TruQuick™ ToRCH IgM Combo 25T

A rapid test for the qualitative detection of IgM antibodies to *Toxoplasma gondii* (Toxo), Rubella virus (Rubella), Cytomegalovirus (CMV), and Herpes simplex virus 1/2 (HSV 1/2) in serum or plasma.

REF **TQ1025** IVD **Rx Only**

INTENDED USE
TruQuick ToRCH IgM Combo is a rapid chromatographic immunoassay for the qualitative detection of IgM antibodies to *Toxoplasma gondii* (Toxo), Rubella virus (Rubella), Cytomegalovirus (CMV), and Herpes simplex virus 1/2 (HSV 1/2) in serum or plasma to aid in the diagnosis of ToRCH.

SUMMARY AND EXPLANATION OF THE TEST
ToRCH is an acronym for a group of infectious diseases that, while infecting the pregnant women, may cause birth defects in their newborns.[1] ToRCH stands for four different infections that can adversely affect a pregnant woman and the fetus or newborn often leading to abortion. The infections usually cause few, if any, symptoms in the pregnant woman, but pose greater risks of serious birth defects for neonates. Infections caused by ToRCH is the major cause of BOH (Bad Obstetric History).[2] Risks are severe if the mother gets the infection in the first trimester as the baby's organs start to form in this stage. General symptoms include premature birth, growth retardation, neurological abnormalities, and damage of the eye, liver, heart and ear as well as bone lesions. Microcephaly, hydrocephaly, seizures and psychomotor retardation accompany these malformations.

TruQuick ToRCH IgM Combo is a rapid chromatographic immunoassay for the qualitative detection of IgM antibodies to Toxo, Rubella, CMV, and HSV 1/2 in serum or plasma specimens.

BIOLOGICAL PRINCIPLES
Toxo IgM Rapid Test:
In this test, mouse anti-human IgM are coated in the test line regions of the test. During testing, the serum or plasma specimen reacts with *T. gondii* antigen-coated particles in the test strip. The mixture then migrates forward on the membrane by capillary action and reacts with the mouse anti-human IgM on the membrane in the test line region respectively. The presence of a colored line in the test line region indicates a positive result for *T. gondii* infection, while its absence indicates a negative result for that infection.

Rubella IgM Rapid Test/CMV IgM Rapid Test/HSV 1/2 IgM Rapid Test:
In this test, antigens of Rubella, CMV and HSV 1/2 are coated in the test line regions of each section in the test. During testing, the serum or plasma specimen reacts with Goat anti-human IgM coated particles in the test strip. The mixture then migrates upward on the membrane by capillary action and reacts with the Rubella, CMV and HSV 1/2 specific antigens 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. Rubella, CMV, HSV 1/2, while its absence indicates a negative result for that infection.

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

REAGENTS/MATERIALS PROVIDED
The maximum number of tests obtained from this test kit is listed on the outer box.
- Test Cassettes: The test contains mouse anti-human IgM, goat anti-human IgM and Toxo antigen, Rubella antigen, CMV antigen and HSV ½ antigens. A goat anti-mouse IgG and streptavidin-IgG is employed in the control line system.
- 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 (for plasma only)
- Timer

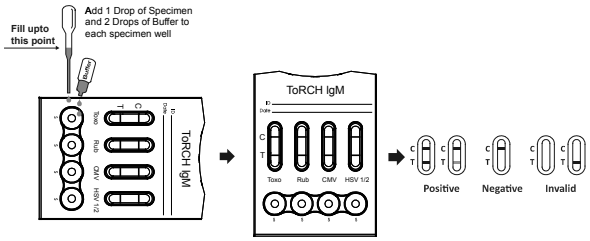
PRECAUTIONS
1. All reagents are for in vitro diagnostic use only. Do not use after the expiration date.
2. Do not smoke, drink, or eat in areas where specimens or kits reagents are handled.
3. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
4. Humidity and temperature can adversely affect results.
5. The used test should be discarded according to local regulations.

HAZARD AND PRECAUTIONARY STATEMENTS
There are no known hazards associated with this product.

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 ToRCH IgM Combo can be performed using either serum or plasma specimens. Collect serum or plasma using standard laboratory methods.
2. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed 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 3 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. If specimens are to be shipped, they should be packed in compliance with local regulations for the transportation of etiologic agents.

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 about **1 cm above** the upper end of the nozzle as shown in illustration below. Transfer 1 full drop (**approx. 20 µL**) of specimen to each sample well, then add 2 drops of Buffer (approximately 80 µL) to each sample well 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:
Toxo Positive: ***Two colored lines appear in the "Toxo" section**. One line should be in the control line region (C) and another line should be in the test line region (T).
Rubella Positive: ***Two colored lines appear in the "Rub" section**. One line should be in the control line region (C) and another line should be in the test line region (T).
CMV Positive: ***Two colored lines appear in the "CMV" section**. One line should be in the control line region (C) and another line should be in the test line region (T).
HSV 1/2 Positive: ***Two colored lines appear in the "HSV 1/2" section**. One line should be in the control line region (C) and another line should be in the test line region (T).
***Note:** The intensity of the color in test line region (T) will vary depending on the concentration of IgM antibodies present in the specimen. Therefore, any shade of color in test line region (T) should be considered positive.
NEGATIVE: **One colored line appears in the control line region (C) of every section**. Lack of a visible line in the test line region (T) of any section is indicative of a negative test result for that specific section, viz. Toxo, Rubella, CMV, and HSV 1/2.
INVALID: **Control line fails to appear in any section**. 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.
A procedural control is included in the test individually for all the four sections. Four colored lines appearing in control line regions (C) of all four sections is the internal 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 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 ToRCH IgM Combo has been compared with leading commercial EIA Toxo, Rubella, CMV, and HSV 1/2 tests, demonstrating an overall correlation of 98.2% for Toxo, 98.3% for Rubella, 98.0% for CMV, and 97.9% for HSV 1/2.

