Rubella IgG/IgM Rapid Test Package Insert

Cat: IRU-422 **Specimens:** Whole Blood/Serum/Plasma
Version: 03 **Effective Date:** 2024-07

For professional *in vitro* diagnostic use only.

INTENDED USE

The Rubella IgG/IgM Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies (IgG and IgM) to Rubella (Virus) in Whole Blood /Serum / Plasma to aid in the diagnosis of RV infection. The test is based on immunochromatography and can give a result within 15 minutes.

INTRODUCTION

Rubella is a herpes virus. Generally, rubella is considered a mild adolescence disease. However, a maternal infection could be transmitted through the placenta to the fetus, causing congenital rubella. Congenital rubella may result in chronic cardiac disease, growth retardation, hepatosplenomegaly, malformations and other severe anomalies. Children born asymptomatic may develop these abnormalities later in life. To reduce the risk of such severe complications, accurate serological methods must be performed to determine the serologic status of childbearing aged women. The presence of rubella specific IgG in the bloodstream attests immunity to rubella. A woman tested to be non-immune can be educated on the availability of vaccination. An increase in rubella IgG denotes an acute infection and differentiates rubella from other exanthematous diseases. Expecting women with current rubella infection should be counseled on the consequences of congenital infection.

PRINCIPLE

The Rubella IgG/IgM Rapid Test is a qualitative membrane strip based immunoassay for the detection of RV antibodies (IgG and IgM) in Whole Blood /Serum / Plasma. The test device consists of: 1) a burgundy colored conjugate pad containing RV recombinant envelope antigens conjugated with Colloid gold (RV conjugates) and rabbit IgG-gold conjugates,2) a nitrocellulose membrane strip containing two test bands (T1 and T2 bands) and a control band (C band). The T1 band is pre-coated with the antibody for the detection of IgM anti-RV, T2 band is coated with antibody for the detection of IgG anti-RV, and the C band is pre-coated with goat anti rabbit IgG. When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. IgG anti-RV, if present in the specimen, will bind to the RV conjugates. The immunocomplex is then captured by the reagent pre-coated on the T2 band, forming a burgundy colored T2 band, indicating a RV IgG positive test result and suggesting a recent or repeat infection. IgM anti-RV if present in the specimen will bind to the RV conjugates. The immunocomplex is then captured by the reagent coated on the T1 band, forming a burgundy colored T1 band, indicating a RV IgM positive test result and suggesting a fresh infection. Absence of any T bands (T1 and T2) suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on any of the T bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

KIT COMPONENTS

Individually packed test devices	Each device contains colored conjugates and reactive reagents pre-spreaded at the corresponding regions
Droppers	For adding specimens use
Buffer	Phosphate buffered saline and preservative
Package insert	For operation instruction

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Handle all specimens as if they contain infectious agents.
- Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Follow standard biosafety guidelines for handling and disposal of potential infective material.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device 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 (from venipuncture or fingerstick), serum or plasma.
- 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.
  - 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 Fingersitck Whole Blood specimen to the test device by using a capillary tube or hanging drop.
- 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. 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. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. 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.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

MATERIALS

Materials Provided

- Test devices
- Buffer
- Droppers
- Package insert

Materials Required But Not Provided

- Specimen collection containers
- Centrifuge
- Lancets (for fingerstick whole blood only)
- Timer
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

DIRECTIONS FOR USE

Allow the test, specimen, buffer and/or controls to reach room temperature 15-30℃ (59-86℉) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface.
3. Hold the dropper vertically and transfer 1 drop of specimen (approximately 10µl) to the specimen well(S) of the test device, then add 2-3 drops of buffer (approximately 80µl-120µl) and start the timer. See illustration below.
4. Wait for the colored line(s) to appear. Read results at 15 minutes. Do not interpret the result after 20 minutes.

Notes:

Applying sufficient amount of specimen is essential for a valid test result. If migration (the wetting of membrane) is not observed in the test window after one minute, add one more drop of buffer to the specimen well.

INTERPRETATION OF RESULTS

POSITIVE RESULT:



IgM Positive:* The colored line in the control line region (C) appears and a colored line appears in test line region 1 (T1). The result is positive for Rubella virus specific-IgM antibodies and is indicative of primary Rubella infection.



IgG Positive:* The colored line in the control line region (C) appears and a colored line appears in test line region 2 (T2. The result is positive for Rubella virus specific-IgG and is probably indicative of secondary Rubella infection.



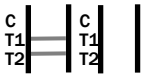
IgG and IgM Positive:* The colored line in the control line region (C) appears and two colored lines should appear in test line regions 1 and 2 (T1 and T2). The color intensities of the lines do not have to match. The result is positive for IgG & IgM antibodies and is indicative of secondary Rubella infection.

NEGATIVE RESULT:



The colored line in the control line region (C) appears. No line appears in test line regions 1 or 2 (T1 or T2).

INVALID RESULT:



Control line (C) falls to appear. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

NOTE:

1. The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered positive. Besides, the substances level cannot be determined by this qualitative test.
2. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms 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

1. The Rubella IgG/IgM Rapid Test is for in vitro diagnostic use only. The test should be used for the detection of RV antibodies in Whole Blood /Serum / Plasma specimens only. Neither the quantitative value nor the rate of increase in RV antibodies can be determined by this qualitative test.
2. The Rubella IgG/IgM Rapid Test will only indicate the presence of RV antibodies in the specimen and should not be used as the sole criteria for the diagnosis of RV infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of RV infection.

EXPECTIED VALUES

The Rubella IgG/IgM Test has been compared with a reference ELISA, demonstrating an overall Rubella IgM Rapid Test accuracy of 98.6%,demonstrating an overall Rubella IgG Rapid Test accuracy of 98.7%.

PERFORMANCE CHARACTERISTICS

1. Clinical Performance For IgM Test

A total of 146 patient samples from susceptible subjects were tested by the Rubella IgG/IgM Rapid Test and by a reference ELISA. Comparison for all subjects is showed in the following table:

	Rubella IgM Rapid Test		
ELISA Results	**Positive**	**Negative**	**Total**
Positive	42	2	44
Negative	0	102	102
Total	42	104	146

Relative Sensitivity: 95.5% (84.53%~99.44%)
Relative Specificity: >99.9% (96.45%~100%)
Overall Agreement: 98.6% (95.14%~99.83%) 95%CI

2. Clinical Performance For IgG Test

A total of 156 patient samples from susceptible subjects were tested by the Rubella IgG/IgM Rapid Test and by a reference ELISA. Comparison for all subjects is showed in the following table:

	Rubella IgG/IgM Rapid Test		
ELISA Results	**Positive**	**Negative**	**Total**
Positive	54	0	54
Negative	2	100	102
Total	56	100	156

Relative Sensitivity: >99.9% (93.4%~100%)
Relative Specificity: 98.0% (93.1%~99.76%)
Overall Agreement: 98.7% (95.45%~99.84%) 95%CI

PRECISION

Intra-Assay

Within-run precision has been determined by using replicates of 10 tests for each of three lots using Rubella IgG/IgM specimen levels at negative, low positive sample and medium positive sample. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 3 independent assays on the same five specimens: negative, low positive sample and medium positive sample of Rubella IgG/IgM. Three different lots of the Rubella IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) have been tested using these specimens. The specimens were correctly identified >99% of the time.

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