ClearPoint DIAGNOSTIC LABORATORIES
Clear Point Diagnostic Laboratories | 2501 South State Highway 121 Business | Suite 1200
| Lewisville, TX 75067-8188
Phone: 972.966.7700 | Fax: 972.966.7799 | www.clearpointlabs.com

LAB ALERT: GENERAL COMMUNICATION

NOTIFICATION DATE: 7/24/2013
EFFECTIVE DATE: 7/30/2013

CMV VIRAL LOAD IN INTERNATIONAL UNITS BY FDA-APPROVED RT-PCR

We are pleased to announce that we will begin offering viral load testing of Cytomegalovirus (CMV) in EDTA plasma using FDA-approved RT-PCR. Results will be reported in International Units/mL (IU/mL) and log IU/mL based on the World Health organization (WHO) CMV standard.

CLINICAL UTILITY:

CMV viral load in peripheral blood is a very useful marker for the management of transplant recipients and immunocompromised individuals. 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 2010, the first CMV 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 CMV WHO Standard to facilitate consensus across transplant centers on patient management by common reporting.

RESULTS:

The analytical measurement range of the new test is 137 to 9,100,000 IU/mL ($\log_{10}$ 2.14 to $\log_{10}$ 6.96 IU/mL). This is wider than the range of the current CMV assay (250 to 1,000,000 copies/mL). Our preliminary data shows a good linear correlation between the current and the new assay.

However, please note that:

- Since the limit of detection is lower for the new assay, it is possible that a NOT-DETECT result on the current test may have a low viral load on the new test.
- 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 CMV 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 CMV viral load result on the FDA approved assay will be reflexed to be tested by the old laboratory developed assay at no charge upon physician request. 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:

The new test will require 5 ml blood collected in lavender top EDTA tube. The lavender top tube must be centrifuged at 800-1600xg for 20 min at room temperature within 6 hours of collection. Plasma aliquot (Min. 2 mL) must be transferred into standard transport tube and sent to med fusion for testing.

IMPORTANT: Please note that additional specimen will be required for shared tests on EDTA blood such as EBV viral load effective 7/30/2013.

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STABILITY /TRANSPORT: Refrigerated up to 7 days. Frozen up to 6 weeks.

NON-BLOOD CMV TESTING: CMV testing on non-blood samples such as CSF, urine, amniotic fluid, respiratory sources and tissues will be performed by a qualitative test and results will be provided as POSITIVE or NEGATIVE using threshold comparable to the current assay. 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 CMV FDA-approved RT-PCR viral load assay and the qualitative assay for non-blood specimens will replace our current laboratory developed CMV assay. The following codes will be deactivated effective 7-30-2013:

Test Code	Test Name	Interface Code
CMVMOL	Cytomegalovirus (CMV), Quantitative by PCR	1002488
CMVPCR	Cytomegalovirus, PCR, Blood	1000227
CMVNB	Cytomegalovirus PCR, Non Blood	1000221

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 CMV viral load testing.

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