TORCH IgM DEVICE (2–30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADTOR1	25 Tests

Intended Use:
The TORCH IgM Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection of IgM antibodies to Toxoplasma gondii (Toxo), Rubella virus (Rub), Cytomegalovirus (CMV) and Herpes simplex virus 1/2 (HSV 1/2) in whole blood, serum or plasma to aid in the diagnosis of diseases caused by these organisms.

Summary:
The TORCH IgM Rapid Test Device is designed to detect antibody to five infectious diseases that in pregnant women may lead to abortion or can cause birth defects in the newborn. The risks are severe if the mother gets any of the infections in the first trimester when organs are developing in the foetus. General symptoms in the newborn include premature birth, growth retardation, neurological abnormalities and damage to the eye, liver, heart, ear and bone.

Test Principle:
In the Toxo IgM test mouse anti-human IgM is immobilized on the membrane at the test line. During the test the sample is added to the sample well and reacts with T gondii antigen coated particles in the sample well. The mixture moves upwards on the membrane by capillary action and reacts with the anti-human IgM on the test line. A positive result for Toxo is indicated when a coloured line forms at the test line, no coloured line in the test line indicates a negative result.
Antigens of Rub, CMV, and HSV 1 and 2 are coated on the respective test line regions of the device. During testing the sample reacts with goat anti-human IgM coated particles loaded in the sample wells. The mixture moves upwards on the membrane by capillary action and reacts with the Rub, CMV, and HSV 1 and 2 antigens at the respective test line regions.
To serve as a procedural control, a coloured line should always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

Reagents:
The test device contains goat anti-human IgM, Toxo antigen, Rubella antigen, CMV antigen and HSV 1/2 antigen.

Materials Provided
Individually pouched test devices
Disposable pipettes
Buffer
Instructions For Use sheet

Materials not provided: Micropipette, timer, specimen collection container, centrifuge

Precautions:
1. For professional in vitro diagnostic use only. Do not use after the expiry date.
2. The test should remain in the sealed pouch until ready to use.
3. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
4. The used test should be discarded according to local regulations.

Reagent Preparation and Stability:
Store as packaged at room temperature or refrigerated (2-30°C). The test is stable until the expiry date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiry date.

Specimen Collection and Storage:
1. The TORCH IgM Rapid Test Device can be performed using whole blood from venepuncture or fingerstick, serum or plasma.
2. Separate serum or plasma from blood as soon as possible to avoid haemolysis. Use only clear, non-haemolyzed specimens.
3. To collect Fingerstick Whole Blood specimens:
   a) Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
   b) Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
   c) Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
4. Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
5. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Venepuncture blood should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
6. 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.
7. If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

Assay 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 device from the sealed pouch and use it as soon as possible or within one hour.
2. Place the device on a clean and level surface.
Draw the sample into the disposable pipette and transfer 1 drop (approximately 20 µl) to each sample well then add 2 drops of buffer (approximately 80 µl) to each sample well and start the timer.
3. Wait for coloured bands to appear. The result should be read at 15 minutes. Do not interpret results after 20 minutes.

Interpretation of Results:

POSITIVE for Toxo, Rubella, CMV, HSV 1/2: Two coloured bands appear. One band appears in the control region (C) and another band appears in the test region (T) of the respective sections.

NEGATIVE: Only one coloured band appears, in the control region (C). No apparent coloured band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:
1. The intensity of the colour in the test region (T) will vary depending on the concentration of IgM antibodies present in the sample. Therefore, any shade of colour in the test region (T) should be considered positive.

Quality Controls:
- Internal procedural controls are included in the test. A coloured band appearing in the control region (C) is an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations of the Test:
1. The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of antibodies to Toxo, Rubella, CMV and HSV 1/2 in samples from individual subjects. Failure to follow the procedures may give inaccurate results.
2. The TORCH IgM Rapid Test Device is limited to the qualitative detection of IgM antibody to Toxo, Rubella, CMV and HSV 1/2 in whole blood, serum or plasma. The intensity of the test band does not have linear correlation with the antibody titre in the sample and the quantitative concentration or the rate of increase in IgM antibodies cannot be determined by this device.
3. A negative result for an individual subject indicates absence of detectable IgM antibody. However, a negative test result does not preclude the possibility of exposure to or infection with the TORCH infections. If symptoms persist, follow-up testing by other clinical methods is recommended.
4. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

Expected Values:
The TORCH IgM Rapid Test Device has been compared with leading commercial EIA tests for Toxo, Rub, CMV and HSV 1/2 with the results showing 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
The TORCH IgM Rapid Test Device was compared with a leading commercial ELISA EIA tests for Toxo, Rub, CMV and HSV 1/2 and demonstrated high sensitivity and specificity for each.

Toxo

Method		T gondii IgM ELISA		Total Results
TORCH IgM Rapid Test Device	Result	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 IgM ELISA		Total Results
TORCH IgM Rapid Test Device	Result	Positive	Negative	
	Positive	57	3	60
	Negative	4	307	311
Total Results		61	310	371

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

CMV

Method	CMV IgM ELISA	Total Results

TORCH IgM Rapid Test Device	Result	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 IgM ELISA		Total Results
TORCH IgM Rapid Test Device	Result	Positive	Negative	
	Positive	32	4	36
	Negative	3	301	304
Total Results		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 was determined using 10 replicates of three samples containing negative, low positive and high positive concentrations of Toxo, Rub, CMV and HSV 1/2. The negative and positive results were correctly identified >99 % of the time.

Inter-Assay

Between-run precision was determined by running 10 separate assays on 10 different days on three samples containing negative, low positive and high positive concentrations of Toxo, Rub, CMV and HSV 1/2. Three different lots of the TORCH IgM Rapid Test Device were tested using these samples. The specimens were correctly identified > 99 % of the time.

Cross-Reactivity

The TORCH IgM Rapid Test Device has been tested using HAV, HBV, HCV, HIV, RF, Syphilis and *H. pylori* positive samples and the results showed no cross-reactivity.

Interfering Substances

The following compounds have been tested using the TORCH IgM Rapid Test Device and no interference was observed.

Acetaminophen: 20 mg/dl	Caffeine: 20 mg/dl	EDTA: 20 mg/dl
Acetylsalicylic Acid: 20 mg/dl	Gentisic Acid: 20 mg/dl	Ethanol: 10 %
Ascorbic Acid: 2 g/dl	Phenylpropanolamine: 20 mg/dl	Glucose 20 mg/dl
Bilirubin 1000 mg/dl	Salicylic Acid: 20 mg/dl	Phenothiazine: 20 mg/dl

References:

1. Kadri SM Torch Test: Test and Interference. Indian Journal of the Practising Doctor, 2005; 1: 16-18.
2. Surpam RB, Kamlakar UP et al. Serological study for TORCH infections in woment with bad obstetric history. J Obs & Gyn of India, 2006; 56: 41 – 43.

GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		Do not reuse