

Enhancing Access to TB Diagnostic Services through Rollout of Truenat MTB/RIF Assay in Marginalized Regions in Kenya

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Context

Globally, approximately 4 million patients with TB were missed by the national notification systems in 2021. One of the most significant barriers to TB case detection and diagnosis is lack of a rapid, accurate point-of-care diagnostic test. Out of the 5.3 million people diagnosed with pulmonary TB worldwide in 2021, only 63% were bacteriologically confirmed (WHO). In Kenya, 44% of incident TB cases were either missed or not notified, 57% of the total notified cases were bacteriologically confirmed, and 51% of the presumptive TB tested for TB against a target of 81%. In 2021, only 32% of the 47 counties had optimal access to sample referral systems in Kenya (Annual TB report). Whereas an increment in WHO-recommended rapid diagnostic tests (mWRDs) in the country from four (2011) to 275 (2022) has been noted, the coverage remains suboptimal, with only 66% of sub-county hospitals covered against a target of 100%. Previously, TB diagnostic tools have been rolled out without proper strategic planning leading to over-clustering of TB diagnostic tools and underutilization in some areas while the moderate and hard-to-reach areas remained sub-optimally covered. Availability of few instruments in moderate and hard-to-reach areas and other high volume health facilities would translate to missed TB testing opportunities given that sample referral systems (SRS) is not yet fully optimized in the country.

To accelerate the global TB response, the United Nations General Assembly convened a High-Level meeting on TB in September 2018 where several global targets were endorsed by Heads of States and governments, and country targets set. While Kenya has not met the various UNHLM targets, the Global Plan to End TB 2023-2030 modeling scenarios identify Kenya as a high priority country that could achieve the End TB goals if a comprehensive package of TB interventions is implemented. Through the introducing new tools project (iNTP) Center for Health Solution-Kenya (CHS)-USAID Tuberculosis Accelerated Response and Care activity (TB ARC II) through the United States Agency for International Development (USAID) funded TB ARC II activity, in collaboration with STOP TB (STP) to support Division of National Tuberculosis, Leprosy, and Lung Disease Program (DNTLD-P) to spearhead the implementation of Truenat MTB/RIF assay in 2022. The implementation approach started with a diagnostic spatial analysis to help identify possible candidate health facilities based on population to be served by the facility, the number of other health facilities the candidate can network with, demand for tests, and distances from one molecular test site to the other. This approach was geared towards ensuring equal chance to get a mWRDs across the eligible facilities in the country.

Further, an implementation roadmap was developed, costed, an aligned with DNTLD-P for ease of implementation starting with launch of the project, training of National Program managers, county coordinators, superusers and end-users, installation of the machines, quality assurance measures through PT schemes, data reporting, and technical assistance missions to facilities to monitor implementation. By engaging the national, county, sub-county staff, and implementing partners ensured an all hands approach to rollout of the new TB testing tools.

