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

CTK BIOTECH
SIMPLIFYING DIAGNOSTICS

REF
Catalog Number R0223C
IVD
In vitro Diagnostic

INTENDED USE

The *OnSite* Duo CMV IgG-IgM Rapid Test is a lateral flow immunoassay for the simultaneous detection and differentiation of IgM and IgG antibodies to 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 *OnSite* Duo 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[1]. The relatively frequent incidence and the severity of the disease in newborns and immunosuppressed individuals clearly establishes this agent as an important human pathogen[2-4]. 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. 10% to 25% of these infants may subsequently develop hearing loss[6]. 5% to 10% may exhibit various degrees of mental retardation and central nervous system motor disorders during their life[5]. 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[7].

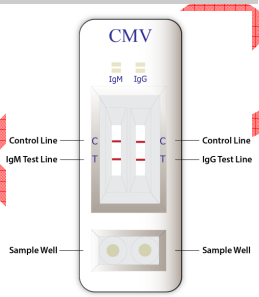
The age at which most postnatal CMV infections are acquired varies with socioeconomic conditions. Only about 10% to 15% of the children in the United States are seropositive; by the age of 35, however, about 50% of the population is seropositive[2-4]. The majority of individuals that contract postnatal 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 be life-threatening[2-4].

Antibodies of the IgM class are produced during the first 2-3 weeks of infection with CMV and exist only transiently in most patients[8,9]. Serologic procedures which measure the presence of IgM anti-CMV and IgG anti-CMV help to discriminate between primary and recurrent infections since IgM anti-CMV are rarely found in recurrent infections[8].

The *OnSite* Duo CMV IgG-IgM Rapid Test allows detection and differentiation of IgG and IgM antibodies to CMV in one test within 15 minutes. The test is user friendly and can be performed without cumbersome laboratory equipment.

TEST PRINCIPLE

The *OnSite* Duo CMV IgG-IgM Rapid Test contains two test strips (left panel: CMV IgM test; right panel: CMV IgG test).



The CMV IgM Rapid Test in the left panel is a lateral flow chromatographic immunoassay. The test cassette consists of 1) a burgundy colored conjugate pad containing mouse anti-human IgM conjugated with colloidal gold (IgM conjugates) and a control antibody conjugated with colloidal gold, 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre-coated with recombinant CMV antigen, and the C line is pre-coated with a control line antibody.

The CMV IgG Rapid Test in the right panel is a lateral flow chromatographic immunoassay. The test cassette consists of 1) a burgundy colored conjugate pad containing CMV antigens conjugated with colloidal gold (CMV conjugates) and a control antibody conjugated with colloidal gold, 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre-coated with anti-human IgG antibody, and the C line is pre-coated with a control line antibody.

When an adequate volume of test specimen is dispensed into the sample well (S well) of the cassette, the specimen migrates by capillary action across the cassette. IgM anti-CMV, if present in the specimen, will bind to the IgM conjugates. The immunocomplex is then captured on the membrane by the pre-coated CMV antigen forming a burgundy colored T line in the left panel, 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 on the membrane by the pre-coated anti-human IgG forming a burgundy colored T line in the right panel, indicating a CMV IgG positive test result.

Absence of color development on both T lines suggests a negative result. The test contains an internal control (C line) which should exhibit burgundy colored lines of the immunocomplex of the control antibodies in both the left and right panels regardless of the color development on any of the T lines. If the C line does not develop in a panel, the test result is invalid and the specimen must be retested with another device. An invalid result in one panel does not invalidate the test result in the other panel.

REAGENTS AND MATERIALS PROVIDED

1. Individually sealed foil pouches containing:
   a. One cassette device
   b. One desiccant
2. Plastic droppers
3. Sample Diluent (REF SB-R0223, 5 mL/bottle)
4. One package insert (instructions for use)

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer

WARNINGS AND PRECAUTIONS

For *in Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the instructions provided in the insert may lead to inaccurate test results.
2. Do not open the sealed pouch unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15°C-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolyzed blood specimens for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
11. Handle the negative and positive controls in the same manner as patient specimens.
12. The test results should be read 15 minutes after a specimen is applied to the sample well of the device. Reading the results after 20 minutes may give erroneous results.
13. Do not perform the test in a room with strong air flow, i.e. 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. 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 to temperatures above 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

Plasma

Step 1: Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by venipuncture.
Step 2: Separate the plasma by centrifugation.
Step 3: Carefully withdraw the plasma into a new pre-labeled tube.

Serum

Step 1: Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by venipuncture.
Step 2: Allow the blood to clot.
Step 3: Separate the serum by centrifugation.
Step 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 for up to 5 days if not tested immediately. 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. Once thawed, mix the specimen well prior to assay.
Step 2: When ready to test, open the pouch at the notch and remove the device. Place the test device on a clean, flat surface.
Step 3: Be sure to label the device with the specimen's ID number.
Step 4: Fill the plastic dropper with the specimen.

