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**Roche announces FDA approval of HIV viral load test**  
*Test is based on innovative dual-target approach*

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that a new HIV viral load test has been approved by the United States Food and Drug Administration (FDA) and will be commercially available in the US later this year. Like other innovative Roche HIV tests, this one targets two highly conserved regions of the HIV-1 genome and avoids any regions which are current drug targets, thus providing increased reliability as compared to other single target assays should a mutation occur.

“The approval of the Roche HIV test expands the availability to more laboratories, clinicians and patients,” said Paul Brown, PhD, Head of Roche Molecular Diagnostics. “Roche is committed to developing new diagnostic tools such as this highly innovative HIV ‘dual target’ test to help improve the ability of physicians to monitor viral load and properly treat people living with HIV.”

**About this test**

The COBAS® TaqMan® HIV-1 Test, v2.0 utilizes the FDA-approved High Pure System Viral Nucleic Acid Kit for manual specimen preparation and the COBAS® TaqMan® 48 Analyzer for automated amplification and detection.

**About the dual-target test approach**

Roche's dual-target approach for HIV viral load testing ensures enhanced reliability of results and increased confidence in assessing viral loads even in the face of the rapidly growing
genetic diversity of HIV-1.\textsuperscript{1,2} This approach targets two highly conserved regions of the HIV-1 genome and avoids any regions which are current drug targets, thus providing reliable test results even with rare mismatches in primer/probe binding sites and when mutations are present. Since Roche first introduced this innovative dual-target approach for monitoring HIV-1 patients on antiretroviral therapy in 2008, over eight million tests have been performed worldwide on Roche fully automated real-time PCR platforms.

About HIV

According to the Centers for Disease Control and Prevention (CDC), an estimated 1.2 million persons were living with HIV infection in the United States at the end of 2010. Of those, 20% had undiagnosed HIV infections.\textsuperscript{3} Highly active antiretroviral treatment (HAART) and viral load tests that determine the amount of circulating HIV have contributed to a profound increase in life expectancy for people living with HIV.\textsuperscript{4}

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 2011, Roche had over 80’000 employees worldwide and invested over 8 billion Swiss francs in R&D. The Group posted sales of 42.5 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.

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