NS Bio-Tec

ASOT

A rapid latex slide test for detection of Antistreptolysin O antibodies in serum

REF: ASO-MA-100 (100 TEST)
REF: ASO-MA-100 L (100 TEST)
REF: ASO-MA- 050 (50 TEST)
REF: ASO-MA-050 L (50 TEST)

INTENDED FOR USE

Rapid latex agglutination test for the qualitative screening and semi-quantitative determination of antistreptolysin O antibodies (**ASO**) in serum.

PRINCIPLE:

ASO is a stabilized buffered suspension of polystyrene latex particles that have been coated with streptolysin O. when the latex reagent is mixed with a serum containing antibodies to streptolysin O, agglutination occurs. The latex reagent has been produced so that agglutination will take place only when the level of antibodies to streptolysin O is greater than 200 lU/ml, a level determined to be indicative of disease by epidemiological and clinical studies. Sera having titers of between 200 lU/ml and 3500 lU/ml will be reactive

SPECIMEN COLLECTION

The test should be performed on serum. Specimens can be drawn by venipuncture or convenient fingertip method.

Plasma should not be used because fibrinogen may cause nonspecific agglutination of the latex particles.

Strongly lipemic sera and/or bacterial contamination may cause false positive agglutination.

The serum specimen should be stored refrigerated. If testing is to be prolonged in excess of 24 hours, serum should be frozen.

REAGENT COMPOSITIONS

1- Latex Reagent: a suspension of polystyrene latex particles in glycine-saline buffer pH: 8.6 ± 0.2. The latex particles are coated with streptolysin O.
2- Positive Control Serum: is prepared from stabilized human serum pool containing more than200 lU/ml antistreptolysin O.
3- Negative Control Serum: is prepared from stabilized human serum pool containing less than200 IU/ml antistreptolysin O.
All components contain 0.1% sodium azide as preservative.
4- slides .

PACKAGE: COLLECTION AND STORAGE.

All reagents are stable up to the expiration date specified when stored at 2 - 8°C. Do Not Freeze. Avoid extended exposure of reagents to elevated temperatures.

PRECAUTIONS & WARNING

All human blood components used to prepare controls have been tested for Hepatitis B surface antigen (HBsAg) and HTLV-lll antibodies by an FDA approved procedure and found to be non-reactive. No known test method for HbsAg or HTLV-lll antibodies offers total assurance that a human derived product will not transmit hepatitis or HTLV-lll virus. The user is therefore cautioned to handle reagents as if being capable of transmitting these diseases.
The reagents in each kit are matched. Reagents from different kits must not be interchanged or pooled. If the kit does not yield expected results when controls are tested, the kit should be discarded. Mix the reagents well before use. Use clean equipment. Traces of detergent to dried reactants on the test slide may adversely affect test performance and results.
The components of the test kit contain sodium azide. Sodium azide may react with lead and copper plumbing to form explosive metal azides. Upon disposal, flush lines with a large volume of water to prevent azide build up.

REAGENT PREPARATION & STABILITY

Expiration date is specified on the kit label. Biological indication of product instability is evidence by inappropriate reaction of the latex reagent with the corresponding positive control serum.

REQUIRED MATERIALS NOT PROVIDED

General Laboratory Equipment and instrumentations.

Materials supplied with ASO kit:
ASO latex reagent, Positive control serum, Negative control serum, Glass slide & Straws.

Material required, but not provided:
Pipettes (serological), Lab rotator & Laboratory timer.

PROCEDURE:

1. Bring all reagents and specimens to room temperature.
2. Shake the ASO test reagent gently, expel contents of dropper and refill, then place one drop (50 µl) onto glass slide. Using pipette, add one drop of the patient serum (50 µl) onto the glass slide, and mix both together with the flat end of the straws.
3. Continue to mix for about 2 minutes with rotator or by hand and observe for macroscopic clumping using the indirect oblique light source.
4. Positive control and Negative control should be run with each series to test sera. The positive control supplied is to be used exactly as outlined in steps 1 through 3 above.
5. The reaction of the test serum is compared to the ASO positive control serum and negative control serum

WASTE DISPOSAL

The disposal of the product must be in accordance with local regulation concerning waste disposal.

QUALITY CONTROL

A positive control will produce, usually within 1 minute, coarse agglutinated flocs against a clear background, as demonstrated by the positive control.
If the indicated results, using the positive control is not obtained, the ASO kit should not be used.

Result
Negative result: No agglutination of the latex particle suspension will occur within two minutes.
Positive result : An agglutination of the latex particle suspension will occur within two minutes, showing ASO level of more than 200 lU/ml. Same as described in screening test.
Results
The serum ASO concentration can then be calculated approximately by multiplying the dilution factor (i.e. 2, 4, etc) by the detection limit (200 lU/ml).
e.g. if the agglutination titer appears at 1:4 the approximate serum ASO level is 4 x 200 = 800 lU/ml.

PERFORMANCE:

- A detectable level of 200 lU/ml Antistreptolysin O antibodies is usually regarded as the normal upper limit since less than 15-20 % of healthy individuals demonstrate titers greater than
200 lU/ml when their sera are assayed. In most newborns the titer is initially greater than that of the mother due to maternally acquired lgG but the newborn levels fall sharply during the first few weeks of life.
- Normal ASO levels for preschool children are generally less than 100 lU/ml but the levels rise with age, peaking in school age and decreasing in adulthood.
- Increases in ASO titer generally occur one (1) to four (4) weeks after onset of infection with
β-hemolytic streptococci Group A. As the infection subsides, the titer declines and returns to normal levels within six months. If the titer does not decrease, a recurrent or chronic infection may exist.
- Elevated ASO titers may be associated with ankylosing spondylitis, glomerulonephritis, scarlet fever, and tonsillitis. Increased ASO levels are generally not found in sera of patients with rheumatoid arthritis except during acute episodes.
- Extremely low levels of ASO have been observed in the blood specimens of patients with nephrotic syndrome and antibody deficiency syndromes.
- A comparison of 354 serum specimens was tested comparing the undiluted with the direct 1:6 dilution procedure. Equivalent results were obtained on the qualitative method on 349 of the 354 random specimens. The overall agreement is approximately 99%.

LIMITATIONS :

Results obtained must be evaluated together with the clinical information available to the physician.
Serum specimens showing gross hemolysis, lipemia, turbidity, or contamination should not beused since falsely positive results may occur.
Both elevated Beta-lipoprotein and cholesterol level may suppress a rise in ASO titer.
The test reaction must be read immediately following the two minutes rocking. Delayed readings may result in false positive results.
The degree of agglutination observed in undiluted specimens is not indicative of antibody levels since prozone effect may limit agglutination.
ASO latex reagent vial must be kept tightly closed to prevent evaporation and subsequent flocculation.
Patients on therapy of penicillin or other antibiotics may suppress a rise in ASO titer .

REFERENCES:

1. Rantz LD, DiCapri JM, Randall E. Am. J. Med. Sci., 24, 1952
2. Halbert, SP. Ann. N.Y. Acad. Sci., 103,1027:1051;1963.
3. Klein GL, Applied Microbiology, 21:999, 1971.
4. Klein GC: Manual of Clinical Immunology ASM 264-273:1976.

	Consult Instruction for Use
	Caution Consult Accompanying Documents
IVD	In Vitro Diagnostic Medical Device
	Temperature Limitation
	Manufacturer
EC REP	Authorized Representative In The European Community
REF	Catalogue Number
LOT	Batch Code
	Use By

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