THE REPUBLIC OF UGANDA

MINISTRY OF HEALTH

Implementation Plan for Near Point of Care tools for Molecular Diagnosis of Tuberculosis

COUNTRY: UGANDA

AUGUST 2026

Contents

Abbreviations & Acronyms

Acronym	Full term
ALIS	Africa Lab Information System
AMP	Loop-mediated Isothermal Amplification
DHIS2	District Health Information Software 2
DR-TB	Drug-Resistant Tuberculosis
DST	Drug susceptibility testing
eMR	Electronic Medical Records
EQA	External Quality Assessment
MDR-TB	Multidrug-Resistant Tuberculosis
mWRD	WHO-recommended rapid molecular diagnostic tests
NAAT	Nucleic Acid Amplification Test
NDA	National Drug Authority
NHLDS	National Health Laboratory and Diagnostic Services
nPOC	Near Point-of-Care
NSRTN	National Sample and Results Transport Network
NTLP	National Tuberculosis and Leprosy Programme
NTRL	National Tuberculosis Reference Laboratory
QC	Internal Quality Control
RR-TB	Rifampicin-Resistant Tuberculosis
TB	Tuberculosis
ToT	Training of Trainers
WHO	World Health Organization

Definition of Terms

Bacteriologically Confirmed TB: TB diagnosed based on laboratory evidence such as positive smear microscopy, culture, or molecular tests detecting *M. tuberculosis*.

Cartridge-Based Nucleic Acid Amplification Test (CBNAAT): A fully automated NAAT system in which sample processing, amplification, and detection occur within a closed cartridge, minimizing contamination risk and simplifying laboratory requirements. Examples include Xpert MTB/RIF and Xpert Ultra systems.

Drug Susceptibility Testing (DST): Laboratory testing used to determine whether *Mycobacterium tuberculosis* is susceptible or resistant to anti-TB drugs, ensuring patients receive the most effective treatment.

External Quality Assessment (EQA): A system for objectively evaluating laboratory performance by an external agency through proficiency testing, sample rechecking, or inter-laboratory comparison to ensure accuracy and reliability of test results.

Genotypic DST: Molecular techniques that rapidly detect the specific genetic mutations in a pathogen that confer resistance to a drug.

High-Complexity Molecular Test: Diagnostic testing requiring advanced laboratory infrastructure, highly trained personnel, strict biosafety conditions, and centralized laboratory settings.

Internal Quality Control (IQC): Routine procedures conducted within a laboratory to ensure that diagnostic tests are performing correctly on a day-to-day basis, including the use of controls and monitoring of test validity.

Loop-mediated Isothermal Amplification (LAMP): A simple molecular diagnostic method that detects *Mycobacterium tuberculosis* DNA by amplifying genetic material at a constant temperature, without the need for a thermocycler.

Low-Complexity Molecular Test: A diagnostic assay that requires minimal laboratory infrastructure, limited technical expertise, and simplified workflows, making it suitable for decentralized health facilities.

Multidrug-Resistant TB (MDR-TB): TB caused by strains of *M. tuberculosis* resistant at least to rifampicin and isoniazid.

Near Point-of-Care (nPOC) Testing: Diagnostic testing conducted close to the patient care setting (e.g., peripheral or primary health facilities) with rapid turnaround time, but not necessarily at the bedside.

Near point-of-care nucleic acid amplification tests (nPOC-NAATs): Swab-based molecular tests for TB detection that can produce results from a primary sputum or tongue swab sample in less than one hour using instruments that can be battery operated and do not require specialized infrastructure for use or storage.

Nucleic Acid Amplification Test (NAAT): A molecular diagnostic method that detects genetic material (DNA or RNA) of *Mycobacterium tuberculosis* through amplification techniques. NAATs are highly sensitive and form the basis of WHO-recommended rapid diagnostic tests for TB.

Person presumptive to have TB: An individual presenting with symptoms, signs, or risk factors suggestive of TB who requires diagnostic testing to confirm or exclude disease.

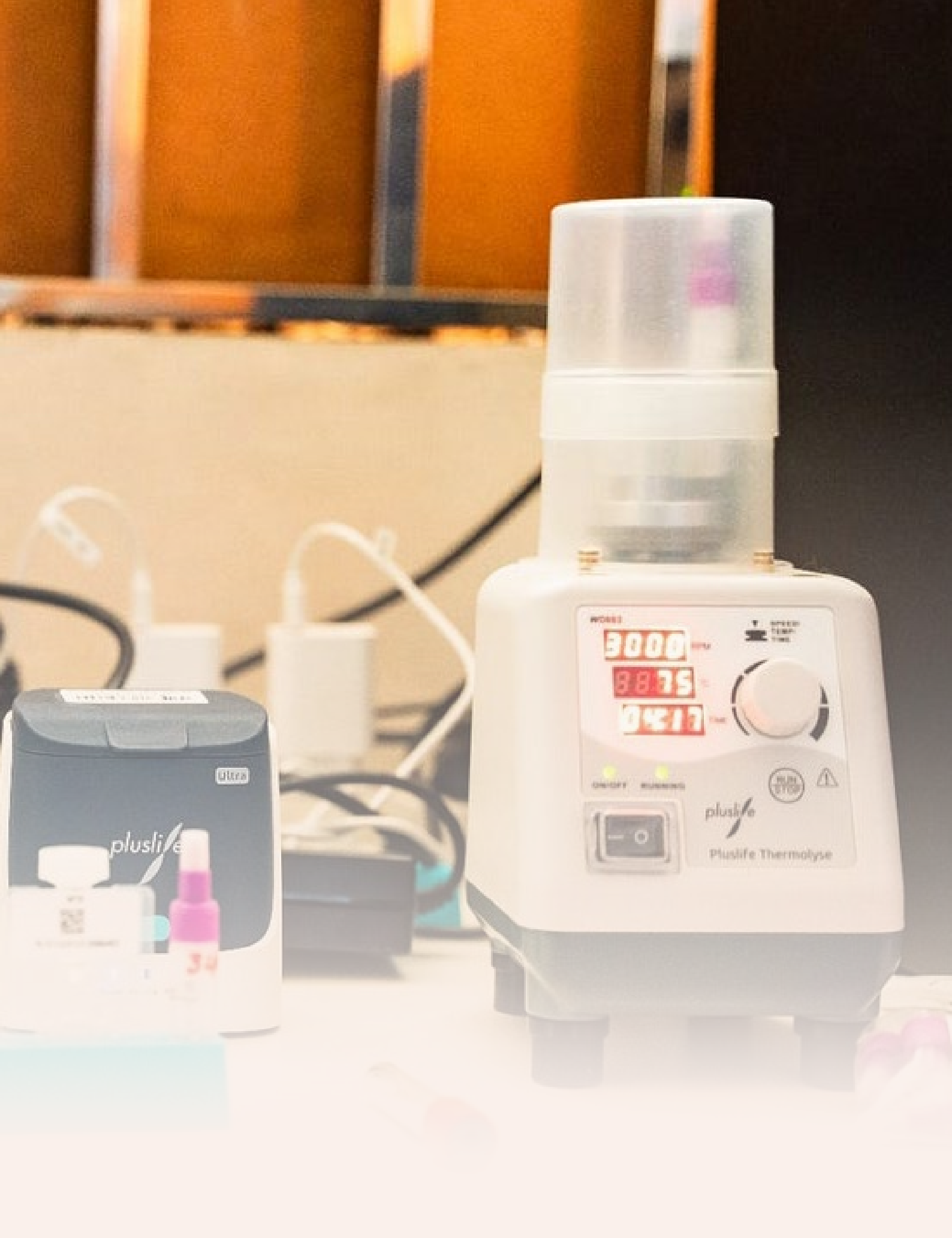
Point-of-Care (POC) Testing: Diagnostic testing performed at or near the site of patient care, with results available during the same clinical encounter to enable immediate decision-making.

Rifampicin Resistance (RR): Resistance of *M. tuberculosis* to rifampicin, detected by molecular or phenotypic methods, and used as a proxy marker for multidrug-resistant TB (MDR-TB).

Truenat: A chip-based, portable NAAT platform endorsed by WHO for TB diagnosis and rifampicin resistance detection.

Turnaround Time (TAT): The total time from specimen collection to the availability of a validated test result that can inform clinical decision-making.

