GH LABS PHASE II: CLINIC VISITS

DELIVERABLE: Assessing Usability of NAATOS Testing Product
DATE: 26 November 2024

PRESENTED BY: MARKET ACCESS AFRICA

Contents

Executive Summary | Assessing Usability of NAATOS Testing Product (1/5)

Objective	1. Assess the usability of the NAATOS TB device in primary healthcare settings 2. Identify the clinic characteristics, roles, needs, and challenges faced by potential users in TB testing processes 3. Provide actionable recommendations for effective integration of the NAATOS device into clinic workflows.
Methodology	• Formative feedback with 41 health workers on health facility characteristics, workflow, usability and end-user requirements. • Visited 13 health facilities in primary health settings within South Africa and Kenya. • Systematic approach to collect and analyze data on NAATOS' usability and user requirements • Conducted through surveys, audio- and video-recorded interviews.

Executive Summary | Assessing Usability of NAATOS Testing Product (2/5)

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Facility characteristics

Findings

- **Facilities are largely paper based:** with no health workers were using computers at their workstation, and electronic systems being dedicated to the reception or data capturing area.
- **Undocumented operating temperatures:** where only 4 on-site laboratories and most pharmacies measured room temperatures.
- **Waiting areas, triage or observation 2-line** are where patients are identified based on symptoms such as cough, weight loss, or fever. This is before they are seen in the consultation room by the TB nurse or clinical officer.

Recommendations

- **Connectivity an add-on feature:** due to it not being essential for current facility set-up, but valuable for integration into national TB programs and lab data systems.
- **Robust for variable temperatures:** sample prep tube contents, device & modules must be robust enough to handle varying and undocumented temperatures in Africa temperature settings.
- **Triage/Observation/Vitals Room:** placing the device in the triage room ensures early TB testing as soon as TB symptom screening questionnaire is done with the client, aligning with current symptom assessments and helping reduce transmission risk.

Executive Summary | Assessing Usability of NAATOS Testing Product (3/5)

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TB clinic workflow

Findings

- **Sputum collection is challenging** where patients must find a place on the far corners of the clinic properties, hiding themselves as they attempt to produce the sputum sample. It was indicated that patients are often uncomfortable and embarrassed through the process.
- **Limited on-site TB NAAT testing:** highlights clear need for NAATOS-like solutions with 3 of the 13 clinics visited having on-site TB NAAT services.
- **Significant variability in daily TB NAAT volumes:** across all clinics with high monthly volumes (e.g., 0-16 samples per day) and low monthly volumes (0-4 samples per day). It was expressed that onsite testing would enable identification of more presumptive TB cases.
- **Quickest turnaround time is vital:** health workers expressed the need for faster, more reliable testing to reduce patient wait times and improve TB case follow-up, especially in high-traffic urban clinics

Recommendations

- **Module configuration needs:** single and two-test module systems would be sufficient for clinics visited, but this could be validated further. Tongue swabs could increase accessibility and increase demand for TB NAAT. Module system enables flexibility to meet increased demand, but cost of add-ons needs to be further evaluated.

- **Module instrument labeling:** require clear labeling of lights & user-friendly solution influenced by UI/UX design. Add a clear battery life indicator (battery icon) to keep users informed about remaining power levels

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Executive Summary | Assessing Usability of NAATOS Testing Product (4/5)

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Usability

Findings

- **Challenges with sample module:** they found it difficult to find the sample module lid; they struggled to place the sample tube into the sample module; they did not close the lid before pressing start; they struggled to find the start button.
- **Struggled with power module:** participants couldn't find the front of the power module; they didn't fully insert the test device.
- **Struggled to interpret the results on the device:** unclear on how to read the 3 lines due to being very familiar with a 2-line test.

Recommendations

- **Sample module lid:** redesign the sample module lid to be easier to locate and open, possibly with visual cues or ergonomic design improvements.
- **Tube insertion guidance:** implement a mechanism or visual guide to ensure users insert the tube fully, allowing the sample prep module to close properly.
- **Power module test device insertion point:** Redesign the interface to make the insertion point for the test device more intuitive and easier to locate.
- **Correct test device insertion:** Implement a mechanism or visual guide to ensure the test device is inserted correctly to prevent incorrect insertion.
- **Contamination risks:** NAATOS test consumables need a secure design to prevent contamination during disposal, due to potential incineration or off-site dumping. Sample collection tube needs design modifications (e.g., wider base for sample tubes) could reduce spillage risks.
- **Control lines understanding**: Explore options to visually guide users to read both control lines as one, such as minimizing the space between C1 and C2 or using a wash-away design. Provide clear quick reference guides and basic training to help non-laboratory users confidently interpret the two control lines and one test line.

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Executive Summary | Assessing Usability of NAATOS Testing Product (5/5)

Next Steps 	• **Revise product specifications:** Considering findings from usability and interview feedback from facilities visited. • **Conduct Pilot Implementation**: Launch a pilot at selected facilities to gather additional real-world data and feedback. • **Refine Training Programs**: Develop and roll out tailored training for healthcare workers on NAATOS use, sample handling, and error prevention. • **Implement Follow-Up Mechanisms:** Establish a robust system for monitoring test results and patient follow-ups, especially for rural clinics with low connectivity. • **Advocacy:** Engage iteratively with the TB Programs by providing regular updates and seeking their feedback after implementing changes to the product.
Future Partnerships 	• **Ministries of Health:** For nationwide implementation, regulatory guidance, and integration with national TB programs. • **Local TB Implementation Science Groups:** For data generation implementation and outcomes research to help inform policy and guidelines • **Community Health Networks:** For outreach, education, and follow-up, especially in rural areas. • **Technology Partners:** To address connectivity challenges and integrate NAATOS with health information systems, allowing seamless data reporting and result relay.

