Rapid Response®

Rubella Test Cassette
(Whole Blood/Serum/Plasma)

REF RUB-13C
RUB-13C25
RUB-13C40

Product Insert

A rapid test for the qualitative monitoring of IgG and IgM antibodies to Rubella in human whole blood, serum or plasma, for patients who have an existing, diagnosed Rubella infection.

For professional laboratory *in vitro* diagnostic use only.

Intended Use

The Rapid Response® Rubella Test Cassette is a lateral flow chromatographic immunoassay for the qualitative monitoring of IgG and IgM antibodies to Rubella in whole blood, serum or plasma specimens, for patients who have an existing, diagnosed Rubella infection.

Summary

The relationship between rubella virus infection and perinatal adverse outcomes has been widely regarded. Generally speaking, Rubella virus infection in pregnant women is a rash disease that causes a mild degree of fever and can heal itself without treatment. However, once the rubella virus is vertically transmitted from the placenta to the fetus during pregnancy, it can lead to serious adverse pregnancy outcomes and the occurrence of birth defects, and even congenital rubella syndrome (CRS) in newborns.[1] Symptoms of CRS include blindness, deafness, congenital heart disease, and mental retardation. Positive RV-IgM indicated acute RV infection, and significantly elevated RV-IgG titer also indicated acute RV infection.[2]
The Rapid Response® Rubella Test Cassette is a rapid chromatographic immunoassay for the qualitative monitoring of IgG and IgM antibodies to Rubella in whole blood, serum or plasma specimens, for patients who have an existing, diagnosed Rubella infection.

Principle

The Rapid Response® Rubella Test Cassette is a qualitative, lateral flow immunoassay for the detection of Rubella virus IgM and Rubella virus IgG antibodies in whole blood, serum or plasma. Each test consists of two components, an IgG component and an IgM component. In the IgG component, mouse anti-human IgG is coated in IgG test line region. During testing, the specimen reacts with Rubella virus antigen-coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the mouse anti-human IgG in the IgG test line region. If the specimen contains IgG antibodies to Rubella virus, a coloured line will appear in the IgG test line region. In the IgM component, mouse anti-human IgM is coated in IgM test line region. During testing, IgM antibodies to Rubella virus, if present in the specimen, reacts with the Rubella virus antigen-coated particles in the test cassette, and this complex is captured by the mouse anti-human IgM, forming a coloured line in IgM test line region.
Therefore, if the specimen contains IgG antibodies to Rubella virus, a coloured line will appear in IgG test line region. If the specimen contains IgM antibodies to Rubella virus, a coloured line will appear in the IgM test line region. If the specimen does not contain IgG and IgM antibodies to Rubella virus, no coloured line will appear in either of the test line regions, indicating a negative result.
Whether or not the IgG or IgM antibodies to Rubella virus are present in the sample, the Chicken IgG conjugated with colloid gold is bound to Goat anti-Chicken IgG in the membrane quality control zone (C) during chromatography, where a coloured line appears. The coloured line displayed in the quality control area (C) is the standard for determining whether there are enough specimens and whether the chromatographic process is normal. It also serves as the internal control standard for reagents.

Reagents

The test contains particles coated with mouse anti-human IgG and mouse anti-human IgM antibodies and Rubella virus antigens coated on the membrane. Chicken IgG and goat anti chicken IgG employed in the control line region.

Precautions

- For professional laboratory *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure 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.
- The used tests, specimens and potentially contaminated material should be discarded according to the local regulations.
- Humidity and temperature can adversely affect results.

Materials

Materials provided

- Test cassettes
- Droppers
- Buffer
- Product insert

Materials required but not provided

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

Storage and Stability

The kit can be stored at room temperature or refrigerated 35.6-86°F (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

Specimen Collection and Preparation

- The Rapid Response® Rubella Test Cassette can be performed using whole blood, 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.
  - 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 50 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 the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 35.6-46.4°F (2-8°C) for up to 3 days and stored at -4°F (-20°C) for up to 3 months. Whole blood collected by venipuncture should be stored at 35.6-46.4°F (2-8°C) if the test is to be run within 2 days of collection. Do not freeze whole blood specimens.
- 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.

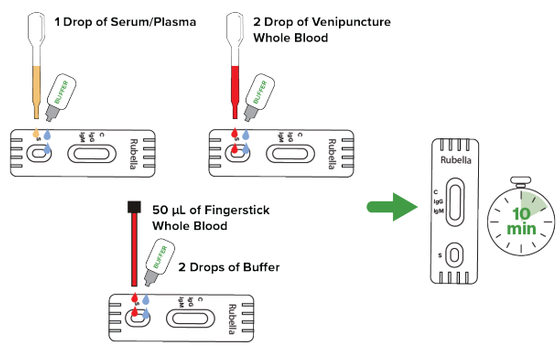
Test Procedure

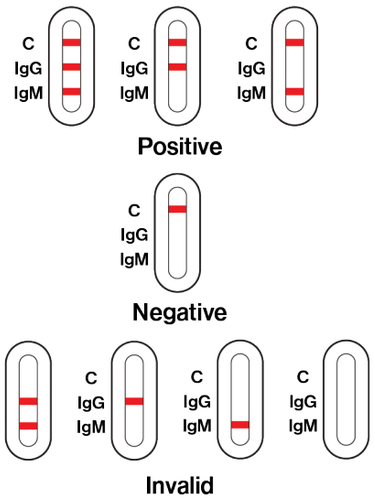
Allow the test, specimen, buffer and/or controls to reach room temperature (59-86°F; 15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
2. Place the cassette on a clean and level surface.
   For **Serum or Plasma** specimen:
   - Hold the dropper vertically and transfer **1 drop of serum or plasma (approximately 25µL)** to the specimen area, then add **2 drops of buffer (approximately 80 µL)** and start the timer. See illustration below.

