Rubella IgG/IgM Rapid Test Cassette (Serum/Plasma)

Package Insert

REF IRGM-302	English

A rapid test for the qualitative detection of IgG and IgM antibodies to Rubella in human serum or plasma.
For professional in vitro diagnostic use only.

INTENDED USE

The Rubella IgG/IgM Rapid Test Cassette is a lateral flow chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to Rubella in 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 Rapid Test Cassette (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to rubella virus in serum or plasma specimens.

PRINCIPLE

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

REAGENTS

The test contains anti-human IgM, anti-human IgG and Rubella antigen. A goat anti-mouse 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 Rapid Test Cassette (Serum/Plasma) can be performed using 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.
- EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium can be used as the anticoagulant tube for collecting the blood specimen.

MATERIALS

Materials provided

- Test Cassettes
- Droppers
- Package Insert
- Buffer

Materials required but not provided

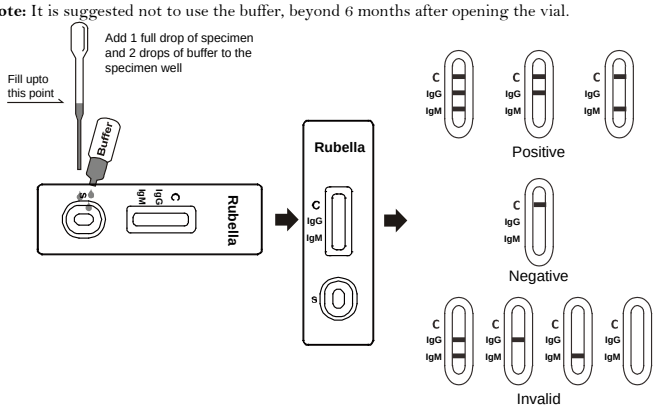
- Specimen Collection Containers
- Centrifuge (for plasma only)
- Timer

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 sealed pouch and used it within one hour. Best results will be obtained if the assay is performed immediately after opening sealed pouch.
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 sample well, then add **2 drops of buffer (approximately 80µL)** to 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.

Note: It is suggested not to use the buffer, beyond 6 months after opening the vial.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE:* Two or three lines appear. One colored line should always appear in the control line region (C) and another one or two apparent colored line(s) should be in the test line region(s) (IgM and/or IgG).

IgM Positive: One colored should be in the control line region (C), another line appears in IgM test line region. It indicates a positive test result for IgM antibody to Rubella.

IgG Positive: One colored should be in the control line region (C), another line appears in IgG test line region. It indicates a positive test result for IgG antibody to Rubella.

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

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

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. A colored line appearing in the control region (C) is an internal positive 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

1. The Rubella IgG/IgM Rapid Test Cassette (Serum/Plasma) is for in vitro diagnostic use only. This test should be used for detection of IgM and IgG antibodies to Rubella in 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.
2. The Rubella IgG/IgM Rapid Test Cassette (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.
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 at any time does not preclude the possibility of Rubella infection.

EXPECTED VALUES

The Rubella IgG/IgM Rapid Test Cassette (Serum/Plasma) has been compared with leading commercial ELISA Rubella tests, demonstrating an overall accuracy of 97.7%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

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

Method		Rubella ELISA (IgM)		Total Results
Rubella IgG/IgM Rapid Test Cassette for IgM	Results	Positive	Negative	
	Positive	33	3	36
	Negative	2	262	264
Total Results		35	265	300

Relative Sensitivity: 94.3% (95%CI*: 80.8%-99.3%) *Confidence Interval
Relative Specificity: 98.9% (95%CI*: 96.7%-99.8%)
Overall Accuracy: 98.3% (95%CI*: 96.2%-99.5%)

Method		Rubella ELISA (IgG)		Total Results
Rubella IgG/IgM Rapid Test Cassette for IgG	Results	Positive	Negative	
	Positive	32	4	36
	Negative	3	261	264
Total Results		35	265	300

Sensitivity: 91.4% (95%CI*: 76.9%~98.2%) *Confidence Interval
Specificity: 98.5% (95%CI*: 96.2%~99.6%)
Accuracy: 97.7 %(95%CI*: 95.3%~99.1%)

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 Rapid Test cassette (Serum/Plasma) have been tested over a 3-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 Rapid Test Cassette (Serum/Plasma) has been tested for anti-HAV IgG, anti-HBV IgG, anti-HCV IgG, anti-HIV IgG, anti-RF IgG, anti-Syphilis IgG, anti-*H. Pylori* IgG, anti-CMV IgG, TOXO IgG, anti-HSV 1 IgG and anti-HSV 2 IgG positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have also been tested using the Rubella IgG/IgM Rapid Test Cassette (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 of Clinical 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		Consult Instructions For Use
	Do not use if package is damaged		Manufacturer		

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