Activity Description

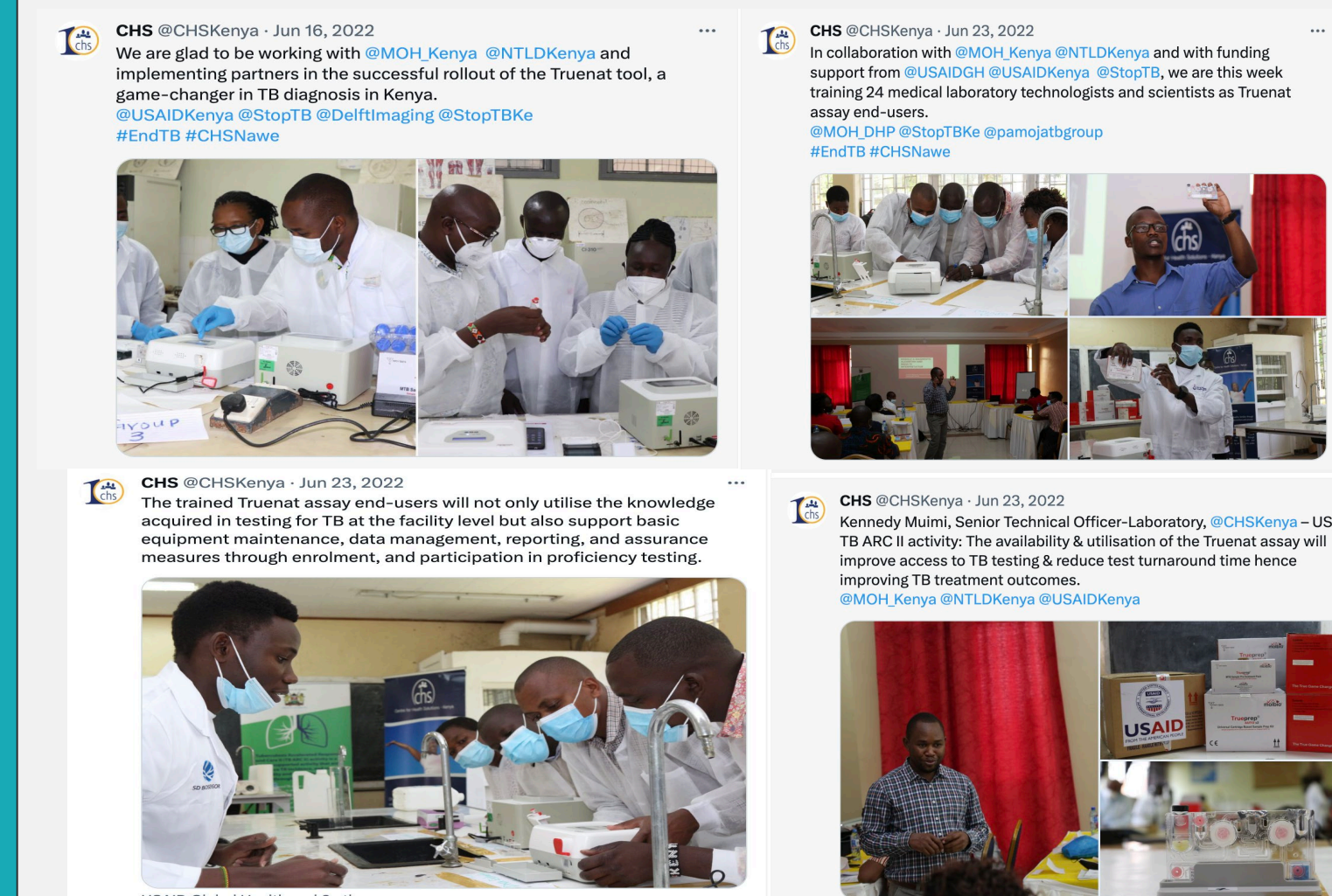
USAID TB ARC II started the implementation of iNTP in 2022 with the critical objective of strengthening health systems towards ending the TB pandemic in the country through equitable distribution of molecular WHO-recommended rapid diagnostic tests (mWRDs) for TB diagnosis.

The Ministry of Health, through DNTLD-P, took the lead in planning and coordination to help design the implementation. The USAID and STP collaborated to fund USAID TB ARC II. The STP ensured the contractual and financial agreements were completed as per the implementation roadmap. The DNTLD-P took the lead in the process to ensure ownership of the project design and implementation towards sustainability at both national and sub-national (county) levels.

The implementation approach started with a National TB diagnostic spatial analysis to help identify possible candidate health facilities targeting 14,000 health facilities in Kenya. The facility selection criteria were based on the population to be served by the facility, the number of other health facilities the candidate can network with, the demand for tests, and distances from one molecular test site to the other, especially sites more than 50 kilometers from the adjacent GeneXpert testing site. This approach was geared towards ensuring an equal chance to get mWRDs across the eligible facilities in the country. The spatial analysis initially prioritized 146 health facilities based on the available resources as per the grant that had only provided 38 Truenat instruments as part of the pilot phase; however, the other facilities assessed are to benefit from the global fund instruments. Through the county laboratory engagement, 80 health facilities were prioritized for capacity assessment. The capacity assessment was done using a Global Laboratory Initiative (GLI) - Stop TB Partnership (GLI) customized tool with additional indicators but not limited to the infrastructure (adequate testing space, benches), human resources, stable power, waste disposal systems and drainage facilities, security, ventilation, and commodity stores. A total of 80 health facilities were assessed, with 60 being ready for equipment support. Recommendations were given to the non-ready sites to work on the gaps identified during the assessment. A prioritization matrix was used based on the criteria and the number of available instruments; 38 facilities were finally selected.

