

Pleasanton, 25 October 2010

Roche receives FDA approval for a second-generation hepatitis C viral load test

Another Roche FDA approval in the COBAS® TaqMan® viral load portfolio

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the U.S. Food & Drug Administration (FDA) has approved the real-time PCR COBAS® TaqMan® HCV Test, v2.0. Clinical research organizations have depended on COBAS® TaqMan® technology to support hepatitis C pharmaceutical trials and development. This new test will help clinicians to more confidently and effectively monitor their patients, and to improve treatment outcomes.

“This HCV quantitative test is key to measuring the effectiveness of many antivirals that are currently in clinical development for the treatment of hepatitis C,” said Teresa Wright, M.D., Chief Medical Officer of Roche Molecular Diagnostics. “Roche is committed to providing complete diagnostic and treatment solutions for this important global disease.”

About COBAS® TaqMan® HCV Test, v2.0 For Use With High Pure System

Designed for use with the High Pure System Viral Nucleic Acid Kit, the COBAS® TaqMan® HCV Test, v2.0 is intended to quantify the amount of hepatitis C viral RNA in human plasma or serum of HCV infected individuals. The test incorporates a manual specimen preparation and the COBAS® TaqMan® 48 Analyzer for automated amplification and detection. Roche now offers HCV viral load test for both automated and manual specimen preparation methods; further demonstrating Roche’s commitment in providing workflow options and flexibilities for the diverse needs of laboratories. The test system benefits from the proven contamination controls designed into all COBAS® TaqMan® assays, including built-in Roche-proprietary AmpErase enzyme.

About Hepatitis C

According to the Centers for Disease Control, Hepatitis C virus (HCV) infection is the most common chronic blood borne infection in the United States; approximately 3.2 million persons are chronically infected. .

Each year in the U.S. approximately 8,000 – 10,000 people die from hepatitis C-related liver disease. An estimated 3.2 million persons in the United States have chronic hepatitis C virus infection. Most people do not know they are infected because they don’t look or feel sick. However, approximately 75 – 85% of people who become infected with hepatitis C virus develop infection.¹

Hepatitis C infections can range in severity from a mild “acute” illness lasting a few weeks to a serious, lifelong or “chronic” illness. For most people, acute infection leads to chronic infection. Chronic hepatitis C infection is a serious disease that can result in long-term health problems, including liver damage, liver failure, liver cancer, or even death. Hepatitis C is the leading cause of cirrhosis and liver cancer and the most common reason for liver transplantation in the United States.

Hepatitis C virus is passed when infected blood enters the body of someone who is not infected. People can be infected by sharing contaminated needles, high risk sex with an infected partner, and from an infected mother to her infant during pregnancy and childbirth.

About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company with truly differentiated medicines in oncology, virology, inflammation, metabolism and CNS. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2009, Roche had over 80'000 employees worldwide and invested almost 10 billion Swiss francs in R&D. The Group posted sales of 49.1 billion Swiss francs. Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan. For more information: www.roche.com.

¹ Us. Centers for Disease Control. <http://www.cdc.gov>

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