ASTAM DIAGNOSTICS

PRODUCT INSERT

REF ASOS

PRATHAM®
ASO Test (Latex)

INTENDED USE

PRATHAM® ASO Test (Latex) is a latex slide agglutination test intended used for the qualitative and semi-quantitative detection of an antistreptolysin-O in human serum.

INTRODUCTION

Streptolysin O (SLO) is a lethal, exocellular protein produced by Group A streptococci bacteria. It is so named because it is reversibly inactivated by atmospheric oxygen. The binding of active SLO to the surface of erythrocytes causes disruption of the cytoplasmic membrane resulting in cell lysis. Anti-streptolysin O antibodies (ASO) are produced by the host to neutralise the haemolytic action of the SLO. Measurement of ASO in serum is used for the diagnosis of streptococcol infections such as rheumatic fever and glomerulonephritis. The ASO level can be used as a measure of the extent and degree of infection. Elevated ASO levels may also be present in other conditions such as scarlet fever, acute rheumatoid arthritis, tonsillitis and various other streptococcal infections and in healthy carriers.

TEST PRINCIPAL

PRATHAM® ASO Test (Latex) method is based on an immunological between streptococcal exoenzymes bound to biologically inert latex particels and streptococcal antibodies in the test specimen. The reagent has been adjusted in the way that presence of an ASO titer of 200 IU/ml of higher in the serum gives a visible agglutination of the latex particles without previous specimen dilution.

KIT COMPONENTS

1. Latex Reagent
2. Positive Control
3. Negative Control
4. Test Slide
5. Mixing Sticks
6. Sample Droppers
7. Product Insert

MATERIAL REQUIRED BUT NOT PROVIDED

Micro pipettes, Vortex mixer, Tissue paper, Normal saline, Test Tube, Centrifuge Marker, Timer, Specimen Collection Device.

STORAGE AND STABILITY

PRATHAM® ASO Test (Latex) slide test components are stable up to expiry date indicated on the component label/box label. ASO kit needs to be stored at 2-8º C.

SPECIMEN COLLECTION AND STORAGE

1. Use fresh serum collected by centrifuging clotted blood.
2. If the test cannot be carried out on the same day, the serum may be stored between 2-8º C for no longer than 48 hours after collection. For longer periods the sample must be frozen.
3. As in all serological tests, hemolytic or contaminated serum must not be used.
4. Do not use plasma.

WARNING AND PRECAUTION

- Cap the vial properly after use to avoid drying of the latex reagent. Do not freeze the latex reagent.
- Positive & negative controls are ready to use & should not be diluted while using in test procedure.
- As with all diagnostic tests, the final diagnosis should be based on a correlation of test results with other clinical symptoms & findings.
- Drying of the specimen and latex reagent mixture at the periphery of the circle could lead to erroneous results.

- In addition to Rheumatoid Arthritis, positive result may also be found in Syphilis, Systemic Lupus, Erythematosus, Hepatitis, Hypergammaglobulinema etc.
- This package insert must be read completely before performing the test. Failure to follow the insert may give inaccurate test results.
- Do not use expired test kit.
- Bring all components to room temperature (15º C-30º C) before use.
- Do not use the components of any other type of test kit as for the components in this kit.
- Apply standard bio-safety precautions for handling and disposal of potentially infective material.
- Do not smoke, drink or eat in areas where specimens or kit is being handled.
- Handle all specimen as potentially infections.
- Wear gloves while handling specimens and performing the test.
- Avoid splashing and aerosol formation.
- Clean up spills throughly using an appropriate disinfectand.
- Do not use if the product has been exposed to excessive heat.
- Dispose off all specimens and materials used to perform the test as bio- hazardous waste.
- Firmly shake the latex reagent vial properly to get the homogenous latex particles before testing.

TEST PROCEDURE

A. QUALITATIVE TEST:

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperature.
2. Place 1 drop of the sample with the help of specimen dropper and one drop of each positive and negative controls into separate circle on the test slide.
3. Mix the ASO-latex reagent vigorously or on a vortex mixer before using and add one drop to each test circle.
4. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Gently rock the slide for two (2) minutes and read agglutination reaction if any immediately under direct light.

B. SEMI-QUANTITATIVE TEST:

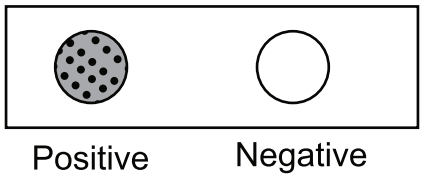
1. Make serial two fold dilutions of the sample in normal saline solution (9 g/L).
2. Proceed for each dilution as in qualitative method.

INTERPRETATION OF RESULTS

A. QUALITATIVE TEST:

A negative reaction is indicated by a uniform milky suspension with no agglutination as observed and compose 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.



B. SEMI-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.

INTERNAL 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 in observed with the ASO Negative Control and agglutination with large aggregates is observed with the ASO Positive Control.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity: 200 (±50) IU/ml.
PROZONE EFFECT: No prozone effect was detected up to 1500 IU/ml.
SENSITIVITY 98.3%.
SPECIFICITY 97.5%.

LIMITATION OF THE TEST

1. False positive results may be obtained in conditions such as, rheumatoid arthritis, scarlet fever, tonsilitis, several streptococcal infections and healthy carriers.
2. Early infections and children from 6 months to 2 years may cause false negative results.
3. A single ASO determination does not produce much information about the actual state of the disease. Titration at biweekly intervals during 4 or 6 weeks are advisable to follow the disease evolution. Clinical diagnosis is should not be made on findings of a single test results, but should integrate both clinical and laboratory data.

DISPOSAL

Consider all test run with human specimen as potentially infectious and discard using standard biosafety practices.

DISCLAIMER:

Whilst every precaution has been taken to ensure the diagnostic ability and accuracy of this product the product is used outside of the control of the Manufacturer and Distributor and the result may accordingly be affected by environmental factors and / or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

The manufacturer and distributors of this product shall not be liable for any losses, liability, claims, coasts or damages whether direct or indirect or consequential out of or related to an incorrect diagnosis, whether positive or negative in the use of this product.

REFERENCES

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SYMBOLS

	See instruction for use		Storage temeprature	IVD	For in-vitro diagnostic use
	Expiry date	REF	Catalogue number		Manufactured by
	Keep away from sunlight		Manufacturing date		No. of tests

Manufactured By:
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