Reactivos GPL

Barcelona, España

CE

- ASO TURBI -

ASO
TURBILATEX

Store at: +2+8ºC.

Presentation:
Cod. TL015 CONT: R1 1 x 40 ml / R2 1 x 10 ml. / CAL 1 ml.
TL016 CONT: R1 2 x 40 ml / R2 2 x 10 ml. / CAL 1 ml.
TL017 CONT: R1 4 x 40 ml / R2 4 x 10 ml. / CAL 1 ml.

Procedure

Diagnostic reagent for qualitative measurement of ASLO.

Only for in vitro use in clinical laboratory (IVD)

TEST SUMMARY

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 COMPOSITION

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	Ref.: TL012 Control ASO/CRP/RF Level L Ref.: TL022 Control ASO/CRP/RF Level H

PRECAUTIONS

Components from human origin have been tested and found to be negative for the presence of HBsAg and HCV, and of antibody to HIV (1/2). However, handle cautiously as potentially infectious.

Good laboratory safety practices should be followed when handling laboratory reagents or human samples.

REAGENT PREPARATION AND STABILITY

ASO Calibrator: Reconstitute (→) with 1.0 mL of distilled water. Mix gently and incubate 10 minutes at room temperature before use.
Stable for 1 month at 2-8ºC or 3 months at -20ºC.
Do not freeze; frozen reagents could change the functionality of the test.
Signs of reagent deterioration:
- Presence of particles (R1, R2) and turbidity (R1).

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. Reagents should not be left inside the analyser after use, they must be stored refrigerated at 2-8ºC. Latex may sediment. Mix reagents gently before use. Do not use reagents over the expiration date.

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.

SPECIMEN

Fresh serum. Stable 7 days at 2-8ºC or 3 months at –20ºC.
The samples with particles or fibrin should be centrifuged to eliminate them.
Do not use hemolyzed or lipemic samples.

Discard contaminated specimen

MATERIAL REQUIRED BUT NOT PROVIDED

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

General laboratory equipment

TEST PROCEDURE

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

		Micro Test
Diluent R1	800 µL	400 µL
Latex R2	200 µL	100 µL
Calibrator or sample	10 µL	5 µL

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

CALCULATIONS

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

QUALITY CONTROL

Serum controls Ref.: TL012 and Ref.: TL022 are recommended to monitor the performance.

Serum controls are recommended for internal quality control. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES

Up to 200 IU/ml (adults) and 100 IU/mL. (children<5 years old)[6].

It is suggested that each laboratory establish its own reference range.

CLINICAL SIGNIFICANCE

Streptolysin O is a toxic immunogenic exoenzyme produced by β-hemolytic Streptococci of groups A, C and G. Measuring the ASO antibodies is 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 glomerulus.

REAGENT PERFORMANCE

- *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 1000 IU/mL.
- *Sensitivity:* Δ 0.73 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%
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 used analyzer.

INTERFERING SUBSTANCES

Bilirubin (20 mg/dL), hemoglobin (10 g/L), lipemia (10 g/L) and rheumatoid factors (600IU/mL), do not interfere.
Other substances may interfere[6].

NOTES

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

BIBLIOGRAPHY

1. I Haffejee, Quarterly Journal of Medicine 1992, New series 84; 305: 641 – 658
2. Alouf et al. Biocheimie 1973; 56-61
3. M Fasani et al. Eur J Lab Med 1994 ; vol2.nº1 : 67
4. E W Todd. J Exp Med 1932; 55: 267 – 280
5. Klein et al. Applied Microbiology 1970; 19: 60-61
6. Klein et al. Applied Microbiology 1971; 21: 999-1001
7. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

CHEMELEX, S.A.
Pol. Ind. Can Castells. C / Industria 113, Nave J
08420 Canovelles –BARCELONA-
Tel- 34 93 849 17 35 Fax- 34 93 846 78 75