



New Hepatitis C Virus PCR Assay

Hepatitis C virus (HCV) causes liver infections and is transmitted by contact with blood from an infected person. Symptoms of disease begin 2-12 weeks after exposure and include fever, fatigue, dark urine, clay-colored stool, abdominal pain, nausea, joint pain, and jaundice. The incidence of HCV infection is highest in association with intravenous drug abuse and to a lesser extent with other percutaneous exposures¹. Following exposure, 75% to 85% of HCV-infected individuals develop chronic hepatitis, with up to 20% of these chronic cases progressing to cirrhosis. In cirrhotic patients, hepatocellular carcinoma is observed in 1% to 4% of the population every year. An estimated 2.4 million people in the United States were living with hepatitis C during 2013–2016². In 2018 alone HCV was responsible for 15,713 deaths, and is the leading cause of liver transplantation³.

On Sept. 1, 2020 WSLH will begin testing with the Hologic Panther Aptima HCV Quant Dx assay. This test uses transcription mediated amplification and fluorescent probes to detect and quantify HCV RNA from genotypes 1-6⁴. It is approved for use in patients who are seropositive for HCV to evaluate for active infection and to evaluate treatment efficacy by quantifying a viral load. Viral loads may differ from those produced with the previous testing method at WSLH (Roche Cobas). Caution should be used when monitoring viral loads tested by different methods.

This test has been approved by the U.S. Food and Drug Administration for the quantitation of HCV viral load in confirmed positive patients. It has also been validated at the WSLH as a test to confirm HCV infection in seropositive patients.

Test Information:

- **Test name:** Hepatitis C Virus PCR, Quant
- **Test code:** SS00053
- **CPT code:** 87522
- **Price:** \$158
- **Test method:** Transcription mediated quantitative PCR
- **Acceptable specimen types:** Minimum of 2 mL of serum or plasma (EDTA) separated within 24 hours of collection
- **Specimen handling:** Store specimens at 2-8C and transport to the lab with frozen cool packs. Freeze specimen if testing will not be performed within 5 days of collection and ship on dry ice.
- **Unacceptable Conditions:** Uncentrifuged specimens or specimens that have not been handled as described above will be rejected.
- **Turn-around time:** 1-8 days, performed once per week
- **Additional testing:** HCV Antibody EIA SS00049-P automatically reflexes to this test if antibody positive
- **Possible Results:** Hepatitis C Virus RNA Detected or No Hepatitis C Virus RNA Detected. Quantitative value (IU/ml and Log₁₀ IU/mL) if HCV RNA detected.

Reference:

1. Lauer GM, Walker BD. Hepatitis C virus infection. *N Engl J Med* 2001;345(1):41-52.
2. Hofmeister MG, Rosenthal EM, Barker LK, Rosenberg ES, Barranco MA, Hall EW, Edlin BR, Mermin J, Ward JW, Ryerson AB. Estimating prevalence of hepatitis C Virus Infection in the United States, 2013-2016. *Hepatology*. 2018
3. CDC Testing Recommendations for Hepatitis C Virus Infection. <https://www.cdc.gov/hepatitis/hcv/guidelinesc.htm>
4. Hologic Panther package insert- https://www.hologic.com/sites/default/files/2019-03/AW-14498_002_01_0.pdf

