

Roche awarded WHO prequalification for the HIV and HCV tests on the cobas 6800/8800 Systems

- **For patients living in areas with limited healthcare resources, WHO prequalification ensures access to the highest quality diagnostics**
- **Access to broader reliable diagnostic solutions helps healthcare communities working to expedite and increase disease elimination programs**
- **Roche's Global Access Program provides innovative diagnostic solutions improving disease and patient management for those most in need**

Basel, 11 March 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the cobas® HIV-1 and cobas® HCV Tests for use on the cobas® 6800/8800 Systems have been awarded World Health Organization (WHO) prequalification. WHO prequalification helps regulators and procurers in low and middle-income countries to identify products that meet high quality standards and are safe and suitable for their intended use. This is of benefit to healthcare professionals and patients, for whom quality assured IVDs are essential for effective diagnosis and monitoring of therapeutic efficiency. Increased access to diagnostic testing and monitoring for HIV and hepatitis C virus (HCV) provides broader reliable solutions to patients living in remote settings. Without accurate diagnosis, appropriate disease management may be delayed.

For people who can not easily access healthcare facilities, the ability to simplify blood collection and sample transportation on a stable device improves access to reliable diagnostics. The cobas HIV-1 Test can be used in conjunction with the first-of-its-kind cobas® Plasma Separation Card to process dried plasma spot samples collected in remote areas, where access to testing facilities can be difficult.

“We are focusing on improving patient and disease management where it is needed most. Sustainable solutions can help healthcare providers more efficiently work towards eliminating infections,” said Thomas Schinecker, CEO Roche Diagnostics. “Since we launched the Global Access Program in 2014, access to innovative diagnostics solutions has improved in countries with high disease burdens. There is still more work that needs to be done and with the WHO prequalification more people around the world will have access to high-quality diagnostics.”

Roche is committed to helping countries scale up HIV elimination programs and reach the WHO 2030 goals of 95% of people living with HIV knowing their HIV status; 95% of HIV-positive people on treatment; and 95% of people on treatment having suppressed viral loads. Roche also strives to help reach the 2030 hepatitis elimination targets of 90% reduction in new chronic hepatitis B and C cases; 65% reduction in hepatitis-related deaths and 80% of eligible people with chronic hepatitis B and C infections receiving treatment.

About the Global Access Program

In 2014, Roche announced the Global Access Program for increased access to HIV diagnostics. Roche partnered with national governments, local healthcare facilities, communities and international agencies, including UNAIDS, Clinton Health Access Initiative (CHAI), Unitaaid, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), Global Fund and Center for Disease Control and Prevention (CDC), to establish programs that would go beyond providing diagnostic tests.

Since its inception, the program has expanded substantially in menu and geographic footprint to provide increased access to diagnostics at affordable pricing for qualifying organizations in eligible countries with the highest disease burden. The Global Access Program includes diagnostic solutions for HIV, Mycobacterium tuberculosis (MTB), Hepatitis B and C (HBV and HCV), and Human Papillomavirus (HPV) to help towards implementation of elimination programs in efforts to eradicate disease and in line with the WHO 2030 elimination goals.

About the cobas Plasma Separation Card

According to the WHO, plasma is the preferred sample type for viral load diagnostic testing to ensure accurate results versus potential excessive quantification of the viral load result in whole blood.¹ In the size of a simple credit card, the cobas Plasma Separation Card is a stable and easy-to-use sample collection device for HIV plasma viral load testing. By providing a small amount of a patient's blood from a fingertip, this specially designed card simplifies blood collection and sample transportation - even in areas of extreme heat and humidity - as it is sent by post to the testing laboratory, no refrigeration required. The card is the only CE-marked plasma sample collection device which meets the WHO sensitivity standard of < 1000 cp/mL and fundamentally changes the way plasma samples are taken and processed allowing for reliable quantitative testing for determining HIV viral load.

About the cobas® 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® Systems are designed to ensure a lab's long-term sustainability and success ... now, more than ever.

Learn more now: <http://diagnostics.roche.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 twelfth 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 2020 employed more than 100,000 people worldwide. In 2020, Roche invested CHF 12.2 billion in R&D and posted sales of CHF 58.3 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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References

[1] WHO. HIV Molecular Diagnostics Toolkit To Improve Access To Viral Load Testing And Infant Diagnosis. <https://apps.who.int/iris/bitstream/handle/10665/325961/9789241516211-eng.pdf?ua=1> Accessed 16 Sept. 2020.

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