

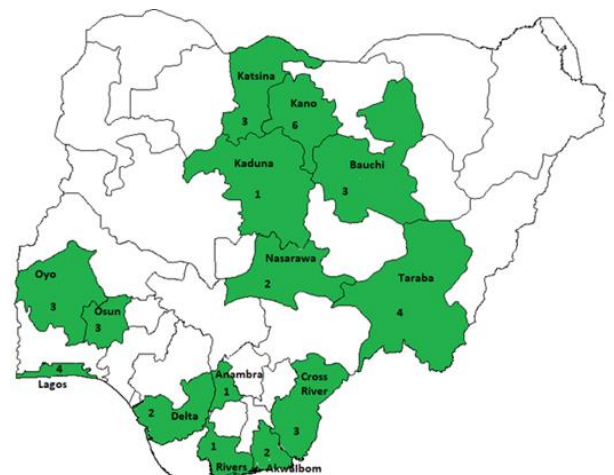
# EARLY EXPERIENCE OF KNCV NIGERIA AND IHVN IN IMPLEMENTATION OF TRUENAT TESTING IN NIGERIA

## STOP TB / USAID INTRODUCING NEW TOOLS PROJECT (iNTP)

Nigeria has the largest burden of TB in Africa, and only 30% of people with TB are diagnosed and treated, according to the most recent WHO estimates.<sup>1</sup> One of the main factors contributing to the country's low case detection rate is the lack of access to rapid molecular testing: only half of the people with TB get tested with a rapid molecular test at the time of diagnosis.

The Stop TB Partnership / USAID's [Introducing New Tools Project](#) (iNTP) aims to help countries reach UNHLM targets around the detection of TB and drug-resistant TB. Under the iNTP, Nigeria is implementing **38 Truenat Duo systems and TB tests for 77,500 people** (Truenat MTB Plus tests), including 15,500 tests for rifampicin resistance (Truenat MTB-RIF Dx tests).

USAID implementing partners KNCV Nigeria and the Institute for Human Virology Nigeria (IHVN), implementing the TB LON 1 & 2 and TB LON 3 projects respectively, in collaboration with the National TB Program (NTP), have rolled out the 38 Truenat instruments in peripheral sites across 14 states to bring access to molecular testing to hard-to-reach populations. KNCV Nigeria and IHVN have also started piloting the use of Truenat instruments together with ultraportable Delft Light digital X-ray systems provided under the iNTP.



*Distribution of 38 Truenat systems in 14 states in Nigeria*

<sup>1</sup> WHO Global Tuberculosis Report 2021. <https://www.who.int/publications/i/item/9789240037021>

