ASO-Turbilatex

Quantitative determination of anti-streptolysin 0 (ASO) IVD

DIAGNOSTIC SIGNIFICANCE:
SLO is a toxic immunogenic exoenzyme produced by (3-hemolytic 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.

PRINCIPLE:
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's sample that can be quantified by comparison from a calibrator of known ASO concentration.

PRESENTATION:

	No. of Bottles / Vials 1x50 ml
• R1 Diluent	1
• R2 Latex	1
• ASO Calibrator	1

PREPARATION OF WORKING REAGENT:
Mix 0.9 ml of Diluent (R1) with 0.1 ml of latex (R2).
PREPARATION OF WORKING CALIBRATOR:
Reconstitute with 1.0 ml of distilled water. Mix gently and incubate at room temperature for 10 minutes before use.

REAGENT STORAGE AND STABILITY:
All reagents are stable at 2-8° C till the expiry date mentioned on the label. Working reagent: Stable for 30 days at 2-8°C.
ASO Calibrator: Stable for 1 month at 2-8°C or 3 months at -20°C. Do not freeze; frozen Latex or Diluent could change the functionality of the test. Reagent deterioration: Presence of particles and turbidity.

SAMPLES:
Fresh serum : Stable 7 days at 2-8°C or 3 months at -20°C. Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolysed or Lipemic samples.

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.

REACTION PARAMETERS:

• Type of Reaction	:	Two Point Fix Time
• Wavelength	:	540 nm (530-550)
• Flow cell temperature	:	37^0C
• Sample/Calibrator Volume	:	10µl
• Reagent Volume	:	1 ml
• Zero setting with	:	Distilled Water
• Light Path	:	1 cm

PROCEDURE:

PIPETTE IN TEST TUBE	TEST
• Working Reagent (mL)	1.0
• Calibrator or sample (µl)	10

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

TEST RESULTS:

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

QUALITY CONTROL:
Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

NORMAL VALUES:
Adults: Up to 200 IU/mL Children (<5 years): Up to 100 IU/mL
Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS:
1. **Linearity:** 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 as 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. **Sensitivity :** Δ 0.73 mA / IU/mL

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.

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

REFERENCE:
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