Legacy Laboratory Services

Hepatitis C RNA, Quantitative by PCR Test Upgrade

May 2014

Legacy responds to the new era of HCV therapeutics with an improved quantitative HCV test.

Legacy Laboratory Services is now offering an improved Hepatitis C Virus (HCV) Viral Load test with greater sensitivity and improved lower limit of detection. This test is the FDA-approved Roche COBAS® AmpliPrep TaqMan® method, which is standardized against the WHO International Standard for HCV RNA Nucleic Acid Amplification Technology Assays.

- Quantitative range: 15 - 100,000,000 IU/mL (1.2 - 8.0 Log)
- Lower limit of detection: 10 IU/mL
- Accurately detects and quantitates HCV RNA of genotypes1-6

This test can be used to confirm active infection in accordance with CDC guidelines that recommend an FDA-approved HCV RNA test for patients with a reactive (positive) HCV antibody test result [(1)] (Figure 1). This test can also be used to predict the probability of sustained virologic response (SVR) early during a course of antiviral therapy or to assess viral response to antiviral treatment (response guided therapy) as measured by changes of HCV RNA levels in serum or EDTA plasma. This test is intended for use in the management of patients with chronic HCV in conjunction with clinical and laboratory markers of infection.

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LEGACY HEALTH

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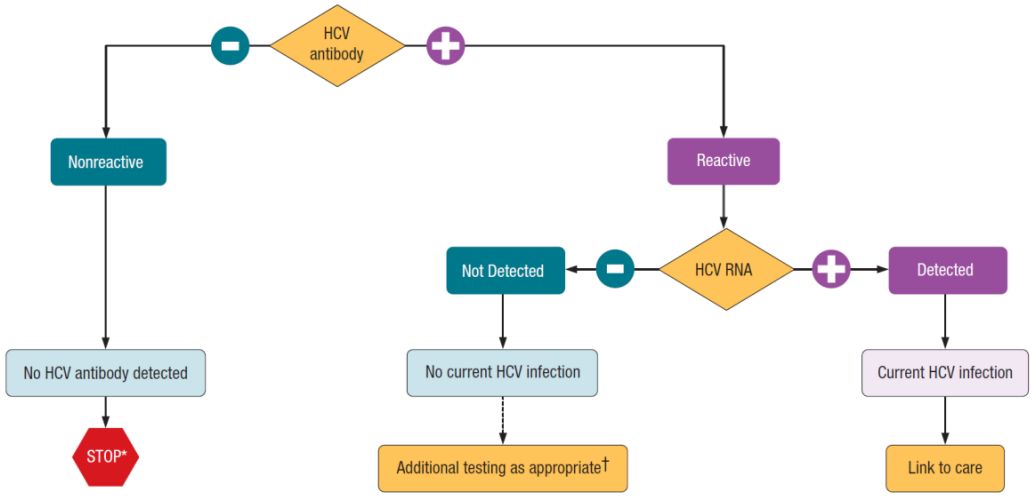
Figure 1. Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection



* For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

† To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. Repeat HCV RNA testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

Source: CDC. Testing for HCV Infection: An Updated of Guidance for Clinicians and Laboratories. MMWR 2013;62(18)

HEPATITIS C RNA, QUANTITATIVE BY PCR

Order Information	
Mnemonic	HEPC QNT
Synonym	Hepatitis C Viral Load – Hep C – HCV
Specimen Collection Requirements	
Collect	Serum or plasma, one 8.5 mL gold (SST) or two 4.0 mL lavender (EDTA) top tube
Handling	Separate the serum or plasma from the collection tube. Place 1.5 mL into two plastic aliquot tubes.
Preferred Volume	3.0 mL
Minimum Volume	1.5 mL
Transport	Frozen
Rejection Criteria	Heparin samples
Stability	Ambient: 6 hours; Refrigerated: 3 days; Frozen: Up to 6 weeks
Testing Information	
Performed	Tue and Fri (AM)
Reported	1-4 days
CPT Codes	87522

Reference:

1. CDC. Testing for HCV Infection: An Updated of Guidance for Clinicians and Laboratories. MMWR 2013;62(18)
2. COBAS® AmpliPrep/COBAS® TaqMan® HCV Test, v2.0 – Roche package insert, 06450393001-01EN, Doc Rev 1.0.