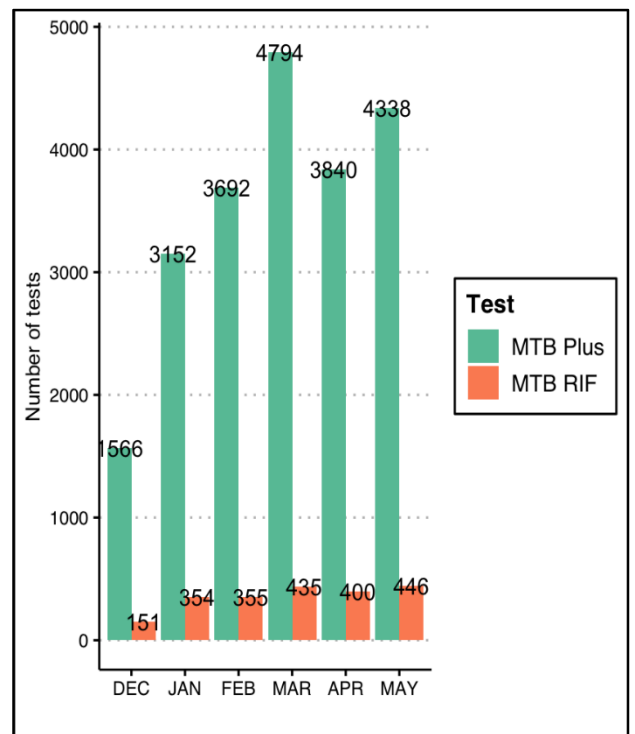
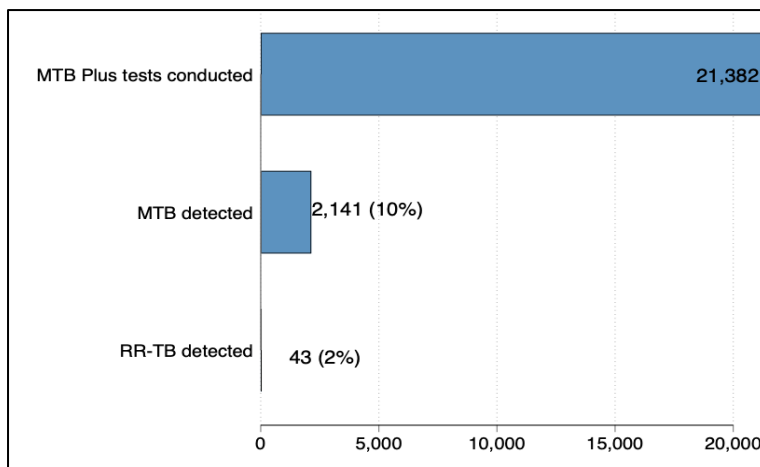
## IMPLEMENTATION PROGRESS

- 38 Truenat systems were installed in November-December 2021: 28 at KNCV-supported sites and 10 systems at IHVN-supported sites
  - Facilities selected were predominantly microscopy sites, with no access to a molecular diagnostic. The median distance from a Truenat facility to another molecular diagnostic facility is 13.6 km (ranges from 2.1 km to 292 km).
  - Truenat instruments at all sites are being used as the first-line diagnostic test for the evaluation of presumptive TB.

Truenat was recommended by WHO in 2020 as the first near point-of-care rapid molecular test for detection of TB and rifampicin resistance. Truenat instrument systems have in-built batteries allowing for 8 hours of use, can be used in temperatures up to 40 degrees Celsius, and have in-built connectivity functionalities.

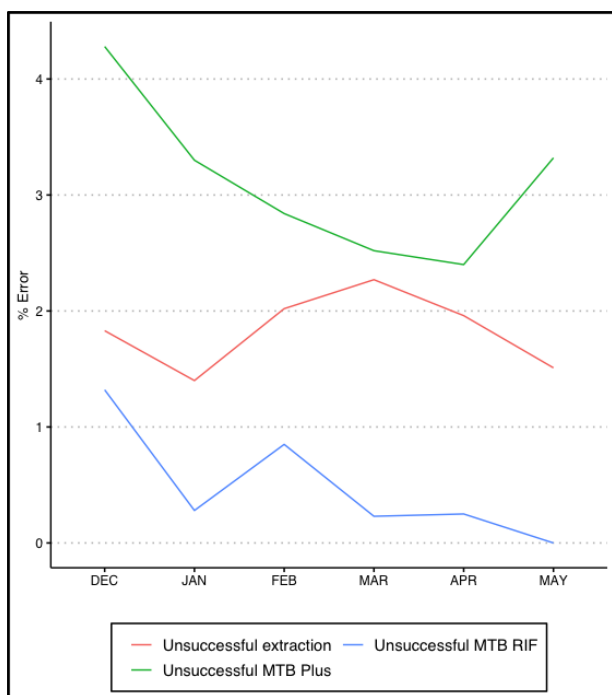
- **Highlights from December 2021 to May 2022:**

- A total of 21,825 samples from individuals undergoing investigations for TB were received at the facilities. 21,503 DNA extractions, 21,382 MTB Plus tests and 2,141 MTB RIF tests were performed (Figure 1).
- The average number of tests performed per month per Truenat system increased from 41 at inception to 114 tests in May 2022, representing a 178% increase in utilization rate.
- MTB was detected in 2,141 of the samples (10%) and rifampicin resistance was detected in 43 samples (2%) (Figure 2).



