THE INTRODUCING NEW TOOLS PROJECT (iNTP)

Ending TB One Test at a Time: Kenya's Experience in Implementation of Truenat Testing for Detection of TB and Rifampicin Resistance

Loise Wangui, Laboratory Manager, Lari Sub County hospital Kiambu, Kenya, loads a chip into a Truenat instrument placed in the facility through the *introducing New Tools Project*.

Background

The 2016 National Tuberculosis (TB) Prevalence Survey in Kenya revealed a high number of people with undiagnosed TB, including those who had previously sought treatment for respiratory symptoms at health facilities.

To address this, the country issued guidelines recommending molecular WHO-recommended rapid diagnostic tests (mWRDs) as the initial tests for TB diagnosis. However, implementing the new mWRDs presented a complex technical problem of ensuring widespread access to such testing. To tackle this challenge, the United States Agency for International Development (USAID), in collaboration with the Stop TB Partnership, provided 38 Truenat Duo systems and reagents for the detection of TB (Truenat MTB Plus) and rifampicin resistance (Truenat MTB-RIF Dx) through the *introducing New Tools Project* (iNTP). The National TB Leprosy and Lung Disease Program (NTLD-P) and the National TB Reference Laboratory (NTRL), in collaboration with the USAID supported Tuberculosis Accelerated Response and Care II (TB ARC II) activity implemented by Centre for Health Solutions - Kenya (CHS) and Infectious Diseases Detection and Surveillance Project (IDDS), initiated the rollout of Truenat tests in Kenya to increase TB detection in individuals with both rifampicin-susceptible and rifampicin-resistant TB. Additionally, this effort aimed to reduce diagnostic delays and shorten the time to initiation of treatment.

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Truenat Implementation Steps

