

DIAQUICK CMV IgM Cassette

for serum and plasma samples

REF

J15030

Content

- 25 cassettes individually packed (25 x Ref. No: J15030B)
- 25 disposable pipettes
- 1x 3 mL buffer
- 1 package insert

For professional in vitro diagnostic use only

GENERAL INFORMATION

Method	sandwich type immunochromatographic assay
Shelf life	24 months from date of production
Storage	2 – 30 °C
Sample	human serum or plasma
Results	after 15 minutes

INTENDED USE

The DIAQUICK CMV IgM Cassette (serum, plasma) 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 the 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 DIAQUICK CMV IgM Cassette is a rapid chromatographic immunoassay for the qualitative detection of IgM antibodies to CMV in serum or plasma specimens.

TEST PRINCIPLE

The DIAQUICK CMV IgM Cassette 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 coloured 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 coloured 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.

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.

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.

MATERIAL REQUIRED BUT NOT PROVIDED

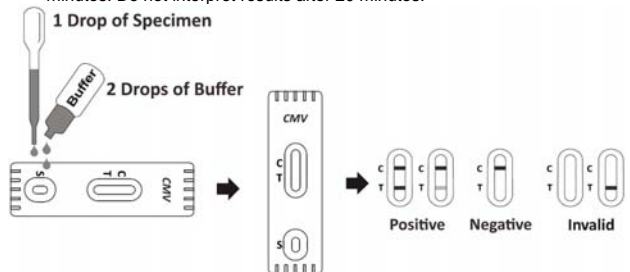
- Specimen collection container
- Centrifuge (for plasma only)
- Timer

SPECIMEN COLLECTION AND PREPARATION

- The DIAQUICK CMV IgM Cassette can be performed using either serum or plasma specimens.
- Separate the serum or plasma from blood as soon as possible to avoid haemolysis. Only clear, non-haemolysed 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.

ASSAY PROCEDURE

1. 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.
2. Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer 1 drop of serum or plasma (approx. 10 µL) and 2 drops of buffer (approx. 80 µL) to the specimen well of the test cassette. Avoid trapping air bubbles in the specimen well. See the illustration below.
3. Wait for the coloured 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 coloured lines appear. One coloured 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 colour in the test line regions may vary depending on the concentration of CMV antibodies present in the specimen. Therefore, any shade of colour in the test line region should be considered positive.

NEGATIVE: One coloured 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 cassette. 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 coloured 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 DIAQUICK CMV IgM Cassette has been compared with leading commercial EIA CMV tests, demonstrating an overall accuracy of 98.9%.

LIMITATIONS

1. The DIAQUICK CMV IgM Cassette is for in vitro diagnostic use only. This test should be used for detection of IgM antibodies 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 DIAQUICK CMV IgM Cassette 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.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The DIAQUICK CMV IgM Cassette was compared with leading commercial EIA CMV tests; the results show that the DIAQUICK CMV IgM Cassette has a high sensitivity and specificity.

Method	CMV EIA (IgM)		Total Results
	Positive	Negative	
DIAQUICK CMV IgM Cassette	22	3	25
	1	350	351
Total Results		353	376

Sensitivity = 95.7% (78.1 – 99.9%)*

Accuracy = 98.9% (97.3 – 99.7%)*

Specificity = 99.2% (97.5 – 99.8%)*

* 95% 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 DIAQUICK CMV IgM Cassette have been tested over a 3-day period using negative, low positive, and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The DIAQUICK CMV IgM Cassette 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 DIAQUICK CMV IgM Cassette has been tested and no interference was observed in specimens containing 110 mg/mL human albumin, 1 mg/mL bilirubin, 10 mg/mL haemoglobin, 0.2 mg/mL cholesterol and 15 mg/mL triglycerides. The following compounds have also been tested using the DIAQUICK CMV IgM Cassette and no interference was observed.

Acetaminophen	Caffeine	EDTA
Acetylsalicylic Acid	Gentisic Acid	Ethanol
Ascorbic Acid	Phenylpropanolamine	Glucose
Bilirubin: 1g/dL	Salicylic Acid	Phenothiazine

REFERENCES

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, 1988
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.

