

prieturb™ ...Latex Turbidimetric Immunoassay

ASO

In vitro diagnostic test kit, for professional use only

INTENDED USE : Quantitative determination of Anti-Streptolysin O (ASO) in serum.

ORDERING INFORMATION **Pack Size** **Cat. No.**
50 ml PTLASO 01 50

CLINICAL SIGNIFICANCE :

(Anti-Streptolysin O)
ASO was one of the first bacterial markers used for diagnosis and prognosis of rheumatism or scarlet fever. Anti-Streptolysin O (ASO or ASLO) is the antibody produced against an enzyme called streptolysin O (oxygen-labile) produced by β-Haemolytic Streptococci belonging to Lancefield's group A, C and G. The other antigen being oxygen stable, streptolysin-S. Both the enzymes are involved in producing haemolysis. Increased or increasing levels may indicate a past or ongoing infection.

METHOD :

Particle Enhanced Turbidimetric immuno Assay (PETIA), where inert latex particles are used to increase the sensitivity of the reaction.

PRINCIPLE :

Prieturb ASO – Latex is a particle based immunoassay for quantitative determination of Anti-Streptolysin O (ASO) in human serum. Latex particles coated with purified Streptolysin O, when allowed to react with samples containing ASO agglutinate causing a change in absorbance. This change depends on the concentration of ASO and is determined by comparing it with a calibrator (standard) of known concentration.

REAGENTS :

COMPONENTS AND CONCENTRATIONS :

- 1. R1 Activation Buffer (40 ml)**
Buffer Solution
(Preservative : Sodium Azide 0.95 g/L)
- 2. R2 Latex Reagent (10 ml)**
Suspension of Latex Particles coated with Human Immunoglobulin
(Preservative : Sodium Azide 0.95 g/L)
- 3. Calibrator 400 IU/ml (0.2 ml)**
Human serum Containing known concentration of ASO
(Preservative : Sodium Azide 0.95 g/L)

STORAGE INSTRUCTIONS AND REAGENT STABILITY :

- 1) Store the reagents at 2 to 8°C. DO NOT FREEZE.
- 2) The shelf life of the reagent, activation buffer and the calibrator is as per the expiry date mentioned on the respective vial label.

WARNINGS AND PRECAUTIONS :

1. To avoid contamination. Use clean laboratory materials. Use clean dry disposable pipette tips for dispensing. Close reagent bottle immediately after use. Avoid direct exposure of reagent to light.
2. Components of human origin have been tested & found to be negative for the presence of HBsAg, HCV & antibody to HIV (1/2). However specimen should be treated as potentially infectious & handled with appropriate caution.

WASTE MANAGEMENT :

Please refer to local regulation requirements.

REAGENT PREPARATION :

1. All reagents are ready to use no special preparation is required.
2. ASO Calibrator : Ready to use.

MATERIALS REQUIRED BUT NOT PROVIDED :

Photometer, stopwatch, well calibrated micropipettes, disposable tips, isotonic saline, particulate free distilled water, test - tube rack, incubator / waterbath set at 37°C, optically clean disposable cuvettes such as Semi micro cuvettes / glass cuvettes.

SPECIMEN :

No special preparation of the patient is required prior to specimen collection by approved techniques.

Only serum should be used for testing. Should a delay in testing occur, store the samples at 2 to 8°C. Samples can be stored for up to two days at 2 to 8°C, provided they are not contaminated. Do not use hemolysed, icteric, or highly turbid sera. Turbid or particulate serum samples must be clarified by centrifugation at 2000 rpm for 15 minutes prior to testing. Use the clear supernatant for testing.

ASSAY PROCEDURE : For single point calibration.

Application sheets for automated systems are available on request.

- Wavelength : Hg 578 nm
- Temperature : 37°C
- Cuvette : 1 cm light path
- Read Against : Distilled Water
- Mode : Fixed Time / Initial Rate

Bring reagents, calibrator & samples to room temperatures before use. Prewarm reagent at 37°C for 2 minutes.

TEST PROCEDURE

A) With single point calibration and read time 5 min (300 Sec):

Label the test tube as calibrator, sample, control and pipette into respective test tube the reagent, calibrator, sample, control sample as per the table given below :

	Calibrator	Sample
R1 Buffer	400 µl	400 µl
Calibrator	5 µl	—
Sample	—	5 µl
R2 Latex	100 µl	100 µl

Mix well and read the variation of absorbance (Δ A) between **5 seconds** and **300 seconds**.

