WISCONSIN DIAGNOSTIC LABORATORIES

Microbiology Testing Update

EFFECTIVE JUNE 25, 2025
NEW TEST ANNOUNCEMENT: CONGENITAL CMV NAAT

Effective June 25, 2025, Wisconsin Diagnostic Laboratories (WDL) will offer the congenital CMV NAAT (LAB6202).

Congenital CMV (cCMV) is a leading non-genetic cause of childhood hearing loss and neurodevelopmental delays. To aid in the detection and diagnosis of cCMV, WDL will offer the congenital CMV NAAT.

The DiaSorin Simplexa Congenital CMV Direct test utilizes real-time polymerase chain reaction (RT-PCR) to qualitatively identify CMV DNA by targeting a conserved region of the UL83 gene. The assay is FDA approved to be performed on urine specimens from neonates <21 days of age. WDL has extended the stability of urine specimens outside of the FDA-approved indication with acceptable performance.

Congenital CMV testing may be performed on urine or saliva specimens, and both sources are available within the cCMV order.

Source	Performing Lab	TAT	Collection Container	Volume	Collection Notes
Urine	WDL	24 hours	Unpreserved urine in sterile container	Requested: 0.5 mL Minimum: 0.2 mL	
Saliva	Viracor	3-5 days	Swab in Universal (Viral) Transport Media (UTM)	NA	Saliva should be collected by placing a swab in mouth of infant and collecting pooling saliva at the corners or under the tongue by rotating for 10-15 sec until saturated, repeating on both sides of the mouth. Saliva specimens should ideally be collected at least 90 minutes after breastfeeding to reduce the risk of falsely positive results.

For the diagnosis of scenarios other than congenital CMV in non-blood specimens, order Cytomegalovirus Nucleic Acid Amplification Test (NAAT) Qualitative (LAB6061).

For Questions or Additional Information, Please Contact:

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