SEROCON®

ASO LATEX

(Slide Agglutination Method)

Code	Product Name	Pack Size
SE021A	ASO Latex (Slide Agglutination Method)	25 T
SE021B	ASO Latex (Slide Agglutination Method)	50 T
SE021C	ASO Latex (Slide Agglutination Method)	100 T
SE021D	ASO Latex (Slide Agglutination Method)	250 T

BEACON®

Intended Use

For the qualitative determination of Antistreptolysin -O activity in human serum.

Principle of The Method

The ASO-latex is a slide agglutination test for the qualitative and semiquantitative detection of anti-streptolysin O (ASO) in human serum.

Latex particles coated with streptolysin O (SLO) are agglutinated when mixed with samples containing ASO.

Clinical Significance

Streptolysin O is a toxic immunogenic exoenzyme produced by β - heamolitic 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 glommerulus.

Reagents

Reagent 1: ASO Latex Antigen	Latex particles coated with streptolysin O, pH 8.2. Preservative
Reagent 2: Positive Control	Positive control with preservative
Regent 3: Negative Control	Negative control with preservative

Accessories :

Disposable Plastic Droppers, Disposable Applicator Sticks,Rubber Teat, Disposable Plastic Slides.

Precautions

Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2).

However handle cautiously as potentially infectious.

Calibration

The ASO-latex sensitivity is calibrated against the ASO International Standard from NIBSC 97/662.

Storage And Stability

All the kit components are ready to use, and will remain stable until the expiration date printed on the label, when stored tightly closed at +2-+8ºC and contaminations are prevented during their use. Do not freeze: frozen reagents could change the functionality of the test. Always keep vials in vertical position. If the position is changed, gently mix to dissolve aggregates that may be present.

Reagents deterioration: Presence of particles and turbidity.

Additional Equipment

- Mechanical rotator with adjustable speed at 80-100 r.p.m.
- Vortex mixer.
- Pipettes 50 µL.

Samples

Fresh serum. Stable 7 days at +2-+8ºC

Samples with presence of fibrin should be centrifuged.

Do not use highly hemolized or lipemic samples.

Procedure

Qualitative Method

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place 50 µL of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
3. Mix the ASO-latex reagent vigorously or on a vortex mixer before using and add one drop (50 µL) next to the sample to be tested.
4. Mix the drops using a Disposable Applicator Sticks, spreading them over the entire surface of the circle. Use different Disposable Applicator Sticks for each sample.
5. Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read later than two minutes.

Semi-quantitative Method

1. Make serial two fold dilutions of the sample in 9 g/L saline solution.
2. Proceed for each dilution as in the qualitative method.

Reading and Interpretation

Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator.

The presence of agglutination indicates an ASO concentration equal or greater than 200 IU/mL.

The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

Calculations
The approximate ASO concentration in the patient sample is calculated as follows:
200 x ASO Titer = IU/mL

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 result different from the negative control result, will be considered as a positive.

Reference Values
Up to 200 IU/mL (adults) and 100 IU/mL (children < 5 years old).
Each laboratory shoild 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. Diagnostic sensitivity: 98 %.
4. Diagnostic specificity: 97 %.

Interferences
Bilirubin (20 mg/dL), hemoglobin (10 g/L), lipids (10 g/L), rheumatoid factors (300 IU/mL) do not interfere. Other substances may interfere.

Limitations of The Procedure
- False positive results may be obtained in conditions such as, rheumatoide arthritis, scarlet fever, tonsilitis, several streptococcal infections and healthy carriers.
- Early infections and children from 6 months to 2 years may cause false negative results.
- A single ASO determination does not produce much information about the actual state of the disease. Titration 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

1. Haffejee. Quarterly Journal of Medicine 1992. New series 84; 305: 641-658.
2. Ahmed Samir et al. Pediatric Annals 1992; 21: 835-842.
3. Spaun J et al. Bull Wld Hlth Org 1961; 24: 271-279.
4. The association of Clinical Pathologists 1961. Broadsheet 34.
5. Picard B et al. La Presse Medicale 1983; 23: 2-6.
6. Klein GC. Applied Microbiology 1971; 21: 999-1001.
7. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

Symbols Used On Labels

REF	Catalogue Number		Manufacturer
	See Instruction for Use	LOT	Lot Number
CONT	Content		Storage Temperature
	Expiry Date	IVD	In Vitro Diagnostics

BEA/24/ASL/SE/IFU Ver-02
21/09/2025