LabCoP Cookbook

of best practices

Governance
Planning
Synergy
Training
Demand Creation
Quality
Maintenance

Lab CoP

AS LM

ACKNOWLEDGEMENTS

Tuberculosis (TB) remains a major public health challenge and a leading cause of death by an infectious disease.[1] The World Health Organization (WHO) has set targets to reduce TB deaths by 90% and to cut new TB cases by 80% between 2015 and 2030 as part of the United Nations Sustainable Development Goals.[2] Considerable progress has been made toward the set targets; however, the coronavirus disease 2019 (COVID-19) pandemic has unfortunately reversed years of progress in providing essential TB services.[3, 4] This was evident especially in high-burden TB countries, which were disproportionately affected by the impact that the COVID-19 pandemic had on health systems and disease rates.[3, 4] Global statistics on the number of people newly diagnosed with TB decreased from 7.1 million in 2019 to 5.8 million in 2020, an 18% decline back to the level of diagnosis in 2012.[5]
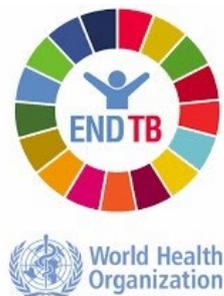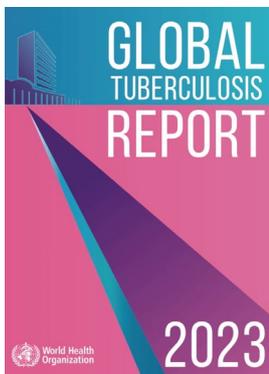
According to the *WHO's Global Tuberculosis Report 2023*, an estimated 10.6 million persons fell ill with TB globally in 2022, of which only 7.5 million were diagnosed, and 1.3 million died from the disease.[1] Improving case detection to find the 'missing' cases is one of the biggest priorities for controlling the disease. Testing is central to controlling TB. As per WHO recommendations, major efforts are needed to expand access to rapid diagnostic tools and universal drug-resistance detection[6] to achieve the global targets of the End TB Strategy.[2, 7]

Despite advances in developing rapid molecular diagnostic technology over the last decade, only 47% of the 7.5 million cases notified in 2022 received a WHO-recommended rapid diagnostic (WRD) test as an initial test.[1] Rapid molecular testing for TB remains out of reach in many high TB-burden areas, especially at the lower tier of the healthcare pyramid, mostly due to lack of testing capacity, human resource expertise and access to electrical power for the few available devices.[8, 9]

The Truenat® MTB-RIF Dx TB testing system (Molbio Diagnostics, Goa, India) is a chip-based, rapid molecular test for detection of TB and rifampicin resistance. The test is conducted on a portable system, consisting of a Trueprep® device (Molbio Diagnostics, Goa, India) for DNA extraction and a Truelab® PCR analyser (Molbio Diagnostics, Goa, India). This system is designed to withstand high temperatures and can operate independently for up to eight hours on its power supply. In contrast to the GeneXpert® (Danaher Corporation, Washington, D.C., United States) system, also recommended by WHO for the initial diagnosis of TB and drug resistance,[6] the Truenat system provides an opportunity to expand access to rapid molecular testing for TB in decentralised settings.

In Africa, iNTP is supporting rollout of the latest innovations in diagnostics, treatment and digital health technologies in high TB-burden countries.[10] The project is a collaboration between the Stop TB Partnership and USAID, which aims to help countries reach ambitious targets for the detection and treatment of TB, drug-resistant TB and TB infection. In the scope of this project, Truenat instruments and tests have been provided to five African countries (Nigeria, Zimbabwe, Democratic Republic of the Congo [DRC], Uganda and Kenya) for early adoption and rollout.

In this LabCoP Recipe, we highlight key considerations and best practices from the five countries that have implemented the Truenat system as a case scenario that can inform the broader and decentralised use of molecular diagnostic tools for TB across the continent.

Source: USAID's Infectious Disease Detection and Surveillance (IDDS) project

Key to introducing the Truenat testing system for initial diagnosis of TB is seeking the input and guidance of the national laboratory governance entity within the country's ministry of health, such as a national TB programme (NTP) and/or a national TB reference laboratory. This is important to ensure strategic coordination, planning for Truenat implementation and the development of a costed operational plan with timelines and milestones. While the regulatory requirements for the introduction of the Truenat system will vary between countries, regulations would in general need to comply with relevant regulations related to medical devices, diagnostic testing and data privacy.

COVID-19 Laboratory Pillar, Uganda

KEY CONSIDERATIONS

- **Meeting country regulatory requirements.** Country regulatory approval processes are required to guarantee the safety and quality of new diagnostic technologies prior to their introduction. Priority should be given to expediting approval for rapid molecular diagnostic tools like Truenat that have the potential to substantially broaden access to testing and allow prompt treatment initiation for TB patients.

