



CMV IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma)

Package Insert

REF ICGM-425 English

A rapid test for the qualitative detection of IgM and IgG antibodies to Cytomegalovirus in human whole blood, serum or plasma.

For professional in vitro diagnostic use only

INTENDED USE

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

PRINCIPLE

The CMV IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of IgG and IgM antibodies to CMV in whole blood, serum or plasma specimens. In this test, mouse anti-human IgG and goat anti-human IgM are coated in the test line regions of the test. During testing, the whole blood, 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 mouse anti-human IgG or goat 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 respective control line regions of all the two strips indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

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

PRECAUTIONS

- For in vitro diagnostic use only. Do not use after the expiration date.
- Do not smoke, drink, or eat in areas where specimens or kits reagents are handled.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.
- 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 Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum or plasma.
- Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.
- 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.
 - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger
 - 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.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. For long term storage, specimens should be kept below -20°C. 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 for more than three times.
- If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

MATERIALS

Materials provided

- Test cassettes
- Droppers
- Package insert
- Buffer

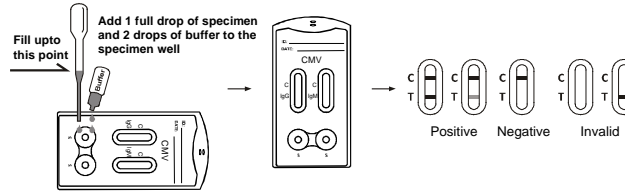
Materials required but not provided

- Specimen collection contain
- Centrifuge (f or plasma only)
- Timer

DIRECTIONS FOR USE

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

- Remove the test cassette from the sealed pouch and use it within one hour. Best results will be obtained if the assay is performed as soon as possible.
- 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.
- Wait for the colored line(s) to appear. The result should be read at 15 minutes. Do not interpret results after 20 minutes.



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 IgG or IgM 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

- The CMV IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for detection of IgG or IgM antibodies to CMV in whole blood, 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.
- The CMV IgG/IgM Combo Rapid Test Cassette (Whole Blood/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.
- As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
- 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 Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with leading commercial EIA CMV tests, demonstrating an overall accuracy of 98.1%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

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

Method	CMV EIA (IgM)		Total Results	
	Results	Positive		Negative
	CMV IgM Rapid Test Cassette	Positive		36
	Negative	3	328	331
Total Results		39	332	371

Relative Sensitivity: 92.3% (95%CI*: 79.1%-98.4%) *Confidence Interval

Relative Specificity: 98.8% (95%CI*: 96.9%-99.7%)

Accuracy: 98.1% (95%CI*: 96.2%-99.2%)

Method	CMV EIA (IgG)		Total Results	
	Results	Positive		Negative
	CMV IgG Rapid Test Cassette	Positive		43
	Negative	3	321	324
Total Results		46	325	371

Relative Sensitivity: 93.5% (95%CI*: 82.1%-98.6%) *Confidence Interval

Relative Specificity: 98.8% (95%CI*: 96.9%-99.7%)

Accuracy: 98.1% (95%CI*: 96.2%-99.2%)

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 Combo Rapid Test Cassette (Whole Blood/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 IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested for HAV, HBV, HCV, HIV, RF, Syphilis, *H. Pylori*, Rubella, TOXO, HSV 1/2 positive specimens. The results showed no cross-reactivity.

Interfering Substances

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

Acetaminophen: 20mg/dl	Caffeine: 20mg/dl	EDTA: 20mg/dl
Acetylsalicylic Acid: 20mg/dl	Genetic Acid: 20mg/dl	Ethanol: 10%
Ascorbic Acid: 2g/dl	Phenylpropanolamine: 20mg/dl	Glucose: 20mg/dl
Bilirubin: 100mg/dL	Salicylic Acid: 20mg/dl	Phenothiazine: 20mg/dl

BIBLIOGRAPHY

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

Index of Symbols

	Attention, see instructions for use		Tests per kit		Do not reuse
	For in vitro diagnostic use only		Use by		Catalog #
	Store between 2-30°C		Lot Number		

Hangzhou AllTest Biotech Co., Ltd.
#550, Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou - 310018, P. R. China
www.alltests.com.cn

Number: 145402901
Effective date: 2017-02-10