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## FDA Approves New Roche Dual-PCR Target HIV-1 Test

*First dual-PCR target viral load test approved for monitoring HIV patients receiving antiretroviral therapy*

Roche Molecular Diagnostics (SIX: RO, ROG: OTCQX: RHHBY) announced today that the Food and Drug Administration (FDA) approved its new dual-PCR target HIV-1 viral load test to quantify the amount of virus in a patient's blood. The COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test, v2.0 is the first quantitative viral load test to amplify and detect two separate regions of a target genome and offers a fully automated and reliable solution for physicians to make informed treatment decisions for HIV-1 patients undergoing antiretroviral therapy.

“With the introduction of this test, Roche is the only company in the world to offer a dual-PCR target quantitative viral load assay,” said Paul Brown, president and CEO of Roche Molecular Diagnostics. “By virtue of its design, the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test, v2.0 can improve the ability of physicians and laboratories to obtain reliable information about HIV-infected patients in order to make informed treatment decisions.”

Highly active antiretroviral treatment (HAART) and viral load tests, which are used to monitor the amount of human immunodeficiency virus (HIV) circulating in blood, have contributed to a 13-year increase in life expectancy for people infected with HIV. According to the World Health Organization, 33 million people were living with HIV at the end of 2008. That same year, some 2.7 million people became newly infected, and 2.0 million died of AIDS, including 280,000 children. Roche is firmly committed to expanding access to laboratory testing in resource-limited settings via its humanitarian programs, such as [AmpliCare](#) and other initiatives.

“Treatment of HIV patients with new anti-viral therapies, such as integrase inhibitors, has met with success, but can also introduce selective pressures that result in changes to the HIV genome, which could make it harder to detect and treat,” said Tri Do, M.D., director for clinical research and scientific affairs, Roche Molecular Diagnostics, and an HIV-treating physician. “Roche’s new dual-PCR target HIV-1 viral load test is designed to detect current and emerging genomic variants of HIV with increased sensitivity.”

### **About the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test, v2.0**

The COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test, v2.0 delivers a wide dynamic range of detection, with the ability to detect HIV-1 RNA (Group M and O) down to 20 copies per milliliter in EDTA plasma. The test is fully automated on the COBAS® AmpliPrep / COBAS® TaqMan® System, which is in use by over 250 laboratories in the United States for clinical viral load testing. For improved laboratory workflow efficiency and quick turnaround time of results to clinicians, the new HIV-1 viral load test may be run in parallel with Hepatitis C viral load testing on the same system.

This test is intended for use in conjunction with clinical presentation and other laboratory markers of disease progress for the clinical management of HIV-1 infected patients. The test can be used to assess patient prognosis by measuring the baseline HIV-1 RNA level or to monitor the effects of antiretroviral therapy by measuring changes in EDTA plasma HIV-1 RNA levels during the course of antiretroviral treatment.

### **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 2009, Roche had over 80,000 employees worldwide and invested almost 10 billion Swiss francs in R&D. The Group posted sales of 49.1 billion Swiss francs. Genentech, United States, is a

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