

Technical Bulletin

Detailed information concerning methodology, specimen requirements, and reference ranges on new and specialized tests.

• Test Name:	Hepatitis C Virus (HCV) RNA PCR, Quantitative
• Test Order Number:	2257
• CPT code:	87522
• Department:	Molecular Diagnostics (476)
• Testing Schedule:	Monday, reported the following day
• Specimen Requirement:	EDTA-Plasma (Pink Top), 6 ml
• Reference Range:	Not Detected
• Methodology:	Real-time PCR

Test Information

ACM Medical Laboratory offers the Roche COBAS™ AmpliPrep / COBAS™ TaqMan HCV Test, Version 2.0 for the detection and quantitation of HCV viral loads in EDTA-plasma. The assay accurately quantifies HCV genotypes 1-6.

The benefits of the Version 2.0 assay include a lower limit of detection compared to the previous version (10 IU/ml vs. 18 IU/ml), as well as an extended analytical measuring range from (15 IU/ml to 100,000,000 IU/ml). In addition, the assay uses two primer sets that improve the sensitivity for detecting HCV that may have mutations.

Laboratory Results

Results for the Roche COBAS™ AmpliPrep / COBAS™ TaqMan HCV Test, Version 2.0 are reported as follows:

HCV Viral Load Result:	Reported As:
Target Not Detected	Not Detected
Detected , Below the Quantitation Range	HCV RNA Detected, <15 IU/ml HCV RNA Detected, <1.2 log ₁₀ IU/ml
Detected , Within the Quantitation Range	HCV RNA Detected, <u>xxx</u> IU/ml HCV RNA Detected, <u>x.xx</u> log ₁₀ IU/ml
Detected , Above the Quantitation Range	HCV RNA Detected, > 100,000,000 IU/ml HCV RNA Detected, > 8.00 log ₁₀ IU/ml

Clinical Information

The Roche COBAS™ AmpliPrep / COBAS™ TaqMan HCV Test, Version 2.0 is intended for use in the management of patients with chronic HCV in conjunction with clinical and laboratory markers of infection. The test can be used to predict the probability of sustained virologic response early during a course of antiviral therapy, and to assess viral response to antiviral treatment (response guided therapy) as measured by changes of HCV RNA levels in EDTA-plasma.

Questions? Call (585) 429-2300 (Client Services) or Dr. Suzanne Dale, Director of Microbiology and Molecular Diagnostics, (585) 429-2360. Additional copies of this Technical Bulletin are available at: www.acmlab.com.