Reactivos GPL

Barcelona, España

CE

- ASO TURBI -

ASO
TURBILATEX

Store at: +2+8ºC.

Presentation:
Cod. TL010 CONT: R1 45 ml / R2 5 ml. / CAL 1 ml.

Procedure

Diagnostic reagent for qualitative measurement of ASLO.

Only for *in vitro use in clinical laboratory* (IVD)

TEST SUMMARY

Latex particles coated with human anti-ASO are mixed with a serum sample. Agglutination is formed when a sample containing ASO is combined with the reagent. The degree of agglutination is directly proportional to the concentration of ASO in the sample.

REAGENTS COMPOSITION

Diluent (R1)	Tris buffer 20 mmol/L, sodium azide 0.95 g/L. pH 8.2.
Latex (R2)	Latex particles coated with streptolysin O, pH 10.0, sodium azide 0.95 g/L.
Calibrator (R3)	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

Working reagent (WR): Shake gently the latex vial gently before use. Prepare the necessary amount as follow: 1 mL Latex Reagent + 9 mL Diluent. WR: Stable for 1 month at 2-8º C. Anyway it is recommended to prepare a fresh Working Reagent based on its workload.

ASO Calibrator: Ready to use and stable up to the end of the indicated month and year of expiry. Store at tightly closed at 2-8º C. Carefully invert the bottles before use.

Do not freeze; frozen reagents could change the functionality of the test.

~~Signs of reagent deterioration:~~

- Particles and turbidity indicates contamination or reagents deterioration.

All the reagents of the kit are stable up to the end of the indicated month and year of expiry. Store at tightly closed at 2-8º C. Do not use reagents over the expiration date.

CALIBRATION

The assay is calibrated to the ASO International Calibrator (WHO 1961). The use of other commercially available ASO calibrators is not recommended.

SPECIMEN

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

Discard contaminated specimen

MATERIAL REQUIRED BUT NOT PROVIDED

- Thermostatic bath at 37º C.
- Spectrophotometer capable of accurate absorbance readings at 550 nm.
- Cuvettes with 1 cm light path.

General laboratory equipment

TEST PROCEDURE

Calibration Curve (range up to 940 IU/mL):

Prepare the following ASO calibrator dilutions in ClNa 9 g/L as diluent. Multiply the concentration of the ASO calibrator by the corresponding factor stated in table bellow to obtain the ASO concentration of each dilution.

The Standard dilutions must be sued for measurement within 24 hours.

Calibrator 1	100 µL Calibrator ASO*
Calibrator 2	100 µL Calibrator 1 + 100 µL ClNa 9 g/L
Calibrator 3	100 µL Calibrator 2 + 100 µL ClNa 9 g/L
Calibrator 4	100 µL Calibrator 3 + 100 µL ClNa 9 g/L
Calibrator 5	100 µL ClNa 9 g/L
*See the values on the label. Multiply by the appropriate factor	

MANUAL PROCEDURE

1. Bring the working reagent and the photometer to 37º C.
2. Set spectrophotometer wavelength to 550 nm and adjust to zero absorbance against water.
3. Pipette into a Cuvette:

	Calibrator	Sample	Blank
Working reagent (µL)	500	500	500
Calibrator (µL)	5	--	--
Sample (µL)	--	5	--
Diltilled water (µL)	--	--	5

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

CALCULATIONS

Multipoint Calibration:

1- Calculation of sample concentration is against interpolation of the absorbance ($A_2 - A_1$) in the calibration curve.
2- Calibration Curves are stable for 10 days, after which a new curve must be generated. Additionally, recalibration must be performed whenever reagent lots are changed or QC so indicate.

One point calibration:

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

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-heamolitic 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 glommerulus.

Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

REAGENT PERFORMANCE

1. *Linearity limit:* Up to 940 IU/mL[(note1)] (calibration curve) (under the described assay conditions)n and Up to 450 IU/mL[(note1)] (one point calibration).
2. *Prozone effect:* No prozone effect was detected up to 1500 IU/mL.
3. *Detection limit:* Values less than 20 IU/mL give non-reproducible results.
4. *Sensitivity:* Δ 0.73 mA. IU/mL.
5. *Precision:*

	Intra-assay n=10			Inter-assay n=10		
Mean (IU/mL)	135	236	372	135	236	372
SD	3.4	5.4	5.9	7.9	13.2	17.7
CV (%)	2.5	2.3	1.6	5.9	5.5	4.8

6. *Accuracy:* Results obtained using these reagents (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 42 ASO samples ranging from 20 to 800 IU/mL were assayed. The correlation coefficient (r) was 0.987 and the regression equation was y=1.07x + 1.1.

The results of the performance characteristics depend on the used analyzer.

INTERFERING SUBSTANCES

Do not interfere:

- Rheumatoid factors: < 300 IU/mL
- Bilirubin: < 20 mg/dL
- Hemoglobin: < 10 g/L
- Lipids: < 20 g/L.

Other substances may interfere[6].

NOTES

1- 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.

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