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## **FDA approves expanded use of Roche hepatitis C virus RNA test as aid in diagnosis**

### **Test speeds treatment decisions, contributes to better patient care**

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has received approval from the U.S. Food and Drug Administration (FDA) for its hepatitis C virus (HCV) quantitative RNA test to be used as an aid in the diagnosis of HCV infection for certain patient populations. Results from the COBAS AmpliPrep/COBAS TaqMan HCV Test, v2.0 can now be used to confirm an active hepatitis infection, in addition to providing an accurate measurement of how much virus is in a patient's blood, to help a physician determine the best course of treatment. This expanded use for the test saves a physician time in making a treatment decision and helps improve patient care.

"Hepatitis C can be a silent killer, but with several highly effective new antiviral drugs on the market, there is a very high cure rate," said Alan Wright, MD, MPH, chief medical officer at Roche Diagnostics. "That's why the CDC recommends HCV testing for persons at risk for infection and for everyone born between 1945 and 1965. But a positive HCV antibody test alone does not indicate an active infection. So it's critical for physicians to diagnose an active infection by detecting the presence of hepatitis C virus RNA."

The Roche test is the first quantitative HCV RNA test to be approved for use as an aid in diagnosis for active HCV infection. This expanded indication is in addition to its approved use as a viral load test to help physicians assess a patient's response to antiviral therapy. Roche HCV viral load tests have also been used to establish the treatment efficacy of direct-acting antiviral treatment regimens recently approved by the FDA. The COBAS AmpliPrep/COBAS TaqMan HCV Test, v2.0 is part of Roche's expanding portfolio of diagnostic tests to diagnose,

confirm and manage hepatitis C infection.

### **About the test**

The COBAS AmpliPrep/COBAS TaqMan HCV Test, v2.0 represents the latest innovation in Roche's virology test portfolio. The dual-probe PCR assay is intended for use in the management of patients with chronic HCV, in conjunction with clinical and laboratory markers of infection, and as an aid in diagnosis for individuals with antibody evidence of HCV infection with evidence of liver disease, individuals suspected to be actively infected with HCV antibody evidence, and individuals at risk for HCV infection with antibodies to HCV. Detection of HCV RNA indicates that the virus is replicating and therefore is evidence of active infection. The test is an *in vitro* nucleic acid amplification test for the detection and quantitation of hepatitis C virus RNA genotypes 1 to 6 in human EDTA plasma or serum. It can be used to predict the probability of sustained virologic response (SVR) early during a course of antiviral therapy and to assess viral response to antiviral treatment (response-guided therapy), as measured by changes of HCV RNA levels.

The real-time polymerase chain reaction (PCR)-based HCV test is designed for use on Roche's fully automated COBAS AmpliPrep/COBAS TaqMan System, an established platform for viral load monitoring of multiple infectious diseases that improves workflow in testing laboratories. The system can be combined with the cobas p 630 instrument, which provides an integrated pre-analytical primary tube handling solution.

### **About hepatitis C**

According to the World Health Organization, HCV affects some 200 million people globally. Approximately 170 million people are chronic carriers of the hepatitis C virus, and most do not know they are infected. According to the Centers for Disease Control and Prevention, in the U.S. there are about 5 million people living with hepatitis C. 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**

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in *in vitro* diagnostics and tissue-based cancer diagnostics, and

a frontrunner in diabetes management. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalized healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. 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 cancer medicines. Roche has been recognized as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences industry seven years in a row by the Dow Jones Sustainability Indices.

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2015 employed more than 91,700 people worldwide. In 2015, Roche invested CHF 9.3 billion in R&D and posted sales of CHF 48.1 billion. 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) or [usdiagnostics.roche.com](http://usdiagnostics.roche.com).

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