

# TOXOPLASMOSIS LATEX TEST KIT

Catalogue number	Product Description
TOX/010	50 Test Kit
TOX/012	100 Test Kit

## INTENDED USE

The Plasmatec Toxoplasmosis Latex Test kit is for the detection of antibodies to *Toxoplasma gondii* in serum or plasma by slide agglutination.

Toxoplasma is an infectious disease affecting various mammalian species including man. Infection is caused by the protozoan parasite *Toxoplasma Gondii*. Infection is usually acquired by ingesting inadequately cooked meat or from faeces of infected cats.

The acquired disease is usually mild and not diagnosed. In pregnant women patients can transmit the infection across the placenta to the foetus causing congenital Toxoplasmosis. Disease manifestations depend on the stage of foetal development; although the foetus is less likely to be infected early in pregnancy, the effects on those infected are more severe during the first trimester of pregnancy. The consequences of congenital toxoplasmosis range from spontaneous abortion and prematurity to neurological congenital abnormalities. Some infants may be asymptomatic at birth and develop disease during childhood or adolescence (chorioretinitis).

## WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use only

For professional use only

### Health and Safety warnings:

All patient samples and reagents should be treated as potentially infectious and the user must wear protective gloves, eye protection and laboratory coats when performing the test.

Non disposable apparatus must be sterilised after use by an appropriate method.

Disposable apparatus must be treated as biohazardous waste and autoclaved or incinerated.

Spillages of potentially infectious material should be absorbed and disposed of as above. The site of spillage must be sterilised with disinfectant or 70% alcohol.

Do not pipette by mouth.

The Reagents contain less than 0.1% sodium azide as a preservative. Avoid ingestion and contact with skin or mucus membrane.

Each donor used in the preparation of the materials of this kit was tested by a FDA approved method for the presence of HIV antibodies and Hepatitis B antigen and found to be negative. However normal laboratory precautions should be maintained while handling the test reagents.

### Analytical precautions:

Do not modify the test procedure.

Do not dilute or modify the reagents in any way.

Allow all reagents and samples to reach room temperature (18 to 30°C) before use.

Do not interchange reagents from different kit batches.

## COMPOSITION

### Kit contents:

??Latex reagent sufficient for 50/100 tests (Yellow label).

The latex reagent should be well shaken to ensure homogeneity.

??Positive control. (Red label) This reagent is ready for use and will give a positive result when tested with Plasmatec Toxoplasmosis latex

??Negative control. (Blue label) This reagent is ready for use and will give a negative result when tested with Plasmatec Toxoplasmosis latex

??Pipette/ Stirrers/ agglutination slides.

??Pack insert.

### STORAGE AND SHELF LIFE

Store reagents, upright at 2-8°C. The components of the kit, when stored at 2 – 8 °C, will remain stable until the expiration date stated on the label. DO NOT FREEZE THE LATEX REAGENT

Do not use reagents after the stated expiry date.

Discard reagents if they become contaminated or do not demonstrate the correct activity with controls.

### MATERIALS AND EQUIPMENT REQUIRED BUT NOT PROVIDED.

Saline (0.9% NaCl)

Pipettes

### SPECIMEN AND SAMPLE PREPARATION

Use fresh serum obtained by centrifugation of clotted blood. The samples may be stored for up to 48 hours. If storage is required for longer samples may be frozen.

Discard contaminated or haemolysed sera.

### PROCEDURE

#### Principle:

The Toxoplasmosis latex reagent is a suspension of polystyrene particles sensitised with *Toxoplasma gondii* antigens. When serum or plasma from an infected individual is mixed with the latex particles a distinct agglutination pattern is observed as a result of the formation of antigen-antibody complexes. In the absence of infection no agglutination will be observed. A positive result indicates a level of infection greater than 4 IU/ml

#### Method:

1. Bring reagents and serum samples to room temperature.
2. Dilute samples 1/2 - 1/8 in physiological saline (0.9% NaCl).
3. Place one drop of diluted serum onto a slide black area.
4. Mix the Latex reagent well and add one drop over each serum drop.
5. Mix both drops with the aid of a stirrer and tilt the slide.
6. Observe the presence or absence of agglutination within a period no longer than 3 minutes.
7. When all results are positive (clear agglutination), prepare serial two-fold dilutions in physiological saline from dilution 1/16, 1/32, 1/64... and repeat steps 3-6. The titre is the highest dilution with a clear agglutination.

**Normal levels in adults less than 4 IU/ml**

**RESULTS**

A clear **Positive** reaction indicates the presence of toxoplasma antibodies

A **Negative** reaction indicates the absence of toxoplasma antibodies.

**INTERPRETATION OF RESULTS**

The presence of toxoplasma antibodies reflects either a past infection or an evolving infection. In these cases the final titre should be determined.

**REACTION OF SERUM WITH 2-MERCAPTOETHANOL**

Negative sera and positive IgG are not affected in its reactivity pattern. Titers of positive IgM sera are, at least, 2 dilutions lower after treatment.

**PROCEDURE**

1. Mix 0.2 ml of serum with 0.2 ml of 2-Mercaptoethanol 70 mM.
2. Incubate 1 hour at 37°C.
3. After letting cool, test the treated sample as usual.

The serum treated titer is two-fold the test titer because of the serum dilution in the treatment.

**LIMITATIONS OF THE METHOD**

Lipemic and highly haemolised sera, as well as plasma, interfere with the assay.

**REFERENCES**

1. Jacob, L. Adv. Parasitol. (1973). 11, 631-669.
2. Desmonts, G. Couvreur, J. Bull. N.Y. Acad. Med. (1974). 50, 146-159.
3. Desmonts, G. Fauletts de Biologie, (1975). 16, 61.

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