

## Hepatitis C Virus, RNA Quantitative (HCV)

**Test Code:** HCVQ1

**Use:** The Cobas AmpliPrep / Cobas TaqMan 48 HCV test is intended for use as an aid in the management of HCV-infected individuals undergoing anti-viral therapy.

**Clinical Significance:** Hepatitis C virus infection is the most common chronic blood borne infection in the United States with an estimated seroprevalence of 1.6%. An estimated 3.2 million Americans suffer from chronic HCV infection making it the leading cause of chronic liver disease. In the United States, chronic hepatitis C is responsible for an estimated 8,000 to 10,000 deaths per year and is the leading cause of liver transplantation.

**Methodology:** The Cobas AmpliPrep / Cobas TaqMan 48 HCV test is a quantitative real time RT-PCR assay that is based on three major processes: 1) specimen preparation to isolate HCV RNA; 2) reverse transcriptase of the target RNA to generate complementary DNA (cDNA); and 3) simultaneous PCR amplification of target cDNA and detection of cleaved dual-labeled oligonucleotide detection probes specific to the target.

**Normal Range:** Not Detected

**Reportable Range:** 43 – 69,000,000 International Units / mL of plasma

### Interpretative Data:

**Not Detected:** Indicates that no HCV viral nucleic acid was detected.

**<43 IU/mL :** Indicates that a small amount of viral nucleic acid was detected but is in quantities below the lowest reportable limit (7.2 – 43 IU/mL)

**>69,000,000 IU/mL:** Indicates that the number of viral nucleic acid is above the upper limit of detection for this assay.

**Assay Availability:** HCV is batched Monday – Friday, specific days are dependent on volume of tests.

**Results Reported:** 1 - 3 days

**Volume:** Peripheral blood should be collected in a 6 ml Lavender top (EDTA) tube and sent to the laboratory immediately. A minimum of one milliliter of plasma is required to perform this test.

**Storage:** Send whole blood to the laboratory at room temperature. Samples must be centrifuged and the plasma separated off within 6 hours of collection. Plasma may be transported and stored at 2 - 8°C up to 3 days prior to testing.

**Causes for Rejection:** Samples collected in Heparin, or other non-approved collection tubes will be rejected. Samples received in the laboratory without proper identification will be rejected.

**Notes:** This assay is not to be used as a donor screening test of HCV or as a diagnostic test to confirm the presence of HCV infection. Specimens containing HCV genotypes 1-6 have been validated for quantitation in this assay.

**Laboratory Contact:** For further information, please call the Molecular Diagnostics Laboratory at (501) 526-6439.