Contents

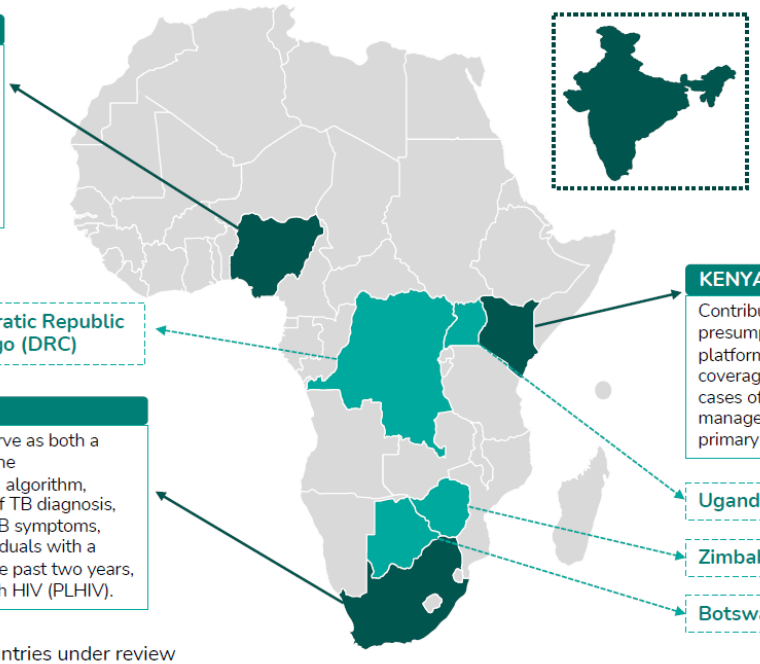
Project Overview | The voice of the customer analysis highlighted the need to conduct formative feedback on end-user requirements in clinic settings

Q4 2023
Phase 1: Key informant interviews to understand needs against current TPP and opportunities for NAATOS adoption

COUNTRIES UNDER STUDY

NIGERIA

NAATOS to serve as both a triage test and a screening tool which will improve testing at L1 facilities; where today there's limited testing being done at L1. Patient samples are collected and sent to more to L2 & L3 for diagnosis using the existing TB Dx. These Dx require storage, temperature , and power infrastructure amongst other things.



INDIA

Potential to support India's ambitious plans for intensified case finding using molecular testing: presumptive TB testing targets have been increased from ~1700 per 100,000 population to ~3000 per 100,000, to an overall target of 42 million TB tests per year.

KENYA

Contributors highlighted the critical need for presumptive cases to be tested with a molecular platform as a first test. There is significantly low coverage at lower-level facilities resulting in 40% of cases of being missed in the TB diagnosis and management cascade. NAATOS can become the primary TB diagnostic tool at L1 and L2 facilities.

Democratic Republic of Congo (DRC)

Uganda

Zimbabwe

Botswana

SOUTH AFRICA

NAATOS presents an opportunity to serve as both a triage test and a screening tool within the Targeted Universal Test & Treat (TUTT) algorithm, enhancing the efficiency and accuracy of TB diagnosis, across a spectrum of clients including TB symptoms, close contacts of recent TB cases, individuals with a history of completed TB treatment in the past two years, and newly diagnosed People Living with HIV (PLHIV).

xx Spotlight countries

xx Other countries under review

Q3 2024
Phase 2: Formative feedback on usability and end-user requirements in primary health clinic settings

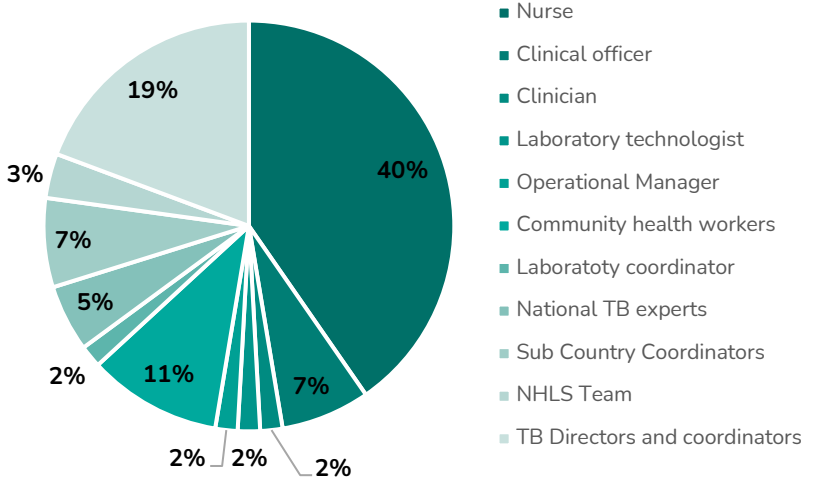
Background:

- To optimize the future implementation of NAATOS, we continue collaborating with experts in multiple countries to gather feedback on design and deployment strategies.
- A key next step is evaluating NAATOS' usability and user requirements in primary healthcare settings.

Objectives:

- Assess the usability of NAATOS in primary care settings.
- Evaluate potential users' roles, goals, needs, and constraints in relation to TB testing.
- Develop recommendations for integrating NAATOS into clinic workflows.

