Test Definition: CCMVU

Congenital Cytomegalovirus (cCMV), Molecular Detection, PCR, Urine

Overview

Useful For
Aiding in the rapid diagnosis of cytomegalovirus infections in neonates 21 days of age or younger using urine specimens

Method Name
Real-Time Polymerase Chain Reaction (PCR)

NY State Available
Yes

Specimen

Specimen Type
Urine

Ordering Guidance
This test should be ordered to test urine specimens from patients aged 21 days or younger. To test urine from patients older than 21 days, order CMVPV / Cytomegalovirus (CMV) Molecular Detection, PCR, Varies.

To test saliva specimens from patients aged 21 days or younger, order CCMVS / Congenital Cytomegalovirus (cCMV), Molecular Detection, PCR, Saliva. To test saliva from patients older than 21 days, order CMVPV / Cytomegalovirus (CMV) Molecular Detection, PCR, Varies.

Specimen Required
Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Container/Tube: Plastic sterile container, 5 mL
Specimen Volume: 0.2 mL
Collection Instruction:
1. Collect a random urine from a urine bag, container, or catheter.
2. Transfer urine to sterile container.
3. No preservative

Specimen Minimum Volume
0.1 mL

Reject Due To

All specimens will be evaluated at Mayo Clinic Laboratories for test suitability.

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Urine	Frozen	72 hours	

Clinical & Interpretive

Clinical Information

Cytomegalovirus (CMV) is a double-stranded DNA virus of the Herpesviridae family. CMV is transmitted through direct contact from a variety of infected body fluids, as well as through sexual contact, organ transplantation, and intrauterine transmission during pregnancy.(1) CMV infection may be asymptomatic but can cause a wide range of symptoms, especially in immunocompromised individuals. Congenitally acquired CMV (cCMV) may lead to long-term sequelae, including visual and hearing impairments, and cognitive and motor deficits.(2) Current recommendations indicate testing urine and saliva swabs for cCMV using a nucleic acid amplification detection method.(3)

Reference Values

Negative

Interpretation

A positive result indicates the presence of cytomegalovirus (CMV) DNA in the patient sample.

A negative result indicates the absence of CMV DNA in the patient sample.

An invalid result indicates inability to conclusively determine presence or absence of CMV DNA in the patient sample.

Cautions

This test is not validated for sample types other than urine and saliva from infants 21 days of age or younger.

Negative results do not preclude cytomegalovirus (CMV) infection and should not be used as the sole basis for treatment or other patient management decisions.

False-negative results may occur if viral nucleic acid is present at a level that is below the analytical sensitivity of the assay or if the virus has genomic mutations, insertions, deletions, or rearrangements, or if the assay is performed very early in the course of illness.

The performance of this test has not been established for monitoring treatment of CMV infection.

Supportive Data

Accuracy:

To assess the accuracy of the Simplexa Congenital CMV (cytomegalovirus) Direct assay, clinical urine specimens (n=60) were tested and the results compared to those of a routine, lab-developed (LDT) CMV polymerase chain reaction (PCR) assay.(4) Results are summarized below in the Table.

Table. Urine Accuracy

Simplexa Congenital	CMV LDT PCR results

CMV Direct results		
	Positive	Negative
Positive	31(a)	0
Negative	2(b)	26
Invalid	1(c)	0

a. One sample initially positive by CMV LDT PCR tested negative after frozen storage, but repeated positive results were obtained in triplicate by CMV LDT PCR (crossing point range: 36.94 to 40.00), and the sample was therefore included in accuracy experiments.
b. Two samples were negative by Simplexa but noted to have amplification curves and cycle threshold values (38.3 and 40.3) visible within the software, but outside of the defined positivity cutoff per the manufacturers instructions for use (< or =37.5). These samples were also positive by CMV LDT (Cp, 36.62 and 36.94 to 40.00 [see footnote a]), indicating the presence of CMV DNA at or below the limit of detection of the Simplexa cCMV Direct assay.
c. There was one initial Simplexa internal control failure; the urine sample was retested by Simplexa in singlet but repeated as invalid.

Simplexa cCMV Direct assay accuracy results for urine samples produced 91% positive agreement, 100% negative agreement, and 95% overall agreement.

Clinical Reference

1. Manicklal S, Emery VC, Lazzarotto T, Boppana SB, Gupta RK. The "silent" global burden of congenital cytomegalovirus. Clin Microbiol Rev. 2013;26(1):86-102. doi:10.1128/CMR.00062-12
2. Cannon MJ, Griffiths PD, Aston V, Rawlinson WD. Universal newborn screening for congenital CMV infection: what is the evidence of potential benefit?. Rev Med Virol. 2014;24(5):291-307. doi:10.1002/rmv.1790
3. Rawlinson WD, Boppana SB, Fowler KB, et al. Congenital cytomegalovirus infection in pregnancy and the neonate: consensus recommendations for prevention, diagnosis, and therapy. Lancet Infect Dis. 2017;17(6):e177-e188. doi:10.1016/S1473-3099(17)30143-3
4. Binnicker MJ, Espy ME. Comparison of six real-time PCR assays for qualitative detection of cytomegalovirus in clinical specimens. J Clin Microbiol. 2013;51(11):3749-3752. doi:10.1128/JCM.02005-13
5. Fernholz EC, Vidal-Folch N, Hasadsri L. Rapid and direct detection of congenital cytomegalovirus using a commercial real-time PCR assay. J Clin Microbiol. 2023;61(3):e0178122. doi:10.1128/jcm.01781-22

Performance

Method Description

The Simplexa Congenital CMV (cytomegalovirus) Direct assay is a real-time polymerase chain reaction system that enables the direct amplification and detection of CMV DNA from either saliva swab or urine specimens without nucleic acid extraction. The system consists of the Simplexa Congenital CMV Direct Reaction Mix, the LIAISON MDX (with LIAISON MDX Studio Software), the direct amplification disc, and associated accessories.

In the Simplexa Congenital CMV Direct assay, bifunctional fluorescent probe-primers are used together with corresponding reverse primers to amplify CMV DNA. A well-conserved region of the CMV UL83 gene is targeted to

identify CMV DNA. An internal control is used to detect PCR failure and/or inhibition.(Package insert: Simplexa Congenital CMV Direct. Diasorin; REF MOL2255. Rev. 01, 11/2022)

PDF Report
No

Day(s) Performed
Monday through Sunday

Report Available
Same day/1 to 2 days

Specimen Retention Time
3 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 has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information
87496

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
CCMVU	Congenital CMV, PCR, Urine	4999-9

Result ID	Test Result Name	Result LOINC® Value
620658	Congenital CMV, PCR, Urine	4999-9