

CMV IgG/IgM Rapid Test

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



In-vitro diagnostic use only



Not reuse

Introduction

Cytomegalovirus (CMV) infections are widespread and usually asymptomatic; however, the virus may persist as a latent or chronic infection. The relatively frequent incidence and severe disease in newborns and immunosuppressed individuals clearly establishes this agent as an important human pathogen. CMV infection can be classified as Congenital (Acquired before birth), Perinatal (Acquired at birth) and Postnatal (Acquired after birth). The prognosis for congenitally infected infants who are asymptomatic at birth must be guarded. Ten to 25% may subsequently develop hearing loss. Five to 10% may exhibit various degrees of mental retardation and central nervous system motor disorders. Surveys show the incidence of congenital CMV infection to be from 0.5 to 2.5 %. Consequently, a careful documentation of the long-term effects of intrauterine infection is important. Although the age at which CMV infection is acquired varies with socioeconomic condition, only about 10-15% children in the United States are seropositive. By the age 35 however, about 50% of the population is seropositive.

The majority of individuals contracting postnatal CMV infections remain asymptomatic. A small percentage of individuals will develop a negative heterophile-antibody infectious mononucleosis syndrome. In immunocompromised patients CMV infections happen frequently, often from reactivation of latent infection, and may be life-threatening. Antibody of the IgM class is produced during the first 2-3 weeks of infection with CMV and exists only transiently in most patients. Serologic procedures which measure the presence of IgM and IgG antibodies help discriminate between primary and recurrent infections since IgM antibodies are rarely found in recurrent infections.

Principle

CMV IgG/IgM test device has 3 pre-coated lines, "G" (CMV IgG Test Line), "M" (CMV 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 CMV in the sample. If IgG and/or IgM antibodies to Cytomegalovirus are not present in the sample, there is no color appearance in "G" and/or "M".

Materials Included and Active Ingredients

- 1) CMV IgG/IgM test kit contains the following items to perform the assay.
 - CMV IgG/IgM test device foil pouched with a desiccant
 - Disposable dropper capable of delivering 15 µL sample volume (may not be provided)
 - Assay diluents
 - Instruction for use
- 2) Active ingredients of main components of one CMV IgG/IgM test strips
 - Gold Conjugates (as main component): Mouse monoclonal anti-cytomegalovirus – 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 °C). Do not expose the kit to temperature over 30 °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°C. For storage periods longer than 2 weeks, freezing is recommended. They should be brought to room temperature (1-30°C) 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.

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 CMV. This is an indication of a primary CMV 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 CMV. This is indicative of secondary or previous CMV infection.

4) IgG and IgM Positive

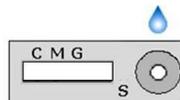
The control line (C), IgG (G) and IgM (M) lines are all visible on the test device. This is positive for both IgG and IgM antibodies. This is indicative of late primary or early secondary CMV infection.

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.

CMV 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

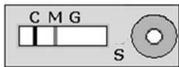
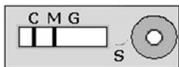
(No dengue infection)
-One pink line "C" in result window at right



Positive

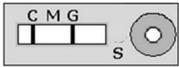
1. IgM positive

(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.



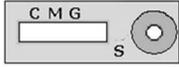
3. IgG and IgM positive

(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) The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to CMV in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
- 2) The CMV IgG/IgM Rapid Test is limited to the qualitative detection of antibodies to CMV in human serum or plasma. The intensity of the test band does not correlate with antibody titer of the specimen.
- 3) A negative result for an individual subject indicates absence of detectable CMV antibodies. However, a negative test result does not preclude the possibility of exposure to or infection with CMV.

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) Schinazi RF, eds. The Human Herpes Viruses, an interdisciplinary perspective. Elsevier/North Holland Publishing Co., New York, pp. 20-30, 1980.
- 2) Adler SP: Transfusion-associated cytomegalovirus infections. Rev. Infct. Dis. 5: 977-993, 1983
- 3) Phipps PH, Gerogire L, Rossier E, and Perry E: Comparison of five methods of cytomegalovirus antibody screening of blood donors. J. Clin. Micro. 18:1296-1300, 1983.
- 4) Stagno S, Tinker Mk, Elord C, Fuccillo DA, Cloud G, and O'Beime AJ: Immuno-globulin M antibodies detected by enzyme-linked immunosorbent assay and radioimmunoassay in the diagnosis of cytomegalovirus infections in the pregnant women and newborn infants. J Clin. Micro 21:930-935,1985
- 5) Chamesky MA, Ray CG, and Smith TF: Laboratory diagnosis is viral infections. Cumitech 15, American Society for Microbiology, Washington, DC, 1982.

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BIOGATELABS Manufactured & Quality Controlled by
Biogate Laboratories Ltd.
110-4238 Lozells Avenue, Burnaby, BC
Canada, V5A 0C4
Tel: 1-604-322-2955
Fax 1-604-322-2955
www.biogatelab.com