Stakeholder Categories



Project Overview | National TB program was consulted throughout the project process

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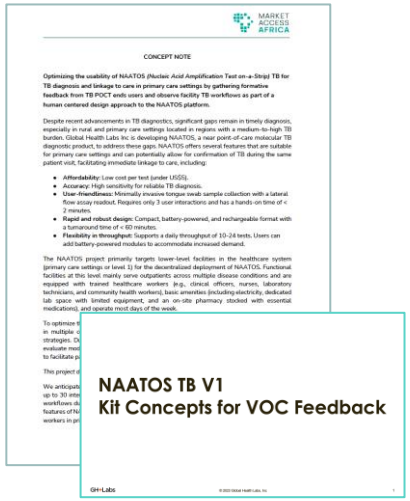
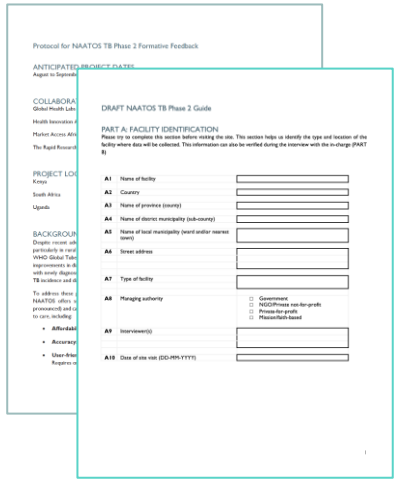
Stakeholder buy in

Introduced NAATOS to the TB Program Leads



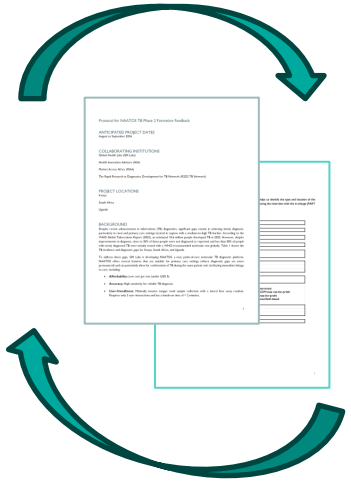
Protocol development

Developed guide and protocol



Stakeholder buy in

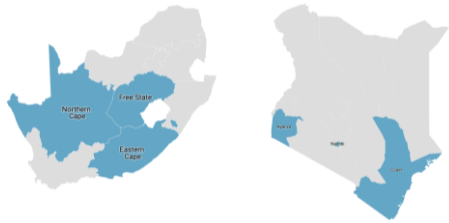
Shared protocol with TB Program Leads and BMGF country offices



Site selection

TB Program Leads selected provinces and clinics

Visit Dates	Country	Province/City	Clinic	PHC/ CHC/Level
Thursday, August 1, 2024	ZAF	EC	Walmer 14 Clinic	PHC
Friday, August 2, 2024	ZAF	EC	Motherwell	CHC
Monday, August 5, 2024	KEN	Nairobi	Rhodes Chest Clinic	Level 2
	KEN	Nairobi	Baraka Dispensary (Nairobi) – Main	Level 2
Tuesday, August 6, 2024	KEN	Nairobi	Riruta Health Centre	Level 3
Wednesday, August 7, 2024	KEN	Mombasa	Bamburi Dispensary	Level 2
	KEN	Mombasa	Kongowea Health Centre	Level 3
Thursday, August 8, 2024	KEN	Kisumu	Pand Pieri Community Health Centre	Level 2
	KEN	Kisumu	Nyalenda Health Centre	Level 3
Friday, August 9, 2024	KEN	Nairobi	Debfrief with Dr. Macharia	HOP
Thursday, August 15, 2024	ZAF	FS	Heidedal	CHC
Friday, August 16, 2024	ZAF	FS	Batho Clinic	PHC
Monday, August 19, 2024	ZAF	NC	Warrenvale Clinic	CHC
Tuesday, August 20, 2024	ZAF	NC	Kimberley City Clinic	PHC



Stakeholder involvement

Accompanied by TB Program district representatives

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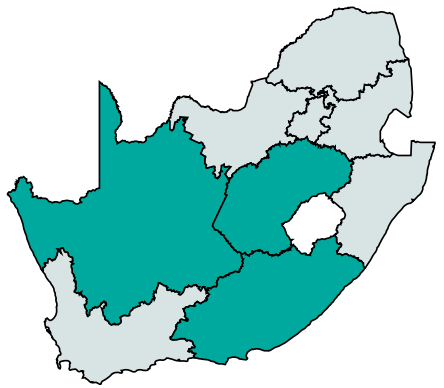
Methodology | In August 2024, we visited 13 primary health care facilities in Kenya and South Africa

South Africa



South Africa's **National Department of Health - National TB Control & Management Cluster** Identified **4 PHCs** (primary health centre) and **2 CHCs** (community health centre) facilities in **3 provinces**

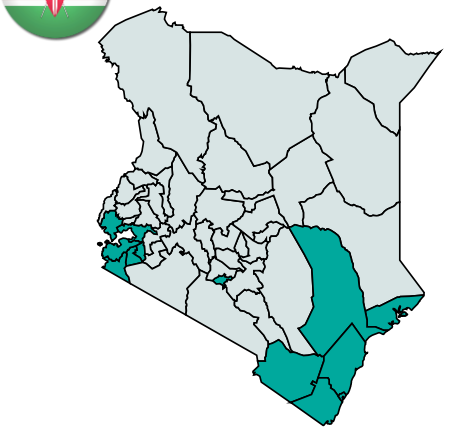
PHC Facilities

1. Walmer 14 Clinic (Eastern Cape)
2. Batho Clinic (Free State)
3. Kimberly City Clinic (Northern Cape)
4. Warrenvale Clinic (Northern Cape)

CHC Facilities

1. Motherwell (Eastern Cape)
2. Heidedal (Free State)

Kenya



Kenya's **National Tuberculosis, Leprosy and Lung Disease Program** Identified **4 Level 2** and **3 Level 3** facilities in **4 sub counties**