As per the roadmap, the assessment was followed by the official launch of the project and subsequent cascaded Truenat training. The training started by targeting national program officers and partners on the new tools, followed by county staff, sub-county superusers, and end-users from the target facilities. The instruments were installed jointly with Molbio Ltd. Company in-country agent Step-Labs Kenya, county leadership, superusers, partners, and end-users. This approach ensured that all the key stakeholders were engaged in providing ownership at the county level.

The end-users were further sensitized on data collection tools, specifically the Open Data Kit (ODK) tool, to assist data reporting. The data reporting timelines were set at weekly, monthly, and quarterly for the first two quarters and thereafter rescheduled to monthly.



Media posts of the Truenat end-users training.

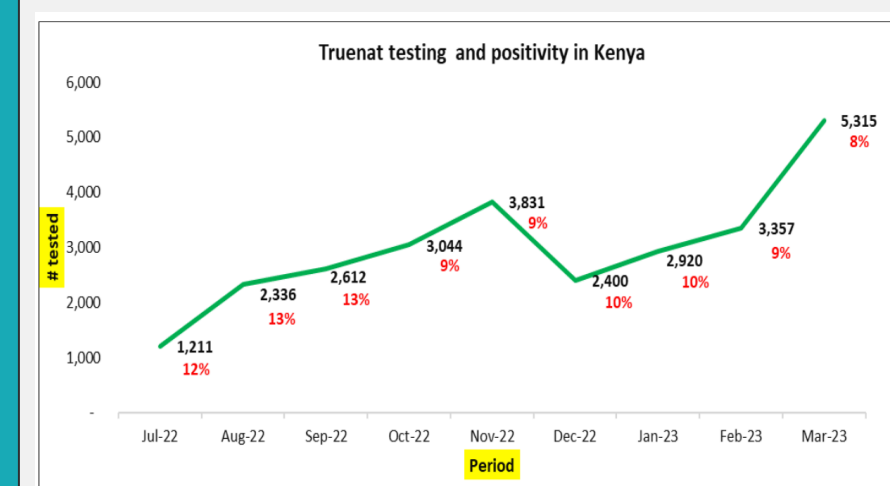
Activity Impact

To address inequities in access to TB diagnostic services among moderate and hard to reach populations, clustered based on Country zoning by the NTP, the USAID introducing new tools project (iNTP) aimed to strengthen access to new WHO recommended rapid diagnostics (Truenat assay) by providing health financing, supporting human resource capacity through training and strengthening leadership and governance by the NTP and County TB coordination structures in 33 of 47 Counties in Kenya. The use of a data driven decision approach at National TB Program level that looked at issues of moderate to hard-to-reach, prevalence, TB case notification indicator performance ensured that only the eligible facilities were supported with instruments for TB testing. Strengthening of local capacity of end-users to correctly and optimally use the Truenat instrument especially in the underserved populations in the moderate and hard-to-reach regions in Kenya:

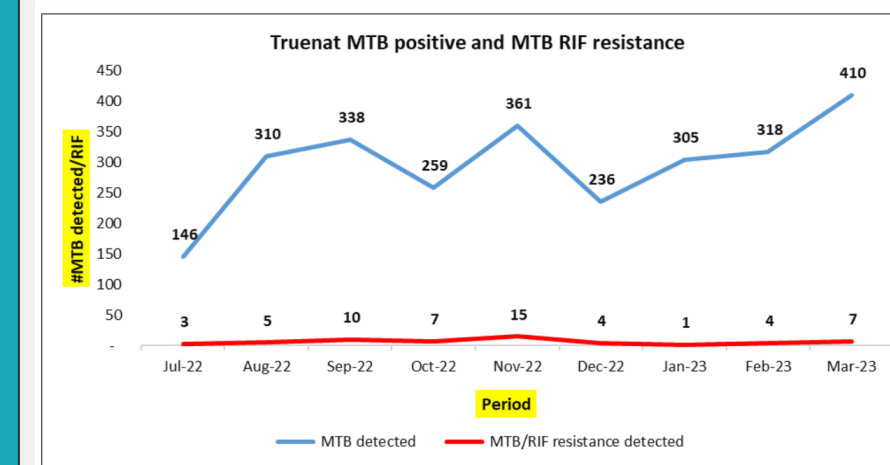
Development of a training package with facilitator guide, participant manuals, training slide deck, standard operating procedures, and job aids available to enhance capacity building for key stakeholders developed jointly with Stop TB Partnership, Infectious Disease Detection and Surveillance, and USAID. 33 counties with human resource capacity build (County Medical Laboratory Coordinators (CMLCs), 33 Truenat Superusers, and 76 Truenat end-users) to spearhead implementation of Truenat, offer sample testing for testing to improve TB case finding.

