QUALITY ASSURANCE PACKAGE FOR TB LF-LAM TESTING

- A USER GUIDE -

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Acknowledgements

The development of the Quality Assurance Package for TB LF-LAM Testing – A User Guide and related package contents were supported by the African Field Epidemiology Network (AFENET) with technical and financial support from the U.S. Centers for Disease Control and Prevention (CDC) and funding from the United States President's Emergency Plan for AIDS Relief (PEPFAR) under the terms of cooperative agreement NU2GGH002140 titled *"Supporting HIV-Related Laboratory Networks and Partnerships to Facilitate Laboratory Strengthening and Management Activities for Countries Supported under PEPFAR."*

The following experts and institutions of affiliation are appreciated for their contribution towards the preparation, review, and finalization of manual content:

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Disclaimer

Abbreviations and Acronyms

AFB	Acid-Fast Bacilli
AFENET	African Field Epidemiology Network
CDC	U.S. Centers for Disease Control and Prevention
CQI	Continuous Quality Improvement
EQA	External Quality Assessment
FIND	Foundation for Innovative New Diagnostics
LF-LAM	Lateral Flow Lipoarabinomannan
GLI	Global Laboratory Initiative
ISO	International Organization for Standardization
IQC	Internal Quality Control
M&E	Monitoring and Evaluation
MDR-TB	Multi-Drug Resistant Tuberculosis
MoH	Ministry of Health
MTBC	*Mycobacterium tuberculosis* Complex
NHLS	National Health Laboratory Services
NTRL	National TB Reference Laboratory
PLHIV	People Living with HIV
POCT	Point-of-Care testing
PPE	Personal Protective Equipment
PT	Proficiency Testing
QA	Quality Assurance
QC	Quality Control
QI	Quality Indicator
QMS	Quality Management System
SOP	Standard Operating Procedures
SPI	Stepwise Process for Improving Quality
TB	Tuberculosis
TWG	Technical Working Group
TOT	Training of Trainers
WHO	World Health Organization
WRD	WHO-Recommended TB Diagnostic

Executive Summary

Lateral Flow Lipoarabinomannan (LF-LAM) tests are the first urine-based TB diagnostic point-of-care assays recommended by the World Health Organization (WHO) for bacteriological confirmation of tuberculosis (TB) among eligible people living with HIV in both in- and out-patient settings[1]. Since 2019, many countries have included the LF-LAM test in their national TB diagnostic algorithms and initiated implementation[2]. However, there have been widespread challenges and gaps in the implementation of Quality Assurance (QA) activities to ensure LF-LAM testing is accurate, reliable, timely, and maximally impacting patient care and disease control programs[3].

To address gaps in LF-LAM QA program roll-out and quality management system establishment, the LF-LAM QA Package was developed Content was informed by (i) International Laboratory Branch (US CDC, Global Health Center, Division of Global HIV and TB) authors and Global Laboratory Initiative Core Group member reviewer and endorser practical experiences with implementation of quality management systems, activities, and tools for CD4, LF-LAM, and HIV point-of-care diagnostic tests, (ii) published accounts of LF-LAM performance and quality assurance gaps and documentation needs, (iii) feedback from countries implementing LF-LAM collated from Global Health Impact Group, African Field Epidemiology Network, and African Society for Laboratory Medicine webinars on LF-LAM testing held from 2020 - 2023 and (iv) select de-identified LF-LAM quality assurance documentation volunteered from several implementing countries with high burdens of TB/HIV disease. The content is intended to complement existing Global Laboratory Initiative[4] and World Health Organization materials and recommendations for LF-LAM testing[1,5].

Stakeholders implementing LF-LAM testing may consider adapting the phased QA system approach outlined within the User Guide, and/ or adopting and adapting included considerations and tools, based on their specific context to ensure local and sustainable quality assurance program ownership.

