Pariksha Biotech
A game changer in IVD

ASO Estimation Kit

High-Q ASO (Anti Streptolysin O)

Latex Enhanced Turbidimetric Immuno Assay(LETIA)

HIGH Q®
Command on Quality

Intended Use:
Kit for the quantitative determination of anti-streptolysin O (ASO) in human Serum.

Principle of the method:

The ASO-Turbilatex is a quantitative turbidimetric test for the measurement of ASO in human serum or plasma. Latex particles coated with streptolysin O (SLO) are agglutinated when mixed with samples containing ASO. The agglutination causes an absorbance change, dependent upon the ASO contents of the patient sample that can be quantified by comparison from a calibrator of known ASO concentration.

Clinical Significance:

SLO is a toxic immunogenic exoenzyme produced by β-heamolitic Streptococci of groups A, C and G. Measuring the ASO antibodies are useful for the diagnostic of rheumatoid fever, acute glomerulonephritis and streptococcal infections. Rheumatic fever is an inflammatory disease affecting connective tissue from several parts of human body as skin, heart, joints etc. Acute glomerulonephritis is a renal infection that affects mainly to renal glomerulus.

Reagents:

Diluent (R1): Tris buffer 30 mmol/L, pH 8.2. Sodium azide 1.00 g/L.

Latex (R2) : Latex particles coated with streptolysin O, pH 8.0. Sodium azide 1.00 g/L.

ASO-CAL : Calibrator. Human serum. (Concentration lot specific. Check the Calibrator Labels)

Calibration:

The sensitivity of the assay and the target value of the calibrator have been standardized against the ASO reference material.

Preparation:
All the reagents are ready to use.

ASO Calibrator: Calibrator is Liquid Stable and does not need any reconstitution. Calibrator is stable till the expiry date mentioned on the label

Storage and Stability:

All the components of the kit are stable till the expiration date on the labels when stored at 2-8ºC and the contaminations is prevented during their use.

Samples:

Fresh serum. Stable 7 days at 2-8ºC or 3 months at –20ºC.

Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolized or lipemic samples.

Procedure: Test Procedure:

ASO Diluent (R1)	**400 µl**
Serum	**5 µl**
ASO Latex Reagent (R2)	**100 µl**

Mix well and immediately aspirate in to the analyzer. Read absorbances of Calibrator (C) and Test (T) against distilled water at 546 nm (530-550) as follows

Initial absorbance A1 -exactly after 5 sec.
Final absorbance A2 - exactly 120 sec. after A1
Determine Δ A for Calibrator (C) and Test (T)

CALCULATIONS :

$$\text{ASO Conc.: (IU/ml)} = \frac{\text{(A2-A1) Sample}}{\text{(A2-A1) Calibrator}} \times \text{Calibrator Concentration on the label)}$$

System Parameters:

Reaction Type	:	Fixed Time / Initial Rate / Two Point Kinetic
Reaction Direction	:	Increasing
Sample Volume	:	5 µl
Reagent Volume	:	400 µl R1+ 100 µl R2
Wave Length	:	546nm (530-550 nm)
Calibrator Conc.	:	Concentration on the label
Flow Cell Temp.	:	37℃
Linearity	:	800
Zero setting with	:	Distilled Water
Units	:	IU/mL
Delay	:	5 sec.
Interval	:	120 sec

Quality Control:

Control Sera are recommended to monitor the performance of manual and automated assay procedures.

Each laboratory should establish its own Quality Control scheme

Reference Values:

Up to 200 IU/ml (adults)

Up to 100 IU/ml (children < 5 years old)

Each laboratory should establish its own reference range.

Performance Characteristics:

1. Linearity limit: Up to 800 IU/mL, under the described assay conditions. Samples with higher concentrations should be diluted 1:4 (10 parts serum sample + 30 parts saline ex: 10µl serum sample+30 µl saline) in saline and retested again and the results should be multiplied by 4. The linearity limit depends on the sample-reagent ratio as well the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.
2. Detection limit: Values less than 20 IU/mL give non-reproducible results.
3. Prozone effect: No prozone effect was detected up to 3000 IU/mL.

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Precision:

4. **Accuracy:** Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 80 samples ranging from 20 to 800 IU/ml of ASO were assayed. The correlation coefficient (r) was 0.98 and the regression equation y = 1.305 x –7.65.

The results of the performance characteristics depend on the analyzer used.

	Intra-assay (n=10)			Inter-assay (n=10)		
Mean (IU/mL)	135	236	372	135	236	372
SD	3.4	5.4	5.9	7.9	3.2	17.7
CV	2.5	2.3	1.6	5.9	5.5	4.8

Interferences:

Bilirubin (20 mg/dl), hemoglobin (10 g/l), lipemia (10 g/l) and rheumatoid factors (600 IU/ml) do not interfere.

Notes:

Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

Bibliography:

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; vol2.nº1: 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 Microbiology 1971; 21: 999-1001.
7. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995

Ordering information:

Ref./Cat. No.	Pack Size	Presentation
P-ASO (T) - 50	50 ml	Two Liquid Reagents with Calibrator

Product Features

- Latex Enhanced Turbidimetric Immuno Assay(LETIA)
- Two liquid reagents (Turbilatex and Diluent).
- Linearity : 800 IU/mL.
- Liquid Calibrator provided .
- No Prozone effect was detected upon 3000 IU/mL.
- No interference from Bilirubin (20 mg/dl), hemoglobin (10 g/l), lipemia (10 g/l) and rheumatoid factors (600 IU/ml) do not interfere.
- Can be used on semi and fully auto analyzers.

Symbols used with IVD devices

	Date of manufacture		Manufactured by
IVD	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)	R	Reagent
CAL	Calibrator Material	LOT	Batch code
2°C 8°C	Temperature limitation (store at)	CONTROL	Control
	Consult instructions for use		Keep dry Keep away from rain
REF	Catalog Number		

Pariksha Biotech
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eIFU Indicator

Pariksha's world inside
SCAN TO EXPLORE MORE

Manufactured in India by :
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