

Overview: WHO/ GLI TB Near Point-of-Care & Swab Testing Toolkit

Patricia Hall-Eidson, PhD MS

Lead - HIV, TB, Hepatitis & STI Testing & Diagnostics Team

Department for HIV, TB, Hepatitis & STIs

WHO Headquarters – Geneva

Background

- ❖ Uptake of new WHO policies is often delayed
- ❖ Previous class- and product-specific implementation materials have been developed only after use in intended settings
- ❖ Manufacturers & researchers producing evidence for policy have practical resources & experiences with new tools

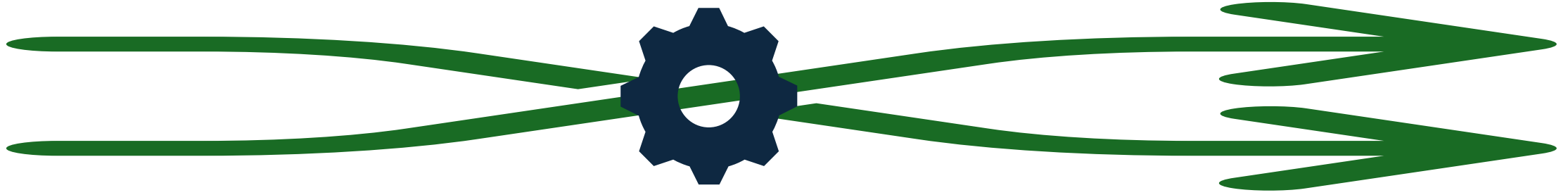
Avg time from new policy to implementation in Africa

2 – 9 Years

Predisposing Factors

**Policy/ Algorithm Reform
Laboratory Readiness
Staff Training/ Competency**

Methods for TB NPOC/ Swab Toolkit development



- In 2025, WHO piloted new, parallel processes for **policy**, prequalification & **operational guidance**
- Simultaneously with the guideline development process, WHO:
 - ✓ Drafted a GLI-endorsed generic implementation toolkit for new TB diagnostic tests, sample types, or strategies
 - ✓ Developed stakeholder-specific surveys & resource requests and for manufacturers and evidence generators
 - ✓ Established conflict of interest, confidentiality, and resource/ information use agreements with respondents
 - ✓ Assessed, refined, and compiled all feedback and resources into the new NPOC/ Swab Toolkit
 - ✓ After recommendation pre-release, achieved rapid GLI Core Group endorsement & co-publication

THE TB NEAR POINT-OF-CARE AND SWAB-BASED TESTING TOOLKIT

Planning, Readiness and Capacity tools



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Planning

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Procedures, Job Aids, QA and M&E



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Training slides



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Training and competency checklists



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Training and Competency
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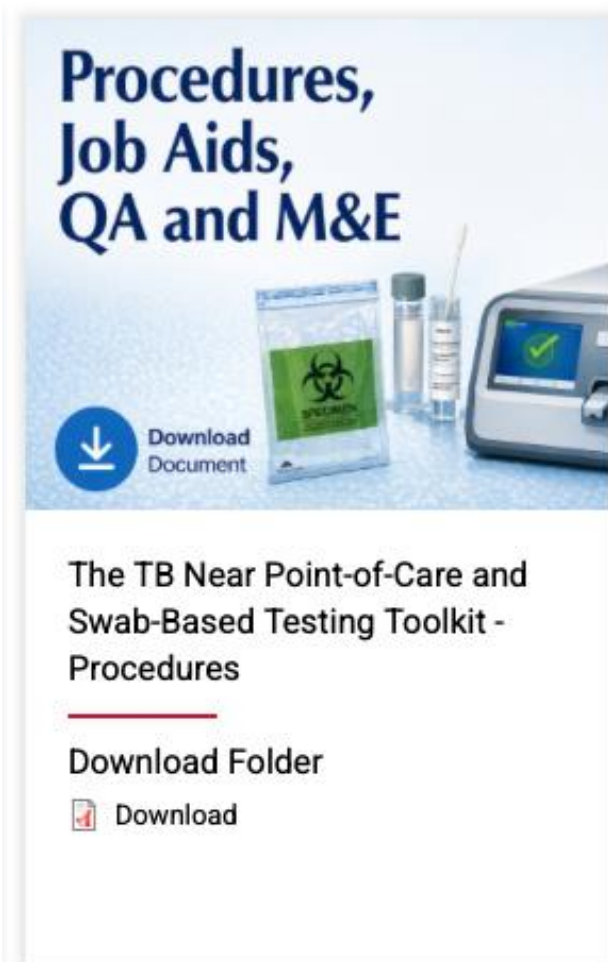
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Toolkit contains NPOC-NAAT class & Pluslife-specific tools

Tools	NPOC-NAAT Class	Pluslife MTB MiniDock
Training Modules	X	X
Gantt Chart	X	
Readiness Checklists	X	
Budget Considerations	X	
Verification Protocol	X	
SOPs, Job Aids, & Forms	X	X
SPI-NPOC Quality Checklist	X	
Competency Checklist: Training of Trainers	X	
Competency Checklist: Testers	X	
M&E Excel Tool	X	
Pluslife Capacity calculator		X



