ASO Latex Test

IVD CE

Rapid latex agglutination test for the detection of anti-Streptolysin O (ASO) antibodies in human serum

Technical sheet

ORDERING INFORMATION

Form	Code	Composition
Kit 100 test	**REF CSA087020**	**n° 1 fl. x 5 ml** (ASO Reagent) **n° 1 fl. x 1 ml** (Positive Control) **n° 1 fl. x 1 ml** (Negative Control)

INTENDED USE

In vitro diagnostic medical device for the execution of the rapid latex agglutination test for qualitative research, and / or semi-quantitative dosage, of Anti-Streptolysin-O (ASO) in human serum. Test results should always be interpreted in relation to the clinical context. For professional use only.

CLINICAL SIGNIFICANCE

ASO antibodies are found in patient's sera due to infection with hemolytic Streptococci of groups A, C, or G. Streptolysin O is highly antigenic therefore patients with these infections produce specific antibodies detectable by the ASO Latex test.

PRINCIPLE

The ASO Latex particles are coated with stabilized Streptolysin O. When the latex suspension is mixed with serum containing elevated levels of ASO antibodies on a slide, clear agglutination is observed within 2 minutes.

Storage and stability

= Storage temperature 2-8 °C

If stored closed at 2-8°C, avoiding direct light, the reagent is stable until the expiration date printed on the label. Do not freeze. Sensitivity of the test depends on the volume of the drop of reagent dispensed (50 µL). Do not use dropper different than that supplied in the kit and place it perpendicularly to the slide surface. If stored closed at 2-8°C, avoiding direct light, the reagent is stable until the expiration date printed on the label.

CONTENTS OF THE KIT AND PACKAGING

Reagent ASO Ready to use. Suspension of latex particles coated with stabilized Streptolysin O. *Contains Preservative*

Reagent 2 Positive control containing up to 200 UI/mL of ASO*.
Red Cap Human serum. *Contains Preservative*

Reagent 3 Negative Control. Human serum negative for ASO. *Contains*
Blue Cap *Preservative*

*Warning: biohazard. Human sera used in control sera have been tested and found to be negative for the presence of HBsAg and HCV and anti-HIV antibodies. However, handle cautiously as potential infectious human material (Biosafety Level 2).

16 slides x 6 six circles' slides, black screen

n. 50 Disposable stirrers for mixing the reaction mixture

OTHER REQUIRED MATERIALS, BUT NOT SUPPLIED

- 50 µl micropipettes; Isotonic saline

PRECAUTIONS AND WARNINGS

1. Reagents and waste materials shall be disposed of in accordance with Community waste provisions or national or regional provisions.
2. In addition to any risk claims relating to active components, reagents may contain non-active components such as preservatives and detergents. The total concentration of these components is below the limits set out in Regulation 1272/2008 EC and subsequent amendments and additions.
3. It is recommended that the reagent be handled in accordance with the rules of good laboratory practice and that appropriate personal protective equipment be used.
4. All human samples must be handled and disposed as potentially infectious materials.
5. The kit should only be used by qualified and properly trained technical personnel.
6. Diagnoses shall only be carried out by authorised and qualified personnel.
7. It is recommended to handle the reagent according to the rules of good laboratory practice and to use appropriate personal protective equipment.
8. Comply with national directives on occupational safety and quality assurance.
9. Use equipment that comply with current standards.
10. Laboratory standards for protection against infection shall be used.

Reporting of serious incidents

Please inform the manufacturer (through your distributor) and the competent authority of the member state of the European Union in which the user and/or patient is established, of cases of serious incident that has occurred in relation to the device. For other jurisdictions, reports of serious incidents must be made in accordance with the regulatory requirements of the home Member State. By reporting serious incidents, you help provide more information about the safety of your in vitro medical diagnostic device.

PROCEDURE

Quality control

Positive and Negative controls are recommended to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation.

CALIBRATION

The ASO-latex sensitivity is calibrated against the ASO International Standard from NIBSC ASO

REAGENT PREPARATION

Reagents are liquid and ready to use. Swirl gently Reagent ASO before using.

PREPARATION AND STORAGE OF SAMPLES

Blood specimen obtained by venipuncture has to be used. Allow it to clot. Centrifuge for 10-15 minutes at 2500 g. Collect the serum aseptically and refrigerate at 2-8°C. If not used within 2 days, freeze at -20°C or below. Frozen sera are stable at least 2 months. Do not use hemolyzed or contaminated samples. Do not dilute the test sera prior to use in the Qualitative test

PROCEDURE

Qualitative test

1 - Allow the reagent and samples to reach room temperature before use.
2 - Transfer one drop of control or undiluted sample serum to the test circle on the slide.
3 - Shake the Latex reagent until homogeneous suspension, then, using the dropper provided, add one drop of reagent to the test circle.
4 - By using a disposable stirrer, mix and spread the drops on the surface of test circle.
5 - Gently and evenly, rock and rotate the test slide for 2 minutes whilst observing the test slide

Semi-Quantitative technique

Prepare a series of doubling dilutions of the patient's serum in isotonic saline (i.e. 1:2; 1:4; 1:8; 1:16). Repeat the test procedure for each dilution as described above. The serum ASO concentration can be calculated approximately by multiplying the dilution factor (i.e. 2; 4; 8; 16) by the detection limit of method (200 IU/mL), to express as IU/mL the value of ASO antibodies.

Example: If the agglutination appears until the 1:8 dilution, the approximate titer will be: 8 x 200 = 1600 IU/mL *(200 x ASO titer=IU/ml)*

Reading

Examine the test slide under a strong light source in two minutes: a positive result is indicated by the evidence of agglutination of the latex, in a clear solution; a negative result is indicated by no change in the latex suspension in the test slide. ASO Latex has a detection limit of 200 IU/mL or more and negative results will be obtained at an ASO concentration below 200 IU/mL. Aspecific agglutination could appear over two minutes.

REFERENCE VALUES

Adults <200 UI/mL
Children <100 UI/mL

Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

1. *Analytical Sensitivity*: 200 (± 50) IU/mL, under the described assay conditions
2. *Prozone Effect*: no prozone effect was detected up to 1500 IU/mL.
3. *Diagnostics Sensitivity*: 98%
4. *Diagnostics Specificity*: 97%

INTERFERENCES

Hemoglobin (< 10g/L), bilirubin (< 20mg/dL) and e lipemia (< 10g/L) do not interfere. Other substances may interfere

INTERPRETATION

Results obtained with the ASO Latex test compare favorably with those obtained by the classical hemolytic method. False positive results may be obtained in conditions such as, rheumatoid arthritis, scarlet fever, tonsillitis, several streptococcal infections and healthy carriers. A single ASO 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.

LIMITATION OF PROCEDURE

False positive results may be obtained in conditions such as, rheumatoid arthritis, scarlet fever, tonsilitis, several streptococcal infections and healthy carriers.

- Early infections and children from 6 months to 5 years may cause false negative results.
- A single ASO 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.

Bibliography

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Symbols used for IFU and Packaging	
IVD In vitro diagnostics medical device	Manufacturer
REF Catalog number	Instruction for Use
LOT Lot Number	Storage Temperature
Expiration Date	Biological Risk

REVISION	DATE	CHANGES
D	10-2022	Modified for IVDR Compliance

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