LIMITATIONS OF THE PROCEDURE
1. TruQuick ToRCH IgM Combo is for in vitro diagnostic use only. This test should be used for the detection of IgM antibodies to Toxo, Rubella, CMV and HSV 1/2 in serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of IgM antibodies to Toxo, Rubella, CMV and HSV 1/2 can be determined by this qualitative test.
2. TruQuick ToRCH IgM Combo will only indicate the presence of IgM antibodies to Toxo, Rubella, CMV and HSV 1/2 in the specimen and should not be used as the sole criteria for the diagnosis of ToRCH infections for which the positive result is obtained.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result for any one out of the four infections of ToRCH at any time does not preclude the possibility of that particular infection.

SPECIFIC PERFORMANCE CHARACTERISTICS
Sensitivity and Specificity
TruQuick ToRCH IgM Combo was compared with leading commercial EIA Toxo, Rubella, CMV and HSV 1/2 tests; the results show that the TruQuick ToRCH IgM Combo has a high sensitivity and specificity for each of its sections.

TOXO

Method		Toxo EIA (IgM)		Total Results
TruQuick Toxo IgM	Results	Positive	Negative	
	Positive	71	7	78
	Negative	2	674	676
Total Results		73	681	754

Sensitivity: 97.3% (95% CI*: 90.5%~99.7%)
Specificity: 99.0% (95% CI*: 97.9%~99.6%)
Correlation: 98.8 %(95% CI*: 97.7%~99.5%)
*Confidence Interval

Rubella

Method		Rubella EIA (IgM)		Total Results
TruQuick Rubella IgM	Results	Positive	Negative	
	Positive	35	2	37
	Negative	1	356	357
Total Results		36	358	394

Sensitivity: 97.2% (95% CI*: 86.5%~100%)
Specificity: 99.4% (95% CI*: 98.0%~100%)
Correlation: 99.2 %(95% CI*: 97.8%~99.8%)
*Confidence Interval

CMV

Method		CMV EIA (IgM)		Total Results
TruQuick CMV IgM	Results	Positive	Negative	
	Positive	35	3	37
	Negative	1	327	328
Total Results		36	329	365

Sensitivity: 97.2% (95% CI*: 86.5%~100%)
Specificity: 99.4% (95% CI*: 97.8%~99.9%)
Correlation: 99.2 %(95% CI*: 97.6%~99.8%)
*Confidence Interval

HSV 1/2

Method		HSV 1/2 EIA (IgM)		Total Results
TruQuick HSV 1/2 IgM	Results	Positive	Negative	
	Positive	28	1	29
	Negative	2	348	350
Total Results		30	349	379

Sensitivity: 93.3% (95% CI*: 77.9%~99.2%)
Specificity: 99.7% (95% CI*: 98.4%~100.0%)
Correlation: 99.2 %(95% CI*: 97.7%~99.8%)
*Confidence Interval

REPRODUCIBILITY
Intra-Assay Precision
Within-run precision was determined by using 10 replicates of serum and plasma for four specimens containing negative, low positive and medium and high positive concentrations of Toxo, Rubella, CMV and HSV 1/2. The negative, low positive, and medium and high positive values were correctly identified > 99% of the time.
Inter-Assay Precision
Between-run precision was determined by using the same four specimens of negative, low positive, medium positive and high positive of Toxo, Rubella, CMV and HSV 1/2. Three different lots of TruQuick ToRCH IgM Combo were tested. The specimens were correctly identified > 99% of the time.

CROSSREACTIVITY
TruQuick ToRCH IgM Combo was tested with specimens from patients diagnosed with HAV, HBV, HCV, HEV, HIV, RF, Syphilis, HAMA, Rubella, Mononucleosis, Toxoplasmosis, HSV 1/2 positive specimens. The results showed no crossreactivity.

TESTS FOR INTERFERING SUBSTANCES

TruQuick ToRCH IgM Combo has been tested and no interference was observed in specimens containing 110 mg/mL human albumin, 1 mg/mL bilirubin, 10 mg/mL hemoglobin, 0.2 mg/mL cholesterol and 15 mg/mL triglycerides.

The following compounds have also been tested using the TruQuick ToRCH IgM Combo and no interference was observed.

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

REFERENCES

1. Kadri SM. Torch Test: Test & Inference, Indian J Prac Dr. 2005 Jan; Vol.I(4):16-18.
2. Surpam RB, Kamlakar UP, Khadse RK, Qazi MS, Jalgaonkar SV. Serological study for TORCH infections in women with bad obstetric history. J Ob Gyn India. 2006 Jan/Feb; Vol.56(1):41-43.

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Manufactured By

Meridian Bioscience, Inc.
USA/Corporate Office
3471 River Hills Drive
Cincinnati, Ohio 45244
Telephone: 513.271.3700
Orders/Customer Service:
800.543.1980
Technical Support Center:
800.343.3858
Information Fax: 513.272.5432
Ordering Fax: 513.271.0124

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.