

Toxoplasma IgG/IgM Rapid Test

For detection of *Toxoplasma* antibodies in Human Serum, Plasma or Whole Blood.

IVD In-vitro diagnostic use only



Not reuse

Introduction

Toxoplasmosis is caused by infection with *Toxoplasma gondii*, an eucaryotic Pathogen - belongs to the group of sporozoites. The obligatory intracellular living parasite is spread worldwide. Typical for sporocytes is the "flip-flop" between sexual (which only takes place in cats, the final host) and asexual reproduction. The Infection is often highest in areas of the world that have hot, humid climates and lower altitudes. The main source of infection is direct contact with cat feces or from eating undercooked meats. Toxoplasmosis is not passed from person-to-person, except in instances of mother-to-child (congenital) transmission and blood transfusion or organ transplantation. Toxoplasmosis generally presents with mild symptoms in immunocompetent individuals, but women newly infected with *Toxoplasma* during pregnancy and anyone with a compromised immune system should be aware that toxoplasmosis can have severe consequences for them. Acute toxoplasmosis in pregnant women can result in miscarriage, poor growth, early delivery or stillbirth. IgG and IgM antibodies to *Toxoplasma* can be detected with 2-3 weeks after exposure. IgG remains positive, but the antibody level drops overtime.

Intended Use

Toxoplasma IgG/IgM Rapid test is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to *Toxoplasma gondii* in human serum or plasma. This test provides only a preliminary test result. Therefore, more specific alternative diagnosis method such as Sabin-Feldman dye test for IgG antibodies, the IgM-IFA (Immuno-fluorescent Antibody) test and the PCR test must be used in order to obtain a confirmation of *Toxoplasma* infection.

Principle

Toxoplasma IgG/IgM test device has 3 pre-coated lines, "G" (*Toxoplasma* IgG Test Line), "M" (*Toxoplasma* IgM Test Line) and "C" (Control Line) on the surface of the membrane. All three lines in result window are not visible before applying any samples. The "Control Line" is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working. A purple "G" and "M" lines will be visible in the result window if there are enough IgG and/or IgM antibodies to *Toxoplasma* in the sample. If IgG and/or IgM antibodies to *Toxoplasma* are not present in the sample, there is no color appearance in "G" and/or "M".

Materials Included and Active Ingredients

- 1) Toxo IgG/IgM test kit contains the following items to perform the assay.
 - Toxo IgG/IgM test device foil pouched with a desiccant
 - Disposable dropper capable of delivering 15 µL sample volume (may not be provided)
 - Assay diluents
 - Instruction for use
- 2) Active ingredients of main components of one Toxo IgG/IgM test strips
 - Gold Conjugates (as main component): Recombinant *Toxoplasma* antigen – gold colloid (1.5 ± 0.2 µg),
 - Test Line "M" (as main component): Mouse monoclonal anti-human IgM (4 ± 0.8 µg),
 - Test Line "G" (as main component): Mouse monoclonal anti-human IgG (4 ± 0.8 µg),
- 3) Control Line (as main component): Goat anti- mouse IgG (8 ± 0.4 µg)

Kit Precautions and Storage Instructions

- 1) For best results, adhere to instructions provided
- 2) All specimens should be handled as potentially infectious

- 3) The test device should be stored at room temperature
- 4) The test device is sensitive to humidity as well as heat
- 5) Do not use beyond expiration date
- 6) Do not use test kit if pouch is damaged or seal is broken
- 7) Use test device immediately after removing from the pouch
- 8) The components (test device and assay diluents) in this kit have been quality control tested as a standard batch unit. Do not mix components from different lot numbers.
- 9) Store kit at room temperature (2 -30 °C). Do not expose the kit to temperature over 30 °C.

Warnings

- 1) For in vitro diagnostic use only. DO NOT RE-USE test device
- 2) The instructions must be followed to obtain accurate results. Anyone performing an assay with this product must be trained in its use and laboratory procedures.
- 3) Do not eat or smoke while handling specimens
- 4) Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
- 5) Avoid splashing or aerosol formation
- 6) Clean up spills thoroughly using an appropriate disinfectant
- 7) Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
- 8) Do not mix with other specimens.

Specimen Collection, Storage and Precautions

- 1) Serum (S): Collect the whole blood into a collection tube (NOT containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant .
- 2) Plasma (P): Collect the whole blood into a collection tube (containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.
- 3) Whole Blood (WB): Collect the whole blood by lancing devices. WB can be delivered by pipette directly to the test card.
- 4) If serum or plasma specimens are not tested immediately, they should be refrigerated at 2-8°C. For storage periods longer than 2 weeks, freezing is recommended. They should be brought to room temperature (1-30°C) prior to use.
- 5) Serum or plasma specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.
- 6) Anticoagulants such as heparin, EDTA and sodium citrate do not affect the test results.
- 7) Use separately disposable capillary pipettes or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause erroneous results.
- 8) As known relevant interference, hemolytic samples, rheumatoid factors-contained samples and lipaemic, icteric samples can lead to impair the test results.

