

THE INTRODUCING NEW TOOLS PROJECT (iNTP)

Transforming Access to TB Diagnosis with Truenat in Peripheral Facilities in Nigeria



Country in Focus: Nigeria

Background

Nigeria has the largest burden of TB in Africa and is one of eight countries contributing to two-thirds of the global burden of TB. Furthermore, Nigeria is one of the 5 countries contributing to more than 50% of the global gap between the estimated TB incidence and the reported number of people newly diagnosed with TB.¹

According to estimates by the World Health Organization (WHO), 41% of people with TB in 2022 went without a diagnosis or were not accounted for in national data.¹ One of the main factors contributing to the country's low detection rate for TB is the lack of access to rapid molecular testing: only 68% of people with TB undergo testing with a rapid molecular test at the time of diagnosis.¹

¹ WHO Global Tuberculosis Report 2023. <https://www.who.int/publications/i/item/9789240083851>

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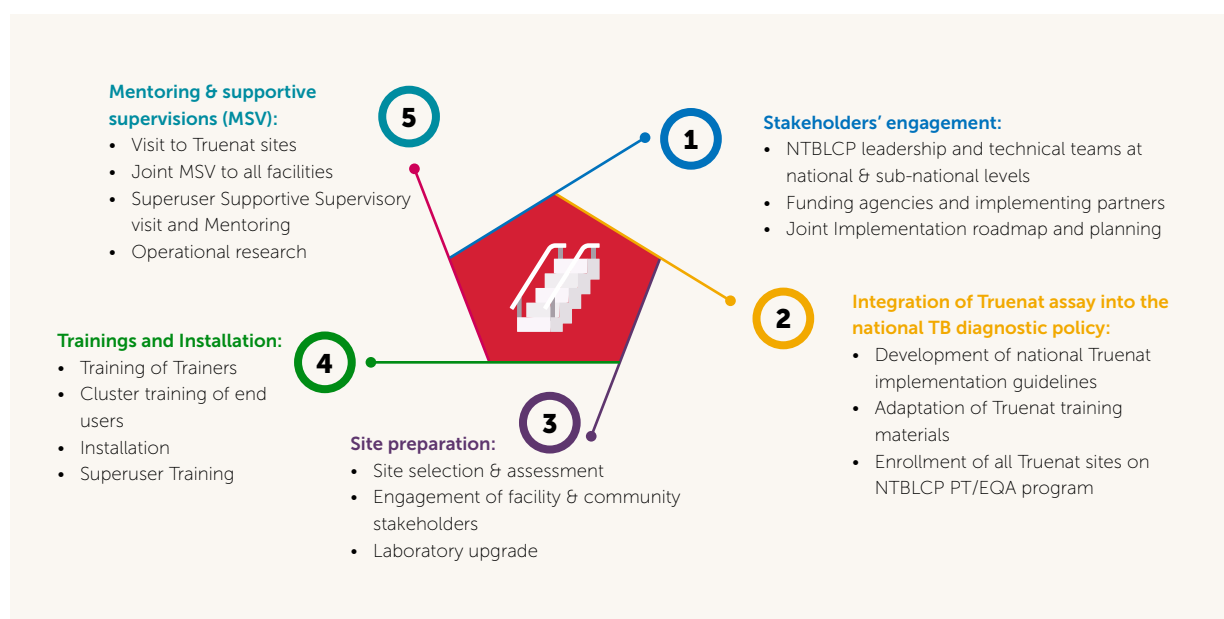


The Stop TB Partnership / USAID's *introducing New Tools Project* (iNTP) supported the National Tuberculosis & Leprosy Control Program (NTBLCP) and implementing partners, KNCV Tuberculosis Foundation Nigeria, and the Institute for Human Virology Nigeria (IHVN), to roll out Truenat systems in Nigeria. KNCV Nigeria and IHVN rolled out 38 Truenat instrument systems in peripheral sites across 14 states to bring access to molecular testing to hard-to-reach populations. At the same time, KNCV Nigeria and IHVN also started piloting the use of Truenat instruments in community active case finding together with ultra-portable Delft Light digital X-ray systems provided under the iNTP.

