Rubella IgM DEVICE (2-30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADRUB1	20 Tests

Intended Use:
The Rubella IgM Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection of IgM antibody to Rubella in whole blood, serum and plasma.

Summary:
Rubella virus is a member of the Togaviridae family found mainly in human populations. Generally rubella is considered a mild adolescence disease. However, a primary maternal infection can be transmitted through the placenta to the fetus causing congenital rubella and when contracted during early pregnancy may have severe consequences including severe fetal damage, stillbirth or abortion. Children born asymptomatic may develop abnormalities later in life. Despite widespread vaccination significantly reducing incidence of Rubella in all age groups, 10 to 20 % of young adults may still appear susceptible to the virus. The Rubella IgM Rapid Test Device, a lateral flow chromatographic immunoassay, is used to determine the serologic status of women of childbearing age.

Test Principle:
In the device goat anti-human IgM is coated on the membrane at the test line. During the test, the whole blood, serum or plasma added to the sample well (S) reacts with Rubella antigen coated particles immobilised on the test strip near the sample well, capturing any anti-Rubella antibodies present in the sample. The reaction mixture migrates up the membrane by capillary action and only the anti-Rubella IgM-particle complexes will bind with the anti-human IgM on the test line. The development of a coloured line in the test region indicates a positive result for Rubella infection, no coloured line in the test zone indicates a negative result. To serve as a procedural control, a coloured line should always appear in the control line region indicating that proper volume of sample has been added and membrane wicking has occurred.

Reagents:
The test device contains goat anti-human IgM and Rubella antigen. A goat anti-mouse IgG is used for control line development.

Materials Provided
Test devices in individually sealed pouches
Disposable pipettes
Buffer
Instructions for Use sheet

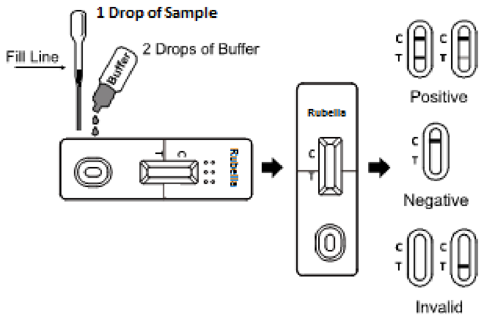
Materials not provided: Micropipette, timer, specimen collection container, centrifuge

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 samples should be considered potentially infectious and handled as such.
4. The used test should be discarded according to local regulations.

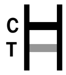
Reagent Preparation and Stability:
Store as packaged at room temperature or refrigerated (2-30°C). The test is stable to the expiry date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze. The Buffer is stable for 6 months after opening.

Sample Collection and Storage:
1. The Rubella IgM Rapid Test Device can be performed using whole blood, serum or plasma.
2. Separate serum or plasma from blood as soon as possible to avoid haemolysis. Use only clear, non-haemolysed samples.
3. Testing should be performed immediately after sample collection. Do not leave the samples at room temperature for prolonged periods. Serum and plasma samples may be stored at 2 - 8°C for up to 3 days. For long term storage, samples should be kept below -20°C.
4. Bring samples to room temperature prior to testing. Frozen samples must be completely thawed and mixed well prior to testing. Samples should not be frozen and thawed repeatedly.
5. To collect Fingerprick Whole Blood Samples:
   Wash the patient's hand 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. Draw up whole blood sample from the next drop formed into the dropper.
6. If samples are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

Assay Procedure:
Bring tests, samples, and/or controls to room temperature (15-30°C) before use.
1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results the assay should be performed immediately after opening the pouch.
2. Holding the dropper vertically draw up the sample up to the fill line in the dropper and then dispense one drop (approximately 20 µl) into the sample (S) well of the test device. Add 2 drops (approximately 80 µl) of Buffer to the sample well of the device and start the timer.
3. Wait for the coloured lines to appear. Read the result in 15 minutes, do not interpret the result after 20 minutes.

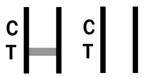


Interpretation of Results:



POSITIVE: Two coloured lines appear. One line appears at the control region (C) and another line develops at the test line (T).

NEGATIVE: Only one coloured line appears in the control region (C). No coloured line develops at the test line (T).



INVALID: Control line 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 colour at the test line will vary depending on the concentration of Rubella IgM present in the sample. Therefore, any shade of colour at the test line should be considered positive.

Quality Controls:

Internal procedural controls are included in the test. A coloured line appearing in the control region is considered an internal positive procedural control, confirming sufficient sample 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 result interpretation must be followed closely when testing the presence of Rubella IgM in samples from individual subjects. Failure to strictly follow the protocol may give inaccurate results.
2. The Rubella IgM Rapid Test Device is limited to the qualitative detection of Rubella IgM in whole blood, serum or plasma. Neither the quantitative value nor the rate of increase in the concentration of IgM antibody to Rubella can be determined.
3. The Rubella IgM Rapid Test Device will only indicate the presence of IgM antibody to Rubella and should not be used as the sole criteria for diagnosis, the results obtained with this test should be interpreted in conjunction with other diagnostic procedures and clinical findings.
4. If the test result is negative yet clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not rule out the possibility of Rubella infection.

Performance Characteristics:

Sensitivity and Specificity

The Rubella IgM Rapid Test Device (Whole Blood/Serum/Plasma) has been compared with leading commercial Rubella EIA tests, and the results show that this device has a high sensitivity and specificity.

Method		ELISA		Total Results
Rubella IgM Rapid Test Device	Result	Positive	Negative	
	Positive	57	3	30
	Negative	4	307	311
Total Results		61	310	371

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

Precision
Intra-Assay
Intra Assay precision has been determined by using 10 replicates of three samples: a negative, a low positive and a high positive. The samples were correctly identified >99 % of the time.
Inter-Assay
Inter Assay precision has been determined by 10 independent assays on the same three samples: a negative, a low positive and a high positive. Three different lots of the Rubella IgM Rapid Test Device (Whole Blood/Serum/Plasma) have been tested using these samples. The samples were correctly identified > 99 % of the time.

Cross-Reactivity
The Rubella IgM Rapid Test Device has been tested using samples positive for HAV, HBV, HCV, HIV, RF, Syphilis, *H. pylori*, CMV, Toxo, HSV1/2. The results showed no cross-reactivity of these disease markers in the assay.

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Interfering Substances

The following compounds have been tested using the Rubella IgM Rapid Test Device and no interference was observed at the concentrations below.

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. Mellinger AK, Cragan ID, Atkinson WL et al. High incidence of congenital rubella syndrome after a rubella outbreak. Pedi-tr Infect Dis J, 1995; 14: 573-575.
2. Herrman KL. Rubella virus. In: Lennette EH, Balows AC, Hausler WJ and Hadomy HJ eds. Manual of Clincal Microbiology. American Society for Microbiology. Washington. DC. Ch 76 1985; pp 779-754.

GLOSSARY OF SYMBOLS

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

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