ASO TURBILATEX

Latex Turbidimetry

PRODUCT CODE
TL001

INTENDED USE
The ASO-Turbilatex is a quantitative turbidimetric test for the measurement of ASO in human serum or plasma.

CLINICAL SIGNIFICANCE
Streptolysin O (SLO) is a toxic immunogenic exoenzyme produced by ß-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.… and acute glomerulonephritis is a renal infection that affects mainly to renal glomerulus.

PRINCIPLE
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

REAGENTS

Diluent (R1)	Tris buffer 20 mmol/L, pH 8, Preservative.
Latex (R2)	Latex particles coated with Streptolysin O, pH 10 Preservative.
ASO-CAL	Calibrator. Human serum. ASO concentration is stated on the vial label.

PREPARATION
ASO Calibrator: Reconstitute with 1.0 mL of distilled water. Mix gently and incubate at room temperature for 10 minutes before use.

STORAGE AND STABILITY
All the kit components are ready to use, and will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8°C and contaminations are prevented during their use.
Do not freeze: frozen reagents could change the functionality of the test.
Always keep vials in vertical position. If the position is changed, gently mix to dissolve aggregates that may be present.
Reagent's deterioration: Presence of particles and turbidity.

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

SPECIMEN AND SAMPLE PREPARATION
Fresh serum or plasma, Stable 7 days at 2-8°C or 3 months at –20°C. Samples with presence of fibrin should be centrifuged.
Do not use highly hemolyzed or lipemic samples.

PROCEDURES
1. Bring the reagents and the photometer (cuvette holder) to 37ºC.
2. Assay conditions:
   Wavelength: 540 nm (530-550)
   Temperature: 37 ºC
   Cuvette light path: 1 CM
3. Adjust the instrument to zero with distilled water.
4. Pipette into a cuvette:

Diluent R1	800 µL
Latex R2	200 µL
Calibrator or sample	10 µL

5. Mix and read the absorbance immediately (A_1) and after 2 minutes (A_2) of the sample addition

CALCULATIONS

$$\frac{(A_2\text{-}A_1)\ \text{sample}}{(A_2\text{-}A_1)\ \text{calibrator}} \times \text{Calibrator concentration} = \text{IU/mL ASO}$$

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 and corrective actions if controls do not meet the acceptable tolerances.

NORMAL RANGE
Up to 200 IU/mL (adults) and 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 1/3 in NaCl 9 g/L and retested again. 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 1000 IU/mL
4. **Sensitivity: Δ 0.73 mA. IU/ML**
5. **Precision:** The reagent has been tested for 20 days**,** using three different ASO concentrations

EP5	CV (%)		
	± 100 IU/mL	± 200 IU/mL	± 400 IU/mL
Total	6.4%	5.7%	5.1%
Within Run	2.4%	1.7%	1.4%
Between Run	3.6%	4.2%	4.9%
Between Day	4.7%	3.5%	0.7%

6. **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 correlation coefficient (r) was 0.99 and the regression equation y = 0,915x –4,844. The results of the performance characteristics depend on the analyzer used.
7. **NOTES**
   Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.
8. **INTERFERENCES**
   Bilirubin (20 mg/dL), hemoglobin (10 g/L), lipemia (10 g/L) and rheumatoid factors (600 IU/mL), do not interfere. Other substances may interfere.
9. **NOTES**
   Clinical diagnosis should not be made on findings of a single test\result, but should integrate both clinical and laboratory data.

SYMBOL ON LABELS

Symbols	Signify	Symbols	Signify
REF	Catalogue Number	SIZE	Pack Size
	Expiry Date	VOL	Volume
	Storage Condition	LOT	Lot Number
	Instruction for Use	IVD	In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests	2	For Single Use Only
EC REP	EC Representative	CE	European conformity

REFRENCES

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4. M Fasani et al. Eur J Lab Med 1994; vol2.n°1: 67.
5. Todd EW.J Exp Med 1932; 55:267-280
6. Klein GC. Applied Microbiology 1971; 21: 999-1001.
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