

THE INTRODUCING NEW TOOLS PROJECT (iNTP)

Introducing Truenat Testing in Peripheral Facilities: Lessons Learned from Bangladesh



Country in Focus: Bangladesh

Background

Bangladesh is one of six countries that have achieved or surpassed the first milestone of the End TB Strategy, a 35% reduction in TB deaths compared to 2015.¹ However, despite this remarkable progress, the ongoing challenge of rapidly and accurately identifying individuals with TB remains a substantial impediment to the efficacy of TB control initiatives.

Out of the estimated 2 million people with signs and symptoms of TB that are tested each year, only 24% are tested with a rapid molecular diagnostic (RMD) at the time of diagnosis. This stark reality underscores the urgent need to accelerate the adoption and implementation of RMDs to bolster case detection rates. To address this pressing need, the Stop TB Partnership / United States Agency for International Development (USAID) *Introducing New Tools Project* (iNTP) provided the National TB Program (NTP) with 38 Truenat Duo systems and reagents for the rapid detection of TB and rifampicin resistance in peripheral healthcare facilities. The USAID-supported Infectious Disease Detection and Surveillance (IDDS) Project has been supporting the NTP in the implementation of Truenat testing.

¹ WHO Global Tuberculosis Report 2022: <https://www.who.int/teams/global-tuberculosis-programme/tb-reports/global-tuberculosis-report-2022>

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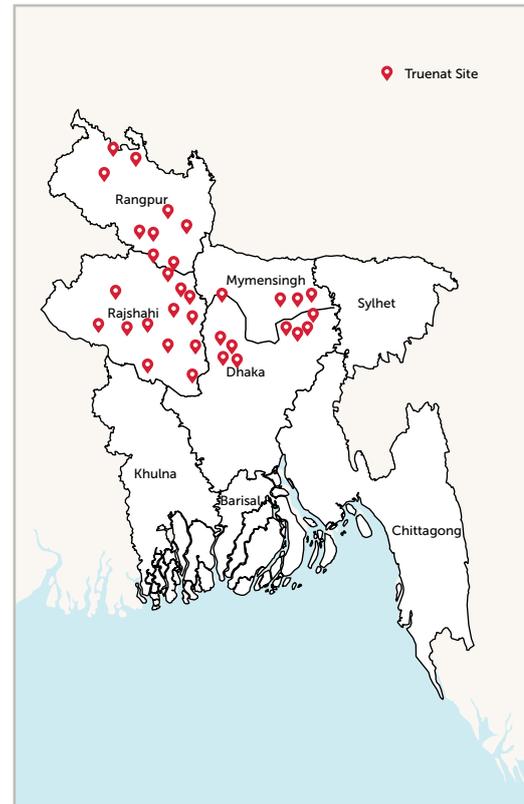
As an RMD that can be placed in peripheral health facilities closer to the point-of-care, Truenat has been used to fill critical gaps in access to RMD testing in Bangladesh. By enhancing TB diagnostic services in outlying areas, hard-to-reach communities now have access to same-day diagnosis of TB and rifampicin-resistant TB, allowing for prompt enrollment on appropriate treatment.

Implementation Experience

Site Selection and Readiness

- 1 **Implementation began with a planning period** between December 2021 and April 2022 that included selection and assessment of sites and development of the schedule of works.
- 2 **Sites were selected based on distance from an existing RMD site**, current TB notification gaps, number of people with signs and symptoms of TB seen at the site, electricity and availability of a laboratory technician.
- 3 **A checklist developed by the Stop TB Partnership, USAID and Global Laboratory Initiative** (Annex 6 of the Practical Guide to Implementation of Truenat™ Tests for the Detection of TB and Rifampicin Resistance²) was used to conduct the site assessments to identify resources needed for site readiness.
- 4 **Sites were selected in 16 districts within four divisions:** Rangpur, Mymensingh, Dhaka and Rajshahi (Figure 1).
- 5 **In parallel, meetings were held with health managers** from relevant districts and divisions to raise awareness about the availability of Truenat testing and generate demand.
- 6 **Orientation meetings were held with local public and private physicians**, and field workers to sensitize them on the Truenat technology and improve referral of people with symptoms of TB and improve quality of specimens collected in the field.

