Overview

PathGroup Labs is pleased to announce the availability of the Roche Molecular Diagnostics FDA-cleared assay for the quantitative measurement of Hepatitis C Virus. This assay has a broad linear range from 43 IU/ml (1.63 log IU/ml) to 69 million IU/ml (7.84 log IU/ml). The limit of detection for the assay is 18 IU/ml (1.26 log IU/ml). The assay will accurately quantify HCV genotypes 1 through 6, and is standardized against the First WHO International Standard for Hepatitis C Virus RNA for Nucleic Acid Amplification Technology Assays.

There are two important changes with the new assay:

1) **Minimum of 2.0 ml of serum or plasma.**
   The previous minimum was 1.0 ml.

2) **This assay reports an average of approximately 0.3 log lower viral load than the previous assay.**
   This difference can range from a slightly higher viral load in the new assay to the uncommon instance of a 1 log decrease between the two assays. Re-baseline analysis is available upon request for those patients currently undergoing treatment. A minimum of 3.0 ml of specimen will be required for re-baseline analysis.

   The reports for the new assay will now incorporate log IU/ml units, and no longer include copies/ml. The inclusion of log IU/ml should be more convenient for following patients during therapy. There will be no changes to the test codes for ordering this test. The same codes and descriptions used for the previous test are available for this test.

Clinical Utility

- Quantitation of Hepatitis C Virus (HCV) RNA in human plasma or serum.
- Aid in the management of HCV-infected patients undergoing anti-viral therapy.

**Methodology:** Reverse Transcription Real-Time PCR

**Test Codes:** HCVRL (Hepatitis C Virus Quantitation by PCR); HCVQG (Hepatitis C Virus Quantitation by PCR with Reflex to HCV Genotyping); HCVQL (Hepatitis C Virus Qualitative by PCR)

**CPT Codes:** 87522 (Hepatitis C Virus, quantitation)

**Specimen Collection, Shipping and Handling:** Serum or plasma are acceptable specimen types.
- Blood should be collected in SST® Serum Separation Tubes or in sterile tubes using EDTA (lavender top) as the anticoagulant.
• Store whole blood at 2-25°C for no longer than 6 hours.
• Separate serum or plasma from whole blood within 6 hours of collection by centrifugation at 800-1600 x g for 20 minutes at room temperature. Transfer serum or plasma to a sterile polypropylene tube.
• Store and transport at 2-8°C if receipt by the lab will be in less than 3 days. If storage and transport will exceed 3 days, freeze at -70°C or on dry ice.
• Transportation conditions are the same as the storage conditions.
• Do not allow a specimen to thaw once frozen.

**Reference Ranges:** Normal reference range is Not Detected

**Turnaround Time:** 5-7 days

**References**


