Toxo IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) Package Insert

REF ITM-402	English

A rapid test for the qualitative detection of IgM antibody to Toxoplasma Gondii(T.gondii) in human whole blood, serum or plasma.
For professional in vitro diagnostic use only

【INTENDED USE】

The Toxo IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a lateral flow chromatographic immunoassay for the simultaneous detection and differentiation of IgM anti-Toxoplasma Gondii (T. gondii) in human whole blood, 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 Toxo IgM Rapid Test Cassette must be confirmed with alternative testing method(s) and clinical findings.

【SUMMARY】

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 serologic 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 Toxo IgM Rapid Test Cassette was introduced into the clinic for the serodiagnosis of T. gondii infection.

【PRINCIPLE】

The Toxo IgM Rapid Test Cassette (Whole blood/Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of IgM antibody to Toxoplasma in whole blood, serum or plasma specimens. In this test, mouse anti-human IgM are coated in the test line regions of each section in the test. During testing, the whole blood, serum or plasma specimen reacts with T.gondii antigen coated particles in the test strip. The mixture then migrates upward on the membrane by capillary action and reacts with the mouse anti-human IgM on the membrane in the test line regions of the respective sections. The presence of a colored line in the test line region of a particular section indicates a positive result for the corresponding infection, viz. While its absence indicates a negative result for that infection.

To serve as a procedural control, a colored line will always appear in the control line region of the strip indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test contains mouse anti-human IgM and Toxoplasma T.gondii antigen. A goat anti-mouse IgG is employed in the control line system.

【PRECAUTIONS】

1. For in vitro diagnostic use only. Do not use after the expiration date.
2. Do not smoke, drink, or eat in areas where specimens or kits reagents are handled.
3. Dispose of all specimens and materials used to perform the test as biohazardous waste.
4. This package insert must be read completely before performing the test.
5. Bring all reagents to room temperature (15 °C 30 °C) before use.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- The Toxo IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood.
- Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.
- To collect **Fingerstick Whole Blood specimens**:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. For long term storage, specimens should be kept below -20°C. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly for more than three times.
- If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

【MATERIALS】

Materials provided

- Test cassettes
- Droppers
- Package insert
- Buffer

Materials required but not provided

- Specimen collection contain
- Centrifuge
- Timer

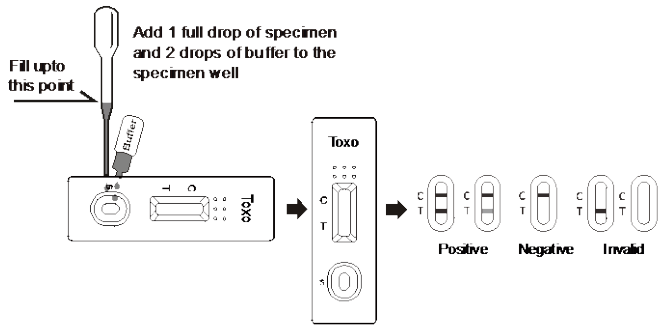
【DIRECTIONS FOR USE】

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

a. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.

b. Place the test cassette on a clean and level surface. Hold the dropper vertically; draw the specimen about **1cm above** the upper end of the nozzle as shown in illustration below. Transfer 1 full drop **(approx. 20μL)** of specimen to each sample well, then add 2 drops of buffer (approximately 80μL) to each sample well and start the timer. See the illustration below.

c. Wait for the colored line(s) to appear. The result should be read at 15 minutes. Do not interpret results after 20 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:* Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the test line region.

***NOTE:** The intensity of the color in the test line regions may vary depending on the concentration of T.gondii IgM antibodies present in the specimen. Therefore, any shade of color in the test line region should be considered positive.

NEGATIVE: **One colored line appears in the control line region (C)**. No line appears in the test line regions.

INVALID: **Control line fails to appear**. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

【LIMITATIONS】

1. The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to T.gondii in whole blood, serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Toxo IgM Rapid Test Cassette is limited to the qualitative detection of the antibody to T.gondii in human whole blood, serum or plasma. The intensity of the test band does not linear correlation with the antibody titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable T. gondii antibody. 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 T. gondii antibody present in the specimen is below the detection limits of the assay, or the antibody that is detected is not present during the stage of disease in which a sample is collected.
5. Some specimens containing unusually high titer of heterophile antibody or rheumatoid factor may affect expected results.
6. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

【EXPECTED VALUES】

The Toxo IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with a leading commercial Toxo IgM ELISA test. The correlation between these two systems is 98.2%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

A clinical evaluation was conducted comparing the results obtained using the Toxo IgM Rapid Test Cassette to Toxo IgM ELISA Testing. The study included 450 IgM specimens, and about the IgM specimen both assays identified 395 negative and 47 positive results.

IgM Results

Method		T.Gondii EIA (IgM)		Total Results
Toxo IgM Rapid Test Cassette	Results	Positive	Negative	
	Positive	47	5	52
	Negative	3	395	398
Total Results		50	400	450

Relative Sensitivity: 94.0% (95%CI*: 83.5%-98.7%) *Confidence Interval
Relative Specificity: 98.8% (95%CI*: 97.1%-99.6%)
Accuracy: 98.2% (95%CI*: 96.5%-99.2%)

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of three specimens: a negative, a low positive, and a high positive. The negative, low positive, and high positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same three specimens: a negative, a low positive, and a high positive. Three different lots of the Toxo IgM Rapid Test cassette (Whole Blood/Serum/Plasma) have been tested over a 10-days period using negative, low positive, and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The Toxo IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested for HBsAg, HBsAb, HbeAg, HBeAb, HBcAb, HCV, HIV, Syphilis, H. Pylori, CMV, HSV1/2 and Rubella positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have also been tested using the Toxo IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) and no interference was observed.

Acetaminophen: 20mg/dl	Caffeine: 20mg/dl	EDTA: 20mg/dl
Acetylsalicylic Acid: 20mg/dl	Gentisic Acid: 20mg/dl	Ethanol: 10%
Ascorbic Acid: 2g/dl	Phenylpropanolamine: 20mg/dl	Glucose: 20mg/dl
Bilirubin: 1000mg/dL	Salicylic Acid: 20mg/dl	Phenothiazine: 20mg/dl

【BIBLIOGRAPHY】

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Index of Symbols

	Attention, see instructions for use		Tests per kit		Do not reuse
IVD	For in vitro diagnostic use only		Use by	REF	Catalog #
2-30°C	Store between 2-30°C	LOT	Lot Number		

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