University of Nebraska Medical Center

Department of Pathology and Microbiology
Regional Pathology Services

LAB ALERT

Date: June 27, 2014

To: Regional Pathology Services Clientele

From: Regional Pathology Client Services

Test Name: Cytomegalovirus (CMV) DNA Detection and Quantitation

Test Code: CMVQB

RE: Changes in CMV Testing Methodology

Effective June 23rd, the Molecular Diagnostics laboratory will change the methodology of the CMV Viral load test from an in-house developed real-time amplification method to a real-time amplification method using Focus Diagnostics reagents with the 3M™ Integrated Cycler.

The previous test targeted the CMV UL54 polymerase gene. Sequence variation in the target site, affecting assay performance, has been detected in our patient population. The new Focus test targets the CMV UL83 gene. Validation studies demonstrate that the Focus test is modestly more sensitive than the previous test.

The viral load generated by the Focus test will be, on average, 0.67 $\log_{10}$ IU/mL higher compared to the previous assay. Differences as great as 2.22 $\log_{10}$ IU/mL were observed for samples with sequence variation. Clinicians following currently positive patients can contact the laboratory and request re-testing of previous samples by the Focus method at no charge to assist in following viral load through the transition period.

Test Code	CMVQB
Test Name	Cytomegalovirus (CMV) DNA Detection & Quantitation
Reference Interval:	Negative, CMV virus not detected, <300 IU/mL plasma *(Old value: <176 IU/mL)*
Lower Limit of Quantitation:	300 CMV IU/mL plasma *(Old value: 290 CMV IU/mL)*
Upper Limit of Quantitation:	3,000,000 CMV IU/mL plasma *(Old value: 2,900,000 CMV IU/mL)*

Ordering codes, specimen requirements and turnaround times will remain the same.

Please call Regional Pathology Services with any questions or concerns regarding this lab alert at 402.559.6420 or Toll free at 1-800-334-0459.

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