

TECHNICAL BULLETIN

☐NEW TEST ☒TEST CHANGE

NOTIFICATION DATE: 07/25/2024

EFFECTIVE DATE: Immediate

Congenital Cytomegalovirus Detection in Saliva by PCR (CMVSAL NEO)

On the effective date, Northwell Health Laboratories will update the qualitative detection of congenital Cytomegalovirus (cCMV) DNA in saliva samples from neonates younger than 21 days old using the DiaSorin Liaison MDx system, which offers improved sensitivity and accuracy. The current Alethia CMV assay from Meridian Bioscience and Sent outs test for neonatal saliva swabs will be replaced with the Simplexa cCMV direct assay by DiaSorin Molecular, specially intended to aid in the diagnosis of congenital CMV infection.

It is important to note that samples from patients aged 21 days and older should continue to be **ordered** through the existing test, **CMV by qualitative PCR, Saliva (Test order: CMVSAL; PDM: 1659370)** and will be sent to **Viracor for testing**.

Test Requirement	New	Current	Current
Methodology	Real-time PCR	Loop-Mediated Isothermal Amplification (LAMP)	Real-time PCR
Assay Manufacturer	DiaSorin Molecular LLC	Meridian Bioscience, Inc	Eurofins Viracor Laboratory
Specimen Collection Container	Saliva swab in 1.0 mL or 3.0 mL UTM / VTM	Dry swab or saliva swab in 1.0 mL UTM / VTM	Saliva swab in 1 to 3.0 mL UTM
Specimen Requirement	Saliva from neonates: under 21 days old	Saliva from neonates: under 21 days old	Saliva from patient: all ages
Specimen Stability	Room temperature for 48 hours Refrigerated for 7 days Frozen immediately at -20 ±10°C, up to 14 days	Room temperature for 48 hours Refrigerated for 7 days Frozen immediately at ≤20°C, up to 14 days.	Room temperature for 48 hours Refrigerated or frozen for 7 days
Specimen Transport	Refrigerated	Refrigerated	Frozen
Computer Interface Code	PDM# 228000	PDM# 228000	PDM# 1659370
Test Order	CMVSAL NEO	CMVSAL NEO	CMVSAL

If you have any questions, please contact Client Services at (800) 472-5757.