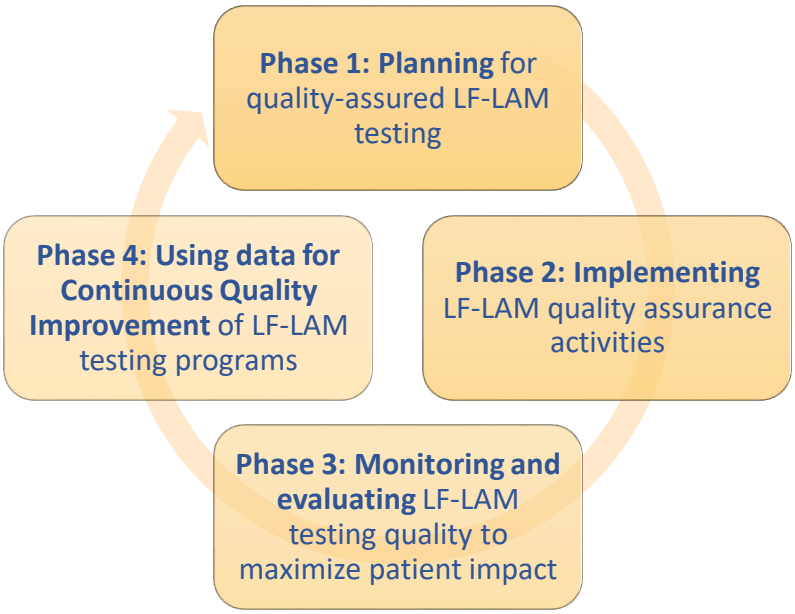
PACKAGE OVERVIEW

Purpose

As one component of the LF-LAM Quality Assurance (QA) Package, this User Guide:

- Outlines best practices and key considerations for phased LF-LAM quality assurance system planning, implementation, monitoring, and continuous quality improvement (Figure 1), and
- Describes and contextualizes an included set of customizable quality assurance documentation specific to LF-LAM testing for use at both above-site and testing site levels (Figure 2)
- Provides a high-level overview of how to implement the practical and customizable quality assurance protocols, forms, and training slides in the Package

Figure 1: Quality Assurance Cycle for LF-LAM Testing



The Package is designed to capacitate stakeholders on the minimum requirements and activities needed to assure the quality of LF-LAM testing. Package documentation may be rapidly adopted and used across a range of settings implementing LF-LAM at in-patient, out-patient, and community settings.