- **Aligning with existing global policy and guidelines.**
  To avoid slowing down approval and subsequent introduction of new molecular WRDs (mWRDs) for TB, such as Truenat, the NTP and/or the national TB reference laboratory need ensure that the national TB diagnostic algorithm is aligned with existing guidelines requiring the use of an mWRD for TB as the initial test for all patients with presumptive TB. Additionally, the NTP and/or national TB reference laboratory need to ensure this is applied in all healthcare facilities nationally, as laid out in the WHO guidelines on rapid diagnostics for TB detection.[5, 6] Particular attention should be paid to WHO recommendations about the use and the limitations of the test in adults and children and how to interpret test results. In addition, practical guidance, such as the Truenat implementation guide developed by the Stop TB Partnership, USAID and Global Laboratory Initiative (GLI), can inform the planning phase of Truenat introduction.[11]

- **Maximising synergies and collaborations with other disease programmes.** Based on lessons learnt from COVID-19 testing expansion and integration, countries can put in place a task force or laboratory pillar to coordinate the rollout of the new technology and integration across disease programmes. The laboratory pillar would also be able to improve engagement with the private sector and involve key stakeholders from different sectors during implementation.

- **Managing health information.** Health information management tools such as test requisition forms, TB laboratory or clinical registers, etc. need to be updated to account for the specificities of the test and to ensure essential information (patient and test data) are accessible to guide decision making by clinicians and for reporting to the NTP. Consideration should also be given to ensuring connectivity and interoperability between the Truenat system and the electronic laboratory management information system, as well as with the electronic national health information management system, to establish pathways for easy data flow and improve linkage to care. More information is available in the GLI guide to connectivity solutions for TB diagnostics.[12]

BEST PRACTICES

- **Ensure high-level engagement with ministries of health, partners and stakeholders.** In Nigeria, engagement between the director of the NTP and implementing partners such as the Institute of Human Virology Nigeria, KNCV Nigeria, the Stop TB Partnership, USAID and civil society actors was critical to ensure full endorsement of the Truenat system by the Nigerian Ministry of Health and key partners. This began with a stakeholder meeting between the TB programme leadership, technical teams at the national and sub-national levels, funding agencies and implementing partners.[13] This allowed alignment on the project and implementation from the start.[13]

Nigeria NTP engaging with stakeholders in Truenat adoption process

Launch of Truenat in Kenya. Source: Centre for Health Solutions – Kenya.

- **Implement a stepwise national implementation strategy.** Under the leadership of the country's ministry of health, national TB programmes should develop a national roadmap for expanding TB molecular diagnostics, considering priorities and gaps in the National Laboratory or TB Laboratory Strategic Plans. In Nigeria, stakeholders collaborated to develop a joint stepwise national implementation strategy, which outlined plans for stakeholder engagement, integration of Truenat into the national TB diagnostic policy, site preparation, training on Truenat and installation of the devices, and mentorship and supervision.

- **Facilitate tax exemption for essential diagnostic tools.** In Kenya, the Ministry of Health, through its drug regulatory authority, the Pharmacy and Poison Board, was able to facilitate tax-free importation of Truenat instruments and kits. Countries should work closely with the manufacturer and its authorised distributors to outline importation and registration requirements. It is advisable that these steps be taken prior to or concurrently with placing orders to minimise delays in the importation process. and supervision.

- **Ensure clinical validity.** The platform should undergo clinical validation to demonstrate its accuracy, reliability, reproducibility and precision in delivering diagnostic results within the local settings. Prior to the rollout of Truenat, the National TB Reference Laboratory in Kenya conducted a verification study. Depending on national regulatory requirements, it is important to note that countries do not need to undertake complex validation studies, as the performance of the Truenat system was determined through a *large multi-country trial* conducted by FIND, which informed the WHO recommendation.[14]

Integration of new testing instruments within the existing TB diagnostic network is crucial to ensure their effective use for improving the detection of TB cases and prompt treatment initiation. Placement of new TB mWRDs should aim to provide equitable access to diagnostic services for all TB patients. This requires consideration of national targets for expanding patient access to rapid testing in view of infrastructure requirements, specimen transport systems, availability of chest X-ray as a screening test as per national guidelines, linkages to treatment, site connectivity and the possibility of integrating TB testing with testing for other diseases. In the case of molecular devices like the Truenat system that can be used at or near the point of care, careful consideration of their optimal distribution in decentralised settings, where most patients seek healthcare services, will contribute to improved public health outcomes.

Source: IDDS

KEY CONSIDERATIONS

- **Identifying gaps in the diagnostic network.** When considering the placement of new TB mWRDs, priority should be given to closing gaps within the existing laboratory network. A national registry of geo-located information about existing network capacity, such as that established through the ASLM Laboratory Mapping Program (*LabMaP*), which enables data collection on a comprehensive set of parameters (test menu, equipment, workforce, etc.), can effectively inform this prioritisation process.

- **Evidence-based instrument placement.** A situational analysis of the diagnostic network can provide further evidence to guide the placement of new TB mWRDs to achieve greater access to services, while considering existing assets and resource constraints.

  ○ The TB Diagnostic Network Assessment (*TB-DNA)* is a country-driven assessment process developed with the support of USAID, that allows a holistic review of the diagnostic network and supportive systems (governance, human resources, infrastructure, etc.) to establish capacities, identify challenges and bottlenecks, and propose evidence-based interventions to improve the overall ability to meet the targets of national TB strategic plans and the End TB Strategy.

