One Step Rubella Virus (RV) IgM Rapid Test

（Colloidal Gold Chromatography）

【Introduction】

Rubella virus is a member of the *Togaviridae* family, found mainly in human populations. Rubella (also called German measles or 3-day measles) is a disease caused by the rubella virus. In general, infection will manifest itself as a benign and self-limiting disease, characterized by a maculopapular rash *(German measles)*, slight fever and lymphadenopathy. Mild transient arthralgia and arthritis may occasionally occur.

Rubella spreads from person to person through the air (often through close contact such as talking, coughing, or sneezing) and is moderately contagious. Although rubella can strike people of all ages, it poses the greatest danger to unborn babies. Congenital rubella syndrome (CRS) occurs when the rubella virus attacks a developing fetus. Up to 85% of infants infected during the first trimester will be born with birth defects, including deafness, blindness, heart defects, and mental retardation. Miscarriages are also common. Growth retardation and diabetes mellitus have also been associated with late complications of congenital rubella.

In acute infection, specific IgM antibodies to rubella virus appear as the rash fades, and generally do not persist beyond 4-5 weeks. IgM antibodies may also appear following re-infection, after vaccination and there is a possibility of reactivation of IgM following polyclonal stimulation of the immune system. Determination of rubella IgM antibody, therefore, is particularly useful for the effective distinction between recent infection or vaccination, and acquired immunity.

Production of rubella IgM antibodies by congenitally infected infants may last for about one year post partum. Measurement of specific IgM antibody in the newborn enables the diagnosis of congenital rubella virus infection.

【Principle】

Based on the principle of Gold Immunochromatography Assay (GICA), this Rubella virus (RV) IgM rapid test cassette uses RV recombinant antigen and anti-human IgM monoclonal antibody to detect RV IgM antibody in the human serum samples with high sensitivity and specificity.

During the testing process, if there is RV IgM in the specimen added, these antibodies will react with the anti-human RV IgM monoclonal antibody in the membrane strip, chemical complexes will form. These complexes move along the strip chromatographically to the test region (T), where these complexes will be captured by the pre-coated recombinant RV antigen. Then a red or pink line will appear, indicating a positive result. The unbounded complex moves on to the control region (C), where they are captured by the anti-mouse antibody, and a red or pink line will appear, indicating the assay is a valid one. So the control line provides an inner quality control mechanism.

【Materials Provided】

Each test cassette is packed in a single aluminum pouch with silicon gel for long time storage, 25 cassettes per outer box;

Instruction for Use: one copy.

【Specimen Collection & Preparation】

Collect the patient’s venous blood and let it contract in a natural way. Then centrifuge and collect the serum. Do not use haemolytic samples. Once the sample is collected, perform the assay as soon as possible.

If serum is not tested immediately, it should be refrigerated at 2-8 degrees Centigrade. For storage periods greater than three days, freezing is recommended. The specimen should be brought to room temperature prior to testing assay.

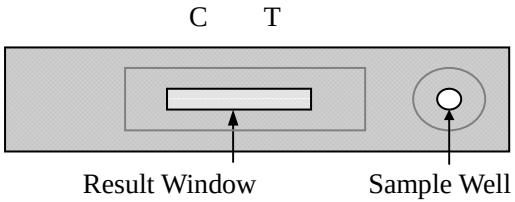
【Test Procedure】

Please read the *Instruction for Use* carefully before carrying out the test.

1. Let the sealed pouch and the samples come to room-temperature range of 15-30℃ before testing.
2. Open the aluminum foil pouch, take out the test cassette and put it on a flat

and dry surface, with the sample well facing up.

3. Add two drops of serum（80μl）to the sample well, and read the result after 15 minutes but within 30 minutes. After 30 minutes, the result should be regarded as invalid.



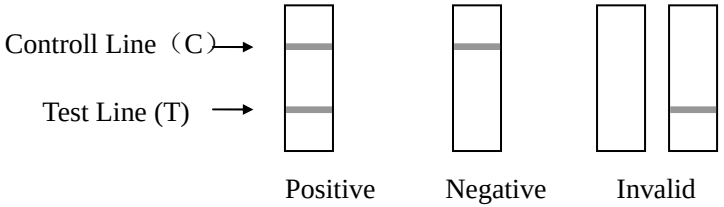
【Interpretation of Results】

Negative: Only one colored band appears on the control region. No apparent band on the test region.

Positive: Distinct color bands appear on both the control region and the test region. Both test line and control line indicate a positive result. Color intensity of the test bands may vary.

Invalid: A total absence of color in both (C) and (T) regions or no color band on the control (C) region is an indication of procedure error and/or the test reagent has deteriorated. Repeat with a new test kit. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Diagram: Interpretation of Results



【Limitations of the test】

1. This RV IgM rapid test is for in-vitro diagnostic test only.
2. This assay is only a qualitative screening test. For positive cases, more complecate quantitative testing method should be used before any clinical conclusion can be made.
3. If it is the first time for the patient to be infected, within 5 days, there is no detectable specific antibody in his/her serum. In this window period, the test will give a negative result when testing with this test cassette.
4. The RV IgM antibody of the mother will appear in the serum sample of a one-year old child, therefore it is improper to use independently the test result of a one-year old baby as the clinical proof either for its history of infection or for its immunization status.
5. Rubella IgM antibodies may not be produced when re-infected, the possibility of re-infection should not be excluded when a negative result appear with a single result of a rubella IgM test.

【Storage, Carriage and Validity】

1. Store the test kits in a dry circumstance with a room-temperature range of 2～30℃.
2. Avoid direct sunlight and heat. Don’t freeze.
3. This reagent can be transported within a short period in a normal temperature range. In summer or winter when the environment is rough, some protective measures should be taken to avoid high temperature or freeze thawing.

【Manufacturer】

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