## FDA Hepatitis Update - CLIA waiver expands availability of rapid blood test for antibodies to the hepatitis C Virus (HCV)

On November 28, 2011, the Food and Drug Administration granted a Clinical Laboratory Improvement Act (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124105.htm) (CLIA) waiver for the first rapid blood test for HCV, the OraQuick HCV Rapid Antibody Test, manufactured by OraSure Technologies, Inc. in Bethlehem, PA.

The OraQuick HCV Rapid Antibody Test is used in clinical settings to test individuals at risk for infection with HCV and individuals who have signs or symptoms associated with hepatitis.

The CLIA waiver will broaden access to the test by permitting more widespread distribution and use of the OraQuick HCV Test to nontraditional laboratory sites, including physicians' offices, health department clinics and other freestanding counseling and testing sites. The broader availability and easier access to this test may contribute to a higher rate of detection for this disease.

OraQuick is a test strip that is read visually and does not require an instrument for diagnosis. Its 20-minute response time allows decentralized testing of HCV enabling the patient to be referred immediately for further testing.

The test qualifies for the CLIA waiver based on data submitted to FDA that demonstrated that the test is simple, accurate, and reasonably free of harm.

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