  ○ *Diagnostic network optimisation* is a geospatial analysis of the current diagnostic network, visualizes potential network designs and recommends the optimal type, number and location of testing instruments and an associated sample referral networks to expand access to diagnostic services and optimize overall efficiencies.[15]

- **Test site requirements.** Truenat is a low complexity TB mWRD suitable for facilities at the lower tiers of the network (i.e., ideal for positioning at the microscopy centre level, including peripheral health centres or mobile vans). However, a minimal set of requirements should be met pertaining to power, biosafety, waste management, temperature, etc., as specified in the *Practical Guide to Implementation of Truenat Tests*, developed by Stop TB Partnership, USAID and GLI, and the *GLI TB Laboratory Safety Handbook*.[11, 16]
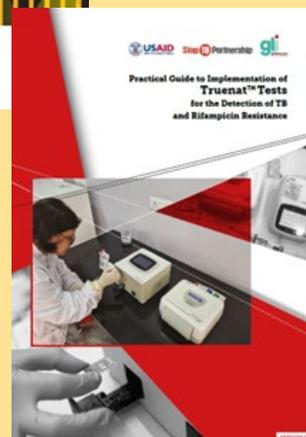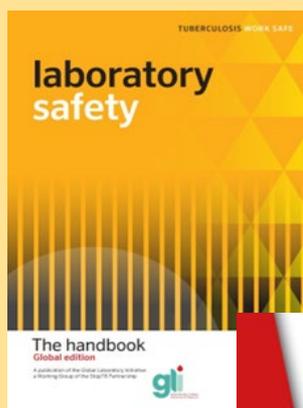
BEST PRACTICES

- **Use evidence to guide placement of Truenat platforms.** Early Truenat-implementing countries in Africa each conducted a form of situational analysis to inform the placement of their devices.

  - Prior to implementation, Zimbabwe conducted a laboratory spatial analysis (assessing testing coverage, population density, laboratory data from geographic information systems) to determine the best location for the devices to expand access. Subsequently, 20 Truenat Duo machines were installed at the peripheral level where TB mWRDs (such as GeneXpert) were not available and the testing volumes were low.

  - In Kenya, an analysis was based on access to existing TB mWRDs, with 38 Truenat instruments installed at the peripheral level and located > 50 km from GeneXpert sites.

  - Nigeria opted to complement their existing GeneXpert network by positioning Truenat instruments in regions that lacked access to mWRDs and had poor electricity coverage.

- **Leverage active case-finding modalities.** In Nigeria, access was further expanded through active case-finding campaigns, where Truenat machines were installed in mobile diagnostic units and vans used for active case-finding campaigns.

Mobile diagnostic unit deployed to communities for quick TB screening and diagnosis in Nigeria

- **Conduct pre-installation site assessments and renovations.** Since Truenat instruments are placed primarily in peripheral facilities, a pre-installation assessment of identified prospective testing sites to determine whether the existing infrastructure can support Truenat testing is recommended. Many of the countries used the checklist from the Stop TB Partnership / USAID / GLI Practical Guide to Implementation of Truenat Tests[11] to assess various criteria such as availability of adequate testing and storage space, staffing, waste disposal systems and drainage facilities.

To maximize clinical and public health outcomes when introducing a new TB mWRD as the initial test for individuals with presumptive TB, it is crucial to strengthen the laboratory and clinical interface to ensure that: 1) a request for testing is placed as required per the (updated) national TB testing algorithm and 2) the test result is used to inform patient management, allowing prompt and appropriate treatment initiation, if drug resistance is detected.

A standardized curriculum from the ministry of health and/or NTP should be developed that addresses all the relevant parts of the diagnostic cascade, from the selection of people to be tested, and collection and transport of quality samples, to the technical requirements of the laboratory technology, to the reporting of test results to the clinician and their proper interpretation. Accordingly, all cadres of personnel, including laboratorians, nurses, clinicians, and other healthcare workers involved in the diagnostic cascade should be targeted by and included in the national training curriculum.


KEY CONSIDERATIONS

- **Personnel requirements.** Both clinical and laboratory staff involved in the utilisation of a new TB mWRD should be provided with in-service training when introducing the test. Because the Truenat test can be decentralized to the lower levels of the health system, the cadre of staff involved in performing the test (i.e., Truenat 'end users') as part of task shifting or sharing modalities may involve individuals with no formal education. It is accordingly important that training programmes be complemented by competency assessments, routine onsite supervisory visits and/or ad-hoc virtual support by advanced users to monitor performance and provide regular monitoring of quality indicators (broken down by operator). These aspects are discussed in more details under the quality section of this document.

- **Guidelines around ordering TB tests.** Clinical staff involved in the diagnosis and management of patients must be sensitised on updated testing algorithms that incorporate Truenat TB testing and new protocols and procedures prior to use of the Truenat TB test with clinical samples. Special consideration should also be given to who can order a TB test using a TB mWRD. This is particularly important for devices like Truenat that are deployed at lower levels of the health system, as there may not be a medical officer present at certain facilities to place a request for testing.

- **Ensuring continuity of testing services.** To account for absences or high turnover, training of staff involved in testing (or end users) at each laboratory should be provided as a cascade or continuous programme to ensure continuity of operations and sufficient testing coverage.