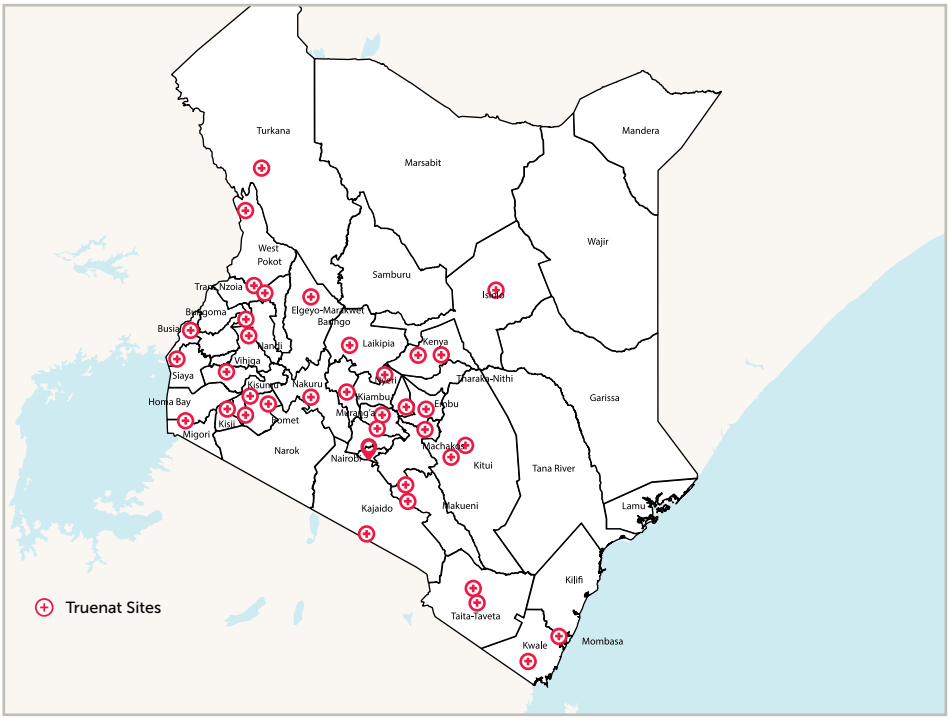
1. Planning Phase

Truenat implementation in Kenya was scheduled to begin in October 2021. In preparation for this, a secretariat chaired by the NTLD-P and comprising other technical and implementing partners was formed. Weekly e-meetings were held to ensure the conceptualization of an implementation plan and budgets, the identification of facilities through spatial analysis, county participation in the agreement of selected sites, site capacity assessments, training, technical assistance missions and data review meetings. The roll-out of the Truenat assays in Kenya was driven by several key factors. Firstly, the 2019 Diagnostic Network Optimization Report highlighted the need for 450–500 mWRD instruments to ensure optimal access to TB testing, and this was subsequently incorporated in the Kenya National Strategic Plan 2019–2023. Secondly, the Kenya TB screening and diagnostic algorithm emphasizes the use of a mWRD as the initial test for TB diagnosis. Therefore, the implementation of the Truenat assay aimed to address gaps in coverage, particularly in hard-to-reach areas, and enhance access to molecular diagnostic testing.

2. Site Selection and Capacity Assessment

The implementation strategy began with a national TB diagnostic spatial analysis to help identify potential health facilities for Truenat placement among Kenya's 14,000 health facilities. The facility selection criteria were based on the population to be served by the facility, the number of other health facilities with which the facility could network, testing demand and distances between mWRD sites, particularly those more than 50 kilometers from the nearest GeneXpert testing site. This approach was designed to ensure that all eligible facilities in the country had an equal opportunity to receive mWRDs. Initially, 146 health facilities were prioritized through application of spatial analysis. County representatives were engaged, and 80 health facilities out of the initial 146 were prioritized for capacity assessment. Capacity assessment was conducted using a customized Stop TB/USAID/GLI tool (Annex 6 of the Practical Guide to Implementation of Truenat™ Tests for the Detection of TB and Rifampicin Resistance) in an electronic version that included several criteria, including the availability of infrastructure (adequate testing space, benches), human resources, power stability, waste disposal systems and drainage facilities, security, ventilation and commodity storage.

Figure 1 : *Map of Kenya showing the counties where Truenat testing has been implemented*



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Out of the 80 health facilities that were evaluated, 60 demonstrated readiness for equipment placement, achieving an impressive score of 90% on the target key performance indicators. The sites that were not ready were guided with recommendations to work on the gaps identified during the assessment. Through the iNTP resources, 38 Truenat Duo systems were provided as part of the pilot phase of the planned Truenat roll-out in Kenya. A prioritization matrix was therefore applied to identify 38 high-priority health facilities to receive this first tranche of instruments. Following this prioritization, 37 Truenat systems were placed in 33 counties (Figure 1). One Truenat system was installed at the NTRL to support panel testing and to help with quality control. The remaining 22 facilities that demonstrated readiness for equipment will benefit from additional systems to be procured through Global Fund support.

3. Training of Super-users and End-users to Strengthen Capacity at the County Level

To ensure the successful adoption and effective use of the Truenat systems, implementation commenced in June 2022 with a five-day centralized Truenat "super-user" training and a three-day end-user training, which included practical sessions. This training was conducted in collaboration with the NTLD-P, NTRL, IDDS, CHS and Molbio's in-country representative. All users received training on instrument operation, basic maintenance, safety and troubleshooting. Super-users were equipped with advanced technical skills to enable them to troubleshoot and perform routine and advanced preventive maintenance of the Truenat instruments. Additionally, super-users were trained to provide on-site mentorship and remote assistance to end-users. After the training, the Molbio local agent travelled to the sites for instrument installation and provided on-site training for the end-users. One month after the installation, the NTLD-P, NTRL technical team and the CHS project team visited all Truenat sites to identify gaps and provide additional on-site mentorship. Furthermore, demand generation and clinician sensitization were prioritized through a variety of activities such as a large-scale project kick-off meeting in Nairobi and targeted meetings and mentorships during on-site support visits. The NTLD-P officers and implementing partners, TB Champions, County Medical Laboratory Coordinators, County TB and Leprosy Coordinators and their colleagues at the sub-county level were also sensitized as part of the demand and awareness creation efforts. These activities played a critical role in promoting optimal Truenat instrument use and driving technology adoption among healthcare providers.

Training of Superusers on Truenat testing in Nakuru on 7-10 June 2022. Jeremiah Ogoro of NTLD-P and Dr. Maurice Maina, USAID Kenya and East Africa, engage participants in a session.

