

Date: May 18, 2022

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

From: Kathleen G. Beavis, MD

Professor of Patholgy

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RE: Epstein- Barr Virus (EBV) Quantitative testing – Plasma

Available Date:

Effective May 25, 2022, the Clinical Microbiology Laboratory will begin performing quantitative PCR testing for EB Virus with the FDA-cleared De Novo Class II Roche cobas® EBV assay. The assay uses a dual target virus specific approach from highly conserved regions of the EBV located in the EBV EBNA-1 gene and the EBV BMRF gene. 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 EBV 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 previous assay, Diasorin, and the Roche cobas® EBV assay. All patient plasma samples that are positive with the Roche assay will have the following comment appended:

"As of May 25, 2022, EB Virus quantitative PCR is performed using Roche cobas ® EBV assay. The Roche assay can detect as few as 35 IU/mL in plasma. While the lower limit of detection for the Roche EBV assay is now at 35 IU/mL, the new use of plasma versus the previous use of whole blood decreases the total EBV that is detectable. Patients who previously had a low reportable level of EBV with the whole blood assay may now be classified as 'not detected' with the plasma assay. Consider any change in quantitation over the implementation date in conjunction with clinical status."

Plasma samples without detectable EB Virus will be reported as follows: "No EB Virus DNA detected". Plasma samples with detectable EB Virus will be reported as follows: "EB Virus DNA detected" and the quantitation will be reported in a range from 35-50,000,000 IU/mL (1.54-7.70 log IU/mL) patient sample.

Specimen requirements, ordering information, and turnaround time:

1. Test code in Epic for plasma specimens is EBVQ.

- 2. Quantitative testing is performed on plasma only. For EBV, 10 mL of whole blood must be collected and transported in a 10mL lavender-top Vacutainer tube containing EDTA.
- 3. The turnaround time for in-house testing is within 4 days of receipt in the laboratory. Testing is currently scheduled three days per week.
- 4. EBV quantitation from CSF is a sendout test; specimens are sent to Mayo Medical Laboratories for testing. A minimum of 0.5 mL of sample in a sterile container is required for sterile fluids; these specimens should be sent to the Laboratory Service Center.

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