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## **Roche's novel tests for the management of hepatitis C virus infection receive CE Mark**

### *Tests change hepatitis C disease and patient management*

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that its novel, state of the art Hepatitis C virus (HCV) qualitative and quantitative tests received CE mark. The tests detect HCV RNA, which is a crucial marker in the management of hepatitis C infection. In the new era of antiviral HCV therapies, sensitive detection and measurement of HCV RNA play an important role in determining treatment duration and predicting treatment response.

“The two tests provide a holistic solution for the management of hepatitis C infection: from the confirmation of a hepatitis C infection to the prediction and assessment of treatment response,” said Paul Brown, Ph.D., Head of Roche Molecular Diagnostics. “Considering the rapidly changing hepatitis C treatment environment, we are pleased to provide two medically relevant tests on one fully automated platform. This offers clinicians the tools to manage their patients effectively and laboratories the automation and flexibility to maximize their workflow efficiency.”

COBAS AmpliPrep/COBAS TaqMan HCV Qualitative Test, v2.0<sup>1</sup> is intended for the confirmation of HCV antibody positive specimens and COBAS AmpliPrep/COBAS TaqMan HCV Quantitative Test, v2.0 is intended for viral load monitoring and the prediction of virological response to antiviral therapy. Both tests are standardized with the World Health Organization (WHO) International Standard and have a limit of detection and lower limit of quantitation of 15 IU/mL. These characteristics make them medically relevant diagnostic tools in the management of hepatitis C infection.

Roche also offers the COBAS TaqMan HIV-1 v2.0, HBV v2.0, and CMV<sup>2</sup> tests on the same fully automated COBAS AmpliPrep/COBAS TaqMan System.

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<sup>1</sup> The COBAS AmpliPrep/COBAS TaqMan HCV Qualitative and Quantitative Tests, v2.0 are not available in the United States

<sup>2</sup> The COBAS AmpliPrep/COBAS TaqMan CMV Test is not available in the United States

### **About Hepatitis C**

According to the World Health Organization, hepatitis C virus affects ~200 million people globally, around 170 million people are chronic carriers of hepatitis C virus and most do not know they are infected. About 65–75% of patients develop chronic HCV which can lead to cirrhosis, liver failure and hepatocellular carcinoma.

### **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, virology, inflammation, metabolism and CNS. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche's personalized healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2010, Roche had over 80'000 employees worldwide and invested over 9 billion Swiss francs in R&D. The Group posted sales of 47.5 billion Swiss francs. Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan. For more information: [www.roche.com](http://www.roche.com).

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