

# Hepatitis C

## TEST ID

1200 Hepatitis C (HCV) Real-time RT-qPCR

## CPT CODE

87522

## CLINICAL UTILITY

Hepatitis C infection should be monitored with an RNA assay capable of detecting 50 IU/ml consistently according to the NIH Consensus on Management of hepatitis C.<sup>1</sup> The HCV level provides important information on the likelihood of response to treatment in patients undergoing antiviral therapy. The ViraCor quantitative HCV RNA assay has been calibrated to the World Health Organization HCV standard to provide accurate and consistent assessment of viral load across the entire assay range.

## PROCEDURE

Extraction of nucleic acid from plasma; reverse transcription of the target RNA to generate complementary DNA, and amplification of target complementary DNA. Detection of hepatitis C genotypes 1 through 6 using real-time, quantitative PCR. An internal control is added to ensure the extraction was performed correctly and the PCR reaction was not inhibited. ViraCor's assay design includes multiple targets to account for viral mutations, which exponentially reduces the chance of false negative results.

## SPECIMENS

**Plasma:** 2 ml (minimum) collected in EDTA, ACD A or PPT. Separate plasma from cells by centrifugation. Transfer plasma to screw-cap tube for shipment. If specimen collected in PPT tube, the entire tube can be shipped following centrifugation. Specimen may be shipped ambient or frozen.

**Serum:** 2 ml (minimum) collected in red-top or SST. Separate serum from cells by centrifugation. Transfer serum to screw-cap tube for shipment. If specimen was collected in SST, the entire tube can be shipped following centrifugation. Specimen may be shipped ambient or frozen.

**Tissue:** Place in a sterile, screw-cap tube, add a small amount of saline to keep moist. Prefer 1 mm x 1 mm specimen. Prefer fresh over formalin fixed for maximum sensitivity; ship ambient. Results for tissue testing will be qualitative.

**Other specimens may be accepted for testing; however the following comment will appear in the final report: "The clinical utility of this result has not yet been demonstrated in the peer reviewed literature and is therefore unknown." Call ViraCor for further information.**

## CAUSES FOR REJECTION

Whole blood frozen. Call ViraCor at 800-305-5198 if specimen is greater than 96 hrs old.

## SPECIFICITY

**Detects all 6 HCV genotypes.** The primers and probes used in this assay are specific for HCV.

## HEPATITIS C VIRUS ASSAY RANGE

5 to 200,000,000 IU/ml plasma

Reported in 2 formats:

- IU/ml
- Log 10 IU/ml

Tissue biopsy results will be qualitative.

## TURNAROUND TIME

Same day (within 8 to 12 hours of receiving specimen), Monday through Saturday

## SHIPPING

Ship Monday through Friday. Friday shipments must be labeled for Saturday delivery. All specimens must be labeled with patient's name and collection date. Multiple tests can be run on one specimen. Ship specimens FedEx Priority Overnight® to:

**ViraCor Laboratories, 1001 NW Technology Dr, Lee's Summit, MO 64086**

Management of Hepatitis C: 2002. NIH Consensus Development Program Web site.



800-305-5198 www.viracor.com

## Hepatitis C

<http://consensus.nih.gov/2002/2002HepatitisC2002116html.htm>. Accessed January 2, 2008.

*The CPT codes provided are based on ViraCor's interpretation of the American Medical Association's Current Procedural Terminology (CPT) codes and are provided for informational purposes only. CPT coding is the sole responsibility of the billing party. Questions regarding coding should be addressed to your local Medicare carrier. ViraCor assumes no responsibility for billing errors due to reliance on the CPT codes illustrated in this material. PCR tests are performed pursuant to a license agreement with Roche Molecular Systems, Inc. This assay was developed and the performance characteristics were determined at ViraCor Laboratories. This test is performed in a CLIA certified laboratory. FDA approval is not required for the performance of this test.*

0609 V2



800-305-5198 [www.viracor.com](http://www.viracor.com)