CHRONOLAB

CE
IVD

ASO-turbilatex

Latex turbidimetry

Quantitative determination of anti-streptolysin o (ASO)

PACKAGING

Ref.: 101-0469	Cont.: 1 x 45 / 1 x 5 mL + 1 x 1 mL Cal.
Ref.: 101-0570	Cont.: 3 x 100 / 3 x 10 mL + 1 x 1 mL Cal.

Store 2-8º C.

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.

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.

REAGENTS

Diluent (R1)	Tris buffer 20 mmol/L, pH 8.2. Preservative.
Latex (R2)	Latex particles coated with streptolysin O, pH 10.0. Preservative.
ASO-CAL	Calibrator. Human serum. ASO concentration is stated on the vial label.

Optional (not included in the kit)

Control serum ASO/CRP/RF Level L	Ref.: 101-0466	4 x 1 mL
Control serum ASO/CRP/RF Level H	Ref.: 101-0467	4 x 1 mL

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 NIBSC 97/662.

The calibration in the SPINLAB 180 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 2-8º C and contaminations prevented during their use. Do not use reagents over the expiration date.

Reagent deterioration: Presence of particles and turbidity.

ASO Calibrator: Stable for 1 month at 2-8ºC or 3 months at –20º C.

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

ADDITIONAL EQUIPMENT

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

SAMPLES

Fresh serum. Stable 7 days at 2-8º C or 3 months at –20º C.

Samples with presence of fibrin should be centrifuged before testing.

Do not use highly hemolized or lipemic samples.

PROCEDURE

Notes: CHRONOLAB SYSTEMS has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

1. Bring the reagents and the photometer (cuvette holder) to 37º C.
2. Assay conditions:
   Wavelength: 540 nm (530-550)Temperature: 37º C
   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

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

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.

REFERENCE VALUES

Normal values up to 200 IU/mL (adults) and 100 IU/mL (children < 5 years old)[6].

Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

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.

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

Prozone effect: No prozone effect was detected up to 3000 IU/mL.

Sensitivity: Δ 0.73 mA. IU/mL.

CHRONOLAB SYSTEMS, S.L., C/Diputación 260, 08007 Barcelona, SPAIN
Tel. +34 617722466, www.chronolab.com, e-mail: comercial@chronolab.es

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 %
Within Run	2.4 %	1.7 %	1.4 %
Between Run	3.6 %	4.2 %	4.9 %
Between 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[7].

NOTES

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

BIBLIOGRAPHY

1. Haffejee I, Quarterly Journal of Medicine 1992, New series 84; 305: 641 – 658.
2. Alouf Jodeph E. Pharma Ther 1980; 11: 661-717.
3. M Fasani et al. Eur J Lab Med 1994; vol2.nº1: 67.
4. Todd E W. J Exp Med 1932; 55: 267 - 280.
5. Klein, GC. Applied Microbiology 1970; 19:60-61.
6. Klein GC. Applied Microbiology 1971; 21: 999-1001.
7. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

CHRONOLAB SYSTEMS, S.L., C/Diputación 260, 08007 Barcelona, SPAIN
Tel. +34 617722466, www.chronolab.com, e-mail: comercial@chronolab.es