



**To:** Interpath Clients  
**From:** Interpath Laboratory, Inc  
**Date:** March 2007

**EFFECTIVE March 26, 2007**

**ALL REQUESTS FOR HEPATITIS C VIRAL LOAD WILL BE TESTED USING THE  
BAYER VERSANT bDNA 3.0 HEPATITIS C (HCV) RNA  
QUANTITATIVE VIRAL LOAD ASSAY (Test 2660)  
THIS TEST WILL REPLACE THE PCR ASSAYS CURRENTLY PERFORMED**

**HOW TO ORDER THIS TEST: *Test 2660 - HCV RNA QUANT by bDNA***

**PERFORMANCE CHARACTERISTICS:**

- This assay has a broad dynamic range of 615-7,690,000 IU/mL. Since viral loads rarely exceed the upper limit of the assay, specimen dilution and repeat testing is eliminated.
- High reproducibility with a standard deviation (SD) of 0.07 Log RNA copies/mL is demonstrated.
- Reference HCV RNA that is verified with the World Health Organization (WHO) HCV international standard (96/790) is used for calibration.
- Equivalent detection of genotypes 1 to 6 has been reported. Assay results expressed in both IU/mL and Log IU/mL are directly comparable with results from other assay methods.
- **For patients whose viral load may be less than 615 IU/mL or less than 2.78 log IU/mL qualitative testing should be requested; therefore *Interpath Laboratory, Inc will automatically reflex the test to run the qualitative testing on the Bayer Versant TMA Qualitative Assay for patients who's viral load is less than 615 IU/mL or less than 2.78 log IU/mL.***

**SPECIMEN COLLECTION**

**Serum:**

- Collect blood in a plain red-top tube or in a Serum Separator Tube (SST).
- Allow blood to clot at room temperature for 30 minutes and centrifuge within 4 hours.
- Remove serum within 4 hours of collection, aliquot into two aliquot into **TWO** standard Interpath Laboratory transportation tubes.
- Store serum frozen at -20°C and transport within 48 hours.

**Plasma:**

- Collect blood in K<sub>2</sub> EDTA Tube.
- Store whole blood at room temperature and centrifuge within 4 hours.
- Remove plasma within 4 hours of collection and aliquot into **TWO** standard Interpath Laboratory transportation tubes.
- Store plasma frozen at -20°C and transport within 48 hours.

**TURN-AROUND TIME:** Testing will be performed in-house Monday with results available the following afternoon. Qualitative assays will be performed on Friday.

**REPORTING:** Results will be reported in International Units IU/mL and in Log IU/mL.

**REFERENCE RANGE:** <615 IU/mL and <2.78 Log IU/mL.