SERVICE ANNOUNCEMENT

Congenital cytomegalovirus (cCMV) by PCR Testing

cCMV infection

cCMV is a common infection passed from mother to child *in utero* that impacts approximately one out of every 200 live births.[1] The majority of infants born with cCMV infection are asymptomatic. However, about 10%-15% may show symptoms including hearing or vision loss, seizures, microcephaly, low birth rate, rash and intellectual disability.[2] Of the approximately 85%-90% of infants who are asymptomatic at birth and infected with cCMV, 10%-15% will ultimately develop sensorineural hearing loss.[2]

cCMV screening

- CMV screening can encompass multiple approaches, including assessing clinical presentation (most commonly sensorineural hearing loss) and/or directly testing for the presence of CMV in the infant
  - While there is no clear consensus on cCMV screening, many states test for cCMV after a failed hearing screen
  - Infants who are asymptomatic at birth for cCMV infection may ultimately develop hearing loss and may benefit from a universal screening approach[3]
- Specimens should be collected from infants less than 21 days of age to confirm a diagnosis of cCMV infection
- Saliva is a convenient sample that is commonly used to test for cCMV; urine samples provide definitive results for the detection of cCMV
  - A "Detected" or "Positive" result in saliva is considered a Presumptive Positive result since CMV can be shed in breast milk
  - A "Detected" or "Positive" result in a urine is considered a confirmed result for cCMV

cCMV diagnostic testing

cCMV is most commonly detected in neonates using viral culture and molecular assays. Although CMV is readily shed in saliva and urine, viral cultures have a prolonged turnaround time compared to molecular methods. PCR performed from dried blood spots (DBS) is a convenient method for detecting CMV. However, the sensitivity for detecting CMV in DBS is lower than other specimen types and may result in false negative results. PCR performed using saliva and urine exhibits the highest sensitivity and specificity for detecting cCMV.[4]

Labcorp offers a PCR-based cCMV screening test that can be performed on a saliva swab (collected in Universal Transport Media (UTM) or Viral Transport Media (VTM)) or using unpreserved urine in infants less than 21 days of age.

Test No.	Test Name	Sample Type	Use and Interpretation

139865	Congenital CMV PCR, Saliva Swab	Saliva collected using a synthetic swab and placed in Universal Transport Media (UTM)* or Viral Transport Media (VTM)	• In infants less than 21 days of age, a **Detected** result is considered a Presumptive Positive since CMV may be shed in breast milk
			  • Confirmatory testing should be performed from a urine collection
			• In infants less than 21 days of age, a **Not Detected** result is considered Negative for cCMV infection
			  • The negative predictive agreement in a prospective clinical trial enrolling greater than 1,800 infants was less than 99.9% (95% CI: 99.7–100%)[4]

139840	Congenital CMV PCR, Urine	Urine collected in a sterile cup (Urine may be collected from urine bags, containers and catheters.)	• In infants less than 21 days of age, a **Detected** result is considered Positive for cCMV infection • In infants less than 21 days of age, a **Not Detected** result is considered Negative for cCMV infection • The negative predictive agreement in a prospective clinical trial enrolling greater than 1,600 infants was 100% (95% CI: 99.8–100%)[4]
The preferred collection for a saliva swab is the Copan UTM-RT collection kit provided by Labcorp (PeopleSoft No. 24674).* ***Note: For detailed testing and specimen collection information, visit the online Test Menu at Labcorp.com or contact your account representative.*			

1. Congenital CMV Infection. U.S. Centers for Disease Control and Prevention website: https://www.cdc.gov/cmv/clinical/congenital-cmv.html. Updated April 28, 2020. Accessed May 2023.
2. Kabani N, Ross SA. Congenital cytomegalovirus infection. *J Infect Dis.* 2020 Mar 5;221(Suppl 1):S9-S14.
3. Gantt S, Dionne F, Kozak FK, et al. Cost-effectiveness of universal and targeted newborn screening for congenital cytomegalovirus infection. *JAMA Pediatr.* 2016 Dec 1;170(12):1173-1180.
4. Simplexa™ Congenital CMV Direct [package insert]. Cypress, CA: DiaSorin Molecular, LLC; January 2022.

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