Atlas Medical

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ANTISTREPTOLYSIN-O (ASO) LATEX SLIDE TEST

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

IVD *For in -vitro diagnostic and professional use only*

Store at 2-8°C

INTENDED USE

ATLAS 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 ß-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 pre-titrated 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

MATERIALS PROVIDED

- ASO Latex Reagent: Latex particles coated with streptolysin O, pH, 8,2. Preservative
- ASO Positive Control(Red cap): Human serum with an ASO concentration > 200 IU/mL.Preservative
- ASO Negative Control (Blue cap) Animal serum. Preservative
- Reaction Slide.
- Stirring Sticks.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer.
- Test Tubes 12x75mm.
- Test Tube Rack.
- Serological pipettes.
- High intensity light.
- Saline Solution, 0.9% NaCL.

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 be combined 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 serum 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 specified expiry 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

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 50 µL of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
3. Mix the ASO-latex reagent vigorously or on a vortex mixer before using and add one drop (50 µL) 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.

Semi-quantitative method

1. Make serial two fold dilutions of the sample in 9 g/L saline solution.
2. Proceed for each dilution as in the qualitative method.

QUALITY CONTROL

Positive and Negative Controls should be included in each test batch.

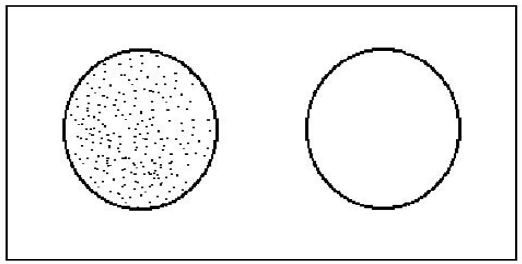
Acceptable performance is indicated when a uniform milky suspension with no agglutination is observed with the ASO Negative Control and agglutination with large aggregates is observed with the ASO Positive Control.

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

Figure 1

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.	

REFERENCE VALUES

Up to 200 IU/mL(adults) and 100 IU/mL (children < 5 years old)[6]. Each laboratory should establish its own reference range.

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

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PPI003A01
Rev H (09.09.2017)

REF	Catalogue Number		Store at
IVD	For In-Vitro Diagnostic use		Caution
Σ	Number of tests in the pack		Read product insert before use
LOT	Lot (batch) number		Manufacturer
	Fragile, handle with care		Expiry date
	Manufacturer fax number		Do not use if package is **damaged**
	Manufacturer telephone		