(CMV) Cytomegalovirus IgM/G Antibody Rapid Test Kit

(Immunochromatography)

This package insert must be read carefully prior to use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are deviations from the instructions in this package insert.

Product Name

(CMV) Cytomegalovirus IgM/G Antibody Rapid Test Kit (Immunochromatography)

Intended Use

The reagent is used to detect the cytomegalovirus IgM/G antibody in serum /plasma qualitatively.It is used as an aid in the diagnostic of past infection and epidemiological investigation.

Test Principle

The test utilizes antibodies including a recombinant CMV antigen and goat anti-mouse IgG antibody on the nitrocellulose membrane with colloidal gold marked anti-human IgM/G as a mark tracer. The reagent is used to detect the CMV IgM/G according to the principle of capture method and gold immunochromatography assay.

The sample mixing up anti-human IgM/G–marker move along the membrane to the T line, and form the T line with recombinant CMV antigen when the sample contains CMV IgM/G, which is a positive result. Conversely, it is a negative result.

Main Components

CMV-IgM: Sample pad, colloidal gold labeled anti-human IgM, nitrocellulose membrane coated with recombinant CMV antigen and goat anti-mouse IgG antibody, absorbent pad, PVC board

CMV-IgG: Sample pad, colloidal gold labeled anti-human IgG, nitrocellulose membrane coated with recombinant CMV antigen and goat anti-mouse IgG antibody, absorbent paper and PVC board

Storage and Expiry

Store as packaged in the sealed pouch at 4-30°C, keep out of hot and direct sunlight, keep in dry place, valid for 24 months. DO NOT FREEZE. Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw. The product is humidity-sensitive and should be used immediately after being opened.

Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

Sample Requirement

Sample Collection:

1. Serum: Use disposable syringe (vacuum blood collection tube) to extract a certain amount of venous blood, and place at room temperature for blood coagulation, take the supernatant after centrifugation of blood for detection. Separate the serum from the clot or plasma from the packed cells as soon as possible to avoid any hemolysis.

2. Plasma: Use vacuum blood collection tube with anticoagulants to extract a certain amount of venous blood, and rock repeatedly, take plasma separation for detection.

3. EDTA, sodium citrate, sodium oxalate, heparin can be used as the anticoagulants.

Sample Storage:

Serum and plasma samples may be stored at 2-8℃ for 3 days prior to assay, and at -20 ℃ for 2 years. If testing is delayed more than 7 days, the sample should be frozen (-20°C or colder). Repeat freeze and thaw for no more than 3 times.

Material Required But Not Provided

1. Sample Collection Container

2. Timer or Clock

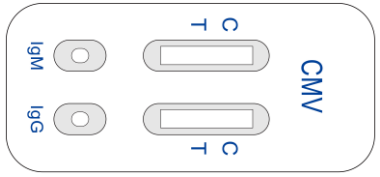
Test Procedure

Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (20℃-30℃) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened (Humidity: 20%~90%, Temp: 10℃-50℃)

1. Take off the outer packing, put the cassette onto the desk with the sample window up.

2. Apply 3 full drops of serum or plasma (80μl-100μl) vertically into the sample hole of cassette. *Avoid air bubble in the pipette, a bubble may prevent the complete transfer of sample and invalidate the test. Use a new pipette for each test performed, even if using the same sample.*

3. Observe the test results immediately within 15~30 minutes, the result is invalid over 35 minutes.



Result Judgment

POSITIVE: Two (2) distinct colored lines appear. One line should be in the control region (C) and the other line should be in the test region (T).

NEGATIVE: One (1) colored line appears in the control region(C). No apparent colored line appears in the test region (T).The negative result does not indicate the absence of analytes in the sample, it only indicates the level of tested analytes in the sample is less than cut-off level.

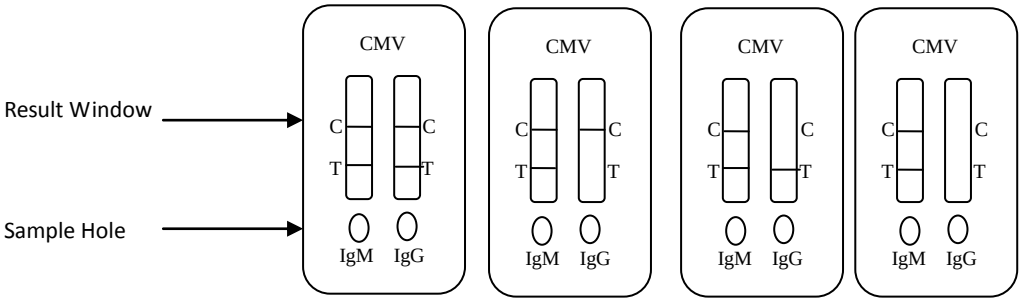
INVALID: No colored lines appear or control line fails to appear, indicating that the operator error or reagent failure. Verify the test procedure and repeat the test with a new testing device.

Note:

1. Any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the sample.

2. Insufficient sample volume, incorrect operating procedure or expired tests are the most likely reasons for control line failure.

3. Control line color intensity of different items on the same cassette may be different, it is a normal phenomenon. The strength of the quality control line doesn't indicate the quality problem of the reagent, a test result that is clearly visible demonstrates the reagent is effective.



Result Illustration: IgM(+),IgG(+) IgM(+),IgG(-) IgM(+),IgG(0) IgM(+),IgG(0)

The results can be as follows: IgM (+),IgG (+); IgM (+),IgG (-); IgM (+),IgG (invalid); IgM (-),IgG (+); IgM (-),IgG(-); IgM (-),IgG (invalid); IgM (invalid),IgG (+); IgM (invalid),IgG (-); IgM (invalid), IgG (invalid)

Limitation

1. This reagent is designed for the qualitative screening test. Concentration of analytes cannot be determined by this qualitative test.

