Toxo IgG/IgM Rapid Test - Cassette (Serum / Plasma)

OnSite

REF

Catalog Number R0233C

IVD

In vitro Diagnostic

INTENDED USE

The *OnSite* Toxo IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay for the simultaneous detection and differentiation of IgG and IgM anti-*Toxoplasma gondii* (*T. gondii*) in human serum or plasma. This kit is intended to be used as a screening test and as an aid in the diagnosis of infection with *T. gondii*. Any reactive specimen with the *OnSite* Toxo IgG/IgM Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

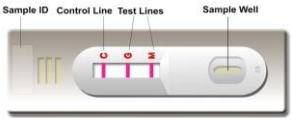
SUMMARY AND EXPLANATION OF THE TEST

T. gondii is an obligate intracellular protozoan parasite with a worldwide distribution[1,2]. Serological data indicates that approximately 30% of the population of most industrialized nations is chronically infected with the organism[3].

A variety of serological tests for antibodies to *T. gondii* have been used as an aid in diagnosis of acute infection and to assess previous exposure to the organism. These tests are: the Sabin-Feldman dye test, direct agglutination, indirect hemagglutination, latex agglutination, indirect immunofluorescence and ELISA[4-7]. Recently, lateral flow chromatographic immunoassay such as the *OnSite* Toxo IgG/IgM Rapid Test has been introduced to the clinic for the instant detection of *T. gondii* infection.

TEST PRINCIPLE

The *OnSite* Toxo IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant *T. gondii* antigens conjugated with colloidal gold (*T. gondii* conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing two test bands (M and G bands) and a control band (C band). The M band is pre-coated with monoclonal anti-human IgM for detection of IgM anti-*T. gondii* antibody, G band is pre-coated with reagents for detection of IgG anti-*T.gondii* antibody, and the C band is pre-coated with goat anti-rabbit IgG.



When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. IgM anti-*T. gondii* if present in the specimen will bind to the *T. gondii* conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM antibody forming a burgundy colored M line, indicating a *T. gondii* IgM positive or reactive test result.

IgG anti-*T. gondii* if present in the specimen will bind to the *T. gondii* conjugates. The immunocomplex is then captured by the pre-coated reagents on the membrane forming a burgundy colored G line, indicating a *T. gondii* IgG positive or reactive test result.

Absence of any T lines (M and G) suggests a negative or non-reactive result. The test contains an internal control (C band) which should exhibit a burgundy colored line of the immunocomplex of goat anti-rabbit IgG/rabbit IgG-gold conjugate regardless of color development on any of the T lines. Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

1. Individually sealed foil pouches containing:
   a. One cassette device
   b. One desiccant
2. Plastic droppers
3. Sample diluent (1 bottle, 5 mL)
4. One package insert (instruction for use)

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

1. Positive Control
2. Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer

WARNINGS AND PRECAUTIONS

For *in Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15°C-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolized blood for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
11. Handle the negative and positive control in the same manner as patient specimens.
12. The test results should be read within 15 minutes after a specimen is applied to the sample well or sample pad of the device. Reading the results after 15 minutes may give erroneous results.
13. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2°C-30°C. Do not freeze the kit. Do not expose the kit over 30°C. The positive and negative controls should be kept at 2°C-8°C or the temperature indicated. If stored at 2°C-8°C, ensure that the test device is brought to 15°C-30°C before opening. The test device is stable through the expiration date printed on the sealed pouch.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

Plasma

1. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by veinpuncture.
2. Separate the plasma by centrifugation.
3. Carefully withdraw the plasma into new pre-labeled tube.

Serum

1. Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by veinpuncture.
2. Allow the blood to clot.
3. Separate the serum by centrifugation.
4. Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2°C-8°C if not tested immediately.

Store specimens at 2°C-8°C for up to 5 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well, prior to assay, once thawed.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3: Be sure to label the device with the specimen's ID number.

Step 4: Fill the plastic dropper with the specimen.

Holding the dropper vertically, dispense 1 drop (about 30-45 µL) of specimen into the sample well.

Then add 1 drop (about 30-45 µL) of Sample Diluent immediately.

Step 5: Set up timer.

Step 6: Results can be read in 15 minutes. Positive results can be visible in as short as 1 minute.

