ToRCH IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) Package Insert

REF ITOGM-485	English

A rapid test for the qualitative detection of IgG antibodies to Toxoplasma gondii (Toxo), Rubella virus (Rubella), Cytomegalovirus (CMV) and Herpes simplex virus 1/2 (HSV 1/2) in human whole blood, serum or plasma.
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 human whole blood, serum or plasma.
For professional in vitro diagnostic use only

【INTENDED USE】

ToRCH IgG Combo Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of IgG antibodies to Toxoplasma gondii (Toxo), Rubella virus (Rubella), Cytomegalovirus (CMV), and Herpes simplex virus 1/2 (HSV 1/2) in whole blood, serum or plasma to aid in the diagnosis of ToRCH.

ToRCH IgM Combo Rapid Test Cassette 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 whole blood, serum or plasma to aid in the diagnosis of ToRCH.

【SUMMARY】

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 4 different infections that can adversely affect the pregnant women and the fetus, newborn children including birth defects and often leading to abortion. The four infections are Toxomplasma gondii (A spirochete), Rubella (Virus), CMV – Cytomegalovirus (Virus), HSV 1/2 – Herpes Simplex Virus 1 and/or 2 (Virus). 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 – Toxoplasma, Rubella Virus, Cytomegalo Virus (CMV) and Herpes Simplex Virus (HSV) – 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.

The ToRCH IgG Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgG antibodies to Toxo, Rubella, CMV, and HSV 1/2 in whole blood, serum or plasma specimens.

The ToRCH IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgM antibodies to Toxo, Rubella, CMV, and HSV 1/2 in whole blood, serum or plasma specimens.

【PRINCIPLE】

ToRCH IgG Combo Rapid Test Cassette is a qualitative, lateral flow immunoassay for the detection of IgG antibodies to Toxo, Rubella, CMV, and HSV 1/2 in whole blood, serum or plasma specimens.

Toxo IgG Rapid Test:

In this test, mouse anti-human IgG are coated in the test line regions of 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 forward on the membrane by capillary action and reacts with the mouse anti-human IgG 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 IgG Rapid Test/CMV IgG Rapid Test/HSV 1/2 IgG Rapid Test:

In this test, antigens of Rub, CMV and HSV 1/2 are coated in the test line regions of each section in the test. During testing, the whole blood, serum or plasma specimen reacts with Mouse anti-human IgM coated particles in the test strip. The mixture then migrates upward on the membrane by capillary action and reacts with the Rub, 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. Rub, 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.

ToRCH IgM Combo Rapid Test Cassette is a qualitative, lateral flow immunoassay for the detection of IgM antibodies to Toxo, Rubella, CMV, and HSV 1/2 in whole blood, serum or plasma specimens.

Toxo IgM Rapid Test:

In this test, mouse anti-human IgM are coated in the test line regions of 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 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 Rub, CMV and HSV 1/2 are coated in the test line regions of each section in the test. During testing, the whole blood, 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 Rub, 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. Rub, 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】

The test contains mouse anti-human IgM, mouse anti-human IgG, goat anti-human IgM , Toxo antigen, Rub antigen, CMV antigen and HSV 1/2 antigens. A goat anti-mouse IgG and streptavidin-IgG is employed in the control line system are 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. 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.

【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 ToRCH IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum or plasma specimen.
- 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 fingersticks 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

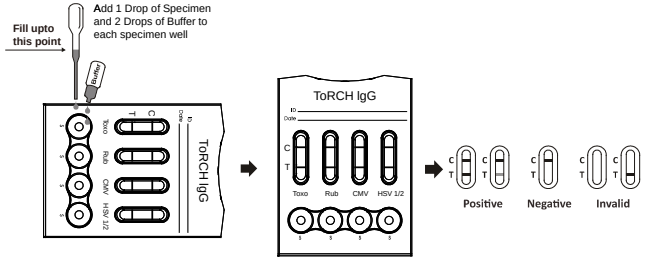
- Specimen collection contain
- Centrifuge (for plasma only)
- Timer