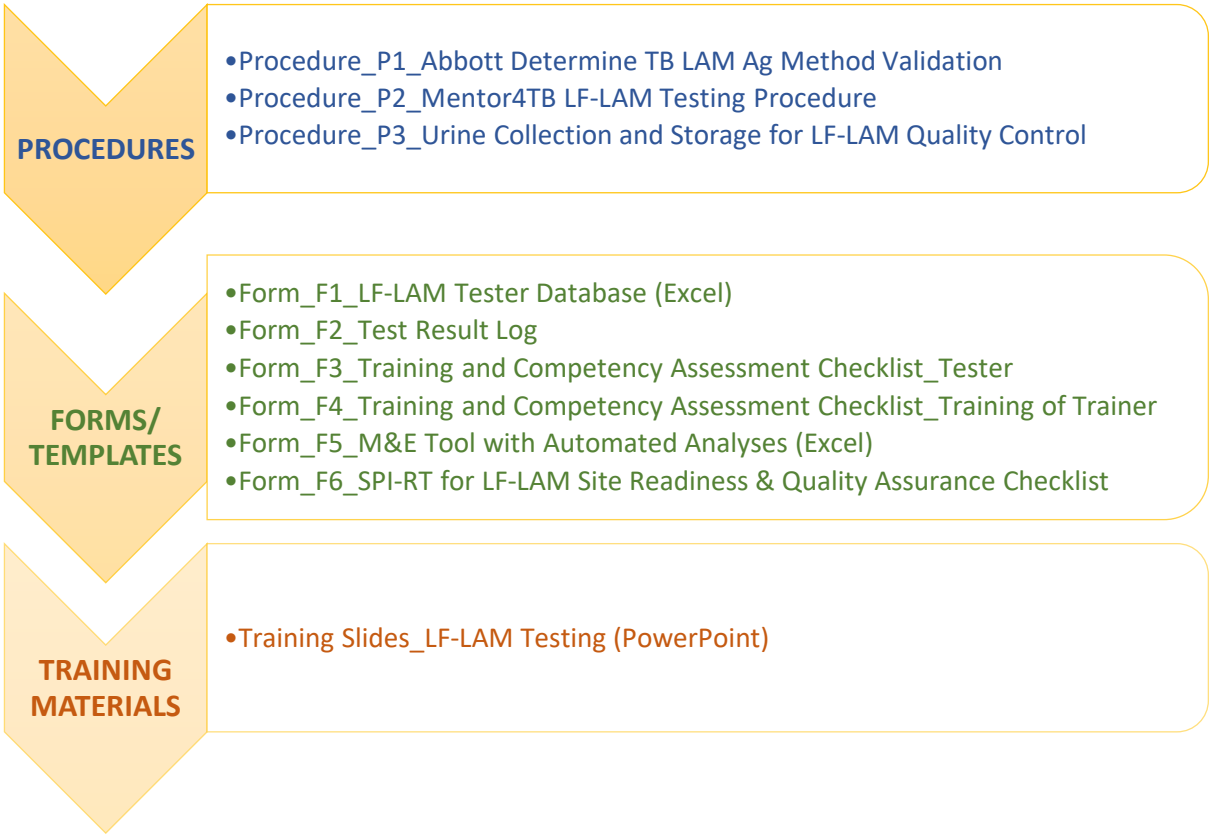
Target audience

This guide is intended for stakeholders (laboratory and non-laboratory) involved in test implementation across the TB cascade of care, including (but not limited to): policy makers, TB and HIV Programme managers, advanced HIV disease technical working groups, testing program trainers, supervisors, and staff, healthcare workers (including those in the community), and implementing partners.

Scope

The Package applies to LF-LAM testing conducted in any setting (i.e., laboratories, clinical service points, hospitals, and clinics, community, or outreach healthcare settings) and includes materials relevant to both above-site (supervisory) and testing site levels (Figure 2).

Figure 2: Contents of the LF-LAM Quality Assurance Package



Phase 1: Planning for quality-assured LF-LAM testing

1.1 Establishing governance mechanisms, defining roles and responsibilities, and strategic planning for test implementation

Realistic and practical planning with involvement of all relevant stakeholders across HIV and TB disease programs is critical for the successful introduction and rollout of LF-LAM. The foremost action for countries to ensure establishment, impact, and sustainability of an LF-LAM Quality Assurance (QA) program includes setting up a comprehensive governance structure. The structure will be most beneficial if it includes clear roles, responsibilities, lines of communication and reporting for performance and quality monitoring of LF-LAM testing at all levels of the health system. Countries may consider integrating LF-LAM testing governance structures into existing national laboratory, TB, HIV, and/ or advanced HIV disease governance structures, including existing technical working groups[4].

While governance structures, roles and responsibilities at the national and supervisory levels may differ by country, those involved in governance will benefit most if clear communications linkages between HIV and TB disease programs are used to establish or coordinate and standardize TB/HIV testing policies, plans, and provide oversight at the national level, and guide coordination for test implementation across disease programs and technical areas (clinical and testing/ laboratory) at testing sites. Lastly, introduction, use, and scale-up of LF-LAM testing services may be considered when revising National Laboratory and Disease Program Strategic Plans to ensure the testing services are appropriately planned, contextualized among other program priorities, and matched with setting-specific multi-year targets and goals for LF-LAM testing services.