WHO-recommended rapid molecular diagnostic tests (mWRDs): Molecular assays endorsed by the World Health Organization as the initial diagnostic test for TB. These include automated NAAT platforms capable of detecting *M. tuberculosis* and, in many cases, rifampicin resistance.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1.0 Introduction

1.1 Uganda TB Burden and Diagnostic Gap

According to the 2024TB profile for Uganda, the country had a population of 45.9 million people with an estimated TB incidence of 99,000 cases (rate of 197 per 100,000 population). TB incidence in people living with HIV is estimated at 33,000 cases, reflecting the significant TB/HIV co-infection burden in the country. Despite challenges, Uganda has made notable progress, with a 2% reduction in TB incidence rate and a 54% reduction in the total number of TB deaths between 2015 and 2023.

Uganda remains a high TB-burden country. In 2024, 90% of estimated TB cases were detected, leaving approximately 9,000 people undiagnosed — concentrated among children, PLHIV, people in rural settings, and those in the private sector. Key diagnostic bottlenecks identified in the NTLP include:

- Only 4% of HCIIIs have on-site WHO-recommended rapid molecular diagnostic tests (mWRDs) such as GeneXpert/Truenat/TB LAMP
- Only 35% of public health facilities offer any TB services
- 24% of symptomatic TB patients first seek care at private facilities, many without mWRD
- Only 16% of patients with chronic cough (≥2 weeks) are evaluated with sputum and/or chest X-ray
- Sub-optimal specimen referral system, contributing to diagnostic delays and loss to follow-up
- Drug susceptibility testing (DST) remains centralized, limiting access outside major towns

Uganda is introducing near point-of-care (nPOC) testing through a 2026 Global Fund SI/CIFF-supported pilot involving 220 devices and 110,000 tests, with future expansion expected to be phased and evidence-driven. Under a conservative scenario, the diagnostic market is projected to grow modestly from about 1.17 million tests in 2025 to 1.23 million by 2030, largely due to financing constraints. Within this market, nPOC testing could scale from approximately 65,000 tests in 2026 to about 474,000 tests by 2030, representing around 38% of the diagnostic market. Uganda's low-complexity nucleic acid amplification test (LCNAAT)-based testing landscape creates a strong economic rationale for nPOC, as much of the future nPOC volume is expected to replace centralized LCNAAT testing while preserving GeneXpert and other molecular platforms for drug resistance testing and more complex cases. If savings from this transition are reinvested into diagnostics, Uganda could potentially expand total testing volumes to nearly 1.9 million tests by 2030, with nPOC accounting for up to 1.2 million tests. However, successful uptake will depend on overcoming key operational challenges, including financing, staffing, supervision, reporting systems, supply chain reliability, electricity, connectivity, and regulatory readiness. The 2026 pilot is therefore expected to play a critical role in generating operational evidence, refining deployment strategies, and building a scalable implementation model for nationwide expansion.

1.2 Strategic Alignment with NSP 2025/26–2029/30

The NSP explicitly mandates development and implementation of an mWRD implementation strategy to accommodate new tools and near-point-of-care diagnostic tools. It calls for expanding mWRD coverage using a need-informed, continuous quality improvement (CQI) approach and targets to increase the proportion of primary health-care facilities that have access to mWRDs either on site or through sample referral increased from 39% to 60%.

1.3 Characteristics of nPOC devices

Several nPOC molecular diagnostic devices are currently in the pipeline globally. Under the Global Fund Early Adopters Initiative, Uganda will deploy MiniDock MTB platform. This is a compact, portable, nPOC molecular diagnostic tool designed for high-burden, resource-limited settings. Its key features include:

- Time-to-result: <30 minutes from sample to result
- Hands-on time: approximately 2 minutes operator time
- Portable, battery/solar-operated — no stable electricity or refrigeration required
- Daily throughput: >9 tests per day per device
- Multi-disease testing capacity supporting testing for other diseases including HPV
- Supports alternative specimen types: sputum and tongue swabs — critical for paediatric TB
- Connectivity-ready: supports digital result transmission compatible with LabXpert and eCBSS

Table 1: Clinical evaluation of Minidock PlusLife MTB:

Test / Sample	Error Rate	Sensitivity (95% CI)	Specificity (95% CI)
Minidock PlusLife MTB — Tongue swab	1/322 (0.3%)	85.7% (75.3–92.9)	100% (98.4–100)
Minidock Pluslife MTB — Sputum swab	2/318 (0.6%)	89.9% (80.2–95.8)	98.2% (95.5–99.3)
Comparator: Sputum Smear	N/A	67.1% (54.9–77.9)	100% (98.4–100.0)
Comparator: Sputum Xpert Ultra	2/322 (0.6%)	94.1% (85.6–98.4)	99.5% (97.5–100.0)

Source: *Steadman et al.2025. doi: 10.1016/j.ebiom.2025.105991.*

1.4 Situational Analysis and Implementation Rationale

1.4.1 Current TB Diagnostic Network

Uganda's diagnostic network comprises 403 GeneXpert machines deployed across 355 facilities, 41 Truenat and 50 TB-LAMP covering all districts. Ninety six percent of HCIIIs lack on-site molecular testing and rely on sputum referral to mWRD sites, which results in delays and specimen rejection risks. Access to mWRD among notified TB patients stands at 82%. The NSP Diagnostic Network Assessment (2024) confirmed these persistent bottlenecks.

Table 2: Current Distribution of mWRDs within Uganda Diagnostic Network (See Annex 1 for details)

Health Facility Level	No. of Health Facilities	No. of Facilities with mWRDs	No. of facilities without mWRDs
HC II	5106	1	5105
HC III	2137	52	2085
HC IV	275	186	89
General Hospitals	198	100	98
Regional Referral Hospital	16	16	0
National Referral Hosp	5	5	0

Source: *MOH Facility Master List, 2024*

1.5 Goal & Objectives of the nPOC Implementation Plan

1.5.1 Goal

To ensure universal access to molecular-WHO recommended rapid TB diagnostic test.

1.5.2 General Objective

To strengthen Uganda's TB diagnostic network through decentralized nPOC testing services to increase access to timely, accurate, and patient-centered molecular TB diagnosis, particularly among under-served and high-burden populations.

1.5.3 Specific Objectives

i) To increase access to mWRD by deploying nPOC platforms in prioritized health facilities with limited access to centralized molecular testing services.

ii) To reduce turnaround time for TB diagnosis and treatment initiation through decentralized testing among key and vulnerable populations, including children, people living with HIV, and populations in hard-to-reach areas.

iii) To establish sustainable operational and maintenance systems for nPOC

iv) To incorporate performance monitoring, evaluation, and impact measurement systems for the nPOC TB testing into the existing M&E system

1.6 Implementation Rationale

Despite over a decade of implementing LC-NAATs (GeneXpert) in Uganda, molecular mWRD coverage remains low (25% of DTUs have mWRD on site). In 2025, the market size estimation for molecular nPOC conducted by CHAI indicated that out of the 3,026 PHC facilities, only 168 are currently equipped with an LC-NAATs platform, despite 2,903 being designated microscopy sites. This highlights a significant opportunity to leverage existing microscopy infrastructure for mWRD expansion, and therefore, a need to cover more than 3,000 health facilities with nPOC devices to address this gap. The introduction of nPOC is expected to address the gaps of;

- limited access to TB rapid molecular testing,
- long result turnaround time (TAT) among

referring facilities,

- limited access to mWRD the private sector,
- failure to produce sputum, especially among children,
- urgent need for cheaper alternative molecular tools amidst the challenging funding landscape.

1.7 Criteria for site selection

The use of nPOC will be guided by the revised TB diagnostic algorithm in Figure 1.

Phase One (Year 1)

During phase one, priority will be given to regions with high burden of TB based on case notification. Among these regions, health facilities were selected based on microscopy workload, distance to nearby mWRD site and inclusion of private sector. A total of 90 facilities (220 devices) will be deployed during this phase. Technical assistance during phase one will be provided through the Aurum Institute and Makerere University Lung Institute (MLI) with funding from Children's Investment Fund Foundation (CIFF).

