

## **REPORTING CHANGE**

**NOTIFICATION DATE:** September 22, 2009

**EFFECTIVE DATE:** October 20, 2009

### **HEPATITIS C VIRUS (HCV) RNA DETECTION AND QUANTIFICATION BY REAL-TIME REVERSE TRANSCRIPTION-PCR (RT-PCR), SERUM #83142**

**EXPLANATION:** Effective October 20, 2009, an FDA-approved, quantitative real-time PCR assay is replacing the current laboratory-developed, analyte-specific reagent assay.

The quantification range of the new assay will change from the current range of 10 to 50,000,000 IU/mL to the new range of 43 to 69,000,000 IU/mL.

Test results will be reported in the 4 following possible scenarios:

- “Undetected”
- “Detected”, with the comment, “HCV RNA is detected but less than 43 IU/mL (1.63 log IU/mL).”
- Integer and corresponding log values within the assay quantification range.
- “Detected”, with the comment, “HCV RNA is detected but greater than 69,000,000 IU/mL (7.84 log IU/mL).”

These changes in quantification range and reporting comments do not require test file definition changes.

QUESTIONS: Contact your Mayo Medical Laboratories’ Regional Manager  
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