
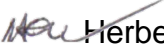




## Memorandum - Micro #229

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

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Date: October 30, 2023

**Subject: Changes to BK Virus Quantitative PCR (Viral Load) Testing**

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Effective November 6, 2023, the Clinical Molecular Microbiology Laboratory at UNC Medical Center will implement a change to the BKV viral load testing performed on blood (EPIC: “BK Virus Quantitative PCR, Blood” or LAB1374) and urine (EPIC: “BK Virus Quantitative PCR, Urine” or LAB1375). BKV quantification will be performed using the FDA cleared cobas® BKV assay from Roche Diagnostics.

Important changes are:

- BKV quantitative PCR (blood and urine) will now be performed using an FDA cleared test. The previous test was a laboratory developed test.
- The Roche assay targets the BKV small t-antigen and VP2 regions, while the previous assay targeted the VP1 region.
- The new assay has a broader reportable linear range.
  - Blood: 22 – 100,000,000 IU/ml (1.33 log<sub>10</sub> – 8.00 log<sub>10</sub> IU/ml). The previous reportable range was 200 – 20,000,000 IU/mL (2.30 – 7.30 log<sub>10</sub> IU/ml).
  - Urine: 200 – 100,000,000 IU/mL (2.30 – 8.00 log<sub>10</sub> IU/mL). The previous reportable range was 200 – 20,000,000 IU/mL (2.30 – 7.30 log<sub>10</sub> IU/mL).
- Positive results below 22 IU/ml for blood and 200 IU/ml for urine will be reported as “Detected, <22 IU/ml” or “Detected, <200 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 of blood are ~0.15 log<sub>10</sub> higher on the Roche assay than the previous assay. Viral loads of urine are ~0.8 log<sub>10</sub> higher.
- 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 and sterile cup for urine.
- First-time positive results ≥10,000 IU/ml on blood will be called to the ordering provider (UNC Medical Center or Hillsborough Campus) or affiliate laboratory. Positive urine results are not called.
- 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: [BKV Quantitative PCR, Blood Website](#) and [BKV Quantitative PCR, Urine Website](#). 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).