

In vitro Diagnostics

INTENDED USE

Sensit Toxoplasma IgG/IgM Antibody Rapid Test Kit is a qualitative Immunochromatographic assay for rapid detection of Anti-Toxo IgG and Anti-Toxo IgM antibodies in human whole blood, serum or plasma. Sensit Toxoplasma IgG/IgM Antibody Rapid Test is only intended for initial screening and reactive samples should be confirmed by a supplemental assay such as ELISA.

SUMMARY & TEST DESCRIPTION

Toxoplasmosis is an infection caused by the *Toxoplasma gondii* (*T. gondii*) parasite. It is one of the most common parasitic diseases and is known to affect nearly all warm-blooded animals and humans. Humans are infected by ingestion of food or water contaminated with cat feces or through eating uncooked meat containing viable oocysts and by transmission from mother to fetus. Cats are the primary source of infection to human hosts, although contact with raw meat, especially lamb, is a more significant source of human infections in some countries. Fecal contamination of hands is a significant risk factor.

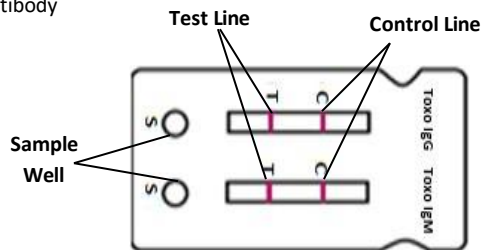
Sensit Toxoplasma IgG/IgM Antibody Rapid Test captures the antibody developed during the infection. The captured antibody is detected using colloidal gold conjugate.

TEST PRINCIPLE

Sensit Toxoplasma IgG/IgM Antibody Rapid Test works on chromatographic immunoassay. Basic components of test strip include: a) Conjugate pad, which contains detection molecule, colloidal gold conjugated; b) a nitrocellulose membrane strip containing 2 panels.

Toxo IgG Panel; T: Toxoplasma IgG Antigen and C: Goat Anti-Mouse Antibody

Toxo IgM Panel; T: Toxoplasma IgM Antigen and C: Goat Anti-Mouse Antibody



Test sample that is added to the sample well, with adequate amount of buffer migrates from the sample pad along the conjugate pad, where any antibody present in the sample will bind to the colloidal gold conjugate. The sample then continues to migrate across the membrane until it reaches the capture zone, where the conjugate complex will bind to the respective immobilized toxoplasma antigen (on test line) producing a visible line on the membrane. If the respective antibody is not present in the sample, no reaction occurs in the capture zone and no test line is formed. The sample then migrates further along the strip until it reaches the control zone, where it produces another visible line on the membrane. This control line indicates that the sample has migrated across the membrane as intended.

REAGENTS & MATERIALS PROVIDED

1. Each sealed in a foil pouch containing following items:
 - a. One test card
 - b. dropper
 - c. Desiccant
2. Assay Diluent - In dropper bottle.
3. Instruction Leaflet.

STORAGE & STABILITY

Store the test kit between 2-30°C until the expiration date indicated on the pouch / carton. DO NOT FREEZE. Ensure that the test device is brought to room temperature before opening.

PRECAUTIONS & WARNING

1. Use within 10 minutes after opening pouch.
2. Do not touch result window.
3. For veterinary use only.
4. Use only the buffer supplied along with the kit.
5. Do not mix components from different kits.
6. The Kit components must not be frozen.

SAMPLE COLLECTION & PREPARATION

Whole Blood:

- Collect the whole blood by venipuncture using a syringe or vacutainer into a container containing anticoagulants such as heparin, EDTA or sodium citrate.

Plasma

- Collect the whole blood by venipuncture using a syringe or vacutainer (containing anticoagulants such as heparin, EDTA or sodium citrate).
- Centrifuge the blood to obtain plasma specimen from the supernatant.

Serum:

- Collect the whole blood by venipuncture using a syringe or vacutainer (NOT containing anticoagulants such as heparin, EDTA or sodium citrate). Leave the syringe or vacutainer, preferably at an angle, to settle for 30 minutes. Once blood coagulates, centrifuge the blood to obtain serum specimen from the supernatant.

Note:

- If the specimen is not used for testing immediately, they should be refrigerated at 2-8°C.
- For storage period longer than 5 days, freezing is recommended. Store at -20°C
- The specimen should be brought to room temperature prior to use.

Treat the specimen as infectious and handle with standard biosafety measure.

TEST PROCEDURE

1. Take out the test card from the foil pouch and place it on a horizontal surface.
2. Add 10µl of the specimen without air bubbles into the sample well using the dropper provided as per diagram 1.

Diagram 1. 10µl sample

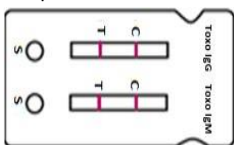


Aspirate to the bubble to obtain a 10µl sample

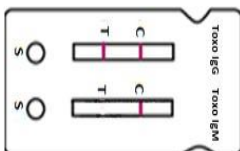
3. When the sample is fully absorbed, add 2 drops of the diluent provided with the assay to the sample well.
4. Wait for 15 minutes and interpret results. The result is considered invalid after 20 minutes. All results where control band does not appear are considered invalid.

INTERPRETATION OF TEST RESULT

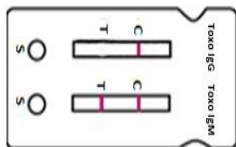
Toxoplasma IgG & IgM Positive: Colour lines at position C and T. Presence of anti-*T. gondii* IgG and IgM in the sample.



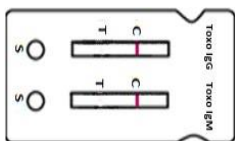
Toxoplasma IgG Positive: Colour lines at position C and T. Presence of anti-*T. gondii* IgG in the sample.



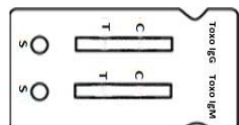
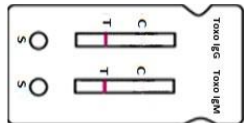
Toxoplasma IgM Positive: Colour lines at position C and T. Presence of anti-*T. gondii* IgM in the sample.



Toxoplasma IgG & IgM Negative: Colour line at position C. Absence of Anti-*T. gondii* in the sample



Invalid: If the control line fails to appear within the result window, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be retested.



Note: IgG positive means that the organism was infected with T.gondii at most 1 year ago. IgM positive means that the organism was infected with T.gondii at most 4 months ago. Both IgG and IgM positive means that the infection is between 2 weeks and 4 months old, and that the infection may be acute

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in Toxoplasma IgG/IgM Antibody Rapid Test for single-step detection of Toxoplasma IgG/IgM antibodies are the most common signs appearing on medical devices and their packaging. They are explained in more detail in the European Standards EN 980: 2008 and INTERNATIONAL Standard ISO 15223-1:2016

Key to symbols used			
	Manufacturer		Expiration/use by date
	Do not reuse		Date of manufacture
	Consult IFU [Instructions For Use]		Batch code
	Temperature limitation 2-30°C		In Vitro diagnostic medical device
	Contains sufficient for 'X' kits		Do not use if package is damaged
	Catalogue No		Keep dry

Manufactured by,

ubio Biotechnology Systems Pvt Ltd
 No 15A Biotechnology Zone
 KINFRA Hi-Tech Park, Kalamassery
 Cochin, Kerala, India 683503
 Ph:+91-484-2970043
<http://www.ubio.in>
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