



**MEMORANDUM #172**

TO: UNCHCS Attending Physicians, Housestaff, Clinical Nurse Coordinators, Department Heads and Supervisors

FROM: *MM* Melissa B. Miller, PhD, Director, Clinical Molecular Microbiology Laboratory  
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SUBJECT: **Changes to CMV Quantitative PCR (Viral Load) Testing**

DATE: August 1, 2017

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Effective August 1, 2017, the UNCH McLendon Clinical Laboratories will implement a change to the CMV viral load testing performed on blood (EPIC: "CMV DNA Quantitative PCR"). CMV quantification will be performed using the new FDA approved real-time PCR assay from Abbott Molecular.

Important changes are:

- CMV quantitative PCR will now be performed with an **FDA approved test**. The previous test was a laboratory developed assay.
- The FDA approved assay amplifies two targets of conserved regions of the CMV genome unique long region: UL34 and UL80.5. The dual target design mitigates the risk of signal loss due to mutation. The previous assay amplified only one target.
- The new FDA-approved assay has a limit of detection of 31 IU/ml and a reportable linear range of 50-1,000,000 IU/ml ( $1.70 \log_{10} - 6.00 \log_{10}$  IU/ml).
- Positive results below 50 IU/ml will be reported as "Detected, <50 IU/ml" with no further quantification provided. Specimens with results above the reportable range (>1,000,000 IU/ml) will be diluted to obtain a quantitated value.
- **Due to the increased sensitivity and improved standardization of the FDA approved assay, viral loads will be  $\sim 1 \log_{10}$  higher than the previous assay. This also allows for earlier detection of low level viremia.**

Remaining the same:

- Collection tube remains pearl top tube (purple top for infants).
- Testing will be performed daily, Monday through Friday.
- Positive results > 10,000 IU/ml and any positive result on infants <3 months of age will be called to the ordering provider.
- 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 3-4 days. Testing requests outside of these parameters will be cancelled after discussion with the ordering physician.

Questions can be directed to the Molecular Microbiology Laboratory at 984-974-1820 or Dr. Melissa Miller at [Melissa.Miller@unchealth.unc.edu](mailto:Melissa.Miller@unchealth.unc.edu).