Test Procedure (Refer to Figure)

- 1) Allow all test components and specimen to come to room temperature prior to testing
- 2) Remove the test device from the foil pouch, and place it on a flat, dry surface
- 3) With a micropipette (not provided) or a disposable dropper, add about 10 µL of serum/ plasma or whole blood specimen into the sample well marked "S"; **Allow about 30 seconds for the specimen to be absorbed totally.**
- 4) Add 3 drop of diluents buffer to the sample well.
- 5) As the test begins to work, you will see red color move across the result window in the center of the test device.
- 6) Interpret test results at 15-20 minutes. Caution: Do not read test results after 20 minutes. Reading too late can give false results.

Interpretation of Test Results (Refer to Figure)

Interpretation of the test (Refer to figure)

Negative

The control line is only visible on the test device. No IgG and IgM antibodies were detected.

IgM Positive

The control line (C) and IgM line (M) are visible on the test device. This is positive for IgM antibodies to Toxoplasma.

IgG Positive

The control line (C) and IgG line (G) are visible on the test device. This is positive for IgG antibodies to Toxoplasma.

IgG and IgM Positive

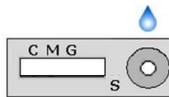
The control line (C), IgM (M) and IgG line (G) are visible on the test device. This is positive for both IgM and IgG antibodies to Toxoplasma.

Invalid

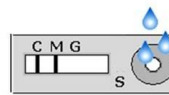
The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Repeat the test using a new test device.

Toxo IgG/IgM Test Procedure

Using micropipette, add 10 µl of serum, plasma or whole blood specimen in the sample well "S"



Put 2 or 3 drops (~80 µl) of assay diluents into the sample well marked as "S"



Interpret test results in 15-20 minutes.

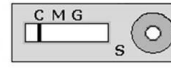


Do not read the results after 20 minutes
Reading too late can give false results.

Interpretation

Negative

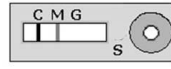
One pink line "C" in result window



Positive

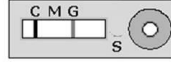
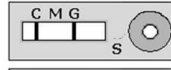
1. IgM positive

Two pink lines "C" and "M" in result window. It is positive even if "M" line is weak.



2. IgG positive

Two pink lines "C" and "G" in result window. It is positive even if "G" line is weak.



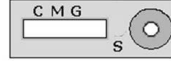
3. IgG and IgM positive

Three pink lines "C", "M", "G" in result window. It is positive even if "G" line is weak.



Invalid

-No control (C) line in result window.
-It is recommended that the specimen be re-tested.



Limitations of the Test

- 1) This test detects the presence of IgG and antibodies to Toxoplasma gondii in the specimen and should not be used as the sole criterion for the diagnosis of Toxoplasma infection.
- 2) As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
- 3) A negative result can occur if the quantity of IgG and IgM antibodies to Toxoplasma gondii present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.

Internal Quality Control

The "Control Line" is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required

Suggested Reading List

- 1) Diagnosis of congenital toxoplasmosis: prenatal and neonatal evaluation of methods used in Toulouse University Hospital and incidence of congenital toxoplasmosis. Bessières MH, Berrebi A, Cassaing S, Fillaux J, Cambus JP, Berry A, Assouline C, Ayoubi JM, Magnaval JF.
- 2) Dynamic Imaging of CD8(+) T cells and dendritic cells during infection with Toxoplasma gondii. John B, Harris TH, Tait ED, Wilson EH, Gregg B, Ng LG, Mrass P, Roos DS, Dzierszynski F, Weninger W, Hunter CA.
- 3) Congenital toxoplasmosis: evaluation of serological methods for the detection of anti-Toxoplasma gondii IgM and IgA antibodies. Rodrigues IM, Castro AM, Gomes MB, Amaral WN, Avelino MM. Mem Inst Oswaldo Cruz. 2009 May;104(3):434-40.
- 4) Seroprevalence of Toxoplasma gondii infection and characteristics of seropositive patients in general hospitals in Daejeon, Korea. Shin DW, Cha DY, Hua QJ, Cha GH, Lee YH. Korean J Parasitol. 2009 Jun;47(2):125-30. Epub 2009 May 27

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