BEST PRACTICES

- **Develop training materials.**
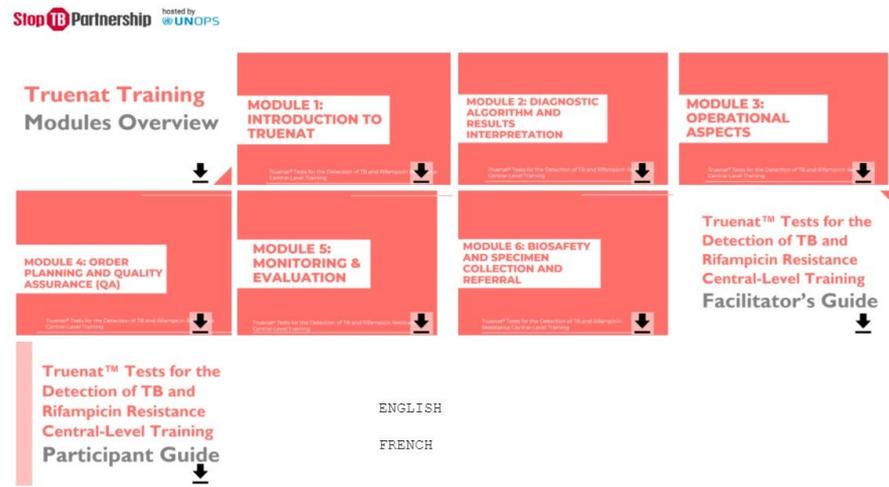
Source: STOP TB Partnership

A comprehensive set of training materials, standardised procedures, including clinical protocols, and guidelines have been developed by the iNTP team around Truenat testing. These provide guidance on the selection of patients to be tested, ordering tests, interpreting test results and making patient care decisions. Early implementing countries have adapted the *training curriculum developed by the Stop TB Partnership*, USAID, the USAID-supported Infectious Disease Detection and Surveillance (IDDS) Project and GLI to their local context to support test introduction and scale up.

- **Sensitise all healthcare worker cadres.** Healthcare workers at the different levels of the health system were sensitised on TB mWRDs and the national TB programme to improve awareness and uptake of the Truenat test. In Nigeria and Kenya healthcare workers were trained on the updated national TB diagnostic algorithm with a special emphasis on the role and utility of the Truenat test. In Kenya, clinician training was done in parallel with the training of laboratory staff to ensure that everyone involved in the screening and care of TB patients understood the benefits and limitations of the Truenat TB test.

Training of superusers on Truenat testing in Nakuru, Kenya. Dr Maurice Maina USAID Kenya, and East Africa engages participants

Source: Truenat training in Nakuru Kenya

Training of superusers in DRC through the support of USAID IDDS project. Source: PNLT-RDC.

- **Plan for anticipated staff turnover.** Truenat end user staff trained at each laboratory were responsible for training other staff from their facility. For example, in Zimbabwe, Kenya and DRC, more than one laboratory technician or microscopist was trained from each of the selected testing sites. Refresher training sessions are being provided periodically to ensure laboratory technicians maintain competency. For example, in Zimbabwe refresher training is provided every 6 months. End user refresher training was also completed in Uganda and Kenya.

- **Implement training of trainers.** The USAID-supported IDDS project developed a Truenat 'super-user' training-of-trainers package that was first piloted in Zimbabwe and later expanded to DRC, Kenya and Uganda. 'Super-users' are individuals particularly experienced with the Truenat system who are tasked with cascading training sub-nationally at lower tiers of the laboratory network, and to assist Truenat end users to solve routine technical problems when performing the test.[16]

Community engagement and demand creation are crucial mechanisms for expanding access to TB diagnostic services. These strategies aim to raise awareness about TB, educate the public on its symptoms, how to access diagnostic services and create demand for TB testing and treatment among those who may not otherwise seek care. Effective community engagement and demand creation initiatives can help overcome barriers to accessing TB diagnostic services, such as stigma, lack of knowledge about the disease and lack of trust in the healthcare system. Involving community members in the design and implementation of TB diagnostic services can increase understanding of and trust in the new mWRDs and therefore increase the demand for access and use.

Community engagement to improve TB services in Zimbabwe. Source: EGPAF-Zimbabwe/ZNNP+.

KEY CONSIDERATIONS

• **Providing accurate information.** Timely provision of accurate information is crucial to generate demand for testing. Consideration should be given to ensuring adequate understanding of the advantages and/or benefits of newly introduced TB mWRDs to increase acceptability among healthcare providers, communities and individuals who should be accessing the new diagnostic tool.

• **Preparing for test demand surge.** Various approaches for demand creation may result in a surge in the number of tests. Countries need to consider methods to monitor an increase in the number of tests at the testing sites and put in place mitigation measures such as replacing low throughput devices with high throughput devices.

Targeted active case-finding in the DRC. Source: HPP-Congo/STOP TB Partnership.