> The main objective of the iNTP is to help scale up the introduction of new WHO-approved TB molecular diagnostic tools. This will help increase access to molecular diagnostic tools and tuberculosis drug resistance surveillance and support the roll-out of treatment and digital health tools to strengthen TB care in Kenya.
>
> Jeremiah Ogoro | Head of the Diagnostic Section, NTLD-P, Ministry of Health - State Department for Public Health and Professional Standards

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4. Site Support Visits

Two months after the project's implementation began, a technical site support visit conducted by the NTRL, NTLD-P and CHS staff in August 2022 revealed encouraging results for the Truenat testing program. The team discovered that most of the visited facilities had a high level of acceptance and interest in Truenat testing and that the clinic-laboratory interface had been reorganized to accommodate the availability of on-site testing. Results were properly documented and provided to clinicians within 24-48 hours, while implementing partners referred samples for testing at Truenat sites through the sample referral network. However, there were gaps in sample quality and processing, and result documentation. Furthermore, not all sites repeated testing of samples with MTB-RIF indeterminate results. These gaps were filled by providing additional training on how to use the instruments and the diagnostic algorithm during the site visits. WhatsApp groups formed for all end-users, super-users and NTLD-P/NTRL staff have proven useful in bridging these gaps by enhancing communication and improving the Truenat testing program's quality.

Truenat TA mentorship in collaboration with NTLD-P, Kisumu county, USAID HQ, USAID Kenya Mission and USAID TB ARC II

5. Customizing a Local Connectivity Solution for Transmission of mWRD Test Results

In 2013, the DNTLD-P and its partners developed the GxLIMS system to visualize GeneXpert performance indicators monitoring, instrument connectivity and commodity management. With the roll-out of Truenat instruments and ultraportable chest X-ray systems equipped with artificial intelligence software, a new connectivity platform named Tibulims was created, enhancing the existing GxLIMS system to visualize and manage all diagnostic systems. While most Truenat facilities are in remote areas with limited internet access, customized Tibulims modules were successfully integrated with all Truenat systems by the second quarter of 2023. To prevent network downtime and other challenges, stable networks were identified during the Truenat site identification process, and mobile SIM cards were installed in facilities with Truenat systems. Currently, all instruments with monthly data bundle provision are operational. The IT team promptly addressed any connectivity issues encountered by the sites, ensuring seamless data transmission and reporting.

> Before the installation of the Truenat machine here, we had a challenge in TB diagnosis as we do not have a GeneXpert machine in the entire sub-county. Previously, we were using smear microscopy and referring samples to Kakamega County Referral Hospital for GeneXpert testing, which is located over 80 kilometers away. The sample networking was suboptimal due to the poor terrain.
>
> Emily Vuguza | Kakamega County TB, Leprosy and Lung Disease Coordinator

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> Truenat MTB Plus and MTB-RIF Dx assay availability in facilities has improved access to TB testing for people with signs and symptoms of TB, especially in hard-to-reach areas where sample referral systems are unavailable or not properly constituted.
>
> Kennedy Muimi | Senior Technical Officer-Laboratory, CHS - USAID TB ARC II

Early Impact

Between July 2022 and June 2023, 41,805 Truenat MTB Plus tests were conducted, resulting in the detection of 3,920 MTB-positive samples, with a positivity rate of 10% (Figure 2). Rifampicin resistance was identified in 95/3,920 (2.4%) of these samples. Comparing the period before Truenat implementation (July 2021 to June 2022) with the period during Truenat implementation (July 2022 to June 2023), a 25% increase in the number of notified pulmonary TB cases was observed (Figure 3). Furthermore, the introduction of Truenat assay testing led to a significant increase in the proportion of newly diagnosed people with TB who received a rapid molecular test as their initial diagnostic test. This percentage increased from 48% in the period before Truenat implementation to 68% in the period during Truenat implementation (Figure 4).

