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## **Roche to provide HIV diagnostic solutions to Global Fund**

### *Framework agreement with Global Fund strengthens access to HIV diagnostics*

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has been selected to provide HIV-1 viral load and early infant diagnostic technologies for the Global Fund. This marks a further step in the collaboration between Roche and the Global Fund, an organization that has pioneered providing effective and economic solutions for healthcare to achieve the best results for patients.

“We are proud to be chosen as a supplier for the Global Fund and to continue to provide reliable HIV-1 diagnostics where they are needed most,” said Paul Brown, Head of Roche Molecular Diagnostics. “Leveraging our vast number of systems already installed around the world and continuing to work with organizations such as the Global Fund, we expand our commitment to healthcare solutions which make a real difference in those regions most impacted by HIV.”

The HIV-1 tests<sup>1</sup> eligible for the Global Fund collaboration utilize a unique dual-target design to simultaneously amplify and detect two separate regions of the HIV-1 genome, which are not subject to selective drug pressure. This innovative fully-automated solution will provide reliable results for laboratories and physicians to more confidently and efficiently treat HIV-1 patients undergoing therapy. For early infant diagnostics, the dual-target HIV-1 qualitative test, v2.0<sup>2</sup> works with both plasma and dried blood spot (DBS) collection cards, eliminates the need for refrigeration, drastically reduces the volume of blood required and makes sample collection and transportation easy, even from the smallest infant in the most rural area.

In 2014, Roche announced the Global Access Program in partnership with the Joint United Nations Programme on HIV/AIDS (UNAIDS), the Clinton Health Access Initiative (CHAI), the President’s Emergency Plan For AIDS Relief (PEPFAR) and the Global Fund to fight

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<sup>1</sup> COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test, v2.0 and COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Qualitative Test, v2.0

<sup>2</sup> COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Qualitative Test, v2.0

AIDS, TB & Malaria. With this program, Roche continues its commitment towards the UNAIDS 90/90/90/ goals and an AIDS-free generation, unmatched in the marketplace by providing efficient solutions to the unique challenge of expanding HIV-1 diagnostics.

### **About Global Fund**

The Global Fund is a 21st-century partnership designed to accelerate the end of AIDS, tuberculosis and malaria as epidemics. As a partnership between governments, civil society, the private sector and people affected by the diseases, the Global Fund mobilizes and invests nearly US\$4 billion a year to support programs run by local experts in countries and communities most in need. By challenging barriers and embracing innovative approaches, partners are working together to end these epidemics.

### **About Roche's tradition of commitment to HIV care**

Roche has been at the forefront of achievements for HIV and a global market leader in HIV viral load testing since the introduction of PCR-based HIV viral load testing in the mid 1990s. In 1998, at the International AIDS Conference in Geneva, Roche inaugurated the Global Surveillance Program. Initially designed to monitor changes in the HIV-1 genomic sequence, the Program and its database have since expanded to include thousands of genomic sequences for multiple viruses, including HCV, HBV and WNV, in the world's most relevant geographic regions. The Program's efforts have played a monumental role in helping to maintain, and improve, the reliability of molecular assays.

Roche reinforced its commitment in 2002 with the AmpliCare Initiative. Roche partnered with national governments, local healthcare facilities, communities and international agencies, including the Clinton Health Access Initiative (CHAI) and Centres for Disease Control (CDC), to establish programs that would go beyond providing diagnostic tests. The AmpliCare Initiative was a proactive response to the enormous humanitarian challenge of HIV/AIDS and TB. Since its inception in 2002, the program has increased access to HIV viral load tests at substantially reduced prices in sub-Saharan Africa and countries where the disease burden is highest.

Most recently, as part of its commitment towards an AIDS free generation and in support of the UNAIDS 90/90/90/ goals, Roche announced the Global Access Program for HIV viral load testing. This program, will greatly help drive viral load testing scale-up in countries with the highest disease burden.

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

The COBAS® AmpliPrep / COBAS® TaqMan® HIV-1 Test, v2.0 is the first dual-target test to be offered on the COBAS® AmpliPrep / COBAS® TaqMan® System. The test has been designed to detect all HIV-1 (Group M and O) strains even in the presence of potential HIV-1 mutations.

It is critical for viral load monitoring tests to be able to quantify very low and high levels of virus, an indicator of the need for more or less aggressive treatment. The test is highly sensitive and has a broader dynamic range than previous generation tests with the ability to detect the World Health Organization HIV-1 RNA Standard in EDTA plasma as low as 20 copies per milliliter of patient sample up to 10 million copies/mL. This innovative fully-automated solution will provide reliable results for laboratories and physicians to more confidently and efficiently treat HIV-1 patients undergoing therapy.

The test is designed for use on the fully-automated, real-time PCR platform, providing sample-in/results-out capability. The COBAS® AmpliPrep / COBAS® TaqMan® System is flexible and customizable to meet the space and workflow needs of any laboratory. In 2005, Roche received CE Mark certification for the full viral load monitoring menu (HIV-1, HBV, and HCV) on the system.

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

The COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Qualitative Test, version 2.0 is an in vitro diagnostic, total nucleic acid amplification test for the qualitative detection of Human Immunodeficiency Virus Type 1 (HIV-1) DNA and RNA (or total nucleic acid, TNA) in human plasma or dried blood spots using the COBAS® AmpliPrep Instrument for automated specimen processing and the COBAS® TaqMan® Analyzer or COBAS® TaqMan® 48 Analyzer for automated amplification and detection.

The test is a diagnostic test, indicated for individuals who are suspected to be actively infected with HIV-1. Detection of HIV-1 DNA is indicative of active HIV infection. Infants born to mothers infected with HIV-1 may have maternal antibodies to HIV-1, and the presence of HIV-1 nucleic acid in the infant indicates active HIV-1 infection. In adults, the test may be used as an aid in the diagnosis of HIV-1 infection.

### **About HIV-1**

Accordingly to the World Health Organization (WHO), there were 35 million people living with HIV around the world in 2012. That same year 2.5 million people became newly infected with HIV worldwide.<sup>3</sup> In the most impacted region of Sub-Saharan Africa, nearly 1 in every 20 adults are HIV-positive.

The transmission of HIV from an HIV-positive mother to her child during pregnancy, labor, delivery or breastfeeding is called vertical or mother-to-child transmission (MTCT). In the absence of any interventions, HIV transmission rates are between 15-45%.

Accurate diagnosis, highly active antiretroviral treatment (HAART) and viral load testing, a test to determine the amount of circulating HIV, have contributed to a steady increase in life expectancy for HIV infected people of 13 years.<sup>4</sup>

## **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, 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-eight 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](http://www.roche.com).

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For media inquiries please contact:

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<sup>3</sup> The UNAIDS Report on the Global AIDS Epidemic 2012.

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

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