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Roche receives FDA approval for HIV-1 viral load test on the cobas® 6800/8800 Systems

cobas HIV-1 test expands menu for highly automated molecular platforms that offer fastest time to results

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has received FDA approval for the **cobas®** HIV-1 viral load test by the United States Food and Drug Administration (FDA) for use on the **cobas®** 6800 and **cobas®** 8800 Systems. This HIV-1 viral load test is part of the next generation of Roche viral load tests, which clinicians use to manage the disease and treatment of patients infected with HIV-1.

"The **cobas®** HIV-1 test is based on Roche's unique dual-target technology to simultaneously amplify and detect two separate regions of the HIV-1 genome, which are not subject to selective drug pressure," said Paul Brown, Head of Roche Molecular Diagnostics. "The addition of this test on the fully automated **cobas®** 6800/8800 Systems provides laboratories with a comprehensive virology menu to support physicians in making informed treatment decisions for HIV-1 patients undergoing antiretroviral therapy."

In addition to the new HIV-1 assay, Roche offers the FDA-approved **cobas®** HBV and **cobas®** HCV viral load tests on the **cobas®** 6800/8800 Systems. The fully automated systems offer the fastest time to results, the highest throughput and the longest walk-away time available among automated molecular platforms, providing laboratories both improved operating efficiency and flexibility to adapt to changing testing needs. Further menu expansion plans include a viral load test for cytomegalovirus (CMV) and qualitative tests for donor screening, women's health and microbiology.

About the cobas® 6800/8800 Systems

The **cobas**[®] 6800 and **cobas**[®] 8800 Systems are fully integrated, automated solutions that introduce a new standard for routine molecular testing in the areas of donor screening, viral load monitoring, women's health and microbiology. Based on Nobel-prize winning PCR technology, the systems are designed to deliver full automation, increased throughput and faster turnaround time, providing users with greater flexibility to increase overall workflow efficiencies.

The systems provide up to 96 results in less than 3.5 hours, and a total of 384 results for the **cobas**[®] 6800 System and 960 results for the **cobas**[®] 8800 System in an eight-hour shift. Both make it possible for labs to perform up to three tests in the same run with no pre-sorting required. The systems also enable up to eight hours (**cobas**[®] 6800) and four hours (**cobas**[®] 8800) of walk-away time with minimal user interaction.

For more information about the systems, please visit www.cobas68008800.com or <http://molecular.roche.com>.

About the **cobas[®] HIV-1 viral load test for use on the **cobas**[®] 6800/8800 Systems**

The **cobas**[®] HIV-1 test is built upon the dual-target assay design from Roche. The test simultaneously amplifies and detects two separate regions of the HIV-1 genome, which are not subject to selective drug pressure, allowing for more reliable results to confidently and effectively quantify the amount of HIV-1 RNA in a patient's blood.

About HIV-1

According to the World Health Organization (WHO), there were 37 million people living with HIV around the world in 2014. That same year 2 million people became newly infected with HIV worldwide.¹ For the most impacted region of Sub-Saharan Africa nearly 1 in every 20 adults or 69% of all people living in this region are with HIV positive.

Diagnosis, highly active antiretroviral treatment (HAART) and viral load testing—testing to determine the amount of circulating HIV—have contributed to a steady increase in life expectancy for HIV infected people of 13 years.²

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, immunology, infectious diseases,

¹ The UNAIDS Report "How AIDS Changed Everything" 2014.

² Lancet. Volume 372, Issue 9635, 26 July 2008-1 August 2008, Pages 293-299.

ophthalmology and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostics that enable tangible improvements in the health, quality of life and survival of patients. Founded in 1896, Roche has been making important contributions to global health for more than a century. 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 chemotherapy.

In 2014, the Roche Group employed 88,500 people worldwide, invested 8.9 billion Swiss francs in R&D and posted sales of 47.5 billion Swiss francs. 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.

* The **cobas**® CMV test is not available in the U.S. PMA submissions are under review.

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