Figure 2: *Number of Truenat tests conducted and percentage of MTB positivity between July 2022 and June 2023 at implementation facilities in Kenya*

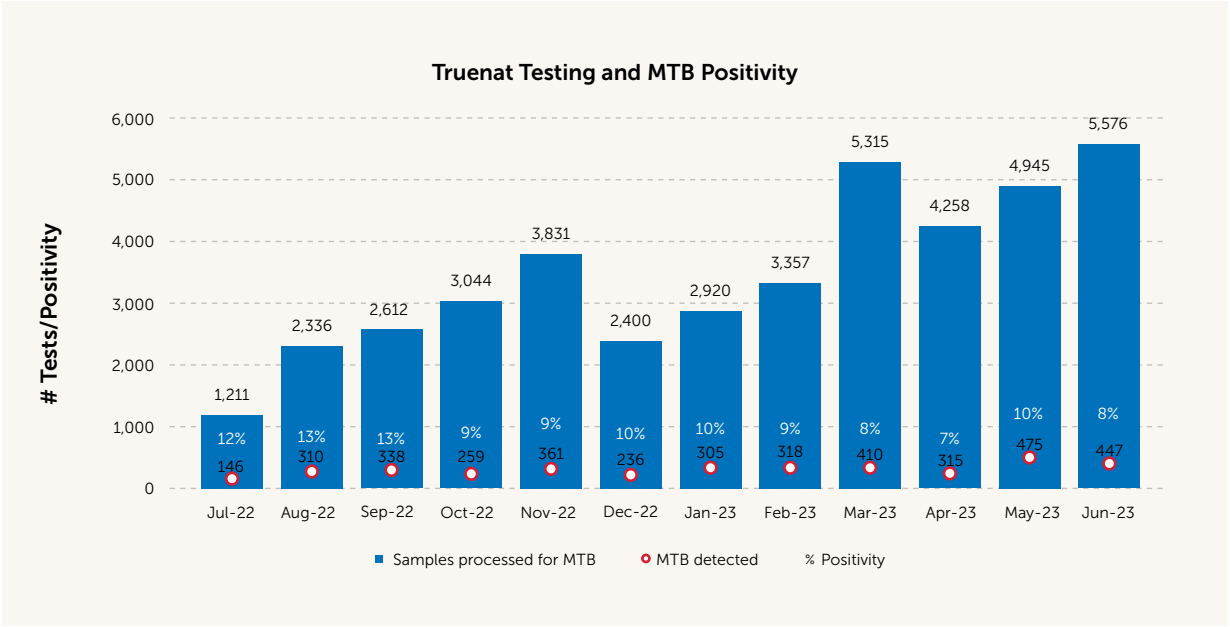

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Figure 3: *Increase in the number of newly diagnosed people with TB notified at the Truenat hub sites comparing before (July 2021 - June 2022) and during (July 2022 - June 2023) Truenat implementation. Figure does not account for people whose samples were referred for testing at the hub sites.*

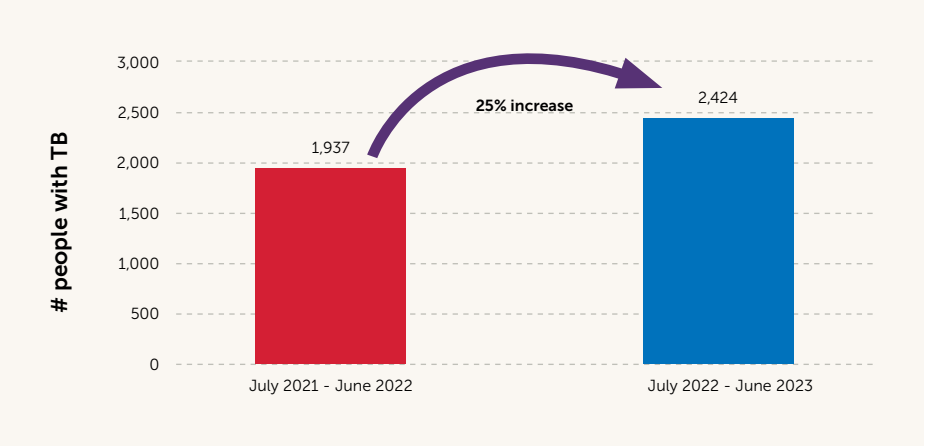
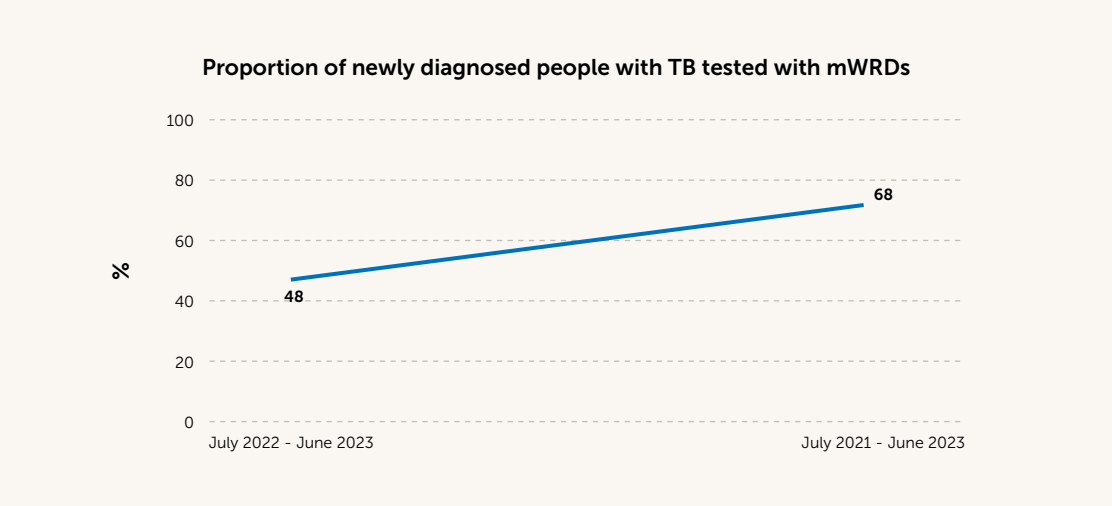