BEST PRACTICES

• **Raise awareness among key stakeholders.** In Nigeria, Kenya and DRC, the handover of the Truenat machines was widely publicised on national media and among key stakeholders. WHO recommendations on Truenat, as well as information on all the national regulatory checks that Truenat had undergone, was amply shared with stakeholders. In Nigeria, the national TB programme leadership, and national and sub-national technical teams ensured early engagement with local stakeholders, community leaders and facility managers so they could fully understand the new technology and associated benefits. In Zimbabwe, specimen collection workshops involving both local healthcare workers and communities were conducted to increase awareness and create demand.[16]

• **Involve communities in the design of TB diagnostic services.** In Nigeria, following pre-installation site assessments, local communities were involved in the refurbishment of the sites and procurement of some support equipment.[17]

• **Leverage community outreach programmes.** To improve utilization of Truenat tests, in Nigeria, Truenat machines were installed in mobile diagnostic units and vans, and used in conjunction with ultraportable digital X-ray systems for active case finding in hard-to-reach communities.[17]

Ensuring the quality of TB diagnostic services is crucial for accurate and timely detection of cases, prompt and appropriate treatment initiation, improved patient outcomes and reduced disease transmission in communities. Failure to deliver quality-assured mWRD test results can result in either under-diagnosis of TB, leading to sustained disease spread in communities, or overdiagnosis of TB, leading to unnecessary patient treatment and stigma. Quality assurance is an essential part of implementing a new TB mWRD, and implementation of quality management systems is vital to validate the competency of diagnostic services.

Technicians in DRC going through Truenat test instructions. Source: IDDS.

Source: Centre for Health Solutions – Kenya

KEY CONSIDERATIONS

- **Implementing a quality management system.**
  A functioning quality management system should be implemented at testing sites, including those decentralized at the primary healthcare level, to ensure they meet minimum essential quality standards and can provide accurate, reliable and timely diagnostic services. The *Practical Manual on Tuberculosis Laboratory Strengthening* (2022 update) developed by WHO and GLI can be referred to for guidance around these points.[18] The manual includes guidance on training and competence assessments, instrument verification, equipment maintenance, quality control processes, external quality assessments (EQA) and quality indicator monitoring and continuous quality improvement.

Practical manual on tuberculosis laboratory strengthening
2022 update

gli   World Health Organization

KEY CONSIDERATIONS (Cont.)

- **Quality assurance.** Quality assurance includes all activities undertaken along the diagnostic cascade, from the pre-analytical to the analytical and post-analytical phases, to ensure the accuracy and reliability of test results. Quality assurance is important to continuously improve the reliability and efficiency of testing services. Laboratories involved in providing TB mWRD testing should implement three main components of quality assurance, namely:[19]

  - **Quality control.** Quality control allows the laboratory to demonstrate that the test is functioning properly and can produce an accurate result. It includes using internal controls to detect, evaluate and correct errors due to test system failure, environmental conditions, or operator performance. It provides a means to detect carry-over contamination by nucleic acids, when it occurs, or to verify new lots of reagents.

  - **Quality assurance.** EQA includes processes that allow the evaluation of testing site performance, competency of TB mWRD end users, and accuracy of the results. Unacceptable EQA results should be followed up with corrective actions.

  - **Quality improvement.** Quality improvement involves the continuous monitoring of laboratories through test data collection and analysis to identify issues and provide remedial and preventative actions to improve quality, anticipating problems before they occur.
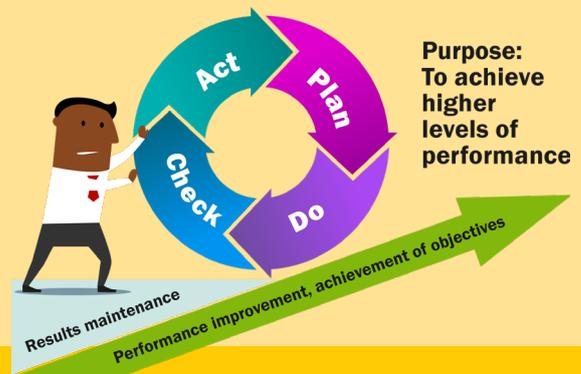

BEST PRACTICES

- **Implement quality control measures.**

  - **Run internal quality controls.** Molbio recommends periodically running internal positive and negative controls (which can be purchased from the manufacturer as part of the Truenat® Positive Control Kit - Panel I). Data on the quality controls should be recorded and reviewed on a regular basis by the individual laboratories and super-users.

  - **Monitor environmental contamination.** Regular swab testing, whereby surface areas around and on the Truenat system (Truelab and Trueprep devices) are sampled with a sterile swab, can also allow the detection of any DNA or amplicon contamination within the work environment.

  - **Verify reagents.** Internal positive and negative controls can also be used for lot-to-lot verification to assess the performance of reagents when new lots are received and as required, i.e., if the temperature of storage areas falls outside of the recommended ranges.[20]

Source: Molbio Diagnostics
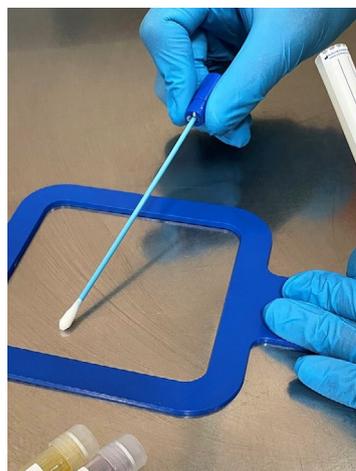
Source: KairoSafe

Source: Zimbabwe

- **Establish an external quality assessment programme.** Various modalities can be established to implement an EQA programme and monitor the performance of testing sites and competency of Truenat end users as detailed below:

Source: SmartSpot

Source: Truenat TA mentorship in collaboration with NTP, USAID HQ, and USAID Kenya Mission, USAID TB ARC II

