

THE INTRODUCING NEW TOOLS PROJECT (iNTP)

# Early Experience of the Democratic Republic of the Congo in Implementation of Truenat MTB Plus and MTB-RIF Dx Testing



Country in Focus: Democratic Republic of the Congo (DRC)



One of the main challenges in detecting TB in the Democratic Republic of the Congo (DRC) is the lack of access to rapid molecular testing: only 9% of people with TB in 2021 were tested with a rapid molecular test at the time of diagnosis.

The Democratic Republic of the Congo is one of the top thirty high burden TB, TB/HIV, and drug-resistant TB countries.<sup>1</sup> According to estimates by the World Health Organization (WHO), 30% of people with TB in DRC were considered “missing” in 2021, i.e., they went without a diagnosis or were not accounted for in national data.<sup>1</sup> The coverage of rapid molecular testing in DRC is currently only one site per 300,000 people, compared to one microscopy site per 50,000 people.

Through the Stop TB Partnership / USAID’s introducing New Tools Project (iNTP), Truenat MTB Plus and MTB-RIF Dx testing was implemented at 38 facilities in four provinces of DRC. Supporting the National TB Program in the introduction of this new tool were USAID advisors, an in-country team from the USAID’s Infectious Disease Detection and Surveillance (IDDS) Project and consultants from the Stop TB Partnership.

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

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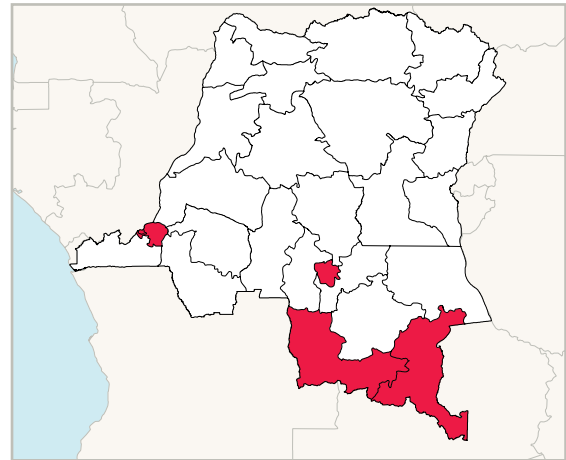


## Implementation Experience

### Site Selection and Readiness

Sites were selected from 38 facilities across four geographical regions (Figure 1) and eight health zones having a high TB case notification with the aim of reaching a minimum of 30-40% of people with TB being detected with a rapid molecular test. Facilities selected were microscopy sites without GeneXpert machines, located in a prison or at a mining site, or at centers for displaced populations. An assessment was done at all sites before the installation of Truenat systems using the checklist provided in the Stop TB/USAID/Global Laboratory Initiative (GLI) Practical Guide to Implementation of Truenat tests.<sup>2</sup> Implementation of Truenat testing started in April 2022.

**Figure 1:** Map of DRC showing the four provinces where Truenat testing sites are located



## Early Impact



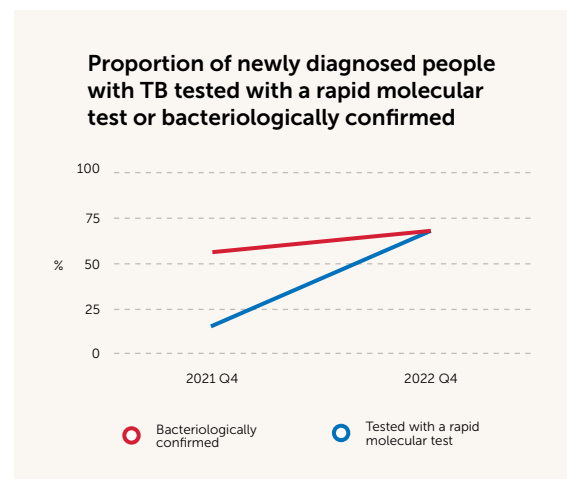
**A total of 12,700 samples from individuals** undergoing investigations for TB were received at the facilities between April and December 2022



**MTB was detected in 3,437 of the samples (28.1%)** and rifampicin resistance was detected in 283 samples (8.2% of MTB-positive samples)

- The proportion of newly diagnosed people with TB tested with a rapid molecular test as an initial diagnostic increased significantly from **11.7% (220/1,881)** pre-Truenat implementation to **65.9% (1,112/1,688; p<0.001)** during Truenat implementation, comparing Q4 2021 vs Q4 2022 (Figure 2).
- Similarly, the proportion of newly diagnosed people with TB that were bacteriologically confirmed also increased significantly from **54.9% (1,032/1,881)** pre-Truenat implementation to **66.8% (1,127/1,688; p<0.001)** during Truenat implementation (Figure 2).
- Truenat implementation increased the number of people diagnosed with rifampicin-resistant TB for sites in Kasai Oriental such as Notre Dame, Siloe, and Kayembe, all of which had not reported people diagnosed with rifampicin-resistant TB in the previous 2 years (see Table 1).