Phase Two (Year 2-4)

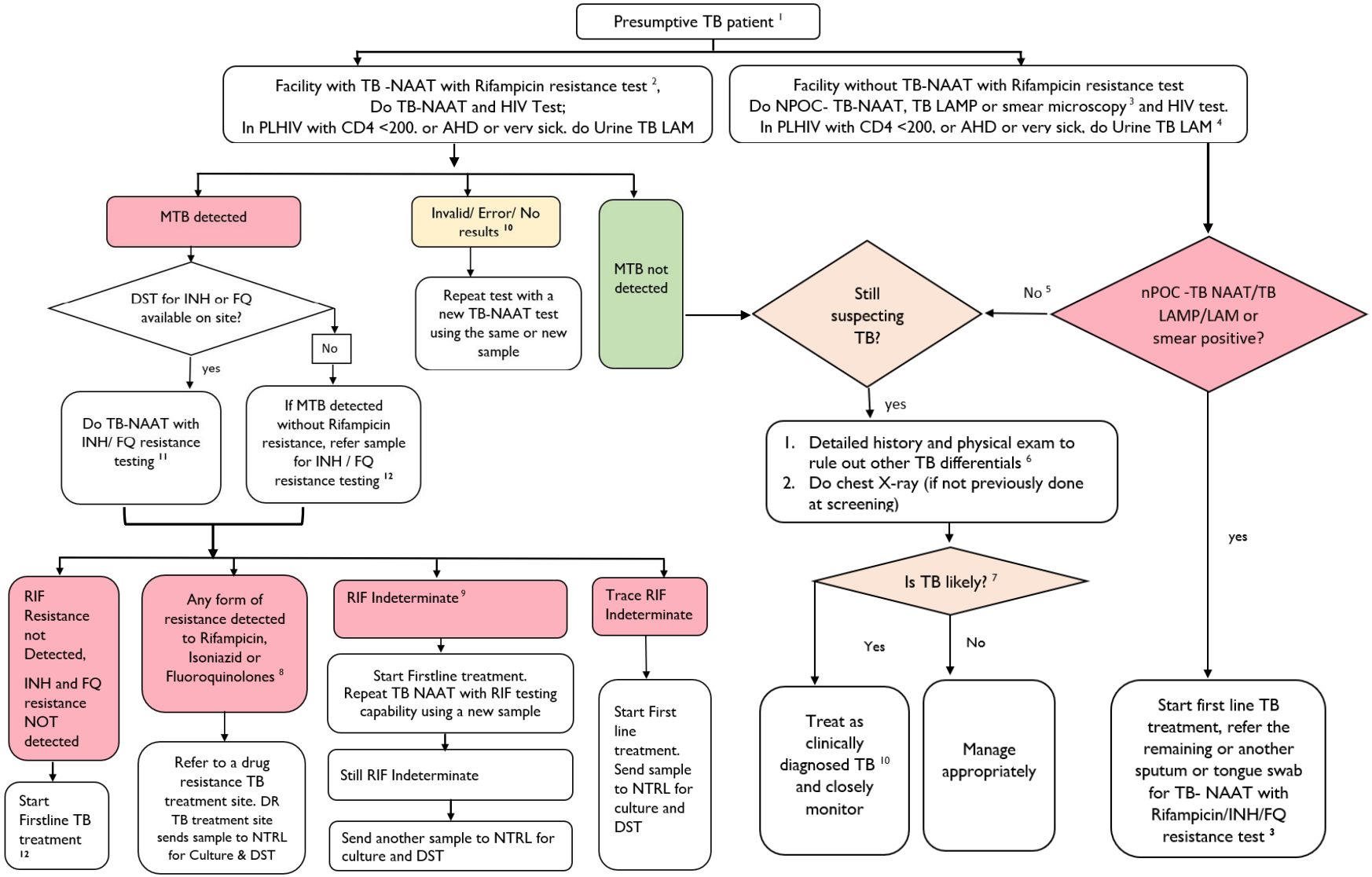
Site selection will be guided by the following criteria drawn from the NSP framework and GIS-enabled TB hotspot mapping:

- High TB notification burden
- Absence of on-site mWRD
- High volume of presumptive TB patients/ microscopy workload
- Proximity to key vulnerable populations: PLHIV, children, miners, prisoners, refugees, border communities
- Private sector facilities with high patient volume and willingness to engage
- TB hotspots identified using AI tools such as EPCON.

In this phase, 1,012 health facilities are targeted for nPOC deployment. The 1,012 health facilities were based on the number of HC IIIs without mWRD, and the plan is to cover 50% of these facilities during this phase. Additionally, the plan is to provide 2 nPOC devices per facility resulting into a requirement of 2,024 devices. Refer to Annex 2 for grading of health facilities.

1.8 TB Diagnostic algorithm

The use of nPOC will be guided by the revised TB diagnostic algorithm in Figure 1.



1. Presumptive TB is presence of any or a combination of the following:
   - If the individual has persistent cough for 2 weeks or more
   - If the individual is a high-risk for TB and has current cough, irrespective of duration. These include (PLHIV, TB contacts, diabetic patients, undernourished people, miners, prisoners and refugees etc.)
   - If individual is not high risk for TB and has current cough with any other TB symptoms.
   - If the individual has no cough but has other symptoms suggestive of TB, refer to clinician for further evaluation (detailed history and physical examination) to ascertain if presumptive TB or not.
   - Abnormal chest x-ray in a high-risk patient
   - CRP test >5mg/L among patients living with HIV.
2. TB-NAAT with rifampicin resistance testing refers to a test done using either Xpert TB Ultra or Truenat or other TB-NAAT with rifampicin resistance testing capability platforms
3. At facilities without TB-NAAT with rifampicin resistance testing

   a. NPOC-TB NAAT or TB-LAMP should be prioritised over other tests such as microscopy or TB LAM.
   b. In cases where a positive result is obtained using NPOC-TB NAAT, TB-LAMP, microscopy or TB LAM, a sputum sample, or Tongue swab (if patient cannot provide a sputum sample) should be referred to a facility offering TB-NAAT with rifampicin resistance testing capability.
   c. In cases where a negative result is obtained using Microscopy or TB LAM, a sputum sample should be referred to a facility offering TB-NAAT with rifampicin resistance testing capability.
   d. In cases where a negative result is obtained using NPOC-TB NAAT or TB-LAMP, patient has to be comprehensively assessed by clinician for other definitive diagnosis. Sending a sputum sample to a facility offering TB-NAAT with rifampicin resistance testing capability may not be of added benefit

4. Urine TB LAM test should be offered to HIV positive individuals with CD4 ≤ 200 (AHD) or very sick (Temperature >39°C, Respiratory Rate >30 breaths/min, Heart Rate >120 beats/min, New Seizure, Unable to walk without assistance / Bed-ridden).

5. Smear negative: defined as at least one negative smear. Carry out other investigations such as CXR if available. Those with CXR suggestive of TB should be discussed as a team for a possible diagnosis and treatment for clinically diagnosed TB. If not available or CXR not suggestive, do further history, physical examination and other investigations to exclude other causes of chronic cough, fever and weight loss.

6. Differential Diagnoses of TB: Silicosis, Chronic Obstructive Pulmonary Disease (COPD), heart disease, asthma, bronchiectasis, emphysema; Histoplasma pneumonia, trypanosomiasis, brucellosis; Fungal infection of the lung: Malignancy (lung cancer, lymphoma etc.).

7. TB diagnosed based on abnormal X-ray findings suggestive of TB: Features include: heterogeneous opacities and cavitation in the upper parts of the lung, mediastinal L/nodes, pleural effusion and milliary picture.

8. In case of any form of resistance to Rifampicin, Isoniazid or Fluoroquinolones is detected, refer patient to health facility that treats drug resistant TB. The DR TB treatment site should send another sample to NTRL for culture and DST

9. If MTB detected Rifampicin Resistance Indeterminate; Start first line TB treatment, Repeat Test using another sample. If still indeterminate, send another sample to NTRL for culture and DST.

10. If Error/No result on Xpert, repeat the test with a new cartridge. If Invalid on Xpert, repeat the test with a new sample and new cartridge. For Truenat, repeat the test and follow algorithm to interpret. If both Truenat tests give indeterminate, treat with 1st line TB regimen and promptly conduct additional investigations to assess resistance to rifampicin e.g., culture and DST. Review treatment based on DST result

11. All Gene Xpert machines will be progressively upgraded to support INH and FQ resistance testing in a phased manner.

12. If MTB detected without Rifampicin resistance, start Firstline treatment as you wait for INH / FQ resistance test result.

Figure 1: TB Diagnostic algorithm

1.8.1 Expanding access to molecular DST

DST for Rifampicin

Since the currently available nPOC do not perform DST, it is a requirement that all nPOC positive samples are tested with LC-NAATs that test for Rifampicin resistance. There is a need to ensure presence of nearby mWRD with DST capacity to act as referral centers for all nPOC positive samples. Therefore, the existing GeneXpert and Truenat sites will act as referral centers for all nPOC positive samples for DST testing. Furthermore, as we expand nPOC testing and in line with scaling up multi-disease testing approach, there is a need to increase the number of GeneXpert sites. In this regard, at least 200 mWRD with DST capacity will be required to cover all the remaining Hospitals, HCIVs and some high volume HCIIIs.

