Lab Dept:	**Molecular Diagnostics**
Test Name:	**Congenital Cytomegalovirus (CMV) PCR Urine (≤ 20 days old)**

General Information

Lab Order Codes:	CCMVU
Synonyms:	Congenital CMV, cCMV
CPT Codes:	87496 – Infectious agent detection by nucleic acid, cytomegalovirus; amplified probe technique
Test Includes:	Detection of CMV by Real-Time PCR reported as positive or negative from patients 20 days of age and younger.

Logistics

Test Indications:	Diagnosis of congenital CMV infection.
Lab Testing Sections:	Molecular Diagnostics, Mpls campus only
Phone Numbers:	612-813-7103
Test Availability:	Samples accepted daily, 24 hours Testing performed 0600-1400
Turnaround Time:	3 - 24 hours
Special Instructions:	For patients 20 days of age and younger. Date/time of collection must be documented.

Specimen

Specimen Type:	Urine
Container:	Urine can be collected from urine bag, container or catheter then transferred to a sterile container with no preservative.
Specimen Volume:	0.2 mL (minimum 0.1 mL)
Collection:	Aseptic collection and aliquot technique, deliver to the laboratory immediately after collection.

Transport/Storage:	Transport to the Laboratory refrigerated (2-8°C). If a delay is anticipated, freeze specimen between -20 and -70°C. ● Specimens are stable at room temperature for 2 hours.
Patient Preparation:	None
Sample Rejection:	Urine collected from patients 21 days of age and older; urine at room temperature longer than 2 hours, urine in preservative or inappropriate transport container, improperly labeled specimen. If an unacceptable specimen is received, the patient's care giver will be notified and another specimen will be requested or the original specimen will be reordered as a sendout to Mayo Clinic Laboratories.

Interpretive

Reference Range:	Negative for CMV.
Alert Values:	Positive CMV results will be phoned to the patient's caregiver.
Limitations:	1. This test is not validated for sample types other than urine from patients 20 days of age and younger. 2. The detection of viral nucleic acid is dependent upon proper sample collection, transport, handling, storage, and preparation. Failure to observe proper procedures in any one of these steps can lead to incorrect results. 3. Negative results do not rule out CMV infection and should not be used as the sole basis for treatment or other patient management decisions. 4. False-negative results may occur if the virus has genomic mutations, insertions, deletions, or rearrangements or below analytical sensitivity of the assay. 5. As with other tests, false-positive results may occur. Repeat testing may be required in some settings. 6. This test is a qualitative test and does not provide the quantitative value of detected organisms present. 7. The performance of this test has not been established for monitoring treatment of CMV infection.
Methodology:	Real-Time Polymerase Chain Reaction (PCR)
References:	Simplexa Congenital CMV Direct Package Insert, REF MOL2255, Rev. 01. (November, 2022). In: DiaSorin Molecular LLC
Updates	7/16/2024: Initial Version