Implementation Experience

In preparation for the roll-out of Truenat testing, the implementing partners, KNCV Nigeria and IHVN developed a five-step implementation strategy that included stakeholder engagement, updating the national diagnostic algorithm, and preparing sites for implementation as shown in Figure 1.

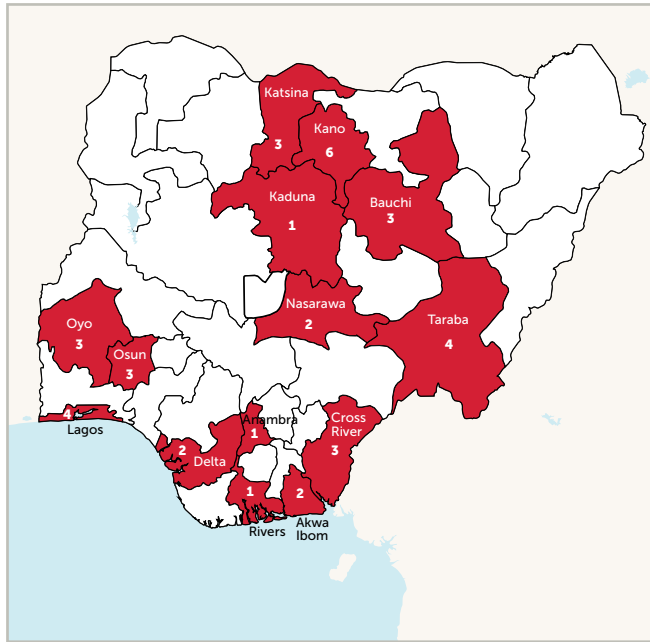
Figure 1 : Stepwise implementation strategy for Truenat testing



Following a centralized training of 76 end-users, the Molbio local agent installed the Truenat instrument systems between November and December 2021: 28 at KNCV-supported sites and 10 at IHVN-supported sites (Figure 2). Facilities selected were predominantly microscopy sites, with no access to a molecular diagnostic test. The median distance from a Truenat facility to another molecular diagnostic facility is 13.6 km (ranging from 2.1 km to 292 km). Truenat instruments at all sites are currently being used as the first-line diagnostic test for the evaluation of presumptive TB.

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Figure 2 : Map of Nigeria showing the states in which Truenat sites are located (in red) and the numbers of Truenat sites per state



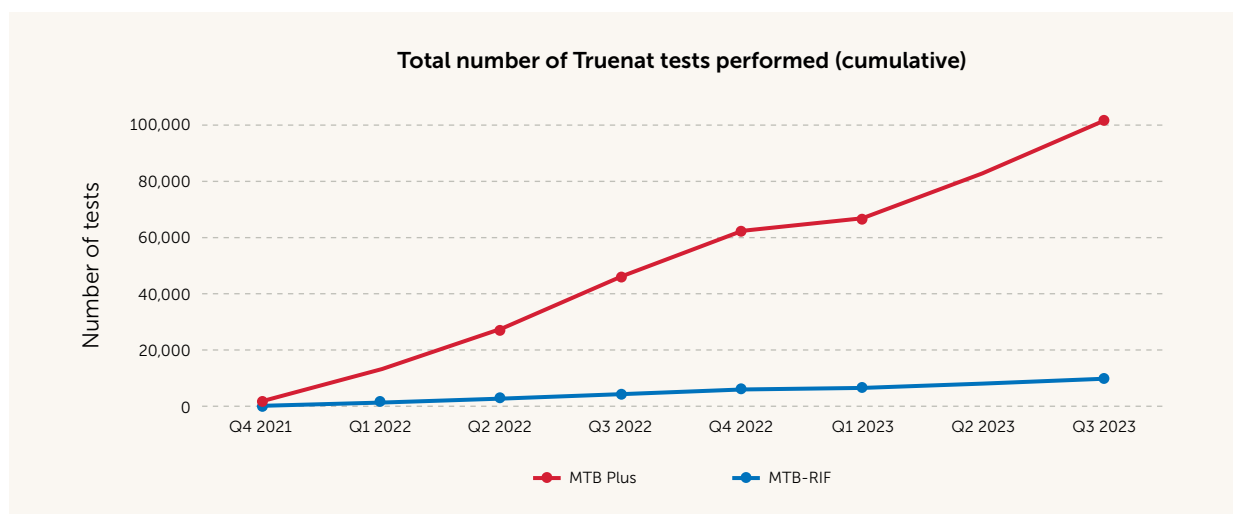
The Truenat systems have helped to bridge gaps in molecular diagnosis for TB for populations in hard-to-reach areas where they were installed and at relatively cheaper set-up costs in terms of infrastructure. The impact of Truenat on finding missing TB cases has been impressive. We are grateful to the Stop TB Partnership and USAID for this innovative diagnostic.

