ANTISTREPTOLYSIN-O (ASO) LATEX SLIDE TEST KIT

For the qualitative and quantitative measurement of antibodies to Antistreptolysin-O in human serum.

INTENDED USE

The ANTISTREPTOLYSIN-O (ASO) latex slide Test is used for the qualitative and quantitative measurement of antibodies to Antistreptolysin-O in human serum.

INTRODUCTION

The group A -hemolytic streptococci produces various toxins that can act as antigens. One of these exotoxins streptolysin-O, was discovered by Todd in 1932.

A person infected with group A -hemolytic streptococci produces specific antibodies against these exotoxins, one of which is antistreptolysin-O. The quantity of this antibody in a patient's serum will establish the degree of infection due to the

-hemolytic streptococcal.

The usual procedure for the determination of the antistreptolysin titer is based on the inhibitory effect that the patient's serum produces on the hemolytic power of a pretitrated and reduced streptolysin-O. However, the antigen- antibody reaction occurs independently of the hemolytic activity of streptolysin-O. This property enables the establishment of a qualitative and quantitative test for the determination of the antistreptolysin-O by agglutination of latex particles on slide.

PRINCIPLE

ASO test method is based on an immunologic reaction between streptococcal exotoxins bound to biologically inert latex particles and streptococcal antibodies in the test sample. Visible agglutination occurs when increased antibody level, are present in the test specimen.

MATERIALS ROVIDED

- ASO Latex Reagent: A suspension of polystyrene particles coated with streptococcal exotoxins. **Mix well before use**.
- ASO Positive Control: A stabilized human serum reactive with the test reagent. Ready for use; do not dilute. (>200 IU/ml)
- ASO Negative Control: A stabilized human serum non- reactive with the test reagent. Ready for use; do not dilute.
- Glycine Buffer (20x): add one part to nineteen parts of distilled water before use.
- Reaction Slide.
- Stirring Sticks.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer.
- Test Tubes 12x75mm.
- Test Tube Rack.
- Serological pipettes.
- High intensity light.

PRECAUTIONS

- All reagents contain 0.1% (w/v) sodium azide as a preservative. Store all reagents at 2 - 8°C. DO NOT FREEZE.
- Reagents containing sodium azide may combine with copper and lead plumbing to form highly explosive metal azides. Dispose of reagents by flushing with large amounts of water to prevent azide build-up.
- For In Vitro diagnostic use.
- Positive and negative controls prepared using human sera found negative for hepatitis B surface antigen (HBsAg) and HIV-III by FDA required test; however, handle controls as if potentially infectious.

REAGENT STORAGE AND STABILITY

- Reagents are stable until stated expiration date on bottle label when stored refrigerated (2 - 8°C).
- DO NOT FREEZE.
- The ASO Latex Reagent, once shaken must be uniform without visible clumping. When stored refrigerated, a slight sedimentation may occur and should be considered normal.
- Do not use the latex reagent or controls if they become contaminated.

SPECIMEN COLLECTION AND STORAGE

- Use fresh serum collected by centrifuging clotted blood.
- If the test cannot be carried out on the same day, store the specimen for 7 days at 2-8(C and for 3 months at - 20(C.
- For longer periods the sample must be frozen.
- As in all serological tests, hemolytic or contaminated serum must not be used.
- **DO NOT USE PLASMA**.

PROCEDURE

A. Qualitative Test:

1. Bring reagents and specimens to room temperature before use.
2. Place one drop (40 µl) of ASO Positive Control on field #1 of the reaction slide. Place one drop (40 µl) of the ASO Negative Control on field #2. Using a serological pipette place (40µl) of undiluted test sample to field #3. Continue likewise with additional unknowns. Use different pipette tips for different samples.
3. Gently resuspend the ASO Latex Reagent and add one drop to each test field.
4. Mix well using the stirring sticks. Gently rock the slide for three (3) minutes and read immediately under direct light.

