Roche receives FDA approval for first HIV-1/HIV-2 Qualitative Test on the cobas 6800/8800 Systems in the fight against HIV/AIDS

- **Detects, confirms and differentiates HIV-1 and HIV-2 infections providing clinicians with critical diagnostic data for personalised management of patients with HIV - from appropriate counseling on disease differences to targeted therapy**
- **Supports rapid molecular detection of acute HIV infection, which is critical in curbing further disease transmission**
- **Combines confirmatory HIV testing and HIV-1/HIV-2 differentiation into one single test**

Basel, 1 September 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced U.S. Food and Drug Administration (FDA) approval for the cobas® HIV-1/HIV-2 Qualitative Test for use on the fully automated cobas® 6800/8800 Systems in the U.S. The test provides healthcare professionals with a single result to confirm HIV diagnosis and differentiate HIV-1 and HIV-2, an important distinction needed to identify appropriate treatment options.

"Roche is committed to improving diagnostic technologies in the fight against HIV/AIDS," said Thomas Schinecker, CEO Roche Diagnostics. "Being able to reliably determine a person's HIV status and accurately diagnose which HIV type they may have is crucial for patients and healthcare providers in preventing further community transmission and selecting an individual's best treatment options."

Studies show that 50% of new HIV infections may be transmitted during the acute period, between three days and three weeks from the time of infection[1]. Current serology-based testing methods rely on the ability to detect an antibody or antigen response. As a result, they can fail to identify an infection if the person is tested prior to having a detectable antibody or antigen response, which can take several weeks to generate. The higher sensitivity of PCR technology, which is used with the cobas HIV-1/HIV-2 Qualitative Test, can reduce this time-to-detection period by one week or more. This significant reduction in time to detection is critical to improve personalised healthcare while curbing further disease transmission.

About the cobas HIV-1/HIV-2 Qualitative Test
cobas HIV-1/HIV-2 Qualitative for use on the cobas 6800/8800 Systems is an in vitro nucleic acid amplification test for the qualitative detection and differentiation of human immunodeficiency virus type 1 (HIV-1) and type 2 (HIV-2) RNA in human serum and plasma.

The test is intended to be used as an aid in diagnosis of HIV-1/HIV-2 infection. Detection of HIV-1 or HIV-2 nucleic acid is indicative of HIV-1 or HIV-2 infection, respectively. The presence of HIV-1 or HIV-2 nucleic acid in the plasma or serum of individuals without antibodies to HIV-1 or HIV-2 is indicative of acute or primary infection. cobas HIV-1/HIV-2 Qualitative may also be used as an additional test to confirm the presence of HIV-1 or HIV-2 infection in an individual with specimens reactive for HIV-1 or HIV-2 antibodies or antigens. The assay may also be used as an aid in the diagnosis of infection with HIV-1 and/or

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HIV-2 in pediatric subjects and pregnant women.

About HIV-1 and HIV-2 in the U.S.
The U.S. Centers for Disease Control and Prevention (CDC) estimated in 2018 that 1.2 million people were living with HIV in the United States. Among them, more than 160,000 people did not know their HIV status, and only 53 percent were virally suppressed having low amounts of virus circulating in their blood. During this same year, 37,968 people became newly infected with HIV[2].

Human immunodeficiency virus (HIV) is categorized into two types, HIV-1 and HIV-2. Worldwide, most HIV infections are HIV-1, whereas HIV-2 largely has been confined to persons in or from West Africa. However, HIV-2 has been steadily increasing in the U.S. due to immigration[3]. HIV-1 and HIV-2 have the same routes of transmission, and both can cause acquired immunodeficiency syndrome (AIDS); however, it is important to differentiate HIV-2 infections from HIV-1 infections because they require different clinical management[4].

About the cobas 6800/8800 Systems
When every moment matters, the fully automated cobas 6800/8800 Systems offer the fastest time to results with the highest throughput and the longest walk-away time available among automated molecular platforms. With proven performance, absolute automation and unmatched flexibility delivering unparalleled throughput 24/7 — cobas 6800/8800 Systems are designed to ensure a lab's long-term sustainability and success … now, more than ever.

Learn more now: www.cobas68008800.com

About Roche
Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. More than thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Moreover, for the eleventh consecutive year, Roche has been recognised as one of the most sustainable companies in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2019 employed

about 98,000 people worldwide. In 2019, Roche invested CHF 11.7 billion in R&D and posted sales of CHF 61.5 billion. 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.

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