Dr. Chukwuma Anyaike | Director of Public Health / Federal Ministry of Health, Nigeria

Early Impact

- A total of 102,156 samples were received at the facilities between November 2021 and September 2023. 101,338 Truenat MTB Plus and 9,747 Truenat MTB-RIF tests were performed (Figure 3).
- MTB was detected in 9,747 of the samples (9.6%) and rifampicin resistance was detected in 131 samples (1.3% of MTB-positive samples).

Figure 3: Plot of the cumulative number of Truenat tests conducted at implementation sites between November 2021 and September 2023



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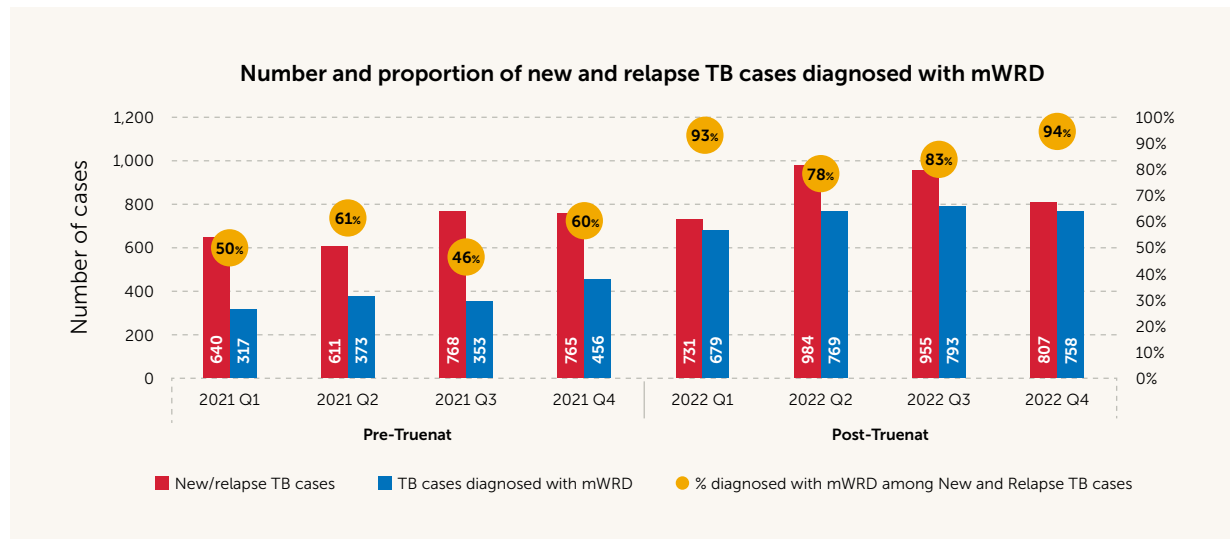
- At 4 sites, Truenat was used in community active case finding, coupled with ultra-portable digital chest X-ray systems equipped with software for the computer-aided detection (CAD) of TB. Samples were collected from 1,054 individuals who were either symptomatic or had an abnormal CAD score of more than 50, or both. From the samples collected, 94 people (9.0%) tested positive for TB using Truenat (Table 1). All individuals diagnosed with TB were placed on TB treatment.

