Rubella IgG/IgM Rapid Test

For detection of Toxoplasma antibodies in Human Serum, Plasma or Whole Blood.

IVD In-vitro diagnostic use only   Not reuse

Introduction

Rubella (commonly known as German measles or 3-day measles) is an infection that primarily affects the skin and lymph nodes. It is caused by the rubella virus (not the same virus that causes measles), which is usually transmitted by secretions from the nose or throat. It can also pass through a pregnant woman's bloodstream to infect her unborn child. As this is a generally mild disease in children, the primary medical danger of rubella is the infection of pregnant woman, which may cause congenital rubella syndrome in developing babies.

Intended Use

RubellaIgG/IgM Rapid test is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to Rubella virus in human serum plasma or whole blood. This test provides only a preliminary test result. Therefore, more specific alternative diagnosis method such as Sabin-Feldman dye test for IgG antibodies, the
IgM-IFA (Immuno-fluorescent Antibody) test and the PCR test must be used in order to obtain a confirmation of Rubella infection.

Principle

Rubella IgG/IgM test device has 3 pre-coated lines, "G" (Rubella IgG Test Line), "M" (Rubella IgM Test Line) and "C" (Control Line) on the surface of the membrane. All three lines in result window are not visible before applying any samples. The "Control Line" is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working. A purple "G" and "M" lines will be visible in the result window if there are enough IgG and/or IgM antibodies to Rubella virus in the sample. If IgG and/or IgM antibodies to Rubella virus are not present in the sample, there is no color appearance in "G" and/or "M".

Materials Included and Active Ingredients

1) Rubella IgG/IgM test kit contains the following items to perform the assay.
➢ Rubella IgG/IgM test device foil pouched with a desiccant
➢ Disposable dropper capable of delivering 15 μL sample volume (may not provided)
➢ Assay diluents
➢ Instruction for use

2) Active ingredients of main components of one Rubella IgG/IgM test strips
➢ Gold Conjugates (as main component): Mouse monoclonal anti-Rubella virus – gold
➢ colloid (1.0 ± 0.2 μg),
➢ Test Line "M" (as main component): Mouse monoclonal anti-human IgM (4 ± 0.8 μg),
➢ Test Line "G" (as main component): Mouse monoclonal anti-human IgG (4 ± 0.8 μg),
3) Control Line (as main component): Goat anti- mouse IgG(8 ± 0.4 μg)

Kit Precautions and Storage Instructions

1) For best results, adhere to instructions provided
2) All specimens should be handled as potentially infectious
3) The test device should be stored at room temperature
4) The test device is sensitive to humidity as well as heat
5) Do not use beyond expiration date
6) Do not use test kit if pouch is damaged or seal is broken
7) Use test device immediately after removing from the pouch
8) The components (test device and assay diluents) in this kit have been quality control tested as a standard

batch unit. Do not mix components from different lot numbers.
9) Store kit at room temperature (2 -30 ^{o}C). Do not expose the kit to temperature over 30 ^{o}C.

Warnings

1) For in vitro diagnostic use only. DO NOT RE-USE test device
2) The instructions must be followed to obtain accurate results. Anyone performing an assay with this product must be trained in its use and laboratory procedures.
3) Do not eat or smoke while handling specimens
4) Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
5) Avoid splashing or aerosol formation
6) Clean up spills thoroughly using an appropriate disinfectant
7) Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
8) Do not mix with other specimens.

Specimen Collection, Storage and Precautions

1) Serum (S): Collect the whole blood into a collection tube (NOT containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant .
2) Plasma (P): Collect the whole blood into a collection tube (containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.
3) Whole Blood (WB): Collect the whole blood by lancing devices. WB can be delivered by pipette directly to the test card.
4) If serum or plasma specimens are not tested immediately, they should be refrigerated at 2-8℃. For storage periods longer than 2 weeks, freezing is recommended. They should be brought to room temperature (1-30℃) prior to use.
5) Serum or plasma specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.
6) Anticoagulants such as heparin, EDTA and sodium citrate do not affect the test results.
7) Use separately disposable capillary pipettes or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause erroneous results.
8) As known relevant interference, hemolytic samples, rheumatoid factors-contained samples and lipaemic, icteric samples can lead to impair the test results.