1.2 Projecting and budgeting for LF-LAM commodities and supplies

As highlighted in the GLI Practical implementation of LF-LAM for detection of active TB in people living with HIV | Stop TB Partnership, both TB and HIV programs should use their expected number of patients eligible for LF-LAM testing (according to the country's testing algorithm) to inform procurement needs[4]. Eligible patient populations include HIV-positive presumptive TB patients with signs and symptoms of TB, advanced HIV disease (including those with CD4 cell counts less than 200 cells/ mm^3), and severe HIV illness[1,5]. If countries have other eligibility criteria for LF-LAM testing, these will be best reviewed to ensure setting-specific testing volumes are estimated. Wherever possible, these data will be best reviewed against the geographic distribution of patients to match projected budgetary needs with test distribution plans that consider kit size(s). If the data are not readily available, HIV and TB disease programs may elect to use proxy datasets (such as HIV/TB co-infection rates) to inform more immediate procurement needs, while working together to develop a plan for more comprehensive data collection that may be used refine procurement needs. Lastly, once data are on hand, the GLI Planning and budgeting tool for TB and drug resistant TB testing may be used to estimate the number of commodities required for LF-LAM (and other TB) testing services[6].

Phase 2: Implementing LF-LAM quality assurance activities

2.1. Quality procedures and documentation

Documentation of quality activities and procedures across the LF-LAM testing cascade, including the pre-testing, testing, and post-testing phases is key to ensuring standardized testing services that can be monitored for performance, quality, and impact. *Box 1* provides a summary of considerations for the establishment and management of LF-LAM QA operational documents including plans, guides/guidelines, procedures, job aids and related tools. This package represents a collection of LF-LAM testing quality documentation (procedures, forms, and training materials) that enables standardized training, recording, reporting, and monitoring of quality procedures specific to LF-LAM testing. Package contents are intended to compliment other advanced HIV disease, TB diagnostic testing, and site- and equipment-specific quality policies, algorithms, job aids, and other materials.

Box 1: Considerations for LF-LAM testing procedure and documentation activities	
Above site/ Supervisory level	☐ Develop or adapt, control, and disseminate LF-LAM testing QA documents ☐ Perform LF-LAM testing QA supervisory activities using established procedures ☐ Support lower-level facilities to maintain an up-to-date document control log ☐ Coordinate the withdrawal and disposal of obsolete documents from testing sites
Testing Site	☐ Obtain approved LF-LAM testing and QA documents for use at testing locations ☐ Perform site level LF-LAM testing and QA activities following approved procedures and using approved and controlled documents ☐ Maintain an up-to-date document control log detailing all available documents in use ☐ Remove obsolete documents from use

2.2. Test performance validation/ verification

New method validation, a process that evaluates the performance of LF-LAM testing against the performance reported by the manufacturer using a standardized testing procedure, should be performed before rollout[1,7]. New method validation should not be done to evaluate the diagnostic accuracy of LF-LAM testing[1,4,7]. Successful validation testing is always designed, completed, and documented to ensure that the established diagnostic accuracy is achievable by the new testing location (including lab staff) using the kits provided and a site-specific standardized operating procedure. The standardized, country- and site-customizable ***GLI Mentor4TB Abbott Determine TB LAM Ag Testing Procedure*** is provided as part of this Package. As with introduction of any new test to a disease program, per WHO and international accrediting body standards, new method validation testing is coordinated and conducted by the national reference laboratory (NRL), in line with established standards. Results from validation and routine testing may also be documented on the Package's provided ***Form_F2_Test Result Log.***

2.2 Key Package Documents:

Procedure_P1_Abbott Determine TB LAM Ag Method Validation

Procedure_P2_Mentor4TB Abbott Determine TB LAM Ag Testing Procedure

Procedure_P3_Urine Collection and Storage for LF-LAM Quality Control

Form_F2_Test Result Log

After new method validation, LF-LAM tests that perform acceptably may be distributed to testing sites. Testing sites do not need to repeat new method validations completed by national or other in-country reference laboratories. However, testing sites should use positive and negative controls to verify the performance of each new lot and competence of the testers of using their site-specific procedures[1,4,7]. This new lot testing can be done in parallel with initial or refresher tester trainings. Similarly, the NRL should conduct post market validation of new kit lots received in country prior to their distribution. Performance validation testing should also be completed after major modification(s) to the testing procedure or any time there are changes in test version or formulation[7]. The standardized operating ***Procedure_P1_Abbott Determine TB-LAM Ag Method Validation*** provided with this Package may be customized and used by NRLs, supervisory sites, and/ or testing sites for all types of method validation. If external quality control materials with known LF-LAM results are not available for use as validation samples, well-characterized patient urine samples may be used. The standardized operating ***Procedure_P3_Urine Collection and Storage for LF-LAM Quality Control*** that is provided with this package may be referenced to guide urine collection, characterization, and appropriate storage for use as validation material. As always, these procedures should be reviewed and customized for use at each testing site[8].

