

MEMORANDUM

To: All RML Clients

From: Patti Loykasek, HTL, QIHC (ASCP), Manager of Molecular Pathology,

Cindi Starkey, M.D., Ph.D., Chief of Molecular Pathology

Date: April 23, 2018

Updated August 20, 2018

Subject: Changing Quantitative Viral Load reporting from copies/ml to IU/ml for EBV, CMV and BKV

UDPATE: After client feedback that not all clients received this memo, we decided to re-send the memo. Please note that results in copies/mL were provided in a footnote for 60 days.

The utility of viral load testing is well established in clinical practice and generally is performed for patients with chronic viral diseases or in those with a prior transplant. RML provides quantitative testing for Epstein Barr Virus (EBV), Cytomegalovirus (CMV), and BK virus (BKV) for these patients. These assays currently report in copies/mL, but are moving to a result of IU/mL (International Units/mL). Reference ranges for EBV and BKV will also be changing as noted in the table below. This change has been driven by laboratory accreditation agencies, and to enhance standardization of results. Patient results should not be compared between testing performed at different laboratories due to variability in methodology and assay design.

This change will go into effect April 30, 2018. For the first 60 days, the result will be footnoted with the result also in copies/mL. The following tests are impacted by this change:

| TEST NAME | TEST MNEMONIC | TEST ORDER NUMBER | OLD REFERENCE RANGE | NEW REFERENCE RANGE |
|---|------------------|----------------------|------------------------|----------------------------------|
| Cytomegalovirus (CMV) DNA, Quantitative | CMV QT PCR | 3800225 | ≤199 Copies/mL | <200 IU/mL No change in value |
| Epstein Barr Virus DNA, Quantitative Real-Time PCR | EBV PCR QN | 5580775 | ≤199 Copies/mL | <98 IU/mL |
| BK Virus DNA, Quantitative PCR, Plasma | BK VIRUS P | 5504325 | ≤499 Copies/mL | <1560 IU/mL |
| BK Virus DNA, Quantitative PCR, Urine | BK VIRUS U | 5504425 | ≤499 Copies/mL | <1560 IU/mL |

This information was also sent on a live wire April 10, 2018.

If you have questions or need clarification, please contact anyone listed above at 918-744-2553.