Figure 1: Map of Bangladesh showing the 38 facilities where Truenat testing has been conducted under the iNTP



Training and Instrument Installation

Prior to implementation, 12 individuals were selected from the NTP and the engaged implementing partners, and were trained as trainers. These individuals were provided with advanced training to develop the capacity of end-users at testing sites. This was followed by the organization of a basic training covering the theoretical, practical and programmatic aspects of Truenat testing which was conducted for 38 medical technologists by IDDS in collaboration with the NTP and the Molbio local agent. After the training, the local agent traveled to all the sites to install the instruments and conduct on-site training which covered instrument operation, troubleshooting and maintenance. Existing recording and reporting forms were updated to capture Truenat data while integrating the reporting mechanism with the existing NTP system. This ensured a seamless transition from training to implementation.

² <https://www.stoptb.org/gli-guidance-and-tools/practical-guide-to-implementation-of-truenat-tests>

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Supervisory Site Visits

Routine supervisory visits were conducted to offer continuous on-site support and troubleshooting assistance. The NTP also organized joint monitoring and support supervision visits to all 38 Truenat sites. The objective of these visits was to identify the gaps and challenges, to standardize and optimize the Truenat implementation at all levels, to develop local capacity in conducting monitoring and supportive supervision and to formulate solutions to any gaps identified.

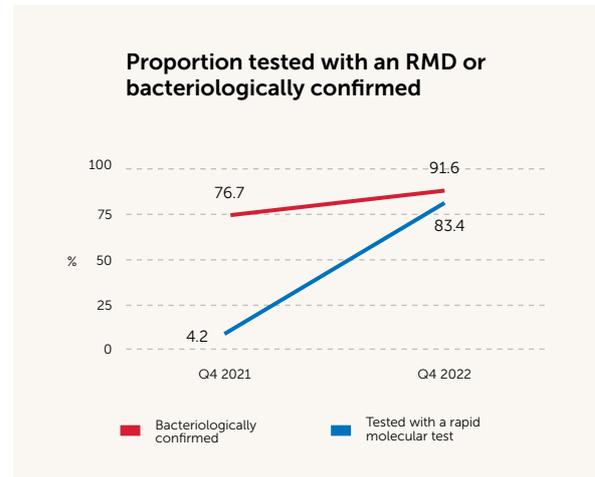
Additionally, the creation of a WhatsApp group for end-users facilitated valuable discussions and sharing experiences, enabling the identification of common errors and corresponding corrective actions. This fostered a collaborative environment among end-users and proved instrumental in identifying and addressing challenges effectively. The Molbio local agent provided on-site support for any equipment-related issues, and prompt repair and replacement of any faulty instruments in accordance with the service warranty agreement.

Early Impact

Between August 2022 and May 2023, a total of 62,155 tests were carried out among 59,008 people with signs and symptoms of TB. This resulted in the detection of TB in 4,446 (7.5%) individuals and rifampicin-resistant TB in 58 (1.3%) individuals.

- There was a **20-fold increase in the proportion of newly diagnosed people with TB** that were tested with an RMD at the time of diagnosis, comparing pre-Truenat implementation (Q4 2021) to during Truenat implementation (Q4 2022) (Figure 2).
- A modest increase from **76.7% to 91.6%** was observed in the proportion of newly diagnosed people with TB that were bacteriologically confirmed, comparing pre-Truenat implementation to during Truenat implementation (Figure 2).

Figure 2: Increases in the proportions of newly diagnosed people with TB that were bacteriologically confirmed or tested with a rapid molecular diagnostic (RMD) as an initial diagnostic test, comparing before (Q4 2021) and during (Q4 2022) Truenat implementation



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Best Practices Identified and Lessons Learned

1. Local Ownership

Prior to implementation, meetings were held with key stakeholders to ensure that they were well-informed about the benefits and potential applications of Truenat testing. Throughout implementation, the project team actively engaged with the health managers to create a supportive environment where the demand for Truenat testing would be fostered and sustained. The stakeholders recognised the potential of Truenat to increase detection of TB and rifampicin resistance at peripheral sites and expressed support for plans to introduce a Truenat testing network.

2. Training and Competence

A robust pool of skilled individuals who could provide assistance and guidance throughout the implementation process was established through a training of trainers. Additionally, fostering a collaborative environment among end-users and working closely with the local agent proved instrumental in identifying and addressing challenges early, thereby optimizing the performance and reliability of the Truenat instruments throughout implementation.

