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 or 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 test Rubella antigen is immobilized on the membrane within the test zone. During the test, the whole blood, serum or plasma added to the sample area (S) reacts with goat anti-human IgM coated particles in the test strip. The reaction mixture migrates up the membrane by capillary action and only anti-rubella IgM-particle complexes will bind with the antigen 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 will 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 and Rubella antigen. A Streptavidin-rabbit IgM is used in the control line region.

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

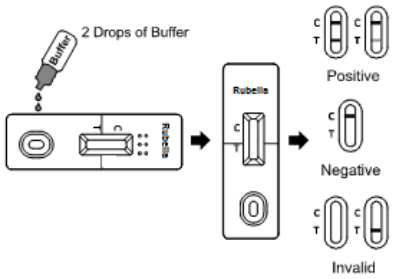
Materials not provided: Micropipette, Timer, Specimen collection container, Centrifuge

Precautions:
1. For professional in vitro diagnostic use only. Do not use after the expiration 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 to 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 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 specimens.
3. 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.
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. 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.
6. If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

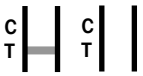
Assay Procedure:
Bring tests, specimens, and/or controls to room temperature (15-30°C) before use.
1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results the assay should be performed immediately after 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) area of the test device. Add 2 drops (approximately 80µl) 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 bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

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 Rubella IgM present in the specimen. 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 considered 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 Rubella IgM in serum or plasma from individual subjects. Failure to follow the procedures may give inaccurate results.
2. The Rubella IgM Rapid Test Device is limited to the qualitative detection of Rubella IgM in human serum or plasma. Neither the quantitative value or 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 preclude the possibility of Rubella infection.

Expected Values:
The Rubella IgM Rapid Test Device (Whole Blood/Serum/Plasma) has been compared with leading commercial Rubella EIA tests, demonstrating an overall accuracy of 98.1%.

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
Within-run precision has been determined by using 10 replicates of three specimens: a negative, a low positive and a high positive. The samples were correctly identified >99 % of the time.
Inter-Assay
Between-run precision has been determined by 10 independent assays on the same three specimens: 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 specimens. The specimens were correctly identified > 99 % of the time.

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Cross-Reactivity

The Rubella IgM Rapid Test Device has been tested using HAV, HBV, HCV, HIV, RF, Syphilis, *H. pylori*, CMV, Toxo, HSV1/2 positive samples and the results showed no cross-reactivity.

Interfering Substances

The following compounds have been tested using the Rubella 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. Melinger 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	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		Do not reuse

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