

Intended Use

This reagent is intended for *in vitro* qualitative & semi quantitative determination of Anti Streptolysin O (ASO) in serum.

- No prozone effect detected up to 1500 IU/mL
- Rapid procedures; test time only 2 minutes
- Excellent clarity; clear agglutination

Clinical Significance

Streptolysin O is a toxic immunogenic exoenzyme produced by β -haemolytic Streptococcus group A, C and G. ASO antibodies are useful for the diagnosis 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. Acute glomerulonephritis is a renal infection that affects mainly glomerulus.

Principle

ASO Latex kit is a rapid agglutination procedure for the direct detection and semi-quantitation (on slide) of antistreptolysin-O (ASO). The antigen, latex particles suspension coated with Streptolysin-O, agglutinates in the presence of specific antibodies present in the sera of patients with streptolysin O.

Kit Components

Reagent/Component	Product Code 52201002	Product Code 52201003	Description
ASO Latex	1 x 2.5 mL	1 x 5 mL	Suspension of polystyrene particles coated with streptolysin-O.
ASO Positive Control	1 x 0.5 mL	1 x 0.5 mL	Human pooled serum
ASO Negative Control	1 x 0.5 mL	1 x 0.5 mL	Human pooled serum
Physiological Saline Buffer Concentrate	1 x 5 mL	1 x 5 mL	Dilute 1:20(v/v) with distilled water
Reaction Slide	1 no	1 no	
Serum Droppers	50 nos	100 nos	
Applicator Sticks	50 nos	100 nos	
Rubber teat	1 no	1 no	

Risk & Safety

Material Safety data sheets (MSDS) will be provided on request.

Precaution

Reagent components of human origin have been tested and found to be negative for the presence of antibody to HIV (1/2) as well as for HBsAg and HCV antibody. However, handle cautiously as potentially infectious.

The reagent and controls contain less than 0.1% sodium azide.

Storage and Stability

When stored at 2-8 °C and protected from light, the reagent and the controls are stable until the expiry date stated on the label. DO NOT FREEZE.

Preparation of physiological saline buffer:

Prepare physiological saline buffer by adding 95mL of distilled water to 5 mL of physiological saline buffer concentrate (provided). It is stable up to expiry date, when stored at room temperature.

Analytical Sensitivity

The ASO latex reagent sensitivity has been adjusted to detect a minimum of **200 (± 50) IU/mL** ASO antibodies in the undiluted samples.

Sample

Fresh serum (free of haemolysis)

Qualitative Test

Allow all reagents as well as the sample to reach room temperature. Mix well before use.

1. Place 1 drop of serum sample on the slide using a disposable serum dropper.
2. Add one drop of ASO-latex reagent to the above drop and mix with disposable applicator stick.

3. Rock the slide gently to and fro for 2 minutes and immediately examine under a good light source for agglutination, do not examine beyond 2 minutes.
4. For positive & negative controls follow the same procedure as mentioned above by taking control serum from respective vials.

Result and Interpretation

Positive Result:

The presence of agglutination indicate concentration of ASO in the sample equal or greater than 200 IU/mL (above normal).

Negative Result:

The lack of agglutination indicates ASO level lower than 200 IU/mL in the sample, (within the normal range).

Semi-Quantitative Test

In the cases in which it is desired to find out the titre of a positive sample, it is possible by the serial dilution methodology.

1. Place 50 μ L diluted physiological saline Buffer onto each of five circles of the slide.
2. Using a 50 μ L micro pipette add 50 μ L of the serum sample to the drop of saline buffer in 1st circle.
3. Using the same micro pipette, mix the sample with saline by aspirating back & forth several times. Aspirate 50 μ L from 1st circle and transfer to 2nd circle. Repeat the same operation up to 5th circle. Aspirate 50 μ L from 5th circle and discard. Dilutions obtained as 1/2, 1/4, 1/8, 1/16, 1/32.
4. Then add 1 drop of ASO latex to the above circles. Mix and rock the slide gently to and fro for 2 minutes; observe the agglutination under good source of light.

Calculation

ASO Conc. (IU/mL) = Sensitivity X Titre (Highest dilution serum showing agglutination)
 Where, ASO Sensitivity = 200 IU/mL

Note:

1. False positive results may be obtained in conditions such as rheumatoid arthritis, scarlet fever, several other streptococcal healthy carriers.
2. Early infections and children from 6 months to 2 years may cause false negative results.
3. A single ASO determination does not produce much information about the actual state of the disease. Titrations at bi weekly intervals during 4 or 6 weeks are advisable to follow the disease evolution.

Performance Characteristics

1. Diagnostic sensitivity : 98%
2. Diagnostic specificity : 97%
3. Prozone effect : No prozone effect detected up to 1500 IU/mL

Interferences

No interference
 Hemoglobin up to : 10 g/L
 Bilirubin up to : 20 mg/dL
 Rheumatoid factor up to : 500 IU/mL

Bibliography

1. CURTIS G. D.W, KRAAK W.A.G., MITCHELL R.G. Comparison of latex and hemolysis test determination of antistreptolysin O (ASO) antibodies. J. Clin. Pathol. 41, 1331 (1988).
2. TADZYNSKY L.A., RYAN M.E. Diagnosis of rheumatoid fever. A guide to criteria and manifestations. Post grad Med. 79, 295 (1986).
3. D'ANGELO W.A. Rheumatic Diseases. Diagnostic tests and procedures. in: The Laboratory in Clinical Medicine (Halsted J.A. Ed.) Saunders Company, Philadelphia, chapter 29 (1976).
4. Young D.S., Effects of Drugs on Clinical Laboratory Test 4th ed. AACCC Press, 1995.

SYMBOLS USED ON THE LABELS

SYMBOLS USED ON THE LABELS:  IN VITRO DIAGNOSTIC USE  SEE PACKAGE INSERT FOR PROCEDURE  LOT NUMBER  MANUFACTURER'S ADDRESS  MANUFACTURING DATE  EXPIRY DATE  TEMPERATURE LIMIT



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