

Overview

Useful For

Rapid qualitative detection of cytomegalovirus (CMV) DNA

This test is **not intended** for the monitoring of cytomegalovirus (CMV) disease progression.

Highlights

Qualitative detection of cytomegalovirus (CMV) DNA

Method Name

Real-Time Polymerase Chain Reaction (PCR)/DNA Probe Hybridization

NY State Available

Yes

Specimen

Specimen Type

Varies

Ordering Guidance

For plasma specimens order CMVQN / Cytomegalovirus (CMV) DNA Detection and Quantification by Real-Time PCR, Plasma.

Necessary Information

Specimen source is required.

Specimen Required

Submit only 1 of the following specimens:

Supplies: Aliquot Tube, 5 mL (T465)

Specimen Type: Fluid

Sources: Spinal, pleural, peritoneal, ascites, pericardial, amniotic, or ocular

Container/Tube:

Preferred: Sterile screw-cap 5-mL aliquot tube

Acceptable: Sterile Container

Specimen Volume: 0.5 mL

Collection Instructions: Do not centrifuge.

Supplies: Aliquot Tube, 5 mL (T465)

Specimen Type: Fluid

Sources: Respiratory; bronchial washing, bronchoalveolar lavage, nasopharyngeal aspirate or washing, sputum, or tracheal aspirate

Container/Tube:

Preferred: Sterile screw-cap 5-mL aliquot tube

Acceptable: Sterile container

Specimen Volume: 1.5 mL

Supplies:

-Culturette (BBL Culture Swab) (T092)

-M4-RT (T605)

-Bartels FlexTrans VTM-3 mL (T892)

-Jiangsu VTM-3 mL (T891)

Specimen Type: Swab

Sources: Genital; cervix, vagina, urethra, anal/rectal, or other genital sources

Container/Tube: multimicrobe media (M4-RT) (T605) and ESwabs

Collection Instructions: Place swab back into multimicrobe media (M4-RT, M4, or M5)

Supplies:

-Culturette (BBL Culture Swab) (T092)

-M4-RT Media (T605)

-Bartels FlexTrans VTM-3 mL (T892)

-Jiangsu VTM-3 mL (T891)

Specimen Type: Swab

Sources: Miscellaneous; dermal, eye, nasal, saliva, or throat

Container/Tube: multimicrobe media (M4-RT) (T605) and ESwabs

Collection Instructions: Place swab back into multimicrobe media (M4-RT, M4, or M5)

Supplies:

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M4-RT (T605)

-Bartels FlexTrans VTM-3 mL (T892)

-Jiangsu VTM-3 mL (T891)

Specimen Type: Tissue

Sources: Brain, colon, kidney, liver, lung, etc.

Container/Tube: Sterile container containing 1 mL to 2 mL of sterile saline or multimicrobe medium (M4-RT [T605], M4, or M5)

Specimen Volume: Entire collection

Collection Instructions: Submit only fresh tissue in multimicrobe media (M4-RT) (T605) or a sterile container with 1 to 2 mL sterile saline

Specimen Type: Urine

Container/Tube: Sterile container

Specimen Volume: 1 mL

Collection Instructions: Collect a random urine specimen.

Specimen Type: Bone marrow

Container/Tube: Lavender top (EDTA)

Specimen Volume: 0.5 mL

Forms

If not ordering electronically, complete, print, and send a [Microbiology Test Request](#) (T244) with the specimen.

Specimen Minimum Volume

Body Fluid, Ocular Fluid, Spinal Fluid, or Urine: 0.3 mL

Respiratory Specimens: 1 mL

Tissue: 2 x 2-mm biopsy

Reject Due To

Hemolysis	Calcium alginate-tipped swab, wood swab, or transport swab containing gel Blood Serum Feces Paraffin blocks Breast milk
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Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Refrigerated (preferred)	7 days	

Specimen Type	Temperature	Time	Special Container
	Frozen	7 days	

Clinical and Interpretive

Clinical Information

Infection with cytomegalovirus (CMV) is a significant cause of morbidity and mortality in transplant recipients and other immunocompromised hosts. Specific neurologic syndromes associated with CMV infection include subacute radiculomyelopathy, peripheral neuropathy, and encephalitis.

CMV-associated central nervous system (CNS) disease occurs most commonly in immunocompromised patients. Histologic evidence of CMV infections in autopsy brain tissue was identified in 20% to 40% of AIDS patients. In 2 separate studies, CMV (DNA) was the most common herpesvirus (29/181, 16/49) detected from cerebrospinal fluid of patients with AIDS.

CNS infections with CMV can also occur in immunocompetent patients. CMV is a leading cause of congenital viral infections worldwide, and laboratory testing by real-time PCR is useful in the diagnosis of neonatal CMV disease.

Reference Values

Negative

Interpretation

Detection of cytomegalovirus (CMV) DNA in a specimen supports the clinical diagnosis of infection due to this virus.

Studies indicate that CMV DNA is not detected by PCR in cerebrospinal fluid from patients without central nervous system disease caused by this virus.

Cautions

A negative result does not eliminate the possibility of cytomegalovirus (CMV) infection.

This assay is only to be used for patients with a clinical history and symptoms consistent with CMV infection, and must be interpreted in the context of the clinical picture. This test should not be used to screen asymptomatic patients.

Supportive Data

The following validation data support the use of this assay for clinical testing.

