Reactivos GPL

Barcelona, España

CE

- ASO LATEX-

ASO LATEX
Agglutination test.

Store at: +2+8ºC.

Presentation:
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 a 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. Preservative.
Control (+) **1 mL**	Human serum with an ASO concentration >200 IU/mL. Preservative.
Control (-) **1 mL**	Animal serum. Preservative.

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 kit components are ready to use. Mix reagents gently before use.
Do not freeze: frozen reagents could change the functionality of the test.

Reagents deterioration:

- Presence of particles and turbidity.

All the kit components will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not use reagents over the expiration date.

CALIBRATION

The ASO-latex sensitivity is calibrated against the ASO International Standard from NIBSC ASO.

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 haemolized or lipemic samples.

Discard contaminated specimen.

MATERIAL REQUIRED BUT NOT PROVIDED

- Mechanical rotator with adjustable speed at 80-100 r.p.m.
- Vortex mixer.
- Pippetes 50 µL.

General laboratory equipment

TEST PROCEDURE

Qualitative method

1. Allow the reagents and samples 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 controls into separate circles on the slide test.
3. Mix the ASO-latex reagent vigorously or on a vortex mixer before using and add one drop (50 µL) next to the sample to be tested.
4. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Place the slide on 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.
All result different from the negative control result, will be considered as a positive.

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 5 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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