ASO Turbilatex

Code	Product Name	Pack Size
SE027A	ASO Turbilatex	50 ml

Intended Use
For the quantitative determination of Antistreptolysin -O activity 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. And acute glomerulonephritis is a renal infection that affects mainly to renal glommerulus.

Reagents

Reagent 1: Diluent	Tris buffer 20 mmol/L, Preservative.
Reagent 2: Latex Antigen	Latex particles coated with streptolysin O, Preservative.
Regent 3: ASO Calibrator	Calibrator ASO concentration is stated on the vial label.

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.

Calibration
Use ASO Calibrator Provided with kit. The sensitivity of the assay and the target value of the calibrator have been standardized against the ASO International Standard from NIBSC 97/662.

Preparation
ASO Calibrator: Ready to use.

Storage And Stability
All the components of the kit are stable until the expiration date on the label when stored tightly closed at +2-+8°C and contaminations prevented during their use. Do not use reagents over the expiration date.

Reagent Deterioration: Presence of particles and turbidity. **Do not freeze; frozen Latex or Diluent could change the functionality of the test.**

Additional Equipment
- Thermostatic bath at +37°C.
- Spectrophotometer or photometer thermo statable at +37°C with a 540 nm filter.

Samples
Fresh serum. Stable 7 days at +2-+8°C.Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolized or lipemic samples.

Procedure
1. Bring the reagent and photometer (cuvette holder) to +37°C.
2. Assay conditions:
   Wavelength : 540 nm (530-550)
   Temperature : +37°C
   Cuvette ligth path : 1 cm
3. Adjust the instrument to zero with distilled water.
4. Pipette into a cuvette:

Diluent R1	900 uL
Latex R2	100 uL
Calibrator or Sample	10 uL

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

Calculation

$$\frac{(A_2\text{-}A_1)_{Sample}}{(A_2\text{-}A_1)_{Calibrator}} \times \text{Calibrator Concentration} = \text{IU/mL ASO}$$

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.

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Reference Values

Normal values 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:** Δ0.73 mA. IU/mL.
5. **Precision:**

Intra-assay precision Within run (n=20)	Mean (IU/mL)	SD (IU/mL)	CV (%)
Sample 1	90.25	1.45	1.61
Sample 2	239.579	2.44	1.02

Inter-assay precision Run to run (n=20)	Mean (IU/mL)	SD (IU/mL)	CV (%)
Sample 1	87.404	3.09	3.54

6. **Accuracy:** Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similer characteristics. 80 samples ranging from 20 to 800 IU/mL of ASO were assayed. The correlation coefficient(r) was 0.999 and the regression equation y = 0.975x + 0.1515 IU/mL

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

Interferences

Bilirrubin (20 mg/dL), hemoglobin (10 g/L), lipemia (10 g/L) and rheumatoid factors (600 IU/mL), do not interfere. Other substances may interfere.

Notes

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

Bibliography

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Symbols Used On Labels

REF	Catalogue Number		Manufacturer
	See Instruction for Use	LOT	Lot Number
CONT	Content		Storage Temperature
	Expiry Date	IVD	In Vitro Diagnostics

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