DST for Isoniazid and second line drugs (Fluroquinolones)

Equally, there is a need to expand molecular DST for Isoniazid and second line drugs e.g fluroquinolones (FQ). Currently, the country plans to achieve this through deploying tests that do INH and FQ such as the Xpert MTB/XDR assay in all facilities with GeneXpert. Rolling out of INH and FQ DST for all bacteriologically confirmed TB patients (refer to Algorithm in Figure 1) will start with DR-TB treatment initiation facilities. Scale up to other GeneXpert sites will be subject to availability of cartridges.

The following activities will be conducted to scale up DST for INH and FQ.

- Upgrade GeneXpert modules from 6 color to 10 color (upgrade to 10-Color module will be done upon failure)
- Supply Xpert MTB/XDR cartridges to facilities
- Upgrade of the GXDX to 6.5, replacement of CPU with Win OS 7 to WIN 10 LTSC
- Train health workers on Xpert MTB/XDR assay
- Provide SOPs
- Monitoring use of INH&FQ testing

2.0 Regulatory Requirements

The section covers the regulatory steps required before and during deployment of nPOC device. These activities ensure the device, and its consumables meet national and international quality standards, receive necessary approvals, and are properly listed in procurement catalogues.

2.1 Key Processes

2.1.1 Global Pre-qualification/ endorsement

All nPOC devices used in Uganda should have prior endorsement by WHO.

2.1.2 Laboratory Validation & Field Evaluation

- Laboratory validation of the nPOC device against reference standards.
- Field evaluations at selected pilot sites to confirm performance under real world setting
- Report submitted to MoH for approval

2.1.3 Regulatory Approvals

- National Drug Authority (NDA) import approval required for equipment, reagents and consumables prior to shipment
- Incorporation of the nPOC device into the National Essential Diagnostic List (NEDL) and National Warehouses procurement catalogues.

> ***NB:*** *The* nPOC Manufacturer is *responsible for supporting registration in relevant procurement catalogues to facilitate uninterrupted supply.*

2.1.4 Post Market Surveillance

This will be done by NDA in collaboration with Ministry of Health to ensure that the device continue to be safe, accurate, effective and of acceptable quality after deployment.

3.0 Supply Chain Management

Effective supply chain management ensures that reagents, and consumables are continuously available at all implementing health facilities. The supply chain management system coordinates quantification, procurement, warehouse and distribution, stock management at both national and facility level to ensure continuous availability.

3.1 National Level Procurement & Warehousing

3.1.1 Quantification & Procurement

- Annual national forecasting and quantification of nPOC commodities will be conducted by Quantification Procurement Planning Unit (QPPU) under the Department of Pharmaceuticals and Natural Medicines (DPNM) jointly led by the National Laboratory and Diagnostic Service (NHLDS) working with Tuberculosis and Leprosy Programme (NTLP).
- The national quantification exercise will be conducted annually, complemented by quarterly supply plan reviews to monitor stock availability, identify funding, and supply gaps, recommend corrective actions, and support timely resource mobilization.
- Forecasts will be based on estimated TB morbidity, historical consumption, available stock, and pipeline data, planned service expansion, and programme targets outlined in the National Strategic Plan (NSP) for all implementing sites.
- Commodities financed by the Global Fund will be procured through the applicable pooled procurement mechanism (PPM), while commodities financed by the Government of Uganda will be procured in accordance with Public Procurement and Disposal of Public Assets Authority (PPDA) guidelines through National Medical Stores (NMS)and Joint Medical Store (JMS).

3.1.2 Warehousing & Distribution

- All procured equipment will be delivered to the Central Public Health Laboratories (CPHL) stores for receipt, inspection, verification, engraving, asset registration, and inventory documentation.
- Following engraving and documentation, the equipment will be dispatched to designated district or hub stores for onward delivery, installation, commissioning, and use at the beneficiary health facilities.
- NHLDS/NTLP will prepare and share approved facility allocation lists and distribution schedules with NMS and JMS to guide the quantities to be delivered to each implementing site. The facilities will be transition direct ordering with the warehouse systems upon including the commodities into the ordering platforms of the warehouses.
- TB cartridges and other laboratory commodities will be received, stored, and distributed through the National Medical Stores (NMS) and Joint Medical Stores (JMS), taking into consideration their shelf life, storage conditions, consumption rates, and available warehouse capacity.
- Commodities will be delivered to the NMS and JMS warehouse in quarterly consignments to reduce the risks of stock-outs, overstocking, and expiries while maintaining adequate national stock levels.
- NMS and JMS will distribute commodities according to the approved allocation

schedule and apply the First Expiry-First-Out (FEFO) principle throughout storage and distribution.

- QPPU, NHLDS, and relevant stakeholders will monitor stock status, consumption, expiries, and pipeline information through routine reporting and quarterly supply plan reviews. Where stock imbalances are identified, NHLDS/NTLP will coordinate timely redistribution, adjustment of future deliveries, and other corrective actions to ensure continuous commodity availability at implementing facilities.

3.1.3 Facility-Level Supply Management

- Facilities will store cartridges and other commodities under the manufacturer-recommended conditions, with routine monitoring of temperature, security, and cleanliness.
- The inventory tools such stock cards will be updated immediately after every stock transaction.
- Facilities will apply the First Expiry-First-Out (FEFO) principle and conduct routine physical stock counts to reconcile physical balances with stock records.
- Facilities will monitor stock status regularly and submit emergency orders or redistribution requests through the district, regional hub, or NHLDS/NTLP when stocks reach established minimum levels or a potential stock-out is identified.
- Facilities will verify the quantities, batch numbers, expiry dates, and physical condition of commodities against the delivery documentation. Any discrepancies or damaged products will be documented and reported promptly to warehouse.
- Districts and regional hubs will provide routine oversight, mentorship, and supportive supervision to strengthen inventory management, redistribution, data quality, timely ordering, and compliance with national commodity-management requirements.

4.0 Equipment Installation & Maintenance

This section describes the procedures for the installation, commissioning, verification, preventive maintenance, and repair of near-point-of-care (nPOC) devices. A structured maintenance and repair system will be implemented to ensure continuous device functionality, minimize downtime, extend equipment lifespan, and safeguard the accuracy and reliability of TB test results.

4.1 Installation

Device Placement & Installation

- The nPOC supplier's representative, Ministry of Health, district teams, and implementing partners will jointly coordinate the delivery, installation, and commissioning of devices at each selected health facility.
- An installation and commissioning report will be completed for each facility, documenting the device model, serial and asset-identification numbers, installation date, location, site conditions, accessories supplied, and responsible personnel.
- Following successful verification, the installation team will formally hand over the device to the facility, accompanied by the relevant user manuals, standard operating procedures, maintenance schedules, warranty documentation, and service-contact information.
- The National Tuberculosis Reference Laboratory (NTRL) will update the national equipment inventory, while the receiving facility will update its equipment and asset registers upon confirmation of installation.
- Geographic Information System (GIS) mapping will be conducted for each facility where an nPOC device is installed to support equipment tracking, service mapping, maintenance planning, and monitoring of diagnostic coverage.
- Each facility will update its laboratory test menu to include the TB tests available on the newly installed nPOC device and communicate the updated services to clinicians and other relevant healthcare workers.
- Routine testing will commence only after successful installation, verification, documentation, staff training, and formal authorization by the responsible Ministry of Health programme.

4.2 Routine Preventive Maintenance

Facility-Level Maintenance: Designated facility laboratory personnel will perform daily, weekly, and monthly preventive-maintenance checks in accordance with the manufacturer's instructions, approved standard operating procedures, and the equipment maintenance schedule.

Routine activities will include device cleaning, inspection of components, review of error logs, temperature and environmental checks, and other manufacturer-recommended procedures.

All maintenance activities, identified faults, corrective actions, and device downtime will be documented in the facility equipment maintenance log.

Annual servicing: The authorized nPOC service representative will conduct annual preventive servicing, calibration, performance verification, and software or firmware updates in accordance with the manufacturer's requirements.

A service report or calibration certificate will be completed after each visit and retained at the facility, with a copy submitted to the National Tuberculosis Reference Laboratory (NTRL) for

national equipment records.

NTRL will maintain and monitor the national servicing schedule to ensure that all devices receive timely maintenance.

