# RUBELLA IgG/IgM

(Serum/Plasma)

# IMMUNOPAK

Last update 10-2020

Ref. RDT-RBL.117, 25 Test

## INTENDED USE

The Rubella IgG/IgM Rapid Card Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies (IgG and IgM) to Rubella (Virus) in Serum/Plasma. It provides an aid in the diagnosis of infection with RV.

## INTRODUCTION

Rubella is an acute respiratory infection caused by the rubella virus (RV), including congenital infection and acquired infection. Clinical features include short precursors, low fever, rash, and occipital lymph node enlargement. The general condition is mild, the course of the disease is short and the prognosis is good. But rubella is very easy to cause outbreaks, which can happen throughout the year, with many diseases in winter and spring. The susceptible age is mainly 1~5 years old. So the prevalence is prevalent in preschool children. Although the clinical symptoms are mild, the virus can infect the fetus through the fetal blood barrier. Both overt and non-dominant infection can lead to congenital rubella syndrome (CRS), such as congenital fetal malformation, stillbirth, premature birth, etc. Therefore, the early diagnosis and prevention of Rubella are very important.

## PRINCIPLE

The Rubella IgG/IgM Rapid Test Card is a qualitative membrane strip based immunoassay for the detection of RV antibodies (IgG and IgM) in Serum/Plasma. The test cassette consists of: 1) a pink-purple 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 lines (IgM and IgG lines) and a control line (C line). The IgM line is pre-coated with the antibody for the detection of IgM anti-RV, IgG line is coated with antibody for the detection of IgG anti-RV, and the C line 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 nitrocellulose membrane. 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 IgG line, forming a pink-purple colored IgG line, 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 IgM line, forming a pink-purple colored IgM line, indicating a RV IgM positive test result and suggesting a fresh infection. Absence of any T lines (IgM and IgG) suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

## PRESENTATION

| | 25 Tests |
|---|---|
| Rubella IgG/IgM Test Card | 25 Cards |

## PRECAUTION

- For in vitro diagnostic use only.
- For healthcare professionals and professionals at point of care sites.
- Do not use after the expiration date.
- Please read all the information in this leaflet before performing the test.
- The test cassette should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test cassette should be discarded according to federal, state and local regulations.

## STORAGE & STABILITY

- Store as packaged in the sealed pouch at temperature 2°C-40℃. The kit is stable within the expiration date printed on the labeling.
- Once open the pouch, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.
- The LOT and the expiration date were printed on the labeling.

## SPECIMEN COLLECTION AND STORAGE

- The test can be used to test Serum/Plasma specimens.
- To collect serum or plasma specimens following regular clinical laboratory procedures.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Store specimens at 2°C-8℃, if not tested immediately. Store specimens at 2°C-8℃ up to 7 days. The specimens should be frozen at -20℃ for longer storage.
- Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.
- Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

## TEST PROCEDURE

Allow the test device and specimens to equilibrate to temperature 15°C-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 as soon as possible.
2. Place the test cassette 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 cassette, then add 2 drops of buffer (approximately 70µl) and start the timer. See the illustration.
4. 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.

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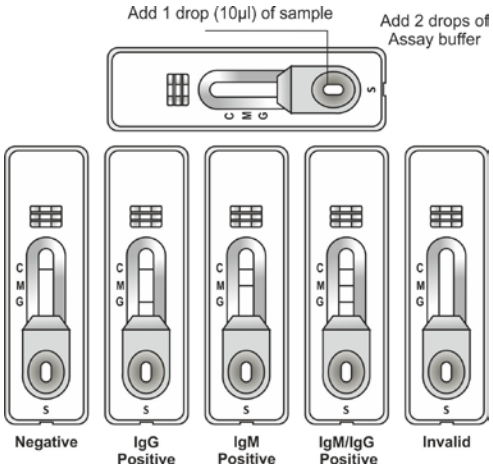


