Roche launches next-generation viral load assay for HBV in markets accepting the CE mark

**cobas HBV assay offers unparalleled performance on the cobas 6800/8800 Systems**

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today the commercial availability of the cobas® HBV quantitative nucleic acid test for use on the cobas® 6800/8800 Systems—adding to the viral load monitoring portfolio on the newest molecular diagnostic platforms from Roche. The new assay offers broad coverage of all known Hepatitis B (HBV) genotypes (A-H) with high sensitivity, across all critical medical decision points.

“With the cobas® HBV assay, laboratories now have a highly robust and sensitive assay for quantifying HBV DNA, with a lower sample requirement that provides a new standard of flexibility,” said Roland Diggelmann, COO, Roche Diagnostics.

This assay builds on the viral load monitoring portfolio (cobas® HIV-1, HCV and CMV) for the cobas® 6800/8800 Systems that was launched in late 2014. The cobas® 6800/8800 Systems, combined with the viral load assay portfolio, are designed to improve laboratory efficiencies while providing the rapid results needed to make informed treatment decisions. The cobas® HBV assay and the cobas® 6800/8800 Systems are commercially available in markets that recognize CE-Mark. Both products are not currently available in the United States.

**About the cobas® 6800/8800 Systems**

The cobas® 6800 and 8800 Systems are fully automated solutions designed for blood donor screening, viral load monitoring, women’s health and microbiology testing. They are available in medium and high throughput models, respectively. Based on the Nobel-prize winning PCR technology, the systems are designed to deliver increased automation and throughput with shorter time to results, providing users with greater testing flexibility to increase overall workflow efficiencies.
The systems provide up to 96 results in less than 3.5 hours, and a total of 384 results for the cobas® 6800 System and 960 results for the cobas® 8800 System in an 8 hours shift³. Both systems allow for mixed batching, making it possible for labs to perform up to three tests in the same run with no pre-sorting required. The systems also enable up to eight hours (cobas® 6800) and four hours (cobas® 8800) of “work-away” time² with minimal user interaction.

For more information about the systems, please visit www.cobas68008800.com.

The cobas® 6800/8800 Systems are not available in all markets, including the U.S.

About the Assays for the cobas® 6800/8800 Systems

Assays for viral load monitoring

cobas® HIV-1 is a real-time PCR test built upon the dual-target assay design from Roche. The test simultaneously amplifies and detects two separate regions of the HIV-1 genome, which are not subject to selective drug pressure, allowing for more reliable results to confidently and effectively quantify the amount of HIV-1 RNA in a patient’s blood.

cobas® HCV is a real-time PCR test that employs Roche’s unique dual-probe approach to provide an extra layer of protection against mutations that can occur in the viral genome and is designed to accurately detect and quantify hepatitis C virus ribonucleic acid (RNA) with state-of-the-art sensitivity in order to assess a patient’s response to antiviral therapy.

cobas® HBV is a real-time PCR test designed to offer an expanded linear range with two input volumes coupled with broad coverage of all known HBV genotypes (A-H), including pre-core mutations with high sensitivity.

cobas® CMV is a real-time PCR test traceable to the first WHO International Standard for Human Cytomegalovirus for Nucleic Acid Amplification Techniques (NIBSC 09/162), therefore provides consistent, reliable results across the dynamic range of the assay and across institutions.

Assays for blood donor screening

cobas® MPX is a real-time PCR multiplex test covering five critical viral targets: HIV-1 Group M, HIV-1 Group O, HIV-2, HCV and HBV, from a single sample. It offers real-time detection and identification of
HIV, HCV and HBV, eliminating both the need for discriminatory testing and the potential for discrepant results. Plus, the dual-target approach with amplification of separate regions of HIV-1, and dual probes for HCV, improve coverage of new virus variants.

**cobas® WNV** is a real-time PCR test for West Nile virus (WNV) that is highly sensitive for both WNV lineages 1 and 2. It also provides broad coverage of other flaviviruses that cause transfusion-transmitted infectious diseases.

**cobas® HEV** is a real-time PCR test for hepatitis E virus (HEV), providing broad coverage of all 4 major HEV genotypes.

**About Hepatitis B Virus (HBV)**
According to the World Health Organization (WHO), an estimated 2 billion people worldwide have been infected with the hepatitis B virus, and more than 350 million are chronically infected. Over 1,000,000 people die every year due to the consequences of hepatitis B. Because many HBV infections are either asymptomatic or never reported, the actual number of new infections is estimated to be tenfold higher.

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**
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, immunology, infectious diseases, ophthalmology and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche’s personalised healthcare strategy aims at providing medicines and diagnostics that enable tangible improvements in the health, quality of life and survival of patients. Founded in 1896, Roche has been making important contributions to global health for more than a century. Twenty-four medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and chemotherapy.
In 2014, the Roche Group employed 88,500 people worldwide, invested 8.9 billion Swiss francs in R&D and posted sales of 47.5 billion Swiss francs. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit roche.com. All trademarks used or mentioned in this release are protected by law.

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2COBAS® AmpliPrep/COBAS® TaqMan® HBV Test, v2.0
3 May vary based on workflow demands