Table 1: Truenat use combined with X-ray/CAD in active case finding

Total number of people screened for symptoms and with digital chest X-ray/CAD	Total number of people with samples collected (based on symptoms and/or abnormal CAD score) and tested using Truenat	Total number of people diagnosed with TB using Truenat	Total number of people diagnosed with rifampicin-resistant TB
10,354	1,054	94 (9%)	0 (0%)

- Implementation of Truenat led to a 100% increase in access to WHO-recommended rapid molecular diagnostics (mWRD) in supported facilities (1,499 people tested with a mWRD in 2021 vs 2,999 in 2022) (Figure 4). In Q4 2022, a year after implementation started, the proportion of new and relapse TB cases that were diagnosed with a mWRD was 93.9%, reflecting a median increase of 34.3 percentage points compared to a year prior in Q4 2021.

Figure 4: Increase in the number and proportion of newly diagnosed people with TB tested with a WHO-recommended molecular diagnostic (mWRD) at the time of diagnosis, comparing pre-Truenat implementation (2021) with Truenat implementation period (2022)



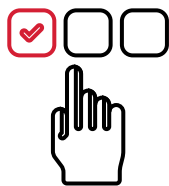
Truenat has been very useful for prompt TB diagnosis on the TB-LON 3 Project. We are grateful to USAID for bringing this new innovation to us in IHVN.

Dr. Aderonke Agbaje | TB LON 3 Project Chief of Party- IHVN

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Lessons Learned



1. Feasibility and Acceptability of Truenat

As part of operational research, the implementing partners interviewed 33 healthcare workers including technicians, clinicians and program staff to understand their perspectives on Truenat testing. Preliminary analysis of the interview transcripts showed a high acceptance rate of Truenat, with clinicians and technicians mentioning the battery operation and portability as key features that made the test useful in hard-to-reach areas. Other features that contributed to the positive perception by the technicians were that the Truenat tests were easy to use and technicians felt competent within a week of hands-on testing with Truenat. Many expressed excitement that they were finally using a molecular test that would provide rapid diagnosis of TB to the people seen at their facilities.

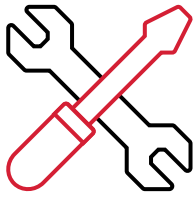


There has been prompt training of people using the Truenat machine. Since we got Truenat we have had refresher training two or three times which helped us to get more versatile with the working of the machine.

Mr. Jimoh | Laboratory Manager at Total PHC, Osun State, Nigeria



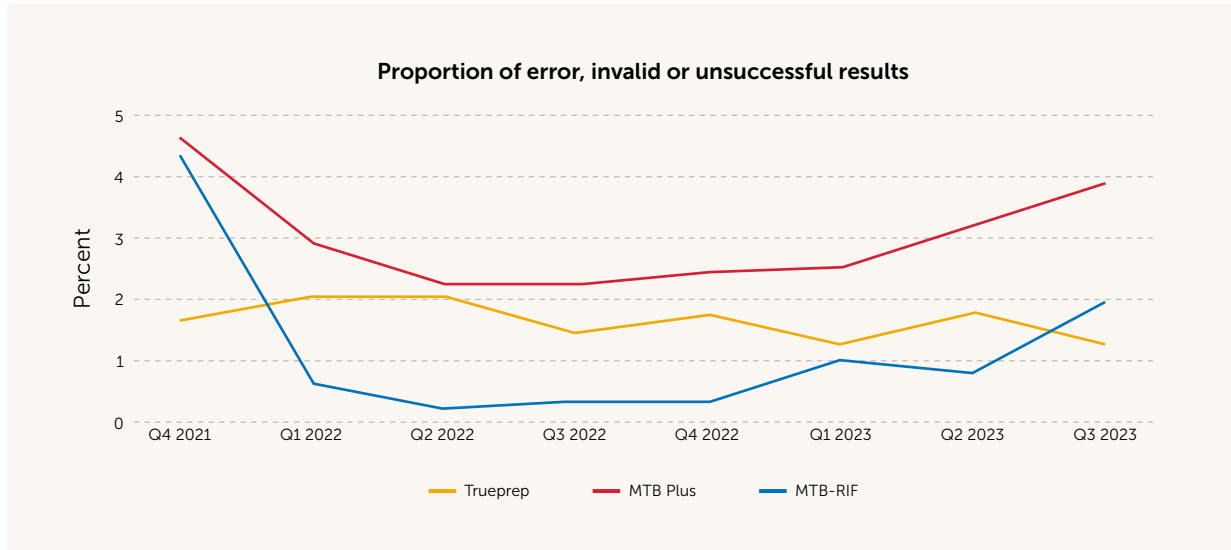
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2. Equipment Maintenance and Errors