- ○ **Proficiency testing-based EQA.**
  Proficiency testing providers for the Truenat TB assay are still limited. At present, *SmartSpot Quality Pty Ltd* is the only available ISO/IEC 17043:2010-accredited proficiency testing provider in Africa.
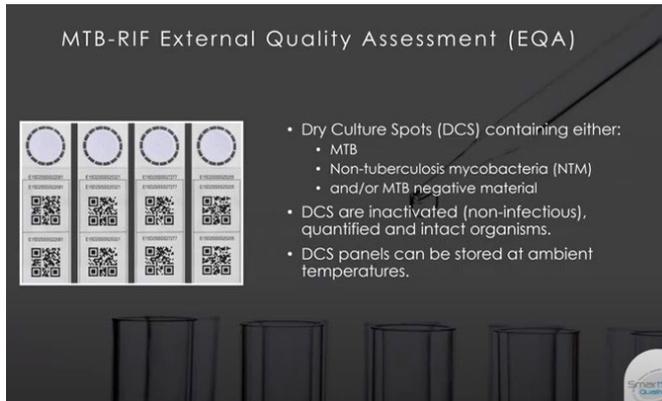
  The SmartSpot *proficiency testing panel* includes four dry culture spots (per site), which are provided three times a year.

  Zimbabwe and DRC have enrolled all their Truenat testing sites in the SmartSpot EQA programme. Stakeholders were also debriefed after each EQA cycle. In Zimbabwe and DRC, root cause analysis was performed, and corrective actions were implemented for sites that failed the proficiency testing programme. Uganda's national TB reference laboratory has developed a *proficiency testing scheme based on dried tube specimens* for Truenat, which will be added on the scope of their existing ISO 17043 accreditation, providing a local EQA solution for all testing sites in the country.

- ○ **Retesting-based EQA.** This can be implemented through interlaboratory comparison, whereby samples that have been tested at one laboratory are retested at another laboratory. This EQA programme modality should be implemented by the national reference laboratory and/or higher-tier (i.e., regional) laboratories.

- ○ **Onsite evaluation-based EQA.** A routine visit schedule of the national or regional reference laboratory (at least annually, but preferably every three to six months) provides experienced subject matter experts the opportunity to observe and assess the quality management systems across the three phases of testing (pre-analytical, analytical and post analytical). Nigeria, Kenya, DRC and Zimbabwe have introduced regular supportive supervision and mentorship process visits to the testing sites.

- **Define and monitor quality indicators.** Performance indicators for the Truenat TB test should be documented and analysed for trends as set out in the *Practical Guide to Implementing a Quality Assurance System for Xpert MTB/RIF Testing*.[19] Kenya and Zimbabwe included periodical virtual meetings with testing sites to review and discuss performance and challenges at the sites. In addition, all countries also created WhatsApp groups on Truenat implementation, where prompt technical advice and support were provided to the sites via Truenat 'super-users'. Sites with consistently high error rates or challenges were identified, and supportive visits were organised for root cause analysis and implementation of corrective actions.

Equipment maintenance is essential for ensuring the reliability and quality of TB diagnostic services. Inaccurate test results due to malfunctioning equipment can lead to misdiagnosis and inappropriate treatment, putting patients at risk and contributing to the spread of the disease. Regular maintenance also extends the lifespan of equipment, reducing the need for costly replacements, and helps maintain the integrity of test results over time.

KEY CONSIDERATIONS

- **Equipment management programmes.** Equipment management is one of the essential elements of a quality management system, necessary to ensure accurate, reliable and timely testing. A good equipment management programme will contribute to fewer breakdowns and failures in well-maintained instruments, longer instrument life and reduced interruption of services.[21]

- **Customer and technical support.** Agreements should be in place with manufacturers to ensure availability of customer and technical support for when introducing a new TB mWRD. Importantly, countries planning to implement Truenat should inform the manufacturer in advance to allow them to plan as needed for expansion of their network of service providers, so countries have access to representatives of the manufacturer for onsite and remote support for installation of new equipment and troubleshooting when needed.due to test system failure, environmental conditions, or operator performance. It provides a means to detect carry-over contamination by nucleic acids, when it occurs, or to verify new lots of reagents.

- **Setting up back-up power sources.** The Truenat system includes built-in batteries that allow testing without power for up to 8 hours; however, devices will not allow a cycle to start if battery power is too low. Therefore, access to power is still required to charge batteries (4 hours for the micro PCR Analyzers, 9 to 10 hours for the Trueprep device and 4 to 6 hours for the micro printer).[11] Furthermore, the Truenat system and associated printers are prone to electricity surge damage and can be adversely affected, if installed in a location where the power supply is unstable.

BEST PRACTICES

- **Provide equipment maintenance training.** Countries should consider refresher training of the laboratory technicians on the basics of quality management systems, including equipment maintenance, and plan for service and preventive maintenance of Truenat equipment. In Nigeria, Kenya, DRC, Uganda and Zimbabwe, testing sites were provided with standardised preventive maintenance logs, which are periodically checked by super-users during site visits. In Zimbabwe, DRC and Kenya, locally authorised service providers, alongside super-users, installed the Truenat instruments at the target sites. During these visits, onsite training was further provided to ensure that technicians were competent to perform maintenance on Truenat machines.

