ASO LATEX

Rapid latex agglutination slide test for the qualitative and semiquantitative *in-vitro* determination of Post Streptococcal diseases.

DIAGNOSTIC SIGNIFICANCE:
The group A beta-hemolytic 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. If ASO is absent there will be no agglutination, which is a negative test result.

PRESENTATION:

	No. of Bottles/Packs 25test/50 test/100 test
1. Latex Reagent	1
2. Positive Control Serum	1
3. Negative Control Serum	1
4. Test Slide	Provided as per pack size
5. Mixing Sticks	
6. Plastic Droppers	
7. Glass Dropper	

REAGENT STORAGE AND STABILITY:
All reagents are stable at 2-8^{0}C till the expiry date mentioned on the labels.

SPECIMEN:
Only serum should be used for testing. In case of a delay in testing, Store at 2-8^{0}C.

PRECAUTION:
1. Bring all the reagents and samples to RT before use.
2. Do not freeze the Latex reagent.
3. Do not use hemolysed 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 (1) 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.

PROCEDURE:
(A) QUALITATIVE TEST:
1. Place approx 25 µl of Test sample in the circle where latex is added using separate plastic dropper.
2. Add one drop (25 µl) of Latex reagent in each circle of disposable slide.
3. Mix well and spread the reaction mixture in the entire circle.
4. Rock the slide gently for 1-2 minutes (100 rpm) and look for agglutination.

INTERPRETATION OF RESULTS:
Agglutination within 1-2 minutes is positive test and indicates presence of ASO in the test specimen, No agglutination upto 2 minutes is a negative test and indicates absence of ASO in the test specimen.

(B) SEMI QUANTITATIVE TEST:
1. Dilute the specimen serially 1:2, 1:4, 1:8. 1:16 using normal saline.
2. Place one drop of each diluted serum sample using plastic dropper in each circle of disposable slide & proceed further as in Qualitative Test (A.)

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.

SENSITIVITY:
The reagent has a sensitivity of 200 IU/ml.

QUALITY CONTROL PROCEDURE:
The use of Positive Control is recommended along with serum sample.

NOTES:
1. Positive Control is ready to use & should not be diluted while using in test procedure.
2. Improper mixing and drying of reagents may lead to erroneous results.
3. Contaminated sera and a longer reaction time beyond 2 minutes may lead to false positive results.
4. As with all diagnostic tests, the final diagnosis should be based on correlation of test results with other clinical symptoms & findings.
5. Non specific positive reaction may occur if plasma is used or serum is highly lipaemic or hemolysed.
6. For accuracy of results, the procedure has to be followed meticulously.

REFERENCES:
1. Rantz, L.D., Di Caprio, J.M., Randall, E., (1952); AM. J. Med. Sci.24
2. Johnson, G.D., and Holborrow, E.J.; In Weir, D., editor: Immu nochemistry, Handbook of experimental, immunology. Oxford, En gland, 1973, Blackwell Scientific Publications, Vol. 1.

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3/7,B.I.D.C., Gorwa, Vadodara 390 016 (INDIA)
Web: www.reckondiagnostics.com
Phone: +91·265·2281631
Email: mail@reckondiagnostics.com
RECKON DIAGNOSTICS P. LTD.