ASO-Latex

Agglutination assay on glass slides without prior dilution of the sample.
For «in vitro» use only.
Store at 2 - 8 °C.

INTRODUCTION:

Streptolysin O is a hemolytic factor produced by most beta-hemolytic streptococcal strains in group A. Anti-Streptolysin O (ASO) is a specific neutralizing antibody produced after infection with these microbes. ASO can be detected in the serum one month after streptococcal infection. The ASO assay is useful for the diagnosis of rheumatic fever and glomerulonephritis.

PROPOSED USE:

For determining ASO in human serum.

MATERIALS

Micropipettes.

FUNDAMENT OF THE METHOD

The method is based on the agglutination reaction of a suspension of polystyrene latex particles sensitized with stabilized Streptolysin O. Agglutination becomes visible at a ASO serum concentration equal to or over 200 UI/ml.

CONTENT

R1 Latex White cap Latex particles sensitized with Streptolysin O in a borate buffer solution of 50 mmol/L. Contains sodium azide- 0.95 g/l

R2 Positive Control Red cap ASO Concentration > 200 IU/ml Human Serum Contains sodium azide 0.95 g/l

R3 Negative Control Blue cap ASO concentration: 0 IU/ml, rabbit serum. Contains sodium azide 0.95 g/L.

Latex Slides Code. 1200101: 8 x 6 slides
Code. 1200102: 16 x 6 slides

Applicator Code. 1200101: 1 pack x 25
Code. 1200102: 2 packs x 25

CALIBRATION

Sensitivity of the latex reagent is standardized against 1st WHO ASO International Standard [Anti-Streptolysin O, Human ref: 97/662].

PREPARATION AND STABILITY

R1 Latex is a suspension of latex particles which should be homogenized by shaking gently before use. The volume of drops dispensed by conventional droppers is approximately 50 μL, which is ideal for a good sensitivity. Reagents should be stored at 2 - 8 °C. Avoid freezing. Under these conditions the components will remain active until the date of expiry
Indicate don the label.

SAMPLE

Use serum. Sera stored at 2 -8 °C remain active for 7 days. For longer periods of time, the reagents should be frozen at –20 C.

Do not use hemolyzed sera. Do not use highly lipemic sera as this can cause nonspecific agglutination.

PROCEDURE: Qualitative method

1. Temper reagents and samples to room temperature: sensitivity of the assay drops with low temperatures.

2. Add 50 μl of the trial sample and 1 drop from the positive and negative controls to different circles on a cover slip.

3. Gently homogenize the R1 Latex before using. Add 1 drop (50 μl) next to each of the drops described above.

4. Mix the two drops with an applicator and spread throughout the circle. Use a different applicator for each of the samples and handle through both ends.

5. - Place the slide on a rotatory stirrer (80-100 RPM) and observe the presence (or not) of agglutination exactly after two minutes. Do not wait too long as this can give rise to false positives. If a rotatory stirrer is not
available, shake the preparation manually with circular movements.

**INTERPRETATION OF RESULTS**

Examine the preparation macroscopically, looking for the presence or absence of agglutination immediately alter withdrawing the slide.

- The presence of agglutination indicates a level of ASO in the sample equal to or over 200 UI/ml.

- The absence of agglutination indicates a level of ASO less than 200 UI/ml in the sample.

**Semi-Quantitative Method**

1. Prepare double dilutions of the sample in a saline solution 9g/l.
2. Proceed as indicated in the qualitative method.

**CALCULATIONS**

The approximate ASO concentration in the sample from the patient is obtained with the following formula:

\[ 200 \times \text{ASO Titter} = \text{UI/ml} \]

In the semi-quantitative method, the titer is defined as the highest dilution that bears positive results.

**QUALITY CONTROL**

Users are advised to use both the positive and the negative controls in order to control the activity the latex reagent and as a comparison model when interpreting results.

**REFERENCE VALUES**

Up to 200 UI/ml Laboratories should establish their own reference values.

**CHARACTERISTICS OF THE METHOD**

- Detection limit: 200 UI/ml.
- Prozone value: negative up to 1500 UI/ml.
- Sensitivity: 98 %.
- Specificity: 97 %.
- Do not interfere:

  - Bilirubin: up to 342 µmol/l.
  - Hemoglobin: from 0.63 to 10 g/l
  - Lipids: from 0.63 to 10 g/.
  - Rheumatoid factor: from 37.5 to 300 UI/ml.

**LIMITATIONS OF THE METHOD**

- Rheumatoid arthritis, scarlet fever, tonsillitis, several streptococcal infections and some healthy carriers can give false positive results.

  - Recent infections and children from 6 months to two years of age can give false results.

  - One determination does not provide sufficient information regarding the actual status of the disease. In case of doubtful cases and for follow-up of the disease, we recommend repeating the test every 12 days during the following 4 or 6 weeks. Clinical diagnosis should not be based only on the results of one test. The clinical record of the patient should also be considered.

**PRECAUTIONS**

The positive control is human serum. Although the presence of HB or anti-HIV antibodies has not been detected the preparation should be handled with the same precaution as the trial serum, in other words, as potentially infectious. The reagents contain small amounts of sodium azide. Avoid contact with irritated skin and mucosa. Do not freeze.

**REFERENCE**


**PRESENTATION**

| Cid: 120001 | 48 Dterm |
| Cid: 120002 | 96 Dterm |