Figure 4: *Increase in the proportion of newly diagnosed people with TB tested with a WHO-recommended molecular diagnostic test (mWRD) comparing before (July 2021 - June 2022) and during (July 2022 - June 2023) Truenat implementation*



I visited various private hospitals and was given antibiotics with no improvement. On 31 August 2022, I went to Mikinduri Sub County Referral Hospital where upon examination, the clinician sent me to the laboratory. At the laboratory I was asked to produce a sputum sample for testing. Testing was done and after one hour the results were out indicating I had TB.

Simon Murungi | diagnosed using the Truenat system placed at Mikinduri Sub-County hospital, Meru

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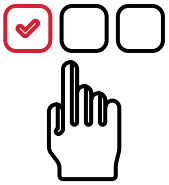
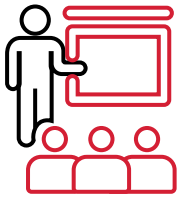
> In 2022 we diagnosed 121 cases, compared to 2021 when we diagnosed only 76 cases (in Navakholo sub-county). The presence of the machine has improved bacteriological diagnosis. Of the 121 cases reported in 2022, 78% were bacteriologically confirmed and only 22% were clinically diagnosed.
>
> Emily Vukusa | Kakamega County TB, Leprosy and Lung Disease Coordinator

Lessons Learned



1. Site Selection and Capacity Assessment

It is critical to ensure equity in instrument distribution, diagnostic network expansion and strengthening by using a spatial analysis in site identification for new TB tools, followed by site level capacity assessment and strengthening.



2. Training and Competence

- Prior to equipment installation, training for Truenat super-users and end-users proved to be beneficial in knowledge transfer, particularly for testing procedures, results interpretation and troubleshooting.
- The use of super-users as county leads to support Truenat roll-out in the country has been critical in site level mentorships, addressing gaps, managing proficiency tests and reporting data to the national level, particularly prior to Tibulims roll-out in the country.

3. Errors & Corrective Actions

Practical sessions and follow-up mentorships are useful to ensure end-users understand the sample preparation procedures and reduce testing errors especially during the initial phase of Truenat implementation.

- **Trueprep Error Rates:** Although the overall error rates on the Trueprep were low, averaging 2%, the main error was Error 3 (cartridge clogged) due to sample quality issues, and was resolved by extending the incubation time or re-extraction. Mentorship and refresher training on Truenat testing were implemented to address these challenges and ensure consistent proficiency among staff.
- **High RIF-indeterminate Results:** The RIF-indeterminate rate was 22% out of 3,920 MTB-positive samples tested for rifampicin resistance. This high rate persisted throughout the implementation period, ranging between 15-28% (Figure 5), primarily due to poor specimen quality and a low mycobacterial load in most samples. Obtaining a second sample for Truenat testing, culture and DST as described in the diagnostic algorithm was often difficult due to linkage issues.

