TOXO LATEX KIT

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

IVD *For In-Vitro and professional use only*
Store at 2- 8°C

INTENDED USE

TOXO Latex kit is intended to be used to measure the anti-Toxoplasma antibodies in serum for qualitative and semi-quantitative detection.

INTRODUCTION

Toxoplasmosis is an infectious disease affecting both animals and humans, which is caused by the protozoan parasite Toxoplasma gondii.

PRINCIPLE OF THE TEST

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.

REAGENT PREPARATION & STABILITY

- The reagents are stable when stored refrigerated at 2 - 8°C. **DO NOT FREEZE**. A slight sedimentation should be considered normal when stored refrigerated.
- These reagents are stable until the expiry date stated on the product label. Do not use the reagents past the expiration date.
- The reagent should be uniform without visible clumping once shaken.
- Avoid using the latex reagents and controls if contamination occurred.
- The vials must always be in an upright position. If changes of position occurred, gently mix to dissolve aggregates that may present.
- Presence of particles and turbidity will result in reagents deterioration.

SPECIMEN COLLECTION & HANDLING

- Use fresh serum collected by centrifuging clotted blood.
- Stable for 2 days at 2-8^{0}C or up to 3 months at -20^{0}C.
- Avoid using highly hemolysed for testing.
- Turbid samples should be clarified.

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 (Red cap) Animal serum with an antibody (anti-toxoplasma concentration >4 IU/mL).
- TOXO Negative Control (Blue cap) Animal serum.
- Glass Reaction Slide.
- Stirring Sticks.

MATERIALS NEEDED BUT NOT PROVIDED

- Mechanical rotator with adjustable speed at 80-100 r.p.m.
- Vortex mixer.
- Serological pipette.

PROCEDURES

A.QUALITATIVE TEST

1. Bring the reagents and samples to reach to room temperature.
2. Using a serological pipette apply 40uL of undiluted serum samples and one drop of each Positive and Negative controls to slide.
3. Shake the vial well and add one drop (20uL) 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.

CALCULATIONS

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

4 x anti-TOXO Titer= IU/mL

READING & INTERPRETATION OF RESULTS

Observe macroscopically the presence of any visible agglutination latex particles. Visible agglutination of latex particles indicates an antibody concentration equal or more than 4 IU/ml.
The titer, in semi-quantitative method, is defined as the highest dilution showing a positive result.

REFERENCE VALUES

Up to 4 IU/mL
Each laboratory should establish its own reference range.

STABILITY OF THE REACTIONS

The results should be read immediately after removing the slide from the rotator. Delay may cause the possibility of misinterpreting the results in positive or falsely negative due to drying reagents.

PROCEDURES LIMITATION

1. False positive results may be obtained with hepatocellular diseases.
2. A 25% of serum containing heterophile antibodies may give false Positive results.
3. All positive sera should be tested with a confirmatory test.
4. Clinical diagnosis should be based on both clinical and laboratory data and not only based on findings of a single test result.

Limitations of The Procedure Sources of Error
Heavily lipaemic sera and plasma must be excluded since they can cause non-specific reactions.

QUALITY CONTROL

Positive and Negative Control are recommended to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation.

PERFORMANCE CHARACTERISTICS

ANALYTICAL SENSITIVITY:
4(3-7) IU/mL, under the described assay conditions.

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.

SENSITIVITY
100%.

SPECIFICITY
84.2%

INTERFERENCES
None Interfering Substances:

- Hemoglobin (10 g/L)
- Bilirubin (20 mg/dL)
- Lipemia (10 g/L)
- Rheumatoid factors (1000 IU/mL)

Other substances may interfere.

PRECAUTIONS & WARNNINGS

- The reagents are intended for in vitro diagnostic use only
- All reagents contain 0.1% (w/v) sodium azide as a preservative.
- **The reagents which contain sodium azide which are toxic and can be absorbed through the skin. When drained, flush with a large volume of water to prevent azide build up.**
- Make sure to wear protective clothing when handling the reagents, such as disposable gloves and a laboratory coat.
- When the testing is completed, wash hands and clean the test table top with water and soap.
- Materials used to produce the kit were prepared using human

serum found to be negative for hepatitis B surface antigen (HBsAg), HCV and antibody HIV (1/2) by FDA required test. Care must be taken in the use and disposal of each vial and its contents as it is potentially infectious.

- Use provided dropper and hold perpendicularly when dispensing as the drop size of the latex reagent (40µl) will determine the accuracy of the test.
- For each use, make sure to rinse the slide test thoroughly with water and wiped with lint-free tissue.
- Discard properly the test materials and samples in a biohazard container.
- Use provided controls to check reactivity of the reagent.

REFERENCES

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