



MEMORANDUM #14

TO: UNC Hospitals Attending Physicians, Housestaff, Nursing Coordinators, Department Heads and Supervisors

FROM: Margaret L. Gulley MD, Director of Molecular Pathology  
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DATE: January 15, 2013

SUBJECT: **Cytomegalovirus (CMV) Viral Load Test has New Units of Measurement that Shift Numeric Values**

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Effective January 15, 2013, the Molecular Genetics Laboratory is changing our procedure for Cytomegalovirus (CMV) viral load tests on plasma.

**What change was made and why?** The change involves a newly available World Health Organization calibrator. Use of a new calibrator renders our laboratory results comparable to other clinical laboratories using similar specimen type and analytic methods. Reporting results in the new unit of measurement (IU/mL) facilitates development of practice guidelines for intervention that are independent of the testing facility.

**How does the change affect our medical practice?** As of January 15<sup>th</sup> 2013, CMV viral load results are reported in IU/mL of plasma (*versus* previous copies/mL). **This new unit of measurement means that numeric results are about 1.7 fold lower than the units used prior to January 15<sup>th</sup> 2013.** For example, a result now reported as 1,000 IU/mL would have previously been reported at 1,700 CMV copies per mL. In patients who are being serially monitored, a shift in numeric results applies to CMV loads reported after January 15<sup>th</sup> 2013, related to the change in units of measurement.

**Clinical Indications for CMV viral load test:**

1. Predict, diagnose, or monitor CMV disease.
2. Evaluate efficacy of therapy for CMV disease.

**Normal Range is unchanged:** CMV DNA is usually undetectable in plasma from healthy persons even if they were previously exposed to the virus and harbor latent viral infection.

**Actionable Thresholds:** Immunosuppressed patients may have stable low CMV viral loads in the absence of disease. Increasing viral load over time suggests progression of active infection. There is emerging evidence on thresholds for intervention (see reference). **A CMV viral load of 6,000 IU/mL or higher is a critical value for actionable CMV infection in an immunocompromised patient.**

In neonates (age <1 week), any amount of plasma CMV DNA is abnormal and signifies congenital CMV infection.

**Sample requirements remain the same:** 3mL EDTA blood (purple-top).

**Method and analytic performance characteristics:** Quantitative PCR amplifies a segment of the CMV immediate-early gene using analyte specific reagents from Qiagen on an Abbott m2000 instrument. The assay is sensitive to as few as 300 IU/mL of plasma, and measurable values below this level are reported as "Detected, <300 IU/mL". Technical variability of the assay is up to three fold so, for example, a viral load we report as 900 IU/mL represents a value between 300 and 2,700 IU/mL.

**Reference:** Martín-Gandul C, et al for the The Spanish Network for Research in Infectious Diseases (REIPI): Determination, validation and standardization of a CMV DNA cut-off value in plasma for preemptive treatment of CMV infection in solid organ transplant recipients at lower risk for CMV infection.). J Clin Virol 56:13-18, 2013.

For further information, consult the McLendon Clinical Laboratories website [http://labs.unchealthcare.org/directory/molecular\\_pathology](http://labs.unchealthcare.org/directory/molecular_pathology) or contact the Molecular Genetics Laboratory at 966-4408, or Dr. Gulley at [margaret\\_gulley@med.unc.edu](mailto:margaret_gulley@med.unc.edu).