



WORLD HEALTH ORGANIZATION ENDORSES TRUENAT TESTS FOR INITIAL DIAGNOSIS OF TUBERCULOSIS AND DETECTION OF RIFAMPICIN RESISTANCE

- World Health Organization (WHO) endorses rapid molecular Truenat™ assays as initial tests to identify tuberculosis and detect rifampicin resistance in updated policy guidelines
- Truenat molecular diagnostic tests for TB are now approved by WHO; these are suited for use at the point-of-care in low-resource primary healthcare settings
- Evaluation by the Indian Council of Medical Research and The Foundation for Innovative New Diagnostics (FIND) indicate high diagnostic accuracy of Truenat, at par with international standards

Geneva, Switzerland, Goa & New Delhi, India– 2 July 2020 –The Foundation for Innovative New Diagnostics (FIND), Molbio Diagnostics and the Indian Council of Medical Research (ICMR) announced today that the World Health Organization (WHO) has now endorsed three of their rapid molecular Truenat™ assays for initial diagnosis of tuberculosis (TB) and subsequent detection of rifampicin resistance in adults and children with signs and symptoms of pulmonary TB. Both Truenat MTB and Truenat MTB Plus detect *Mycobacterium tuberculosis* bacteria for TB diagnosis, while Truenat MTB-RIF Dx identifies resistance to rifampicin, the most commonly used first-line treatment. All three tests are run on the portable, battery-operated Truenat device and provide results in less than an hour.

TB remains the leading cause of death from an infectious disease worldwide, with around 10 million cases and 1.5 million deaths in 2018.¹ Drug-resistant TB poses a particular challenge, with growing resistance to rifampicin and other drugs that treat the disease. In 2018, around half-a-million new cases of rifampicin-resistant TB were diagnosed. Urgent action is needed to close the gap in TB diagnosis and treatment, particularly in low-resource settings, to reach the WHO target of ending TB by 2030. To that end, bringing sensitive TB diagnosis and drug susceptibility testing closer to patients is a key priority for global TB control, but requires robust point-of-care diagnostic tests that are easily implementable at lower levels of the healthcare system.

The Truenat tests use real-time micro polymerase chain reaction (PCR) technology. Truenat devices function in a widerange of environmental conditions with minimal user input, making them suitable for

¹World Health Organization. Global tuberculosis report 2019. <https://apps.who.int/iris/bitstream/handle/10665/329368/9789241565714-eng.pdf?ua=1> (accessed 8 June 2020)

use in primary healthcare settings that typically have fewer facilities than reference laboratories in which rapid molecular tests are usually conducted.

Truenat was developed by Bigtec Labs, the R&D subsidiary of Molbio Diagnostics. ICMR conducted multicentre validation of Truenat MTB and Truenat MTB-RIF Dx assays followed by a feasibility study under the national programme and found them to be on par with the internationally recognized Xpert® MTB/RIF molecular assay (Cepheid, Sunnyvale, USA) in terms of sensitivity and specificity, and detection of rifampicin resistance. Truenat assays have now been incorporated into the India National TB Elimination Programme (NTEP) after recommendation from ICMR.

The performance and accuracy of the Truenat assays has been assessed by FIND in a real-world multicentre diagnostic accuracy study conducted in India, Peru, Ethiopia and Papua New Guinea. The study determined the diagnostic accuracy of the Truenat tests when performed in peripheral laboratories, compared with culture as the reference standard as well as the internationally recognized Xpert MTB/RIF Ultra and Xpert MTB/RIF assays. These results also indicate that the Truenat tests have accuracy comparable with Xpert MTB/ Ultra and Xpert MTB/RIF, and can be performed in peripheral laboratories and primary health centres, at temperatures up to 40°C and in the absence of reliable electricity.

Alongside endorsement by WHO, the Truenat tests are listed by the Global Fund to Fight AIDS, Tuberculosis and Malaria² as eligible for procurement and are also planned to be added to the diagnostics catalogue of the Stop TB Partnership's Global Drug Facility (GDF).³

“We are thrilled to have WHO endorsement of Truenat as a point-of-care platform that would help universal access to TB molecular diagnostics in countries with endemic TB. India has already leveraged the power of Truenat to decentralize TB detection and we look forward to working with other national TB programmes to help achieve their TB elimination goals,” said Sriram Natarajan, CEO of Molbio Diagnostics.

“This is a matter of pride for ICMR, Department of Health Research (DHR), New Delhi. It was a long journey to advance indigenous diagnostic technologies for diagnosis of TB and MDR/XDR-TB. Truenat is already accepted for use under the NTEP in India. Endorsement of Truenat by WHO will enable other low- and middle-income countries to procure Truenat for diagnosis of TB and rifampicin resistance, thus supporting TB elimination in developing countries,” said Dr Balram Bhargava, Secretary DHR and Director General ICMR.

