ASO LATEX

Slide Agglutination

PRODUCT CODE
SL001

INTENDED USE
This reagent is intended for *in vitro* qualitative & semi quantitative determination of Anti Streptolysin O (ASO) in serum.
No prozone effect detected up to 1500 IU/mL
Rapid procedures; test time only 2 minutes.

CLINICAL SIGNIFICANCE
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 (skin, heart, joints, etc…) and acute glomerulonephritis is a renal infection that affects mainly to renal glomerulus.

PRINCIPLE
ASO latex kit is a rapid agglutination procedure for the direct detection and semi-quantitation (on slide) of antistreptolysin-O (ASO). The antigen, latex particles suspension coated with Streptolysin-O, agglutinates in the presence of specific antibodies present in the sera of patients with Streptolysin O.

REAGENTS

Latex	Latex particles coated with Streptolysin O, pH8.2, Preservative
Control + Red Cap	Human serum with ASO concentration > 200 IU/ml
Control – Green Cap	Animal serum, preservative

ACCESSORIES
Reaction slide, Mixing pipettes

ADDITIONAL REQUIREMENTS
Mechanical rotator with adjustable speed at 80-100 rpm

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 2-8°C 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.

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 calibrator (WHO).

SPECIMEN AND SAMPLE PREPARATION
Fresh serum, Stable 7 days at 2-8°C or 3 months at –20°C.
Samples with presence of fibrin should be centrifuged.
Do not use highly hemolyzed or lipemic samples.

PROCEDURES

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 40 ul of the sample and one drop of each Positive and Negative control into separate circles on the slide test.
3- Swirl the ASO - Latex reagent vigorously before using and add one drop (40 ul) next to the sample to be tested.
4- Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers 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 2 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.

INTERPRETATION OF RESULTS
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)[6]. 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. *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[4].

LIMITATIONS OF THE PROCEDURE
1- False positive results may be obtained in conditions such as, rheumatoid arthritis, scarlet fever, tonsillitis, several streptococcal infections and healthy carriers.
2- Early infections and children from 6 months to 2 years may cause false negative results.
3- 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.
4- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

SYMBOL ON LABELS

Symbols	Signify	Symbols	Signify
REF	Catalogue Number	SIZE	Pack Size
	Expiry Date	VOL	Volume
	Storage Condition	LOT	Lot Number
	Instruction for Use	IVD	In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests	2	For Single Use Only
EC REP	EC Representative	CE	European conformity

REFERENCES

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

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