Toxo-Latex

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For in vitro diagnostic use only

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**PRINCIPLE**

Toxo-Latex Test is a rapid slide agglutination procedure, developed for the direct detection of antibodies anti-Toxoplasma in human serum. The assay is performed by testing a suspension of latex particles coated with antigenic extract of *Toxoplasma gondii* against unknown samples. The presence or absence of a visible agglutination indicates the presence or absence of anti-Toxoplasma antibodies in the sample tested.

**REAGENT COMPOSITION**

- **R** Toxo-Latex Reagent. Suspension of polystyrene latex particles coated with antigenic extract of *T. gondii* in a buffered saline solution. Contains 0.95 g/L of sodium azide.
- **CONTROL+** Human serum with an antibody anti-Toxoplasma concentration > 10 IU/mL. Contains 0.95 g/L of sodium azide.
- **CONTROL-** Animal serum. Contains 0.95 g/L of sodium azide.

**Precautions:** Components of different human origin have been tested and found to be negative for the presence of antibodies anti-HIV 1+2 and anti-HCV, as well as for HBsAg. However, the controls should be handled cautiously as potentially infectious.

**Warning:** 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.

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**PACKAGING CONTENTS**

- **REF 2740005** kit 50 tests.
  - 1x1.7 mL Toxo-Latex Reagent, 1x0.5 mL Positive control.
  - 1x0.5 mL Negative control. 9 Test cards and 1 x 50 disposable pipettes.

- **REF 2740010** kit 100 tests.
  - 2x1.7 mL Toxo-Latex Reagent, 1x0.5 mL Positive control.
  - 1x0.5 mL Negative control, 17 Test cards and 1 x 50 disposable pipettes.

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**STORAGE AND STABILITY**

Store at 2-8°C. Do not freeze. Frozen reagents could change the functionality of the test. Reagent and Controls are stable until the expiry date stated on the label.

**REAGENT PREPARATION**

Reagent and Controls are ready to use.

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**SAMPLES**

Fresh, clear serum. Samples should be stored at 2-8°C up to one week or for longer periods at −20°C.

**MATERIAL REQUIRED**

- Automatic pipettes.
- Saline solution (0.9% NaCl, only for semi-quantitative procedure).
- Mechanical rotator, adjustable at 100 r.p.m.
- Laboratory alarm clock.

**PROCEDURE**

### I. Qualitative Test

1. Bring the test reagents and samples to room temperature (Note 1).
2. Resuspend the antigen vial gently. Aspirate dropper several times to obtain a thorough mixing.
3. Place 1 drop (50 µL) of the sample under test into one of the circles on the card. Dispense 1 drop of positive control and 1 drop of negative control into two additional circles.
4. Add 1 drop (50 µL) of Toxo-Latex Reagent to each circle next to the sample to be tested.
5. Mix the contents of each circle with a disposable pipette while spreading over the entire area enclosed by the ring. Use separate pipettes for each sample.
6. Rotate the slide slowly by means of a mechanical rotator (100 r.p.m.) for a period of 5 minutes (Note 2).
7. Observe immediately under a suitable light source for any degree of agglutination.

#### Reading

**Nonreactive:** Smooth suspension with no visible agglutination, as shown by negative control.

**Reactive:** Any degree of agglutination visible macroscopically.

### II. Semi-quantitative Test

1. For each specimen to be tested place with an automatic pipette 50 µL of 0.9% saline solution into each of the circles of a card. Do not spread diluent.
2. To circle one add 50 µL of specimen to the saline solution and, using the same tip, mix the saline solution with the sample by repeated aspiration and expulsion of the fluid and transfer 50 µL of the mixture to the saline solution in the second circle.
3. Continue with the 2-fold serial dilutions in a similar manner up to the sixth circle, and discard 50 µL from this circle. Final sample dilutions will be: 1:2, 1:4, 1:16, 1:32, 1:64.
4. Test each dilution as described in steps 3-7 for the Qualitative Test.
**NOTES**

1. The sensitivity of the test may be reduced at low temperatures. The best results are achieved at 15-25°C.
2. Delays in reading the results may generate in over-estimation of the antibody present.

**SOURCES OF ERROR**

- Bacterial contamination of controls and specimens as well as freezing and thawing of the Toxo-Latex Reagent may lead to false positive results.
- Traces of detergent in the test cards may give false positive results. Wash used cards first under tap water until reactants are removed and then with distilled water. Allow to dry in air, avoiding the use of organic solvents as they may impair the special finish on the slide.
- The Toxo-Latex Reagent must not be used beyond its expiry date because a prolonged storage can affect the sensitivity of the suspension.

**REFERENCES**


**QUALITY CONTROL**

Positive and negative controls should be run daily following the steps outlined in the Qualitative Test, in order to check the optimal reactivity of the reagent.

The positive control should produce clear agglutination. If the expected result is not obtained, do not use the kit.

**EXPECTED VALUES**

The presence of agglutination indicates an antibody concentration ≥ 10 IU/mL.

**CLINICAL SIGNIFICANCE**

Toxoplasmosis is an infectious disease, 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 than 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. 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 can be spontaneous abortion and prematurity with visceral and neurological symptoms in the fetus.

**ANALYTICAL PERFORMANCES**

- The analytical sensitivity has been adjusted to detect more than 10 IU/mL. The assay is calibrated against the 3rd International Standard for anti-Toxoplasma (WHO).
- Diagnostic sensitivity: 92%.
- Diagnostic specificity: 95 %.
- 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.
- Results obtained with this reagent did not show significant differences when compared with reference reagents. Details of the comparison experiments are available on request.
- The hemoglobin (<10 g/L), bilirubin (<20 mg/L), lipemia (< 10 g/L), and rheumatoid factors (<300 IU/mL), do not interfere. Other substances may interfere.

**LIMITATIONS OF THE PROCEDURE**

- Patients with hepatocellular diseases may result give false positive results.
- A 25% of serum containing heterophile 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.