ASO-turbilatex

Latex turbidimetry

CE

Determination of ASO in human serum or plasma.
Store at 2-8 °C

REF: KASO-T41B14 / KASO-T41B24

Summary:

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 glommerulus.

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.

Composition:

R1 (diluent): Tris buffer - 20 mmol/L, pH 8,2. Preservative
R1 (Latex): Latex particles coated with streptolysin O, pH 10,0. Preservative
ASO-CAL: Calibrator. Human serum. 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.
The sensitivity of the assay and the target value of the calibrator have been standardized against the ASO International Standard from NIBSC ASO.
The calibration is stable for 3 weeks.
Recalibrate when control results are out of specified tolerances, when using different lot of reagent and when the instrument is adjusted.

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 components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC and contaminations prevented during their use. Do not use reagents over the expiration date. Do not freeze; frozen Latex or Diluent could change the functionality of the test.
Reagent deterioration: Presence of particles and turbidity.
ASO Calibrator: Stable for 1 month at 2-8ºC or 3 months at –20ºC.

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.

Equipment:

- Thermostatic bath at 37ºC.
- Spectrophotometer or photometer thermostatable at 37ºC with a 540 nm filter.

Procedure:

1. Bring the reagents and the photometer (cuvette holder) to 37ºC.

2. Assay conditions:
Wavelength: . . . . . 540 nm (530-550)
Cuvette: . . . . . 1 cm. light path
Temperature 37ºC

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 (A1) and after 2 minutes (A2) of the sample addition.

Calculations:

$$\frac{(A2\text{-}A1)\ \text{Sample}}{(A2\text{-}A1)\ \text{calibrator}} \times \text{Concentration of Calibrator.} = \text{IU/mL ASO}$$

Quality control:

All clinical laboratories should establish an Internal Quality Control program. Check instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.
Controls should be assayed:
- Prior reporting patient results.
- Following any maintenance procedure on the photometer used.
- At pre-established intervals following the Q.C. Laboratory recommandations.

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:

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 the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.

Detection limit:
Values less than 20 IU/mL give non-reproducible results.

Prozone effect:
No prozone effect was detected up to 1000 IU/mL.

Sensitivity:
Δ0,73 mA. IU/mL.

Precision:
The reagent has been tested for 20 days, using three different ASO concentrations in a EP5-based study.

EP5	%CV		
	+/- 100 IU/mL	+/- 200 IU/mL	+/- 400 IU/mL
Total	6.4	5.7	5.1
Intra-assay	2.4	1.7	1.4
Inter-assay	3.6	4.2	4.9
Inter-day	4.7	3.5	0.7

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.

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, butshould integrate both clinical and laboratory data.

References:

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