

## **WHO guidelines now include Roche's diagnostic tests in expanded effort to eliminate tuberculosis by providing patients greater access to timely diagnosis**

- Tuberculosis is a disease of poverty, and economic distress with 1.4 million deaths annually<sup>1</sup> and the growing challenge of drug resistance is adding to the global health crisis
- WHO guidelines support the expansion of tuberculosis diagnostics in resource-limited countries, enabling patients to receive timely diagnosis leading to proper treatment, which benefits their recovery and slows the transmission of disease
- Roche's Global Access Program aids clinicians in improving disease and patient management through increased access to innovative diagnostic solutions, allowing more patients to get test results promptly

Basel, 09 July 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the cobas® MTB and cobas® MTB-RIF/INH tests for use on the cobas® 6800/8800 Systems are included as part of the updated World Health Organization (WHO) policy guidelines on nucleic acid amplification tests (NAATs) to detect tuberculosis (TB) and drug-resistant TB. The new guidance expands the number of rapid molecular tests available to national TB programmes in high-burden countries, enabling multi-partner diagnostic approaches that can benefit patients and communities.

The WHO estimates that about 1.7 billion people are living with tuberculosis globally, with an estimated 10 million new active tuberculosis cases and 1.4 million deaths annually. Approximately 29% of new infections were undiagnosed and untreated, potentially contributing to further transmission. When drug-resistant TB (RR/MDR-TB) is present, the challenge is greater, with only 44% properly diagnosed.<sup>1</sup> Although TB can be cured once it is diagnosed, people affected are often faced by vulnerability, marginalization, stigma and discrimination.

To increase early detection, diagnosis, and treatment of TB among vulnerable populations, the updated WHO guidelines aim to help countries identify populations at highest risk of infection and the locations most affected. This includes 30 low- and middle-income countries (LMICs), which bear the majority of the TB burden.<sup>1</sup> These countries rely on the WHO to evaluate test performance and provide centralised testing guidance and diagnostic guidelines prior to the use of any TB test. The new policy guidance enables LMICs to use donor funds for implementation and purchase of TB tests, increasing diagnostic options for people living with TB and drug-resistant TB.

“Roche's diagnostic solutions detect both TB and drug-resistant TB, enabling patients to be diagnosed earlier and treated with the appropriate regimen to stop the spread of the disease,” said Thomas Schinecker, CEO Roche Diagnostics. “Roche plays a significant role in the fight against TB through our Global Access Program, which focuses on sustainable solutions that can help diagnose infections and save lives.”

WHO guidelines are an important step toward ending the global TB epidemic by increasing patient access to high-quality diagnostics. The organisation's multi-faceted End TB Strategy aims in part for a 90 percent overall reduction in TB incidence and a 95 percent reduction in TB deaths by 2035. High-volume, multi-disease testing systems and innovative diagnostic tests can accelerate eradication efforts and further improve health outcomes for people living with TB.

### **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), Unitaid, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), Global Fund and Center for Disease Control and Prevention (CDC) to establish programmes 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 organisations 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 programmes in efforts to eradicate disease and in line with the 2030 elimination goals.

### **About the cobas MTB and cobas MTB-RIF/INH tests**

The cobas MTB and cobas MTB-RIF/INH molecular tests provide clinicians flexibility to detect a combination of tuberculosis and drug-resistant tuberculosis infections from a single patient sample. When a patient presents with symptoms of tuberculosis, the highly sensitive cobas MTB test is performed. If positive, the patient should be evaluated for drug resistance using cobas MTB-RIF/INH test. Roche's mycobacteria tests are for use on the cobas 6800/8800 Systems.

### **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. The cobas 6800/8800 Systems are part of the Molecular Work Area—a fully integrated laboratory workflow strategy that empowers labs to further elevate their levels of efficiency, flexibility and scalability. 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: [www.molecularworkarea.com](http://www.molecularworkarea.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, as well as growing capabilities in the area of data-driven medical insights help Roche deliver truly personalised healthcare. Roche is working with partners across the healthcare sector to provide the best care for each person.

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. In recent years, Roche has invested in genomic profiling and real-world data partnerships and has become an industry-leading partner for medical insights.

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](http://www.roche.com).

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## **References**

[1] Global tuberculosis report 2020. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO.

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