## INTERPRETATION OF RESULTS

- **Negative**
  The control line is only visible on the test device. No Rubella Specific IgG and IgM antibodies were detected.
- **IgG Positive**
  The control line (C) and IgG line (G) are visible on the test device. This is positive for IgG antibodies. This is indicative of a recent or repeat Rubella infection.
- **IgM Positive**
  The control line (C) and IgM line (M) are visible on the test device. This is positive for IgM antibodies to Rubella virus. This is indicative of a primary Rubella infection.
- **IgG and IgM Positive**
  The control line (C), IgM (M) and IgG (G) are visible on the test device. This is positive for both IgM and IgG antibodies. This is indicative of a late primary or early secondary Rubella infection.
- **Invalid**
  The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques may be reason for control line failure. Repeat the test using a new test device.

## LIMITATIONS

- The Rubella IgG/IgM Rapid Card Test is limited to provide a qualitative detection. The intensity of the test line does not necessarily correlate to the concentration of the antibody in the blood.
- The results obtained from this test are intended to be an aid in diagnosis only. Each physician must interpret the results in conjunction with the patient's history, physical findings, and other diagnostic procedures.
- A negative test result indicates that antibodies to IgG and IgM antibodies to Rubella virus (Rubella) are either not present or at levels undetectable by the test.

## PERFORMANCE CHARACTERISTICS

### Accuracy

A statistical comparison for IgM was made between the results yielding a clinical relative sensitivity: 96.8%, relative specificity: 98.0%, overall agreement: 97.6%. A statistical comparison for IgG was made between the results yielding a clinical relative sensitivity: 97.4%, relative specificity: 98.5%, overall agreement: 98.1%.

### Cross-Reactivity and Interference

1. Other common causative agents of infectious diseases were evaluated for cross reactivity with the test. Some positive serum specimens of other common infectious diseases were spiked into the positive and negative specimens and tested separately. No cross reactivity was observed with specimens from patients infected with HIV, HAV, HTLV, HCV and TP.
2. Potentially cross-reactive endogenous substances including common serum components, such as lipids, hemoglobin, bilirubin, were spiked at high concentrations into the positive and negative specimens and tested, separately. No cross reactivity or interference was observed to the device.

| Analytes | Conc. | Specimens | |
|---|---|---|---|
| | | Positive | Negative |
| Albumin | 20mg/ml | + | - |
| Bilirubin | 20µg/ml | + | - |
| Hemoglobin | 15mg/ml | + | - |
| Glucose | 20mg/ml | + | - |
| Uric Acid | 200µg/m l | + | - |
| Lipids | 20mg/ml | + | - |

3. Some other common biological analytes were spiked into the positive and negative specimens and tested separately. No significant interference was observed at the levels listed in the table below.

| Analytes | Conc. (µg/ml) | Specimens | |
|---|---|---|---|
| | | Positive | Negative |
| Acetaminophen | 200 | + | - |
| Acetoacetic Acid | 200 | + | - |
| Acetylsalicylic Acid | 200 | + | - |
| Ampicillin | 200 | + | - |
| Ascorbic Acid | 200 | + | - |
| Atropine | 200 | + | - |
| Benzoylecgonine | 100 | + | - |
| Caffeine | 200 | + | - |
| EDTA | 800 | + | - |
| Ethanol | 1.0% | + | - |
| Gentisic Acid | 200 | + | - |
| ß - Hydroxybutyrate | 20,000 | + | - |
| Methanol | 10.0% | + | - |
| Phenothiazine | 200 | + | - |
| Phenylpropanolamine | 200 | + | - |
| Salicylic Acid | 200 | + | - |
| Tetracycline | 200 | + | - |

## REFERENCES


1. Bardeletti G, Kessler N, Aymard-Henry M, Morphology, biochemical analysis and neuraminidase activity of rubella virus. Arch. Virol ; 1975 49 (2–3): 175–86.
2. Ryan KJ, Ray CG (editors) ,Sherris Medical Mi crobiology (4th ed.). McGraw Hill. pp; 2004 556; 566–9.



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