Technical Bulletin

Congenital CMV (cCMV)

July 2026

Background: Effective July 20, 2026, Methodist Pathology Center will begin performing Congenital Cytomegalovirus (cCMV) testing in-house. Previously, this assay was referred to an external reference laboratory for testing.

Congenital CMV is the most common congenital infection worldwide and occurs when the virus passes from the mother's blood through the placenta to infect the unborn fetus. It is also the leading non-genetic cause of childhood hearing loss and a significant cause of neurodevelopmental delays like cognitive deficit and vision impairment. Timely diagnosis of congenital CMV is critical for disease management and intervention. Infants with congenital CMV shed high levels of the virus in their urine and saliva. Direct detection from these samples can provide a definitive diagnosis.

Specimen Requirements:

Only from infants less than 21 days old (specimens collected after 21 days cannot reliably distinguish congenital from postnatal CMV infection).

- Urine collected from urine bags, containers, or catheters- stable 8 hours at 2-8ºC, otherwise frozen at -20 ºC
- Saliva flocked swab in Viral Transport Media (VTM) or Universal Transport Media (UTM) (1mL or 3mL)- stable 48 hours 18-25 ºC, otherwise 7 days 2-8 ºC

Collection: To collect a saliva sample from a baby, gently insert the swab into the mouth and collect pooling saliva at the corners of the mouth or under the tongue. Rotate the swab for 10-15 seconds and move it to the opposite side of the baby's mouth to repeat the process.

Order: CMV Congenital Qual PCR

Turn Around Time: 24 hours. Routine testing is performed daily

Reporting/Interpretation: Results will be reported as "Detected" or "Not Detected"

Note:

- Only valid for specimens from infants less than 21 days old
- A positive Saliva result is considered a presumptive positive and should be confirmed with a urine sample collected within the first 21 days of life.
- cCMV Assay is a qualitative test and does not provide quantitative values of the detected organisms.
- Specimens collected after 21 days will be referred to our reference laboratory for testing.

References:

1. Simplexa™ Congenital CMV Direct Package Insert. IFUK.US.MOL2255 Rev 3. DiaSorin Molecular LLC. Cypress, California. March 19, 2024.

Please direct any questions to Reddy Cheemarla, Clinical Microbiology Director at (402)354-4560 or LaNett Whisler, Microbiology service leader at (402)354-4586.