- **Provide peer-to-peer support fora.** In Zimbabwe, a WhatsApp group including Truenat end users was created to enable sharing challenges and best practices for troubleshooting among peers.[17] Super-users are also essential to provide remote support and technical assistance through WhatsApp group communications between visits, so errors that are encountered can be rapidly troubleshot and solved to reduce equipment downtime. This approach was applied successfully in DRC to minimise interruptions in service.
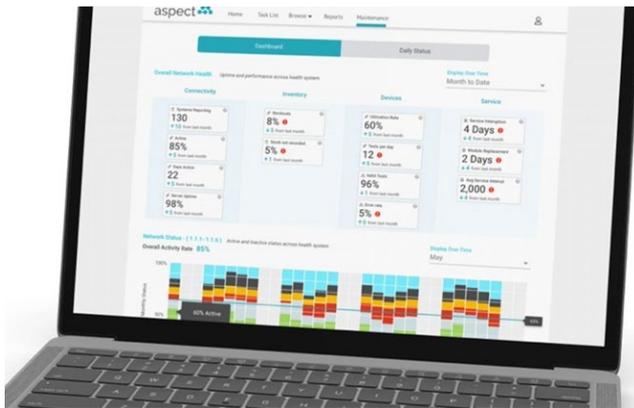
Aspect Software. Source: SystemOne.

LabXpert DS diagnostic connectivity solution. Source: MedX.

- **Implement remote monitoring.** Remote and real-time monitoring of instrument performance through diagnostic connectivity solutions can facilitate prompt diagnosis and troubleshooting of issues related either to the end user or the testing device. IDDS has engaged a private software company, *SystemOne*, to provide a connectivity solution in Truenat early implementing countries to enable remote monitoring by Truenat super-users in Zimbabwe, whereas Uganda and Kenya are working towards the development of customised local connectivity solutions with the *LabXpert* and *Tibulims* software, respectively.

- **Establish service-level agreements.** It is key that countries have access to local representatives of the manufacturer for timely support response. Early Truenat implementing countries (Kenya, Zimbabwe, Uganda, DRC and Nigeria) all have access to a growing network of local service providers authorised by Molbio for equipment service and maintenance (including on-site visits), that can offer prompt technical support in resolving complicated issues. In Nigeria, Kenya and DRC, the manufacturer also pre-positions extra Truenat systems and spare parts at the level of local representatives to *ensure continuity of services* in case of a defective instrument or equipment malfunction.

Source: Sight & Sound Limited

- **Ensure device safety.** A back-up power source (e.g., solar panels) might be necessary in regions that experience periods of extended power outages. Furthermore, to account for unstable power supply, Nigeria and Kenya have procured surge protectors.