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



<sup>2</sup> Practical Guide to Implementation of Truenat tests for the Detection of TB and Rifampicin Resistance, 2021: <https://www.stoptb.org/gli-guidance-and-tools/practical-guide-to-implementation-of-truenat-tests>

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Truenat is a robust system that is temperature-resistant. It allows for the analysis of small amounts of sample that are less than 1ml. Quick and easy to use and read.

Jean Claude Kasereka |  
Head of Molecular Biology of the National TB Programme



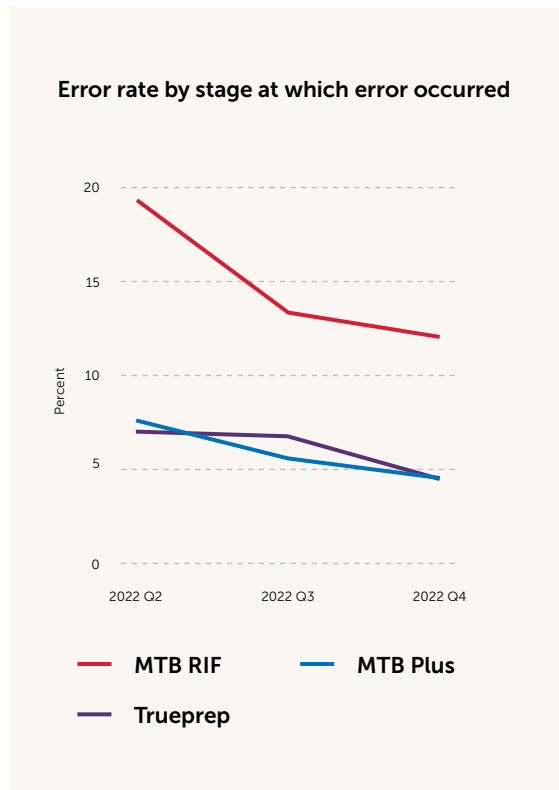
**Table 1:** Numbers of people detected with TB and rifampicin-resistant TB (RR-TB) in Kasai Oriental, 2020-2022; Truenat testing was introduced in April 2022

| Facility   | 2020    |                | 2021    |                | 2022       |                 |
|------------|---------|----------------|---------|----------------|------------|-----------------|
|            | TB<br>n | RR-TB<br>n (%) | TB<br>n | RR-TB<br>n (%) | TB<br>n    | RR-TB<br>n (%)  |
| MIK Geller | 725     | 1 (0.1)        | 400     | 0              | <b>279</b> | <b>22 (7.9)</b> |
| Notre Dame | 376     | 0              | 354     | 0              | <b>314</b> | <b>1 (0.3)</b>  |
| Rogephar   | 405     | 5 (1.2)        | 339     | 7 (0.2)        | <b>309</b> | <b>14 (4.5)</b> |
| Nkuluse    | 162     | 1 (0.6)        | 194     | 9 (4.6)        | <b>152</b> | <b>11 (7.2)</b> |
| Siloe      | 196     | 0              | 296     | 0              | <b>245</b> | <b>17 (6.9)</b> |
| Kayembe    | 179     | 0              | 277     | 0              | <b>290</b> | <b>5 (1.7)</b>  |

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## Lessons Learned

**Figure 3:** The proportion of error, invalid or indeterminate results reported at the 38 facilities in DRC between April and December 2022



### 1. Training and Competence

Truenat testing was implemented in sites where microscopy was used, and many of the staff had little to no experience with molecular diagnostic tools. It was therefore not surprising that during training, challenges related to the operating system and sample processing procedures were encountered. Training materials, SOPs, and job aids were translated into French. A cadre of Truenat “superusers”, trained through the USAID-supported IDDS Project, conducted site-based mentorship and supervision as needed during site support visits, and reinforced good laboratory techniques. A checklist was developed for use by the superusers to collect data during the site monitoring visits in which they would also observe Truenat testing, assist with maintenance and troubleshooting and check testing procedures.

### 2. Errors and Corrective Actions

The proportion of error, invalid or indeterminate results was high during the first months of implementation (Figure 3). Errors were mainly user-related, but a few needed on-site interventions by the local Molbio agent (Table 2). For example, three Trueprep DNA extraction devices needed parts to be replaced. A WhatsApp group was formed to enable end-users and superusers to exchange information and help to solve issues in using Truenat. In this way, most errors were resolved as the users learned from each other. The Molbio local agent was only called upon if the superusers and IDDS team failed to resolve an issue. From Q2 to Q4 2022, the error rates declined, however, the proportion of MTB-RIF Dx tests that resulted in errors, invalids, or indeterminate results remains high.

