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

Package Insert

REF ITGM-302	English

A rapid test for the qualitative detection of IgG and IgM antibodies to Toxoplasma Gondii (T.gondii) in human serum or plasma.

For professional in vitro diagnostic use only

INTENDED USE

The Toxo IgG/IgM Rapid Test Cassette is a lateral flow chromatographic immunoassay for the simultaneous detection and differentiation of IgM anti-Toxoplasma Gondii (T. gondii) and IgG anti-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 Toxo IgG/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 IgG/IgM Rapid Test Cassette was introduced into the clinic for the serodiagnosis of T. gondii infection.

PRINCIPLE

The Toxo IgG/IgM Rapid Test Cassette is a lateral flow chromatographic immunoassay. The test consists of: 1) a red colored conjugate containing recombinant T. gondii antigens conjugated with colloid gold (T. gondii conjugates) and mouse IgG-gold conjugates, 2) a nitrocellulose membrane strip containing two test bands (IgG and IgM bands) and a control band (C band). The IgM band is pre-coated with monoclonal anti-human IgM for detection of IgM anti-T. gondii, IgG band is pre-coated with reagents for detection of IgG anti-T. gondii, and the C band is pre-coated with goat anti mouse IgG.

When an adequate volume of test specimen is applied into the sample pad of the test, the specimen migrates by capillary action across the strip. 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 red colored IgM band, indicating a T. gondii IgM positive 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 red colored IgG band, indicating a T. gondii IgG positive test result.

Absence of any T bands (T1 and T2) suggests a negative result. The test contains an internal control (C band) which should exhibit a red colored band of the immunocomplex of goat anti mouse IgG/mouse IgG-gold conjugate regardless of the color development on any of the T bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS

The test contains mouse anti-human IgM, mouse anti-human IgG 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℃-30℃) 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 IgG/IgM Rapid Test Cassette (Serum/Plasma) can be performed using serum or plasma specimen.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.
- 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.
- If specimens are to be shipped, they should be packed in compliance with local regulations for the transportation of etiologic agents.
- EDTA K2, Heparin sodium, Sodium Citrate and, potassium Oxalate can be used as the anticoagulant tube for collecting the blood specimen.

MATERIALS

Materials provided

- Test Cassettes
- Droppers
- Package Insert
- Buffer

Materials required but not provided

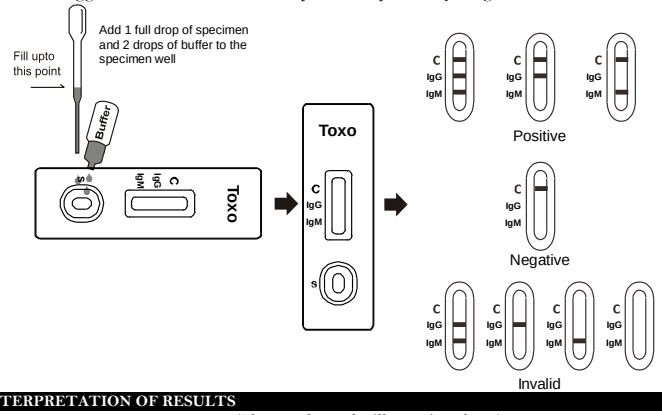
- Specimen collection containers
- Centrifuge
- Timer

DIRECTIONS FOR USE

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

- Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
- 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.
- Wait for the colored line(s) to appear. Read results at **15 minutes**. Do not interpret the result after 20minutes.

Note: It is suggested not to use the buffer, beyond 30 days after opening the vial.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE:* Two or three colored lines appear. One colored line should always appear in the control line region (C) and another one or two apparent colored line(s) should be in the test line region(s) (IgM and/or IgG).

IgM Positive: A colored line appears in control region (C), another colored line appears in IgM region. It indicates a IgM positive test result for antibodies to Toxoplasma.

IgG Positive: A colored line appears in control region (C), another colored line appears in IgG region. It indicates a IgG positive test result for antibodies to Toxoplasma.

***NOTE:** The intensity of the color in the test line regions (IgM and IgG) may vary depending on the concentration of Toxoplasma antibodies present in the specimen. Therefore, any shade of color in the test line region (IgM and/or IgG) should be considered positive.

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

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 serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Toxo IgG/IgM Rapid Test Cassette is limited to the qualitative detection of the antibodies to *T.gondii* in human 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 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 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 titer of heterophile antibodies 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 IgG/IgM Rapid Test Cassette (Serum/Plasma) has been compared with a leading commercial Toxo IgG/IgM ELISA test. The correlation between these two systems is over 98%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

A clinical evaluation was conducted comparing the results obtained using the Toxo IgG/IgM Rapid Test Cassette to Toxo IgG ELISA and Toxo IgM ELISA Testing. The study included 380 IgG specimens and 380 IgM specimens, and about the IgM specimen both assays identified 345 negative and 28 positive results, about the IgG specimen both assays identified 344 negative and 29 positive results.

IgM Results

Method		T.Gondii ELISA(IgM)		Total Results
Toxo Rapid Test Cassette for IgM	Results	Positive	Negative	
	Positive	28	5	33
	Negative	2	345	347
Total Results		30	350	380

Relative Sensitivity: 93.3% (95%CI*: 77.9%-99.2%) *Confidence Interval
Relative Specificity: 98.6% (95%CI*: 96.7%-99.5%)
Accuracy: 98.2% (95%CI*: 96.2%-99.3%)

IgG Results

Method		T.Gondii ELISA(IgG)		Total Results
Toxo Rapid Test Cassette for IgG	Results	Positive	Negative	
	Positive	29	6	35
	Negative	1	344	345
Total Results		30	350	380

Relative Sensitivity: 96.7% (95%CI*: 82.8%-99.9%) *Confidence Interval
Relative Specificity: 98.3% (95%CI*: 96.3%-99.4%)
Accuracy: 98.2% (95%CI*: 96.2%-99.3%)

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 IgG/IgM Rapid Test cassette (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 IgG/IgM Rapid Test Cassette (Serum/Plasma) has been tested for HBsAg, HBsAb, HbeAg, HBeAb, anti-HAV IgM, anti-HCV IgG, anti-HIV IgG, anti-RF IgG, anti-Syphilis IgG, anti-H. Pylori IgG, anti-Rubella IgG, anti-Rubella IgM, anti-CMV IgG, anti-CMV IgM, anti-HSV 1 IgG, anti-HSV 1 IgM, anti-HSV 2 IgG and anti-HSV 2 IgM positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have also been tested using the Toxo IgG/IgM Combo Rapid Test Cassette (Serum/Plasm a) 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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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

⚠	Attention, see instructions for use	Σ	Tests per kit	2	Do not reuse
IVD	For in vitro diagnostic use only		Use by	REF	Catalog #
2°C–30°C	Store between 2-30°C	LOT	Lot Number		Consult Instructions For Use
	Do not use if package is damaged		Manufacturer		

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