

Hepatitis C Quantitative Real-time RNA PCR

Test ID	1200 Hepatitis C (HCV) Real-time RNA qPCR
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. ¹ 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.
Specimens	Whole Blood: 7-10 ml submitted in EDTA, ACD Solution A, or PPT sterile tube. Minimum specimen requirement is 2 ml plasma. <ul style="list-style-type: none">• Separate plasma from cells within 4 hours of collection by centrifuge at 1000 xg for 10-15 minutes. Do not clarify by filtration or further centrifugation.• Ship ambient or frozen.
Specificity	Detects all 6 HCV genotypes. The primers and probes used in this assay are specific for HCV.
Assay Range	5 to 200,000,000 IU/ml plasma Reported in 4 formats: <ul style="list-style-type: none">• IU/ml• Log IU/ml• copies/ml• Log copies/ml
Turnaround Time	Within 24 hours of receiving specimen

¹ Management of Hepatitis C: 2002. NIH Consensus Development Program Web site. <http://consensus.nih.gov/2002/2002HepatitisC2002116html.htm>. Accessed January 2, 2008.

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.

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