Test Definition: LCMV

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.

This test **should not be used** to screen asymptomatic patients.

Highlights

This test provides qualitative detection of cytomegalovirus DNA

Method Name

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

NY State Available

No

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

Specimen source is required.

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 screw cap 5-mL aliquot tube
Acceptable: Sterile container

Specimen Volume: 0.5 mL
Collection Instructions: Do not centrifuge.

Specimen Type: Genital swab
Sources: Cervix, vagina, urethra, anal/rectal, or other genital sources
Supplies:
-Culturette (BBL Culture Swab) (T092)
-M4-RT (T605)
Container/Tube: Multimicrobe media (M4-RT) and ESwabs
Collection Instructions: Place swab back into multimicrobe media (M4-RT, M4, or M5)

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

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, or M5)
Specimen Volume: Entire collection
Collection Instructions: Submit only fresh tissue in multimicrobe media (M4-RT) 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
Collection Instructions: Send bone marrow in original tube. **Do not aliquot.**

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

Calcium alginate-tipped swab, wood	Reject

swab, or transport swab containing gel Feces Paraffin blocks Breast milk Heat-inactivated specimens	

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 cerebrospinal fluid of patients with AIDS.

Central nervous system 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 polymerase chain reaction is useful in the diagnosis of neonatal CMV disease.

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 assays 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/Diagnostic Sensitivity and Specificity:
To assess the accuracy of the cytomegalovirus (CMV) laboratory-developed test, multiple clinical specimen types spiked with CMV control material (40 positive, 44 negative) were tested and the results compared to those of a laboratory-developed reference polymerase chain reaction (PCR) method.

CMV LDT		CMV Reference LDT	
		Positive	Negative
	Positive	40	0
	Negative	0	44
	Total	40	44

Sensitivity (95% CI): 100% (89-100)
Specificity (95% CI): 100% (90-100)

Analytical Sensitivity/Limit of Detection:
To evaluate the analytical sensitivity, whole virus control (Acrometrix, Life Technologies) at a starting concentration of 100,000 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 1 copy/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.

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-6 (HHV6), HHV7, HHV8, and parvovirus.

Precision:
Interassay precision was 100%, and intraassay precision was 95%.

Reportable Range:
This is a qualitative assay, and the results are reported as either negative or positive for targeted CMV DNA.

Clinical Reference

1. Binnicker MJ, Espy ME. 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

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 Hind III X fragment produce a 291-base pair amplicon. The LightCycler 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 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 MJ, Smith TF. Detection of cytomegalovirus [CMV] in clinical specimens by LightCycler PCR. Abstr Gen Meet Am Soc Microbiol. 2000 May 21-25; 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 Saturday

Report Available

Same day/1 to 3 days

Specimen Retention Time

14 days

Performing Laboratory Location

Mayo Clinic Jacksonville Clinical Lab

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
LCMV	Cytomegalovirus PCR	5000-5

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