Troubleshooting, Repair & Software Updates: Facility staff will undertake basic troubleshooting in accordance with the manufacturer's instructions and approved procedures. Any unresolved malfunction will be reported immediately to the authorized nPOC service representative, with NTRL copied on the notification.

The facility will suspend testing where a device fault may compromise the accuracy, safety, or reliability of test results and will activate the approved referral or backup testing arrangement.

The authorized nPOC service representative will diagnose reported faults and undertake the required repairs, replacement of defective equipment or spare parts, and installation of approved software or firmware updates. NTRL will monitor equipment functionality, response and repair times, recurrent faults, service history, and device downtime to inform performance management and corrective action.

5.0 Specimen referral system

The NSRTN currently comprises 103 hubs geographically distributed across the country to optimize coverage, access, referral efficiency, and turnaround time. The geographical coverage of the network is presented in Annex 4: Map Showing Coverage of the NSRTN. This will be used to transport specimens from designated peripheral health facilities equipped with nPOC devices. Samples collected at nPOC sites that require drug-susceptibility testing (DST), confirmatory testing, or other specialized investigations will be referred through the same network to regional or national reference laboratories.

The NSRTN will operate through the established hub-and-spoke model. Motorcycles will collect samples from peripheral health facilities and transport them to nearest Laboratory with either GeneXpert or TrueNat machines or designated hubs, while sample-transport vehicles will move samples from the hubs to regional hubs and reference laboratories.

Referring facilities will use the Integrated Results Reporting and Download System (IRRDS) to capture laboratory test requests and support the electronic registration, collection, packaging, referral, and tracking of samples. Testing laboratories will upload results to IRRDS, enabling requesting facilities to view, download, and print results for timely clinical decision-making and patient management.

All samples will be collected, packaged, labelled, stored, and transported in accordance with national biosafety, biosecurity, infection-prevention, and specimen-transport requirements. Samples will be tracked using the RESTRACK application to maintain an electronic chain of custody from the referring facility to the testing laboratory and during the return of results.

NTLP/MoH, NTRL, districts, hubs, and implementing partners will routinely monitor sample volumes, referral completion, rejection rates, turnaround times, results delivery, and other NSRTN performance indicators.

The activities to be implemented for optimization of the NSRTN to support nPOC testing for TB include the following.

;

Phase One (Year 1)

- Mapping all nPOC sites and incorporating them in the Specimen referral system

Phase Two (Year 2-4)

- Upgrade of IRRDS to track proportion of results returned and results return TAT
- Sample tracking using available systems
- Configuration of LabXpert on the nPOC devices
- Training users on LabXpert
- Procurement of Routers to provide internet for the nPOC devices
- Internet subscription for routers at the nPOC devices
- Training laboratory staff and clinicians on use of the Integrated Request and Report Dispatch system, RESTRACK and sample and results management.
- Integration of nPOC into existing LIS (ALIS).
- Procure sample and tracking barcodes.
- Orientation of hub coordinators, hub riders and drivers on nPOC defining their roles and responsibilities.
- Procure sample collection and packaging materials.

6.0 Training and Capacity Building

6.1 Scope of Training:

The training will target all cadres at all levels of the diagnostic network.

It covers:

- Technical operation of nPOC systems
- Quality assurance and biosafety
- Data management and reporting
- Troubleshooting and system support
- Training, mentorship, and supervision capacity

6.2 Training Methodology (Integrated Cascade Model)

The program adopts a **cascade, competency-based, and multimodal training approach**, combining:

- Face-to-face, role-based instruction
- Hands-on practical sessions
- Mentorship and supervised practice
- A continuous virtual self-paced learning platform

Table 3: The cascade model of training for nPOC

Category	Training of Trainers (ToT)	Super User Training	End User Training
Objective	• Expand the national training pool to support cascade rollout	• Establish a network of advanced users for on-site support and mentorship	• Ensure all users perform routine tasks accurately and consistently
Target Participants	• MoH, NTLP, NHLDS staff, national reference laboratories, regional referral hospitals, and key partners; N2M, Pluslife team	• National Reference Laboratories staff, regional laboratory focal persons, TB focal persons, clinicians, and district trainers	• Health facility staff including laboratory staff, clinicians and data staff
Delivery Approach	• Standardized training modules delivered by Master Trainers and manufacturers with co-facilitation by trainees	• Standardized training modules delivered by Master Trainers and manufacturers, Advanced practical and support-focused training sessions	• Facility onsite sessions by super users or master trainers, hands-on practice, self-paced learning
Key Activities / Content	• Development of standardized modules by Master Trainers • Conduct National TOT workshops covering; nPOC TB diagnostic technologies and algorithms, Quality assurance, biosafety, and data reporting, • Adult learning principles and facilitation skills • Co-facilitation of sessions by trainees Structured mentorship and feedback	• Training on advanced nPOC system use (sample workflow, reporting, troubleshooting, user administration) Hands-on practical sessions • Development of standardizes end user SOP	• Hands on sample core workflows (testing, data entry, reporting, troubleshooting) Customize of SOP, Job aids and quick reference materials

Outputs	• Standard training package including PowerPoint presentations, facilitator guides • Standardized nPOC-SOP	• Complete training manual for end users	• Competent end users are able to perform routine tasks consistently • nPOC training curriculum
Duration	3 days	5 days	• Approximately 2 hours per participant
Frequency	Once	Once	• nitial training • Refresher training after 6months following installation training
Location	Centralized training	Centralized training	• Facility based training

7.0 Quality Assurance (IQC AND PT)

7.1 Internal Quality Control

Most nPOC have inbuilt internal quality control mechanism. For example, Pluslife has inbuilt internal control in the reaction card that confirms sufficient specimen volume and correct procedural technique for each card. If the IC fails (device flags Invalid) by the MiniDock, repeat the test with a new Reaction Card.

Additionally, another set of internal control called external quality controls (vials of MTB Positive Control and MTB Negative Control) will be provided by the manufacturer. This is mainly used to verify/validate each new lot of test kits on its specific assay detection system before routine use. The MoH will procure and provide MTB IQC materials to the testing sites and testing will be conducted according to the SOP.

7.2 Proficiency testing

Proficiency testing is aimed at ensuring continuous quality improvement at all nPOC testing sites.

The NTRL, an ISO 17043 accredited laboratory shall be responsible for providing Proficiency Testing panels. During Phase one, the implementing partner (AURUM-MLI) will fund provision of the PT Materials during the project. During Phase Two (scale up phase), the MoH and partners will support the procurement and distribution of PT materials.

Table 2: nPOC PT Schedule

Type of PT	Frequency	Sending out month	Quantity	Turnaround time
Dried Tube Specimen	Biannual	February and August	5 tubes/round	44 days

PT performance: The PT performance criteria will be 80%

7.3 Targeted supervision and mentorship

The overall aim of support supervision is to ensure effective early implementation, quality performance, and optimal use of the nPOC within Uganda's TB diagnostic network during the initial rollout phase.

- **Early implementation:** This will be financed through the Aurum-MLI project for early implementation for each round. Persons in groups of two people will comprise the support/target supervision team.
- **During scale up:** At least quarterly basis by the MoH following NTRL/NTLP support supervision schedule to sites with unsatisfactory performance.

8.0 Biorisk Management Considerations

nPOC molecular diagnostic platforms are considered low-risk procedures, but still involve handling potentially infectious clinical specimens and therefore require structured biosafety and Biosecurity implementation guidelines.

8.1 nPOC Biorisk Management Implementation Guidelines

All nPOC require the same biosafety guidelines including.

- Maintaining well-ventilated laboratory spaces to minimize the risk of infection from aerosols during specimen collection and specimen treatment steps.
- Near POC operators will be trained in Biorisk Management practices based on the National Biosafety guidelines and related standards
- Personnel Protective Equipment (PPE) will be deployed on a risk-based approach and nPOC operators are required to ensure adherence to appropriate use of the PPE.

8.2 Waste Management:

nPOC procedures generate a significant amount of plastic waste, which should be properly disposed of and incinerated as per national regulations. All waste generated should be decontaminated in an appropriate disinfectant prior to incineration as per the national medical waste disposal guidelines. Chemical waste disposal will be implemented by the aid of material safety data sheet or database (MSDS).

9.0 Key Players in Implementing nPOC

The stakeholder analysis identified a broad range of internal and external actors with defined roles in supporting implementation, coordination, quality assurance, and sustainability of the nPOC rollout.

Ministry of Health plays a broader role in policy oversight, memorandum of understanding (MOU) signing, financing, recruitment of human resources, and strengthening laboratory infrastructure.