B. Quantitative Test:

1. Set up at least five test tubes: 1:2, 1:4, 1:8, 1:16, 1:32, etc.
2. Dilute samples according to dilution factors on each test tube with prediluted glycine buffer.
3. Place one drop each of positive and negative controls on to the slide rings. Place one drop of each dilution on successive fields of the reaction slides.
4. Gently resuspend the ASO Latex Reagent and add one drop to each test field.
5. Mix well with the stirring stick. Gently rock the slide for three (3) minutes and read immediately under direct light.

QUALITY CONTROL

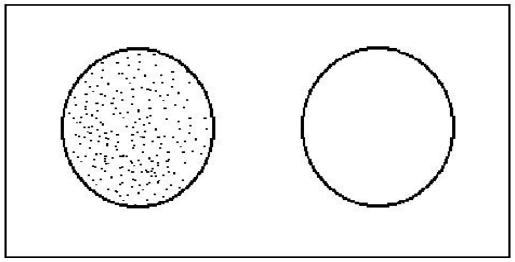
1. Positive and Negative Controls should be included in each test batch.
2. Acceptable performance is indicated when a uniform milky suspension with no agglutination is observed with the ASO Negative Control and agglutination with large aggregates is observed with the ASO Positive Control.

RESULTS

A.QUALITATIVE TEST:

A **negative** reaction is indicated by a uniform milky suspension with no agglutination as observed with the ASO Negative Control.

A **positive** reaction is indicated by any observable agglutination in the reaction mixture. The specimen reaction should be compared to the ASO Negative Control (Fig. 1).



Positive Negative

B.QUANTITATIVE TEST

A positive reaction is indicated by any observable agglutination in the reaction mixture. Record the last dilution showing a positive reaction. Concentration of ASO can be determined by multiplying the last positive dilution factor of the sample with the concentration of the positive control (200 IU/ml).
The titer of the serum is the reciprocal of the highest dilution which exhibits a positive reaction.

IU/ml of sample = conc. of positive control (200) x specimen titer

DILUTION	IU/ml
1:1	200
1:2	400
1:4	800
1:8	1600
etc.	

LIMITATIONS

- Results should be read three (3) minutes after the mixing of the reagent on the slide. A reading obtained after this period of time may be incorrect.
- Existence of prozone at high titers has not been encountered.

EXPECTED VALUES

- Although normal values can vary with age. season of the year and geographical area, the "upper limit of normal" antistreptolysin-O titers is up to 200IU/ml for adults and 100.0 IU/ml for Children. Because of the validation titers above the upper limits may be indicative of a streptococcal infection. But only a two dilution rise in titer between acute and convalescent stage specimens should be considered significant

- Following acute streptococcal infection, the antistreptolysin- O titer will usually rise after one week increasing to a maximum level within 3 to 5 weeks and usually returning to the pre infection levels in approximately 6 to 12 months

PERFORMANCE CHARACTERISTICS

Analytical sensitivity:

200 (±50) IU/ml.

PROZONE EFFECT

No prozone effect was detected up to 1500IU/ml.

SENSITIVITY

98%.

SPECIFICITY

97%.

INTERFERENCES

NON INTERFERING SUBSTANCES:

- Hemoglobin (10g/dl)
- Bilirubin(20mg/dl)
- Lipemia(10g/dl) Other

substances may interfere

REFERENCES

Manual of Clinical Immunology, American Society of Microbiology, (1974).

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3. Klein, G.C., et al. Applied Microbiology, 21:999 (1971).
4. Rantz, L.A. et al. Proc. Soc. Exp. Biol. and Med. 59:22 (1945).
5. Hodge, B.K. Exp. Med. 58:277 (1933).
6. Todd. E.W., J. Exp. Med. 55:267-280, (1932)
7. Klein. O.C. Immune Response to Streptococcal Infection,

Pack Size

Cat No.	Configuration	TEST
ASO00025	1.Latex Reagent - 1 x 1ML 2.Positive and Negative Control-2X0.3ML	25
ASO00100	1.Latex Reagent - 1 x 4ML 2.Positive and Negative Control-2X0.3ML	100

IVD In Vitro Diagnostic Use | See Pack Insert For Procedure | Single Use only | CE
Temperature Limit | Manufacturer's Address | Manufacturing Date | Expiry Date | LOT Lot Number

Manufactured in India by :

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