**Figure 1: Number of Truenat MTB Plus and MTB-RIF Dx tests conducted in Nigeria between December 2021 and May 2022**

**Figure 2: Cascade of samples where MTB and RR-TB was detected at Truenat implementation sites in Nigeria between December 2021 and May 2022**



**Figure 3: Truenat errors classified by stage at which error occurred in Nigeria between December 2021 and May 2022**

- The error rate for MTB testing has decreased from 4.3% in December 2021: Since January 2022 the error rate for MTB Plus testing has remained at 3% or lower, and the error rate for MTB RIF-Dx testing has remained at 1% or lower (Figure 3).

“The Truenat systems have really 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 on finding missing TB cases has been impressive. We are grateful to the Stop TB Partnership and USAID for this innovative diagnostic tool.”

*Dr. Chukwuma Anyaike, Director / National Coordinator, NTBLCP*

## LESSONS LEARNED

- **Engagement with key stakeholders:**
  - 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 larger printers, air conditioners, fridges and connected the Truenat lab to the facility inverter system to charge batteries.
  - Close collaboration with the NTP also increased acceptability and will be useful for planning for sustainability beyond the project implementation.
- **Demand creation:**
  - 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 sensitization of health care workers and refinement of sample referral networks.



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- **Technical support:**

- Molbio has a local agent in-country that is able to provide prompt technical support when a service request is raised. When a challenge cannot be resolved remotely via WhatsApp call or video call, the Molbio agent will travel to a site to repair or replace instrument system components: this is covered by the standard warranty. All Truenat systems come



with a 1-year standard warranty, and extended warranties are available (\$1,120 annually, available through Stop TB Partnership's GDF).

- The Molbio in-country agent has 3 spare instrument systems and parts, allowing for faster swap-out of instruments and parts when required; Molbio has made spare systems available for all countries under the iNTP at no cost.
- The Molbio in-country agent was able to provide on-site installations and hands-on training for a fixed cost (\$500 per site, available through GDF).

“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*

- Facilities provide weekly reports to an implementation coordination team at USAID, which enables issues to be addressed early, including escalation of issues to the Molbio local agent. Furthermore, real-time monitoring of challenges is provided through a WhatsApp challenge tracker and a Google Form system.

- **Infrastructure considerations:**

- At least three hours of electricity is required to optimally charge the instrument, which is challenging in sites with prolonged periods of electricity outages. One instrument system had to be moved to another site for charging at some point during implementation due to power outages. The procurement of solar systems is being considered for some sites.
- Surge protectors have been procured locally for some sites to protect instrumentation from potential damage arising from power surges.

- **Active case finding:**

- For a community-based TB case finding outreach campaign on World TB Day, a Truenat instrument system was used together with an ultraportable digital chest X-ray system with software for computer-aided detection (CAD) of TB, also provided under the iNTP. By using the X-ray/CAD system and testing on-site with Truenat, 735 people were first screened using portable X-ray, 68 identified as presumptive TB, and 3 people were diagnosed with TB (1 bacteriologically confirmed).
- Carrying cases were provided by the iNTP to facilitate the transport of Truenat systems. However, the logistics of setting up the Truenat instruments for the purposes of outreach are cumbersome e.g., pack and unpack instruments, prepare workstations, and set up for testing. A preferred option would be the use of a mobile truck with a dedicated Truenat workstation for active case finding in the community with a CAD-enabled portable X-ray machine.