The rate of error/invalid/other unsuccessful results was relatively low, ranging from 1-5% depending on the testing stage (Figure 5). In the initial implementation period, most of the unsuccessful results observed were at the MTB Plus and MTB-RIF stages, primarily related to pipetting errors. These were resolved through mentorship and refresher training during supervisory visits. An increase in MTB Plus unsuccessful results was also observed between Q1 and Q3 of 2023, and this was likely related to a high staff attrition rate and user competency that had declined during a period of interrupted testing.

Figure 5: Truenat error/invalid/other unsuccessful results classified by the stage at which the unsuccessful result occurred between November 2021 and September 2023



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Common sources of errors on the Truenat and Truelab instruments are described in Table 2 below.

Table 2: Truenat use combined with X-ray/CAD in active case finding

Description of error	Resolution
Incomplete liquefaction of samples during extraction	Staff were advised to incubate samples up to 15 minutes to allow complete liquefaction of viscous samples.
Invalid results	During the initial implementation phase, frequent instances of invalid results were attributed to pipetting errors. This was addressed by conducting site-based refresher training to enhance user competence. Additionally, invalid results arose from poor specimen quality, particularly when samples were bloody or contained food particles. Repeat sample collection was necessary in such instances. Furthermore, failing to replace the slider glasses after every 50 tests, as recommended by the manufacturer, led to an increase in the rate of invalid results. In these instances, the Molbio local agent offered virtual support to sites requiring assistance in changing the slider glass.
Cartridge clog error	This was a common error that often occurred when samples were not completely liquefied during the sample processing step. Users were advised to increase the incubation time and gently swirl the sputum cup for complete liquefaction of the sample. Sometimes running a flush protocol on the Truenat instrument resolves the error.
Shifting of the chip bay	This was mainly due to the application of force during the closure of the bay. The Molbio local agent provided technical assistance for the resolution of this error.
Errors requiring repair or replacement of instruments	In cases where an error persisted despite troubleshooting or on-site visits by the local agent, a loaner machine was dispatched to the facility to minimize equipment downtime. Common issues on the Truelab included electrical or mechanical faults, such as valve-related, door closure problems and failure to power up. Meanwhile, with Truenat, the frequent issue was the failure to elute DNA in the cartridge chamber. Truenat instruments required repairs at least once in 27 facilities whilst 9 Truelab instruments needed repairs. In most instances, a loaner machine was dispatched within 5-7 days of reporting the issue. At the same time, the faulty instruments were taken for repair and later returned to the facility once the problem was resolved.



Ensuring TB diagnostic access to the hard-to-reach rural communities will be key in finding missing TB cases in Nigeria. The addition of Truenat to the TB diagnostic menu in the country is helping to address this key barrier to TB case finding.

Dr. Bethrand Odume | Executive Director of KNCV Nigeria

Additional lessons learned are summarized below in Table 3.

Table 3: Summary of Lessons Learned

Engagement with key stakeholders	<ul style="list-style-type: none"> • Early engagement with community stakeholders (including chiefs and community leaders) increased acceptability and anticipation. • In some facilities, the community was involved in the refurbishment of the site in anticipation of the instruments. For example, at some sites, the facility and community leadership procured large printers, air conditioners and fridges, and connected the Truenat lab to the facility inverter system to charge batteries. • Close collaboration with the NTP also increased acceptability and was useful for planning for sustainability beyond the project implementation.
Demand creation	<ul style="list-style-type: none"> • At some sites, the instruments were initially underutilized because of a lack of awareness of the availability of molecular testing at the site; this improved with the sensitization of healthcare workers and refinement of sample referral networks.

