TEST CHANGE: Molecular Microbiology PCR Assays
NOTIFICATION DATE: 06/10/2022
EFFECTIVE DATE: 06/27/2022

Affected Tests Name (Epic Test Number):

- EPSTEIN BARR (EBV) DNA, QUANTITATIVE PCR, PLASMA (LAB304550)

EXPLANATION:
Quantitative Epstein-Barr virus (EBV) testing by PCR (EBV qPCR) is used to detect and quantify the level of EBV DNA present in the plasma of transplant recipients at risk of developing EBV-associated post-transplant lymphoproliferative disorder and in individuals with infectious mononucleosis. WVU Medicine Laboratories has sent this testing to Quest Diagnostics since 25 April 2022 because of issues with the availability and quality of reagents needed to perform EBV qPCR testing in-house. However, WVU Laboratories has implemented a new FDA-cleared method for EBV qPCR testing on the Roche Cobas platform and will resume testing on the effective date. This will reduce testing turnaround times.

Verification studies of the Cobas EBV qPCR test confirm high reproducibility, a very low limit of detection (~20 IU/mL) and a broad reportable range (50 – 50,000,000 IU/mL). Importantly, correlation studies suggest the new test will report EBV copy numbers **~10-12-fold (i.e. ~1.0 log10) lower** than the previous test used at WVU Medicine. As a result, decision thresholds should be adjusted accordingly.

For providers with any concerns or questions about the new viral loads in immunosuppressed patients with new-onset or persistent viremia, please contact the laboratory. In these cases, residual specimen can be sent to Quest Diagnostics, recognizing that no correlation data exists comparing Cobas values to those of the lab-developed test performed there.

QUESTIONS ABOUT THIS TESTING

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