



# OraQuick HCV Test Gets Clearance for Wider Use

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Good news for doctor's offices, outreach clinics and community-based organizations looking to use OraSure Technologies' rapid test for hepatitis C virus (HCV): The test has been granted a CLIA waiver, meaning that its use is no longer limited to professionals who have received laboratory certification from the U.S. Department of Health and Human Services.

With the waiver, an [OraSure news release](#) states, "the OraQuick HCV [Rapid Antibody Test] now can be used by more than 180,000 sites in the United States to test persons who are at risk for hepatitis C or have signs or symptoms of hepatitis."

OraQuick's assay is the first and only U.S. Food and Drug Administration (FDA)-approved rapid test to detect antibodies to HCV, which causes liver disease. The test, using fingerstick or vein-drawn blood specimens, provides results in 20 minutes. It's important to note that positive results must be confirmed, notably with the use of PCR testing to determine whether or not the infection is still active in the liver.

"Today, more than 4 million Americans are infected with hepatitis C, and the vast majority do not know it," said Willis Maddrey, MD, president of the Chronic Liver Disease Foundation. "Hepatitis C is a leading cause of chronic liver disease, cirrhosis and liver cancer. However, new therapies are now available that can effectively treat a high percentage of people with HCV infection, making expanded and accessible testing for HCV a critical step in fighting this epidemic."

"A CLIA waiver for our OraQuick HCV test represents a critical milestone in our quest to make the test available to the widest possible range of at-risk individuals in the U.S.," said Douglas Michels, president and chief executive officer of OraSure Technologies. "The CLIA waiver will enable health care providers, those on the front lines of fighting this devastating disease, to use this simple and accurate test in physician offices and outreach settings so more individuals infected with hepatitis C can be diagnosed and treated."