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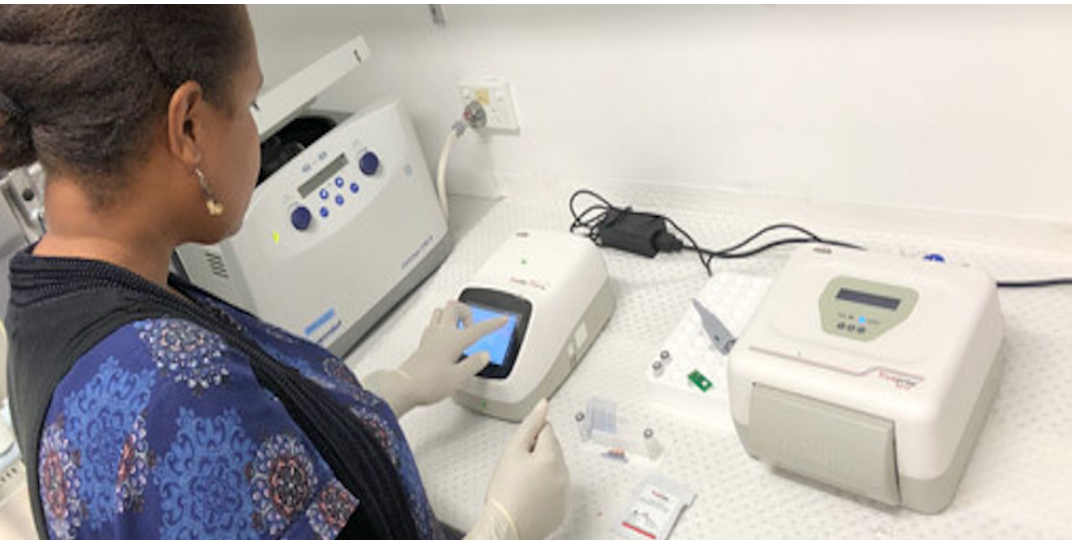
TRUENAT® MTB

Accurate, Rapid TB Diagnosis in Challenging Conditions



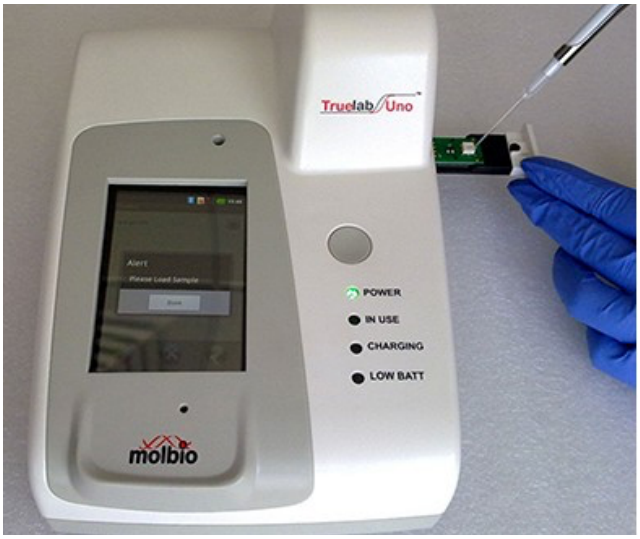
USAID's Infectious Disease Detection and Surveillance (IDDS) project is a cross-cutting project that supports priority countries' goals for the Global Health Security Agenda (GHS) and tuberculosis (TB). IDDS works with host countries to strengthen disease detection networks and surveillance systems for diseases of public health importance and improve identification of antimicrobial-resistant pathogens.

When the World Health Organization (WHO) made its recommendation to use Molbio Diagnostic's Truenat® micro-polymerase chain reaction (PCR) tests for tuberculosis (TB) and rifampicin resistant TB detection in 2019, only one country, India, had the instrument in regular use. Truelab®, an Indian designed and built instrument, uses the Truenat® MTB[1] chips to detect specific DNA sequences through a rapid PCR to identify the TB bacteria. Since the WHO's recommendation and the release of Stop TB Partnership's Practical Guide to Implementation of Truenat® Tests, high TB burden countries have begun to explore the use of the Truenat® MTB to augment existing TB detection.