2.3. Testing, Training, Competency Assessment and Certification of Testing Personnel

While LF-LAM testing is a simple urine-based point of care test (POCT), to ensure accuracy of results, all testing should be performed by trained and competent testers[7,8]. To ensure competence of testing personnel, countries should ensure that training and competency assessment programs are available to all testers across the testing network and may consider establishing or expanding certification programmes for LF-LAM assays. These programs are particularly important for POCTs, which are often geographically dispersed across established laboratory and non-laboratory settings, including health facilities, hospital wards at bedside, and community testing sites, and often require a high number of decentralized lab and non-lab testers. Establishment of national or regional tester database(s) can facilitate awareness of tester number, type, location, training/ competency assessment/ certification status, and training/ competency assessment needs in the capture area. This Package therefore includes the Excel-based ***Form_F1_LF-LAM Tester Database*** that can be adopted by implementing countries and used to track national, subnational, and site-based tester numbers and service needs.

2.3 Key Package Documents:

Form_F1_LF-LAM Tester Database (Excel)

Form_F2_Test Result Log

Form_F3_Training and Competency Assessment Checklist_Tester

Form_F4_Training and Competency Assessment Checklist_Training of Trainer

Training Slides_LF-LAM Testing (PowerPoint)

To ensure all personnel performing LF-LAM testing are trained using standardized training materials with content relevant for stakeholders, healthcare workers, clinicians, and testers (among others), this QA Package also provides a customizable LF-LAM Training PowerPoint slide deck. The ***Training Slides_LF-LAM Testing*** review relevant facts and processes related to TB disease, TB/HIV co-infection, mycobacterial LF-LAM as the testing target, the LF-LAM testing algorithm and procedure (with a placeholder for an in-person testing demo), essential LF-LAM quality assurance program elements, and case scenarios that review appropriate LF-LAM result interpretation for clinical action. Slide content was developed based on best practices for testing procedure trainings offered to healthcare workers and testers, as well as common errors and reported re-training needs specific to LF-LAM testing (i.e., algorithm adherence, result interpretation for clinical use, improper quality control material).

To document initial trainings and competency assessments, two checklists are provided in this Package. The first is the ***Form_F3_Training and Competency Assessment Checklist_Tester*** document that is used to document tester training. The second is a complementary ***Form_F3_Training and Competency Assessment Checklist_Training of Trainer*** document that may be used to ensure competency of trained testers to train others. This Training of Trainers approach is useful for POCT networks, which often include a high number of testers across a large geographic area. By ensuring the program has sufficient on-site or supervisory Master Trainers, POCT training and competency programs are less reliant on a low number of centralized trained staff and may more easily sustain tester turnover and network expansion.

Once trained, all testers and trainers and the dates their competency was assessed may be captured in the ***Form_F1_LF-LAM Tester Database*** described above for program awareness and monitoring.

Following initial training and competency, LF-LAM testers should be re-assessed for competency after six months and annually thereafter or based on other national requirements for point-of-care tests[10]. ***Box 2*** below provides a summary of recommended activities for rolling out a training, competence assessment and tester certification program for LF-LAM testing.

