

Pleasanton, 8 December 2008

Improved Testing for Hepatitis B Virus from Roche

A sensitive and fully automated platform improves viral load testing in serum and plasma

Roche Molecular Diagnostics announced today that it has received CE Mark certification for its new COBAS® AmpliPrep / COBAS® TaqMan® HBV Test v2.0, allowing it to be sold for clinical use in the European Union. This highly sensitive test offers Roche's fully automated real-time PCR technology to achieve a broad dynamic range for the quantitative detection of hepatitis B virus (HBV) DNA in patient plasma and serum. According to the World Health Organization, approximately 2 billion people worldwide and about 350 million live with chronic HBV infection and are at risk of developing end stage liver disease and liver cancer.¹

“It is critical to monitor the levels of circulating hepatitis B virus as an indicator as to when hepatitis B therapies should be started, and to determine response to treatment,” said Teresa Wright, M.D., Chief Medical Officer at Roche Molecular Diagnostics. “This test enables doctors to optimize patient treatment with standardized viral load measurements and enables laboratories to test efficiently with improved automation.”

Hepatitis B viral load testing enables clinicians to quantify the amount of hepatitis B virus in a patient's blood, select patients for treatment, predict and assess individual responses to therapy and assess patients' responses to therapy when they undergo treatment.

About the COBAS® AmpliPrep/COBAS® TaqMan® HBV Test v2.0

The Roche COBAS® AmpliPrep / COBAS® TaqMan® HBV Test v2.0 can detect genotypes A-H and pre-core mutants. It offers a broader dynamic range than previous generation tests, from as low as 20 IU/mL and as high as 1.7E+08 IU/mL, enabling physicians to improve viral load monitoring. The assay offers both serum and plasma specimen type and only uses 650 µl sample processing volume.

This test is designed for use on Roche's automated platform that was CE Mark certified in 2005. The platform combines the COBAS® AmpliPrep Instrument for automated sample

preparation and the COBAS® TaqMan® Analyzer or the smaller COBAS® TaqMan® 48 Analyzer for automated real-time PCR amplification and detection.

“Sample in/results out” testing eliminates manual intervention between steps and configuration options allow for customizable solutions for throughput needs. For a flexible throughput solution, the test offers up to 72 tests per kit in self sealing, ready-to-use reagent cassettes. Roche’s proprietary AmpErase enzymes are also included in each test and are designed to prevent cross-contamination of samples and labs.

About Hepatitis B

According to the World Health Organization, three quarters of the world’s population live in areas where there are high levels of hepatitis B infection. Even with a Hepatitis B vaccine, which has been available since 1982, about 600,000 people a year die from chronic active hepatitis, cirrhosis or primary liver cancer.¹

The Hepatitis B virus is spread through having unprotected sex, by sharing needles, or from an infected mother to her baby during child birth. Symptoms occur in about 70 percent of patients and 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 totaled 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 World Health Organization. www.who.int

All trademarks used or mentioned in this release are legally protected by law.

For further information please contact:

Jessica E. Brillant
Molecular Diagnostics Communication
925.730.8503