Rubella IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma)

Package Insert

REF IRGM-425	English

A rapid test for the qualitative detection of IgG and IgM antibodies to Rubella in human whole blood, serum or plasma.

For professional in vitro diagnostic use only.

【INTENDED USE】

The Rubella IgG/IgM Combo Rapid Test Cassette is a lateral flow chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to Rubella in whole blood, serum or plasma to aid in the diagnosis of Rubella infection.

【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 maternal infection could be transmitted through the placenta to the fetus, causing congenital rubella. Primary rubella infection contracted during early pregnancy, may have severe consequences as severe fetal damage, stillbirth or abortion. Children born asymptomatic may develop these abnormalities later in life.[1,2] Widespread vaccination has significantly reduced the incidence of rubella in all age groups. However, 10 to 20% of young adults still appear susceptible to the virus. To reduce risk of severe complications, accurate serological methods must be performed to determine the serologic status of childbearing aged women. The Rubella IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to rubella virus in whole blood, serum or plasma specimens.

【PRINCIPLE】

The Rubella IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of IgG and IgM antibodies to Rubella in whole blood, serum or plasma specimens. In this test, Rubella Antigen is coated in the test line regions of the test. During testing, the whole blood, serum or plasma specimen reacts with mouse anti-human IgG or goat anti-human IgM coated particles in the test strip. The mixture then migrates forward on the membrane by capillary action and reacts with the Rubella Antigen 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 Rubella infection, 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 two strips indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test contains goat anti-human IgM, mouse anti-human IgG and Rubella antigen. A streptavidin-IgG is 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 Rubella IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood.
- 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 fingerstick 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
- Buffer
- Droppers
- Package Insert

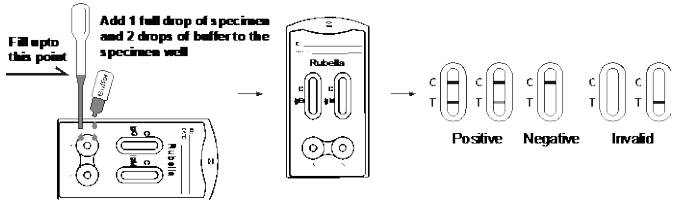
Materials Required But Not Provided

- Specimen Collection Containers
- 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.

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:* Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the test line region.

***NOTE:** The intensity of the color in the test line regions may vary depending on the concentration of Rubella antibodies present in the specimen. Therefore, any shade of color in the test line region should be considered positive.

NEGATIVE: **One colored line appears in the control line region (C).** No line appears in the test line regions.

INVALID: **Control line fails to appear**. 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】

Internal procedural controls are included in the test individually for both two sections. Two colored lines appearing in control line regions (C) for both two 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 a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

4. The Rubella IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for detection of IgM and IgG antibodies to Rubella in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of IgM and IgG antibodies to Rubella can be determined by this qualitative test.
5. The Rubella IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of IgM or IgG antibodies to Rubella in the specimen and should not be used as the sole criteria for the diagnosis of Rubella infections.
6. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
7. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of Rubella infection.

【EXPECTED VALUES】

The Rubella IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with leading commercial EIA Rubella tests, demonstrating an overall accuracy of 97%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The Rubella IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) was compared with leading commercial EIA Rubella tests; the results show that Rubella IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) has a high sensitivity and specificity.

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%)

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%)

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 negative, low positive, and high positive values 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 IgG/IgM Combo Rapid Test cassette (Whole Blood/Serum/Plasma) have been tested over a 10-days period using negative, low positive, and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-Reactivity

The Rubella IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested for HAV, HBV, HCV, HIV, RF, Syphilis, *H. Pylori*, CMV, TOXO, HSV 1/2 positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have also been tested using the Rubella IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) 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. Mellinger AK, Cragan ID. Atkinson WL et al. High incidence of congenital rubella syndrome after a rubella ourbreak. Pedi~tr Infect Dis J 1995:14:573-5
2. Herrman KL: Rubella virus In: Lennette EH, Balows Ac Hausler WJ, and Shadomy HJ eds., Manual ofClinical Microbiology'. American Society for Microbiolog, Washington, DC. Ch. 76. pp.779-754. 1985.

Index of Symbols

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

Hangzhou AllTest Biotech Co., Ltd.
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