Accuracy:

A total of 200 prospective clinical samples (respiratory [n=72], urine [n=67], spinal fluid [n=25], fresh tissue [n=18], amniotic fluid [n=10], and bone marrow [n=8]) were submitted to our reference laboratory for cytomegalovirus (CMV) real-time PCR (Roche analyte specific reagents [ASR], Roche Diagnostics, Indianapolis, IN). Respiratory samples included bronchoalveolar lavage (BAL) fluid (n=25), bronchial washing (n=40), nasal swab (n=4), tracheal secretions (n=2), and throat swab (n=1). Each sample was tested by 6 real-time PCR assays, and the results were compared to consensus reference standard (4 of 6 results being in agreement). The performance of the US9 CMV real-time PCR (laboratory-developed test) is summarized in Table 1 below:

Table 1. Performance of the US9 CMV real-time PCR assay following testing of prospective clinical samples (n=200)

US9 CMV PCR	Consensus Result		Kappa	Sensitivity	Specificity
	Positive	Negative			
Positive	45	0	0.99	97.8 (87.6-99.9)	100 (97.1-100)
Negative	1	154			

Analytical Sensitivity/Limit of Detection (LoD):

To evaluate the analytical sensitivity, whole virus control (Acrometrix, Life Technologies) at a starting concentration of 500,000 copies/mL was used to generate a dilution panel. In brief, samples were diluted 1:2 in tris-EDTA buffer to a final concentration of 8 copies/mL. Each member of the dilution panel was then tested in triplicate, with the LoD being defined as the highest dilution at which all replicates tested positive. The LoD was determined to be 122 copies/mL.(1)

Analytical Specificity:

No PCR signal was obtained from extracts of 44 bacterial and viral isolates including Epstein-Barr virus (EBV), herpes simplex virus (HSV), varicella-zoster virus (VZV), human herpes virus (HSV) 6, HHV7, HHV8, and parvovirus.

Clinical Reference

1. Espy M, Binnicker MJ: Comparison of six real-time PCR assays for the qualitative detection of cytomegalovirus in clinical specimens. *J Clin Microbiol* 2013;51(11):3749-3752
2. Petit CK, Cho ES, Lemann W, et al: Neuropathy of acquired immunodeficiency syndrome (AIDS): an autopsy review. *J Neuropathol Exp Neurol* 1986 November;45(6):635-646
3. Cinque P, Vago L, Dahl H, et al: Polymerase chain reaction on cerebrospinal fluid for diagnosis of virus-associated opportunistic diseases of the central nervous system in HIV-infected patients. *AIDS* 1996 August;10(9):951-958
4. Broccolo F, Iuliano R, Careddu AM, et al: Detection of lymphotropic herpesvirus DNA by polymerase chain reaction in cerebrospinal fluid of AIDS patients with neurological disease. *Acta Virol* 2000 June-August;44(3):137-143
5. Prosch S, Schielke E, Reip A, et al: Human cytomegalovirus (HCMV) encephalitis in an immunocompetent young person and diagnostic reliability of HCMV DNA PCR using cerebrospinal fluid of nonimmunosuppressed patients. *J Clin Microbiol* 1998 December;36(12):3636-3640
6. Sia IG, Patel R: New strategies for prevention and therapy of cytomegalovirus infection and disease in solid-organ transplant recipients. *Clin Microbiol Rev* 2000;13:83-121

Performance
Method Description

Viral nucleic acid is extracted by the MagNA Pure automated instrument (Roche Applied Science) from clinical specimens. Primers directed to the target *Us9* gene produce a 285-base pair amplicon.(1) The LightCycler

instrument amplifies and monitors by fluorescence the development of target nucleic acid sequences after the annealing step during PCR cycling. This is an automated PCR system that can rapidly detect amplicon development through stringent air-controlled temperature cycling in capillary cuvettes. The detection of amplified products is based on the fluorescence resonance energy transfer (FRET) principle. For FRET product detection, a hybridization probe with a donor fluorophore, fluorescein, on the 3'-end is excited by an external light source and emits light that is absorbed by a second hybridization probe with an acceptor fluorophore, LC-Red 640, at the 5'-end. The acceptor fluorophore then emits a light of a different wavelength that can be measured with a signal that is proportional to the amount of specific PCR product. Melting curve analysis is performed following PCR amplification. Starting at 45 degrees C, the temperature in the thermal chamber is slowly raised to 80 degrees C and the fluorescence is measured at frequent intervals. Analysis of the PCR amplification and probe melting curves is accomplished through the use of LightCycler software.(Espy M, Binnicker MJ: Comparison of six real-time PCR assays for the qualitative detection of cytomegalovirus in clinical specimens. J Clin Microbiol 2013;51[11]:3749-3752)

PDF Report

No

Day(s) Performed

Monday through Sunday

Report Available

Same day/1 to 3 days

Specimen Retention Time

1 week

Performing Laboratory Location

Rochester

Fees and Codes**Fees**

- Authorized users can sign in to [Test Prices](#) for detailed fee information.
- Clients without access to Test Prices can contact [Customer Service](#) 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact [Customer Service](#).

Test Classification

This test was developed, and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

87496

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
LCMV	Cytomegalovirus PCR	5000-5

Result ID	Test Result Name	Result LOINC Value
SRC66	Specimen Source	31208-2
81240	Cytomegalovirus PCR	5000-5