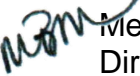





Memorandum - Micro #232

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

From:  Melissa Miller, PhD
Director, Microbiology and Molecular Microbiology Laboratories
UNCMC, McLendon Clinical Laboratories

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

Date: February 27, 2024

Subject: Changes to Hepatitis B virus DNA (Viral Load) Testing

Effective March 4, 2024, the Clinical Molecular Microbiology Laboratory at UNC Medical Center will implement a change to Hepatitis B viral load testing performed on blood (EPIC: "Hepatitis B DNA, Quantitative, PCR" Test ID: LAB951).

Important changes are:

- Real-time RT-PCR detecting Hepatitis B virus DNA will be performed on the Abbott Alinity m instrument instead of the Abbott *m2000* Realtime System.
- Viral loads on the new assay are $\sim 0.8 \log_{10}$ IU/mL higher than the previous assay.
- Testing will be performed daily Monday through Friday instead of once per week allowing for a decrease in turnaround time from 10 days to 3 days.

Remaining the same:

- The limit of detection is 10 IU/mL, and the reportable linear range is 10-1,000,000,000 IU/mL ($1.0 \log_{10} - 9.0 \log_{10}$ IU/ml).
- Specimens with results below 10 IU/mL will be reported as "Detected, <10 IU/mL" with no further quantification provided.
- Specimens with results above the reportable range will be resulted as "Detected, >1,000,000,000 IU/mL" with no further quantification provided.
- Collection tube remains serum separator tube.
- This test requires a dedicated specimen and cannot be added on to specimens already in the laboratory.

Questions can be directed to the UNCMC Clinical Molecular Microbiology Laboratory at 984-974-1820 or Dr. Melissa Miller at Melissa.Miller@unchealth.unc.edu.