INSTRUMENT APPLICATION prietest TOUCH		PARAMETERS FOR INSTRUMENT SETTING	
Name : ASO , Mod : FIX_T		TEST NAME	ASO
Pri.: 578 , Sec.: 0		Reaction	Fixed Time
Temp: 37C , KF: 1.000		Reaction Slope	Increasing
Vol : 400ul , Unit : IU/ml		Wavelength 1	578 nm
Lag : 5 , Read : 300		Temperature	37°C
Blk : N, QC : Y, Norm : Y		Zero Setting	Distilled Water
Std. : 1 , Concen :		Lag Time	5 seconds
Std.: 1 = 400		Read Time	300 seconds
Normal HI = 200		Standard Conc.	400
Normal LO = 0		Units	IU/ml
QCNH : *		Sample Volume	5 µl
QCNL : *		Reagent Volume	500 µl
QCABH = *		Reference Range	0 to 200
QCABL = *		Reagent Linearity	800
Init. OD : = 1.0 H		Initial OD	< 1.0
Max Delta : = 0.15		Max Delta	0.15
Rgnt. Linearity : 800			
NOTE :			
* Indicates user definable parameter.			
NA Implies Not Applicable			

B) With single point calibration and read time 2 min (120 Sec):

Label the test tube as calibrator, sample, control and pipette into respective test tube the reagent, calibrator, sample, control sample as per the table given under A.

Mix well and read the variation of absorbance (ΔA) between 5 seconds and 120 seconds.

INSTRUMENT APPLICATION prietest TOUCH	PARAMETERS FOR INSTRUMENT SETTING	
Name : ASO , Mod : FIX_T Pri.: 578 , Sec.: 0 Temp: 37C , KF : 1.000 Vol : 400ul , Unit : IU/ml Lag : 5 , Read : 120 Blk : N, QC : Y, Norm : Y Std : 1 , Concen : Std.: 1 = 400 Normal HI = 200 Normal LO = 0 QCNH : * QCNL : * QCABH = * QCABL = * Init. OD : = 0.6 H Max Delta : = 0.08 Rgnt. Linearity : 500 NOTE : * Indicates user definable parameter. NA Implies Not Applicable	TEST NAME	ASO
	Reaction	Fixed Time
	Reaction Slope	Increasing
	Wavelength λ	578 nm
	Temperature	37°C
	Zero Setting	Distilled Water
	Lag Time	5 seconds
	Read Time	120 seconds
	Standard Conc.	400
	Units	IU/ml
	Sample Volume	5 μ l
	Reagent Volume	500 μ l
	Reference Range	0 to 200
	Reagent Linearity	500
Initial OD	< 0.6	
Max Delta	0.08	

CAUTION :

Kindly adhere to the duration strictly in case of calibrators as well as Test sample since variations may give erroneous results.

CALCULATIONS :

$$\text{Concentration of Sample} = \frac{\text{Concentration of Calibrator}}{(\Delta A) \text{ Calibrator}} \times (\Delta A) \text{ Sample}$$

CALIBRATION :

For the calibration of automated photometric systems use of the commercially available calibrator is recommended.

QUALITY CONTROL :

To ensure adequate quality, use of the commercially available control sera is recommended.

PERFORMANCE CHARACTERISTICS :

MEASURING RANGE :

The test kit has been developed to determine ASO concentration within a measuring range from 20 to 800 IU/ml. When values exceed higher limit of the range, samples should be diluted 1 + 1 with NaCl solution (9 g/l) and the result is multiplied by 2.

SPECIFICITY / INTERFERENCES :

No interference was observed by Bilirubin up to 20 mg/dl, Lipemia up to 1000 mg/dl.

SENSITIVITY / LIMIT OF DETECTION :

Detection limit: 20 IU/ml

The detection limit represents the lowest measurable ASO concentrations that can be distinguished from zero.

REFERENCE RANGE :

Adults : Serum up to 200 IU/ml

Children <5 years : 100 IU/ml

It is recommended that each laboratory should assign its own reference range.

LITERATURE :

1. Haffeejee, Quarterly journal of Medicine 1992, New series 84; 305 : 641 - 658
2. Aloufetal Biochimie 1973; 56-61
3. Data on file.

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