CMV IgG/IgM Rapid Test Device

Package Insert

Cat: ICM-422
Version: 03

Specimens: Whole Blood/Serum/Plasma
Effective Date: 2024-07
For professional *in vitro* diagnostic use only.

INTENDED USE

The CMV IgG/IgM Rapid Test Device is a rapid qualitative lateral flow test designed for the quantitive detection of IgG and IgM antibodies to Cytomegalovirus (CMV) in human Whole blood, serum or plasma samples.

INTRODUCTION

Cytomegalovirus is a herpes virus and a leading biological factor causing congenital abnormalities and complications among those who receive massive blood transfusions and immunosuppressive therapy. About half of the number of pregnant women who contract a primary infection, spread the disease to their fetus. When acquired in-utero, the infection may cause mental retardation, blindness, and/or deafness. Serological tests for detecting the presence of antibody to CMV can provide valuable information regarding the history of previous infection, diagnosis or active or recent infection, as well as in screening blood for transfusions in newborns and immuno-compromised recipients.

PRINCIPLE

The CMV IgG/IgM Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection of antibodies (IgG and IgM) to CMV in Whole blood, Serum or Plasma. Each test consists of: 1) a burgundy colored conjugate pad containing CMV recombinant envelope antigens conjugated with Colloid gold (CMV conjugates) and rabbit IgG-gold conjugates,2) a nitrocellulose membrane strip containing two test bands (T1 and T2 bands) and a control band (C band). The T1 band is pre-coated with the antibody for the detection of IgM anti-CMV, T2 band is coated with antibody for the detection of IgG anti-CMV, and the C band 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 cassette. IgG anti-CMV, if present in the specimen, will bind to the CMV conjugates. The immunocomplex is then captured by the reagent pre-coated on the T2 band, forming a burgundy colored T2 band, indicating a CMV IgG positive test result and suggesting a recent or repeat infection. IgM anti-CMV if present in the specimen will bind to the CMV conjugates. The immunocomplex is then captured by the reagent coated on the T1 band, forming a burgundy colored T1 band, indicating a CMV IgM positive test result and suggesting a fresh infection. Absence of any T bands (T1 and T2) suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on any of the T bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

KIT COMPONENTS

Individually packed test devices	Each device contains colored conjugates and reactive reagents pre-spreaded at the corresponding regions.
Droppers	For adding specimens use.
Buffer	Phosphate buffered saline and preservative.
Package insert	For operation instruction.

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Handle all specimens as if they contain infectious agents.
- Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Follow standard biosafety guidelines for handling and disposal of potential infective material.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- The CMV IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect Fingerstick Whole Blood specimens:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingersitck Whole Blood specimen to the test device by using a capillary tube or hanging drop.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

MATERIALS

Materials Provided

- Test devices
- Buffer
- Droppers
- Package insert

Materials Required But Not Provided

- Specimen collection containers
- Centrifuge
- Lancets (for fingerstick whole blood only)
- Timer
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

DIRECTIONS FOR USE

Allow the test, specimen, buffer and/or controls to reach room temperature 15-30℃ (59-86℉) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device 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 device, then add 2-3 drops of buffer (approximately 80µl-120µl) and start the timer. See illustration below.
4. Wait for the colored line(s) to appear. 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.

INTERPRETATION OF RESULTS

POSITIVE RESULT:



IgM POSITIVE: * The colored line in the control line region (C) appears and a colored line appears in test line region 1 (T1). The result indicates the presence of CMV specific IgM antibodies.



IgG POSITIVE: * The colored line in the control line region (C) appears and a colored line appears in test line region 2 (T2). The result indicates the presence of CMV specific IgG antibodies.



IgG AND IgM POSITIVE: * The colored line in the control line region (C) appears and two colored lines should appear in test line regions 1 and 2 (T1 and T2). The color intensities of the lines do not have to match. The result indicates that the presence of both CMV specific IgG and IgM antibodies.

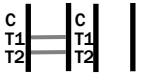
***NOTE:** The intensity of the color in the test line region(s) (T1 and/or T2) will vary depending on the concentration of CMV antibodies in the specimen. Therefore, any shade of color in the test line region(s) (T1 and/or T2) should be considered positive.

NEGATIVE RESULT:



The colored line in the control line region (C) appears. No line appears in test line regions 1 or 2 (T1 or T2).

INVALID RESULT:



Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

1. The CMV IgG/IgM Rapid Test Device is for in vitro diagnostic use only. The test should be used for the detection of CMV antibodies in Whole Blood /Serum / Plasma specimens only. Neither the quantitative value nor the rate of increase in CMV antibodies can be determined by this qualitative test.
2. The CMV IgG/IgM Rapid Test Device will only indicate the presence of CMV antibodies in the specimen and should not be used as the sole criteria for the diagnosis of CMV infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of CMV infection.

EXPECTIED VALUES

The CMV IgG/IgM Test has been compared with a reference ELISA, demonstrating an overall CMV IgM Rapid Test accuracy of 99.6%,demonstrating an overall CMV IgG Rapid Test accuracy of 99.6%.

PERFORMANCE CHARACTERISTICS

A total of 42 IgG positive, 24 IgM positive and 200 negative patient samples from susceptible subjects were tested by the CMV IgG/IgM Rapid Test and by a commercial CMV ELISA kit. Comparison for all subjects is showed in the following table.

Table: CMV IgG/IgM Rapid Test vs CMV ELISA kit for IgG result

Relative Sensitivity: 97.6%(87.43-99.94%)*
Relative Specificity: >99.9% (98.17-100.0%)*
Overall Agreement: 99.6% (97.72-99.99%)*
***95% Confidence Interval**

		CMV IgG/IgM Test		
		+	-	Total
EIA	+	41	1	42
	-	0	200	200
		41	201	242

Table: CMV IgG/IgM Rapid Test vs CMV ELISA kit for IgM result

Relative Sensitivity: 95.8%(78.88-99.89%)*
Relative Specificity: >99.9% (98.17-100.0%)*
Overall Agreement:
99.6%(97.54%-99.99%)*
***95% Confidence Interval**

		CMV IgG/IgM Test		
		+	-	Total
EIA	+	23	1	24
	-	0	200	200
		23	201	224

PRECISION

Intra-Assay

Within-run precision has been determined by using replicates of 10 tests for each of three lots using CMV IgG/IgM specimen levels at negative, low positive sample and medium positive sample. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 3 independent assays on the same five specimens: negative, low positive sample and medium positive sample of CMV IgG/IgM. Three different lots of the CMV IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) have been tested using these specimens. The specimens were correctly identified >99% of the time.

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