Dr César Ugarte-Gil, a lead investigator at the Universidad Peruana Cayetano Heredia site in Lima, Peru, said, “Delays and quality in diagnosis affects the TB cascade of care, and the WHO endorsement of Truenat provides a robust molecular testing option available for primary health centers, where most of the people with TB are seeking care. With a prompt diagnosis we not only help the people with TB, but also we can reduce the risk of transmission in the community.”

² The Global Fund to Fight AIDS, Tuberculosis and Malaria. List of TB diagnostic test kits and equipment classified according to the Global Fund Quality Assurance Policy. https://www.theglobalfund.org/media/9461/psm_productsdiagnosticstb_list_en.pdf?u=637233413800000000 (accessed 8 June 2020)

³ Stop TB Partnership, GDF. Solving procurement & access challenges in TB diagnostics: the role of Stop TB Partnership's GDF. <https://www.teachepi.org/wp-content/uploads/Courses/ADV-2019/McGill-course-VAN-GEMERT-2019.pdf> (accessed 11 June 2020)

“The new WHO guidance addresses the need for expanding access to rapid testing that represents the most critical barrier for millions of people who seek care for TB and drug-resistant TB,” said Dr Tereza Kasaeva, Director of the WHO Global TB Programme. “We now need to work together towards ensuring universal access to rapid molecular tests. This will impact positively on reducing transmission and enabling faster access to accurate life-saving treatment that will lead to better outcomes for those affected.”

“Every year, millions of people with TB miss out on quality care, usually because their infection remains undiagnosed,” said Catharina Boehme, CEO of FIND. “The WHO endorsement of Truenat will enable molecular diagnostics – today’s gold standard test type – to be made available in primary care settings that are much more easily accessible for many people than a hospital or specialist TB centre. This will have a great impact on reducing life-threatening delays in the diagnosis and treatment of TB.”

The independent evaluation studies conducted by FIND were supported by the Indian Council of Medical Research (ICMR) and the Bill & Melinda Gates Foundation.

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About FIND

FIND is a global non-profit organization that drives innovation in the development and delivery of diagnostics to combat major diseases affecting the world's poorest populations. Our work bridges R&D to access, overcoming scientific barriers to technology development; generating evidence for regulators and policy-makers; addressing market failures; and enabling accelerated uptake and access to diagnostics in low- and middle-income countries (LMICs). Since 2003, we have been instrumental in the development of 24 new diagnostic tools used in 150 LMICs. Over 50 million FIND-supported products have been provided to our target markets since the start of 2015. A WHO Collaborating Centre, we work with more than 200 academic, industry, governmental, and civil society partners worldwide, on over 70 active projects that cross six priority disease areas. FIND is committed to a future in which diagnostics underpin treatment decisions and provide the foundation for disease surveillance, control and prevention. For more information, please visit www.finddx.org

About Molbio Diagnostics

Molbio Diagnostics brings to the healthcare professionals worldwide the "Truelab® Real Time quantitative micro PCR system" comprising "Truenat™ micro PCR Chips" that makes Real Time PCR testing simple and possible in all laboratories, in the field and in near-patient settings. With a large and growing menu of Truenat™ assays for infectious diseases including TB, Covid 19, HCV, HPV, Influenza etc. this rapid, portable technology enables early and accurate diagnosis and initiation of correct treatment right at the first point of contact. The platform is infrastructure independent and provides complete end to end solution for disease diagnosis. The smart design of the hardware and the room temperature stable reagent microchip make the assay robust and affordable. With proven ability to work even at Primary Health Centres and with wireless data transfer capability, this game changing technology brings in a paradigm shift to the global fight in control and management of devastating infectious diseases. For more information, visit <http://www.molbiodiagnostics.com>.

About ICMR

The Indian Council of Medical Research (ICMR), New Delhi, the apex body in India for the formulation, coordination and promotion of biomedical research, is one of the oldest medical research bodies in the world. The ICMR has always attempted to address itself to the growing demands of scientific advances in biomedical research on the one hand, and to the need of finding practical solutions to the health problems of the country, on the other. The ICMR has come a long way from the days when it was known as the IRFA, but the Council is conscious of the fact that it still has miles to go in pursuit of scientific achievements as well as health targets. The Council's research priorities coincide with the National health priorities such as control and management of communicable diseases, fertility control, maternal and child health, control of nutritional disorders, developing alternative strategies for health care delivery, containment within safety limits of environmental and occupational health problems; research on major non-communicable diseases like cancer, cardiovascular diseases, blindness, diabetes and other metabolic and haematological disorders; mental health research and drug research (including traditional remedies). All these efforts are undertaken with a view to reduce the total burden of disease and to promote health and well-being of the population. For more information, please visit <https://www.icmr.gov.in/>

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