3. Supervision, Monitoring and Use of Data for Adaptive Changes

Supervisors from the NTP, USAID and implementing partners carried out regular joint supervisory missions to Truenat testing sites between January and March 2023. These visits aimed to identify and address challenges effectively, ensuring the smooth operation of testing services. To facilitate comprehensive evaluations, a standardized checklist was developed, allowing data from different sites to be compared systematically. These visits yielded valuable insights, highlighting specific areas for improvement. Major findings included gaps in proficiency testing, instances of incorrect reporting of results and concerns regarding the quality of specimens. Additional on-site training and standard operating procedures (SOPs) were provided to address these issues. These interventions aimed to enhance the proficiency and skills of the technologists and reinforce result and specimen management.



Initially, the processes seemed not very easy but after training and practice, I am quite at home with Truenat.

Md Aheduzzaman | Medical Technologist, Paba Upazilla, Rajshahi

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4. Truenat Error Rates

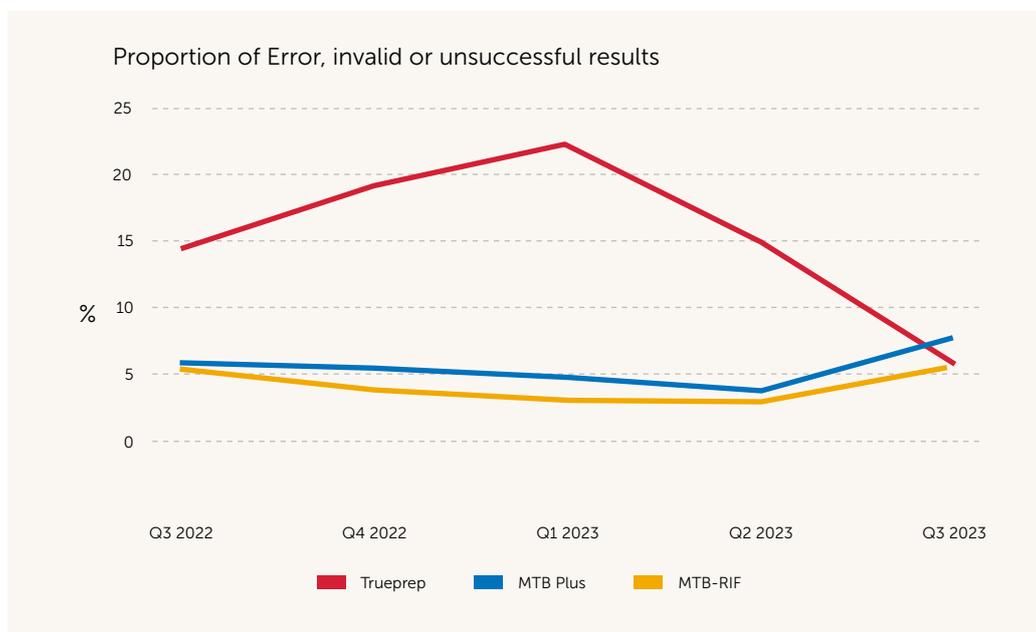
A. Common Error Types

The types of errors observed during implementation were a combination of user-related and instrument-related issues. Incorrect pipetting techniques and poor adherence to maintenance procedures, such as neglecting to change the slider glass after every 50 tests, were found to be common reasons for errors. The primary errors identified were associated with sample processing, specifically inadequate liquefaction (Trueprep Error 3) and insufficient volume loaded onto the reaction chip (Truelab Error 5). On the instrument side, the main errors observed were related to failure in ejecting the cartridge (Trueprep Error 14) or thermal cycling temperature being out of the normal range (Truelab Error 1). Instrument errors could be resolved through remote or on-site support from the Molbio local agent. The routine site visits by the project team were also used as an opportunity to reinforce adherence to SOPs and job aids on sample processing and instrument maintenance.

