Cytomegalovirus IgM Rapid Test Cassette

(Colloidal Gold Chromatography)

For In-Vitro Diagnostic Use Only

【Introduction】

Cytomegalovirus is a member of the *Herpesviridae* family. It is a ubiquitous virus with high rates of infection during the first years of life. At least 80% of the adult population throughout the world carries antibodies against CMV. Infection by CMV may be acquired through congenital infection, at the time of delivery, or later in life following transmission via blood transfusion, blood products, saliva and other body fluids.

Cytomegalovirus infection is mainly asymptomatic. However, persistent fever, pneumonitis, enteritis, mononucleosis, and hepatitis occasionally may occur. In two instances, CMV infection may cause severe complications. First case is the primary infection during early pregnancy, which may lead to congenital abnormalities in the foetus, and the second is infection in immuno-deficient patients, such as recipients of organ or bone marrow transplants and people suffering from acquired immunodeficiency syndrome (AIDS). In transplantation patients, CMV is the most common infectious cause of mortality. In AIDS patients, CMV-induced diseases commonly affect the lungs, intestines and central nervous system. One serious complication, retinitis, may result in blindness.

The detection of CMV IgM antibody enables effective diagnosis of acute or recent CMV infection. The test is particularly useful for the follow-up of pregnant women, who were not previously exposed to CMV and consequently are not protected against the virus. In addition, determination of specific IgM antibody in the newborn is useful for the diagnosis of congenital CMV infection.

【Principle】

Based on the principle of Gold Immunochromatography Assay (GICA), CMV IgM antibody test cassette uses CMV recombinant antigen and anti-human IgM monoclonal antibody to detect CMV IgM antibody with high specification and specificity in human serum/plasma sample.

When the sample added to the sample well contains CMV-IgM antibodies, they will react with the anti-human CMV IgM antibody in the membrane strip, and complexes will form. These complexes will move to the test region (T), where the complexes will be captured by the pre-coated recombinant CMV antigen. A red or pink line will appear when the double sandwich chemical form, thus 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】

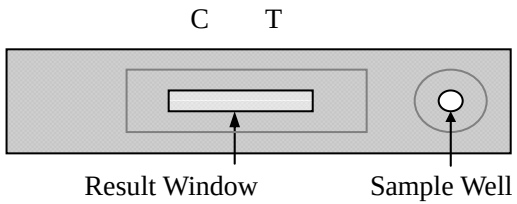
Collect the patient's venous blood and let it contract in a natural way. Then centrifuge and collect the serum/plasma. Do not use haemolytic samples. Once the sample is collected, perform the assay as soon as possible.

If serum/plasma 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/plasma（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.



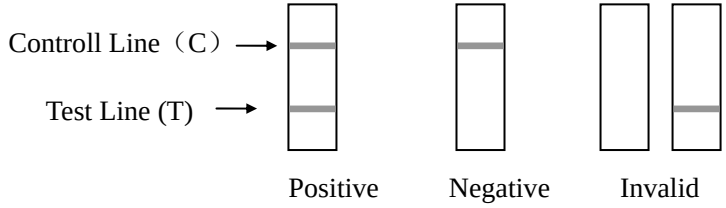
【Interpretation of Results】

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



【Precautions】

1. This CMV IgM test cassette is for in-vitro diagnostic test only.
2. This assay is a qualitative screening test. For positive cases, more complicated 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/plasma. In this window period, the test will give a negative result when testing with this test cassette.
4. The CMV IgM antibody of the mother may appear in the serum/plasma 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.

【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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