Box 2: LF-LAM testing training, competence assessment and tester certification considerations
General considerations
☐ Use standardized training material for all cadres of trainees *[refer to Training Slides_LF-LAM Testing]*
☐ Train Master Trainers using a Training of Trainers approach to support decentralized tester training needs
☐ Adopt a database of all trained LF-LAM testing personnel [*refer to Form_F1_LF-LAM Tester Database*]
☐ Consider developing or expanding a tester certification program for rapid point-of-care LF-LAM testing
Planning for training
☐ Customize standardized LF-LAM training materials to reflect country recommendations/ policies *[refer to Training Slides_LF-LAM Testing]*
☐ Establish an annual (or as needed) LF-LAM training plan and identify resources to support implementation
☐ For LF-LAM testing networks that are geographically widespread or include high numbers of decentralized testing sites, identify candidate Master Trainers that might best support training of geographically dispersed testers
Training of trainers (optional)
☐ Train a pool of Master Trainers using standard and customized LF-LAM materials *[refer to Training Slides_LF-LAM Testing]*
☐ Document the competency of all Master Trainers using a fit-for-purpose checklist *[*refer to *Form_F4_Training and Competency Assessment Checklist_Training of Trainer*]
Training of testers
☐ Coordinate and deliver LF-LAM training for all testers using standard and customized materials *[refer to Training Slides_LF-LAM Testing]*
☐ Ensure tester training is documented using a fit-for-purpose checklist [*refer to Form_F3_Training and Competency Assessment Checklist_Tester]*
☐ Update the Tester Database with trained tester information [*refer to Form_F1_LF-LAM Tester Database*]
Competency assessment
☐ Assess the competency of all trained LF-LAM testers annually [*refer to Form_F3_Training and Competency Assessment Checklist_Tester]*
☐ Integrate regular competency assessments into supportive supervision visits
☐ Consider routine competency assessments for Master Trainers to document continued competency

Refresher training

- ☐ Conduct refresher training as required and based on competency assessment or supportive supervision findings
- ☐ Offer refresher training when an update on knowledge or skills is required in a certain area due to change(s) in guidelines, testing product or protocol, or when there is a significant gap (2- 3 months for new testers and >6 months for experienced testers) between the training and test implementation

2.4. Quality control (QC)

2.4 Key Package Documents:

Procedure_P3_Urine Collection and Storage for LF-LAM Quality Control

Form_F2_Test Result Log

Quality control is the process of verifying that the test kit and the procedures used are performed according to the manufacturer's intended specifications. Built-in internal quality controls, such as the control lines on rapid LF-LAM diagnostic tests, provide information about the adequacy of specimens, operational conditions, and whether the test is working properly. In addition to these built-in quality controls, countries should do routine external quality assurance testing using external quality control specimens (known positive and negative samples). External quality controls are used to assess the adequacy of the entire pre-analytical, analytical, and post-analytical testing processes, including specimen and test management, and reporting procedures. External quality control materials for LF-LAM may include known positive and negative QC samples that are manufacturer-provided or locally produced, or well-characterized urine specimens with known positive or negative LF-LAM and WRD results from patients with known TB disease status. For users without current access to manufacturer-provided and locally produced materials, this Package provides the ***Procedure_P3_Urine Collection and Storage for LF-LAM Quality Control*** to guide users through the process of urine collection, characterization, handling, and storage for use as external QC material. All external QC materials may be used to complete weekly QC during testing is performed, prior to testing of the first patient sample[4]. All quality control results should be recorded and routinely reviewed by testing sites and above site supervisory staff to ensure accurate, reliable, and on-time results are provided for patient care. If needed, this Package provides a ***Form_F2_Result Log*** that may be used to capture both patient testing and QC results.

2.5. Biosafety

As with all infectious materials and test procedures, urine specimens, LF-LAM tests, and testing waste should be managed using appropriate personal protective equipment and work practices[4]. All samples must be treated as potentially infectious materials[10]. Of note, LF-LAM testing does not require a biosafety cabinet or advanced engineering controls for test completion[4]. Testing should not be delayed due to a lack of this on-site infrastructure. However, it is important that all healthcare workers involved

in urine collection for LF-LAM testing and procedural testers are trained on national and site-specific biosafety guidelines and best practices prior to testing. For this purpose, the training materials and checklists included in this package include biosafety sections that may be customized by training programs for setting-specific use (see **Testing, Training, Competency Assessment and Certification of Testing Personnel**). Finally, each testing site should follow site-specific biosafety requirements[10].

