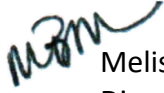
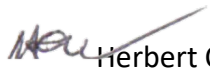




Memorandum - Micro #230

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

From:  Melissa Miller, Ph.D.
Director, Microbiology and Molecular Microbiology Laboratories
UNCMC, McLendon Clinical Laboratories

 Herbert C. Whinna, MD, PhD
Medical Director, McLendon Clinical Laboratories

Date: November 10, 2023

Subject: Changes to EBV Quantitative PCR (Viral Load) Testing

Effective November 27, 2023, the Clinical Molecular Microbiology Laboratory at UNC Medical Center will implement a change to the EBV viral load testing performed on blood (EPIC: “EPSTEIN-BARR VIRUS DNA, Quantitative, Blood” or LAB1373). EBV quantification will be performed using the FDA-approved cobas® EBV assay from Roche Diagnostics.

Important changes are:

- EBV quantitative PCR on blood will now be performed using an FDA-approved test. The previous test was a laboratory developed test.
- The Roche assay targets the EBV EBNA-1 and BMRF genes, whereas the previous assay targeted the BNRF1 gene and the p140 region.
- The new assay has a lower limit of detection (35 IU/mL) and broader reportable linear range of 35 – 100,000,000 IU/ml (1.54 log₁₀ – 8.00 log₁₀ IU/ml). The previous limit of detection was 62 IU/mL, and the reportable range was 100 – 1,000,000 IU/mL (2.00 – 6.00 log₁₀ 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 (>100,000,000 IU/ml) will be reported as “Detected, >100,000,000 IU/mL” with no further quantification provided unless requested by a physician.

- Compared to the previous assay, viral loads are $\sim 0.40 \log_{10}$ lower on the new 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 for blood.
- First-time positive results $\geq 1,000$ IU/ml 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 websites: [EBV Quantitative PCR, Blood Website](#). Questions can be directed to the Molecular Microbiology Laboratory at 984-974-1820 or Dr. Melissa Miller at Melissa.Miller@unchealth.unc.edu.