“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*

- **Common errors:**

- As only a part of the volume of the prepared sample is used for DNA extraction, the remaining volume can still be used when an error has resulted from the extraction step; another sample does not need to be collected and processed.
- Common sources of error:

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	This was mainly due to dirty slider glasses that needed to be replaced. The Molbio local agent provided virtual support to sites that needed assistance in changing the slider glass. Sometimes this was also due to poor specimen quality (bloody samples/food particles in samples). Repeat sample collection was required.
Cartridge clog error	This was a common error that could be resolved by conducting a flushing protocol. Virtual technical assistance on the flushing protocol was provided by the Molbio local agent. Where the problem could not be resolved, a replacement machine was shipped to the facility within a day of reporting 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.



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### Quality assurance:

- The facilities selected for the project were microscopy centers, and adherence to SOPs on monthly Quality Controls and preventive maintenance was not optimal during the early phases of implementation. Supervisory site visits improved this.
- The testing process entails multiple pipetting steps that require significant training and frequent site-based support during the initial stages of implementation. The training focused on good pipetting skills and improved competence of staff.
- The micropipette provided with the Truenat instrument system will require calibration over time. KNCV and IHVN are investigating how to ensure periodic calibration.
- Sample storage and waste management have been a challenge for most sites. SOPs are currently being developed to provide guidance.
- The Truenat instrument system is not yet incorporated into the national reference laboratory External Quality Assurance (EQA)/Proficiency Testing (PT) program.



### • Connectivity:

- The Truenat instrument system produces digital data and has in-built connectivity functionalities. KNCV Nigeria is working to connect instruments to cellular networks to transmit data to SystemOne's Aspect connectivity solution, under a grant provided by the Stop TB Partnership. By connecting to Aspect, the country will have real-time data on the performance of the Truenat and existing GeneXpert instrument fleets, and furthermore, clinicians will be able to rapidly get test results for the people under their care.

“USAID Nigeria is delighted to collaborate with the Government of Nigeria and the Stop TB Partnership in rolling out the Truenat machines for molecular diagnosis of tuberculosis. Through our collaboration, Nigeria has become the first country, aside from India, to introduce this innovative technology on a large scale. Thousands more Nigerians in remote areas can now access life-saving tests for TB, including drug-resistant TB.”

*Dr. Anne E. Patterson, Mission Director, USAID Nigeria*

- **Sustainability:**

- KNCV Nigeria and IHVN are working together to produce evidence on the feasibility of using Truenat to increase nationwide access to rapid molecular testing. KNCV Nigeria and IHVN will work with the National TB Program to plan for sustainability and potential scale-up using Global Fund and other donor and domestic resources.

## GDF ORDERING INFORMATION

Truenat instrument systems and reagents are available for any country through GDF with the following global access prices (prices as of August 2022 and subject to change; contact GDF for detailed terms):

### Truenat systems

- Uno Dx Workstation: \$10,000
- Duo Workstation: \$14,000
- Quattro Workstation: \$18,000

Truenat systems come with initial 1-year warranties, with the possibility to buy annual warranty extensions for \$1,120 (regardless of workstation configuration). All warranties provide comprehensive service and maintenance, including repair and replacement of parts and equipment, plus on-site visits as required.

### Reagents

- MTB or MTB Plus tests are \$9 each (test reagents include MTB sample pre-treatment pack, sample prep kit, chip kit)
- For every 100 MTB or MTB Plus tests procured, 20 MTB Rif Dx tests are provided for free

For more information, see the [GDF Diagnostics, Medical Devices & Other Health Products Catalog](#) and [GDF Diagnostics, Medical Devices & Other Health Products Ordering List](#)

## ABOUT THIS DOCUMENT

This document is the first of a series of case studies spotlighting the experiences of early implementers of technologies provided under the *introducing New Tools Project*. Technical content was provided by Dr Nkiru Nwokoye (Director Laboratory Services, KNCV Nigeria) and Jamiu Olabamiji (Senior Laboratory Advisor, IHVN) and reviewed by Dr Austin Ihesie (Consultant, USAID Mission-Nigeria) and Dr Rupert Eneogu (Program Management Specialist, TB and TB/HIV, USAID Mission-Nigeria).

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