Cytomegalovirus(CMV) IgG/IgM Rapid Test Kit (Colloidal Gold)

IVD

A rapid test for the qualitative detection of CMV IgG/IgM in human serum,plasma or whole blood.
For professional medical institutions use only,Not for self testing.

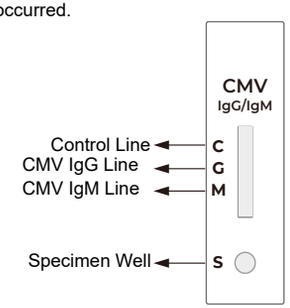
PRODUCT NAME
Cytomegalovirus(CMV) IgG/IgM Rapid Test Kit(Colloidal Gold)

SPECIFICATION
25 tests/kit, 5 tests/kit, 1 test/kit

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 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. Infection during pregnancy may cause mental retardation, blindness, and/or deafness of the fetus.

PRINCIPLES
The CMV IgG/IgM 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 mouse 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 control line region of the strip indicating that proper volume of specimen has been added and membrane wicking has occurred.



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

MATERIALS PROVIDED

1. Individually sealed foil pouches containing:
   a.One cassette device
   b.One desiccant
2.Capillary tubes
3.Sample diluent
4.One package insert (instructions for use)

Components	25 tests/kit	5 tests/kit	1 test/kit
Cassettes	25 cassettes with dependent sealed foil pouch	5 cassettes with dependent sealed foil pouch	1 cassette with dependent sealed foil pouch
Extraction buffer	1 bottle (10ml)	1 bottle (3ml)	300ul/tube
10 μL capillary tubes	25 pcs	5 pcs	1 pcs
Package insert	1 pcs	1 pcs	1 pcs

MATERIALS REQUIRED BUT NOT PROVIDED

1.Specimen collection containers
2.Timer
3.Centrifuge

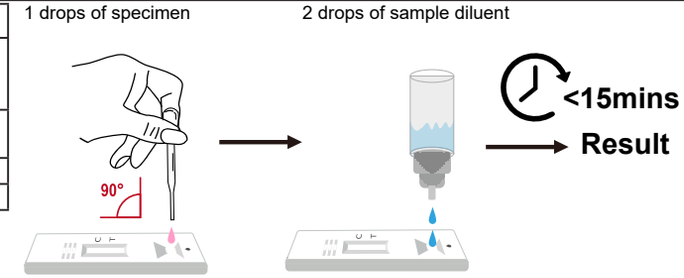
WARNINGS AND PRECAUTIONS
•For professional in vitro diagnostic use only. Do not use after expiration date
•Do not eat, drink or smoke in the area where the specimens and kits are handled.
•Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure 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.
•Humidity and temperature can adversely affect results.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS
All reagents are ready to use as supplied. Store unused test devices unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION
• The CMV IgG/IgM 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.

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

1.Bring the test to room temperature before opening it. 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.
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 each sample well, then add 2 drops of buffer (approximately 80μL) to each 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.

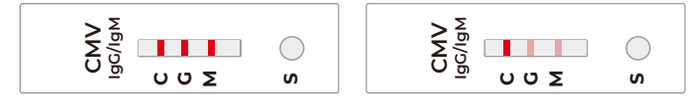


INTERPRETATION OF ASSAY RESULT
Negative Control
One colored line appears in the control line region (C). No line appears in the test line regions (IgM and IgG).

Positive Control
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.

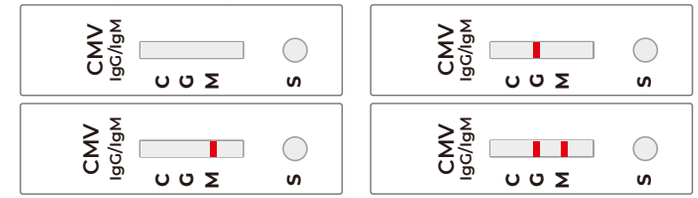
IgG Positive: One colored should be in the control line region (C), another line appears in IgG region. It indicates a positive test result for IgG antibody to CMV.

IgG/IgM 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).



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.

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.

Expected Values

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

Method		CMV EIA (IgM)		Total Results
CMV Rapid Test Cassette for IgM	Results	Positive	Negative	
	Positive	36	4	40
	Negative	3	328	331
Total Results		39	332	371

Relative Sensitivity: 92.3% (95%CI*: 79.1%-98.4%)
Relative Specificity: 98.8% (95%CI*: 96.9%-99.7%)
Accuracy: 98.1% (95%CI*: 96.2%-99.2%)
*Confidence Interval

Method		CMV EIA (IgG)		Total Results
CMV Rapid Test Cassette for IgG	Results	Positive	Negative	
	Positive	43	4	47
	Negative	3	321	324
Total Results		46	325	371

Relative Sensitivity: 93.5% (95%CI*: 82.1%-98.6%)
Relative Specificity: 98.8% (95%CI*: 96.9%-99.7%)
Accuracy: 98.1% (95%CI*: 96.2%-99.2%)
*Confidence Interval

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 (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

he CMV IgG/IgM 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 Rapid Test Cassette (Whole Blood/Serum/Plasma) and no interference was observed.

Acetaminophen: 20mg/dl	Caffeine: 20mg/dl
EDTA: 20mg/dl	Aetylsalicylic 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

LMITATIONS OF TEST

1.The CMV IgG/IgM 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.
2.The CMV IgG/IgM 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.
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.

SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
	Batch code		In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don’t use the product when the package is damaged		Keep dry
	Date of manufacture		Tests per kit
	CE Mark		Biological Risks
	Authorized representative in the European Community		