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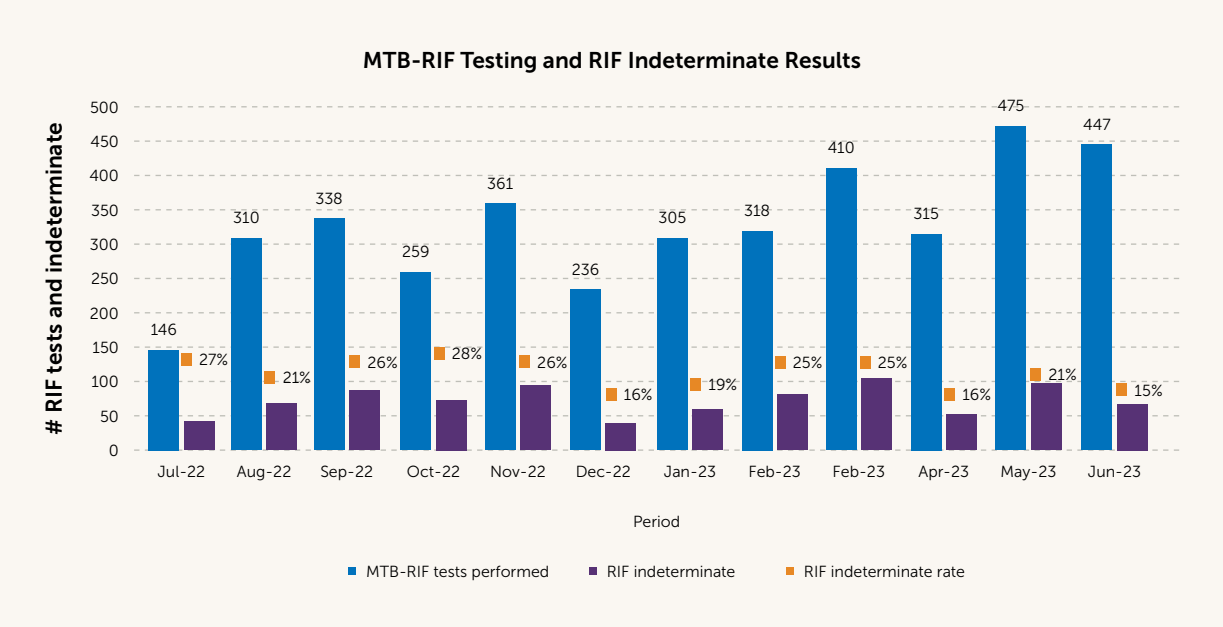
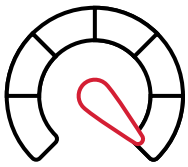
Figure 5: *Number and proportion of MTB-RIF indeterminate results during Truenat implementation*



- **Invalid Tests Outcomes in Coastal Region**: Between July 2022 and June 2023, 4% of Truenat MTB Plus tests (1,788 out of 41,805) yielded invalid results, with a majority reported from a site in the Coastal region. These invalid outcomes were primarily due to challenging environmental conditions. While Truenat instruments can function at temperatures up to 40°C, storage of the chips should be under 30°C, which was not the case at this facility. Furthermore, during the root cause analysis, it was discovered that lab fans were inadvertently spreading dust, posing a risk of sample and equipment contamination. To address this issue effectively, it was recommended to install an air conditioning system for temperature control and enforce strict adherence to Standard Operating Procedures (SOPs), with particular emphasis on the flush and decontamination protocols and the use of fresh chips for retesting using the available eluate.

4. Power and Electricity Issues

Given that Truenat has in-built batteries, this has proven useful in ensuring continued testing during power outages, thus avoiding wastage of cartridges and chips in the testing facilities.



5. Instrument Capacity

While the Stop TB Partnership/USAID/GLI Practical Guide to Implementation of Truenat tests indicates that Truenat Duo workstations can perform 15-18 tests per day under real-world conditions, the optimal target for daily utilization of the Truenat Duo workstations in Kenya has been set at 8 tests per day, given the decentralized positioning of the workstations in the laboratory system. This target has been set in the national Tibulims systems to compute the utilization rates in real-time at sites. At the Jomvu Model Health Centre in Mombasa County, the facility has faced a high workload since the beginning of the project; this facility would have benefited from a higher throughput workstation like the Truenat Quattro. Therefore, as part of scale-up, it is critical to prioritize the use of the Truenat Quattro workstations for sites with high workloads.

