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MAYO CLINIC LABORATORIES

Test Definition: CMVPV

Cytomegalovirus (CMV) Molecular Detection, PCR, Varies

Overview

Useful For
Rapid qualitative detection of cytomegalovirus (CMV) DNA

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

Highlights
This test provides qualitative detection of cytomegalovirus 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.

For lower respiratory specimens, order CMVLR / Cytomegalovirus (CMV) Molecular Detection, PCR, Lower Respiratory.

Necessary Information
1. Specimen source is required.
2. Source information must include main anatomical site of collection.

Specimen Required
Submit only 1 of the following specimens:

Specimen Type: Body fluid
Sources: Spinal, pleural, peritoneal, ascites, pericardial, amniotic, or ocular
Container/Tube:
Preferred: Sterile, screwcap, 5-mL aliquot tube
Acceptable: Sterile container
Specimen Volume: 0.5 mL

Collection Instructions: Do not centrifuge.

Specimen Type: Upper respiratory tract fluid
Sources: Nasopharyngeal aspirate or washing
Container/Tube:
Preferred: Sterile, screwcap, 5-mL aliquot tube
Acceptable: Sterile container
Specimen Volume: 1.5 mL
Collection Instructions: Do not centrifuge.

Specimen Type: Swab
Sources: Dermal, eye, nasal, saliva, throat, or genital
Supplies:
-Culturette (BBL Culture Swab) (T092)
-M4-RT (T605)
Container/Tube: Multimicrobe media (M4-RT, M4, M5, Bartels, or Jiangsu) and ESwab or Culturette
Collection Instructions: Place swab back into multimicrobe media.

Specimen Type: Tissue
Sources : Brain, colon, kidney, liver, lung, etc.
Supplies: M4-RT (T605)
Container/Tube: Sterile container containing 1 mL to 2 mL of sterile saline or multimicrobe medium (M4-RT, M4, M5, Bartels, or Jiangsu)
Specimen Volume: Entire collection
Collection Instructions: Submit only fresh tissue.

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
Collection Instructions: Send bone marrow in original tube. **Do not aliquot.**

Forms

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

Specimen Minimum Volume

Ocular Fluid, Spinal Fluid, or Urine: 0.3 mL; Body Fluid (pleural, peritoneal, ascites, pericardial): See Specimen Required; Upper respiratory tract specimens: (Nasopharyngeal aspirate or washing): 1 mL; Tissue: 2 x 2-mm biopsy

Reject Due To

Calcium alginate-tipped swab Wood swab Transport swab containing gel Dry/flocked ESwab Feces Paraffin blocks Breast milk Heat-inactivated specimens	Reject

Specimen Stability Information

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

Clinical & 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.

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

Central nervous system infections with CMV can also occur in immunocompetent patients, and infection can result in a mono-like illness. A significant percentage of adults are positive for IgG antibodies against CMV, suggesting prior infection with the virus.

Reference Values

Negative

Reference values apply to all ages.

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 polymerase chain reaction 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.

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 polymerase chain reaction (PCR) (Roche analyte specific reagents, Roche Diagnostics). 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 the Table:

Table. Performance of the *Us9* CMV real-time PCR assay following testing of prospective clinical samples (n=200)

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

Analytical Sensitivity/Limit of Detection:
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 limit of detection (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, herpes simplex virus, varicella-zoster virus, human herpes virus (HHV) 6, HHV7, HHV8, and parvovirus.

Clinical Reference

1. Binnicker MJ, Espy M. 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. Petito CK, Cho ES, Lemann W, Navia BA, Price RW. Neuropathy of acquired immunodeficiency syndrome (AIDS): an autopsy review. J Neuropathol Exp Neurol. 1986;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;10(9):951-958
4. Broccolo F, Iulioano 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;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;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(1):83-121
7. Razonable RR, Humar A. Cytomegalovirus in solid organ transplant recipients-Guidelines of the American Society of Transplantation Infectious Diseases Community of Practice. Clin Transplant. 2019;33(9):e13512. doi:10.1111/ctr.13512
8. Febbo J, Revels J, Ketai L. Viral pneumonias. Infect Dis Clin North Am. 2024;38(1):163-182. doi:10.1016/j.idc.2023.12.009

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. The LightCycler 480 instrument amplifies and monitors by fluorescence the development of target nucleic acid sequences after the annealing step during polymerase chain reaction (PCR) cycling. This is an automated PCR system that can rapidly detect amplicon development. 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 40 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.(Binnicker MJ, Espy M. 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 4 days

Specimen Retention Time
7 days

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Main Campus

Fees & 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 account representative. 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. It 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
CMVPV	Cytomegalovirus, PCR	5000-5

Result ID	Test Result Name	Result LOINC® Value
CMVPS	Specimen Source	31208-2
618969	Cytomegalovirus PCR	5000-5