ASO-Turbilatex

Latex turbidimetry

Quantitative determination of anti-streptolysin O (ASO). IVD.
Store 2-8°C.

PRINCIPLE OF THE METHOD
The ASO-Turbilatex is a quantitative turbidimetric test for the measurement ofASO 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 -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 onnective 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

Diluent(R1)	Tris buffer20 mmol/L, pH 8.2. Sodium azide 0.90g/L. Merthiolate 0.05 g/L.
Latex (R2)	Latex particles coated with streptolysin 0, pH 10.0. Sodium azide 0.90 g/L. Merthiolate 0.05 g/L.
ASO-CAL	**ASO** Calibrator. ASO concentration is stated on the vial label.

PREPARATION
Working reagent: Swirl the latex vial gently before use. Prepare the necessary amount as follow:
- 1 ml Latex Reagent+ 4 ml Diluent

ASO Calibrator: Ready to use. Value mentioned on the vial in IU/ml.

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.

Working reagent: Stable for 30 days at 2-8°C.

Reagent deterioration: Presence of particles and turbidity.

ASO Calibrator: Ready to use. Stable till expiry at 2-8°C. Do not freeze.

Do not freeze. Frozen Latex or Diluent could change the functionality of the test.

ADDITIONAL EQUIPMENT
- Thermostatic bath at 37°C.
- Spectrophotometer or photometer thermostatable at 37°C with a 546 nm filter.

SAMPLES
Fresh serum. Stable 7 days at 2-8°C or 3 months at-20°C.
Samples with presence offibrin should be centrifuged before testing.
Do not use highly hemolized or lipemic samples.

GENERALSYSTEMPARAMETERS:

Reaction Type	Fixed Time
Wavelength	546nm (530-550 nm)
Light Path	1Cm
Reaction Temperature	37°c
Blank/ Zero Setting	Distilled Water
Reagent Volume	1ml
Sample Volume	20µl
Delay/ Lag Time	5sec
Read Interval	120Sec
Calibrator Concentration	Stated on Vial Label
Normal Value	Upto 200 IU/ml
Linearity	Upto 800 IU/ml

PROCEDURE
1. Bring the working reagent and the photometer (cuvette holder) to 37°C.
2. Assay conditions:
   Wavelength: 546 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:

Working Reagent (ml)	1.0
Calibrator or sample (µL)	20

5. Mix and read the absorbance after 10 sec. (A1) and after 2 minutes (A2) of the sample addition.

CALCULATIONS

$$\text{ASO (IU/ml)} = \frac{(A2\text{-}A1)_{sample}}{(A2\text{-}A1)_{calibrator}} \times \text{Calibrator concentration}$$

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.

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.

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.

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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