Don't read result after 15 minutes. To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

1. **Internal Control:** This test contains a built-in control feature, the C line. The C line develops after adding the specimen and the sample diluent. If the C line does not develop, review the whole procedure and repeat the test with a new device.
2. **External Control:** Good Laboratory Practice recommends using external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
   a. New operator uses the kit, prior to performing the testing of specimens.
   b. A new lot of test kits is used.
   c. A new shipment of kits is used.
   d. The temperature used during storage of the kits fall outside of 2-30°C.
   e. The temperature of the test area falls outside of 15-30°C.
   f. To verify a higher than expected frequency of positive or negative results.
   g. To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

1. **NEGATIVE RESULT:** If only the C line is present, the absence of any burgundy color in both the test lines (M and G) indicates that no anti-*T. gondii* antibodies are detected in the specimen. The result is negative or non-reactive

2. **POSITIVE RESULT:**

2.1 In addition to the presence of the C line, if only the M line is developed, the test indicates the presence of IgM anti-*T. gondii* in the specimen. The result is positive or reactive.

2.2 In addition to the presence of the C line, if only the G line is developed, the test indicates the presence of IgG anti-*T. gondii* in the specimen. The result is positive or reactive.

2.3 In addition to the presence of the C line, if both the M and the G lines are developed, the test indicates the presence of both IgG and IgM anti-*T. gondii* in the specimen. The result is also positive or reactive.

Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

3. **INVALID:** If no C line is developed, the assay is invalid regardless of any burgundy color in the test bands as indicated below. Repeat the assay with a new device.

PERFORMANCE CHARACTERISTICS

1. **Clinical Performance For IgM Test**

A total of 302 samples from susceptible subjects were tested by the *OnSite* Toxo IgG/IgM Rapid Test and by a commercial IgM EIA kit. Comparison of the results for all subjects is shown in the following table.

	OnSite Toxo IgG/IgM Rapid Test		
IgM EIA	**Positive**	**Negative**	**Total**
Positive	2	0	2
Negative	2	298	300
Total	4	298	302

Relative Sensitivity: 100% , Relative Specificity: 99.3%, Overall Agreement: 99.3%

2. **Clinical Performance For IgG Test**

A total of 324 samples from susceptible subjects were tested by the *OnSite* Toxo IgG/IgM Rapid Test and by a commercial IgG EIA kit. Comparison of the results for all subjects is shown in the following table.

	OnSite Toxo IgG/IgM Rapid Test		
IgG EIA	**Positive**	**Negative**	**Total**
Positive	22	2	24
Negative	3	297	300
Total	25	299	324

Relative Sensitivity: 91.6% , Relative Specificity: 99.0%, Overall Agreement: 98.5%

LIMITATIONS OF TEST

1. The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of antibodies to *T. gondii* in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The *OnSite* Toxo IgG/IgM Rapid Test is limited to the qualitative detection of antibodies to *T. gondii* in human serum or plasma. The intensity of the test line does not have a linear correlation with the antibody titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable anti-*T. gondii* antibodies. However, a negative test result does not preclude the possibility of exposure to or infection with *T. gondii*.
4. A negative result can occur if the quantity of the anti-*T. gondii* antibodies 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.
5. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor may affect expected results.
6. If the symptoms persist when the result from *OnSite* Toxo IgG/IgM Rapid Test is negative or non-reactive, it is recommended to re-sample the patient a few days later or test with an alternative test device.
7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

REFERENCES

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3. Wilson CB, Remington JS, Stagno S, and Reynolds DW: Development of adverse sequelae in children born with subclinical congenital Toxoplasma infection. Pediatrics 1980, 66:767-774
4. Berrebi A; Kobuch WE; Bessieres MH; Bloom MC; Rolland M; Sarramon MF; Roques C; Fournie A: Termination of pregnancy for maternal toxoplasmosis. Lancet 1994, 344: 36-9
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6. Pyndiah N, Krech U, Price P and Wilhelm J: Simplified chromatographic separation of immunoglobulin M from G and its application to Toxoplasma indirect immunofluorescence. J. Clin. Micro.1979, 9:170-174
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Index of Symbols

	Consult instructions for use	IVD	For *in vitro* diagnostic use only		Use by
REF	Catalog #	LOT	Lot Number	Σ N	Tests per kit
2°C 30°C	Store between 2-30°C		Do not reuse		
	Manufacturer		Date of manufacture		

Mfd. By: CTK Biotech, Inc. 10110 Mesa Rim Road, San Diego, CA 92121, USA
having factory premises at M/s Beijing Genesee Biotech Inc., #36 Yanqi Donger Road, Huairou Yanqi Industrial Development Zone, Beijing, China, 101407
Tel: 858-457-8698
Fax: 858-535-1739
E-mail: info@ctkbiotech.com

PI-R0233C-ATH Rev. H
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English version

For Export Only, Not For Re-sale In the USA

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