



TEST INFORMATION UPDATE

BK Virus PCR Quantitative

New In-House

Effective Date: January 11, 2023

BK virus testing is transitioning from a send-out assay to a quantitative PCR assay performed in the VUMC Molecular Infectious Disease Laboratory (MIDL). The MIDL assay will quantitatively measure the BK virus in plasma collected in EDTA-containing tubes or urine. Quantitated values will be reported in international units (IU) / mL. This assay is FDA-approved, with the intended use of diagnosing and monitoring disease related to the BK virus in transplant patients. Results must be interpreted in the clinical context. Results from this assay should not be used as the sole criteria for management decisions.

VUMC MIDL is transitioning to this assay to provide improved patient care. This assay is performed in the laboratory on an automated platform. Accordingly, the turn-around time from sample acquisition to result generation will shorten. Additionally, the analytic range of the new assay is broader, allowing the detection of both smaller and larger quantities of the BK virus.

ORDERING:

- **VUMC providers:** The orderable name remains PCR BK Virus Qt (LAB1374)
- **VPLS Customers:** PCR BK Virus Qt can be ordered using your current process via the Atlas portal or manual paper requisitions.

SPECIMEN COLLECTION

- **VUMC Providers:**
 - PLASMA: The collection is a purple top EDTA tube. Specimens should be sent to the laboratory on the day of collection.
 - URINE: Collect urine in a sterile container. Urine in a sterile container is stable for testing for 24 hours. If able, transfer urine into a cobas PCR Media Tube by filling the tube until the liquid level is between the two black lines on the tube window. Urine in this tube is stable for testing for up to 90 days.
- **VPLS Customers:**
 - PLASMA: The collection is a purple top EDTA tube. Centrifuge and separate plasma. Keep Refrigerated. Refrigerated plasma will be accepted up to 6 days after collection.
 - URINE: Collect urine in a sterile container. Urine in a sterile container is stable for testing for 24 hours. If able, transfer urine into a cobas PCR Media Tube by filling the tube until the liquid level is between the two black lines on the tube window. Urine in this tube is stable for testing for up to 90 days.

RESULTS

Results from the MIDL assay reported in IU/mL are not directly comparable to results from the send-out assay reported in copies/mL. A conversion factor is not available. New baseline results are needed if consecutive results are monitored. Consecutive results from the same specimen source (plasma or urine) generated with the MIDL assay will trend together. Results from the prior send-out assay will not trend with those generated by the MIDL assay.

The quantifiable range of this assay for plasma is 21.5 – 100,000,000 IU/mL and for urine is 200 - 100,000,000 IU/mL. BK virus detected below the lower limit of quantification will be reported as “BK virus detected, less than [lower limit per specimen source]”. BK virus present in a sample below the detection limit will be undetected.

- VUMC Providers: Results will appear in the Virology results section of Epic/eStar.
- VPLS Customers: Will continue to receive BK VIRUS reports like other lab reports.

ADDITIONAL INFORMATION

Additional information regarding specimen collection, minimum required specimen volume, stability requirements, reasons for specimen rejection, and the turn-around time goal are available on the Vanderbilt Pathology Laboratory Services (VPLS) website test directory