Following the rollout of Truenat in Kenya a total of the 27,026 Truenat MTB Plus tests have been conducted resulting in the 2,683 MTB-positive cases between the period July 2022 and March 2023 with 56 Rifampicin Cases identified and treatment started.

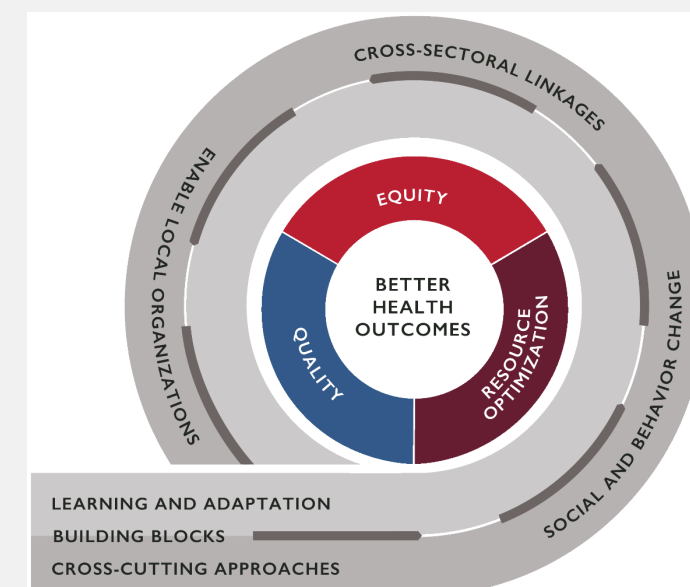
Through the iNTP that provided new TB screening tools like digital chest X-ray with computer aided detection, this has led to rational use of molecular test cartridges by reducing the number needed to test to identify a TB case in 8 facilities in Kenya.



Increase in Truenat testing trend with a dip in December 2022, and catch-up utilization January 2023 following series of demand creation initiatives jointly between USAID TB



Increase in number of MTB positive cases and Rifampicin resistance between July 2022 and 2023 following Truenat implementation through



Evidence

Between June 2022 and March 2023, 27,026 Truenat MTB Plus tests were conducted, resulting in the detection of 2,683 MTB-positive samples, with a positivity rate of 10%. Rifampicin resistance was identified in 56/2,683 (2%) of these samples. Furthermore, the implementation of Truenat testing led to a significant increase in the proportion of newly diagnosed people with TB who received a rapid molecular test as an initial diagnostic, rising from 27% in 2021 Q4 (prior to Truenat implementation) to 55% in 2022 Q4 (Refer Fig 3 below). The number of pulmonary cases notified in all the sites implementing Truenat averagely increased by 20% comparing before (2021 Q4) and during (2022 Q4) Truenat implementation (Refer Fig 4 below).

