



FDA Approves First Point-of-Care Hepatitis C RNA Test

On-site RNA testing can yield results in an hour and link those with hepatitis C to immediate care.

July 1, 2024 By Laura Schmidt

The first point-of-care [hepatitis C](#) RNA test, which allows individuals to be rapidly tested and, if positive, diagnosed and linked to timely care, received marketing authorization from the Food and Drug Administration (FDA), according to an [FDA news release](#).

Guidelines recommend that [all adults should be screened for hepatitis C \(HCV\)](#) at least once, regardless of risk factors. One barrier to timely treatment is a cumbersome two-step testing process.

The first step involves screening for HCV [antibodies](#), which shows whether a person has ever had the virus. The second part is an HCV [RNA](#), or [viral load](#), test to see whether they have active infection and are eligible for [treatment](#).

To allow for the widespread use of HCV RNA testing and linkage to treatment, the FDA permitted marketing authorization to Cepheid for its Xpert HCV test and GeneXpert Xpress System. The on-site HCV RNA test yields results in as little as an hour. What's more, individuals may be linked to care and potentially treated during the same health care visit.

"Despite the existence of a safe and highly effective oral cure for hepatitis C, many people do not know they have the disease due partly to the lack of availability of convenient, widespread testing options," said Jeff Shuren, MD, JD, director of the FDA's Center for Devices and Radiological Health, in the news release.

More than 2.4 million people in the United States are [living with HCV](#), which, if left untreated, can lead to serious health complications including [liver failure](#) and [liver cancer](#). What's more, as many as 75% of U.S. adults with HCV are unaware that they have it, according to the [American Liver Foundation](#).

Point-of-care tests can provide rapid, reliable results that aid in identification and monitoring of chronic disease or acute infections, such as HCV.

“Equipping health care providers with tools to diagnose and treat patients in the same visit can result in hundreds of thousands more hepatitis C patients being diagnosed and treated, preventing individual disease progression and additional spread of the virus,” Shuren said.

To read more, click [#Hepatitis C Testing](#). There, you’ll find headlines such as “[Studying Benefits of Opt-Out Hepatitis C and HIV Testing](#),” “[Universal Hepatitis C Screening Benefits Cancer Patients](#)” and “[Proposed 5-Year Program Aims to Put Country on the Path to Eliminating Hepatitis C](#).”

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