



**Dutch Diagnostics**

Human and animal care



**Qualitative determination of anti-streptolysin O (ASO)**

**IVD**

Store at 2 - 8°C.

**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  $\beta$ -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.

**REAGENTS**

<b>Latex</b>	Latex particles coated with streptolysin O, pH, 8.2. Sodium azide 0.95 g/L.
<b>Control +</b> Red cap	Human serum with an ASO concentration > 200 IU/mL. Sodium azide 0.95 g/L.
<b>Control -</b> Blue cap	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 2-8°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 8 days at 2-8°C or 3 months at -20°C.

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  $\mu$ L of the sample and one 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 one drop (50  $\mu$ L) 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 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:

$$200 \times \text{ASO Titer} = \text{IU/mL}$$

**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)<sup>6</sup>.

Each laboratory should establish its own reference range.

**PERFORMANCE CHARACTERISTICS**

1. *Analytical sensitivity:* 200 ( $\pm$  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 IU/mL) do not interfere. Other substances may interfere<sup>7</sup>.

**LIMITATIONS OF THE PROCEDURE**

- False positive results may be obtained in conditions such as, reumatoide 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.

**BIBLIOGRAPHY**

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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. AACCC Press, 1995.

**PACKAGING**

Ref.: 30.001 Latex white 50 tests	: 2.5 mL ASO-Latex : 1 mL Control + : 1 mL Control - : 8 x 6 disposable slides
Ref.: 30.002 Latex white 100 tests	: 5 mL ASO-Latex : 1 mL Control + : 1 mL Control - : 16 x 6 disposable slides

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