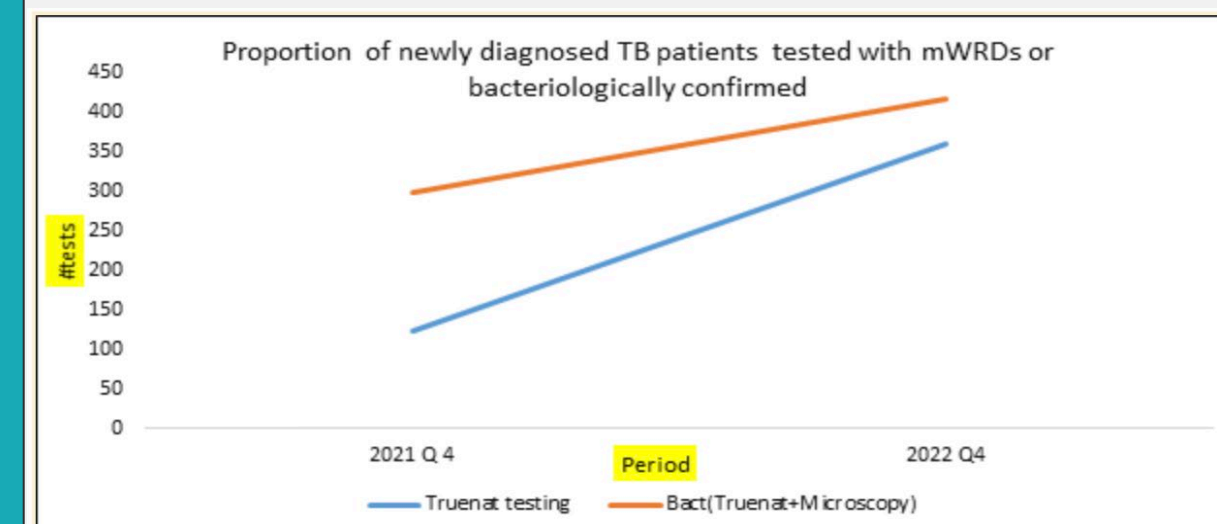


Figure 4: Increases in the proportions of newly diagnosed people with TB that were bacteriologically confirmed and that were tested with a rapid molecular test as an initial diagnostic test, comparing before (2021 Q4) and during (2022 Q4) Truenat implementation



Figure 6: Acknowledgment by Kenya's Ministry of Health on the expected positive impact of introducing New Tools Project; Truenat machine included towards ending TB in Kenya.

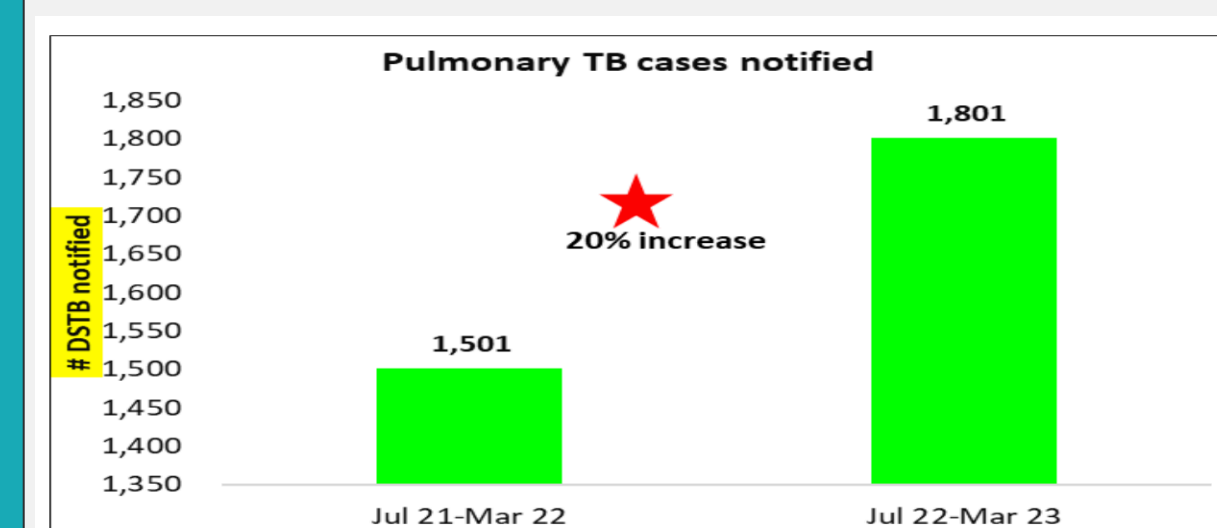


Figure 5: Increases in the number of pulmonary TB cases notified compared before (2021 Q4) and during (2022 Q4) Truenat implementation.



