OraQuick HCV Test Gets Clearance for Wider Use

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Goodnews for doctor's offices, outreach clinics and community-based organizationslooking 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 longerlimited to professionals who have received laboratory certification from theU.S. Department of Health and Human Services.

Withthe waiver, an OraSure news release states, "the OraQuick HCV [Rapid AntibodyTest] now can be used by more than 180,000 sites in the United States to testpersons who are at risk for hepatitis C or have signs or symptoms ofhepatitis."

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

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

"ACLIA waiver for our OraQuick HCV test represents a critical milestone in ourquest to make the test available to the widest possible range of at-riskindividuals in the U.S.," said Douglas Michels, president and chief executiveofficer of OraSure Technologies. "The CLIA waiver will enable health careproviders, those on the front lines of fighting this devastating disease, touse this simple and accurate test in physician offices and outreach settings somore individuals infected with hepatitis C can be diagnosed and treated."

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