

LAB ALERT – GENERAL COMMUNICATION**NOTIFICATION DATE: 10/30/2013****EFFECTIVE DATE: 11/19/2013****EBV VIRAL LOAD IN INTERNATIONAL UNITS BY RT-PCR**

We are pleased to announce that we will begin offering viral load testing of Epstein-Barr Virus (EBV) on International Scale in EDTA Whole Blood using a RT-PCR. Results will be reported in International Units/mL (IU/mL) and log IU/mL based on the World Health organization (WHO) EBV standard.

CLINICAL UTILITY: EBV viral load in peripheral blood is a very useful marker for the management EBV related diseases such as lymphoproliferative disorders in organ transplant recipients (post-transplant lymphoproliferative disorders [PTLD]) and nasopharyngeal carcinomas (NPC). Laboratory developed assays (like one currently offered by med fusion) are highly sensitive and specific and are used for site specific-treatment and monitoring response to therapy. However, lack of standardization prevents the establishment of broadly applicable viral load cutoffs for clinical decision-making and compromises the ability to compare patient results across laboratories. In 2011, the first EBV Standard was released by WHO to address inter-laboratory comparability of results on International Scale. The regulatory agencies require laboratories to calibrate their viral load tests to the EBV WHO Standard to facilitate consensus across transplant centers on patient management by common reporting.

RESULTS: The analytical measurement range of the new test is 317 to 1,100,000 IU/mL (\log_{10} 2.50 to \log_{10} 6.04 IU/mL). The range of the current EBV quantitative assay is 250 to 1,000,000 copies/mL. Our data on extensive analytical verification shows a good linear correlation between the copies/mL result by the current assay and the IU/mL result by the new assay.

However, please note that:

- The results of the new and old test may NOT be directly comparable. This is especially true at a very low and very high viral load which is expected to have maximum variance.
- The results will be reported in IU/mL and \log_{10} IU/mL on the new assay. The log values more closely represent the biological and laboratory processes since each iteration of a RT-PCR process has a multiplicative effect.

In order to provide the best quality care to our patients who are being monitored using the current EBV viral load assay, we will offer testing by both the new and the old assay for a period of 6 weeks after implementation. A positive EBV viral load result on the new assay will be reflexed to be tested by the old laboratory developed assay at no charge upon physician request (positives will be batched and tested once a week). This will allow physicians to re-baseline the viral load in IU/mL if necessary. The parallel testing will only be performed the first time the patient is tested on the new assay. No additional specimen collection required for the reflex testing. If you require parallel testing, please call the lab at 972-966-7167.

COLLECTION:

There are no changes in the specimen collection, transport and storage conditions of the specimens. This change DOES NOT affect the sharing of specimens for other tests.

NON-BLOOD EBV TESTING:

EBV testing on non-blood samples such as CSF and other non-blood sterile body fluids, respiratory sources and tissues will be performed by a qualitative test and results will be provided as POSITIVE or NEGATIVE. The specimen preparation, transport and storage conditions for these specimen types will not be affected.

ORDERING:

Please see additional information related to these assays in the individual new test announcement Lab Alerts (Attached).

The new EBV RT-PCR viral load assay and the qualitative assay for non-blood specimens will replace our current laboratory developed EBV assay. The following codes will be deactivated effective 11/19/2013:

DEACTIVATED TESTS		
Test Code	Test Name	Interface Code
EBMOL	Epstein-Barr Virus (EBV), Quantitative by PCR	1002498
EBVPCR	Epstein-Barr Virus , PCR, Blood	1000287
EBVNB	Epstein-Barr Virus PCR, Non Blood	1000281

Please contact the Technical Director of Molecular Laboratory, Dr. Neelam Dhiman, at 972-966-7359 with any questions or concerns that you may have regarding new EBV viral load testing.

ORDER/CONTACT INFORMATION: *ClearPoint Client Services: 972-966-7700 | Fax: 972-966-7799*