B. High Frequency of MTB-RIF Error, Invalid and Indeterminate Results

The overall rate of errors, invalid and other unsuccessful results was low for the DNA extraction on the Trueprep instrument (median 3.4% [Q1, Q3: 3.0, 4.2]) and the MTB Plus test (median 5.1% [Q1, Q3: 4.5, 5.5]) on the Truelab instrument (Figure 3). However, the rate of MTB-RIF errors, invalids and other unsuccessful results was high especially at testing sites in the Dhaka and Mymensingh divisions and lowest in Rangpur. Although this rate began to decline in Q3 of 2023, it remained above 10% in three of the four regions, and above the 3% target recommended by Stop TB, USAID and GLI in the *Practical guide to implementation of Truenat™ tests*³. An analysis into the cause of the high rate showed that these were mainly results of MTB-RIF indeterminate and occurred when the bacterial load in the sample was low. While a high proportion of invalid errors was also observed in sites where the room temperatures exceeded 30°C and when the kits neared their expiry date, a reversal of this trend was observed when new kits were used from Q3 2023. An increase in the proportion of error, invalid or unsuccessful MTB Plus and Trueprep results in Q3 2023 likely reflects the loss in proficiency during the reagent stock out. Continuous site monitoring, with retraining where necessary, is essential to ensure that the rate of error, invalid or other unsuccessful results remains low. Additionally, it may be important to consider the proportion of tests that are expected to have unsuccessful results when placing orders and consequently plan for a buffer, as well as mechanisms to recall patients for additional testing in cases where the RIF status is indeterminate.

Figure 3: Proportion of Truenat tests that had an error, invalid or other unsuccessful result between the third quarter of 2022 and the third quarter of 2023 in Bangladesh



³ <https://www.stoptb.org/gli-guidance-and-tools/practical-guide-to-implementation-of-truenat-tests>

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5. Quality Management

A. Specimen Quality

Low specimen quality was a major concern at most sites. Approximately 20-30% of samples received were either of poor quality (contained food particles or were salivary) or were inadequate in volume for testing. Sometimes samples received had leaked during transportation or were not properly labeled. To reduce errors when using Truenat, poor quality samples were instead tested with smear microscopy. Consequently, Truenat was not used as the initial diagnostic test for all people presenting with TB symptoms at the implementation sites. Site support visits were used as opportunities to provide training on sample transportation and reinforce adherence to SOPs on specimen collection to improve specimen quality.

B. Reagent Management

Although the manufacturer indicates storage of MTB Plus and MTB-RIF chips at temperatures between 2 and 30°C, storage areas at many sites experienced temperatures exceeding 30°C. Storage at higher temperatures increases the risk of invalid results and errors. To mitigate this, sites were encouraged to store the chips in a 2-8°C refrigerator instead of storing them at room temperature, as air conditioning was not available. During site visits, it was observed that some sites stored chips and patient samples in the same refrigerator, which was subsequently corrected. Furthermore, the project team observed that the estimate used for the procurement of MTB-RIF chips exceeded actual use. Molbio provides 20 MTB-RIF chips for every 100 MTB Plus tests purchased, in contrast to the project team's estimate of 9 MTB-RIF chips for every 100 MTB Plus tests. Therefore, to reduce wastage, procurement estimates should be tailored to the expected use cases in each country and expected MTB positivity rate.

C. Equipment Maintenance

All Truenat instruments are covered by warranty contracts that provide comprehensive service and maintenance, including the travel and labor of the Molbio local agent to repair and replace instruments as needed. The Molbio local agent has worked very closely with the NTP and its partners to provide prompt maintenance and troubleshooting support, with turnaround times (TAT) of approximately 48 hours to resolve most service requests. User level routine maintenance, such as replacing the slider glass, flushing the Trueprep instrument, cleaning the bay and surfaces, replacing the tray, etc., has been done regularly by the laboratory staff as per the manufacturer's instruction. All the sites have updated the maintenance log sheet routinely, which has been monitored closely at all levels for ensuring prompt necessary preventive and troubleshooting support.



I was satisfied to get the TB diagnosis on the same day, and started proper treatment quickly. I feel better now...