2. The results of the reagent are only for clinical reference, which is not the only basis for clinical diagnosis and treatment. A confirmed diagnosis and treatment should only be made by a physician after all clinical and laboratory findings have been evaluated.

3. Negative result may occur when detecting short-term infected samples, indicate that the specific antibodies of CMV does not exist or the concentration is below detection limit. If CMV infection is still suspected, the sample should be collected 2 weeks later and carry the parallel detection with the first sample.

4. Negative results may occur at the beginning of acute infection, other testing method and analysis with clinical symptoms are suggested.

5. Results of patients who used to receive immunosuppressive therapy or with immune function damage (for example HIV), may have a low serology reference value.

6. Positive results of the patients who used to receive blood transfusions or other blood products therapy, should be analyzed cautiously.

Performance Characteristics

CMV IgM:

1. Negative specificity: The results should all be negative when detecting kits of CMV-IgM negative quality control samples.

2. Positive specificity: The results should all be positive when detecting kits of CMV-IgM positive quality control samples.

3. Limit of detection: Positive results may occur when detecting CMV-IgM quality control material.

4. Repeatability: The results should be consistent and the coloration degree should be consistent when detecting the CMV-IgM standards by 10 kits of the same concentration.

5. Diagnostic specificity and sensitivity

A clinical evaluation was conducted on 442 samples (including 152 positive samples and 290 negative samples). The results are as follows:

Positive samples	152	CMV-IgM test kits of MR	CMV-IgM test kits of control group
		149/152（98.0%）	147/152（96.7%）
Negative samples	290	CMV-IgM test kits of MR	CMV-IgM test kits of control group
		286/290（98.6%）	288/290（99.3%）

6. Analytical sensitivity:

6.1 Cross-reactivity: The addition of HBV, HAV, EB- IgA, varicella virus,RF, ASO,ENA, ANA, MP, HAMA, high concentration IgM, systemic lupus erythematosus and other TORCH causative agents showed no cross-reactivity.

6.2 200 μmol/L bilirubin, 10mmol/L total cholesterol, 6mmol/L triglyceride, 10g/L hemoglobin has no effect on the detection result.

6.3 Hook effect: the hook effect will not occur even the CMV-IgM concentration as high of 593.52 U/mL

CMV IgG:

1. Negative specificity: The results should all be negative when detecting kits of CMV-IgG negative quality control samples.

2. Positive specificity: The results should all be positive when detecting kits of CMV-IgG positive quality control samples.

3. Limit of detection: Positive results may occur when detecting CMV-IgG quality control material.

4. Repeatability: The results should be consistent and the coloration degree should be consistent when detecting the CMV-IgG standards by 10 kits of the same concentration.

5. Diagnostic specificity and sensitivity

A clinical evaluation was conducted on 462 samples (including 185 positive samples and 277 negative samples). The results are as follows:

Positive samples	185	CMV-IgG test kits of MR	CMV-IgG test kits of control group
		183/185（98.9%）	182/185（98.4%）

Negative samples	277	CMV-IgG test kits of MR	CMV-IgG test kits of control group
		274/277（98.9%）	273/277（98.6%）

6. Analytical sensitivity:

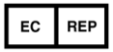
6.1 Cross-reactivity: The addition of HBV, HAV, EB- IgA, varicella virus,RF, ASO,ENA, ANA, MP, HAMA, high concentration IgG, systemic lupus erythematosus and other TORCH causative agents showed no cross-reactivity.

6.2 200 μmol/L bilirubin, 10mmol/L total cholesterol, 6 mmol/L triglyceride, 10g/L hemoglobin has no effect on the detection result.

6.3 Hook effect: the hook effect will not occur even the CMV-IgG concentration as high of 702.12 U/mL .

Precaution

1. For IN VITRO diagnose only.
2. Do not use after the expiration date. Avoid using the test if the package is damaged.
3. This test provides a qualitative and visual outcome. A good light source is required for reading the results.
4. Avoid touching the nitrocellulose membrane with your fingers.
5. The test kit is disposable, not reusable.
6. The test result is invalid over 35 minutes.
7. The strength of the quality control line doesn't indicate the quality problem of the reagent, a test result that is clearly visible demonstrates the reagent is effective.
8. The color depth of the detection line was not necessarily associated with the antibody titer of the sample, positive results cannot be used as the only basis for diagnosis, further confirm experiment should be taken.
9. All samples and reagents should be considered potentially hazardous and handled in the same manner as an infectious agent after use. Laboratory chemical and biohazardous wastes must be handled and discarded in accordance with all local, regional, and national regulations.
10. Do not smoke, drink, or eat in areas where samples or kit reagents are being handled.
11. Do not use other kinds of quality control sample to test the reagent. Components of different batches cannot be exchanged for use to avoid erroneous results.
12. If the filtration speed is very slow or evens no filtration occurs, please test again with new sample. Samples with liquid migration velocity (stopwatch) less than 4.00mm/minis not suitable for this test kit, other detection methods are suggested to use.

	CE Mark		Keep Dry
	Do Not Reuse		Temperature Limitation
	Consult Instruction for Use		In Vitro Diagnostic Medical Product
	Batch Code		Caution
	European Union Representative		Contains Sufficient for <n> Tests
	Manufacturer		Date of Manufacture
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