SPECTRUM

The Creative Approach To Bioscience

ToRCH

Toxo/Rubella/CMV/HSV 1/2 IgM Antibodies Combo Rapid Test Device (Serum/Plasma)

REF: 1204 001 25 test

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.
For professional in vitro diagnostic use only.

INTENDED USE

The ToRCH IgM Antibodies Combo Rapid Test Device (Serum/Plasma) 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

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, damage of the eye, liver, heart and ear as well as bone lesions. Microcephaly, hydrocephaly, seizures and psychomotor retardation accompany these malformations.
The ToRCH IgM Antibodies Combo Rapid Test Device (Serum/Plasma) 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.

PRINCIPLE

The ToRCH IgM Antibodies Combo Rapid Test Device (Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of IgM antibodies to Toxo, Rubella, CMV, and HSV 1/2 in serum or plasma specimens. In this test, antigens of Toxo, Rub, 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 Toxo, 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. Toxo, 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 Goat anti-human IgM coated particles and Toxo antigens, Rub antigens, CMV antigens, and HSV 1/2 antigens coated on the membrane.

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if the package is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.
- The used test should be discarded according to local regulations.

STORAGE AND STABILITY

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

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative	°C	Temperature Limitation
IVD	For in-vitro diagnostic use		Use by/Expiration Date
LOT	Batch Code/Lot number		CAUTION. Consult instructions for use
REF	Catalogue Number		
	Consult instructions for use		Manufactured by

SPECIMEN COLLECTION AND PREPARATION

- The ToRCH IgM Antibodies Combo Rapid Test Device (Serum/Plasma) can be performed using either 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.

MATERIALS

Materials Provided

- Test devices
- Disposable droppers
- Buffer
- Package insert

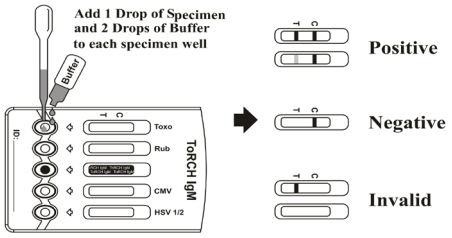
Materials Required But Not Provided

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

DIRECTIONS FOR USE

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

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and useit as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 1 full drop of serum or plasma (approximately 10 µL) and 2 drops of buffer (approximately 80 µL) to each specimen well of the test device respectively, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.
3. Wait for the colored line(s) to appear. The results should be read at 15 minutes. Do not interpret the 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 regions (T) will vary depending on the concentrations of IgM antibodies present in the specimen. Therefore, any shade of color in test line regions (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 device. 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.

LIMITATION

1. The ToRCH IgM Antibodies Combo Rapid Test Device (Serum/Plasma) 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. The ToRCH IgM Antibodies Combo Rapid Test Device (Serum/Plasma) 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 any of the 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.

EXPECTED VALUES

The ToRCH IgM Antibodies Combo Rapid Test Device (Serum/Plasma) has been compared with leading commercial EIA Toxo, Rubella, CMV, and HSV 1/2 tests, demonstrating an overall accuracy of 98.4% for Toxo, 99.1% for Rubella, 98.8% for CMV, and 99.0% for HSV 1/2.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

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

Toxo Rapid Test Device vs. EIA

Method		EIA		Total Results
Toxo Rapid Test	Results	Positive	Negative	
	Positive	54	12	66
	Negative	3	846	849
Total Results		57	858	915

Relative Sensitivity: 94.7% (85.4%-98.9%)*
Relative Specificity: 98.6% (97.6%-99.3%)*
Relative Accuracy: 98.4% (97.3%-99.1%)*
* 95% Confidence Interval

Rubella Rapid Test Device vs. EIA

Method		EIA		Total Results
Rubella Rapid Test	Results	Positive	Negative	
	Positive	19	2	21
	Negative	1	298	299
Total Results		20	300	320

Relative Sensitivity: 95.0% (75.1%-99.9%)*
Relative Specificity: 99.3% (97.6%-99.9%)*
Relative Accuracy: 99.1% (97.3%-99.8%)*
* 95% Confidence Interval

CMV Rapid Test Device vs. EIA

Method		EIA		Total Results
CMV Rapid Test	Results	Positive	Negative	
	Positive	18	5	23
	Negative	1	461	462
Total Results		19	466	485

Relative Sensitivity: 94.7% (74.0%-99.9%)*
Relative Specificity: 98.9% (97.5%-99.7%)*
Relative Accuracy: 98.8% (97.3%-99.5%)*
* 95% Confidence Interval

HSV 1/2 Rapid Test Device vs. EIA

Method		EIA		Total Results
HSV 1/2 Rapid Test	Results	Positive	Negative	
	Positive	12	1	13
	Negative	2	300	302
Total Results		14	301	315

Relative Sensitivity: 85.7% (57.2%-98.2%)*
Relative Specificity: 99.7% (98.2%-100.0%)*
Relative Accuracy: 99.0% (97.2%-99.8%)*
* 95% Confidence Interval

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 or HSV 1/2. The negative and 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 IgM Antibodies Combo Rapid Test Device (Serum/Plasma) have been tested using negative, low positive and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-Reactivity

Sera containing known amounts of antibodies to Toxo, Rubella, CMV and HSV 1/2 have been tested with HIV, HCV, SYP, HBV, and RF. No cross-reactivity was observed, indicating that the ToRCH IgM Antibodies Combo Rapid Test Device (Serum/Plasma) has a high degree of specificity for IgM antibodies to Toxo, Rubella, CMV, and HSV 1/2.

Interfering Substances

The ToRCH IgM Antibodies Combo Rapid Test Device (Serum/Plasma) has been tested and no interference was observed in specimens containing 110 mg/mL human albumin, 1 mg/mL bilirubin, 10 mg/mL hemoglobin, 0.2mg/mL cholesterol and 15 mg/mL triglycerides.
The following compounds have also been tested using the ToRCH IgM Antibodies Combo Rapid Test Device (Serum/Plasma) and no interference was observed

Acetaminophen	Acetylsalicylic Acid	Ascorbic Acid	Bilirubin
Caffeine	Ethanol	EDTA	Glucose
Gentisic acid	Phenothiazine	Phenylpropanolamine	Salicylic Acid

BIBLIOGRAPHY

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ORDERING INFORMATION	
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1204 001	25 test

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