

PACKAGING

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| Ref.: 101-0245 | Cont.: 50 tests |
| Ref.: 101-0216 | Cont.: 100 tests |
| Ref.: 101-0190 | Cont.: 100 tests (latex only) |

Store at 2 - 8° C.

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 OF THE METHOD

The ASO-latex is a slide agglutination test for the qualitative and semi-quantitative detection of anti-streptolysin O (ASO) in human serum. Latex particles coated with streptolysin O (SLO) are agglutinated when mixed with samples containing ASO.

REAGENTS

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| Latex | Latex particles coated with streptolysin O, pH 8.2. Preservative |
| Control + Red cap | Human serum with an ASO concentration > 200 IU/mL. Preservative |
| Control - Blue cap | Animal serum. Preservative |

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. 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.
- Pippetes 50 μ L.

SAMPLES

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.

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 μ L 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 μ 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.

Limitations of the procedure

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

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. 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

Analytical sensitivity: 200 (\pm 50) IU/mL, under the described assay conditions

Prozone effect: No prozone effect was detected up to 1500 IU/mL.

Diagnostic sensitivity: 98 %.

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 interfere⁷.

BIBLIOGRAPHY

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