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*"See Now"*CMV IgG/IgM Test
Whole Blood/Serum/ Plasma
For in vitro Diagnosis Use
Product Code: SN 10.3

INTENDED USE

"See Now" Cytomegalovirus (CMV) IgG / IgM Antibody Test is a rapid and convenient immunochromatographic *in vitro* assay. It is for detection of CMV in human serum, plasma, whole blood.

The test provides a visual, qualitative result, and all positive specimens must be confirmed with other qualified assays. The test is intended for healthcare professional use only.

SUMMARY OF TEST

CMV is a viral genus of the Herpesviruses group. In humans it is commonly known as HCMV or Human Herpesvirus 5 (HHV-5). HCMV infections are frequently associated with salivary glands, though they may be found throughout the body. The symptoms of a CMV infection vary depending upon the age and health of the person who is infected. Most of these infants show no symptoms of CMV infection, however, a few may develop pneumonia or other symptoms, including premature delivery, jaundice, enlarged liver and spleen, microcephaly seizures, rash, and feeding difficulties. Newborns can also contract CMV infection during birth or breast milk by the infected mother. Older children and teens who become infected with the virus may have mononucleosis-like symptoms, including fatigue, muscle aches, headache, fever and enlarged liver and spleen. These symptoms are generally mild, and usually last only 2-3 weeks. In people who have received organ transplants, or in people whose immune systems are weakened, CMV can cause serious infections. In people who have AIDS or HIV, CMV infection may involve the lungs, nervous system, gastrointestinal tract, and the eye, sometimes causing blindness.

"See Now" CMV IgM / IgG test is based on the principle of gold immunochromatography assay. Specific CMV recombinant antigens and anti-human monoclonal antibodies are used to detect CMV IgM and IgG antibodies respectively in the human serum samples with high sensitivity and specificity. If there is CMV IgM/IgG antibody in the specimen, these antibodies will react with the anti-human monoclonal antibodies conjugated with gold to form complexes which move along the strip chromatographically to the test region (T), where these complexes will be captured by the pre-coated recombinant CMV antigens. Then a red or pink line will appear, indicating a positive result. The unbounded complex moves on to the control region (C), where they are captured by the anti-mouse antibody, and a red or pink line will appear, indicating the assay is a valid one. So the control line provides an internal quality control mechanism.

Materials Provided

Pouch Contents: Cassette, Sample Dropper, Desiccant, Test instruction, buffer bottle.

Materials needed but not provided

Clean, specimen collection container..Clock or timer.

SPECIMEN COLLECTION & PREPARATION

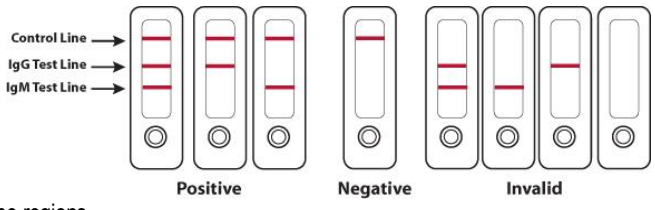
- Collect blood in a tube without anticoagulant for serum samples and allow to clot.
- For whole blood / plasma samples, collect the blood in a tube containing anticoagulant.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.

TEST PROCEDURE

1. Remove the testing device from the sealed pouch by tearing at the notch. Then place the testing device on a leveled surface.
2. Holding the sample dropper vertically add one drop **10µL** of specimen into the sample well, then using buffer bottle add 2 drops, around **80µL** of buffer.
3. Read the result at 15 minutes. Ensure that the background of the test area is white before interpreting the result. Do not read after 30 minutes.

INTERPRETATION OF RESULTS

Negative: Only one pink color band appears on the control region. There is no apparent color band on the test region.
Positive: Distinct pink color bands appear at the control and either/both IgG and IgM



test line regions.
Invalid: A total absence of color in both regions and no colored line appears in the control (C) region is an indication of procedure error and/or test reagent deterioration. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

- This product is designed for in vitro diagnostic use only.
- There is always a possibility that false results will occur due to factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

STORAGE AND STABILITY

- Test device in the sealed pouch can be stored at 2-30ºC up to the expiration date. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture and heat

Performance Characteristics

Method		CMV EIA (IgM)		Total Results
CMV IgM Rapid Test Cassette	Results	Positive	Negative	
	Positive	75	2	77
	Negative	1	327	328
Total Results		76	329	405

Relative Sensitivity: 97,4%
Relative Specificity: 99.7%
Accuracy: 99.25%

Method		CMV EIA (IgG)		Total Results
CMV IgG Rapid Test Cassette	Results	Positive	Negative	
	Positive	44	2	46
	Negative	2	357	359
Total Results		46	359	405

Relative Sensitivity: 95,65%
Relative Specificity: 99.44%
Accuracy: 99.00%