TruQuick™ TOXO IgG/IgM 40T

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

REF **TQ1240** IVD **Rx Only**

INTENDED USE
TruQuick TOXO IgG/IgM is a lateral flow immunoassay for the simultaneous detection and differentiation of IgM anti- *T. gondii* and IgG anti-*T. gondii* in 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 TruQuick TOXO IgG/IgM 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 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 immunoassays, such as The TruQuick TOXO IgG/IgM were introduced into the clinic for the serodiagnosis of *T. gondii* infection.

BIOLOGICAL PRINCIPLES
TruQuick TOXO IgG/IgM is a lateral flow immunoassay. The test consists of: 1) a red colored conjugate 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 (T1 and T2 bands) and a control band (C band). The T1 band is precoated with monoclonal anti-human IgM for detection of IgM anti-*T. gondii*, T2 band is precoated with reagents for detection of IgG anti-*T. gondii*, and the C band is precoated with goat anti rabbit 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 precoated anti-human IgM antibody, forming a red colored T1 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 precoated reagents on the membrane, forming a red colored T2 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 rabbit IgG/rabbit 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/MATERIALS PROVIDED
The maximum number of tests obtained from this test kit is listed on the outer box.
- Test Cassettes: Test Cassettes carry mouse anti-human IgM, mouse anti-human IgG and *T. gondii* antigen. A goat antibody is employed in the control line system. Each cassette is packaged in a foil pouch.
- Buffer: A buffered solution containing ProClin as a preservative. The Buffer is supplied in a dropper vial ready for use.
- Droppers
- Package insert

MATERIALS NOT PROVIDED
- Specimen collection containers
- Centrifuge
- Timer

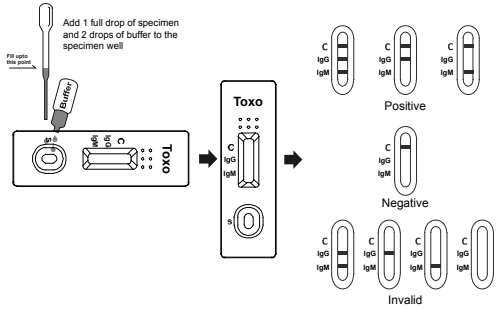
PRECAUTIONS
1. For in vitro diagnostic use only. Do not use after the expiration date.
2. Do not smoke, drink, or eat in areas where specimens or kits reagents are handled.
3. Dispose of all specimens and materials used to perform the test as biohazardous waste.
4. This package insert must be read completely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

HAZARD and PRECAUTIONARY STATEMENTS
Refer to the SDS, available at www.meridianbioscience.com for Hazard and Precautionary Statements.

SHELF LIFE AND STORAGE
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
1. TruQuick TOXO IgG/IgM can be performed using serum or plasma. Collect and prepare whole blood, serum or plasma according to standard laboratory methods.
2. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, nonhemolyzed specimens can be used.
3. 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 three days. For long-term storage, specimens should be kept below -20 C.
4. 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.
5. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation
6. If specimens are to be shipped, they should be packed in compliance with local regulations.

TEST PROCEDURE
Allow the test, specimen, Buffer and/or controls to reach room temperature (15-30 C) prior to testing.
1. 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.
2. Place the Test Cassette on a clean and level surface. Hold the dropper vertically, draw the specimen up to the Fill Line as shown in illustration below (approximately 10 µL). Transfer the specimen to the specimen well, then add 2 drops of Buffer (approximately 80 µL) and start the timer. See the illustration below.
3. 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 or three 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: Along with line in Control region (C), a line appears in IgM region. It indicates a positive Test result for IgM antibodies to Toxoplasma
IgG Positive: Along with line in Control region (C), a line appears in IgG region. It indicates a positive Test result for IGG 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 Meridian's Technical Services Department at 800-343-3858 or your local distributor.

QUALITY CONTROL
This test should be performed per applicable local, state, or federal regulations or accrediting agencies.
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.

External controls are not supplied with this kit; however, it is recommended that positive and negative external controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

If the expected control reactions are not observed, repeat the control tests as the first step in determining the root cause of the failure. If control failures are repeated please contact Meridian's Technical Services Department at 1-800-343-3858 (US) or your local distributor.

