Test Definition: CCMVS

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

Overview

Useful For

Aiding in the rapid diagnosis of cytomegalovirus (CMV) infections in neonates 21 days of age or younger using saliva specimens

Method Name

Real-Time Polymerase Chain Reaction (PCR)

NY State Available

Yes

Specimen

Specimen Type

Swab

Ordering Guidance

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

To test urine specimens from patients 21 days or younger, order CCMVU / Congenital Cytomegalovirus (cCMV), Molecular Detection, PCR, Urine. To test urine from patients older than 21 days, order CMVPV / Cytomegalovirus (CMV) Molecular Detection, PCR, Varies.

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

Specimen Required

Supplies: BD UVT with mini tip flocked swab (T971)
Collection Container/Tube: Flocked swab
Submission Container/Tube: Sterile, screw-capped, tube containing viral transport media with flocked swab containing saliva. See Collection Instructions for acceptable media.
Specimen Volume: 1 Swab in viral transport media
Collection Instructions:
1. Collect a saliva specimen using a flocked swab per swab manufacturer instructions.
2. Place in a sterile, screw capped tube containing BD Universal Viral Transport Medium (UVT) (1 mL or 3 mL), Copan Universal Transport Medium (UTM) (1 mL or 3 mL), Remel M4-RT, Remel M4, or Remel M6.

Specimen Minimum Volume

Saliva swab submitted in minimum volume of 0.3 mL of viral transport media.

Reject Due To

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

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Swab	Frozen	7 days	

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 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 saliva swab and urine specimens 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 the viral nucleic acid is present at a level below the analytical sensitivity of the assay, 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 saliva swab specimens (n=47) and contrived saliva samples (n=8) were tested, and the results compared to those of a routine, lab-developed (LDT) CMV PCR assay.(4) Results are summarized in the Table:

Table. Saliva Accuracy

Simplexa Congenital CMV Direct results	CMV LDT PCR results	
	Positive	Negative
Positive	30(a)	0
Negative	0	24(a)
Invalid	0	1(a)

a. There were three initial Simplexa internal control failures; all saliva swab samples were retested by Simplexa in singlet. Two samples returned valid results and one repeated as invalid.

Simplexa cCMV Direct assay accuracy results for saliva samples produced 100% positive agreement, 96% negative agreement, and 98% 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 Direct assay is a real-time polymerase chain reaction (PCR) 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 or inhibition.(Package insert: Simplexa Congenital

CMV Direct. Diasorin; REF MOL2255. Rev. 01, 011/2022)

PDF Report
No

Day(s) Performed
Monday through Sunday

Report Available
Same day/1 to 2 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 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
CCMVS	Congenital CMV, PCR, Saliva	83065-3

Result ID	Test Result Name	Result LOINC® Value
620659	Congenital CMV, PCR, Saliva	83065-3