Anti Streptolysin-O (ASO)

LATEX AGGLUTINATION SLIDE TEST

Rapid Latex agglutination slide test for the qualitative and semi-quantitative, in-vitro determination of Antistreptolysis-O (ASO) in non-diluted serum for Rheumatic Diseases.

Principle
Specially selected polystyrene latex particles are coated with purified and stabilized Streptolysis-O (antigen). When a serum positive for Antistreptolysis-O is mixed with the latex reagent, a positive reaction is indicated by a distinctly visible agglutination of the latex particle in the test cell of the slide used. In a serum negative for Antistreptolysis-O, the Latex remains in a smooth suspension form, in the test cell.

Contents, reagents and material provided

1. Latex Reagent for 25/50/100 tests. Mix gently before use. Suspension of polystyrene latex particles, coated with purified and stabilized Streptolysis-O.
2. Positive Control
Stabilized serum control, producing a distinct agglutination with latex reagent.
3. Negative Control
Stabilized serum control, non-reactive with the latex reagent.
4. Disposable slides with 8 test cells.
5. Disposable mixing sticks
6. Disposable plastic droppers with rubber teats.

Stability
Latex Reagent and control sera are stable up to expiry date printed on the labels when stored at 2-8°C.

Do not freeze

Specimen
Use fresh serum specimen, However, the same may be stored at 2-8°C for up to 24 hrs and at 20°C for up to 4 weeks. Plasma should not be used because fibrinogen may cause non-specific agglutination of the latex particles. Do not use lipaemic, haemolysed or contaminated specimen.

Procedure

A. Qualitative analysis (Screening)
- Bring the latex reagent, controls and serum specimens to room temperature.
- Mix the latex reagent thoroughly prior to use.

Drop/pipette onto separate cells of the slide:

<table>
<thead>
<tr>
<th>Serum Specimen</th>
<th>1 drop</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive Control Serum</td>
<td>1 drop</td>
</tr>
<tr>
<td>Negative Control Serum</td>
<td>1 drop</td>
</tr>
<tr>
<td>Aso Latex Reagent, on to all sample, and control cells of the slide in use</td>
<td>1 drop each</td>
</tr>
</tbody>
</table>

Mix with separate applicator sticks and spread the fluid over the entire area of the particular cell. Tilt the test slide back and forth for 2 minutes so that the mixture rotates slowly inside the cells or place the slide on an automated rotator or 100 rpm. At the end of 2 minutes read the results under bright light.

Interpretation of results

| Distinct coarse agglutination | Occurring within 0.5 minute (Strongly Positive) |
| Fine agglutination | Usually taking full 2 minutes (weakly Positive) |
| Smooth suspension/ No agglutination | (Negative) |

Distinct agglutination indicates ASO content of more than 200 IU ASO/ml undiluted serum specimen. Sera with positive results in the screening should be tested in the titration test (Semi-quantitative analysis)

Semi quantitative analysis

Prepare 0.9% saline solution, Then dilute specimen with saline solution until the last dilution giving distinct agglutination.

<table>
<thead>
<tr>
<th>Dilution</th>
<th>ASO/1U/ml in non-diluted specimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>1+1 (1:2)</td>
<td>400</td>
</tr>
<tr>
<td>1+3 (1:4)</td>
<td>800</td>
</tr>
<tr>
<td>1+7 (1:8)</td>
<td>1600</td>
</tr>
<tr>
<td>1+15 (1:16)</td>
<td>3200</td>
</tr>
</tbody>
</table>

Continue test as described in 'Qualitative analysis'.

Interpretation of results
Titre is the last dilution step giving visible agglutination. Read the titre in the last dilution step with visible agglutination and multiply the titre with the conversion factor 200, to get the results in IU/ml.
E.g.: If the Titre is 1:4, the ASO concentration will be 4x200=800 IU/ml.

Quality Control - Good Laboratory practice
The Positive and Negative controls may be used for routine performance check.

Diagnostic values
Increased ASO titres may be associated with rheumatoid fever and glomerulonephritis. An elevated ASO titre of more than 200 IU/ml may indicate an acute streptococcal infection. The titre of ASO should be monitored every 2 weeks over a period of 4 to 6 weeks.

Precautions
1. Kit reagents are for in-vitro diagnostic use only.
2. Strictly follow the instructions mentioned in the product inserts.
3. Bring specimens and reagents to room temperature before use.
4. Do not use lipaemic, haemolysed or contaminated serum specimens.
5. Glassware used for specimen collection and test should be free of detergent and dry before use.
7. While dispensing reagents/specimens hold pipette/dropper vertically straight.
8. Improper mixing of specimen/control with the latex reagent may lead to erroneous results.
9. Make sure that the cap of each reagent vial is properly and promptly applied to the same vial. Interchanging of the vial caps and/droppers will lead to contamination of the reagents which might lead to false results.
10. The slide should be tilted back and forth gently to avoid disturbance to the agglutination pattern.
11. Drying of the test mixture at the periphery of the cell may lead to erroneous interpretation of results.
12. Interpret results exactly at 2 minutes.
13. The reagents contain sodium azide as preservative. Do not swallow. Avoid contact with skin & mucous membrane.
14. All reagents of human source have been tested negative for HBsAg & anti-HIV antibodies. However, the same should be treated as potentially infectious.

References

Manufactured by: Asritha Diatech India Pvt. Ltd., Hyderabad.
Marketed By: Euro Diagnostic Systems Pvt. Ltd., Millennium House, M.K.Srinivasan Nagar Main Road, No. 144, Old Mahabalipuram Road, Perungudi, Chennai - 600 096; Email: eurods@vsnl.net