

Pleasanton, December 22, 2015

New Roche HBV Test expands cobas® 4800 System menu

Complete virology portfolio strengthens high medical value capabilities

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today the commercial availability of the **cobas®** HBVassay for use on the **cobas®** 4800 System in countries accepting the CE mark.¹ This new molecular diagnostic assay expands the available virology menu on the **cobas®** 4800 System, improving system efficiency and providing testing flexibility that allows physicians to assess a patient's response to antiviral therapy. The test will play a pivotal role in helping physicians and patients better manage disease caused by the hepatitis B virus.

“The state-of-the-art **cobas®** HBVassay enables clinicians to follow best practices in patient care with standardized viral load measurements, across a broad range of genotypes, with high sensitivity,” said Paul Brown, Head of Roche Molecular Diagnostics. “Having the assay on the **cobas®** 4800 System helps laboratories provide reliable results for an expanded menu of assays--from microbiology and women's health to virology solutions-- in order to enable confident patient management.”

The **cobas®** HBV assay is a test designed to detect the amount of hepatitis B virus circulating in a patient's blood and provides broad coverage of all known HBV genotypes (A-H), including pre-core mutations, with high sensitivity. To increase flexibility for patient sample management, the new test has two sample processing volumes.

About the cobas® 4800 System

The **cobas®** 4800 System offers improved automation of nucleic acid purification, PCR (polymerase chain reaction) set-up and real-time PCR amplification and detection to help laboratories achieve maximum efficiency. The system now has a comprehensive test menu including the **cobas®** HBV Test, **cobas®** HIV-1 Test, **cobas®** HCV Test, **cobas®** HCV Genotyping Test, **cobas®** MRSA/SA Test, **cobas®** HSV 1 and 2 Test, **cobas®** C.diff Test, **cobas®**

¹ Local product availability may vary independently from CE mark approval.

CT/NG Test (chlamydia/gonorrhea), **cobas**[®] HPV Test, **cobas**[®] BRAF V600 Mutation Test, **cobas**[®] EGFR Mutation Test, and the **cobas**[®] KRAS Mutation Test.

For more information about the **cobas**[®] 4800 System, please visit <http://molecular.roche.com>.

About the assays for the cobas[®] 4800 System - assays for viral load monitoring and genotyping

cobas[®] HBV builds on Roche's leadership position in Hepatitis B testing by expanding the linear range of the test to address the high titer samples. **cobas**[®] HBV is designed to accurately detect and quantify HBV DNA, including all major genotypes (A-H including pre core mutation), to allow physicians to assess a patient's response to antiviral therapy.

The **cobas**[®] HIV-1, **cobas**[®] HCV, and **cobas**[®] HCV Genotyping Tests can run simultaneously on the **cobas**[®] 4800 System with two different sample processing volumes for HIV-1 and HCV (200 µL and 400 µL) and only 400 µL for HCV GT streamlining workflow while increasing testing flexibility for patient sample management. The new **cobas**[®] HBV Test can be added into the workflow in a staggered approach with options for 200 µL and 400 µL input volume.

cobas[®] HIV-1 is 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 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 (HCV) ribonucleic acid (RNA) with state-of-the-art sensitivity in order to confirm active HCV infection or assess a patient's response to antiviral therapy.

cobas[®] HCV Genotyping is a highly accurate and sensitive real-time PCR-based test for the qualitative identification of HCV genotypes 1 to 6 and genotype 1 subtypes a and b in human plasma or serum from individuals with chronic HCV infection. Identification of the infecting genotype is required before a patient is prescribed antiviral therapy as response to treatment correlates to the HCV genotype.

About 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.² Over 600,000 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-nine 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 www.roche.com.

COBAS is a trademark of Roche.

For media inquiries, please contact:
Bob Purcell, Roche Molecular Diagnostics
+1-888-545-2443 (US)

² "Hepatitis." World Health Organization, 10 July 2013. <http://www.who.int/immunization/topics/hepatitis/en/>. Accessed 3Dec2015