



Dear Valued Partner:

Solstas Lab Partners® is pleased to announce the addition of the COBAS® AmpliPrep/COBAS® TaqMan® HCV Test, v2.0 and the Abbott Molecular RealTime HCV Genotype II assay to our testing menu. Both of these additions are FDA approved and intended for use as an aid in the management of HCV-infected individuals and will be enhancements to the existing HCV viral load and genotyping assays currently performed.^{1,2}

HCV infection is the most common chronic blood-borne infection in the United States with an estimated 3.2 million Americans suffering from chronic HCV infection.³ The detection and quantification of HCV RNA by polymerase chain reaction (PCR) nucleic acid amplification offers a measure of active viremia in antibody-positive chronic HCV-infected patients undergoing antiviral therapy. The American Association for the Study of Liver Disease (AASLD) practice guidelines indicates “sustained virological response (SVR) is defined as the absence of HCV RNA from serum by a sensitive PCR assay (LOD of 10-50 IU/mL) 24 weeks following the discontinuation of therapy.”^{4,5}

The COBAS® AmpliPrep/COBAS® TaqMan® HCV Test, v2.0 will offer a lower limit of detection (LOD) and lower limit of quantification (LLoQ) at 15 IU/mL to meet the requirements of the AASLD practice guidelines referenced above.¹

The Abbott Molecular RealTime HCV Genotype II assay is the first FDA approved Hepatitis C genotyping test available in the United States. This assay identifies HCV genotypes 1, 1a, 1b, 2, 3, 4, and 5 in plasma or serum from individuals infected with HCV.²

HCV Viral Load Assay:

Unit Code	Reporting Title	Linear Range	Sample Type/Storage	CPT Code	NC Reimbursement
80119	Hepatitis C RNA Quant	15 IU/mL – 100 million IU/mL	Plasma, Critical Frozen Serum, Refrigerated	87522	\$44.77
83155	HCV RNA Quant reflex Genotype	15 IU/mL – 100 million IU/mL	Plasma, Critical Frozen Serum, Refrigerated	87522	\$44.77

HCV Genotype Assay:

Unit Code	Reporting Title	HCV Types Reported	Sample Type/Storage	CPT Code	NC Reimbursement
82925	Hepatitis C Virus Genotype	1, 1a, 1b, 2, 3, 4, and 5	Plasma, Critical Frozen Serum, Refrigerated	87902	\$107.28

If you have any questions, please call your dedicated Solstas Client Relationship Specialist directly, or contact our Customer Service Department at 1-888-664-7601.

Thank you for choosing Solstas Lab Partners to serve the needs of you and your patients. www.solstas.com

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References:

1. COBAS® AmpliPrep/COBAS® TaqMan® HCV v2.0 Test package insert, May 2013.
2. Abbott Molecular RealTime HCV Genotyp II Test package insert, June 2013.
3. Centers for Disease Control and Prevention, Hepatitis C Information for Health Professionals. <http://www.cdc.gov/hepatitis/HCV/index.htm>
4. Ghany, et.al. Diagnosis, management and treatment of Hepatitis C: An update. Hepatology 2009; 49:1333-1374.
5. Ghany, et.al. An update on treatment of Genotype 1 Chronic Hepatitis C Virus infection: 2011 Practice Guideline by the American Association for the Study of Liver Disease. Hepatology October 2011; 1433-1444.