


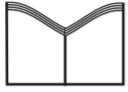


BHAT BIO-TECH INDIA (P) LTD.

ASO TEST
Test for the detection of Anti-Streptolysin O in human serum

For Professional Use IVD



READ THIS PACK INSERT CAREFULLY BEFORE PERFORMING THE TEST

CATALOGUE No.: 1A

INTENDED USE :
ASO latex slide test is a latex agglutination test for qualitative and semi quantitative in vitro determination of Anti-Streptolysin O in human serum.

INTRODUCTION :
The Group A Beta-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 Beta-hemolytic streptococci produces specific antibodies against Streptolysin O which is called Anti-Streptolysin O. The quantity of this antibody in a patients serum will establish the degree of infection due to the Beta-hemolytic streptococci.

PRINCIPLE :
The ASO test is based on passive latex agglutination. Polystyrene latex particles are coated with purified and stabilized streptolysin O antigen. When these coated particles react with Anti-Streptolysin O (ASO), if present in the test sample, visible agglutination of latex particles occur.

STORAGE AND STABILITY :
Storage :
Store the reagents at 2-8°C. Do not use the reagent beyond the expiry date mentioned on it. Before performing the test bring all the reagents to Room temperature. Replace the reagents to 2-8°C soon after performing the test. DO NOT FREEZE THE REAGENTS.

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Stability :

- The unopened kit is stable for 24 months from the date of manufacturing as indicated on the package.
- The opened kit is stable for 6 months from the date of opening.
- Repeated freeze thaw of reagents from 2-8°C to Room temperature several times will reduce the stability of the kit.

PACK SIZE : Available in packs of 25, 50, & 100 Tests.

CONTENTS OF THE KIT :

Materials	25 Tests	50 Tests	100 Tests
ASO Positive Control serum	0.3 ml	0.3 ml	0.3 ml
ASO Negative Control serum	0.3 ml	0.3 ml	0.3 ml
ASO Latex Reagent	0.8 ml	1.6 ml	3.2 ml
Glass slide	1 No.	1 No.	1 No.
Disposable applicator sticks	25 Nos.	50 Nos.	100 Nos.
Disposable plastic dropper with rubber teat	25 Nos.	50 Nos.	100 Nos.
Product pack insert	1	1	1

SPECIMEN :
Use fresh serum for testing. The specimen should be Non-hemolysed and free from contamination.
The specimen may be stored at 2-8°C for up to 8 days and at -20°C for up to 4 weeks.

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SPECIMEN COLLECTION AND HANDLING :
Collect blood in a clean sterilized vial and allow it to clot. Separate the serum by centrifugation at 10000 rpm for 10 minutes at room temperature. It is recommended that fresh samples should be used. If serum is not used for testing immediately it should be stored at 2-8°C or Frozen at -20°C. Bring specimen to room temperature, and specimen should be mixed properly and centrifuged before use. Do not heat or repeatedly freeze thaw the specimens.

PRECAUTIONS :

- For invitro diagnostic use only.
- Bring all reagents and specimens to Room temperature, prior to testing.
- Avoid using lipemic, haemolysed or contaminated specimen.
- All human serum and plasma samples should be considered potentially infectious. It is recommended that all specimens of human origin should be handled as recommended for any potentially infectious human serum or blood specimen in the center for disease control/National Institute of Health Manual "Biosafety in Microbiological and Biomedical Laboratories", 1984.
- Never pipette by mouth.
 - Do not smoke, eat or drink in areas in which specimens or kit reagents are handled.
- Wear disposable gloves while handling specimens and kit reagents. Afterwards wash hands carefully.
- Avoid splashing or forming aerosols.

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9. Discard all materials and specimens as if capable of transmitting infection. The preferred method of disposal is autoclaving for a minimum of one hour at 121°C. Liquid waste containing acid may be mixed with sodium hypochlorite in volumes such that the final mixture contains 50-500mg/l available chlorine. Allow 30 minutes for decontamination to be completed.

NOTE :

- Liquid waste containing acid must be neutralized with a proportional amount of base prior to the addition of sodium hypochlorite.
- Spills should be wiped thoroughly using either an iodophor disinfectant or sodium hypochlorite solution. Materials used to wipe up spills should be added to biohazardous waste matter for proper disposal.
- Deterioration is indicated by a significant decrease by weak agglutination.
- Do not use reagents after the expiration date printed on the label.
- When removing reagents from the bottles, use aseptic technique to avoid contamination.
- Mix the reagent bottle gently before use.
- Do not use clotted blood sample for testing.
- Ensure used glass slide is disinfected, washed thoroughly and rinsed free of detergents.

TEST PROCEDURE:
A. Qualitative Analysis :
Allow all reagents as well as the sample to attain room temperature

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- Using disposable plastic dropper place one drop of specimen in circled area of the slide provided in the kit.
- Add one drop of ASO latex antigen to the above drop and mix well with disposable applicator sticks.
- Rock the slide gently to and fro for two minutes and examine for agglutination. Do not examine beyond two minutes

For Positive and Negative controls follow the same procedure as mentioned above by taking control serum from respective vials.

