ASO

Latex Slide Agglutination Method

INTENDED USE

For the Qualitative and Semi-Quantitative determination of Anti Streptolysin-O Antibodies in Human Serum.

SUMMARY & CLINICAL IMPORTANCE

The group A Beta-Hemolytic Streptococci produces various Exotoxins such as Streptolysin-O & Streptolysin-S which can act as Antigens.
The affected individuals produce specific Antibodies to Antistreptolysin-O (ASO).
Detection of ASO is very useful in the diagnosis of Streptococcal Infections.
The elevated ASO titres may be associated with Acute Rheumatic Fever and Glomerulonephritis.
An elevated ASO titre of more than 200 IU/mL indicates an AcuteStreptococcal Infection.
Testing of successive serum sample after an interval of 10-12 days is diagnostically more important than a single sample.

PRINCIPLE

The latex Reagent is coated with Streptolysin-O Antigen. The Specimen containing ASO, on mixing with Latex Reagent agglutinates, showing the positive test result.
If ASO is absent there will be no agglutination, which is a negative test result.

STORAGE & STABILITY

All the reagents are stable at 2-8°C till the expiry date mentioned on the labels.

SPECIMEN

Only Serum is the preferred specimen. In case of a delay in testing, store the specimen at 2-8°C.
Plasma or Hemolysed/ Lipaemic Serum Samples should not be used.

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PRECAUTIONS

1. **Do not read results after 2 minutes.**
2. Bring all the reagents and samples to RT before use.
3. Do not freeze the Latex Reagent.
4. Do not use Hemolysed or Turbid Specimen.
5. The Latex Reagent should be shaken well before use to ensure a homogeneous suspension of latex.
6. The source material used in the manufacturing of Positive & Negative Controls is tested for HBsAg & HIV antibodies and are found to be negative. However for better safety these controls should be handled as if they are potentially dangerous.
7. While dispensing Latex Reagent, hold the Latex dropper vertically to ensure uniform drop size.

PROCEDURE

QUALITATIVE TEST

1. Place one drop (Approximately 50 µL) of specimen, Positive Control and Negativel Control in separate circles of the glass slide by using the Sample droppers provided.
2. Add one drop of (Approximately 50 µL) Latex Reagent in each of these circles with the Latex dropper.
3. Mix the content of each circle separately and spread it in the entire circle with the mixing sticks provided in the kit.
4. Rock the slide gently for 2 minutes and look for any agglutination
5. **Do not read results after 2 minutes.**

INTERPRETATION OF RESULTS

Agglutination with positive Control and no agglutination with Negative Control validate test results.
Agglutination within 2 minutes is a positive test and indicates presence of ASO in the test specimen.
No agglutination up to 2 minutes is a negative test and indicates absence of ASO in the test specimen.

DO NOT INTERPRET RESULTS AFTER 2 MINUTES

ASO

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A-PRODUCT FEATURES

- Detects ASO as low as 200 IU/mL. (Cut off Sensitivity 200 IU/mL)
- Uniform and Homogenous Latex Particles ensure clear Agglutination.
- Qualitative and Semi quantitative procedures included in the same kit.
- Positive and Negative Controls are provided for the proper validation of the kit.
- Positive and Negative Controls provided in the kit are free from HIV & HBsAg.
- Sample dilution is not required unlike conventional procedures.
- Incorporates Six Sigma methodologies throughout the manufacturing processes wherein the product under goes various stringent process checks like Defining, Measuring, Analyzing, Improving and Controlling. (DMAIC)
- Avid Agglutination ensures proper discrimination between positive and negative results.
- Cut off sensitivity 200 IU/mL is determined in correlation with Quantitative Turbidometry.
- Latex Reagent Sensitivity 200 IU/mL is calibrated against WHO calibrators.
- Optimum Streptolysin-O Antigen concentration coated on to the Latex particles overcomes Immunological interferences like Prozone Effect and Hook Effect.

B. SEMI QUANTITATIVE TEST

1. Dilute the specimen serially 1:2, 1:4, 1:8, 1:16, using normal saline.
2. Place one drop of each diluted serum sample using Samble / droppers in each circle of glass slide & proceed further as in Qualitative Test (A).

INTERPRETATION OF RESULTS

The highest dilution which shows clear-cut agglutination within 2 minutes, indicates the ASO titre. The approximate ASO concentration can be obtained by multiplying the titre by sensitivity of the test.

ASO in IU/mL = D x S

D = Highest dilution showing clear cut agglutination.
S = Sensitivity of the test is 200 IU/mL.

ASO

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NOTES

- Do not read results after 2 Minutes.
- Positive & Negative Controls are ready to use & should not be diluted while using in test procedure.
- Improper mixing and drying of reagents may lead to erroneous results.
- Contaminated sera and a longer reaction time after 2 minutes may lead to false positive results.
- As with all diagnostics tests, the final diagnosis should be based on correlation of test results with other clinical symptoms and findings.
- Non specific positive reaction may occur if plasma is used or serum is highly lipemic or hemolysed.
- For accuracy of results, the procedure has to be followed meticulously.

REFERENCES

1. Rantz, L.D., Di Caprio, J.M., Randall,S., (1952); AM. J. Med. Sci. 24
2. Kilen, G.C. (1976); Manual of Clinical Immunology ASM, 264

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