

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

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**SUBJECT: Hepatitis B Viral DNA, Quantitative Test**

DATE: August 3, 2007

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Effective August 6, 2007, the Molecular Microbiology Laboratory will begin offering a Hepatitis B Viral DNA quantitative test (viral load). The test can be ordered in SMS and CPOE as **Hepatitis B Viral DNA, Quant** (SCC test ID HBVDQ, test # 8600). This test replaces the reference laboratory test offered previously. Testing will be performed twice per week, with a turnaround-time of 3-5 days.

Hepatitis B virus DNA loads are measured using the Roche Quantitative Real-time COBAS TaqMan PCR Analyte Specific Reagents, which amplifies a 145 base-pair sequence in the precore/core region. In-house validation studies demonstrated the limit of detection at 10 IU/mL ( $\log_{10}$  1.0 IU/mL), and the limit of quantification at 15 IU/mL ( $\log_{10}$  1.18 IU/mL). Linearity was tested to 20,000,000 IU/mL ( $\log_{10}$  7.3 IU/mL). Specimens outside of the linear range will be diluted and quantified only upon request.

The specimen required is one full (6mL) Gold-top serum separator tube (SST). This sample must not be shared with any other tests

Hepatitis B Viral Load testing is not intended to be used as a stand-alone diagnostic test for Hepatitis B, and must be used in conjunction with additional testing and clinical information.

For more information, consult the McLendon Clinical Laboratories Manual of Pathology and Laboratory Medicine Clinical Services (<http://www.pathology.unc.edu/labs>) or contact the Molecular Microbiology Laboratory at 966-6101.