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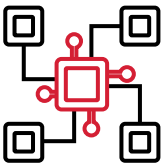

6. Connectivity

The use of a local connectivity solution (Tibulims) for dispatch of results to clinicians through email and SMS has helped to bridge the laboratory-clinical interface gap and ensure prompt availability of results to clinicians and initiation of TB treatment. Connectivity also identifies sites that are not performing as expected, facilitating timely troubleshooting.

7. Quality Assurance

Timely support and provision of a national proficiency testing scheme for new molecular tools during the onset of implementation is useful to help identify critical gaps and opportunities for mentorship.

8. Equipment Maintenance

Availability and utility of services from a local agent with requisite capacity to support training, troubleshooting and maintenance of instruments has been helpful in addressing the instrument-related issues from the testing facilities.

> Our turnaround time of getting the results has improved. Before the installation of the Truenat machine we used to send samples to GeneXpert sites and were reliant on a rider which was very inefficient and unreliable due to the bad roads. It took more than five days to get the results. This led to late diagnosis and community disease transmission.
>
> Anthony Were | Navakholo Sub-County facility TB clinician

> Before the installation of the Truenat, patients would wait for results for more than a week given that we used to refer samples, or we would refer the patient to the level five hospital which is kilometers away. After the machine was installed, we have 1 – 2 hours test turnaround time for all the samples received.
>
> Esther Munywoki | Laboratory Manager, Mikinduri Sub-County hospital, Meru

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Looking Ahead

The following steps will be taken to ensure the sustainability and expansion of the gains made under the iNTP in Kenya:

01 **Sustaining the momentum and gains:** To ensure the continued success of the iNTP, the Kenya DNTLD-P, the NTRL and collaborating implementing partners will work closely with counties to provide ongoing facility-level mentorships, provision of proficiency testing panels and other essential support. These efforts aim to maintain the quality of services provided while ensuring the availability of testing reagents to all facilities.

02 **Expansion of Truenat implementation:** Building on the achievements of the pilot Truenat implementation, the NTRL and DNTLD-P developed an expansion plan that will see an additional 40 systems procured through Global Fund resources. These systems will be installed at peripheral facilities, with a particular focus on inclusion of hard-to-reach facilities. This expansion aims to enhance testing capabilities and access to accurate TB diagnosis in these facilities.

03 **Optimizing testing in target facilities:** To maximize testing efficiency in the target facilities, training for county TB and laboratory coordinators, clinicians and implementing partners will be prioritized. These training initiatives will focus on various aspects, including demand creation, improving quality of collected samples, strengthening linkages between the laboratories and clinicians to increase the ability to obtain second samples for subsequent testing needs, and remapping of referral systems tailored to selected facilities. Improving the efficiency of sample transport networks is also critical to ensure optimal utilization of the instruments. By strengthening the knowledge and skills of staff and enhancing sample transport networks, we aim to optimize the testing processes and ensure effective coordination among all parties involved in the TB diagnostic network.

> One of the biggest advantages of the Truenat machine is that it can detect drug-resistant TB bacteria. By having the machine in the facility, we are not only able to carry out tests for TB drug resistance, which is very rampant in the area, and initiate patients on treatment early hence controlling disease progression in the patient's body and spread in the community. We are also able to monitor drug-resistant TB patients' treatment response and manage them effectively. Previously, we encountered a lot of challenges as we used to refer their samples to Meru County Level hospital, the nearest GeneXpert site and wait for days for the results.
>
> Absalom Wambua, Mikinduri | Sub County Hospital Manager, Meru

