

137 mm x 218 mm



## SLIDE TEST FOR ANTIBODIES TO TOXOPLASMA GONDII

### SUMMARY

Toxoplasmosis is an infectious disease caused by the parasite *Toxoplasma Gondii* and affects both animals and humans. In humans this infection is usually acquired by ingesting inadequately cooked meat or from feces of infected cats. Approximately 25-50% of the adult population are asymptotically affected with Toxoplasmosis. Acquired Toxoplasmosis is usually asymptomatic and benign. In pregnant women however, the infection acquires a special significance as the parasite may enter the fetal circulation through placenta and cause congenital Toxoplasmosis. The consequences of congenital Toxoplasmosis range from spontaneous abortion and prematurity to generalised and neurological symptoms. Some infants with congenital Toxoplasmosis may also remain asymptomatic at birth and develop the disease during childhood or adolescence.

### REAGENTS

1. **TOXOGEN**® latex reagent: A uniform suspension of polystyrene latex particles coated with *Toxoplasma gondii* soluble antigens.
2. Positive control, reactive with the **TOXOGEN**® latex reagent.
3. Negative control, non reactive with the **TOXOGEN**® latex reagent.

**TOXOGEN**® latex reagent is standardised to detect 4 IU/ml or more of *Toxoplasma* antibodies. **TOXOGEN**® latex reagent is standardized against the 3<sup>rd</sup> International standard for anti-*Toxoplasma* (WHO)

Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its specificity, sensitivity and performance.

### ACCESSORIES

Six circle plastic slide, mixing sticks, sample dispensing pipettes, rubber teat.

### REAGENT STORAGE AND STABILITY

1. Store the reagents at 2-8°C. DO NOT FREEZE. 2. The shelf life of the reagent is as per the expiry date mentioned on the reagent vial label.

### PRINCIPLE

Latex particles coated with *Toxoplasma gondii* antigens will agglutinate when mixed with serum containing antibodies to *Toxoplasma gondii*. Agglutination is absent when antibodies to *Toxoplasma gondii* are absent.

### NOTE

1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. All the reagents derived from human source have been tested for HBsAg and antibody to HIV and HCV and found to be nonreactive. However handle the material as if infectious.
3. Reagent contains 0.09% Sodium Azide as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
4. Shake the latex/ reagent vial gently before use to disperse the latex particles uniformly and improve the test readability.
5. Recap the reagent vials immediately after performing the test.
6. Use only a clean and dry slide.
7. Accessories provided with the kit only must be used for optimum results.

### SAMPLE COLLECTION AND STORAGE

No special preparation of the patient is required prior to sample collection by approved techniques. Fresh serum should be used for testing. In case of delay in testing, store the sample at 2-8°C. Samples can be stored for upto a week. Do not use hemolysed or lipemic samples.

### ADDITIONAL MATERIAL REQUIRED

Test tubes (10 x 75 mm), Pipettes, Isotonic saline, Stop watch, Direct light source,

### TEST PROCEDURE

Bring reagent and samples to room temperature before use.

#### Qualitative Method

1. Place one drop of serum (test specimen) on the reaction circle of the glass slide using the sample dispensing pipette provided with the kit.
2. Add one drop of well mixed **TOXOGEN**® latex reagent to the drop of serum sample. Do not let the dropper tip touch the liquid on the slide.

3. Using a mixing stick, mix the sample and the latex reagent uniformly over the entire circle.
4. Immediately start a stopwatch. Rock the slide gently, back and forth. Observe for agglutination macroscopically at four minutes.

#### **Semi Quantitative Method**

1. Using isotonic saline, prepare serial dilutions of the serum samples positive in the qualitative method starting from 1:2, 1:4, 1:8 and so on.
2. Pipette each dilution of the serum sample onto separate reaction circles of the slide.
3. Add one drop of well mixed **TOXOGEN**<sup>®</sup> latex reagent to each dilution of the serum sample.
4. Using a mixing stick, mix the sample and the latex reagent uniformly over the entire circle.
5. Immediately, start a stopwatch. Rock the slide gently back and forth. Observe for agglutination macroscopically at four minutes.

#### **INTERPRETATION OF RESULTS**

##### **Qualitative Method:**

Agglutination is a positive test result and indicates presence of detectable levels of antibodies to *Toxoplasma gondii*.

No agglutination is a negative test result and indicates absence of detectable levels of antibodies to *Toxoplasma gondii*.

##### **Semi Qualitative Method**

The highest dilution of serum showing agglutination corresponds to the approximate concentration of antibodies to *Toxoplasma gondii*.

The concentration of *Toxoplasma gondii* antibodies can be calculated as follows:

Concentration of *Toxoplasma gondii* antibodies (IU/ml) = S X D,

Where, S = Sensitivity of the reagent i.e. 4 IU/ml.

D = Highest dilution of the serum showing agglutination.

#### **REFERENCE VALUE**

The reference value of *Toxoplasma gondii* antibodies in normal population is < 4 IU/ml.

Each laboratory should determine its own reference range for the relevant population.

#### **REMARKS**

1. Markedly lipemic, haemolysed and contaminated serum samples could give rise to non-specific results.
2. Use of plasma rather than serum can lead to false positive results.
3. Positive and negative controls should be run with each series of tests to validate the results.
4. It is recommended that results of the tests should be correlated with clinical findings to arrive at the final diagnosis.

#### **WARRANTY**

This product is designed to perform as described on the label and the package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

#### **BIBLIOGRAPHY**

1. Johnson A.M., The antigenic structure of *Toxoplasma gondii*: A Review Pathology, 1985: 17; 9-19.
2. Ruoss C.F. and Bourne G.L., Toxoplasmosis in Pregnancy, J. Obstet. Gynecol., 1972:79:1115- 1118.
3. Desmonts G. and Couvreur J., Toxoplasmosis in Pregnancy and its transmission to the fetus, Bull. N.Y. Acad. Med., 1974: 50: 146-159.
4. K.D. Pagana and T.J. Pagana, Mosby's Diagnostic and Laboratory Test Reference, 2nd Ed., 1995, Pg. 865.
5. Data on file: Tulip Diagnostics (P) Ltd.

Manufactured by:

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