Level 2 Facilities

1. Baraka Dispensary (Nairobi)
2. Marimani Dispensary (Mombasa)
3. Kuoyo Kaila Dispensary (Kisumu)
4. Asat Beach Dispensary (Kisumu)

Level 3 Facilities

1. Rhodes Chest Clinic (Nairobi)
2. Riruta Health Centre (Nairobi)
3. Kongowea Health Centre (Mombasa)

Methodology | We used a systematic approach to collect and analyze data on NAATOS' usability and user requirements

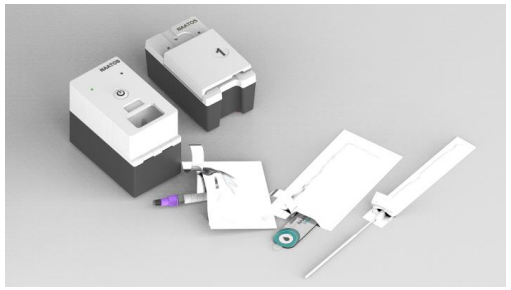
TOPIC	METHODOLOGY	ANALYSIS
HEALTH FACILITY CHARACTERISTICS	• Survey with 11 participants • 5 nurses, 3 operational managers, and 3 other providers (clinical officer, clinician, laboratory technologist)	• Descriptive analysis summarizing ranges for key quantitative variables (e.g. patient volumes) across different health facilities • Key categorical variables (e.g. types of tests) were also tabulated by facility
WORKFLOW	• Conducted semi-structured audio-recorded interviews with 12 participants • ~ 30 minutes per participant on average (range: 13 – 51) • 9 nurses and 3 other staff (operational manager, clinical officer, facility in-charge)	• Transcribed interviews • Charted and summarized data from key questions • Identified resulting themes across questions
USABILITY	• Video-recorded moderated usability study with 18 participants • ~55 minutes per participant on average (range: 34 – 98) • 9 nurses, 6 community health workers, 2 clinical officers, 1 laboratory coordinator	• Transcribed interviews • Charted errors and user feedback by task • Quantified errors and identified themes across tasks

NAATOS TB V1 | User Experience

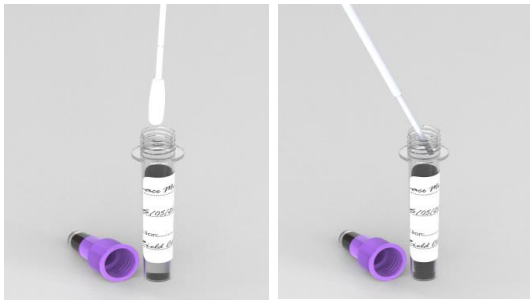
Methodology for usability test

We conducted in-person moderated usability interviews using a structured guide to lead participants through six tasks, ask follow-up questions, and observe their behaviour

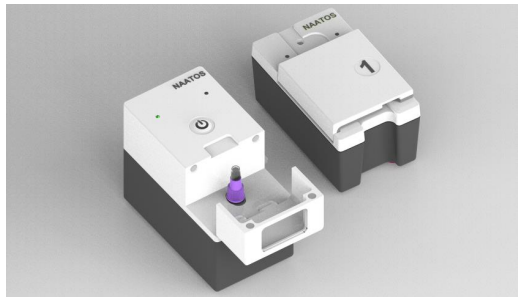
Task 1: Open and label consumables - sample tube and test device



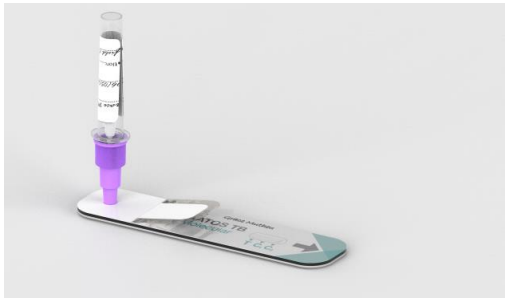
Task 2: Collect the tongue swab from the patient, break off the swab head directly into the sample tube, and close the tube



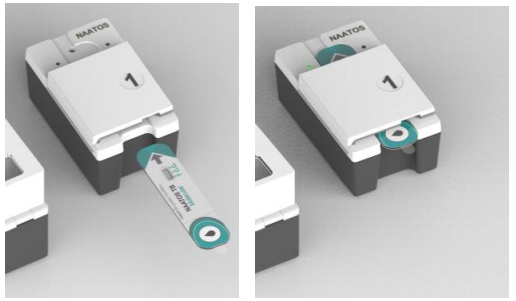
Task 3: Place sample tube into sample prep module and press "start" to process sample



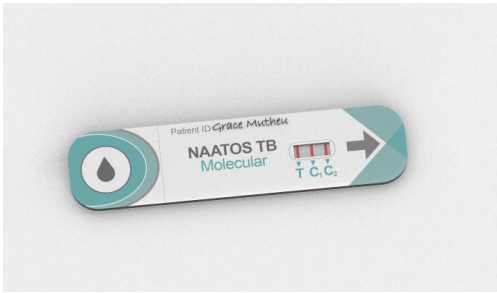
Task 4: Transfer the processed sample into the NAATOS test device and peel the sticker to seal



Task 5: Slide the loaded NAATOS test device into the power module and initiate testing



Task 6: When the power module indicates testing is complete, remove the test device, read the test results, and report



