

## MEMORANDUM # 121

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

FROM: Melissa B. Miller, PhD, Director, Molecular Microbiology  
Peter H. Gilligan, PhD, Director, Clinical Microbiology/Immunology  
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**SUBJECT: HCV RNA Qualitative/Quantitative by Nucleic Acid Amplification**

DATE: May 2, 2007

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Effective May 6, 2007, the Molecular Microbiology Laboratory will introduce a new methodology for the determination of hepatitis C virus (HCV) viral loads. The new methodology, the Roche COBAS TaqMan 48, utilizes analyte specific reagents in a real-time reverse-transcriptase PCR to detect and quantify viral RNA. This test replaces the current Roche COBAS Amplicor PCR viral load.

Advantages to the new technology are primarily increased limits of detection and an increased linear (reportable) range. The reportable range for the current Amplicor test is 600 - 700,000 IU/mL (2.80 – 5.85 log<sub>10</sub> IU/mL); the range of linearity of the new, TaqMan 48 test is **25 - 5,000,000 IU /mL (1.40 – 6.70 log<sub>10</sub> IU/mL)**, with a lower limit of detection of **15 IU/mL (1.18 log<sub>10</sub> IU/mL)**. Results will be reported in IU/mL and also in log<sub>10</sub> IU/mL. Upon request, viral loads exceeding the upper limit of linearity may be diluted and repeated to obtain a reportable result. Viral loads <25 IU/mL will be reported as DETECTED, <25 IU/mL. Specimens negative for the detection of HCV RNA will be reported as NOT DETECTED.

With the increased reportable range and more sensitive lower limit of detection, the new test will replace not only the current HCV Viral Load (HCV RNA PCR QUANT.) but also the two HCV RNA Qualitative Assays (HCV RNA, QUALITATIVE and TMA, HCV, QUALITATIVE) currently sent to reference laboratories. The new test may be ordered through SMS or CPOE under **HCV RNA, QUAL/QUANT**. There is no change in CPT code or price. The test will be performed twice/per week, with a turnaround time of 5 days.

For further information, please contact the Molecular Microbiology Laboratory at 966-6101, or Dr. Melissa Miller, 966-3273.