

SBio Toxoplasmosis Test

Slide Test for screening of *T.gondii* antibodies

REF	90830025
Σ	25 T



Temperature Limitation	Manufacturer	This side up	EC REP Authorised Representative	Xn NaN, R22 S23-46-61
Use by (Last day of stated month)	Consult Instructions for use		CONTROL + Positive control CONTROL - Negative control	Harmful if swallowed. Do not breathe vapour. If swallowed, seek medical advice immediately and show this container or label. Avoid release to the environment. Refer to special instructions.
Date of Manufacture	REF Catalogue Number		REAGENT Description of reagent	
LOT Batch Number	IVD In vitro Diagnostic Medical Device		Σ Contains sufficient for <n> tests	

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.

REAGENT

- SBio Toxoplasmosis Test latex reagent: A uniform suspension of polystyrene latex particles coated with *Toxoplasma gondii* soluble antigens.
- Positive control, reactive with the SBio Toxoplasmosis Test latex reagent.
- Negative control, non reactive with the SBio Toxoplasmosis Test latex reagent.
- 2-Mercaptoethanol : 1:20 diluted (5%) ready to use reducing agent.

SBio Toxoplasmosis Test latex reagent is standardised to detect 10-15 IU/ml or more of *Toxoplasma* antibodies. Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its specificity, sensitivity and performance.

REAGENT STORAGE AND STABILITY

- Store the reagents at 2-8°C. DO NOT FREEZE.
- 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

- In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
- All the reagents derived from human source have been tested for HBsAg and antibody to HIV and found to be non-reactive. However handle the material as if infectious.
- Reagent contains 0.1% Sodium Azide as preservative. Avoid

contact with skin and mucosa. On disposal flush with large quantities of water.

- Shake the latex/ reagent vial gently before use to disperse the latex particles uniformly and improve the test readability.
- Recap the reagent vials immediately after performing the test.
- Use only a clean and dry slide. Clean the slide with distilled water and wipe dry before use.
- Accessories provided with the kit only must be used for optimum results.
- The positive control is pre-diluted and ready to use.

SPECIMEN 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 for upto 48 hours.

MATERIAL PROVIDED WITH THE KIT

Reagent

Toxoplasma gondii latex reagent, Positive control, Negative control.

Accessories

Slide with six reaction circles, Mixing sticks, Rubber teats, Sample dispensing pipettes.

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. Dilute sample to be tested 1:16 with 0.9% saline. (0.1 ml of serum + 1.5 ml of 0.9% saline).

Qualitative Method

- Place one drop of diluted serum on the reaction circle of the slide using a disposable pipette provided with the kit.
- Add one drop of well mixed latex reagent to the drop of diluted serum sample.
- Using a mixing stick, mix the sample and the latex reagent uniformly over the entire circle.
- Immediately start a stopwatch. Rock the slide gently, back and forth. Observe for agglutination macroscopically at five minutes.

Semi Quantitative Method

- Using isotonic saline, prepare serial dilutions of the serum samples positive in the qualitative method starting from 1:32, 1:64, 1:128, 1:256 and so on.
- Pipette each dilution of the serum sample onto separate reaction circles of the slide.

3. Add one drop of well mixed 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 five minutes.

INTERPRETATION OF RESULTS

Qualitative Method:

Agglutination is a positive test result and indicates presence of diagnostically significant level of antibodies to *Toxoplasma gondii*. No agglutination is a negative test result and indicates absence of diagnostically significant level of antibodies to *Toxoplasma gondii*.

Semi Quantitative Method

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

DIFFERENTIATION IgG-IgM

By previous treatment of the sera with reducing agents, such as 2-mercaptoethanol, it is possible to observe the type of immunoglobulins responsible for the reaction.

Add 50 µl of the 2-mercaptoethanol solution to 1 ml of 1:16 diluted serum under test. Incubate for 60 minutes at 37°C.

At the end of the incubation period, proceed using the semi quantitative test procedure as outlined above.

If there is a significant decrease in the reactivity and/or drop in the antibody titre after 2-Mercaptoethanol treatment, it can be considered IgM positive.

SIGNIFICANCE OF TEST RESULTS

- a) Serum samples that test negative in 1:16 dilution indicate absence of diagnostically significant anti toxoplasma titre.
- b) Serum samples positive at 1:16 dilution indicate residual titre due to past exposure.

- c) Positive titres from 1:32-1:128 dilution should be suspect of incipient Toxoplasmosis. Evolution of titre 3 weeks later should be determined. Increase of atleast two dilutions should be considered indicative of acute Toxoplasmosis.
- d) Titre of 1:256 or more suggest possible active infection.
- e) Determination of IgM antibodies is also advisable in (c) and (d) cases.

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.

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