2.6. Management of ancillary equipment and commodities/ supplies

2.6.1. Management of equipment

The ancillary equipment required for LF-LAM testing includes a timer and pipette (to measure appropriate testing times and urine to be tested). Other optional ancillary equipment may include a room thermometer to monitor the temperature of the LF-LAM test kit storage, a refrigerator (if urine will be stored for up to three days after sample collection), a freezer (if urine will be stored between three days and 3 years), and a centrifuge (if frozen urine will be used for testing). Management and verification of these instruments include procedures of routine calibration and verification as well as required maintenance activities according to manufacturer instructions. ***Box 3*** below provides a summary of ancillary equipment with general management considerations.

Box 3: LF-LAM testing ancillary equipment management considerations
General instructions for equipment management ☐ All testing sites should follow manufacturer guidance for routine equipment maintenance and document each instance on standardized or controlled logs or forms ☐ Equipment should only be operated by authorized and competent personnel with access to the relevant equipment instructions for use documents and manuals ☐ Temperature monitoring for spaces with LF-LAM tests and equipment should be routinely monitored and results documented using standard maintenance logs or forms ☐ Ancillary equipment should not be used outside of service/ verification/ calibration dates or if unable to meet calibration/ verification acceptability criteria
Timer Verification ☐ Annual verification or calibration is recommended for timers that have expired or been used one year beyond the provided manufacturer's certificate of calibration
Precision pipette calibration (where applicable) ☐ Pipette calibration is performed annually or as required by local programs, and after unexpected performance, using certified reference standards ☐ Pipettes that have been calibrated should be identified by a label that displays calibration status, equipment identification, the date of calibration, and the date for the next calibration.

Centrifuge calibration/verification (where applicable)

☐ Annual verification of centrifuge speed, time, and temperature (as applicable) is done annually using a tachometer and verified timer (see Timer Verification above)

Services/ maintenance of refrigerators and freezers (where applicable)

☐ Cooling units that have been serviced are identified by a sticker that shows service status, equipment identification, date of service, and the date for the next service.

2.6.2. Management of commodities/ supplies

The effective management of commodities and supplies for LF-LAM testing, including testing kits and related consumables, is critical for ensuring uninterrupted patient access to LF-LAM testing services. National programs must ensure that verified lots of LF-LAM test kits are available at testing sites. Testing sites may refer to considerations for LF-LAM commodity and supply management outlined in ***Box 4*** below.

Box 4: LF-LAM testing commodities management considerations for testing sites

Follow local health commodity supply chain management guidelines

Before ordering:

☐ Ensure testing staff are familiar with site-specific LF-LAM testing commodity lists and ordering schedule

☐ Identify an appropriate storage area that will (1) maintain commodities within appropriate storage temperatures (per manufacturer guidance) and (2) allow testers continuous access during working hours

To order:

☐ Determine the quantity to order for each item, based on historical consumption data, or other testing or national program guidance

☐ Complete the order form, seek supervisory review (if needed), and submit to the health facility store or governing program for processing by the advance due date

Receiving supplies and reagents from providers or suppliers

☐ Verify physical quantities against supply delivery documents

☐ Check the expiry date(s) where applicable

☐ Check for and report any physical abnormalities. Do not use test kits or units with physical abnormalities.

☐ Update related stock card (as applicable) on receipt of new item(s)

☐ Label received supplies and reagents with the date of receipt and receiver's initials

☐ Store in appropriate conditions (following manufacturer recommendation). Arrange items using either First Expiry First Out (FEFO) and/or First-In-First-Out (FIFO) system.

Monitoring stock status

☐ Label received supplies and reagents with 'In Use' when placed into service.

