Media Release

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FDA Approves First Hepatitis B Viral Load Test

Another Roche first in TaqMan® real-time PCR testing for the diagnostic lab

The U.S. Food & Drug Administration (FDA) has approved the Roche COBAS® TaqMan® HBV Test, the first assay for quantitating Hepatitis B Virus DNA approved in the U.S. The test uses Roche's real-time PCR technology to quantify the amount of Hepatitis B virus DNA in a patient's blood. Doctors may use viral load testing results to establish a baseline level of infection and during treatment as an aid in assessing individual responses to therapy. Widespread application of antiviral therapy along with the Hepatitis B vaccine has helped reduce prevalence; however, Hepatitis B remains a serious and potentially life threatening global disease, potentially resulting in death from extensive liver damage or liver cancer for chronically infected people.[1]

"Viral load testing with an FDA approved test has long been the standard for managing patients with HIV and Hepatitis C," said Teresa Wright, M.D., Chief Medical Officer at Roche Molecular Diagnostics. "Availability of this new Roche test enables doctors and laboratories to bring that same level of standardized viral load measurement to Hepatitis B treatment."

Because the goal of Hepatitis B therapy is to treat until the virus is undetectable in the patient's blood, it is critical for viral load monitoring tests to be able to quantify very low levels of virus. Similarly, it is important for the test to quantify very high levels of virus (higher than 100 million IU/mL), an indicator of the need for more or less aggressive treatment. The Roche COBAS® TaqMan® HBV Test can detect the World Health Organization (WHO) HBV International Standard in plasma and serum as low as 3.5 IU/mL and 3.4 IU/mL respectively. The test can measure HBV DNA as high as 1.10E8 IU/mL, representing a significantly broader dynamic range than previously available tests in the U.S.

Other infections concomitant with Hepatitis B are common, with up to 10% of HIV patients in the US also infected with Hepatitis B virus. This makes it essential for the test to quantitate the HBV virus in presence of other viruses.

Designed for use with the High Pure System, the test is run on the COBAS® TaqMan® 48 analyzer and gives labs the added benefits of automated real-time PCR. The test system benefits from the same contamination control protection designed into all COBAS® TaqMan® assays, including closed-tube processing and built-in Roche-proprietary AmpErase enzymes. To help with needed standardization, the Roche COBAS® TaqMan® HBV Test has been calibrated with the WHO standard and reports with the international unit of measure IU/mL. The test was designed to quantify all major Hepatitis B genotypes, including pre-core mutants that can lead to more severe liver disease and reduced response to antiviral therapy.

Roche Diagnostics, a leader in molecular diagnostics, has more than 10 years of global experience in HBV viral load testing and has actively monitored virus mutation through its Global Surveillance program. The COBAS® TaqMan® HBV Test is the latest in a portfolio of increasingly automated real-time PCR Hepatitis and HIV tests that Roche is developing The company's fully automated, real-time HIV monitor test was approved by the FDA in May 2007 and the company has filed a Premarket Approval Application for its test to quantitate HCV virus RNA.

About Hepatitis B

According to the World Health Organization, HBV is the most serious type of viral hepatitis infecting 2 billion people each year and representing a serious public health problem. Even with a Hepatitis B vaccine, which has been available since 1982, the U.S. Centers for Disease Control estimates that 1.25 million people are living with chronic Hepatitis B infection. Another 60,000 people become newly infected each year and 5,000 people die from hepatitis B-related complications.

The Hepatitis B virus is spread through having unprotected sex, by sharing drugs, needles, or from an infected mother to her baby during birth. Symptoms occur in about 70 percent of patients which include jaundice, fatigue, abdominal pain, loss of appetite, nausea, and vomiting.

About Roche and the Roche Diagnostics Division

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused

healthcare groups in the fields of pharmaceuticals and diagnostics. As the world's biggest biotech company and an innovator of products and services for the early detection, prevention, diagnosis and treatment of diseases, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is the world leader in in-vitro diagnostics and drugs for cancer and transplantation, and is a market leader in virology. It is also active in other major therapeutic areas such as autoimmune diseases, inflammatory and metabolic disorders and diseases of the central nervous system. In 2007 sales by the Pharmaceuticals Division totalled 36.8 billion Swiss francs, and the Diagnostics Division posted sales of 9.3 billion francs. Roche has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai, and invested over 8 billion Swiss francs in R&D in 2007. Worldwide, the Group employs about 80,000 people. Additional information is available on the Internet at www.roche.com.

[1] U.S. Centers for Disease Control. http://www.cdc.gov

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