【DIRECTIONS FOR USE】

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

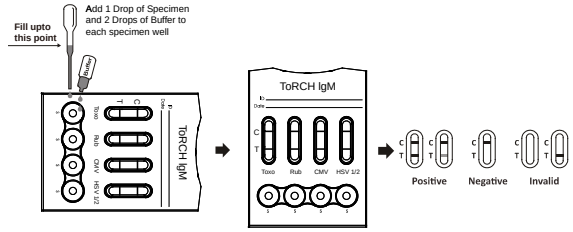
ToRCH IgG Combo Rapid Test

1. Remove the test cassette from the sealed pouch and use it within one hour. Best results will be obtained if the assay is performed as soon as possible.
2. 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.
3. Wait for the colored line(s) to appear. The result should be read at 15 minutes. Do not interpret results after 20 minutes.



ToRCH IgM Combo Rapid Test

1. Remove the test cassette from the sealed pouch and use it within one hour. Best results will be obtained if the assay is performed as soon as possible.
2. 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.
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 IgG 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***. Non-appearance 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, Rub, 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 your local distributor.

【QUALITY CONTROL】

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

【LIMITATIONS】

1. ToRCH IgG Combo Rapid Test Cassette is for in vitro diagnostic use only. This test should be used for detection of IgG antibodies to Toxo, Rubella, CMV and HSV 1/2 in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of IgG antibodies to Toxo, Rubella, CMV and HSV 1/2 can be determined by this qualitative test.
2. ToRCH IgG Combo Rapid Test Cassette will only indicate the presence of IgG 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. ToRCH IgM Combo Rapid Test Cassette is for in vitro diagnostic use only. This test should be used for detection of IgM antibodies to Toxo, Rubella, CMV and HSV 1/2 in whole blood, 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.
4. ToRCH IgM Combo Rapid Test Cassette 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.
5. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
6. 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.

【EXPECTED VALUES】

ToRCH IgG Combo Rapid Test Cassette has been compared with leading commercial EIA Toxo, Rubella, CMV, and HSV 1/2 tests, demonstrating an overall accuracy of 98.2% for Toxo,97.6% for Rubella, 98.1% for CMV, and 97.9% for HSV 1/2.

ToRCH IgM Combo Rapid Test Cassette has been compared with leading commercial EIA Toxo, Rubella, CMV, and HSV 1/2 tests, demonstrating an overall accuracy of 98.2% for Toxo, 98.1% for Rubella, 98.1% for CMV, and 97.9% for HSV 1/2.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

ToRCH IgG Combo Rapid Test Cassette was compared with leading commercial EIA Toxo, Rubella, CMV and HSV 1/2 tests; the results show that the ToRCH IgG Combo Rapid Test Cassette has a high sensitivity and specificity for each of its sections.

TOXO

Method		T.Gondii EIA (IgG)		Total Results
Toxo IgG Rapid Test Cassette	Results	Positive	Negative	
	Positive	48	6	54
	Negative	2	394	396
Total Results		50	400	450

Relative Sensitivity: 96.0% (95%CI*: 86.3%-99.5%) *Confidence Interval
Relative Specificity: 98.5% (95%CI*: 96.8%-99.4%)

Accuracy: 98.2% (95%CI*: 96.5%-99.2%)

Rubella

Method		Rubella EIA (IgG)		Total Results
Rubella IgG Rapid Test Cassette	Results	Positive	Negative	
	Positive	56	4	60
	Negative	5	306	311
Total Results		61	310	371

Relative Sensitivity: 91.8% (95%CI*: 81.9%-97.3%) *Confidence Interval
Relative Specificity: 98.7% (95%CI*: 96.7%-99.6%)
Overall Accuracy: 97.6% (95%CI*: 95.4%-98.9%)

CMV

Method		CMV EIA (IgG)		Total Results
CMV IgG Rapid Test Cassette	Results	Positive	Negative	
	Positive	43	4	47
	Negative	3	321	324
Total Results		46	325	371

Relative Sensitivity: 93.5% (95%CI*: 82.1%-98.6%) *Confidence Interval
Relative Specificity: 98.8% (95%CI*: 96.9%-99.7%)
Accuracy: 98.1% (95%CI*: 96.2%-99.2%)