☐ On a weekly basis monitor the stock status of all items and document quantities on a stock card or other facility-specific stock register. ☐ When stock numbers reach the re-stock or re-order benchmark, repeat the ordering process
Handling of expired test kits ☐ If test kits expire, do not use them for testing. Label them "Expired" and return them to the health facility store, laboratory, or follow other national/ facility guidelines for disposal

Phase 3: Monitoring and evaluating LF-LAM testing quality to maximize patient impact

3.1. Assessing and improving the clinic-testing interface

The utilization of LF-LAM testing relies on clinicians and ordering healthcare worker demand for testing services. It is, therefore, essential to ensure that healthcare workers within the testing site capture area are appropriately trained on urine collection practices and all relevant aspects of LF-LAM testing (see Testing, Training, Competency Assessment and Certification of Testing Personnel). While many sites may perform LF-LAM tests at the point-of-care or even bedside for patients, some may require urine collection from patients in areas separate from where testing is done. In these latter cases, facility-specific processes, including urine transport and/ or cross-facility referral workflows may best be reviewed to achieve the most rapid turn-around times for patients. Similarly, test result reporting processes should be reviewed to ensure that testers provide both positive and negative results back to requesting healthcare workers as soon as results become available using appropriate reporting workflows for rapid tests. To facilitate site-specific assessments of patient access to LF-LAM (and MWRD) testing services, LF-LAM implementers may refer to the Diagnostic Cascade Evaluation (DiCE) Toolkit to quantify patient retention across their diagnostic cascades and develop corrective actions to address gaps[12].

3.2. Performance, Quality, and Cascade Indicator (QI) analysis, supportive supervision, and testing site assessment

While LF-LAM tests are of low complexity and rapid, their performance and quality should still be routinely monitored to identify unexpected results early for prompt corrective action to minimize unintended impact on patient results and care. All relevant stakeholders identified during the initial governance establishment process will be best-positioned to be involved in the development of an LF-

LAM test Monitoring and Evaluation Plan for consensus-building, buy-in, and ownership. As with other TB diagnostic and rapid tests, the plan should include roles and responsibilities for test M&E, the activities to be completed within established timeframes, and plans for how results will be communicated and used for program improvement[11]. At a minimum, M&E plans should include internal and external quality control testing guidelines for testing sites, recommendations or requirements for supportive supervision of testers and/ or testing sites, and a list of performance and quality indicators for monitoring that are matched with acceptability criteria.

A list of key quality and performance indicators for site-level and above-site monitoring are included in the Excel-based Package ***Form_F5_M&E Tool with Automated Analyses*** for user review and customization. As indicated in the title, the Tool includes simple Excel-based automated analyses to facilitate visual review of data, successes, and potential gaps for resolution. All selected indicators should be analyzed, evaluated for any deviations from the expected outcomes, deviations addressed with tailored corrective actions, and corrective action impact monitored for adjustment or success.

To aid with LF-LAM testing site readiness and assessment (before or after introduction of LF-LAM), this Package additionally includes the ***Form_F6_SPI-RT for LF-LAM Site Readiness & Quality Assurance Checklist***. Customized based on the widely used "Stepwise Process for Improving the Quality of Rapid Testing" originally developed for HIV rapid tests[13]. Designed for use within a single day with ready scores and visual color-coded outputs, the tool allows for one-time or serial site assessment to ensure site preparedness and continued readiness for high quality rapid testing services.

Phase 4: Using data for continuous quality improvement of LF-LAM testing programs

Continuous Quality improvement (CQI) is central to expanding LF-LAM testing and QA. Analysis of routine quality control, training and competency assessment, and performance and quality indicators for LF-LAM testing provides a quantifiable indication of the quality of testing services from the tester level to the national network level. Stakeholder review at the testing site and above-site levels according to the country's M&E Plan for LF-LAM Testing (see Section 3.2) will be most impactful when it occurs routinely and be actively used to report successes related to the testing program and strengthen services for patients. Examples of M&E plan data use for CQI include: setting-specific algorithm modifications, training material refreshes to address challenges with accuracy of testing or result use for patient care, revised stock reporting or commodity management processes to address stock-outs or gaps in material availability, and advocacy for procurement or production of external quality assurance materials. Ultimately, HIV and TB program data use for CQI of LF-LAM testing will maximize the impact of LF-LAM tests on TB case detection and care among people living with HIV that remain at elevated risk of TB-related morbidity and mortality.

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