Trilogy Biotechnology LLC

225 Madinah St., 305 Commercial Complex, Amman, Jordan
Post code 11954,
Tel: +962 79 8599872,
Email: info@trilogybiotech.com
Website: www.trilogybiotech.com

Antistreptolysin O (ASO) Latex

Qualitative and semi-quantitative determination of ASO

For Slide agglutination

For professional in vitro diagnostic use only.

INTENDED USE

Slide agglutination test for the qualitative and semi-quantitative determination of ASO (Antistreptolysin O antibodies) in human serum.

GENERALITIES

Streptolysin O is a toxic immunogenic exoenzyme produced by β-hemolytic Streptococci of groups A, C and G. Measuring the ASO antibodies are useful for the diagnostic of rheumatoid fever, acute glomerulonephritis and streptococcal infections. Rheumatic fever is an inflammatory disease affecting connective tissue from several parts of human body as skin, heart, joints, etc... and acute glomerulonephritis is a renal infection that affects mainly to renal glomerulus.

TEST PRINCIPLE

ASO Reagent 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.

REAGENT COMPOSITION

ASO Latex Reagent	
Latex particles coated with Streptolysin O, pH 8.2	
Sodium azide	0.95 g/L
ASO Positive Control (Optional)	
Human serum containing ASO concentation	> 200 IU/mL
Sodium azide	0.95 g/L
ASO Negative Control (Optional)	
Animal serum	
Sodium azide	0.95 g/L

STORAGE AND SHELFLIFE

Reagent up to the expiration date, when stored tightly closed and contamination is prevented during use and stored at 2-8 °C. Always store vials vertically. If the position is changed, the reagent must be mixed up to dissolve any aggregates present. Close immediately after use. Do not freeze. Frozen reagents could change the functionality of the test.

Reagent spoilage: visible particles and turbidity after vertexing.

SAMPLE COLLECTION AND PREPARATION

Use fresh serum obtained by centrifugation of clotted blood.

The specimen may be stored at 2-8 °C for 7 days before performing the test. For longer periods of time the serum must be frozen for a maximum of 3 months (once only). Hematic, lipemic or contaminated serum must be discarded. Samples containing fibrin should be centrifuged before use.

MATERIALS REQUIRED

Mechanical rotator adjustable to 80-100 rpm.

Vortex mixer.

Pipettes with disposable tips.

General laboratory equipment.

TEST PROCEDURE

A. Qualitative Procedure

1. Bring reagents and samples to room temperature (18-25°C). The sensitivity of the test may be reduced at low temperatures.
2. Place one drop of the Negative ASO Control onto a circle of the agglutination slide.
3. Place one drop of the Positive ASO Control onto an adjacent circle of the agglutination slide.
4. Using the pipette, place one drop of serum specimen (40 µL) onto the remaining circle of the agglutination slide.
5. Shake gently and re-suspend the ASO Latex reagent.
6. Add one drop next to each drop of controls and serum on the agglutination slide.
7. Stir with individual stirrers and spread mixture over the entire area of the test circle.
8. Place the slide on a mechanical rotator at 80-100 rpm. Interpret results in three minutes. False positive results can appear if the test is read after >3 minutes

B. Semi-quantitative method (titration) procedure:

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

1. Prepare dilutions in test tubes:

Dilutions	**1:2**	**1:4**	**1:8**
Saline	100 µL	50 µL	75 µL
Specimen	100 µL	50 µL	25 µL
Mix both drops with a disposable mixing stick, spreading the liquid over the entire surface of the test field. Use different sticks for each sample.			
Place the slide on a mechanical rotator at 80-100 rpm for 3 minutes. False positive results can appear if the test is read after >3 minutes.			
Calculate the result as follows:			
200 x Nº of dilution	200 x 2	200 x 4	200 x 8
Results:	400 IU/mL	800 IU/mL	1600 IU/mL

INTERNAL 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.

All results different from the negative control result will be considered positive.

INTERPRETATION OF TEST RESULTS

Examine macroscopically the presence or absence of visible agglutination after 3 minutes immediately after removing from the rotator. The presence of agglutination indicates a ASO concentration ≥ 200 IU/mL. In the semi-quantitative method, the titer is defined as the highest dilution showing a positive result.

PERFORMANCE

Analytical Sensitivity: 200 IU/mL (under the described assay conditions).

No prozone effect was detected up to 600 IU/mL.

Diagnostic Specificity: 98%.

Diagnostic Sensitivity: 97%.

TRACEABILITY

Sensitivity is calibrated against the reference material NIBSC.

EXPECTED VALUES

Reference range: < 200 IU/mL. It is recommended that each laboratory establishes its own normal range.

LIMITATIONS

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

Early infections in children from 6 months to 2 years may cause false negative results.

A single ASO determination does not give 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.

INTERFERENCES

Rheumatoid Factors: 300 IU/mL.

No interference up to:

Hemoglobin	10 g/L
Lipemia	10 g/L
Bilirubin	20 mg/dL

Other substances may interfere.

LITERATURE

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- Bach, G.L./ Cadotte, R, Wiatr, R.A., Bhorade, M. and Anderson, T.O., Amer, Clin. Path. 57 : 209 (1972)
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USED SYMBOLS

IVD	In Vitro Diagnostic Medical Device
	Manufacturer
	Date of Manufacture
REF	Catalogue Number
LOT	Batch Code
	Use by YYYY-MM (MM = end of month)
	Operator's Manual; Operating Instructions
	Keep away from Sunlight
	Keep away from Rain
	Temperature Limit
	Caution
	Do not use if Package is Damaged
	Do Not Re-Use
Σ	Contains Sufficient for <N> Tests