Reactivos GPL

Barcelona, España

CE

- ASO LATEX-

ASO LATEX
Agglutination test.

Store at: +2+8ºC.

Presentatión:
Cod. SE001 50 Test.
Cod. SE002 100 Test.

Procedure

Diagnostic reagent for qualitative measurement of ASO (Anti-streptolysin O).

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

TEST SUMMARY
The ASO-latex is an slide agglutination test for the qualitative and semi-quantitative detection of anti-streptolysin O antibodies.
Latex particles coated with streptolysin O are agglutinated when mixed with samples containing ASO.

REAGENTS COMPOSITION

Latex **Ref. SE003 - 5 mL**	Latex particles coated with streptolysin O, pH, 8.2. Sodium azide 0.95 g/L.
Control (+) **1 mL**	Human serum with an ASO concentration ≥ 400 IU/mL. Sodium azide 0.95 g/L.
Control (-) **1 mL**	Animal serum. Sodium azide 0.95 g/L.

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
All the components are ready to use.
Do not use reagents over the expiration date.
Do not freeze; frozen reagents could change the functionality of the test.
If appear particles and turbidity do not use.

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

CALIBRATION
The ASO-latex sensitivity is calibrated against the ASO International Calibrator (WHO).

SPECIMEN
Fresh serum. Stable 8 days at 2-8ºC or 3 months at –20ºC.
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
Mechanical rotator with adjustable speed at 80-100 r.p.m.

General laboratory equipment

TEST PROCEDURE
Qualitative method
1. Allow the reagents and sample to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place 50 µL of the sample and one drop of each Positive and Negative control into separate circles on the slide test.
3. Shake the ASO-latex reagent gently before using and add a drop of this reagent next to the sample to be tested.
4. Mix both drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Rotate the slide with a mechanical rotator at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read later than two minutes.

Semi-quantitative method
1. Make serial two fold dilutions of the sample in 9 g/L saline solution.
2. Proceed for each dilution as in the qualitative method.

READING AND INTERPRETATION
Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator.
The presence of agglutination indicates an ASO concentration equal or greater than 200 IU/mL.
The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

CALCULATIONS
The approximate ASO concentration in the patient sample is calculated as follows: 200 x ASO Titer = IU/mL

QUALITY CONTROL
Positive and Negative controls are recommended to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation.

Serum controls ASO are recommended for internal quality control. Each laboratory should establish its own Quality Control scheme and corrective actions.

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
- *Analytical sensitivity*:
  200 (± 50) IU/mL, under the described assay conditions
- *Prozone effect:*
  No prozone effect was detected up to 1500 IU/mL.
- *Diagnostic sensitivity: 98 %*
- *Diagnostic specificity: 97 %*

INTERFERING SUBSTANCES
Interferences:
- Do not interfere: Hemoglobin (10 g/L), bilirubin (20 mg/dL), lipemia (10 g/L), rheumatoid factors (300 IU/mL).
- Other substances may interfere[7].

LIMITATIONS OF THE PROCEDURE
- False positive results may be obtained in conditions such as, rheumatoid arthritis, scarlet fever, tonsilitis, several streptococcal infections and healthy carriers.
- Early infections and children from 6 months to 2 years, may cause false negative results.
- A single ASO determination does not produce much information about the actual state of the disease. Titrations at biweekly intervals during 4 or 6 weeks are advisable to follow the disease evolution. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

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