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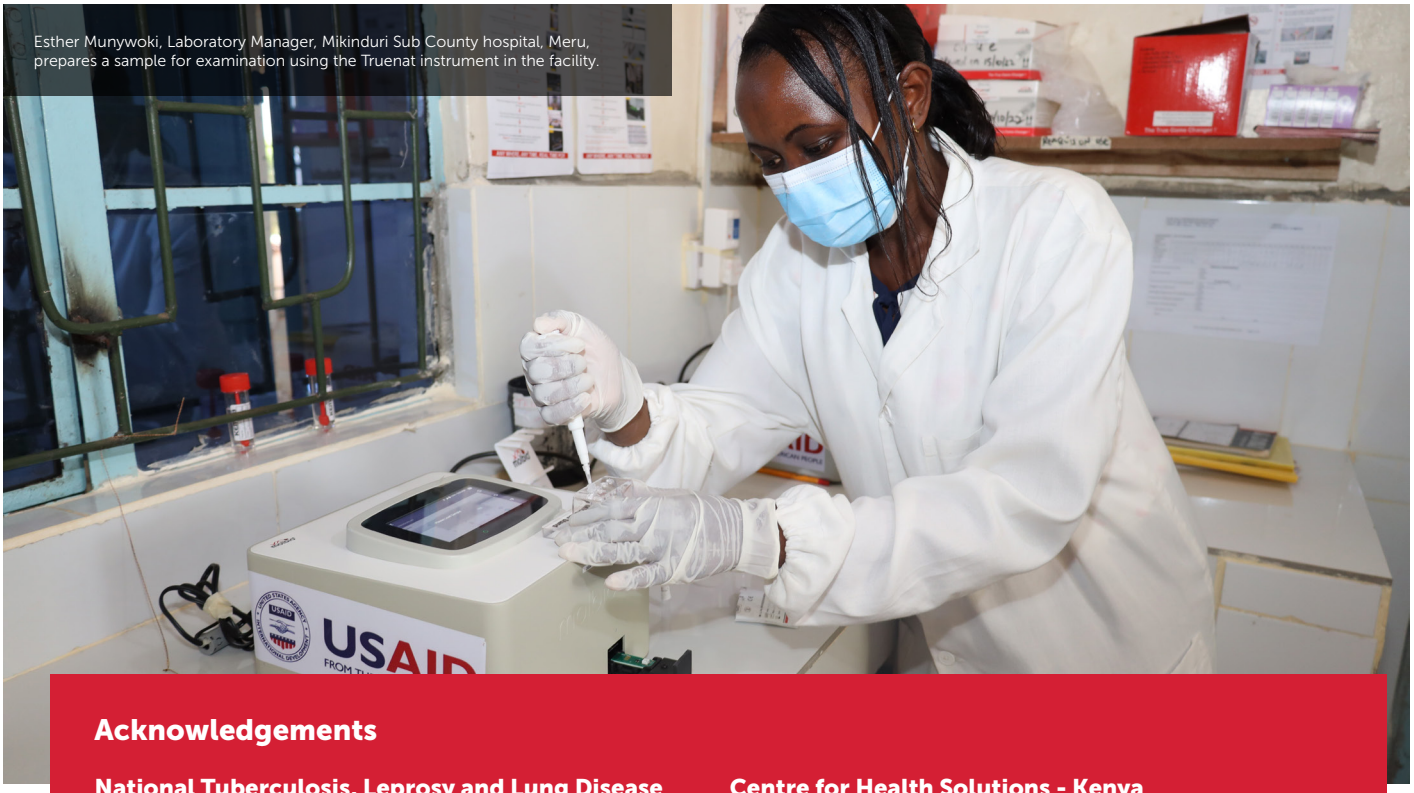

Esther Munywoki, Laboratory Manager, Mikinduri Sub County hospital, Meru, prepares a sample for examination using the Truenat instrument in the facility.

Acknowledgements

National Tuberculosis, Leprosy and Lung Disease Program

Dr. Immaculate Kathure
Dr. Jackie Kisia
Jeremiah Ogoro
Catherine Githinji
Dr. Stephen Macharia
Martin Githiomi
Elvis Murithi
Nicholas Ezati
Richard Kiplimo

United States Agency for International Development

Dr. Maurice Maina
Dr. Phillip Owiti
Judith Ronoh
Ann Masese

Centre for Health Solutions - Kenya

Dr. Paul Wekesa
Dr. Lorraine Mugambi Nyaboga
Kennedy Muimi
Dr. Samson Muga
Dr. Clarice Ambale
Dennis Oira
Maero Lutta
Diana Munjuri
Dr. Josephat Tonui
Dr. Anne Njoroge

National Tuberculosis Reference Laboratory

Nellie Mukiri
Solomon Bundi
Albert Okumu

Infectious Disease Detection and Surveillance Project

Dr. Grace Kahenya

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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