

INTENDED USE

Antistreptolysin-O (ASO) latex slide test is based on slide agglutination technique used for the qualitative and semi-quantitative detection of Antistreptolysin-O (ASO) antibodies in human serum.

INTRODUCTION

ASO Latex Kit is a serologic test for the detection of ASO antibodies. Detection of ASO is vital for the diagnosis of streptococcal infections. In acute streptococcal infections, the exotoxin streptolysin-O is produced in response to streptolysin O antigens liberated by group A β -hemolytic streptococci.

A person infected with group A hemolytic streptococci produces specific antibodies against these exotoxins, known as antistreptolysin-O. The degree of infection due to the hemolytic streptococcal can be obtained through the ASO level in a patient's serum.

Procedure to determine the antistreptolysin titer is based on inhibitory effect that 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 an immunologic reaction between streptococcal exotoxins and streptococcal antibodies. Based on recommended technique, latex particles in the reagent will agglutinate and indicates that increased level of anti-streptolysin O antibodies is present in the test specimen.

STORAGE CONDITIONS

- The reagents are stable when stored refrigerated at 2 - 8°C. **DO NOT FREEZE.** A slight sedimentation should be considered normal when stored refrigerated.
- These reagents are stable until the expiry date stated on the product label. Do not use the reagents past the expiration date.
- The reagent should be uniform without visible clumping once shaken.
- Avoid using the latex reagents and controls if contamination occurred.
- The vials must always be in an upright position. If changes of position occurred, gently mix to dissolve aggregates that may present.
- Presence of particles and turbidity will result in reagents deterioration.

SPECIMEN COLLECTION AND PREPARATION

- Use fresh serum collected by centrifuging clotted blood.
- If testing is delayed, specimen can be stored for 7 days at 2-8°C or up to 3 months at -20°C.
- Make sure the samples with presence of fibrin is centrifuged before testing. Avoid using highly hemolysed or lipemic samples.
- Do not use plasma.

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
- Glass Reaction Slide.
- Stirring Sticks.

NOTE: This package insert is also used for individually packed reagent.

MATERIALS NEEDED BUT NOT PROVIDED

- Mechanical rotator with adjustable speed at 80-100 r.p.m.
- Vortex mixer.
- Pipette 50 μ L.
- Glycine Buffer (20x): add one part to nineteen parts of distilled water before use.

PROCEDURES

A. QUALITATIVE TEST

1. Bring the reagents and samples to reach to room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place (40 μ L) of the sample and one drop of each Positive and Negative control into separate circles on the slide test.
3. Mix the ASO-latex reagent vigorously or using vortex mixer and add one drop (40 μ L) next to the samples to be tested.
4. Use stirrer to mix the drops and spreading them over the entire surface of the circle. Do not use the same stirrer for each sample.
5. Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes. Avoid reading the test after more than two minutes since it may cause false positive results.

B. SEMI-QUANTITATIVE TEST

The semi-quantitative test can be performed in the same way the qualitative test using dilutions of the serum.

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.

READING AND INTERPRETATION

Observe macroscopically the presence of any visible agglutination immediately after removing the slide from the rotator. Visible agglutination of latex particles indicates that ASO concentration equal or greater than 200 IU/mL. The titer, in semi-quantitative method, is defined as the highest dilution showing a positive result.

CALCULATIONS

The approximate ASO concentration in the patient sample is calculated as follows:

$$\text{Sensitivity (Indicated on the label of the latex vial)} \times \text{ASO Titer} = \text{IU/mL}$$

INTERFERENCES

NONE INTERFERING SUBSTANCES:

- Hemoglobin (10 g/L)
- Bilirubin (20 mg/dL)
- Lipids (10 g/L)
- Rheumatoid factors (300 IU/mL)

Other substances may interfere.

PROCEDURES LIMITATIONS

1. Reaction time is critical. False positive result may occur if the reaction time exceeded 2 minutes due to reaction mixture may dried up.
2. Spontaneous agglutination may occur if the ASO Latex Reagent is stored in freezing condition.
3. Intensity of agglutination is not necessarily indicative of relative ASO concentration; therefore, screening reactions should not be graded.
4. Health conditions such as, rheumatoid arthritis, scarlet fever, tonsillitis, several streptococcal infections and healthy carriers may give false positive results.
5. Early infection and children from 6 months to 2 years may cause false negative results. The actual state of the disease cannot be only based on a single ASO determination.
6. It is advisable to follow the disease evolution by doing the titrations at biweekly intervals during 4 or 6 weeks.
7. Clinical diagnosis should be based on both clinical and laboratory data and not only based on findings of a single test result.

QUALITY CONTROL

Make sure to include the Positive and Negative Controls in each test batch. The acceptance performance is based on visible large aggregates of agglutination observed with the ASO Positive Control and only uniform milky suspension with no agglutination is observed with the ASO Negative Control.

REFERENCE VALUES

Up to the reagent sensitivity (Indicated on the label of the latex vial). Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity:

Refer to vial label.

PROZONE EFFECT

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

SENSITIVITY

98%.

SPECIFICITY

97%

PRECAUTIONS

- All reagents contain 0.1% (w/v) sodium azide as a preservative.
- The reagents which contain sodium azide may be combined with copper and lead plumbing to form highly explosive metal azide. When drained, flush with a large volume of water to prevent azide build up.
- Make sure to wear protective clothing when handling the reagents, such as disposable gloves and a laboratory coat.
- When the testing is completed, wash hands and clean the test table top with water and soap.
- The kit is for in vitro diagnostic use only.
- Materials used to produce the kit were prepared using human serum found to be negative for hepatitis B surface antigen (HBsAg), HCV and antibody HIV (1/2) by FDA required test. Care must be taken in the use and disposal of each vial and its contents as it is potentially infectious.
- Use provided dropper and hold perpendicularly when dispensing as the drop size of the latex reagent (40µl) will determine the accuracy of the test.
- For each use, make sure to rinse the slide test thoroughly with water and wiped with lint-free tissue.
- Use provided controls to check reactivity of the reagent.

REFERENCES

1. Ahmed Samir et al. Pediatric Annals 1992; 21: 835-842.
2. Haffejee. Quarterly Journal of Medicine 1992. New series 84; 305: 641-658.
3. Klein GC. Applied Microbiology 1971; 21: 999-1001.
4. Picard B et al. La Presse Medicale 1983; 23: 2-6.
5. Spaun J et al. Bull Wld Hlth Org 1961; 24: 271-279.
6. The association of Clinical Pathologists 1961. Broadsheet 34.
7. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.



VeroTest Sdn. Bhd.
Unit G-E-2A, Enterprise 4, Technology Park Malaysia,
Bukit Jalil, 57000 – Kuala Lumpur – Malaysia
RSPA008N
Rev 1.0 (28.01.2022)

Catalogue Number	Temperature limit	Manufacturer fax number	Fragile, handle with care
<i>In Vitro</i> diagnostic medical device	Caution	Manufacturer telephone number	Use-by date
Contains sufficient for <n> tests and Relative size	Consult instructions for use (IFU)	Keep away from sunlight	Date of Manufacture
Batch code	Manufacturer	Do not use if package is damaged	Keep dry