

To: UPHS Physicians and Staff
From: The Division of Precision and Computational Diagnostics (PCD)
Kojo Elenitoba-Johnson and Vivianna Van Deerlin, M.D., Ph.D.
Directors, Molecular Testing Laboratories at Penn Medicine at Rittenhouse
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Re: **METHOD CHANGE** for quantitative BK virus (BKV) and Epstein-Barr virus (EBV) testing

In early September, the Molecular Testing Laboratory at Penn Medicine at Rittenhouse will bring BKV and EBV viral load testing back in house using a new method. Quantitative viral load testing for BKV and EBV will now be performed using FDA-approved real-time PCR assays on the cobas 8800 instrument from Roche Diagnostics Corporation and will be reported in international units (IU) per mL instead of the former copies (cp) per mL.

Comparison of Roche method to current send-out test:

During comparison testing, the Roche method yielded results that were comparable to, but on average about 0.3 log (BKV) or 0.4 log (EBV) **lower** than, the corresponding result from the send-out laboratory. This difference is within the expected 0.5 log biological and technical variation for both methods. Nevertheless, when comparing longitudinal viral load results during the transition between the old and new methods, variations of greater than 0.5 log difference may be seen, especially at higher viral loads. Therefore, it is recommended that trends be carefully monitored during the method transition.

Although IU/mL and cp/mL are not equivalent units, the assays perform comparably, and a comparison of the limits of detection and linear ranges is provided below. The new assays have a lower limit of detection and are therefore more sensitive than the current send-out test.

Target	New Roche Assay		Current Send-Out Test	
	Limit of Detection	Linear Range	Limit of Detection	Linear Range
BKV	21.5 IU/mL (log 1.3)	21.5 to 100,000,000 IU/mL (log 1.3 – 8.0)	390 cp/mL (log 2.6)	390 to 390,000,000 cp/mL (log 2.6 – 8.6)
EBV	18.8 IU/mL (log 1.3)	35 to 100,000,000 IU/mL (log 1.5 – 8.0)	390 cp/mL (log 2.6)	390 to 39,000,000 cp/mL (log 2.6 – 7.6)

Testing Information

- **Turnaround Time:** 2-3 business days
- **Acceptable specimen:** The preferred specimen for both tests is 5 ml of blood in K₂EDTA pearl white top tube. Blood collected in a lavender top (EDTA) tube will also be accepted.
- **Ordering Information:** There are NO changes to ordering BKV (PxCode BK VIRUS) or EBV (PxCode EBVCASE) viral load testing in PennChart.
- **For additional information:** Call the Rittenhouse Molecular Testing Laboratory (215-893-2270) weekdays during regular business hours.