Memorandum – Micro #228

To: UNC Health System, Attending Physicians and Faculty Practice Physicians, Housestaff, Clinical Nurse Coordinators, Department Heads and Supervisors

From: Melissa Miller, PhD
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Subject: Changes to CMV Quantitative PCR (Viral Load) Testing

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Effective October 30, 2023, the Clinical Molecular Microbiology Laboratory at UNC Medical Center will implement a change to the CMV viral load testing performed on blood (EPIC: "CMV DNA, Quantitative, PCR" or LAB913). CMV quantification will be performed using the FDA approved cobas® CMV assay from Roche Diagnostics. Previously, the test was performed using the FDA approved RealTi*m*e CMV assay from Abbott Molecular. The primary reason for the change is the impending discontinuation of the current test by the manufacturer. The new assay will also allow for more rapid time to results.

Important changes are:

- The Roche assay targets the highly conserved UL54 gene of the CMV genome, while the Abbott assay targeted the UL34 and UL80.5 genes.
- The new assay has a lower limit of quantification (34.5 IU/ml) and broader reportable linear range of 35 – 10,000,000 IU/ml (1.54 $\log_{10}$ – 7.00 $\log_{10}$ IU/ml). The previous reportable range was 50 – 1,000,000 IU/mL (1.70 – 6.00 $\log_{10}$ IU/ml).
- Positive results below 35 IU/ml will be reported as "Detected, <35 IU/ml" with no further quantification provided.
- Specimens with results above the reportable range (>10,000,000 IU/ml) will be reported as "Detected, >10,000,000 IU/mL" with no further quantification provided unless requested by a physician.

- Viral loads are ~0.2 $\log_{10}$ lower on the Roche assay than the previous assay.
- Testing will be performed daily, Monday through Friday with a 1-3 day turnaround time.

Remaining the same:

- Test ordering will not change.
- Collection tube remains pearl top tube (purple top for infants).
- First-time positive results >10,000 IU/ml and any positive result on infants <3 months of age will be called to the ordering provider (UNC Medical Center or Hillsborough Campus) or affiliate laboratory.
- Patients with "Not Detected" results should have a maximum of 1 test performed per week. Patients with "Detected" results will be allowed repeat testing every 3 days. Testing requests outside of these parameters will be cancelled after discussion with the ordering physician.

Additional information is available at the UNCMC McLendon Clinical Laboratories website: CMV Quantitative PCR Website. Questions can be directed to the Molecular Microbiology Laboratory at 984-974-1820 or Dr. Melissa Miller at Melissa.Miller@unchealth.unc.edu.