

Pleasanton, 2 July 2012

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.^{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.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.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

1 Clark SA, Calef C, Mellors JW. Mutations in retroviral genes associated with drug resistance. HIV sequence database.

http://www.hiv.lanl.gov/content/sequence/HIV/REVIEWS/2006_7/RESISTANCE/Resist.html. Accessed August 29, 2008.

2 Chequer-Fernandez SL, Rodrigues CA, Campos-Melo DL, Pilotto JH, Morgado MG. HIV-1 polymorphism: evaluation of its potential implication for the response to antiretroviral therapy of HIV-1 infected patients with prevalent subtypes in Rio de Janeiro, Brazil [abstract]. Presented at: 15th International AIDS Conference; July 11-16, 2004; Bangkok, Thailand. Abstract MoPeC3442.

<http://gateway.nlm.nih.gov/MeetingAbstracts/ma?f=102279743.html>. Accessed August 19, 2008.

3 Centers for Disease Control and Prevention. HIV Surveillance Report, 2010; vol. 22.

<http://www.cdc.gov/hiv/topics/surveillance/resources/reports/>. Published March 2012. Accessed June 18, 2012.

4 Lancet. Volume 372, Issue 9635, 26 July 2008-1 August 2008, Pages 293-299

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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