Tool	Description	Rationale
Gantt Chart	Template for MOH/ TWG/ Lab Directorate planning	Support time-bound planning through 10 areas of new tool implementation
Readiness Checklists	High level checklist for readiness assessment on 10 areas	Assess readiness across implementation areas for gap analysis & prioritization
Budgeting Considerations	List of considerations & components to be considered and costed in NPOC-NAAT implementation plans	Provide a guide for budget planning/ costing to complement the UPDATED WHO IHT
Pluslife MTB MiniDock Capacity Calculator	An interactive online calculator to: 1) determine instrument, battery and kit volumes based on key volume and time assumptions 2) outline an ordering plan for stock management based on instrument and kit volumes, testing rates, & shelf lives	An interactive, site-level tool to assess commodity need & plan for stock management



Tool	Description	Rationale
Verification Protocol	Customizable verification protocol for NRLs & testing sites to verify new NPOC-NAATs for initial use, procedure/ reagent modifications & PMV	Support verification of new NPOC-NAATs to ensure they perform as expected in the setting of use
SOPs, Job Aids & Forms	Customizable documents aligned with accreditation requirements: - Sputum swab preparation - Tongue swab collection - NPOC-NAAT testing - Test request/ reporting forms	Provide procedures, aids, and forms for setting customization that adhere to quality, biosafety and technical requirements
Stepwise Process for Improving Quality for NPOC-NAAT (SPI-NPOC) Checklist	Checklist adapted from the ASLM/ US CDC SPI-RT checklist for HIV rapid tests	Provide a setting-customizable quality assessment checklist for lab- and non-lab TB NPOC-NAAT testing sites
M&E Tool	An Excel workbook with M&E indicators aligned with WHO/ GLI lab strengthening & reporting indicators for supervisory & site use	Provide a standardized set of indicators to monitor NPOC-NAAT quality, process and impact on the cascade of care

Training slides



The TB Near Point-of-Care and Swab-Based Testing Toolkit - Training slides

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MODULE 1: Introduction to TB Near Point-of-Care Tests and the Pluslife MiniDock MTB Nucleic Acid Test (NAT) Card



MODULE 2: DIAGNOSTIC ALGORITHM



MODULE 3: OPERATIONAL ASPECTS OF MINIDOCK MTB TESTING



MODULE 4: PROCUREMENT, QUALITY ASSURANCE (QA) AND M&E



MODULE 5: CLINICAL SCENARIOS

Answer Key Module 1



COMPETENCY ASSESSMENT RECORD

Country:	Department/ Division:	Unit/ Team:
Document Number:	Version Number:	Effective Date:
Form Reviewed by (name, signature, and date):		Form Approved by (name, signature, and date):

1.	NPOC-NAAT Standard Operating Procedure (SOP) Review	Yes	Partially	No	Comments
	Test Name:				
a.	Principle of the assay	☐	☐	☐	
b.	Sample type used	☐	☐	☐	
c.	Associated documents, job aids, and forms/ logs	☐	☐	☐	
d.	Overall summary of the procedure	☐	☐	☐	
2.	Safety	Yes	Partially	No	Comments
a.	Overview of biosafety risks and mitigation measures	☐	☐	☐	
b.	Selection of appropriate personal protective equipment (PPE) for the test procedure in the setting of training.	☐	☐	☐	
c.	Adherence to safe work practices and techniques throughout the procedure.	☐	☐	☐	
d.	Cleaning/decontamination of the work area before starting and after completing work.	☐	☐	☐	
e.	Handling of biologic spills according to procedure.	☐	☐	☐	
f.	Discarding the used test materials and waste according to the procedure and testing site policy.	☐	☐	☐	

- ☐ Training of Trainers and Training of Tester Checklists
- ☐ Pre-read requirements & training instructions
- ☐ Sections for document control, assessment Type (initial, re-training, annual), corrective action, & approval aligned with laboratory ISO 15189/ 17025 and non-laboratory rapid testing program standards

Training and competency checklists



The TB Near Point-of-Care and Swab-Based Testing Toolkit - Training and Competency Checklists

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Coming Soon: New TB Diagnostic Policy FAQ

New WHO policy recommendations for TB near point-of-care nucleic acid amplification tests (NPOC-NAATs), tongue swabs, and sputum pooling

FREQUENTLY ASKED QUESTIONS (Version 1)

- ❖ Use cases & strategies
- ❖ Considerations for children & people with HIV
- ❖ Biosafety & quality considerations
- ❖ Benefits & limitations of each intervention

Thank you

Patricia Hall-Eidson | halleidsonp@who.int

Testing and Diagnostics Team | Department for HIV, Tuberculosis, Hepatitis and STIs | WHO, Geneva

Mikashmi Kohli – Testing & Diagnostics Team Toolkit Lead

Kohlim@who.int

Toolkit Available Now:

<https://www.stoptb.org/who-we-are/stop-tb-working-groups/global-laboratory-initiative-gli/gli-guidance-and-tools/tb-near-point-care-and-swab-based-testing-toolkit>