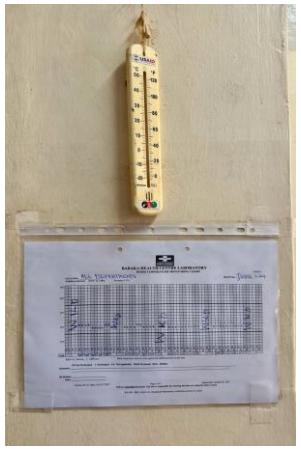
Contents

Facility Infrastructure and Management

Characteristics	Insights
Temperature Control	• Most testing spaces lack dedicated temperature systems and rely on natural ventilation or fans. • Air conditioning is common in dedicated laboratories and pharmacies but not in consulting rooms, triage areas, or observation spaces.
Temperature Recording	• Frequency varies; some facilities record twice daily, others once daily. • Some facilities do not have any temperature monitoring in place.
Electricity and Backup Power	• All facilities are connected to a central electricity supply, but backup power availability varies widely. • Some facilities have backup generators, providing consistent power; others lack backup sources entirely and rely solely on the main power grid. • Outages range from brief interruptions (less than 2 hours) to prolonged periods. In rural areas, at least one clinic reported outages lasting multiple days, which significantly impacts service continuity.
Waste Disposal	• Most facilities manage waste by offsite removal. • A few, Kuoyo Kaila Dispensary and Marimani CDF Dispensary, use open burning and/or dumping of sputum into their placenta pit for waste disposal.

Waste management bins and protocol at the Riruta Health Centre, a Level 2 facility in Kenya.

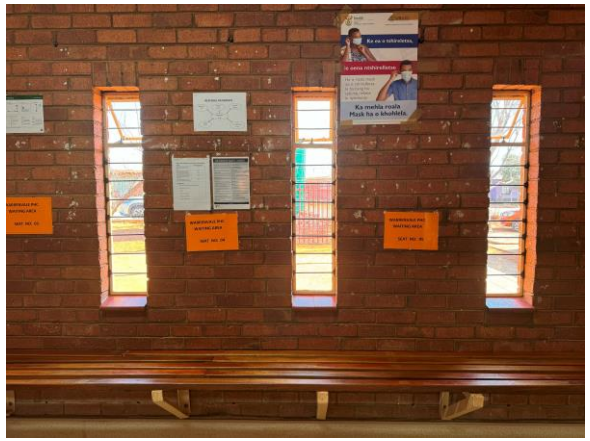
Biohazardous waste storage for collection at entrance to clinic



Room temperature monitoring chart and thermometer provided by USAID at Baraka Health Centre, a Level 1 facility in Kenya.

TB Patient Volumes and Workflow

Characteristic	Insight
Facility Patient Volume	• Health facilities handle 1-80 patients/day in smaller PHC and Level 2 settings and up to 600-700 patients/day in high-volume CHC and Level 3 settings in South Africa and Kenya
TB Patient Volume	• High-level facilities in urban areas report monthly TB sample collection ranging from 50 to 141 samples, while lower-level facilities report between 5-30 samples per month • CHC and Level 3 facilities generally have the highest TB patient volumes, given their capacity and the urban population density
Turnaround Times	• TB NAAT tests typically range from 24-48 hours for facilities with onsite labs; however, when conducted offsite, results can take longer • The longest TB NAAT delay was 3 – 4 months due to laboratory system backlog • TB Culture tests, conducted in specialized labs, have the longest turnaround, requiring up to 6-8 weeks
Facility Operating Hours	• Most facilities operate Monday to Friday (7 AM – 4/5 PM) • Some facilities like Riruta Health Centre, Kenya, offer 24-hour services. • One facility in South Africa provides follow-up services outside regular hours



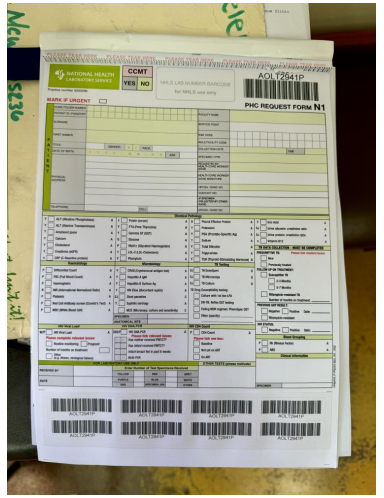
The waiting area at Warrenvale PHC in South Africa.

The waiting area at Kimberly Clinic in South Africa.

Facility TB Services

Characteristic	Insight
TB Services	• All facilities visited provided a full pathway of TB services, including providing TB drugs, managing treatment follow-up, and conducting TB testing. • TB testing services varied, with 6 facilities relying solely on offsite testing and 7 incorporating some form of onsite testing, using LF-LAM at POC or smear microscopy and TB NAAT services through their onsite laboratory. • Onsite TB NAAT services were only found in 3 (2 in Kenya, 1 in South Africa) of the 13 facilities visited, but this was largely due to the focus on PHC and Level 2 clinics.
Types of Onsite TB Tests	• More common onsite tests offered at facilities were LF-LAM (7) and smear microscopy (5). • Fewer facilities offered chest radiography (4) and TB NAAT (3) onsite.
Sample Transport for Testing	• Samples are picked up by the NHLS courier services 2-3 times daily in CHC's, and once a day in PHC's in South Africa • In Kenya, samples are transported using various methods such as hospital transport vehicles (motorbikes and ambulances) and public transport. • At one facility, due to no reliable transport, the patient was required to travel to the off-site laboratory (~10km and 2-hour walk) to hand in their sputum sample.