Figure 7: A highlight on a national TV station on the effective utilisation of the Truenat machine in TB diagnosis in Kenya. Click the link below to access the video; <https://www.youtube.com/watch?v=WKvDNpSiQhg>

Facilitators

- The iNTP secretariat coordination desk that involved donors, NTP, implementing partners and the stop TB partnership among other stakeholders
- The technical support from the USAID that ensured spatial analysis was done as part of the Truenat MTB/RIF assay candidate health facilities identification process to ensure equity in the entire process
- The meaningful engagement and collaboration with different key health sector players like implementing partners, community health groups like TB champions made it possible to generate co-created strategies to strengthen approach towards demand creation following installation of the machines
- The availability of training package within the GLI a Stop TB Partnership initiative made the training process easy and reproducible across the many training sessions that were conducted targeting different groups
- The availability of TB screening diagnostic algorithm for children ≥10 and adults with molecular diagnosis as the recommended initial test for TB diagnosis made onboarding this platform easier
- Availability of a National TB surveillance system that is led by the National TB program made it easy to work with counties towards implementation, rollout, and institutionalization of the platform
- County and Implementing Partner support that ensured remapping and redesigning of the county sample referral networks to accommodate the new molecular diagnostic tool in the interest of connecting other peripheral facilities to the diagnostic network
- Technical support from within USAID TB ARC II and DNTLD-P that ensured real-time resolution of implementation gaps especially on equipment downtime and technical related issues raised through the county superusers
- Support from TB champions and mobilizers to create demand through different platforms that ensured seamless ownership by communities leading to patient referral for testing

Challenges

- In the initial phase of Truenat assay site identification, the site capacity assessment noted infrastructure gaps for the facilities that required light lifting renovations to ensure the sites are ready for machine installations. This led to advocacy for resources to help fix the identified gaps by the hospital administration in readiness for support; however, unavailability of budgets to support was a major setback. Advocacy through the hospital management was key in providing the required budget to fix the gaps however, unavailability of budgets for renovations especially for laboratories was a major setback and hindrance to some of the facilities.
- Secondly, the revamping of the Kenya data connectivity solution Tibulims that ensures results are sent out immediately a test is completed via Email and SMS took longer than expected. The delay consequently affected results relay back to the clinicians; however, the sample rider system helped address the gap before the solution could be finalized and rolled out for use by all the facilities.
- During the initial phase of implementation just after the end-user training and machine installations, sample preparation procedures were still a major gap that led to high invalid tests outcomes, error rates and to misuse of buffers. This led to mobilization of resources for a refresher training to avert

Lessons Learned

The iNTP implementation process, especially rollout of Truenat platform has been a key learning experience for USAID TB ARC II. The entire process taught us the importance of stakeholder engagement in implementation of new tools projects especially in Kenya where the health system is evolved. Meaningful engagement with all the key stakeholders proved useful towards successful implementation of all the set activities within the implementation plan. The success of projects heavily rely on the prior entry process to the Ministry of Health by ensuring the partners roles and responsibilities are clearly defined, ministries expectations, roles and responsibilities well outlined, and clear reporting channels about the project documented. Availability of flexible financial obligations during the initial phase of implementation is necessary to ensure new and emerging needs are supported for ease of implementation.

Other lessons learned include:

- The use of a Diagnostic Network Optimization (Spatial analysis) in site identification for new TB tools followed by site level capacity assessment is critical to ensure equity in instrument distribution, diagnostic network expansion, and strengthening in line with END TB strategy that stresses on patient centered care.
- Use of digital chest X-ray with computer aided detection software to screen presumptive patients helps rational use of the cartridges for molecular testing by reducing the number needed to test to identify one TB case.
- Training of Truenat Superusers and End-Users prior equipment installation has proved helpful in knowledge transfer especially on testing procedures, results interpretation and troubleshooting.
- Use of Superusers as county leads to support Truenat rollout in the country has been key in site level mentorships, addressing gaps, Proficiency test management, and data reporting to national level especially before Tibulims rollout in the country.
- Thorough 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.
- Sample referral networks redesigning and remapping are a pivotal part in increasing demand for testing by ensuring the nearby health facilities are linked and supported to ensure samples are tested and results relayed back.
- Given that Truenat has inbuilt batteries, this has proved useful in ensuring continued testing during power outage thus avoiding waste of cartridges in the testing facilities.
- The use of a local connectivity solution (Tibulims) for dispatch of results to clinicians via Email and SMS has helped to bridge the gap on laboratory-clinic interface and ensure prompt availability of results to clinicians and initiation of TB treatment.
- Timely support and provision of a national Proficiency Test (PT) scheme for new molecular tools during the onset of implementation is useful to help identify critical gaps and opportunities for mentorship.
- Availability and utility of services from a local agent with requisite capacity to support training, troubleshooting, and maintenance of machines has been helpful in addressing the machine related issues from the testing facilities.