Heptatitis C Rapid Test Approved

June 29, 2010

The first rapid blood test for antibodies to the hepatitis C virus (HCV) for individuals 15 years and older was recently approved by the U.S. Food and Drug Administration.

The OraQuick HCV Rapid Antibody Test is used to test individuals who are at risk for infection with HCV and people with signs or symptoms of hepatitis. HCV is transmitted through exposure to infected blood, which, for example, can occur during intravenous drug use. The virus can also be transferred from an infected mother to her child. Hepatitis C can lead to liver inflammation and dysfunction and, over time, to liver disease and liver cancer.

OraQuick is a test strip and does not require an instrument for diagnosis. It takes about 20 minutes to obtain results from the test.

“Approval of OraQuick means that more patients can be notified of their HCV infection faster so that they can consult with their physicians for appropriate health measures,” said Jeffrey Shuren, M.D., J.D., director of the FDA’s Center for Devices and Radiological Health. “Getting faster treatment is an important public health step to control this dangerous disease.”

OraQuick is not approved for HCV screening of the general population.

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