ASO *LATEX*

For in vitro diagnostic use only

Qualitative determination of Anti-streptolysin or (ASO)

PRINCIPLE OF THE METHOD
The ASO Latex is a slide agglutination test for the qualitative and semi-quantitative detection of anti-streptolysin O (ASO) antibodies. Latex particles coated with streptolysin O are agglutinated when mixed with samples containing ASO.

CLINICAL SIGNIFICANCE
Streptolysin O is a toxic immunogenic exoenzyme produced by β-haemolitic 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.

REAGENTS

Latex:	latex particles coated with streptolysin O, pH 8.2; sodium azide 0.95 g/L.
Positive control:	human serum with an ASO concentration > 200 IU/mL; sodium azide 0.95 g/L.
Negative control:	animal serum; sodium azide 0.95 g/L.

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).

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°C - +8°C and contaminations are prevented during their use. Do not freeze: frozen reagents could change the functionality of the test.
Reagents deterioration
Presence of particles and turbidity.
ADDITIONAL EQUIPMENT
Mechanical rotator with adjustable speed at 80 – 100 r.p.m.

SAMPLES
Fresh serum. Stable 7 days at +2°C - +8°C or 3 months at -20°C.
Samples with presence of fibrin should be centrifuged.
Do not use highly haemolized 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 1 drop of each positive and negative controls into separate circles on the slide test.
3. Swirl the ASO latex reagent gently before using and add 1 drop (50 µL) 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.

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.

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
Hemoglobin (10 g/l), bilirubin (20 mg/dl), lipemia (10 g/l), rheumatoid factors (300 UI/ml) do not interfere. Other substances may interfere (7).

LIMITATIONS OF THE PROCEDURE
- False positive results may be obtained in conditions such as rheumatoide arthritis, scarlet fever, tonsillitis, 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. 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.
- **The components of this I.v.D. are tested always each other without verify the compatibility with components produced by others manufacturers. Is not excluded that these components can be used with components of same chemical composition but produced by others manufacturers, but there is not an experimental evidence of this compatibility.**
- The kit must be used by clinical test trained personnel only.

BIBLIOGRAPHY
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4. *The association of Clinical Pathologists 1961. Broadsheet 34*
5. *Picard B. et al. La Presse Medicale 1983; 23: 2-6*
6. *Klein G. C. Applied Microbiology 1971; 21: 999-1001*
7. *Young D. S. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995*

IVD	In Vitro Diagnostic Medical Device		Temperature limitation	LOT	Batch code (EXXX)		Manufacturer		Keep dry	NON STERILE	Non-sterile
	Consult Instructions for use		Use by (year/month)	REF	Catalogue number		Do not reuse		Fragile, handle with care		Keep away from heat

CONTENTS	Cod. UA80300	Cod. UA80315	Cod. UD80320
	62 test	250 test	2 x 0.5 mL
Latex (white cap)	1 x 3.5 mL	4 x 3.5 mL	---
Positive control (red cap)	1 x 0.5 mL	1 x 0.5 mL	1 x 0.5 mL
Negative control (blue cap)	1 x 0.5 mL	1 x 0.5 mL	1 x 0.5 mL
Stirrers (1x25 items)	3 (75 items)	10	---
Black slide	2 items	42 items	---
EDMA Code	**12 11 01 05 00**	**12 11 01 05 00**	**12 50 01 13 00**

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