully according to local guidelines.
ASO Calibrator: Reconstitute with 1ml of distilled water. Mix gently and stand at room temperature for 10 minutes before use. Stable for 4 weeks at 2 - 8°C or 3 months at -20°C.

Sample Collection, Preparation and Stability:
Collect serum by standard venepuncture technique. Stable for 7 days at 2 - 8°C or 3 months at -20°C. Samples with fibrin clots should be centrifuged before testing. Do not use highly lipaemic or haemolysed samples.

Assay Procedure:

WAVELENGTH	540nm (530 – 550 nm)
TEMPERATURE	37°C
CUVETTE	1cm Path Length
BLANK	Distilled Water

R1 - Buffer	800 µl
R2 – Latex Reagent	200 µl
Calibrator /Sample	10 µl
Mix and read the absorbance immediately (A1) and after 2 minutes (A2) of the sample addition.	

Calculation:
ASO Concentration (IU/ml) = $\frac{\text{A2-A1 Sample}}{\text{A2-A1 Calibrator}}$ x Concentration of Calibrator

Performance Characteristics:
Linearity limit:
Up to 800 IU/ml. Samples with higher concentration should be diluted 1/3 in NaCl (0.9%) and retested. The linearity limit depends on the sample reagent ratio as well as the analyser used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.
Detection Limit:
Values less than 20 IU/ml give non-reproducible results.
Prozone Limit:
No prozone effect was detected up to 1000 IU/ml.
Sensitivity: 1 IU/ml = Δ 0.73 mA

Precision:
The reagent has been tested over 20 days, using three different ASO concentrations.

	CV %		
	100 IU/ml	200 IU/ml	400 IU/ml
Total	6.4%	5.7%	5.1%
Intra Assay Precision	2.4%	1.7%	1.4%
Inter Assay Precision	3.6%	4.2%	4.9%

Accuracy:
Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 60 samples of different concentrations of ASO were assayed. The results were as follows:
y = 0.915x - 4.844, r = 0.99.

Interferences:
Bilirubin (20 mg/dl), haemoglobin (10g/l), lipaemia (10 g/l) and rheumatoid factor (600 IU/ml) do not interfere. Other substances may interfere.

Notes:
Clinical diagnosis should not be made on findings of this single test result, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Application for Automated systems:
For Applications on automated systems – contact technical department.

Quality Control and Calibration Material:
It is recommended that a laboratory uses reference control sera to verify the reagent performance. Results obtained should fall within the specified ranges. If results fall outside these ranges actions should be taken in line with the laboratory's internal quality procedures.
Prestige recommend the following controls

References:

1. Haffejee I, Quarterly Journal of medicine 1992, New series 84; 305: 641-658.
2. Alouf Jodeph E Pharma Ther 1980; 11: 661-717.
3. M Fasani et al Eur J Lab Med 1994; vol 2.n1:67
4. Todd E,W. J Exp Med 1932; 55: 267-280.
5. Klein GC, Applied Microbiology 1970; 19:60-61.
6. Klein GC, Applied Micxrobiology 1971; 21: 999-1001.
7. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Prewss 1995.

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

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Prestige Diagnostics UK Ltd 40 Ballymena Business Centre, Galgorm, Co. Antrim, BT42 1FL, United Kingdom. Tel: +44 (0) 28 2564 2100
www.prestigediagnostics.co.uk info@prestigediagnostics.co.uk

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