

Hepatitis C Virus (HCV) RNA Quantitative Real-time PCR

FOR MEASUREMENT OF HCV VIRAL LOAD IN HCV-INFECTED PATIENTS

Test Highlights

- This test provides unrivaled sensitivity combined with extremely broad analytic range

Clinical Background

- The hepatitis C virus was discovered in 1989, ending the search for the cause of non-A, non-B hepatitis.
- The virus is a member of the Flaviviridae family and is transmitted most commonly by parenteral routes to cause both acute and chronic hepatitis. Acute infections are generally mild or asymptomatic, but progression to chronic disease occurs in up to 85 percent of cases.
- Six major genotypes (1–6) exist, with genotype 1 being the predominant genotype in the United States. Genotypes 2 and 3 have more favorable prognoses and treatment response.
- Quantification of hepatitis C virus (HCV), also referred to as viral-load testing, has become a standard of care for the management of HCV-infected patients. Plasma levels of HCV RNA are used as markers of prognosis and disease progression, as a guide for determining when to initiate therapy, and for therapeutic monitoring.
- An important goal for patient management is achieving a decrease of two logs or undetectable levels of serum/plasma HCV RNA by week 12 of treatment. Failure to achieve this decrease correlates with a lower likelihood of treatment success.
- The COBAS[®] AmpliPrep/COBAS[®] TaqMan[®] HCV assay utilizes real-time reverse transcriptase PCR chemistry to measure HCV viral load over a broad dynamic range. The assay has an analytic range of 1.6–7.8 log HCV RNA IU/mL (43 to 69,000,000 IU/mL). It accurately quantifies HCV virus genotypes 1–6.

Disease Overview

- The primary method for the spread of HCV infection worldwide is parenteral. Approximately 50 percent of cases occur from intravenous drug use.
- Chronic disease states occur in up to 85 percent of patients. Cirrhosis occurs in approximately 5–20 percent and hepatocellular carcinoma in approximately 1–5 percent of chronically infected patients.

Epidemiology

An estimated 2 percent of the United States population is infected. There were approximately 17,000 new cases of hepatitis C in the United States in 2007.

Indications for Ordering

- To establish a baseline viral load prior to initiation of therapy.
- To determine therapeutic success during therapy and following therapy.
- Assessment of prognosis and disease progression.

Interpretation

- Because viral-load may vary by orders of magnitude, results of viral load testing are expressed in log units, where each increase of one log corresponds to a factor of 10. Thus, a viral load of 1,000 would be three log units, and the difference between a viral load of 1,000 and 10,000 would be one log unit.
- A change in viral load of >0.5 log copies/mL (approximately three-fold) exceeds assay and diurnal variations, and may represent a true biological event, whereas a change of <0.5 log copies/mL cannot be distinguished from random variability.

Limitations

Single nucleotide polymorphisms in the primer or probe regions could lead to underquantification or false-negative results.

Methodology

- Real-time polymerase chain reaction.
- Samples are extracted for purification and concentration of nucleic acid and presented for amplification and fluorescence detection by the COBAS[®] AmpliPrep/COBAS[®] TaqMan[®] instrument.

Related Tests

- [Hepatitis C Virus Antibody with Reflex to Supplemental RIBA \(0020700\)](#)
- [Hepatitis C Virus RNA Quantitative bDNA \(0051811\)](#)
- [Hepatitis C Virus Genotyping by PCR and Sequencing \(0055593\)](#)

References

- Strader DB, et al. American Association for the Study of Liver Diseases. Diagnosis, management, and treatment of hepatitis C. *Hepatology* 2004 39(4):1147–71.
- COBAS[®] Ampliprep/COBAS[®] TaqMan[®] HCV Test [package insert]. Indianapolis, IN: Roche Diagnostics, 2008.
- U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Hepatitis C. <http://www.cdc.gov/hepatitis/HepatitisC.htm> (accessed October 5, 2009).

Test Information

0098268

Hepatitis C Virus RNA Quantitative Real-Time PCR

For specific collection, transport, and testing information, refer to the ARUP Web site at www.aruplab.com.

For information on test selection, ordering, and interpretation, refer to ARUP Consult® at www.arupconsult.com.