   For **Venipuncture Whole Blood** specimen:
   - Hold the dropper vertically and transfer **2 drops of whole blood (approximately 50µL)** to the specimen area, then **add 2 drops of buffer (approximately 80µL)** and start the timer. See illustration below.

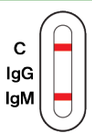
   For **Fingerstick Whole Blood** specimen:
   - To use a capillary tube: Fill the capillary tube and transfer **approximately 50µL of fingerstick whole blood** specimen to the specimen area of test cassette, then add **2 drops of buffer (approximately 80µL)** and start the timer. See illustration below.
3. Wait for the coloured line(s) to appear. Read results at 10 minutes. Do not interpret the result after 20 minutes.



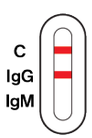


Results Interpretation

Positive



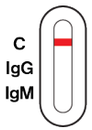
Rubella IgM Positive: One coloured line should be in the control line region (C), and another line appears in IgM region. It indicates a positive test result for IgM antibodies to Rubella virus.



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

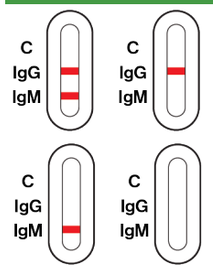
***Note:** The intensity of the colour in IgG and/or IgM test line region (G and M) will vary depending on the concentration of IgG/IgM antibodies present in the specimen. Therefore, any shade of colour in the IgG and/or IgM test line region (G and M) should be considered positive.

Negative



One coloured line appears in the control line region (C) of every section. No line appears in IgG and IgM test line region (G and M). It indicates a negative test result for IgG/IgM antibodies to Rubella virus.

Invalid



Control line fails to appear in any section. 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

An internal procedural control is included in the test. A coloured line appearing in the control line region (C) is an internal valid procedural control, confirming adequate membrane wicking. 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 Rapid Response® Rubella Test Cassette is for professional laboratory *in vitro* diagnostic use only, and is not intended for the diagnosis of Rubella infections. This test should be used for detection of IgG/IgM antibodies to Rubella virus in whole blood, serum or plasma specimens from patients who have an existing Rubella infection diagnosed through a different method. Neither the quantitative value nor the rate of increase in the concentration of IgG/IgM antibodies to Rubella virus can be determined by this qualitative test.
2. The Rapid Response® Rubella Test Cassette will only indicate the presence of IgG/IgM antibodies to Rubella virus in the specimen and should not be used as the sole criteria for the monitoring of Rubella virus infections for which the positive result is obtained.
3. In the early onset of infection, IgM antibodies concentrations may be below detectable levels.
4. The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy.
5. Results from immunosuppressed patients should be interpreted with caution.
6. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
7. Negative results do not rule out Rubella virus infections. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
8. Not for the screening of donated blood.

Performance Characteristics

Sensitivity and Specificity

Item		ELISA		Total Result
Rapid Response® Rubella Test Cassette (for IgG antibody)	Result	Positive	Negative	
	Positive	137	0	137
	Negative	7	156	163
Total Result		144	156	300

Relative Sensitivity: 137/144=95.14% (95%*CI:90.24%~98.02%);
Relative Specificity: 156/156=100% (95%*CI:98.09%~100.0%);
Accuracy: 293/300= 97.66% (95%*CI:95.25%~99.05%);
*CI means confidence interval.

Item		ELISA		Total Result
Rapid Response® Rubella Test Cassette (for IgM antibody)	Result	Positive	Negative	
	Positive	40	0	40
	Negative	0	260	260
Total Result		40	260	300

Relative Sensitivity: 40/40=100.0% (95%*CI:92.78%~100.0%);
Relative Specificity: 260/260=100.0% (95%*CI:98.85%~100.0%);
Accuracy: 300/300=100.0% (95%*CI: 99.0%~100.0%);
*CI means confidence interval.

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of the specimens containing negative, low, middle and high IgG/IgM positive of Rubella. The negative, low, middle and high IgG/IgM positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by using the specimens of negative, low, middle and high IgG/IgM positive of Rubella in 10 independent assays. Three different lots of Rapid Response® Rubella Test Cassette have been tested using negative, low, middle and high IgG/IgM positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The Rapid Response® Rubella Test Cassette has been tested for HAV, HIV, HBsAg, HBsAb, HbeAg, HBeAb, HBcAb, HEV, Syphilis, Rheumatoid Factor (RF), HAMA, MONO, anti-CMV, anti-TOXO, anti-HSV, TB, Dengue, AFP, CEA. The results showed no cross-reactivity.

Bibliography

1. Liang L Z. Overview of rubella and its prevention and control strategies [J]. Internal Medicine, 2019,15(4):452-455. (in Chinese)
2. He Jing, Hong Yanyu. Diagnosis and management of rubella virus infection in pregnancy [J]. Journal of Practical Obstetrics and Gynecology,2018,34(12):892-894. (in Chinese)
3. ZHANG Mingfang, Sun Guowei, Zhao Nannan, Wang Yifan. Significance of TORCH item detection in neonates [J]. Journal of Practical Laboratory Medicine,202,14(3):295-298. (in Chinese).

Glossary of Symbols

Consult instructions for use
Test per Kit
Do Not Reuse
Store between 35.6°F to 86°F (2-30°C)
Use by
REF Catalogue #
LOT Lot Number
IVD For *in vitro* diagnostic use only
Manufacturer
Do not use if package is damaged

BTNX Inc.
722 Rosebank Road,
Pickering, ON L1W 4B2
Canada
Technical Support: 1-888-339-9964