HSV 1/2

Method		HSV 1/2 EIA (IgG)		Total Results
HSV 1/2 IgG Rapid Test Cassette	Results	Positive	Negative	
	Positive	33	5	38
	Negative	2	300	302
Total Result		35	305	340

Relative Sensitivity: 94.3% (95%CI*: 80.8%-99.3%) *Confidence Interval
Relative Specificity: 98.4% (95%CI*: 96.2%-99.5%)
Accuracy: 97.9% (95%CI*: 95.8%-99.2%)

ToRCH IgM Combo Rapid Test Cassette was compared with leading commercial EIA Toxo, Rubella, CMV and HSV 1/2 tests; the results show that the ToRCH IgM Combo Rapid Test Cassette has a high sensitivity and specificity for each of its sections.

TOXO

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%)

Rubella

Method		Rubella EIA (IgM)		Total Results
Rubella IgM Rapid Test Cassette	Results	Positive	Negative	
	Positive	57	3	60
	Negative	4	307	311
Total Results		61	310	371

Relative Sensitivity: 93.4% (95%CI*: 89.4%-99.9%) *Confidence Interval
Relative Specificity: 99.0% (95%CI*: 97.2%-99.8%)
Overall Accuracy: 98.1% (95%CI*: 96.2%-99.2%)

CMV

Method		CMV EIA (IgM)		Total Results
CMV IgM Rapid Test Cassette	Results	Positive	Negative	
	Positive	36	4	40
	Negative	3	328	331
Total Results		39	332	371

Relative Sensitivity: 92.3% (95%CI*: 79.1%-98.4%) *Confidence Interval
Relative Specificity: 98.8% (95%CI*: 96.9%-99.7%)
Accuracy: 98.1% (95%CI*: 96.2%-99.2%)

HSV 1/2

Method		HSV 1/2 EIA (IgM)		Total Results
HSV 1/2 IgM Rapid Test Cassette	Results	Positive	Negative	
	Positive	32	4	36
	Negative	3	301	304
Total Result		35	305	340

Relative Sensitivity: 91.4% (95%CI*: 76.9%-98.2%) *Confidence Interval
Relative Specificity: 98.7% (95%CI*: 96.7%-99.6%)
Accuracy: 97.9% (95%CI*: 95.8%-99.2%)

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of three specimens containing negative, low positive and high positive of Toxo, Rubella, CMV and HSV 1/2. The negative, low positive, and high positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by using the same three specimens of negative, low positive and high positive of Toxo, Rubella, CMV and HSV 1/2 in 3 independent assays. Three different lots of the ToRCH IgG Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) have been tested using negative, low positive and high positive specimens. The specimens were correctly identified >99% of the time.

Between-run precision has been determined by using the same three specimens of negative, low positive and high positive of Toxo, Rubella, CMV and HSV 1/2 in 3 independent assays. Three different lots of the ToRCH IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) have been tested using negative, low positive and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

ToRCH IgG Combo Rapid Test Cassette has been tested for HAV, HBV, HCV, HIV, RF, Syphilis, *H. Pylori*, Rubella, TOXO, HSV 1/2 positive specimens. The results showed no cross-reactivity.

ToRCH IgM Combo Rapid Test Cassette has been tested for HAV, HBV, HCV, HIV, RF, Syphilis, *H. Pylori*, Rubella, TOXO, HSV 1/2 positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have also been tested using the ToRCH IgG Combo Rapid Test Cassette 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

The following compounds have also been tested using the ToRCH IgM Combo Rapid Test Cassette 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】

1. S M Kadri, Torch Test: Test & Inference, INDIAN JOURNAL OF THE PRACTISING DOCTOR, January 2005, Vol. I, No. 4 : P16-18
2. Rajendra B Surpam, Usha P Kamlakar, RK Khadse, MS Qazi, & Suresh V Jalgaonkar, Serological study for TORCH infections in women with bad obstetric history, The Journal of Obstetrics and Gynecology of India, January/February 2006, Vol. 56, No. 1 : P 41-43

Index of Symbols

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

Hangzhou AllTest Biotech Co., Ltd.
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