CMV IgG/IgM Rapid Test Cassette (Serum/Plasma)

Package Insert

REF ICGM-302	English

A rapid test for the qualitative detection of IgM and IgG antibodies to Cytomegalovirus in human serum or plasma.
For professional in vitro diagnostic use only.

INTENDED USE

The CMV IgG/IgM Rapid Test Cassette is a lateral flow chromatographic immunoassay for the qualitative detection of IgG and 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 CMV IgG/IgM Rapid Test Cassette (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgM and IgG antibodies to CMV in serum or plasma specimens.

PRINCIPLE

The CMV IgG/IgM Rapid Test Cassette (Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of IgG and IgM antibodies to CMV in serum or plasma specimens. In this test, anti-human IgG and anti-human IgM are coated in the test line regions of the test. During testing, the serum or plasma specimen reacts with CMV antigen coated particles in the test strip. The mixture then migrates forward on the membrane by capillary action and reacts with the anti-human IgG or anti-human IgM 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 anti-human IgM, anti-human IgG and CMV antigen. A goat anti-mouse 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

- The CMV IgG/IgM Rapid Test Cassette (Serum/Plasma) can be performed using serum or plasma specimen.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- 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.
- 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 for the transportation of etiologic agents.
- EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium can be used as the anticoagulant tube for collecting the blood specimen.

MATERIALS

Materials provided

- Test Cassettes
- Droppers
- Package Insert
- Buffer

Materials required but not provided

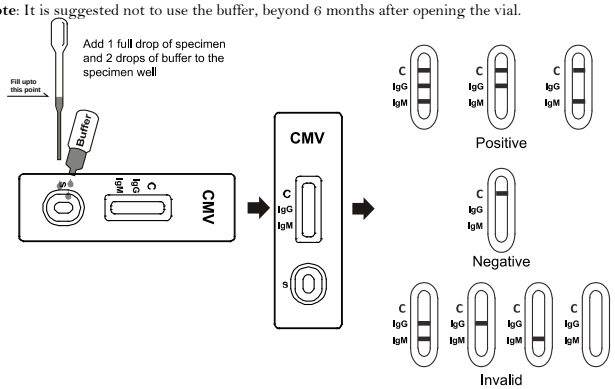
- Specimen Collection Containers
- Centrifuge (for plasma only)
- Timer

DIRECTIONS FOR USE

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

1. Remove the test cassette from sealed pouch and used it within one hour. Best results will be obtained if the assay is performed immediately after opening foil pouch.
2. 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 sample well, then add **2 drops of buffer (approximately 80µL)** to sample well and start the timer. See the illustration below.
3. 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 not to use the buffer, beyond 6 months after opening the vial.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE:* Two or three lines appear. One colored line should always appear in the control line region (C) and another one or two apparent colored line(s) should be in the test line region(s) (IgM and/or IgG).

IgM Positive: One colored should be in the control line region (C), another line appears in IgM region. It indicates a positive test result for IgM antibody to CMV.

IgG Positive: One colored should be in the control line region (C), another line appears in IgG region. It indicates a positive test result for IgG antibody to CMV.

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

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

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.

Control standards are not supplied with this kit; however, 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

1. The CMV IgG/IgM Rapid Test Cassette (Serum/Plasma) is for in vitro diagnostic use only. This test should be used for detection of IgG or IgM antibodies to CMV in serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of IgM or IgG antibodies to CMV can be determined by this qualitative test.
2. The CMV IgG/IgM Rapid Test Cassette (Serum/Plasma) will only indicate the presence of IgM and IgG 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 IgG/IgM Rapid Test Cassette (Serum/Plasma) has been compared with leading commercial ELISA CMV tests, demonstrating an overall accuracy of 97.3%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

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

Method		CMV ELISA (IgM)		Total Results
CMV IgG/IgM Rapid Test Cassette for IgM	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%)

Method		CMV ELISA (IgG)		Total Results
CMV IgG/IgM Rapid Test Cassette for IgG	Results	Positive	Negative	
	Positive	27	5	32
	Negative	3	265	268
Total Results		30	270	300

Sensitivity: 90.0% (95%CI*: 73.5%~97.9%) *Confidence Interval
Specificity: 98.1% (95%CI*: 95.7%~99.4%)
Accuracy: 97.3% (95%CI*: 94.8%~98.8%)

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 IgG/IgM Rapid Test cassette (Serum/Plasma) have been tested over a 3-days period using negative, low positive, and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

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

Interfering Substances

The following compounds have also been tested using the CMV IgG/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	2	Do not reuse
IVD	For in vitro diagnostic use only		Use by	REF	Catalog #
2°C 30°C	Store between 2-30°C	LOT	Lot Number		Consult Instructions For Use
	Do not use if package is damaged		Manufacturer		

ACRO BIOTECH, Inc.
9500 Seventh Street,
Unit M, Rancho Cucamonga,
CA 91730, U.S.A.

Number: 475602
Effective date: 2018-07-28