REFERENCES

1. World Health Organization. Global tuberculosis report 2023, *https://www.who.int/publications/i/item/9789240083851* (2023, accessed 10 November 2023).
2. World Health Organization. The End TB Strategy, *https://www.who.int/teams/global-tuberculosis-programme/the-end-tb-strategy* (accessed 27 April 2023).
3. Pai M, Kasaeva T and Swaminathan S. Covid-19's Devastating Effect on Tuberculosis Care — A Path to Recovery. New England Journal of Medicine 2022; 386: 1490-1493. DOI: 10.1056/NEJMp2118145.
4. Zimmer AJ, Klinton JS, Oga-Omenka C, et al. Tuberculosis in times of COVID-19. Journal of Epidemiology and Community Health 2022; 76: 310-316. DOI: 10.1136/jech-2021-217529.
5. World Health Organization. Global tuberculosis report 2022, *https://www.who.int/publications/i/item/9789240061729* (2022, accessed 27 April 2023).
6. World Health Organization. WHO consolidated guidelines on tuberculosis: module 3: diagnosis: rapid diagnostics for tuberculosis detection, 2021 update, *https://www.who.int/publications/i/item/9789240029415* (2021, accessed 27 April 2023).
7. Ismail N, Nathanson CM, Zignol M, et al. Achieving universal access to rapid tuberculosis diagnostics. BMJ Glob Health 2023; 8 2023/05/26. DOI: 10.1136/bmjgh-2023-012666.
8. Shah HD, Nazli Khatib M, Syed ZQ, et al. Gaps and Interventions across the Diagnostic Care Cascade of TB Patients at the Level of Patient, Community and Health System: A Qualitative Review of the Literature. Tropical Medicine and Infectious Disease 2022; 7: 136.
9. Cazabon D, Pande T, Kik S, et al. Market penetration of Xpert MTB/RIF in high tuberculosis burden countries: A trend analysis from 2014 - 2016 [version 2; peer review: 4 approved]. Gates Open Research 2018; 2. DOI: 10.12688/gatesopenres.12842.2.
10. Stop TB Partnership. Rapid molecular diagnostics for use at peripheral level, *https://www.stoptb.org/introducing-new-tools-project/rapid-molecular-diagnostics-use-peripheral-level* (accessed 27 April 2023).
11. Stop TB Partnership. Practical Guide To Implementation of Truenat Tests, *https://www.stoptb.org/gli-guidance-and-tools/practical-guide-to-implementation-of-truenat-tests* (accessed 26 June 2023).
12. Global Laboratory Initiative. GLI quick guide to TB diagnostics connectivity solutions, *https://stoptb.org/wg/gli/assets/documents/gli_connectivity_guide.pdf* (2016, accessed 26 June 2023).
13. TB CAPT. Event Recording: TB-CAPT Satellite Session at ASLM LabCop 2022 Annual Meeting, *https://www.tb-capt.org/news/blog/event-recording-tb-capt-satellite-session-at-aslm-labcop-2022* (2022, accessed 27 April 2023).
14. World Health Organization. Rapid Communication: Molecular assays as initial tests for the diagnosis of tuberculosis and rifampicin resistance, *https://apps.who.int/iris/bitstream/handle/10665/330395/9789240000339-eng.pdf* (2020, accessed 10 November 2023).
15. FIND. Diagnostic network optimization: A network analytics approach to design patient-centred and cost-efficient diagnostic systems, *https://www.finddx.org/wp-content/uploads/2021/11/Guide-to-Diagnostic-Network-Optimization_15.11.2021.pdf* (2021, accessed 1 June 2022).
16. Global Laboratory Initiative. GLI TB Laboratory Safety Handbook, *https://www.stoptb.org/gli-guidance-and-tools/gli-tb-laboratory-safety-handbook* (2019, accessed 27 June 2023).
17. African Society for Laboratory Medicine. Expanding the diagnostic toolkit for tracking Mycobacterium tuberculosis. Lab Culture 2022.
18. World Health Organization. Practical manual on tuberculosis laboratory strengthening, 2022 update, *https://www.who.int/publications/i/item/9789240061507* (2023, accessed 10 November 2023).
19. Stop TB Partnership. Practical Guide to Implementing a Quality Assurance System for Xpert MTB/RIF testing, *https://www.stoptb.org/working-group-pages/practical-guide-to-implementing-quality-assurance-system-xpert-mtbrif-testing* (2019, accessed 27 June 2023).
20. International Organization for Standardization. ISO 15189:2022 Medical laboratories — Requirements for quality and competence. 2022.
21. World Health Organization. Laboratory quality management system: handbook, *https://www.who.int/publications/i/item/9789241548274* (2011, accessed 27 April 2023).
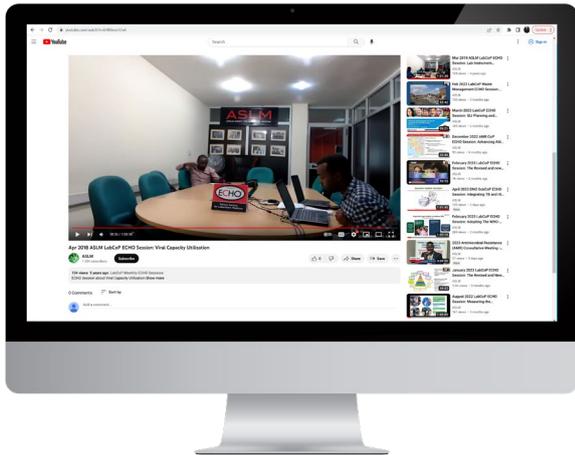
**Watch pre-recorded LabCoP ECHO sessions
on ASLM's YouTube page
http://bit.ly/LabCoPECHOSessionLibrary**
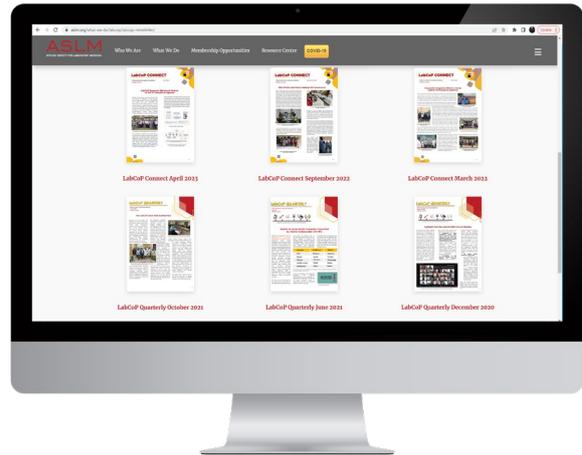
**Read the latest issue
of LabCoP Quarterly at
http://www.aslm.org/labcop/labcop-newsletter/**
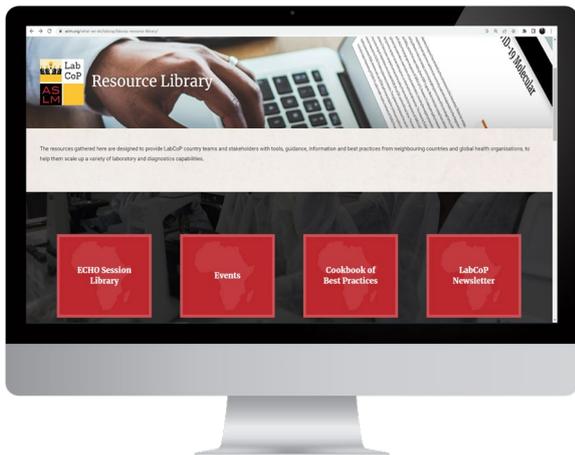
**Resource Centre
https://aslm.org/resource-centre/**

**Find more recipes at
https://aslm.org/labcop/labcop-cookbook/**

ASLM.org