

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 Rapid Test 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 Rapid Test (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.

PRINCIPLES

The Rubella IgG/IgM Rapid Test (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, anti-human IgG and anti-human IgM are coated in the test line regions of the test. During testing, the whole blood, 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 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.

MATERIALS

Materials provided

- Test Cassettes
- Droppers
- Package Insert
- Buffer
- Specimen Collection Containers
- Centrifuge
- Timer

WARNINGS AND 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 (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.
- Add the Fingerstick Whole Blood specimen to the test by using **a capillary tube**:
 - Touch the end of the capillary tube to the blood until filled to approximately 20 µL. Avoid air bubbles.
 - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the test cassette.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- 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.
- EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium can be used as the anticoagulant tube for collecting the blood specimen.

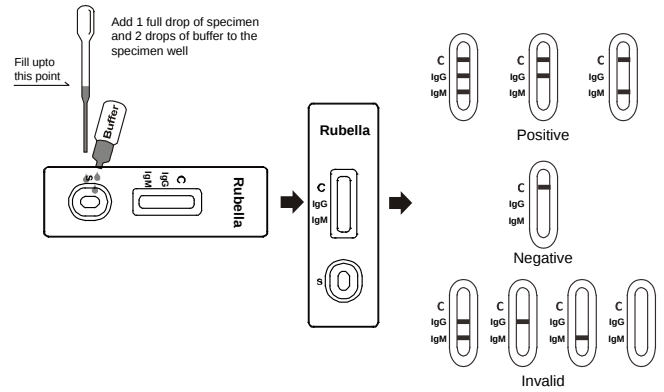
DIRECTIONS FOR USE

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. 20 µL)** of specimen to sample well, then add **2 drops of buffer (approximately 80 µL)** 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 colored lines appear.** One colored line should always appear in the control line region (C) and another one or two colored line(s) should be in the test line region(s) (IgM and/or IgG).

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

IgG Positive: **One colored line should be in the control line region (C), another colored line appears in IgG 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 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 (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.
2. The Rubella IgG/IgM Rapid Test (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.
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.
5. The hematocrit of the whole blood should be between 25% and 65%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

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

Method	Rubella ELISA (IgM)		Total Results
	Positive	Negative	
Rubella IgG/IgM Rapid Test for IgM	57	3	60
	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 ELISA (IgG)		Total Results
	Positive	Negative	
Rubella IgG/IgM Rapid Test for IgG	56	4	60
	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%)

Limitation of Detection

The minimum detection level is 1:8 for Rubella IgM positive specimen and 1:16 for Rubella IgG positive specimen.

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 (Whole Blood/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 (Whole Blood/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 (Whole Blood/Serum/Plasma) 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: 1,000 mg/dL	Salicylic Acid: 20 mg/dL	Phenothiazine: 20 mg/dL

BIBLIOGRAPHY

- Mellinger AK, Cragan ID, Atkinson WL et al. High incidence of congenital rubella syndrome after a rubella outbreak. *Pediatrics Infect Dis J* 1995;14:573-5
- Herrman KL: Rubella virus In: Lennette EH, Balows Ac Hausler WJ, and Shadomy HJ eds., *Manual of Clinical Microbiology*. American Society for Microbiology, Washington, DC. Ch. 76. pp.779-754. 1985.

INDEX OF SYMBOLS

	Consult instructions for use		Contains sufficient for <n> tests
	<i>In vitro</i> diagnostic medical device		Use-by date
	Temperature limit		Batch code
	Do not use if package is damaged		Manufacturer
	Catalogue number		Do not re-use



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