Musharrof | diagnosed as having rifampicin-resistant TB at a Truenat center, Atpara UHC, Netrokona

⁴ <https://www.smartspotq.com/>

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D. External Quality Assessment

With the support of IDDS, the Truenat testing sites engaged in three cycles of external quality assessment (EQA) utilizing the SmartSpot⁴ panels of dried culture spots. Analysis of the results revealed a more favorable performance during the first cycle compared to the subsequent cycles. Specifically, 34/38 sites achieved a Pass/Acceptable score in the first cycle, while in the second and third cycles, this number decreased to 21 and 19 sites respectively (Figure 4). The challenges encountered during the EQA process primarily revolved around incorrect results for MTB detection, identification of rifampicin resistance and reporting results as invalid (Table 1). By addressing the challenges identified through these EQA cycles, IDDS and the NTP were able to enhance the overall quality of testing at the Truenat sites and ensure reliable and accurate results were provided for the management of people with TB. Additionally, a feedback mechanism was created to monitor improvement in the performance of the sites that scored as “concern” or “unacceptable”. Continuous site monitoring is essential to ensure corrective action is instituted when sites receive a low score on EQA.

Figure 4: Performance in SmartSpot EQA during the Truenat implementation period.

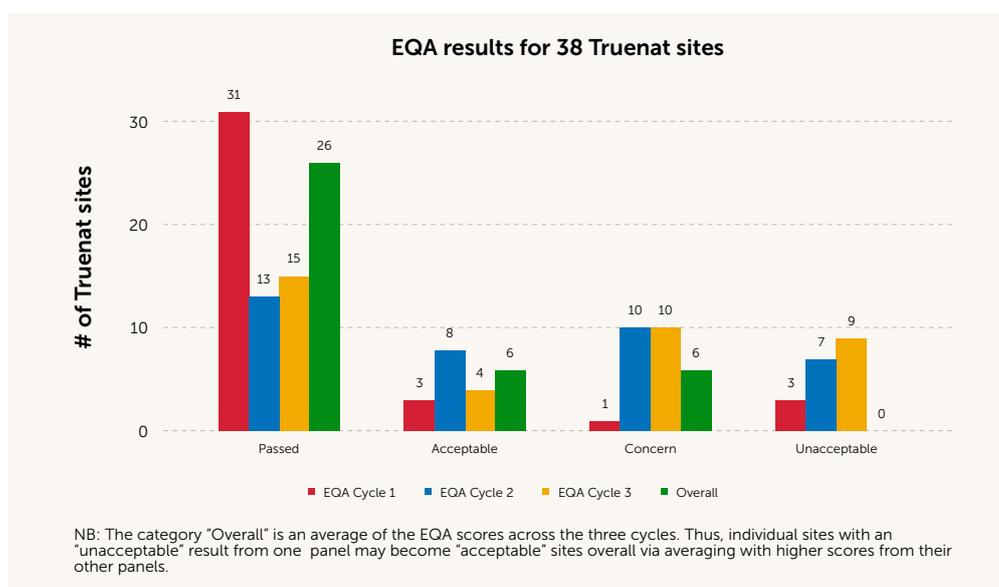


Table 1: EQA results analysis

Score Achieved	No. of Truenat Sites (%)	Grade	Remarks	Possible causes
90-100	26 (68%)	Pass	In some of the cases, sites reported <i>MTB-RIF</i> indeterminate instead of <i>MTB-RIF</i> detected for one panel	1. Pipetting errors 2. Insufficient elution 3. Improper storage of Truenat chips
85-90	6 (16%)	Acceptable	In most of the cases, sites reported <i>MTB-RIF</i> not detected and <i>MTB-RIF</i> indeterminate instead of <i>MTB-RIF</i> detected for 2 panels.	
<85	6 (16%)	Concern	In most of the cases, sites reported <i>MTB</i> not detected instead of <i>MTB</i> detected, <i>MTB-RIF</i> not detected or <i>MTB-RIF</i> indeterminate instead of <i>MTB-RIF</i> detected or had errors during DNA extraction for 3 panels	1. Maintenance not done 2. Inadequate sample liquefaction 3. Improper storage of Truenat chips 4. Mislabelling or submission error 5. Pipetting error

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Looking Ahead

To build on the success of the iNTP, the NTP has plans to procure an additional 112 Truenat systems and 200,000 tests with funding from the Global Fund. The pool of trainers and supervisors established during the iNTP will work closely with the new testing sites, providing training and on-going mentorship to ensure provision of quality testing. USAID implementing partners in-country will also offer technical assistance, ensuring the sustainability and successful scale-up of Truenat implementation in Bangladesh.



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<https://www.stoptb.org/accelerate-tb-innovations/introducing-new-tools-project>