The sputum sample storage and transport log for sputum samples at Kimberly Clinic in South Africa

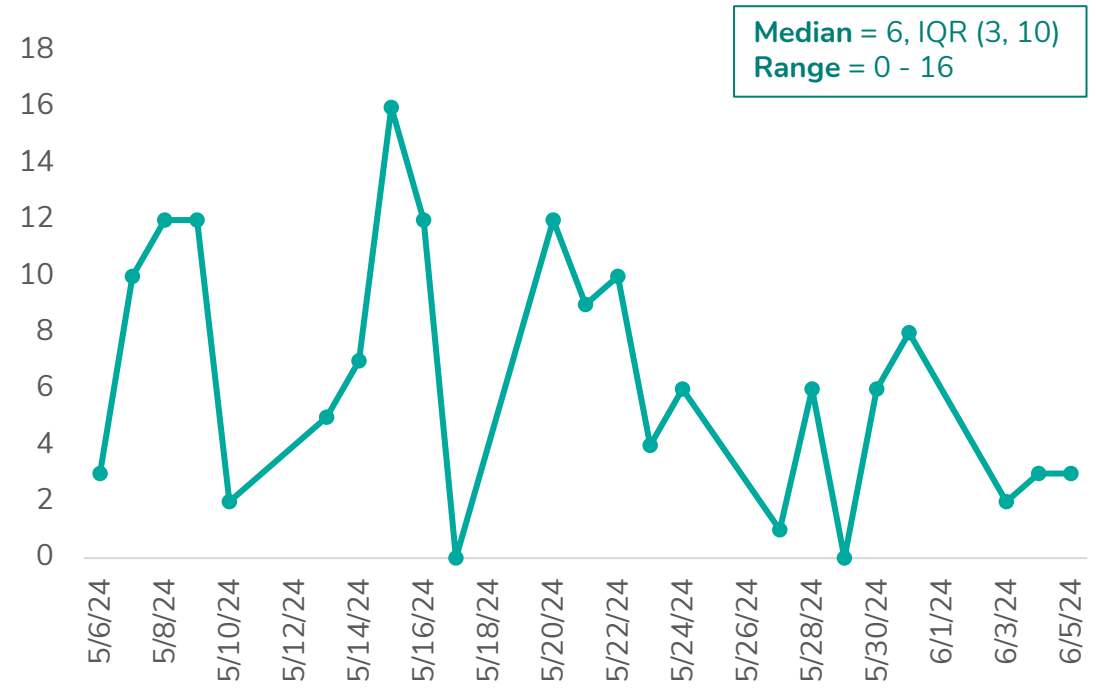


South Africa's National Health Laboratory Service PHC Request Form for sputum sample transport.

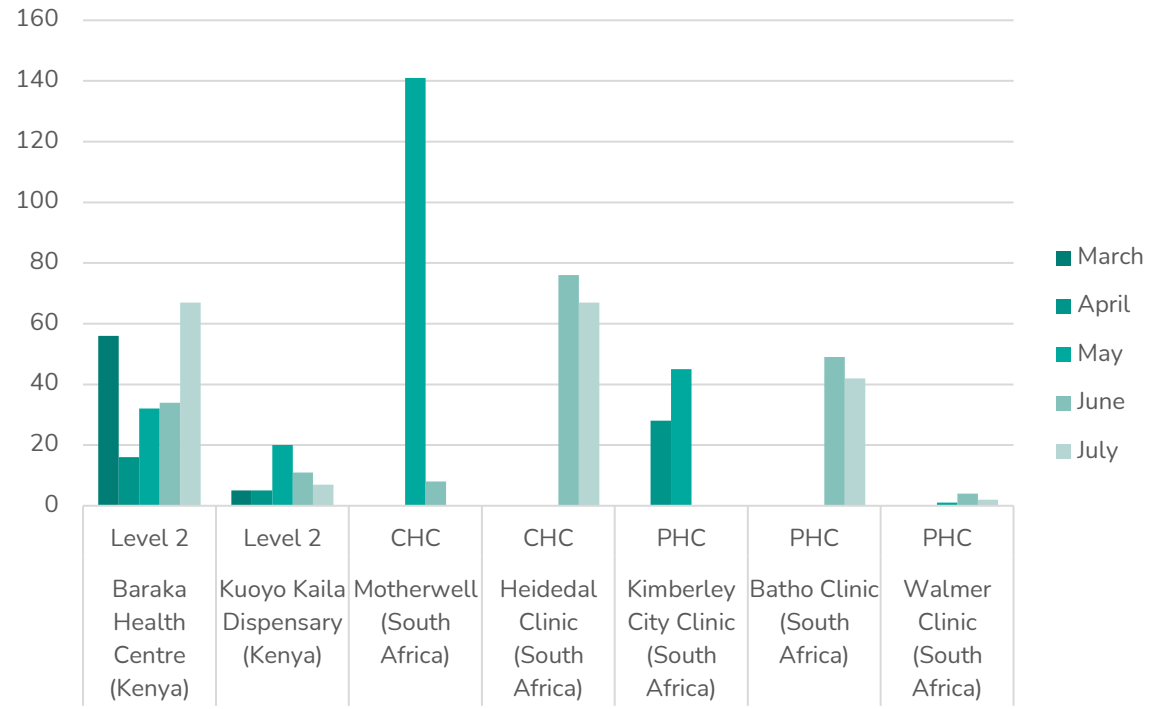
The GeneXpert machine at Rhodes Chest Clinic, Kenya

There is variability in monthly and daily TB NAAT samples collected across and within clinics in Kenya and South Africa

Number of TB NAAT samples collected per day from May 6 to June 5, 2024, at Motherwell Clinic, South Africa.