B. Semi quantitative Analysis :

- Dilute the serum serially 1:2, 1:4, 1:8, 1:16, 1:32 using normal saline.
- Place one drop of diluted sample using plastic dropper in each circle of the glass slide.
- Add one drop of Latex reagent in each of these circles, mix well with applicator sticks.
- Rock the slide gently to and fro for two minutes and examine for agglutination.

INTERPRETATION OF RESULTS:
Read the result under strong source of light.

A. Qualitative Analysis:

- Agglutination is a positive test result and indicates the presence of detectable Anti-Streptolysin O in serum.
- No agglutination is a negative test result and indicates the absence of detectable Anti-Streptolysin O in serum.

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B. Semi Quantitative Analysis :
Agglutination in the highest serum dilution corresponds to the approximate amount of ASO concentration in IU/ml present in test serum.
Concentration of ASO can be calculated as follows :
ASO (IU/ml) = Titre x ASO Sensitivity (IU/ml) Where ASO Sensitivity= 200 IU/ml and titre =Reciprocal of the highest dilution of serum which exhibits a positive result.

TROUBLE SHOOTING :

FALSE POSITIVE	
Cause 1. Contaminated serum or reagents	Remedy Make sure that there is no contamination of serum or reagent. Use clean slide for testing. Do not read the result after 4 minutes.
2. Drying in slide test	Do not read the result after 4 minutes
3. Improper mixing of Latex Reagents	Mix the Latex reagent thoroughly before use.

FALSE NEGATIVE	
Cause 1. Contamination of serum or reagents	Remedy Make sure that there is no contamination of Serum or reagent Use clean slide for testing.
2. Improper mixing of Latex Reagents	Mix Latex Reagent thoroughly before use.

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WEAKLY / DELAYED REACTION	
Cause 1. Improper mixing of latex reagents	Remedy Mix the Latex reagent thoroughly before use.
2. Expired reagent	Check the expiry date on the reagent
3. Improper storage conditions of the kit	The kit has to be stored at 2-8°C.

PERFORMANCE CHARACTERISTICS :
Accuracy : Bhat Bio-Scan® ASO Test kit meets the requirements when tested against DCI approved kits.
SPECIFICITY :

No. of Negative samples tested	No. of Negative by Bhat Bio-Scan® ASO Test	Specificity (%)
40	40	100

SENSITIVITY :

No. of Positive samples tested	No. of Positive by Bhat Bio-Scan® ASO Test	Sensitivity (%)
35	35	100

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LIMITATIONS OF THE TEST :

- It is recommended that with every set of tests, positive and negative controls should be included. The result of positive and negative controls should be read before reading the test results. The satisfactory result of positive and negative control indicates that the reagents are working well.
- Factors other than reagents, which might affect the performance of the test, include cleanliness of glassware, meticulous follow up of the procedure.
- Do not use lipaemic, haemolysed, or contaminated specimens.
- Mix Latex antigen gently before use.
- While dispensing reagents/specimen hold pipette/ dropper vertically straight.
- Improper mixing of specimen/control with Latex may lead to erroneous results.
- Make sure that the cap of each reagent vial is properly and promptly applied to the same vial. Interchanging of the vial caps and or droppers will lead to contamination of reagents, which might lead to false results.
- The slide should be tilted back and forth gently to avoid disturbance to the reaction pattern.
- Contaminated blood specimen or reagents may interfere with test results. Peripheral drying in slide test should not be misinterpreted as agglutination.
- Interpret results exactly at 2 minutes.
- The reagents contain sodium azide as preservative. Do not swallow. Avoid contact with skin and mucous membrane.

REFERENCE :

- Rantz LD, Dicaprio JM, Randall E, Am. J. Med. Sci, 24, 1952.
- Klien GC 1976, Manual of Clinical Immunology ASM, 264.

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EN 980:2008 (E) MEDICAL DEVICES SYMBOL

Temperature Limitation	Date of Manufacture	In vitro Diagnostic Device	Batch Code
Company name (a address)	Refer Operating Instructions	Use by	Company Name
Authorized Representative in European Community	Do Not Reuse	Sufficient for	KEEP AWAY FROM SUNLIGHT
KEEP DRY	NON-STERILE	CONTROL -	CONTROL +
Mfg. in India by BHAT BIO - TECH INDIA (P) LTD. 11-A, 4th Cross, Veerasandra Industrial Area, Electronics City, Bangalore - 560100, Karnataka Tel: 080-4351 4000 (30 lines) Fax: 080-4351 4001 Visit us at: www.bhatbiotech.com		M/S PDB Consulting Bruno Rosen, Flehenburg 48, 42489 Walfraath, Germany P: + 49 - 2056 - 8989861 Fax: + 49 - 2056 - 8989862	

R-2, 4th Oct. 2010