For Detection of CMV IgM

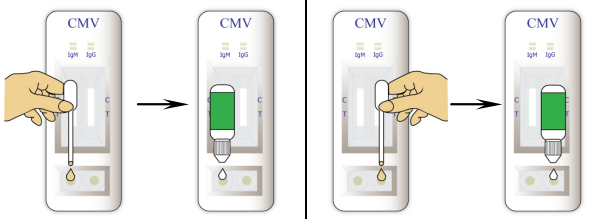
Holding the dropper vertically dispense 1 drop (about 30-45 µL) of specimen into the sample well (S well) making sure that there are no air bubbles.

Immediately add 1 drop (about 30-40 µL) of Sample Diluent to the sample well with the bottle positioned vertically.

For Detection of CMV IgG

Holding the dropper vertically dispense 1 drop (about 30-45 µL) of specimen into the sample well (S well) making sure that there are no air bubbles.

Immediately add 1 drop (about 30-40 µL) of Sample Diluent to the sample well with the bottle positioned vertically.



1 drop of specimen | **1 drop of sample diluent** | **1 drop of specimen** | **1 drop of sample diluent**

Step 5: Set up timer
Step 6: Results can be read in 15 minutes.

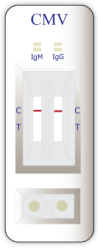
Do not read result after 20 minutes. To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

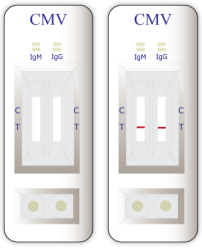
1. **Internal Control:** This test device contains a built-in control feature, the C line. The C line develops after adding specimen and sample diluent. If the C line does not develop, review the whole procedure and repeat the test with a new device.
2. **External Control:** Good Laboratory Practice recommends using external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
   a. New operator uses the kit, prior to performing the testing of specimens
   b. A new lot of test kits is used
   c. A new shipment of test kits is used
   d. The temperature used during storage of the kit falls outside of 2°C-30°C
   e. The temperature of the test area falls outside of 15°C-30°C
   f. To verify a higher than expected frequency of positive or negative results
   g. To investigate the cause of repeated invalid results

INTERPRETATION OF ASSAY RESULT

1. **NEGATIVE RESULT**: If only the C line is present, the absence of any burgundy color in both T lines indicates that neither IgM anti-CMV nor IgG anti-CMV are detected in the specimen. The result is negative.



2. **INVALID:** If the C line does not develop, the assay is invalid regardless of any burgundy color in the T lines as indicated below. Repeat the assay with a new device.

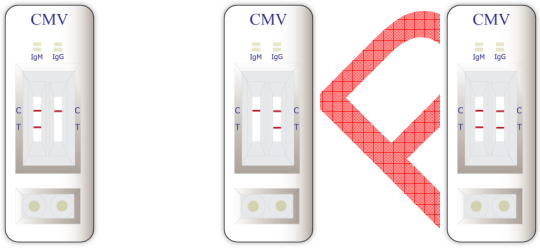


2. **POSITIVE RESULT**:

CMV IgM: In addition to the presence of the C line, if only the T line in the left panel is developed, the test indicates the presence of IgM anti-CMV. The result is IgM positive.

CMV IgG: In addition to the presence of the C line, if only the T line in the right panel is developed, the test indicates the presence of IgG anti-CMV. The result is IgG positive.

CMV IgM/IgG: In addition to the presence of the C lines, if the T lines in both panels are developed, the test indicates the presence of IgM and IgG anti-CMV. The result is IgM and IgG positive.



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

PERFORMANCE CHARACTERISTICS

1. **Clinical Performance For IgM Test**

A total of 286 patient samples from susceptible subjects were tested with the *OnSite* Duo CMV IgG-IgM Rapid Test and with a commercial CMV IgM EIA. Comparison for all subjects is shown in the following table:

	OnSite Duo CMV IgG-IgM Rapid Test		
IgM EIA Test	**Positive**	**Negative**	**Total**
Positive	81	2	83
Negative	3	200	203
Total	84	202	286

Relative Sensitivity: 97.6% , Relative Specificity: 98.5%, Overall Agreement: 98.3%

2. **Clinical Performance For IgG Test**

A total of 341 patient samples from susceptible subjects were tested with the *OnSite* Duo CMV IgG-IgM Rapid Test and with a commercial CMV IgG EIA. Comparison for all subjects is shown in the following table:

	OnSite Duo CMV IgG-IgM Rapid Test		
IgG EIA Test	**Positive**	**Negative**	**Total**
Positive	113	2	115
Negative	2	224	226
Total	115	226	341

Relative Sensitivity: 98.2% , Relative Specificity: 99.1%, Overall Agreement: 98.8%

LIMITATIONS OF TEST

1. The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of antibodies to CMV in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The *OnSite* Duo 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 lines does not have a linear correlation with the antibody titer of the specimen.
3. A negative result for an individual subject indicates absence of detectable IgG and IgM anti-CMV. 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 quantities of the IgG and IgM anti-CMV present in the specimen are 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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Index of Symbols

	Consult instructions for use	IVD	For *in vitro* diagnostic use only		Use by
REF	Catalog #	LOT	Lot Number	Σ N	Tests per kit
2°C 30°C	Store between 2-30°C	2	Do not reuse		
	Manufacturer		Date of manufacture		

CTK Biotech, Inc.
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