Within the Ministry of Health (MOH) structures, the National Health Laboratory and Diagnostic Services (NHLDS) provides overall governance, policy direction, stewardship, quantification, and resource mobilization. The **National Tuberculosis Reference Laboratory** (NTRL) plays a central technical role through training, support supervision, development of guidelines, external quality assessment (EQA), installation support, operational research, data collection and management, quantification, validation, scale connectivity, and monitoring of indicators. The **Central Public Health Laboratories** (CPHL) coordinate sample referral systems and overall laboratory coordination activities, while the **National Tuberculosis and Leprosy Programme** (NTLP) is responsible for policy guidance, document approval, quantification, and validation processes.

At subnational level, **Regional Referral Hospitals** (RRHs) support EQA coordination, supervision, training, mentorship, data compilation, and dissemination. **District Health Management Teams (DHMTs)** are responsible for data collection, compilation, review, training, supervision, and mentorship at district level. Health facility healthcare workers and **Diagnostic and Treatment Units** (DTUs) are critical in implementation through adoption of services, testing, data review and submission, quality assurance, requisition, and proper stock management.

The **National Drug Authority** (NDA) contributes through quality assurance and verification of diagnostic products and commodities.

The Laboratory Technical Committee will review information from manufacturers/ suppliers, identify suitable institutions to conduct evaluation of new nPOC technologies and advise MOH based on these findings.

Development partners such as the United States Government (USG) and the Global Fund (GF), CIFF, Aurum Institute, MLI, which provide financing and technical assistance for program implementation and scale-up activities.

Civil Society Organizations (CSOs) and communities contribute through community awareness creation, advocacy, and promotion of adoption of services.

The private sector is expected to strengthen public-private mix (PPM) engagement by joining the national PPM network, notifying allTB cases, participating in sample referral and connectivity systems, and providing quality-assured TB diagnostic services.

Warehousing and supply chain management: NMS and JMS perform procurement, and last-mile distribution, monitoring stock status and expiry, facilitating access for accredited private notifiers, and implementing performance monitoring.

Vendor/manufacturer: Provision of equipment, installation, maintenance, servicing, and calibration

World Health Organization (WHO) provides guidance on development of policies, technical standards, and standardization of diagnostic and programmatic approaches.

10. Risk Mitigation Plan

Several risks could affect program performance, service delivery, and sustainability. However, the proposed mitigation measures can reduce the likelihood and impact of these risks.

Financing risks this is a low-probability but high-impact risk of inadequate or delayed funding for implementation activities. Mitigation measures include developing a costed implementation and resource mobilization plan, diversifying funding sources, integrating activities into national and district budgets, and conducting regular financial performance reviews.

Human Resource-Human resource risks include limited staff capacity, inadequate staffing, and resistance to adopting new technologies. Mitigation measures include training, mentorship, competency assessments, development of SOPs, supportive supervision, and staff recruitment and retention strategies.

Operational risks- Operational risks include inadequate site readiness and delayed turnaround times that may affect service delivery. Mitigation measures include conducting site readiness assessments, ensuring adequate infrastructure and connectivity, establishing preventive maintenance systems, and routinely monitoring TAT indicators with corrective actions.

Supply chain and logistics risks- Supply chain and logistics risks include last-mile delivery challenges, and stock-outs. Although the probability is low, the impact could be high. Mitigation measures include maintaining buffer stocks, improving redistribution mechanisms, enhancing coordination with NMS/JMS and partners, and using logistics information systems for commodity tracking.

Community and demand- Related risks include low awareness and limited trust or acceptance of the new technology, with medium probability but high impact. Mitigation measures include community sensitization campaigns, engagement of VHTs, CSOs, patient champions and local leaders, development of IEC materials in local languages, strengthening feedback mechanisms, and demonstrating benefits through pilot success stories.

Stakeholder and coordination risks arise from differing interests and weak coordination mechanisms, potentially affecting implementation efficiency. Although the probability is low, the impact is high. Mitigation measures include establishing a multi-stakeholder coordination platform, defining clear roles and responsibilities, conducting regular engagement meetings, strengthening communication and accountability, and formalizing partnerships through MOUs and collaboration frameworks.

11. Sustainability Strategies

The sustainability of early implementation of nPOC will depend on strong governance systems, integration into existing health structures, sustainable financing, and continuous stakeholder engagement.

Under governance and leadership, sustainability will be enhanced by integrating nPOC implementation into existing MOH, NTLP, and NHLDS strategic plans and policies. Working with the laboratory technical working committee will support oversight, coordination, and scale-up activities, while clear governance structures, defined roles, and accountability mechanisms at national and subnational levels.

Promote domestic financing, advocate for inclusion of nPOC commodities, maintenance, and operational costs within national and district health budgets. Activities should be integrated into annual operational plans and funding proposals to secure sustainable financial support.

Sustainability of human resource capacity can be achieved through establishment of a Training of Trainers (ToT) model by training national and regional trainers, Integration of competencies into existing laboratory and clinical training curricula, routine mentorship, supportive supervision, and competency assessments.

Integration into existing systems- nPOC services will be integrated into existing TB diagnostic, sample referral, and laboratory systems, using current reporting, connectivity, and quality management platforms. Aligning with national TB diagnostic algorithms and workflows will enhance efficiency and sustainability.

Supply chain sustainability-integration of nPOC commodities into the national quantification, procurement, and distribution systems. Establishment of minimum and buffer stock, strengthen logistics management information systems to improve forecasting and inventory monitoring.

Equipment maintenance and technical support, sustainability mechanisms include development of service agreements and maintenance plans with vendors and manufacturers. Building local technical support capacity for routine maintenance and troubleshooting. Maintain Equipment uptime monitoring systems and rapid response mechanisms.

Quality assurance sustainability -Include integrating nPOC into national quality management systems and EQA programs. Standardized SOPs, job aids, and validation protocols, alongside routine supervision, internal quality controls, and performance monitoring activities.

Effective data management and connectivity systems are also essential for sustainability. Strengthening digital connectivity and integration with national health information systems will improve real-time reporting and monitoring. Data dashboards can be used to monitor utilization, positivity rates, turnaround times, and stock status, while promoting data use for decision-making at facility, district, and national levels.

Community engagement and demand creation will support long-term uptake and acceptance of nPOC services. Civil Society Organizations (CSOs), Village Health Teams (VHTs), community leaders, and patient networks will be actively engaged in awareness and advocacy activities. Targeted information, education, and communication (IEC) materials will be developed to improve understanding and acceptance of nPOC services, while community feedback and accountability mechanisms should be strengthened to promote ownership.

Public–private partnerships will also contribute to sustainability by engaging private health facilities and laboratories through the national Public-Private Mix (PPM) framework. Access to services can be expanded through accredited private providers linked to national reporting and quality systems, supported by

routine supervision and appropriate incentives for participation.

Monitoring, evaluation, and learning mechanisms- establishment of routine indicators to monitor utilization, quality, coverage, and impact. Periodic program reviews and implementation assessments will help identify gaps and inform improvements. Documentation of lessons learned, best practices, and operational research findings will support evidence-based scale-up and sustainability planning.

Finally, a phased scale-up strategy will be adopted, beginning with implementation in high-burden and high-volume sites to demonstrate impact and feasibility. Early implementation results and pilot experiences will be used to mobilize additional resources, strengthen stakeholder buy-in, and guide gradual expansion based on performance, readiness, and resource availability.

12. Monitoring & Evaluation (M&E) Plan for nPOC Implementation in Uganda

The M&E objectives cover early adopter (Phase 1) and scale-up phases (Phase 2) for nPOC. The overall objective is to track nPOC implementation fidelity, service delivery outputs, and TB case notification and treatment outcomes using routine health information systems.

Under the early adopter phase, operational data will be collected to evaluate the effectiveness of nPOC technologies in improving access to molecular WHO-recommended rapid diagnostics (mWRDs), TB case notification, treatment initiation, and treatment outcomes across decentralized health facilities; determine the most appropriate level of the healthcare system for deployment of nPOC technologies; assess whether these platforms improve timely diagnosis and linkage of people presumed to have TB to treatment; evaluate the feasibility and operational requirements for decentralized testing; identify the appropriate healthcare worker cadres to operate the platforms; assess infection prevention and control measures related to sample collection, testing, and waste management; evaluate feasible approaches for drug-resistance determination and reflex testing; assess patient pathways and sample collection strategies including tongue swab use; examine the implications of nPOC deployment on sample transport systems, equipment maintenance, and supply chain management; and estimate the costs and cost differentials associated with implementing nPOC technologies within the TB diagnostic network.