For a decade, nucleic acid amplification tests (NAATs) have been the standard, near point of care test for the diagnosis of TB replacing sputum smear microscopy as a confirmatory test. GeneXpert®, the first WHO recommended NAAT for TB detection, requires an uninterrupted power supply and a maximum ambient temperature of 30 degrees Celsius (86 degrees Fahrenheit). This has limited GeneXpert®'s introduction in many high TB burden countries, where air-conditioning can be less common and unreliable. By contrast, Truenat® MTB can tolerate ambient temperatures up to 40 degrees Celsius (104 degrees Fahrenheit) and has an integrated battery for up to eight hours of continuous use without access to an external electricity source. Both GeneXpert® and Truenat® MTB provide a high level of confidence in their results and require minimal training to use. Whereas GeneXpert® provides an automatic diagnosis of resistance to rifampicin, Truenat®

[1] Molbio Diagnostics produces three separate chips for TB diagnosis with Truelab®: Truenat® MTB, Truenat® MTB Plus, and Truenat® MTB-Rif Dx. For sake of simplicity, we use the generic term, "Truenat® MTB" to cover all three, except when referencing a specific test, in which case we use the name of that test.

MTB-Rif Dx offers rifampicin resistance testing as a second, linked step using the same sample, if TB is detected.



USAID's IDDS project is supporting the introduction of Truenat® MTB to 10 countries with USAID and the Stop TB Partnership. With more than 300 new instruments available (through the Stop TB Partnership's Global Drug Facility with funding from USAID), IDDS is working to identify the ideal locations for placement to maximize impact, ease of access, and increase the number of people diagnosed and then properly treated. This collaborative roll out will result in thousands of persons in high burden TB countries accessing highly-accurate rapid molecular tests for TB.

IDDS has developed a curriculum for national health sector decision-makers to introduce Truenat MTB®. Combined with Molbio Diagnostic's training to technicians, IDDS's guidance is flexible so that countries can adopt, adapt and roll-out Truenat® within their national contexts. IDDS will work with countries to tailor the curriculum and think through some essential questions:

1. HOW DOES TRUENAT® MTB FIT INTO THE DIAGNOSTIC ALGORITHM FOR TB?

IDDS will analyze national algorithms and revise existing algorithms, especially those that specifically mention GeneXpert® to accommodate all WHO recommended rapid molecular diagnostic tests. Revised algorithms will also include referrals for additional drug resistance testing if needed.

2. WHERE TO PLACE TRUENAT® MTB, GENEXPERT®, OR OTHER WHO RECOMMENDED RAPID MOLECULAR DIAGNOSTIC TOOLS?

Truenat® MTB will not and should not replace GeneXpert® where countries have already established GeneXpert® facilities. Instead, Truenat MTB can be used by countries to increase access to rapid molecular tests for TB and rifampicin resistance in locations that are not currently served. As of September 2021, the WHO's recommendations are for Truenat MTB®, GeneXpert® and loop-mediated thermal amplification (LAMP), all of which can replace sputum smear microscopy. IDDS works with national TB programs to identify microscopy facilities that are candidates for upgrading to one of these molecular tests.

In 1887, Robert Koch, a German physician developed the technique to identify TB bacteria using a microscope. Despite the countless innovations in medicine since that discovery, most cases of TB are still diagnosed using microscopes. The WHO has recommended countries move away from the use of microscopy as the basic diagnostic test, in favor of rapid molecular tests. Sputum smear microscopy, while able to provide a definitive diagnosis using minimal equipment, requires a high number of bacteria in the sample, which only the sickest individuals produce. Since many cases of TB have sub-clinical presentations with few bacteria evident in sputum samples, especially samples from children and persons living with HIV/AIDS, more sensitive tests are needed to detect additional cases of TB. For many countries, the infrastructure (temperature and power) requirements of GeneXpert® put those instruments out of reach and not a viable alternative to microscopy. Truenat MTB's similar diagnostic capacity to GeneXpert® and ability to be used in peripheral health centers provide an excellent alternative to microscopy for TB diagnosis.

3. HOW TO MANAGE THE USE OF THESE NEW INSTRUMENTS?

IDDS supports the monitoring of Truenat® MTB use in conjunction with routine reporting mechanisms — e.g., GXAlert, DataToCare and domestic TB reporting systems — and leveraging Truelab®'s in-built reporting and data transfer capabilities. No additional reporting mechanisms will be needed to accommodate Truenat® MTB and data is comparable to existing sources. IDDS also expands existing external quality assessment programs to provide routine quality reviews. IDDS will deploy teams of technicians to provide on-site monitoring and trouble-shooting for the first six to 12 months of use after introduction. These technicians will be able to follow up on Molbio's and IDDS's trainings to ensure instruments are used according to manufacturer instructions and national guidance.

Truelab®, like GeneXpert®, can test for multiple pathogens. Truelab® uses the Truenat® MTB chips which contain the required reagents and DNA extraction materials for disease detection. By varying the reagents and materials, Truelab® can be used for COVID-19, HIV, and other infectious agents, fulfilling many of the diagnostic needs of a primary health care facility. So, while IDDS's initial target is TB detection, the project recognizes and supports the multiplex application of Truelab® to ensure its use.

Photo by Molbio Diagnostics