Number of TB NAAT samples collected per month at 2 level II facilities (Baraka & Kuoyo Kaila), 3 CHC's (Heidedal & Motherwell) and 3 PHC's (Kimberly, Batho & Walmer)



- Samples are collected from presumptive cases which represent a subset of those screened (e.g., ~2 - 9% of initially screened cases at Kuoyo Kaila Dispensary in Kenya).
- High-level clinics visited collect 5 to over 140 TB NAAT samples per month, while low-level clinics collect between 1 and 50 samples per month.
- There is significant variability in daily sample collection across all clinics with high monthly volumes (e.g., 0-16 samples per day) and low monthly volumes (0-4 samples per day):

"Sometimes in a day we have one. Yeah, sometimes in a week. We don't have any." - *Kuoyo Kaila Dispensary, Kenya*

Data Management

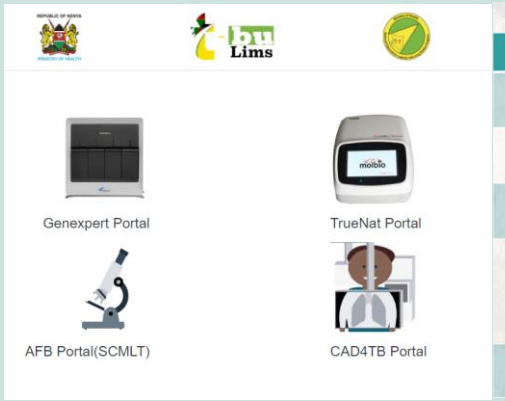
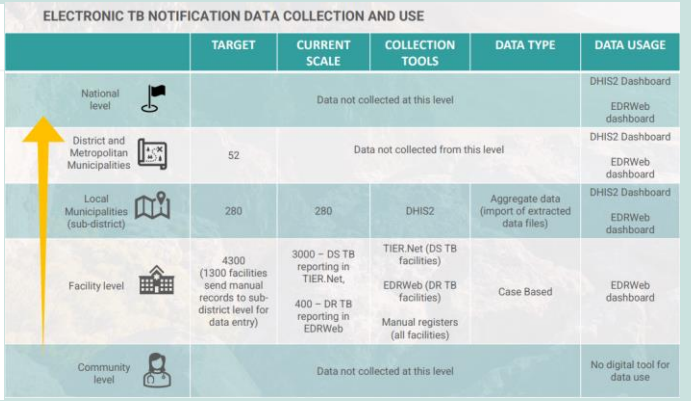
Characteristics	Insights
Connectivity	• Internet connectivity is available in various forms, with many facilities using Wi-Fi or Ethernet. • Facilities, such as Heidedal CHC and Marimani CDF Dispensary, rely on mobile data. • No health workers were using computers are their workstation. • Connectivity was only for the facilities data capturing station, sometimes the facility manager's desk and/or pharmacy.
Records Management	• Most facilities rely on paper-based records • Some facilities, including Baraka Health Centre, Kuoyo Kaila Dispensary, and Warrenvale Clinic, utilize EHR. • All facilities with EHR are only managed through one computer at the data capturing station nearby to the reception area.

One facility, Rhodes Chest Clinic, a Level 2 facility in Nairobi, had a GeneXpert enabled with connectivity to the lab computer and TibuLims system.

Records management at the Kuoyokaila Dispensary, a Level 1 facility in Kenya.

Most facilities, like the Batho Clinic in South Africa, rely on paper-based records.

Peripheral level facility data & connectivity workflow and needs differ from WHO's TPP requirements for TB NAAT

	WHO TPP Minimal/Optimal requirement[1]	Formative Feedback Observations
Built-in analytics (for instrument-based)	Minimal/Optimal: Analytics for instrument and test data should be built into the instrument; a PC should not be required.	• Facilities, such as Heidedal CHC and Marimani CDF Dispensary, rely on mobile data. • No health workers were using computers at their workstation.
Result documentation and data display	Minimal: Digital readouts to display assay details (including a results screen) and the ability to save and export results should be included. Optimal: Access to assay details (e.g. quick response code on a test device or POC tests to digitally record and report data) should be included.	• Lab results are reported to facilities via a combination of SMS, electronic systems (like LabTrak, Tier.net, or TibuLim), and hard copies, but then hand-written into the TB registers. • Facility level test results (e.g. TB-LAM) hand-written in TB registers. • Access is timely for urgent cases, while routine cases depend on the facility's workload and courier schedules. • Manual retrieval from electronic systems without alerts and delays in hard copy delivery are common challenges across facilities - this would change with NAATOS. • Clinics use a combination of phone calls, SMS messages, and in-person visits to communicate results to patients, with a strong emphasis on ensuring patients with positive results return quickly for further care.
Connectivity	Minimal: All test and device data can be securely transmitted via a standard cable connection interface (USB, ethernet) or wireless connection, including at least one of the following: Bluetooth, Wi-Fi or mobile broadband modem (embedded or external). Data from the instruments should be compatible with different information systems at health facility level using industry standard formats or protocols. Optimal: For device-based tests, offline data storage should be available for data up to 3 months; it should be interoperable over WLAN and with information management systems. Non-device-based tests may have ancillary readers and other data capture apps.	 

1. WHO TPP on a rapid test for detecting M. tuberculosis at the peripheral level AUG2024

Health Facility Characteristics Recommendations

Temperature Control	• The NAATOS device must be robust enough to handle varying and undocumented temperatures in these settings.
Waste Disposal	• NAATOS cartridges need a secure design to prevent contamination during disposal, due to potential incineration or off-site dumping.
Connectivity	• With majority of data management being paperwork for the clinic, but there being a strong element of electronic record keeping for monthly national reporting, connectivity should be a supplementary feature, with integration into national TB programs and centralized lab data systems
Instrument Power	• Battery operated devices will be essential since there is limited back-up power and on the odd occasion, long periods of power outages. • Modules must not require overnight charging and must minimize the hours of mains power to charge the battery per day.
TB NAAT test volumes	• Higher facility levels (CHC and Level 3) visited would be required to run 0-16 TB NAAT tests per day, which indicates that a 2-module device may be sufficient. • Lower facility levels (PHC and Level 2) visited would need to be able to run 0-4 TB NAAT tests per day. • Device needs to be modular to accommodate varying TB NAAT volume demands. Tongue swabs could increase demand for TB NAAT, as it make testing more accessible.
Sample logistics	• NAATOS should be deployed to PHC and Level 2 facilities upwards to reduce the reliance on sample logistics. This would be particularly impactful in Kenya.
Instrument portability	• With the potential for theft, the instruments should have an ability to be secured to a counter or table within the clinic environment.

