



AT THE FOREFRONT
UChicago
Medicine

Date: May 19, 2022

To: UCH Medical Staff, House-staff, Patient Care Centers and Outpatient Clinics

From: Kathleen G. Beavis, MD
Professor of Pathology
Medical Director, Clinical Microbiology and Immunology Laboratories

Nilima Trivedi, BS, MT, (ASCP)
Manager, Clinical Microbiology and Immunology Laboratories

RE: BK Virus (BKVP), Quantitative PCR – Plasma
BK Virus (BKVU), Quantitative PCR – Urine

Available Date:

Effective May 25, 2022, the Clinical Microbiology Laboratory will perform quantitative PCR testing for BK Virus (BKV) with the FDA-cleared Roche cobas® BKV assay. This assay uses a dual target virus specific approach from highly conserved regions of the BKV located in the BKV small t-antigen region and the BKV VP2 region. The Roche assay will replace the laboratory-developed assay utilizing reagents from DiaSorin.

The Roche assay is calibrated with standards traceable to the 1st World Health Organization (WHO) international standard for BKV to standardize quantitation. Quantitative results will be reported in International Units per mL of patient sample (IU/mL).

Quantitation cannot be reliably correlated between the DiaSorin and Roche cobas® BKV assays. All patient plasma and urine samples with BK virus detected will have the following comment appended to the Roche result:

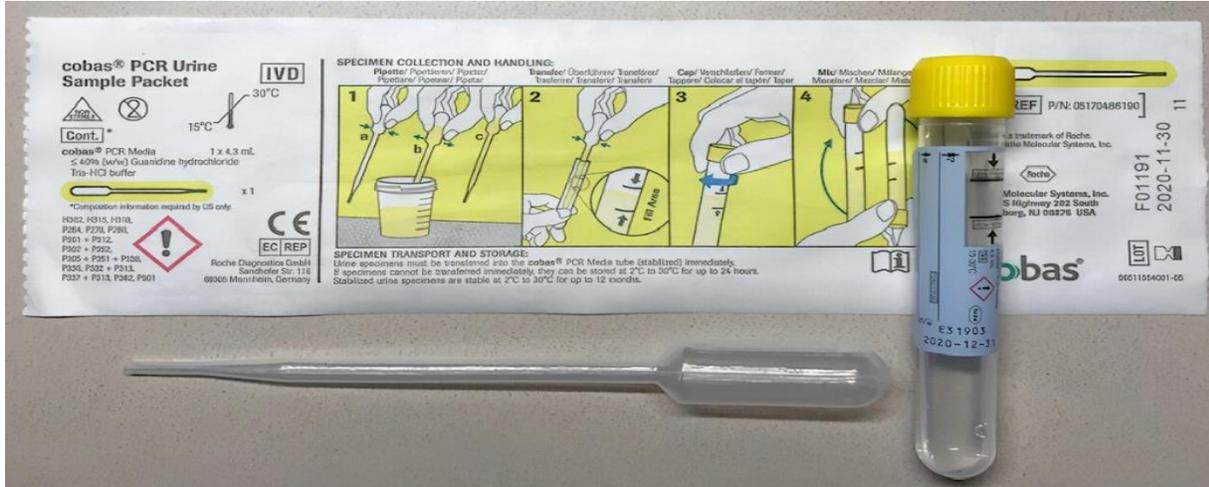
“As of May 25, 2022, BK Virus quantitative PCR is performed using Roche cobas® BKV assay. The Roche assay can quantitate as few as 500 IU/mL in urine and plasma. The previous assay (DiaSorin) had a higher analytical measurement range. Specimens previously classified as ‘not detected’ may have detectable viral load with the new assay. Please correlate any change in quantitation status with clinical findings”.

Urine and plasma samples without detectable BK Virus will be reported as follows: “No BK Virus DNA Detected”. Urine and plasma samples with detectable BK Virus will be reported as follows: “BK Virus DNA detected” and the quantitation will be reported in a range from 500 – 20,000,000 IU/mL (2.70 – 7.30 log IU/mL).

Specimen requirements, ordering information and turnaround time:

1. Epic test codes are BKVP (plasma) and BKVU (urine).

2. Quantitative testing is performed on plasma and urine only.
3. For plasma BK, 10 mL of whole blood must be collected and transported in a 10 mL lavender top Vacutainer tube containing EDTA.
4. **Urine specimens must be collected and transported in the cobas PCR Urine Sample Kit.**



The turnaround time is within 4 days of receipt in the laboratory. Testing is currently scheduled three days per week.

For questions, please contact Nedra Love, Chief Medical Technologist, 773-795-9142, or Nilima Trivedi, Microbiology Manager, at 773-702-6133.