



ATLAS TOXO LATEX KIT

A rapid latex agglutination test for qualitative and semi-quantitative detection of *Toxoplasma gondii* antibodies in serum

For *In-Vitro* and professional use only

Store at 2° to 8° C

INTENDED USE

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INTRODUCTION

Atlas Toxo latex kit is an agglutination test to detect specific antibodies in serum of toxoplasmic patients. Toxo latex consists of an aqueous suspension of polystyrene particles coated with soluble purified antigens from *Toxoplasma gondii*. If specific antibodies are present in the sample a clear agglutination will appear.

MATERIALS

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- Toxo latex reagent (Latex particles coated with soluble T.gondii antigen, pH,7.5 sodium azide 0.95 g/dL).
- Toxo positive control .
- Toxo negative control .
- Test slide.
- Stirring Sticks.
- Plastic Needle.
- Package insert.

MATERIALS NEEDED BUT NOT PROVIDED

- Serological pipette.
- Timer.
- Normal Saline 0.9% NaCl.

PRECAUTIONS

- Reagents containing sodium azide may combine with copper and lead plumbing to form highly explosive metal azides. Dispose of reagents by flushing with large amounts of water to prevent azide buildup.
- For In Vitro diagnostic use.
- Positive and negative controls prepared using human sera found negative for hepatitis B surface antigen (HBsAg) by FDA required test; however, handle controls as if potentially infectious.
- Material used must be free of detergents.
- Do not mix reagents from different lots.
- Glass slide should be thoroughly rinsed with water and wiped with lint-free tissue after each use.

STORAGE AND STABILITY

Reagent and controls may be used up to the expiration date given on the label when stored at 2 - 8 C. **DO NOT FREEZE REAGENTS.**

SPECIMEN

A fresh specimen of serum is recommended, Haemolized samples are not suitable for testing. Turbid samples should be clarified.

PROCEDURES

A) QUALITATIVE TEST

1. Bring samples and reagents to room temperature.
2. Using a serological pipette apply 40uL of undiluted serum samples and two drops of control to slide.
3. Shake the vial well, transfer 1 drop 20uL of toxo latex to the samples, mix well with stirring sticks, and rotate slowly the slide.
4. After 4-6 minutes check for agglutination, at the same time compare with the reaction of the control.

B) SEMI-QUANTITATIVE TEST

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 more than 4 IU/mL.

The titer, in the Semi-quantitative method, is defined as the highest dilution showing a positive result.

LIMITATIONS OF THE PROCEDURE. SOURCES OF ERROR

Heavily lipaemic sera and plasma must be excluded, since they can cause non-specific reactions.

CALCULATIONS

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

$$4 \times \text{anti-Toxo Titer} = \text{IU/mL}$$

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 200IU/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 (10g/L), bilirubin (20mg/dL), lipemia (10g/L), and rheumatoid factors (300IU/mL) do not interfere. Other substances may interfere.

LIMITATIONS OF THE PROCEDURE

- False positive results may be obtained with hepatocellular diseases .
- A 25% of serum containig 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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