TOXO LATEX
Slide agglutination

Qualitative determination of Anti-toxo plasma antibodies

IVD

PACKAGING

Ref. 101-0387	**100 tests:** **2,5 mL Toxo-latex** **1 mL Control +** **1 mL Control -** **18 x 6 disposable slides**

Store at 2-8ºC

CLINICAL SIGNIFICANCE

Toxoplasmosis is an infectious disease affecting both animals and humans, which is caused by the protozoan parasite *Toxoplasma gondii.* Acquired toxoplasmosis is usually asymptomatic and benign. Adults, depending on the geographical area and age, would contain antibodies in more that 50% of cases, being protected to a new infection. In its congenital form may be devastating, causing mental retardation, ocular disease, and death in newborn. In adults, the parasite may be responsible for some forms of eye disease; individuals with impaired immunologic competence are also at serious risk.
Infection in pregnant women acquires a special significance as the parasite may enter the fetal circulation through the placenta and causes congenital toxoplasmosis especially during the first trimester of pregnancy. The consequences range from spontaneous abortion, early delivery or fetal death.

PRINCIPLE

The Toxo-latex is a slide agglutination test for the qualitative and semi-quantitative detection of anti-toxoplasma antibodies.
Latex particles coated with soluble *Toxoplasma gondii* antigen are agglutinated when mixed with samples containing antibodies anti-Toxoplasma.

REAGENTS

Latex	Latex particles coated with soluble *T. gondii* antigen, pH, 7.5. Preservative
Control +	Animal serum with an antibody anti-Toxoplsma concentration > 4 IU/mL. Preservative
Control -	Animal serum. Preservative

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.
- Pippetes 50 µL.

SAMPLES

Fresh serum. Stable 7 days at 2-8ºC or 3 months at –20ºC.
Samples with presence of fibrin should be centrifuged.
Do not use highly hemolized or lipemic samples.

PRECAUTIONS

Sodium azide may react with lead or copper plumbing to form explosive compounds. When disposing of this product through plumbing fixtures, flush with plenty of water. Require Safety Data Sheet for more information.
Personal protection: Wear suitable protective gloves.

CALIBRATION

The Toxo-latex sensitivity is calibrated against the 3rd International Standard for anti-Toxoplasma (WHO).

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 Toxo-latex reagent vigorously or on a vortex mixer before using and add **25 µ**L of this reagent next to the samples 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 **4 minutes**. False positive results could appear if the test is read later than four 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 antibody concentration equal or greater than 4 IU/mL.
The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

CALCULATIONS

The approximate anti-Toxoplasma concentration in the patient sample is calculated as follows:

4 x anti-Toxo 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 4 IU/mL.
Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

1. Analytical sensitivity: 4 (3-7) IU/mL, under the described assay conditions
2. Prozone effect: Up to 200 IU/mL. Occasionally a prozone effect may be observed with strong positive sera. Therefore in these cases where a suspected case of toxoplasmosis gives a negative result, the test should be repeated using 1/5 serum dilution in NaCl 9 g/L.
3. Diagnostic sensitivity: 96.1%
4. Diagnostic specificity: 89.6%

INTERFERENCES

Hemoglobin (10 g/L), bilirrubin (20 mg/dL), lipemia (10 g/L), and rheumatoid factors (300 IU/mL) do not interfere. Other susbstances may interfere[6].

LIMITATIONS OF THE PROCEDURE

- False positive results may be obtained with hepatocellular diseases. A 25% of serum containing heterofile antibodies may give false positive results.
- All positive sera should be tested with a confirmatory test.
- 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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