Table 4: Key Indicators, Numerators/Denominators, Data Sources & Timelines

Strategic Area	Indicator	Numerator	Denominator	Data Source	Frequency
Deployment & Coverage	% of planned sites implementing nPOC	Active nPOC sites	Planned nPOC sites	DHIS2, IRRDS	Quarterly
nPOC Contribution to Regional Referral Diagnostic Services (RRDS)	% TB notifications from nPOC	TB cases diagnosed via nPOC	Total TB notifications	DHIS2, TB registers	Monthly/ Quarterly
Diagnostic Yield	TB positivity rate	TB-positive patients	Total tested patients	EMR/eAFYA, Lab registers	Monthly
Treatment Linkage	Treatment initiation rate	Confirmed TB patients started on treatment	Confirmed TB patients	TB registers, EMR	Monthly
Operational Feasibility	Error/invalid test rate	Invalid/error tests	Total tests performed	Platform logs	Monthly
HR Capacity	Staff competency rate	Competent staff	Trained staff	Training reports	Quarterly
IPC Compliance	IPC adherence rate	Compliant observations	Total observations	IPC checklists	Quarterly
Reflex DST	DST coverage rate	TB-positive patients receiving DST	TB-positive patients	IRRDS, Lab databases	Monthly

Tongue Swab	Paired sample collection rate	Patients with tongue swab + sputum	Eligible presumptive TB patients	TB registers	Monthly
Transport Efficiency	Sample rejection rate	Rejected samples	Samples transported	Transport logs	Monthly
Equipment Performance	Equipment downtime rate	Downtime days	Operational days	Maintenance logs	Monthly
Costing	Cost per TB case detected	Total implementation cost	TB cases detected	Financial records	Midline/ Endline

Key Indicators

Where applicable, indicators will be disaggregated by sex, age group, facility level, and key populations reported under three domains:

Input / Process Indicators

- Number of facilities implementing nPOC
- Number of health workers trained
- Availability of TB screening and diagnostic tools

Output Indicators

- Number of individuals screened for TB
- Number of presumptive TB cases notified
- Number tested for TB (by diagnostic method)
- Number tested for HIV
- Number of samples tested
- Number of samples rejected
- Number of positive nPOC results
- Number of positive nPOC tests with DST result
- Number Rif Resistant patients
- Number of error/invalid results
- Number of nPOC devices working
- Number of tests remaining

Outcome Indicators

- Number of TB cases notified (all classifications, disaggregated by age, sex, HIV)
- Treatment initiation rate
- Treatment outcomes (success, loss to follow-up, mortality)
- Proportion of TB patients that are bacteriologically confirmed
- Proportion of notified new and relapse TB patients tested with nPOC as the initial test
- Proportion of notified new and relapse TB patients tested with nPOC with DST for at least Rifampicin

Data Sources and Collection Systems

The M&E system will draw on multiple data streams to capture both routine service delivery outcomes and implementation/process indicators related to near point-of-care (nPOC) TB testing using a data tool developed for the early adopter phase.

Facility-Level Routine Data (Primary Data Source)

Data will be collected using existing national tools to ensure alignment with the Ministry of Health systems. Aggregate quarterly reporting will be supplemented by individual-level patient data extracted from routine systems as shown below:

National systems

- DHIS2: Aggregated quarterly reporting
- eCBSS: Patient level data
- Restrack sample tracking for sample referral through the hub system
- Integrated requests and results dispatch system (IRRDS)
- Early adopter tool: TB Info

HC IVs, hospitals, GHs and RRHs

- eAFYA: Patient-level data
- ALIS: Laboratory data

HC IIIs and IIs

- Electronic Medical Records (eMR) &TB info: Patient-level data
- Facility-based paper and electronic registers: OPD Register, ANC Register, Linkage Register, ART Register, Presumptive TB Register, Laboratory request form, Unit TB Laboratory Register, Laboratory result forms, Unit TB Register, TPT Register, Patient TB Treatment Card

In line with the phasing out of paper-based systems, we will foster integration with the NTRL information system and IRRDS. Electronic registers and databases will be updated by NHLDS and NTLP to include tongue swab collection, expand platforms to include nPOCs, and update the interface with ALIS (Africa Lab Information System). We will explore tracking the same sample beyond regional hubs for DR TB. These data sources will be used to measure:

- TB testing volumes and yield
- Turnaround time (test ➔ result ➔ treatment)
- Linkage to treatment and treatment outcomes
- Differences in performance by facility level (PHC vs higher-level facilities)

Implementation and Programmatic Data Sources

To answer feasibility and process-related questions for nPOC deployment, additional non-routine data will be collected:

- Training reports and attendance registers (Number and cadre of staff trained)
- Competency assessment results (EQC, EQA)
- Support supervision and mentorship reports
- Data quality findings
- IPC compliance
- Operational challenges and corrective actions
- Site readiness and assessment tools
- Infrastructure availability (space, power, ventilation)
- Equipment functionality and placement
- Logistics and supply chain records
- Stock cards, consumption reports, and stock-out records
- Expiry tracking for test kits and cartridges
- Equipment and maintenance logs
- Platform uptime/downtime
- Frequency and duration of breakdowns
- Service and maintenance agreement performance

Laboratory and Referral System Data

This data will be critical for evaluating the feasibility of reflex testing strategies and efficiency of integrated hub transport systems

Sample referral and transport logs

- Number of samples referred for reflex DST testing
- Transport turnaround time and sample rejection rates
- Reference laboratory databases
- DST results
- Confirmation of rifampicin resistance and DR-TB pathways

Infection Prevention and Control (IPC) and Waste Management Data

These will assess compliance with decentralized testing standards.

- IPC checklists (from supervision visits)
- Facility IPC registers/logbooks
- Waste management records
- Segregation, storage, and disposal practices
- Expiry and wastage of kits

Costing and Economic Data Sources

To assess cost and cost-effectiveness of nPOC deployment:

- Facility financial records and expenditure reports
- Procurement and pricing data (cs, consumables)
- Transport and logistics cost records
- Maintenance and service contract costs
- Staff time allocation (through time-use or activity logs, where feasible)

Data Integration and Management

Patient-level data from eMR/eAFYA systems will be periodically reconciled with aggregate data in DHIS2 during support supervision visits. Unique identifiers (where available) will be used to track patient pathways across testing, diagnosis, and treatment. Data from different sources will be triangulated during quarterly reviews to validate findings and strengthen interpretation.

Data Flow and Reporting Structure

- Facility level: Data recorded daily in registers and EMR/eAFYA systems.
- Monthly reporting: Facilities compile and submit monthly reports to implementing partners/centrally.
- Quarterly reporting: Aggregated data submitted through DHIS2
- Data integration: Patient-level data (EMR/eAFYA) will be periodically reconciled with aggregate reports to ensure consistency

Data Quality Assurance (A)

To ensure quality we will perform:

1. Routine monthly data validation checks at the facility level
2. Quarterly support supervision visits focusing on:
    - Register completeness
    - Data verification to ensure consistency between registers and DHIS2
    - Resolution of data queries
    - Use of data quality checklists and dashboards
    - Feedback loops to facilities with documented action points
    - Mentorship on data recording and reporting
    - Review of key performance indicators
3. Quarterly review meetings at district/regional level to:
    - Compare facility performance
    - Identify gaps and best practices
    - Develop improvement plans
4. Data Use for Decision-Making

Monthly facility-level review of indicators and dashboards (where possible) from eMR/eAFYA to identify:

- Low TB yield sites
- Gaps in screening or diagnosis
- Trigger targeted interventions (training, mentorship, resource allocation)

Data Management and Confidentiality

i) Patient-level data extracted will be de-identified before analysis

ii) Access limited to authorized personnel

iii) Compliance with national data protection guidelines

Appendices

Annex 1: Distribution of mWRD by type and facility level in Uganda

Level	mWRD Availability Yes	mWRD Not Availability	Grand Total	GeneXpert	Truenat	TB LAMP
HC II	1	5105	5106	1	0	0
HC III	52	2085	2137	39	5	8
HC IVs	186	89	275	148	32	**6**
General Hospital	100	98	198	100	3	3
Specialized Hosp	3	7	10			
RRH	16	0	16	21	0	0
NRH	5	0	5	0	0	0
National Reference labs	2	0	2	5		
Research labs	40		Not indicated in the master list		0	0
Clinics	16	14	30	16	0	0
TB vans	5	0	5	GX IV, 6 color, **5**	0	0
Others	2 State house Grace lab			GX IV, 6 color, **2**	0	0

