News & Events

FDA NEWS RELEASE

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En Español

FDA approves first genotyping test for patients with hepatitis C virus

The U.S. Food and Drug Administration today approved a test that identifies the genotypeof hepatitis C virus (HCV) that apatientis carrying The Abbott RealTime HCV Genotype II, which can differentiate genotypes 1, 1a, 1b, 2, 3, 4, and 5,using a sample of an infected patient's blood plasma or serum, will aid health care professionals in determining the appropriate approach to treatment. Because the various HCV genotypes respond differently to available drug therapies, knowing the type of HCV a person is infected with can result in better patient outcomes.

"Tests such as this one can help physicians gain an understanding of a patient's HCV status," said Alberto Gutierrez, Ph.D., director of the Office of In Vitro Diagnostics and Radiological Health in FDA's Center for Devices and Radiological Health. "Along with other clinical factors, the particular type of HCV is an important consideration in aiding health care professionals in determining if and when to initiate treatment and the appropriate type of treatment."

According to the Centers for Disease Control and Prevention, HCV is the most common chronic blood-borne infection in the United States and the leading cause of liver transplants. About 3.2 million people in the United States have a chronic HCV infection and approximately 15,000 people die from the effects of the virus each year. Seventy-five to 85 percent of people infected with HCV are not able to fight off the virus on their own and develop a chronic HCV infection that requires treatment. Untreated chronic HCV infections may lead to liver cancer, severe liver damage and liver failure.

HCV is transmitted through blood and other bodily fluids. Injection drug users who share needles are at the highest risk for HCV infection. Health care workers stuck by needles that have been used on HCV-infected patients and children born to HCV-infected mothers are also at risk.

The Abbott RealTime HCV Genotype II is approved for individuals known to be chronically infected with HCV. It is not approved for use as a diagnostic test or as a screening test for the presence of HCV genetic material in blood, blood products or tissue donors. It has not been evaluated in newborns or pediatric patients, or in patients with compromised immune systems, such as people with AIDS.

The FDA based its approval of the Abbott RealTi**m**e HCV Genotype II, in part, on the assessment of the test's accuracy in differentiating specific HCV viral genotypes compared to a validated genesequencing method. The FDA also reviewed data from investigators demonstrating the relationship between HCV genotype and effectiveness of drug therapy.

The Abbott RealTi*m*e HCV Genotype II test is manufactured by Abbott Molecular Inc., in Des Plaines, Ill.

For more information:

- FDA: Medical Devices[2]
- FDA: Office of In Vitro Diagnostic Device Evaluation and Safety[3]:
- CDC: Hepatitis C Information for Health Professionals [4]
- Testing Recommendations for Chronic Hepatitis C Virus Infection Among Persons Born During 1945-1965[5]
- VA: National Hepatitis C Program[6]
- NIH: What I need to know about Hepatitis C (simple text) [7]
- NIH: Chronic Hepatitis C: Current Disease Management[8]
- NLM: Hepatitis C - Interactive Tutorial [9]

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