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Infrastructure requirements	<ul style="list-style-type: none"> The instruments need a charge time of at least 3 hours after which they can be used on battery power for at least 8 hours. In sites with prolonged power outages, the use of solar systems is recommended. Surge protectors were also needed to protect the instruments from potential damage due to power surges.
Instrument service & maintenance	<ul style="list-style-type: none"> The Molbio local agent provided prompt technical support when a service request was made. Between July and October 2023, 100% of service requests for repair or replacement of failed parts were made within 10 days as stipulated in the Stop TB Partnership GDF KPIs. Responses were first via WhatsApp call or video and then through on-site visits to replace or repair the instrument system components. Facilities provided weekly reports to the implementation coordination team at USAID, enabling issues to be addressed early, including escalation of issues to the local agent.
Quality assurance	<ul style="list-style-type: none"> During the early implementation period, adherence to SOPs and preventive maintenance was suboptimal. Supervisory site visits were used to provide onsite refresher training and mentorship and instill good clinical laboratory practice. Furthermore, as the sites were predominantly microscopy sites, technicians initially struggled with the pipetting steps. Frequent supervisory support visits were done to provide training on pipetting skills and improve staff competence. Molbio recommends the replacement of the micropipette every 6 months. However, the KNCV and IHVN teams are investigating how to ensure periodic calibration. SOPs on waste management and sample storage (where testing could not be done or completed on the same day of testing) were developed. Although the sites did not participate in EQA during the implementation period, with the planned expansion of Truenat sites, there are plans to develop panels through the National Reference Laboratory proficiency testing program.
Connectivity	<ul style="list-style-type: none"> The country has been making efforts to connect the Truenat instrument systems to the Aspect connectivity platform currently being used for other diagnostic instruments to remotely monitor performance in real-time, troubleshoot problems with utilization or maintenance, and allow for the rapid sending of test results. Despite the Truelab analyzer having in-built connectivity functionalities, including possible transmission of data via a SIM card, WIFI or Bluetooth, there have been ongoing challenges with complete transmission of test results to the Aspect platform. The technical challenges, including software issues, lack of power of the in-built antenna to effectively transmit data bundles from very remote locations, difficulties in reliably uploading historic test results, amongst other identified challenges, are currently being explored and addressed by SystemOne and Molbio. As MTB-RIF test results are transmitted separately from MTB Plus results, reconciliation of patient data is challenging when patient identifiers manually entered by lab technicians are duplicated or when MTB-RIF tests are uploaded without a subsequent MTB or MTB Plus test result. Molbio has advised that monthly consumption of data for results transfer (depending on device utilization) and periodic software updates may be 300MB on average; while the experience so far has not seen such a high level of data consumption, such levels would make use of global SIM cards prohibitively expensive.
Use of Truenat in community active case finding	<ul style="list-style-type: none"> Between 10-12 samples could be tested with the Truenat Duo systems per day, which proved challenging during community active case finding where more than 50 samples were collected. To improve efficiency, tricycles were equipped with both Truenat and TB-LAMP so that samples could be tested on the same day.



The U.S. Agency for International Development (USAID) is delighted to see the impact of the roll-out of the Truenat machines. The equipment is essential to improving access to life-saving, molecular diagnostic tests for TB, including drug-resistant TB, for thousands of Nigerians. Our collaboration with the Government of Nigeria under the Stop TB Partnership in adopting new innovative tools for TB diagnosis, such as the Truenat machine, has been exemplary. USAID remains committed to this collaboration to end TB in Nigeria.

Melissa A. Jones | Mission Director, USAID Nigeria

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Sustainability and Plans for Expansion

These early results boosted acceptance of Truenat testing in Nigeria. To increase the size of the Truenat fleet in the country, a private diagnostic laboratory in Lagos donated one Truenat Uno system to the TB control program. Additionally, the NTBLCP included 333 Truenat systems and reagents in the Global Fund's GC7 application cycle.



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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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