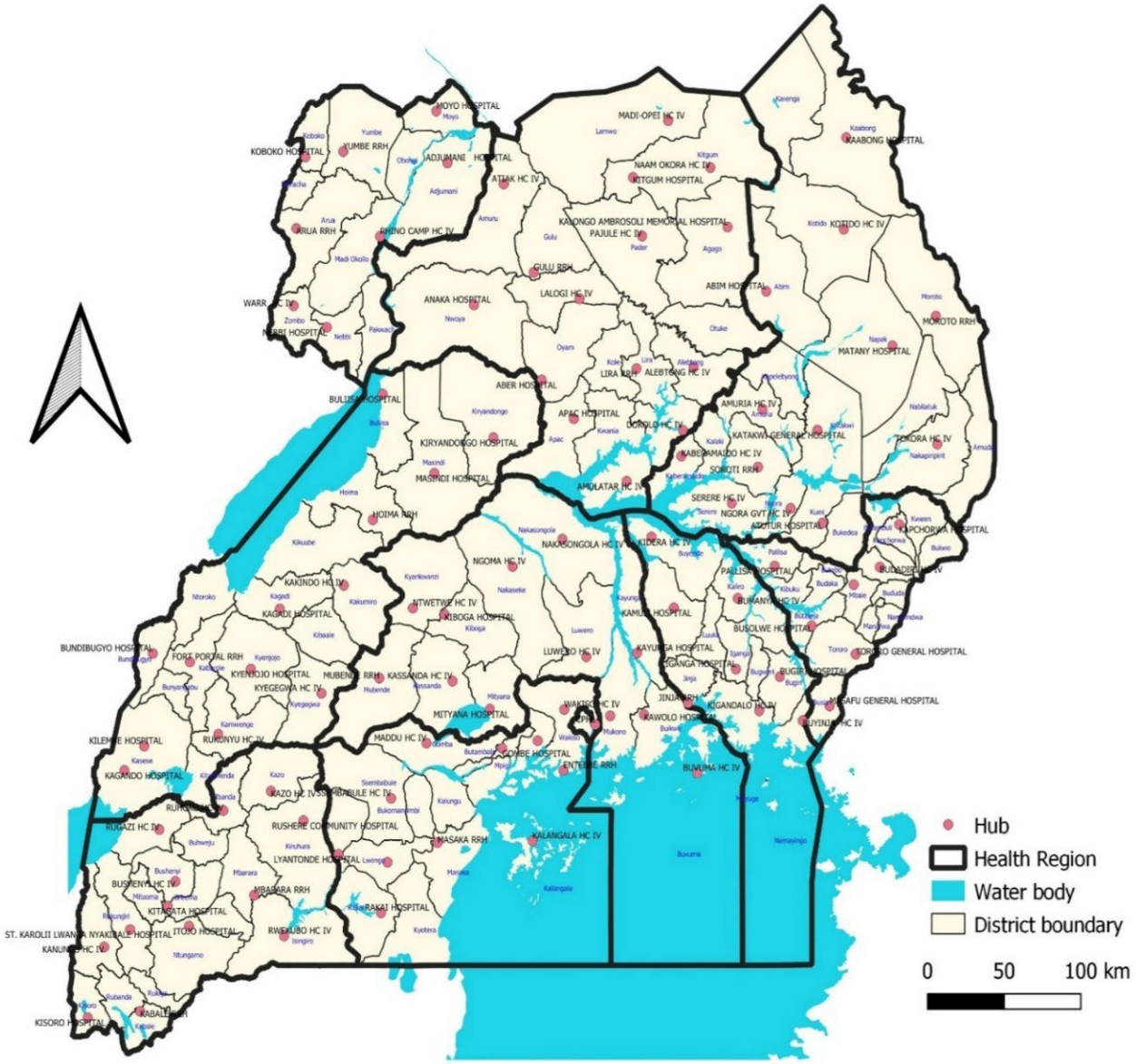
Annex 2: Grading of health facilities.

Criteria	Indicator	Weight
Access gap	Distance to nearest mWRD site	High
TB burden	Notification rates/hotspot classification	High
Facility readiness	Lab space, staffing, and electricity	Medium
Patient volume	OPD/HIV clinic load	Medium
Referral connectivity	Linkage to DST hub	High
Population priority	Presence of key/vulnerable populations	High
Equipment gap	Lack of existing diagnostic tools	High

Annex 3: Activities & Frequency — Regulatory

Activity	Responsible Party	Frequency	Target Timeline
In country Laboratory evaluation of nPOC device	NHLDS	Once (pre-deployment)	Completed
Registration in procurement catalogues (NMS)	NTLP /nPOC representative	Once, then update as needed	Completed
NDA import approval for equipment, reagents & consumables	NDA / MoH	Annually or per shipment	Q2 2026
Field evaluation at selected pilot sites	NTRL / NTLP field teams	Once (pre-roll-out)	Q2 2026
Reporting and formal approval by MoH	MoH / NTLP	Once	Q3 2026
Post Market Surveillance	NDA	After installation	Continuous

Annex 4: Map showing the coverage of the NSRTN



Annex 4: M&E Logframe for nPOC Implementation

Objective	Key Indicators	Data Sources	Key Activities	Frequency	Responsibility
1. Optimal placement of nPOC technologies	Number/proportion of sites implementing nPOC by level; TB testing volume; yield; turnaround time	DHIS2, eAFYA, EMR, facility registers	Conduct facility readiness assessments; deploy platforms; monitor performance by level; comparative analysis	Quarterly	M&E team, District TB focal persons
2. Linkage to treatment	Treatment initiation rate; time from diagnosis to treatment; same-day initiation; pre-treatment LTFU	TB registers, EMR/ eAFYA, DHIS2, LabXpertDS, MDR Hospital Access	Track patient pathways; cohort reviews; monitor linkage timelines; follow-up missed patients	Monthly / Quarterly	Facility staff, M&E officers
3. Feasibility and implementation processes	Sites activated; tests per site; error rates; stock-outs; equipment functionality	Supervision reports, stock records, site assessments	Develop SOPs; site activation; monitor performance; document challenges; conduct process evaluations	Monthly / Quarterly	Implementing partners, facility teams
4. Human resource capacity	Number trained; competency levels; tests performed by cadre; error rates by cadre	Training reports, competency assessments, supervision reports	Train staff; assess competency; mentorship; refresher training	Quarterly	Training team, district supervisors
5. Infection Prevention and Control(IPC) measures	Sites with IPC systems; adherence to SOPs; IPC incidents	IPC checklists, supervision reports, facility logs	Train staff on IPC; ensure supplies; conduct compliance assessments; monitor incidents	Quarterly	Facility IPC focal persons, supervisors
6. Drug-resistance and reflex testing	Proportion receiving DST; time to DST results; DR-TB initiation	Lab registers, referral logs, reference lab data, IRRDS, LabXpertDS, MDR Hospital Access	Establish referral systems; track samples; monitor turnaround time; evaluate DR-TB linkage	Monthly / Quarterly	Lab teams, regional coordinators
7. Patient pathways and sample collection	Proportion with paired samples; return rates; diagnostic completion	TB registers, EMR/ eAFYA	Standardize sample protocols; track patient flow; monitor return visits; assess barriers	Monthly	Facility staff, M&E team

8. Health system integration and equipment maintenance	Sample transport efficiency; downtime; stock-outs; maintenance coverage	Transport logs, maintenance records, stock cards	Integrate transport systems; monitor logistics; track equipment uptime; manage supplies	Monthly / Quarterly	Logistics team, biomedical engineers
9. Cost and cost-effectiveness	Cost per test; cost per case detected; incremental cost	Financial records, procurement data, time-use logs	Collect cost data; conduct costing analysis; compare with standard care	Periodic (mid/ endline)	Health economists, finance team
10. Efficiency of specimen referral system	Proportion of samples referred for which results were returned. Target is ≥96% (assumption that 5% will be the errors and 1% will be rejection rate)	IRRDS	Establish IRRDs	Quarterly	NTRL
11. Result TAT	Proportion of referred samples for which results were returned within 48 hours. Target is ≥90%)			Quarterly	NTRL
12. nPOC Utilisation	Utilisation rate of the nPOC test at the nPOC testing site (Target is ≥80%)		DHIS-2	Quarterly	NTRL

Partners

Cover Picture Source

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