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## **Roche receives FDA approval for viral load tests and cobas 6800/8800 Systems cobas 6800/8800 Systems offer fastest time to results and highest throughput of any molecular platform, helping to improve disease management and patient care**

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has received FDA approval for the **cobas**<sup>®</sup> HBV and **cobas**<sup>®</sup> HCV viral load tests, the first assays approved by the United States Food and Drug Administration (FDA) for use on the **cobas**<sup>®</sup> 6800 and **cobas**<sup>®</sup> 8800 Systems. The fully automated systems offer the fastest time to results, the highest throughput and the longest walk-away time available among automated molecular platforms, providing laboratories both improved operating efficiency and flexibility to adapt to changing testing needs. The new tests are the next generation of Roche's viral load tests, which clinicians use to manage the treatment of patients chronically infected with hepatitis B or hepatitis C virus.

“These new systems will provide laboratories with solutions for routine molecular testing that offer excellent performance, unmatched flexibility and absolute automation,” said Roland Diggelmann, COO, Roche Diagnostics. “The **cobas** HBV and **cobas** HCV tests set new industry standards for viral load assays for the highly evolving hepatitis treatment regimens.”

In addition to the assays approved today, Roche currently has viral load tests under FDA review for HIV-1 and cytomegalovirus (CMV)\*, which, when approved, will complete a comprehensive portfolio of viral load monitoring for the **cobas** 6800/8800 systems. Further menu expansion plans include qualitative tests for donor screening, women's health and microbiology.

### **About the cobas 6800/8800 systems**

The **cobas** 6800 and **cobas** 8800 systems are fully integrated, automated solutions that introduce a new standard for routine molecular testing in the areas of viral load monitoring, donor screening, women's health and microbiology. Based on Nobel prize-winning PCR technology, the systems are designed to deliver full automation, increased throughput and faster turnaround time, providing users with greater 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 eight-hour shift. Both make 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 walk-away time with minimal user interaction.

For more information about the systems, please visit [www.cobas68008800.com](http://www.cobas68008800.com) or <http://molecular.roche.com>.

#### **About the cobas HBV and HCV viral load tests for use on the cobas 6800/8800 Systems**

The two new assays for viral load monitoring can run simultaneously on the **cobas 6800/8800** systems, streamlining workflow while increasing flexibility for patient sample management.

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

**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. It is designed to accurately detect and quantify HCV ribonucleic acid (RNA) of genotypes 1-6 with state-of-the-art sensitivity and is the first assay approved in the United States that can be used both to confirm active HCV infection and to assess a patient's response to antiviral therapy. **cobas HCV** can confirm active HCV infection and provide the baseline viral load at the same time.

#### **About hepatitis B virus (HBV)**

The World Health Organization (WHO) estimates that 2 billion people worldwide have been infected with HBV, with more than 350 million chronically infected. Over 1,000,000 people die every year due to the consequences of hepatitis B1. As many HBV infections are either asymptomatic or never reported, the actual number of new infections is estimated to be tenfold higher.

The main risk factors for HBV transmission are unprotected sex, sharing needles and mother-to-child infection during birth. Symptoms occur in about 70 percent of patients and include jaundice, fatigue, abdominal pain, loss of appetite, nausea and vomiting.

#### **About hepatitis C virus (HCV)**

According to the World Health Organization, HCV affects around 200 million people globally.

Approximately 170 million people are chronic carriers of HCV, most of them unaware of their infection. The disease can ultimately result in cirrhosis, liver failure and hepatocellular carcinoma, which together are responsible for hundreds of thousands of deaths each year.

### **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](http://www.roche.com).

\* The cobas<sup>®</sup> HIV-1 and cobas<sup>®</sup> CMV tests are not available in the U.S. PMA submissions are under review. COBAS is a trademark of Roche. All trademarks used or mentioned in this release are protected by law.

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