BIOLABO
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ASLO-LATEX

Latex agglutination slide test for qualitative and semi-quantitative determination of Antistreptolysin O antibodies (ASLO) in human serum

REF 081050	50 tests :	**R1** 2,0 mL	**R2** 0,5 mL	**R3** 0,5 mL

TECHNICAL SUPPORT AND ORDERS
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CE

IVD **IN VITRO DIAGNOSTIC USE**

CLINICAL SIGNIFICANCE (1) (2)

Streptolysin O, one of the various exotoxins produced by the group A β-haemolytic streptococci, can act as antigen. In patients suspected of having acute post streptococcal glomerulonephritis, evidence of recent infection may be found in increased titres of antibodies to streptococcal extracellular products (antistreptolysin O, Antihyaluronidase, antideoxyribonuclease B).
A single ASLO determination does not produce much information about the actual state of the disease. Titrations at biweekly intervals during 4 or 6 weeks are advisable to follow the disease evolution.
Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

PRINCIPLE (2) (3)

ASLO-LATEX is a stabilized buffered suspension of polystyrene latex particles that have been coated with Streptolysin-O.
When the latex reagent is mixed with a serum containing antibodies to Streptolysin O, agglutination occurs.
The latex reagent has been produced so that agglutination will take place only when the level of antibodies to Streptolysin O is greater than 200 IU/ml, a level determined to be indicative of disease by epidemiological and clinical studies.
Sera having titres of between 200 IU/ml and 1026 IU/ml will be reactive.

REAGENTS COMPOSITION

1. ASLO-LATEX is a stabilized buffered suspension of polystyrene latex particles coated with Streptolysin O.
2. Positive ASLO control serum (human origin).
3. Negative ASLO control serum (human origin).

-- Reusable agglutination slide and disposable stirring pipettes.

REAGENTS PREPARATION

Reagents are ready for use.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Semi-quantitative test: micropipettes and test tubes.
2. Saline (0.9 % NaCl)

STABILITY AND STORAGE

Store at 2-8°C away from light
DO NOT FREEZE THE LATEX REAGENT.

- When free from contamination, stored in the original vial and used as described in this technical data sheet, reagents are stable until expiry date stated on the label of the kit.
- Discard any reagent if contaminated or do not demonstrate correct activity with controls.

SAFETY CAUTIONS

BIOLABO reagents are designated for professional, in vitro diagnostic use.

- Use adequate protections (overall, gloves, glasses).
- Do not pipette by mouth.
- In case of contact with skin and eyes, thoroughly wash affected areas with plenty of water.
- Reagents contain sodium azide (concentration < 0.1%) which may react with copper and lead plumbing. Flush with plenty of water when disposing.
- Controls contain human serum. Human serum used have been tested and found to be negative for HIV, HCV and HbsAg. Because no known test method can offer complete assurance that infectious agents are absent, this material should be handled as potentially infectious.
- For further information, Material Safety Data Sheet is available upon request.
- Waste disposal: Respect legislation in force in the country.

All specimens should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions. Respect legislation in force in the country.

SPECIMEN COLLECTION AND HANDLING (4)

Use fresh serum obtained by centrifugation of clotted blood.
Do not use plasmas.
The specimen may be stored at 2-8° C for 48 hours before performing the test.
For longer periods of time the serum must be frozen (once only).
Haematic, lipaemic or contaminated serum must be discarded.

INTERFERENCES

False positive results may be obtained in conditions such as, rheumatoid arthritis (acute episodes), scarlet fever, tonsillitis, several streptococcal infections and healthy carriers.
Early infections and children from 6 months to 2 years may cause false negative results.

QUALITY CONTROL

Positive and Negative ASLO control serum included in this kit.
External quality control program.
It is recommended to control in the following cases :

- At least once a run.
- At least once within 24 hours.
- When changing vial of reagent.

If control is not correct, apply following actions:

1. Repeat the test with the same control.
2. If control is still not correct, try again with a new vial of control(s).
3. If control is still not correct, try again with a new vial of reagent.
4. If control is still not correct, please contact BIOLABO technical support or your local Agent.

EXPECTED VALUES (1) (3)

A detectable level of 200 IU/mL Antistreptolysin-O antibodies is usually regarded as the normal upper limit.

In most newborns the titre is initially greater than that of the mother due to maternally acquired IgG but the newborn levels fall sharply during the first few weeks of life.

Normal ASLO levels for preschool children are generally less than 100 IU/mL but the levels rise with age, peaking in school age and decreasing in adulthood.

Increases in ASLO titer generally occur 1 to four 4 weeks after onset of infection with B-hemolytic streptococci Group A. As the infection subsides, the titre declines and returns to normal levels within six months. If the titre does not decrease a recurrent or chronic infection may exist.

Elevated ASLO titres may be associated with ankylosing spondylitis, glomerulonephritis, scarlet fever, and tonsillitis. Increased ASLO levels are generally not found in sera of patients with rheumatoid arthritis except during acute episodes.

Extremely low levels of ASLO have been observed in the blood samples of patients with nephrotic syndrome and antibody deficiency syndromes.

PERFORMANCES CHARACTERISTICS

Analytical sensitivity: 200 (± 50) IU/mL.
Prozone effect: No prozone effect was detected up to 1026 IU/mL.
Diagnostic sensitivity: 98 %.
Diagnostic specificity: 97 %.

MANUAL PROCEDURE

QUALITATIVE METHOD

1. Allow each component to reach room temperature.
2. Place a drop of negative control onto a circle of a test slide.
3. Place a drop of positive control onto a circle of a test slide.
4. Place a drop of undiluted specimen(s) onto a circle of a test slide.
5. Gently shake the latex reagent to disperse the particles.
6. Add one drop of the latex reagent next to the drop of control and specimen(s).
7. Stir with individual pipette-stirrers and spread the mixture over the entire area of the test circle.
8. Gently rock the test slide for two minutes and observe the test circles for agglutination. Extended incubation may result in evaporation and erroneous results (false positive).
9. At the end of the test rinse the test slide with distilled water and dry.

SEMI-QUANTITATIVE DETERMINATION

The semi-quantitative test can be performed in the same way as the qualitative test using dilutions of the specimen in saline as follows:

Prepare dilutions in test tubes :

Dilutions	1/2	1/4	1/8
Saline	100 µL	100 µL	100 µL
Specimen	100 µL	-	-
	→	100 µL →	100 µL →
Transfer onto a circle of a test slide :			
Diluted Specimen	50 µL	50 µL	50 µL
Reagent (vial R1)	50 µL	50 µL	50 µL
Calculate the result as follows :			
200 x Nº of dilution	200 x 2	200 x 4	200 x 8
Results : IU/mL	400	800	1600

INTERPRETATIONS OF RESULTS

QUALITATIVE METHOD

Agglutination indicates a level of ASLO equal or > 200 IU/mL.

Positive:
Agglutination appears within 2 minutes

Negative:
No agglutination appears within 2 minutes

No agglutination indicates a level of ASLO of < 200 IU/mL.

SEMI-QUANTITATIVE METHOD

The titre is expressed as the reciprocal of the highest dilution showing macroscopic agglutination:
e.g. if this occurs in dilution 1/4, the titre is 4 x 200 = 800 UI/mL.

REFERENCES

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Manufacturer | Use by | IVD In vitro diagnostic | Temperature limitation | REF Catalogue number | See insert | LOT Batch number | Store away from light | sufficient for | → dilute with