PATHOZYME DIAGNOSTICS

RAPICHEK ASO LATEX

(SLIDE AGGLUTINATION)

CAT No.: ASO

ASO Latex slide test for the qualitative and semi-quantitative determination of Post Streptococcal diseases.

DIAGNOSTIC SIGNIFICANCE:

The group A beta-haemolytic Streptococcal produce various exotoxins such as Streptolysin-O & Streptolysin-S which can act as antigens. The affected individuals produce specific antibodies-Antistreptolysin-O (ASO). Detection of ASO is very useful in the diagnosis of streptococcal infections. The elevated ASO titre may be associated with actual rheumatic fever and glomerulonephritis. An elevated ASO titre of more than 200 IU/ml indicates an interval of 10-12 days is diagnostically more important than a single sample.

PRINCIPLE:

The latex Reagent is coated with streptolysin-O. The specimen containing ASO, on mixing with Latex Reagent agglutinates, Showing the positive test result.

SPECIMEN COLLECTION:

Fresh serum. Stable 7 days at 2-8^{0}C or 3 months at -20^{0}C. Samples with presence of fibrin should be centrifuged. Do not use highly hemolyzed or lipemic samples.

KIT PRESENTATION:

PACK SIZE	25 Test	50 Test	100 Test
Latex Reagent	1 Vial	1 Vial	1 Vial
Positive Control	1 Vial	1 Vial	1 Vial
Negative Control	1 Vial	1 Vial	1 Vial
Glass Slide	1 No	1 No	1 No
Mixing Sticks	25 Nos	50 Nos	100 Nos
Sample Dropper	25 Nos	50 Nos	100 Nos
Latex Dropper	1 No	1 No	1 No

REAGENT STORAGE & STABILITY:

All reagents included in the kit are stable at 2-8^{0}C until the expiry date stated on the label.

PRECAUTION:

1. Bring all the reagents and samples to RT before use.
2. Do not freeze the Latex reagent.
3. Do not use hemolyzed or turbid specimen. The use of plasma instead of serum could lead to erroneous results. Drying of the mixture at the periphery of the circle could lead to erroneous results.
4. The Latex reagent should be shaken well prior to use, to ensure a homogeneous suspension of latex.
5. The source material used in the manufacturing of Positive control is tested for HBsAg & HIV antibodies and found to be negative. However, for better safety the control should be handled with proper care.
6. While dispensing Latex reagent, hold the glass dropper vertically to ensure uniform drop size.
7. Positive Control is ready to use & should not be diluted while using in test procedure.
8. Contaminated sera and a longer reaction time beyond 2 minutes may lead to false positive results.
9. As with all diagnostic tests, the final diagnosis should be based on correlation of test results with other clinical symptoms & findings.

PROCEDURE:

(A) 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 one drop (50 µl) of the sample and one drop of each positive and negative controls into separate circles on the slide test.
3. Swirl the ASO-latex reagent gently before using and add one drop (50µl) 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.

Interpretation Of Results:

Agglutination within 1-2 minutes is positive test and indicates presence of ASO in the test specimen, no agglutination up to 2 minutes is a negative test and indicates absence of ASO in the test specimen.

(B) Semi-quantitative Method:

1. Dilute the specimen serially 1:2, 1:4, 1:8. 1:16 using normal saline.
2. Proceed for each dilution as in the qualitative method.

Interpretation Of Results:

The highest dilution shows positive reaction within 2 minutes indicates the ASO titre. The approximate ASO concentration can be obtained by multiplying titre by sensitivity of the test.

ASO in IU/ml = D X S

D - Highest dilution showing positive reaction

S = Sensitivity of the test is 200 IU/ml.

NORMAL VALUES:

Up to 200 IU/mL for adults and 100 IU/mL for children < 5 years old.

Each laboratory should establish its own reference range

PERFORMANCE CHARACTERISTICS:

1. Analytical sensitivity: 200 IU/mL
2. No prozone effect was detected up to 1500 IU/ml.
3. Diagnostic sensitivity: 98%.
4. Diagnostic specificity: 97%.

INTERFERENCES:

Bilirubin (20 mg/dL), Hemoglobin (10 g/L), Rheumatoid Factors (300 IU/mL) do not interfere other substances may interfere.

REFERENCE:

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Expiry Date | IVD In-Vitro Diagnostics Use | Storage | Mfg. Date | LOT Batch Number | REF Catalogue Number | See Package Insert

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