**Table 2: Errors and resolution**

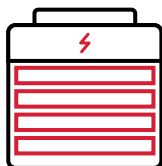
| Description of error  | Resolution  |
|---|---|
| <b>Trueprep</b>   |   |
| <b>E3:</b> Incomplete liquefaction of samples during extraction | Staff were advised to incubate samples for up to 15 minutes with continuous swirling to allow complete liquefaction of viscous samples. If this resulted in an invalid result, they were asked to repeat extraction with a new cartridge or request a new sample.   |
| <b>E9, E10:</b> Problem with the reset card or QR code reader   | At the beginning of implementation, this was a major problem, as users failed to correctly place the reagent card after changing reagents. The local Molbio agent often visited the sites to resolve this problem. IDDS collaborated with Molbio to create and disseminate job aids to show proper card insertion. The end users are now able to insert the reagent reset card correctly. |
| <b>E11, E12:</b> Device heater plates not working               | This required repair of the instrument by the Molbio local agent.   |
| <b>Truelab</b>  |   |
| <b>E5:</b> Probe Check Error                                    | Staff were advised to repeat the test using a new chip and to ensure that the correct volume (6µl) of the eluate was loaded.  |

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The advent of Truenat came at a time when the set of GeneXpert machines of the Provincial TB and Leprosy Coordination in Haut Katanga were having problems. Truenat came to cover 10 sites, this allowed us to increase the number of patients diagnosed with TB. Truenat allows us to do the job well, but like any automation, it has its drawbacks and advantages

Ghislain Mposhi | Truenat user, Haut Katanga



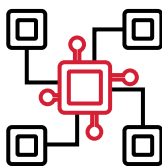
### 3. Electricity

While Truenat instruments are equipped with built-in batteries, providing up to 8 hours of functionality to overcome blackouts, the implications of significant electricity fluctuations were not fully anticipated. Unfortunately, these electricity fluctuations have resulted in damage to the Truelab micro printers that were provided as part of the Truenat workstations. Consequently, a majority of the sites no longer have functional printers due to this unforeseen issue with electricity stability. Some sites have implemented solar energy to cope with power outages and prevent damage. Procurement of voltage stabilizers and surge protectors is being pursued to prevent the risk of further damage to instruments.



### 4. External Quality Assessment

Through IDDS support, implementing sites have participated in three cycles of external quality assessment (EQA) using the SmartSpot<sup>3</sup> panels of dried culture spots. Since many of the sites had limited internet connectivity, results were sent to the superusers via WhatsApp for uploading onto the SmartSpot result portal. Results reviewed for two of the three cycles showed a high participation rate of 97%, with one site failing to submit EQA due to non-functional equipment. In cycle 2, 34% of the sites achieved a score of <83% highlighting that there are still many challenges. Superusers assisted the sites to identify the source of the problems, which was mainly identified as being a failure to correctly follow the SOP on the processing of samples. Other challenges found were related to quality assurance and lack of good biosafety practices.



### 5. Instrument Connectivity

While SIM cards have been added to all devices, their functionality is limited by poor network coverage at many sites, making it difficult to use the SMS feature. Additionally, there is a need to purchase communication credits for sending results by SMS. Internet connectivity is problematic even at the level of the National Mycobacterium Reference Laboratory (LNRM). The country's electronic information system connects the Offices of Health Zones (BCZ) with the Provincial TB and Leprosy Coordination (CPLT) offices, and the LNRM. The country is exploring the use of the DataToCare diagnostics connectivity system for connecting Truenat and GeneXpert instruments to be able to rapidly send results to clinicians, allow for real-time dashboards on instrument network functioning, and facilitate inventory management.

<sup>3</sup> <https://www.smartspotq.com/>

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## Looking Ahead

A Truenat expansion plan has been included in the 2024-2028 National Strategic Plan (NSP). The aim is to purchase 80 to 100 Truenat machines in the near future, with the goal of reaching 400 instruments by the end of the NSP implementation. Procurement of reagents and instruments will be included in the Global Fund concept note for the 2024-2026 period.



Semi-automatic Truenats are well suited for our work settings:

- In terms of energy, for our environments without electricity they are rechargeable. But it is necessary to provide a solar kit to ensure complete autonomy.
- In terms of maintenance and repair, they are easy to maintain.
- In terms of temperature, they adapt to our temperatures.
- In terms of handling, they are very easy to handle for a trained user.
- In terms of accessibility to molecular tests, it's a battle won. Patients can have their tests done within less than a metre away and they made it possible to detect rifampicin resistance.

**Alphonse Lufuluabo, Laboratory Manager of the Eastern Kasai province**



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*Photos courtesy of Infectious Disease Detection and Surveillance (IDDS) Project*

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For more information on the introducing New Tools Project, visit:

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



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