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## Hepatitis C Virus RNA by RT-PCR, Quantitative

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**EFFECTIVE DATE:** June 1, 2004

**DEPARTMENT:** Molecular Pathology

**METHOD:** Real-Time Polymerase Chain Reaction (RT-PCR)

**USE:** HCV RNA quantitation (or viral load) is useful in the detection and monitoring of HCV infection.

**CLINICAL SIGNIFICANCE:**

Testing for hepatitis C RNA is not only a reliable means of detecting HCV infection, it is also currently the most specific test for the infection. Measurement of hepatitis C viral load can identify patients who are actively infected during the "seronegative window" and can be used as a confirmatory test in patients with equivocal serologic studies. It is also helpful for predicting treatment response and relapse. Patients with high initial viral loads have higher relapse rates and benefit more from a 48-week treatment regimen than do patients with low viral loads. After 12 weeks of treatment, patients who demonstrate a less than 2-log decrease from the baseline often have a very low sustained response rate. Accordingly, if fibrosis is not extensive, treatment could be stopped in these patients. However, longer treatment could be justified to reduce fibrosis progression. It is interesting to note that in contrast to HIV infection, HCV viral load does not correlate with the severity of the hepatitis C infection.

HCV infection is a leading cause of chronic hepatitis, cirrhosis, and hepatocellular carcinoma, with more than 170 million people chronically infected worldwide. Very effective treatment is now available, which eradicates the virus in 60% of cases and reduces progression to cirrhosis in the remaining cases. Unfortunately, increasing death due to HCV still occurs even in developed countries because of inadequate detection and treatment. HCV is transmitted mainly through contact with blood and blood products. However, many other patients acquire HCV without any known exposure to blood or intravenous drug use. Patients with high-risk sexual behavior are at highest risk, perhaps because of an association with herpes simplex type-2 infection.

**REFERENCE RANGE:** No HCV RNA detected.

**INTERPRETIVE DATA:**

**Sensitivity for this assay is 50 IU/mL, compared to 600 IU/mL sensitivity for the previous assay.**

This test uses an analyte specific reagent (ASR). The reagent performance has been validated by South Bend Medical Foundation. If detected, result is reported as units of HCV RNA IU/mL.

**IMPORTANT:** A negative result (no HCV RNA detected) does not rule out the presence of HCV infection.

**SPECIMEN AND COLLECTION REQUIREMENTS:**

**PREFERRED SPECIMEN:** Plasma from pearl white top (PPT) tube [contains EDTA plus gel barrier material]

**ALTERNATE SPECIMEN:** Plasma from lavender top (EDTA) tube; use only if PPT tube not available;

EDTA plasma must be promptly transferred to a separate tube

**REQUESTED VOLUME:** Plasma yield from 5.0 mL of whole blood; minimum acceptable: 3.0 mL whole blood  
**PROCESSING:**

- If collected using preferred PPT tube, promptly centrifuge; however, do not remove plasma from original tube (IMPORTANT: sample in PPT tube must be centrifuged within 6 hours of collection)
- If pearl-white top PPT tube is not available, a lavender top (EDTA) tube can be used; however, specimen must be promptly centrifuged and EDTA plasma must be immediately transferred to separate plastic tube

**STABILITY:** Up to 3 days (72 hours) refrigerated (2-8°C)

**STORAGE/TRANSPORT:** Refrigerated

**CAUSES FOR REJECTION:**

- Specimen collected using tube containing heparin
- Pearl white top (PPT) tube not centrifuged within 6 hours of collection
- Lavender top tube not centrifuged immediately; plasma not separated and transferred to separate plastic tube

**TESTING SCHEDULE:** Testing for quantitative HCV RNA will be performed on Monday and Thursday.

**ORDER:** HCV RNA by RT-PCR, Quantitative..... Test #: **25106** .....CPT: 87522

**ALSO AVAILABLE:** HCV RNA by RT-PCR, Qualitative ..... Test #: **36124** .....CPT: 87521

Please direct questions or comments regarding this notice to Francisco A. Deogracias, M.D. or Deborah H. Sun, Ph.D. at the South Bend Medical Foundation, (574) 234-4176 or (800) 544-0925.