EXPECTED VALUES
TruQuick TOXO IgG/IgM was compared with a leading commercial TOXO IgG/IgM ELISA test. The correlation between these two systems is over 98%

LIMITATIONS OF THE PROCEDURE
1. The TEST PROCEDURE and the INTERPRETATION OF RESULTS 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. TruQuick TOXO IgG/IgM is limited to the qualitative detection of the antibodies to *T. gondii* in 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.

SPECIFIC PERFORMANCE CHARACTERISTICS
Sensitivity and Specificity
A clinical evaluation was conducted comparing the results of TruQuick TOXO IgG/IgM to TOXO IgG/IgM ELISA testing. The study included 380 IgG specimens and 380 IgM specimens.

IgG Results

Method		*T. gondii* EIA (IgG)		Total Results
TruQuick TOXO IgG/IgM for IgG	Results	Positive	Negative	
	Positive	28	5	33
	Negative	2	345	347
Total Results		30	350	380

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

IgM Results

Method		*T. gondii* EIA (IgM)		Total Results
TruQuick TOXO IgG/IgM for IgM	Results	Positive	Negative	
	Positive	29	6	35
	Negative	1	344	345
Total Results		30	350	380

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

REPRODUCIBILITY
Intra-Assay Precision
Within-run precision was determined by using 10 replicates of five specimens: a negative, IgM and IgG low positives, and IgM and IgG high positives. The samples were correctly identified > 99% of the time.
Inter-Assay Precision
Between-run precision was determined by 10 independent assays on the same five specimens. Three different lots of TruQuick TOXO IgG/IgM were tested. The specimens were correctly identified > 99% of the time.

CROSSREACTIVITY
TruQuick TOXO IgG/IgM was tested with samples from patients diagnosed with HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, HCV, Syphilis, *H. pylori*, CMV, HSV 1/2 and Rubella. The samples showed no crossreactivity.

TESTS FOR INTERFERING SUBSTANCES
The following potentially interfering substances were added to TOXO negative and positive specimens.

Acetaminophen 20 mg/dL	Caffeine 20 mg/dL	EDTA 20 mg/dL
Acetylsalicylic Acid 20 mg/dL	Gentisic Acid 20 mg/dL	Glucose 20 mg/dL
Ascorbic Acid 2 g/dL	Phenylpropanolamine 20 mg/dL	Phenothiazine 20 mg/dL
Bilirubin 1 g/dL	Salicylic acid 20 mg/dL	

None of the substances interfered in the assay at the concentration tested.

REFERENCES

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SNTQ1240 **REV. 05/17**

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SYMBOL USAGE
You may see one or more of these symbols on the labeling/packaging of this product:
Key guide to symbols

	Use By	CONTROL +	Positive control
LOT	Batch Code	CONTROL −	Negative control
IVD	In vitro diagnostic medical device	EC REP	Authorized Representative in the European Community
CE	This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices	SMP PREP DIL SPE	Sample Preparation Apparatus containing Sample Diluent
REF	Catalogue number		Do not freeze
	Consult Instructions for Use	BUF RXN	Reaction Buffer
	Manufacturer		For IVD Performance Evaluation Only
Σ	Contains sufficient for <n> tests	SOLN STOP	Stopping Solution
	Temperature limitation	CONJ ENZ	Enzyme Conjugate
SN	Serial number	CONTROL	Assay Control
TEST	Test Device	REAG	Reagent
	Date of manufacture	BUF WASH	Wash Buffer
BUF	Buffer		Warning
CONJ	Conjugate	DIL SPE	Specimen Diluent (or Sample Diluent)
SUBS	Substrate	BUF WASH 20X	Wash Buffer Concentration: 20X
RUO	Research Use Only	DET REAG	Detection Reagent
IUO	Investigational Use Only	Rx Only	Prescription Use Only
	Do not use if package is damaged		

For technical assistance, call Technical Support Services at 800-343-3858 between the hours of 8AM and 6PM, USA Eastern Standard Time. To place an order, call Customer Service Department at 800-543-1980.