

CMV IgG/IgM Rapid Test- Cassette (Serum / Plasma)

REF: 1188 001 30 test

INTENDED USE

The Spectrum CMV IgG/IgM Rapid Test is a lateral flow immunoassay for the simultaneous detection and differentiation of IgM and IgG Cytomegalovirus (CMV) in human serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with CMV. Any reactive specimen with the Spectrum CMV IgG/IgM Rapid Test must be confirmed with alternative testing method(s).

SUMMARY AND EXPLANATION OF THE TEST

Cytomegalovirus (CMV) infections are widespread and usually asymptomatic; however, the virus may persist as a latent or chronic infection. The relatively frequent incidence and severe disease in newborns and immunosuppressed individuals clearly establishes this agent as an important human pathogen. CMV infection can be classified as Congenital (Acquired before birth), Perinatal (Acquired at birth) and Postnatal (Acquired after birth). The prognosis for congenitally infected infants who are asymptomatic at birth must be guarded. Ten to 25% may subsequently develop hearing loss. Five to 10% may exhibit various degrees of mental retardation and central nervous system motor disorders. Surveys show the incidence of congenital CMV infection to be from 0.5 to 2.5 %. Consequently, a careful documentation of the long-term effects of intrauterine infection is important. Although the age at which CMV infection is acquired varies with socioeconomic condition, only about 10-15% children in the United States are seropositive. By the age 35 however, about 50% of the population is seropositive.

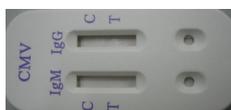
The majority of individuals contracting postnatal CMV infections remain asymptomatic. A small percentage of individuals will develop a negative heterophile-antibody infectious mononucleosis syndrome. In immunocompromised patients CMV infections happen frequently, often from reactivation of latent infection, and may life-threatening⁽²⁻⁴⁾.

Antibody of the IgM class is produced during the first 2-3 weeks of infection with CMV and exists only transiently in most patients (8,9). Serologic procedures which measure the presence of IgM and IgG antibodies help discriminate between primary and recurrent infections since IgM antibodies are rarely found in recurrent infections.

The Spectrum CMV IgG/IgM Rapid allows the discrimination of IgG and IgM antibody in one test within 15 minutes. The test is user friendly, without cumbersome laboratory equipment.

TEST PRINCIPLE

The Spectrum CMV IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay panel device. The test cassette consists of a CMV IgM detection panel (The left panel) and a CMV IgG detection panel (the right panel). The IgM panel has 1) a burgundy colored conjugate pad containing mouse anti-human IgM conjugated with colloid gold (IgM conjugates), 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with recombinant CMV antigen, and the C band is pre-coated with goat anti-mouse IgG. The IgG panel has 1) a burgundy colored conjugate pad containing CMV antigens conjugated with colloid gold (CMV conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with anti-human G antibody, and the C band is pre-coated with goat anti-rabbit IgG.



When an adequate volume of test specimen is dispensed into the sample well (S) of the cassette, the specimen migrates by capillary action across the cassette. The IgM antibody to CMV, if present in the specimen will bind to the IgM conjugates on the left panel. The immunocomplex is then captured on the membrane by the pre-coated

SYMBOLS IN PRODUCT LABELLING

	Authorised Representative		Temperature Limitation
	For in-vitro diagnostic use		Use by/Expiration Date
	Batch Code/Lot number		CAUTION. Consult instructions for use
	Catalogue Number		Manufactured by
	Consult instructions for use		

CMV antigen, forming a burgundy colored T band, indicating a CMV IgM positive test result.

IgG anti-CMV, if present in the specimen, will bind to the CMV conjugates. The immunocomplex is then captured by the anti-human IgG on the membrane on the right panel, forming a burgundy colored T band, indicating a CMV IgG positive test result.

Absence of any T bands suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on any of the T bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

- Each kit contains 25 or 30 test devices, each sealed in a foil pouch with 3 items inside:
 - One cassette device.
 - One pipette dropper.
 - One desiccant.
- 2 bottles of the Sample Diluent (5 mL each bottle)
- One package insert (instruction for use).

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock or Timer

WARNINGS AND PRECAUTIONS

For in Vitro Diagnostic Use

- This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
- Do not open the sealed pouch, unless ready to conduct the assay.
- Do not use expired devices.
- Bring all reagents to room temperature (15°C-30°C) before use.
- Do not use the components in any other type of test kit as a substitute for the components in this kit.
- Do not use hemolyzed blood specimen for testing.
- Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
- Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
- Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
- Dispose of all specimens and materials used to perform the test as biohazardous waste.
- Handle the Negative and Positive Control in the same manner as patient specimens.
- The testing results should be read within 10 minutes after a specimen is applied to the sample well or sample pad of the device. Read result after 10 minutes may give erroneous results.
- Do not perform the test in a room with strong air flow, ie. an electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2°C-30°C. The positive and negative controls should be kept at 2°C-8°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

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

Plasma

- Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by veinpuncture.

2. Separate the plasma by centrifugation.
3. Carefully withdraw the plasma into new pre-labeled tube.

Serum

1. Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by veinpuncture.
2. Allow the blood to clot.
3. Separate the serum by centrifugation.
4. Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2°C-8°C if not tested immediately.

Store specimens at 2°C-8°C up to 5 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

ASSAY PROCEDURE

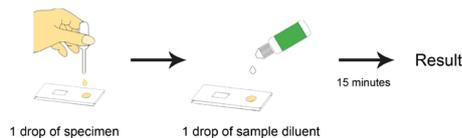
Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3: Be sure to label the device with specimen's ID number.

Step 4: Fill the pipette dropper with the specimen. Holding the dropper vertically, dispense 1 drop (about 30-45 µL) of specimen into the sample well on each panel making sure that there are no air bubbles.

Then add 1 drop (about 35-50 µL) of Sample Diluent immediately to the sample well on each panel.



Step 5: Set up timer.

Step 6: Results can be read in 15 minutes.

Don't read result after 15 minutes. To avoid confusion, discard the test device after interpreting the result

INTERPRETATION OF ASSAY RESULT

1. **NEGATIVE RESULT:** If only the C band is present, the absence of any burgundy color in the both T bands indicates that no anti-CMV IgG neither anti-CMV IgM are detected. The result is negative.



2. **POSITIVE RESULT:**

a. In addition to the presence of C band, if only T band is developed on the left panel, indicates for the presence of IgM anti-CMV; the result is positive for CMV test. It indicates for a fresh infection.



b. In addition to the presence of C band, if only T band is developed on the right panel, the test indicates for the presence of IgG anti-CMV. The result is CMV positive, indicating for a past infection



c. In addition to the presence of C band, if T lines in the both panel are developed, the test indicates for the presence of IgG and IgM anti-CMV. The result is CMV positive, indicating for a current infection.



Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

3. **INVALID:** If no C band is developed, the assay is invalid regardless of any burgundy color in the T bands as indicated below. Repeat the assay with a new device.

Note: Invalid test result in one device does not disqualify the test result on the other device as long as the result on the other device is valid.



PERFORMANCE CHARACTERISTICS

To be established

LIMITATIONS OF TEST

1. The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to CMV in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Spectrum CMV IgG/IgM Rapid Test is limited to the qualitative detection of antibodies to CMV in human serum or plasma. The intensity of the test band does not correlate with antibody titer of the specimen.
3. A negative result for an individual subject indicates absence of detectable CMV antibodies. However, a negative test result does not preclude the possibility of exposure to or infection with CMV.
4. A negative result can occur if the quantity of the anti-virus antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

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