





UNC
HEALTH CARE

MEMORANDUM # 12

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

FROM: Margaret L. Gulley, MD, Director of Molecular Pathology 
 Herbert C. Whinna, MD, PhD, Director, McLendon Clinical Laboratories

DATE: January 3, 2011

SUBJECT: Cytomegalovirus (CMV) Viral Load Testing on Blood Samples

The Molecular Genetics Laboratory has changed the laboratory method for measuring cytomegalovirus (CMV) viral load in blood. Starting January 3, 2011, UNC Hospitals will switch to a more automated assay. **This change should not substantially alter the quantitative values that are reported.**

There is no change to the test ordering or sample collection process. The technology remains the same although the new real time polymerase chain reaction (PCR) targets a different portion of the viral genome (*immediate early* rather than *polymerase* gene). Results are still reported in “copies of CMV per mL of plasma”. Results below the lower limit of assay linearity are reported as “low positive, <500 copies/mL”, whereas results above the upper limit of assay linearity are reported as “high positive >500,000 copies/mL”, and lack of measurable CMV is reported as “undetectable”.

Clinical indications for testing:

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

Sample requirements: 3ml EDTA blood (purple-top tube), refrigerated up to 3 days.

Turn around time: Assays are performed on weekdays. For urgent needs on long holiday weekends, contact the clinical pathology resident on call at 216-1358.

Method and Reporting: Real-time PCR is used to amplify a segment of CMV DNA from patient plasma, and products are quantitated against Acrometrix standards using Qiagen (Artus) analyte specific reagents on an Abbott m2000 instrument. Results are reported as the number of copies of CMV per mL of plasma. The technical variability of the assay is approximately six-fold; for example, a viral load reported as 1000 copies per mL represents a value between 167 and 6000 copies per mL.

Normal Range: CMV is usually undetectable in plasma of healthy persons even if they were previously exposed to the virus. Immunosuppressed patients may have stable low viral loads

in the absence of disease. Increasing viral load over time suggests progression of active disease.

References:

1. Kotton CN, Kumar D, Caliendo AM, Asberg A, Chou S, Snyderman DR, Allen U, Humar A; Transplantation Society International CMV Consensus Group. International consensus guidelines on the management of cytomegalovirus in solid organ transplantation. *Transplantation* 89:779-95, 2010.
2. Guidelines for prevention and treatment of opportunistic infections in HIV-infected adults and adolescents. Recommendations from CDC, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. (revised Apr 10, 2009). www.cdc.gov/mmwr/pdf/rr/rr5804.pdf
3. Caliendo AM, Ingersoll J, Fox-Canale AM, Pargman S, Bythwood T, Hayden MK, Bremer JW, Lurain NS. Evaluation of real-time PCR laboratory-developed tests using analyte-specific reagents for cytomegalovirus quantification. *J Clin Microbiol.* 45:1723, 2007.

For further information, consult the McLendon Clinical Laboratories website:

http://labs.unchealthcare.org/directory/molecular_pathology/index.html

or contact the Molecular Genetics Laboratory at 966-4408, or Dr. Gulley at margaret_gulley@med.unc.edu.