ATLAS TOXO LATEX KIT

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

IVD For *in vitro* diagnostic and professional use only

Store at 2° to 8° C

INTENDED USE

For qualitative and semi-quantitative detection of *Toxoplasma gondii* antibodies in serum

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, and sodium azide 0.95 g/dL).
- Toxo positive control: Animal serum with an antibody (anti-toxoplasma concentration >4IU/mL).
- Toxo negative control: Animal serum.
- Test slide.
- Stirring Sticks.
- Package insert.

MATERIALS NEEDED BUT NOT PROVIDED

- Serological pipette.
- Mechanical Rotator with adjustable speed 80-100 rpm.
- Vortex mixer.

PRECAUTIONS

- Reagents containing sodium azide may combine with copper and lead plumbing to form highly explosive metal azide. Dispose of reagents by flushing with large amounts of water to prevent azide buildup.
- For *in vitro* diagnostic and professional use only.
- 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, stable for 2 days at 2-8°C or 3 months at -20°C. 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 40 µl of undiluted serum samples and 1 drop of control to slide.
3. Shake the vial well, transfer 1 drop (20 µl) of toxo latex to the samples, mix well with stirring sticks, and rotate slowly the slide.
4. After 4 minutes, check for agglutination, at the same time compare with the reaction of the control. False positive results could appear if the test is read later than four minutes.

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 X anti-Toxo Titer= IU/mL

REFERENCE VALUES

Up to 4 IU/mL

Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

1. Analytical sentitvity:4(3-7) IU/mL, under the described assay conditions
2. Prozone effect: Up to 1000IU/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: 100%
4. Diagnostic specificity:84.2%

INTERFERENCES

Hemoglobin (10g/L), bilirubin (20mg/dL), lipemia (10g/L), and rheumatoid factors (1000IU/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 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

- Jacobs L.ADV Parasitol 1973;11;631-669.
- Feldman HA .Hosp .Paracitice 1969;4:64-72
- Ruoss CF at al .The Journal of Obsterics and Gynecology of the British Commonwealth 1972 ;79:1115-1118

- Lunde MN at al.The Journal of Paracytology 1967; 53(5) :933-936.
- Kwantes W at al Journal of Clinical Pathology 1772;25:359.
- Young DS Effects of drugs on clinical laboratory test 4th ed. AACC Press, 1995.

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry
CONTROL +	Positive control	CONTROL -	Negative control