New Roche test aids clinicians in accelerating tuberculosis diagnosis and treatment by detecting antimicrobial resistance within the world’s leading cause of infectious disease deaths

- New tests on cobas 6800/8800 systems provide clinicians information to help speed treatment and reduce the spread of infection
- Rising challenge of drug resistance compounds the tuberculosis global health crisis
- Mycobacteria test menu allows detection of tuberculosis, drug resistant tuberculosis and nontuberculous mycobacteria infections from single patient sample

Basel, 14 May 2019 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced the CE-IVD launch of the cobas® MTB-RIF/INH test to detect resistance to antibiotics within tuberculosis DNA. This assay is part of the mycobacteria test menu that includes the cobas® MTB and cobas® MAI tests for use on the cobas® 6800/8800 Systems. This continues the expansion of the testing menu on the cobas 6800/8800 Systems, supporting true consolidation and efficient testing.

Tuberculosis is the leading cause of infectious disease deaths worldwide.[1,2] The rising challenge of drug resistance compounds the tuberculosis global health crisis. The high sensitivity of the cobas MTB test enables increased detection of tuberculosis in challenging smear-negative samples. A complete mycobacteria test menu provides the flexibility to detect a combination of tuberculosis, drug resistant tuberculosis and nontuberculous mycobacteria infections from a single patient sample. This provides important information for patient care decisions.

“With the addition of cobas MTB-RIF/INH to the mycobacteria test menu, we are able to equip laboratories with flexible, sensitive solutions to best help them diagnose tuberculosis, which is difficult to detect,” said Michael Heuer, CEO Roche Diagnostics. “This menu approach not only aids healthcare providers in addressing the global health challenge that tuberculosis presents, but also provides clinicians the valuable information they need to properly diagnose these respiratory infections to speed treatment and reduce the spread of infection.”

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, providing laboratories with improved operating efficiency and the flexibility to adapt to changing testing demands.

About the Mycobacteria assay portfolio
The cobas MTB test enables the detection of Mycobacterium tuberculosis complex (MTBC) DNA, while the cobas MAI test enables the direct detection and differentiation of Mycobacterium avium and Mycobacterium intracellulare DNA in symptomatic patients. The cobas MTB-RIF/INH test detects mutations associated with resistance to antibiotics rifampicin and isoniazid within tuberculosis DNA. All mycobacteria tests have been

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validated for use with raw sputum, sputum sediment and bronchoalveolar lavage (BAL) sediment samples.

**About Mycobacterium tuberculosis**

The World Health Organization (WHO) estimates that about 1.7 billion people are infected with tuberculosis, with an estimated 10 million new active tuberculosis infections and 1.6 million deaths in 2017. This includes approximately 920,000 tuberculosis infections in people living with HIV/AIDS and 300,000 deaths in this population.\(^1\)

**About Mycobacterium intracellulare and Mycobacterium avium**

Mycobacterium avium and Mycobacterium intracellulare are two closely related, distinct species of nontuberculous mycobacteria (NTM), which comprise the M. avium-intracellulare complex (MAC), and may also be grouped together as M. avium intracellulare (MAI). Although NTM can colonize body surfaces and secretions without causing disease, they have been associated with four distinct clinical syndromes; progressive pulmonary disease, disseminated disease in severely immunocompromised patients, and skin and soft tissue infection usually as a consequence of direct inoculation.\(^3\)

**About the cobas 6800/8800 Systems**

Since 2014, the cobas 6800 and cobas 8800 Systems have established the new standard for routine molecular testing by delivering fully integrated, automated solutions that serve the areas of viral load monitoring, donor screening, sexual health and microbiology. Based on Nobel prize-winning PCR technology, the systems deliver proven performance with full automation, increased throughput, fast turnaround time and complete track connectivity validated for molecular testing, providing users with greater flexibility to consolidate their IVD and LDT testing to a single system while increasing overall workflow efficiencies.

The systems provide up to 96 results in about 3 hours and a total of 864 results for the cobas 6800 System and 1,824 results for the cobas 8800 System from 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 System) and four hours (cobas 8800 System) of walk-away time with minimal user interaction.

For more information about the systems, please visit [www.cobas68008800.com](http://www.cobas68008800.com) or [http://molecular.roche.com](http://molecular.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. 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 tenth consecutive year, Roche has been recognised as the most sustainable company 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 2018 employed about 94,000 people worldwide. In 2018, Roche invested CHF 11 billion in R&D and posted sales of CHF 56.8 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

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