

Ref.	IS-ASO.076, 25 Test
	IS-ASO.76U, 50 Test
	IS-ASO.76V, 100 Test

INTENDED USE

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

All the reagents to be stored at 2-8°C	No. of Vials/Packs
	25test/50 test/100 test
• Latex Reagent	1
• Positive Control Serum	1
• Negative Control Serum	1
• Test Slide	} Provided as per pack size
• Mixing Sticks	
• Plastic Droppers	
• Glass Dropper	

PRECAUTION

- Do not freeze the Latex reagent.
- Drying of the mixture at the periphery of the circle could lead to erroneous results.
- The Latex reagent should be shaken well prior to use, to ensure a homogeneous suspension of latex.
- 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.
- While dispensing Latex reagent, hold the glass dropper vertically to ensure uniform drop size.
- Read and interpret results exactly at 2 minutes.

REAGENT STORAGE AND STABILITY

All reagents are stable at 2-8°C till the expiry date mentioned on the labels.

SPECIMEN COLLECTION

Fresh serum should be used. Serum sample is stable at 2-8°C. Plasma should not be used as fibrinogen may cause nonspecific agglutination of the latex particles. Do not use lipemic hemolysed or contaminated serum.

TEST PROCEDURE

(A) QUALITATIVE TEST

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

PROCEDURE AT A GLANCE
25 µl of sample or control
+
25 µl of ASO Latex Reagent
Mix
Rock the slide; observe for agglutination up to 2 minutes

TEST 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

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

TEST 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

- Positive Control is ready to use & should not be diluted while using in test procedure.
- As with all diagnostic tests, the final diagnosis should be based on correlation of test results with other clinical symptoms & findings.
- For accuracy of results, the procedure has to be followed meticulously.

REFERENCES

- Rantz, L.D., Di Caprio, J.M., Randall, E., (1952); AM. J. Med. Sci.24
- 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.