Test Procedure (Refer to Figure)

1) Allow all test components and specimen to come to room temperature prior to testing
2) Remove the test device from the foil pouch, and place it on a flat, dry surface
3) With a micropipette (not provided) or a disposable dropper, add about 10 μL of serum/ plasma or whole blood specimen into the sample well marked "S**"; Allow about 30 seconds for the specimen to be absorbed totally**.
4) Add 3 drop of diluents buffer to the sample well.
5) As the test begins to work, you will see red color move across the result window in the center of the test device.
6) Interpret test results at 15-20 minutes. Caution: Do not read test results after 20 minutes. Reading too late can give false results.

Interpretation of Test Results (Refer to Figure)

1) Negative

The control line is the only visible line on the test device. No IgG or IgM antibodies were detected. Retest in 3-5 days if rubella infection is suspected.

2) IgM Positive

The control line (C) and the IgM line (M) are visible on the test device. This is positive for IgM antibodies to Rubella virus. This is an indication of a primary rubella infection

3) IgG Positive

The control line (C) and IgG line (G) are visible on the test device. This is positive for IgG antibodies to Rubella virus. This is indicative of secondary or previous rubella infection.

4) IgG and IgM Positive

The control line (C), IgG (G) and IgM (M) lines are all visible on the test device. This is positive for both IgG and IgM antibodies. This is indicative of late primary or early secondary rubella infection.

5) Invalid

The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the likeliest reasons for control line failure. Repeat the test using a new test device.

Rubella IgG/IgM Test Procedure

Using micropipette, add 10 µl of serum, plasma or whole blood specimen in the sample well "S"

Put 2 or 3 drops (~80 µl) of assay diluents into the sample well marked as "S"
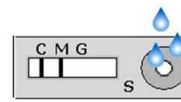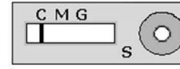
Interpret test results in 15~20 minutes.

Do not read the results after 20 minutes Reading too late can give false results.
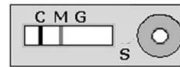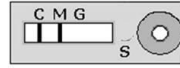
Interpretation

Negative
(No dengue infection)
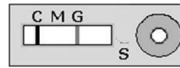-One pink line "C" in result window at right

Positive

1. IgM positive
(Primary dengue infection)
-Two pink lines "C" and "M" in result window.
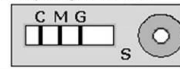-It is positive even if "M" line is weak.

2. IgG positive
(Secondary or past dengue infection)
-Two pink lines "C" and "G" in result window.
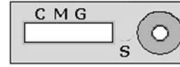-It is positive even if "G" line is weak.

3. IgG and IgM positive
(Late primary or early secondary dengue infection)
-Three pink lines "C", "M" and "G" in result window.

Invalid
-No control (C) line in result window.
-It is recommended that the specimen be re-tested.

Limitations of the Test

1) This test is for vitro diagnostic use only..

2) The amount of antibody necessary for an individual to be immune from Rubella re-infection has not been firmly established. However, a person with a weak positive result who is a candidate for vaccination may be retested using second techniques for a quantitative result.

3) Appropriate timed and paired specimens may be used to determine recent infection significant changes in the intensity of the test band may occur during the timed period. However, it may be useful in difficult cases to use a second technique such as a hemagglutination inhibition test for confirmation.

Internal Quality Control

The "Control Line" is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required

Suggested Reading List

1) Rapid separation of immunoglobulin M from immunoglobulin G antibody for reliable diagnosis of recent rubella infections, Frisch-Niggemeyer W., *J Clin Microbiol*. 1975 Nov; 2(5): 377-81

2) Rapid method to detect rubella immunoglobulin M and immunoglobulin A antibodies., Schmitz H, Shimizu H, Kampa D, Doerr HW., *J Clin Microbiol.* 1975 Feb; 1(2):132-5

3) Difference in antibody responses with rapid agglutination test for the detection of rubella antibodies, Chernsky MA, Delong DJ, Mahony JB, Castriciano S., J Clin Microbiol.1986 Apr; 23(4): 772-6

4) Diagnosis of recent rubella virus infection by demonstration of specific immunoglobulin M antibodies: comparison of soild-phase reverse immunosorbent test with sucrose density gradient centrifugation. Denoyel GA, Gaspar A, Peyramond D., J Clin Microbiol. 1981 Apr; 13(4): 698-704

5) Detection of rubella virus-specific immunoglobulin (IgG), IgM, and IgM antibodies by immunoblot assays., Zhang T, Mauracher CA, Mitchell I.A, Tingle AJ., J Clin Microbiol. 1992 Apr;30(4): 824-30

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