CMV IgM Rapid Test Cassette (Serum/Plasma) Package Insert

REF ICM-302	English

A rapid test for the qualitative detection of IgM antibodies to Cytomegalovirus in human serum or plasma.

For professional in vitro diagnostic use only.

INTENDED USE

The CMV IgM Rapid Test Cassette is a lateral flow chromatographic immunoassay for the qualitative detection of IgM antibodies to CMV in serum or plasma to aid in the diagnosis of CMV infection.

SUMMARY

Cytomegalovirus is a herpes virus. It is a leading etiological agent for congenital abnormalities and complications among those who receive massive blood transfusions and immunosuppressive therapy. About half of pregnant women who contract a primary infection spread the disease to their fetus.[1,2,3] Infection during pregnancy may cause mental retardation, blindness, and/or deafness of the fetus.

The detection of anti-CMV IgM antibodies enables effective diagnosis of acute or recent CMV infection. The CMV IgM Rapid Test Cassette (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgM antibodies to CMV in serum or plasma specimens.

PRINCIPLE

The CMV IgM Rapid Test Cassette (Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of IgM antibodies to CMV in serum or plasma specimens. In this test, antigens of CMV are coated in the test line regions of the test. During testing, the serum or plasma specimen reacts with Goat anti-human IgM coated particles in the test strip. The mixture then migrates forward on the membrane by capillary action and reacts with the CMV specific antigens on the membrane in the test line region. The presence of a colored line in the test line region indicates a positive result for CMV infection, while its absence indicates a negative result for that infection.

To serve as a procedural control, a colored line will always appear in the control line region of the strip indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains goat anti-human IgM, and CMV antigen. A streptavidin-IgG is employed in the control line system.

PRECAUTIONS

1. For in vitro diagnostic use only. Do not use after the expiration date.
2. Do not smoke, drink, or eat in areas where specimens or kits reagents are handled.
3. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
4. Humidity and temperature can adversely affect results.
5. The used test should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

1. The CMV IgM Rapid Test Cassette can be performed using either serum or plasma specimens.
2. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.
4. 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.
5. If specimens are to be shipped, they should be packed in compliance with local regulations for the transportation of etiologic agents.
6. EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium can be used as the coagulant tube for collecting the blood specimen.

MATERIALS

Materials provided

- Test cassettes
- Droppers
- Package insert
- Buffer

Materials required but not provided

- Specimen collection containers
- Centrifuge (for plasma only)
- Timer

DIRECTIONS FOR USE

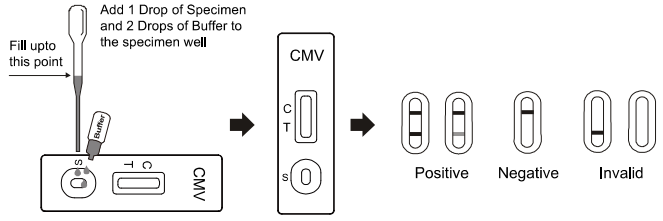
Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

a. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.

b. Place the test cassette on a clean and level surface. Hold the dropper vertically; draw the specimen about **1cm above** the upper end of the nozzle as shown in illustration below. Transfer 1 full drop **(approx. 20μL)** of specimen to each sample well, then add 2 drops of buffer (approximately 80μL) to each sample well and start the timer. See the illustration below.

c. Wait for the colored line(s) to appear. The result should be read at 15 minutes. Do not interpret results after 20 minutes.

Note: It is suggested do not use the buffer which open the cap for 30 days.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE:* Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the test line region.

***NOTE:** The intensity of the color in the test line regions may vary depending on the concentration of CMV antibodies present in the specimen. Therefore, any shade of color in the test line region should be considered positive.

NEGATIVE: **One colored line appears in the control line region (C)**. No line appears in the test line regions.

INVALID: **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. 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 line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS

1. The CMV IgM Rapid Test Cassette (Serum/Plasma) is for in vitro diagnostic use only. This test should be used for detection of IgM antibody to CMV in serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of IgM antibodies to CMV can be determined by this qualitative test.
2. The CMV IgM Rapid Test Cassette (Serum/Plasma) will only indicate the presence of IgM antibodies to CMV in the specimen and should not be used as the sole criteria for the diagnosis of CMV infections.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of CMV infection.

EXPECTED VALUES

The CMV IgM Rapid Test Cassette (Serum/Plasma) has been compared with leading commercial EIA CMV tests. The correlation between these two systems is 98.0%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The CMV IgM Rapid Test Cassette (Serum/Plasma) was compared with leading commercial EIA CMV tests; the results show that CMV IgM Rapid Test Cassette (Serum/Plasma) has a high sensitivity and specificity.

Method		CMV EIA (IgM)		Total Results
CMV IgM Rapid Test Cassette	Results	Positive	Negative	
	Positive	28	4	32
	Negative	2	266	268
Total Results		30	270	300

Relative Sensitivity: 93.3% (95%CI*: 77.9%-99.2%) *Confidence Interval
Relative Specificity: 98.5% (95%CI*: 96.3%-99.6%)
Accuracy: 98.0% (95%CI*: 95.7%-99.3%)

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of three specimens: a negative, a low positive, and a high positive. The negative, low positive, and high positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same three specimens: a negative, a low positive, and a high positive. Three different lots of the CMV IgM Rapid Test cassette (Serum/Plasma) have been tested over a 10-days period using negative, low positive, and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The CMV IgM Rapid Test Cassette (Serum/Plasma) has been tested for anti-HAV IgM, HBsAg, anti-HCV IgG, anti-HIV IgG, anti-RF IgG, anti-Syphilis IgG, anti-H. Pylori IgG, anti-Rubella IgG, anti-Rubella IgM, anti-Toxo IgG, anti-Toxo IgM, anti-HSV 1 IgG, anti-HSV 1 IgM, anti-HSV 2 IgG and anti-HSV 2 IgM positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have also been tested using the CMV IgM Rapid Test Cassette (Serum/Plasma) and no interference was observed.

Acetaminophen: 20mg/dL	Caffeine: 20mg/dL	EDTA: 20mg/dL
Acetylsalicylic Acid: 20mg/dL	Gentisic Acid: 20mg/dL	Ethanol: 10%
Ascorbic Acid: 2g/dL	Phenylpropanolamine: 20mg/dL	Glucose: 20mg/dL
Bilirubin: 1000mg/dL	Salicylic Acid: 20mg/dL	Phenothiazine: 20mg/dL

BIBLIOGRAPHY

1. Starr, S.E. and H.M. Friedman. "Human CMV." Chapter 65. In Manual of Clin. Microbiol., 4th ed., Lennett, E.H. et al ed. Am. Soc. Microbiol. pp. 771-719, 198
2. Jor MC: Latent infection and the elusive cytomegalovirus. Rev. Infect. Dis. 5:205-215, 1983.
3. Starr SE" cytomegalovirus. Ped. Clin. N. Am. 26:282-293, 1979.

Index of Symbols

	Attention, see instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		Consult Instructions for Use

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CE 0123

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