Contents

Patients navigate several steps in the clinic workflow including identification, sample collection, testing, result reporting and treatment initiation

Step	Insights
Patient identification, sputum sample collection, and testing	• Patients are identified through initial community or facility-based screenings, triage, or consultations, based on symptoms such as cough, weight loss, or fever. • Patients are guided by healthcare providers on how to produce an adequate sputum sample, often in designated collection areas which vary by facility e.g., "cough corners," dedicated TB rooms, outdoor ventilated spaces, or offsite locations, depending on space constraints. • Once collected, the sputum sample is securely sealed, labeled with patient identifiers, and stored according to facility protocols (e.g., in coolers or fridges) before being sent for testing. • TB testing either occurs onsite or offsite (samples sent or patient referred) with all patients undergoing testing for drug resistance.
Result reporting	• Facilities receive results through SMS, electronic systems (e.g., LabTrak), and hard copies. Positive or urgent results may be communicated by phone. Patients with positive results are typically contacted directly via phone or SMS and asked to return to the clinic for further care. Negative TB test results may be communicated via SMS, shared in person to discuss preventive care options, or not directly communicated, depending on the facility's protocols. • Community health workers may visit patients who are unreachable by phone. Facilities typically prioritize in-person communication to ensure proper follow-up and initiation of treatment.
Patient referral and treatment initiation	• Patients diagnosed with TB are typically initiated on treatment during the same visit on which they receive their test results. In cases where treatment is unavailable on-site, referrals are made to other units within the facility or external facilities. • Multi-drug resistant (MDR) TB cases are referred to specialized clinics or hospitals for comprehensive management.

TB Clinic Workflow | Current state vs future with NAATOS as a POC solution (1/2)

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Current Workflow

(1) Patient arrival at clinic

- Goes through queueing system
- Proceeds to reception for file collection and creation

(2) Take vitals and triage patients

- Patient moves to Vital room for recording of vitals and creation of patient record
- Assess whether patient has TB symptoms through 5 symptom questionnaire
- Continue waiting in queue, but in a separate area.

(3) Clinical assessment for TB and referral for testing

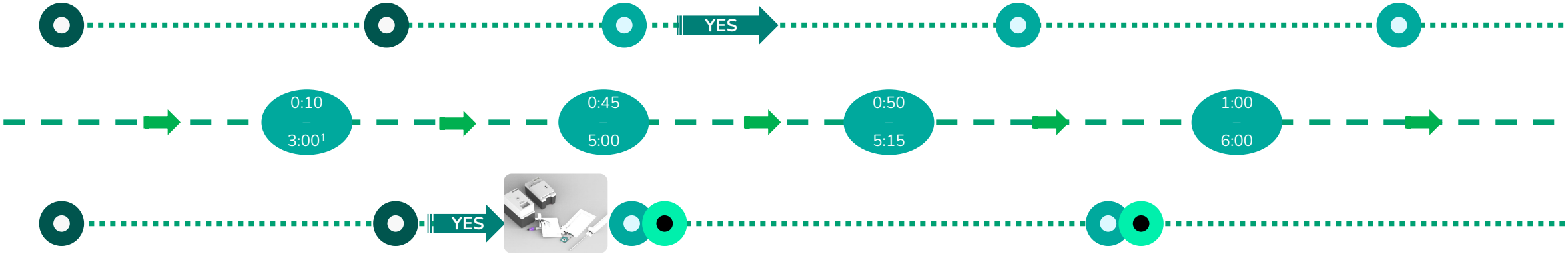
- TUTT for PLHIV, close contacts, previous Rx in 2 years

(4) Patient preparation and sample collection

- Patients are given instructions by the nurse, link assistant, or other staff on how to collect a sputum sample.
- Sputum collection by the patient in the designated cough corner

(5) Wait to hand sample to clinician for inspection

- Clinician ensures sample is sufficient
- There may be a need for recollection



Future Workflow

(1) Patient arrival at clinic

Pre-arrival: Consider improving patient scheduling to optimize workflow early on e.g. initiate patient preparation for testing and testing process during triage and/or clinical assessment

(2) Take vitals and triage patients (Triage/observation/vitals room)

New step: Opportunity for decision to test and NAATOS testing BEFORE clinic assessment

(3) Patient preparation and sample collection

- **New step:** Fasting and oral hygiene required for 30 minutes prior to sample collection.
- Tongue swab collection by the provider, possibly in the triage room.

(4) Conduct test and diagnosis

New step: The provider conducts testing onsite, possibly in the triage room.

(5) Clinical assessment for TB

New step: The provider conducts clinical review with NAATOS result.

(6) Discuss test results

New step: The provider can report results to the patient in person, potentially on the same day, depending on testing volumes.

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1. *Reported in hours.* Stime KJ, Garrett N, Sookrajh Y, Dorward J, Dlamini N, Olowolagba A, Sharma M, Barnabas RV, Drain PK. Clinic flow for STI, HIV, and TB patients in an urban infectious disease clinic offering point-of-care testing services in Durban, South Africa. BMC health services research. 2018 Dec;18:1-9

TB Clinic Workflow | Current state vs future with NAATOS as a POC solution (2/2)

MARKET ACCESS AFRICA

Current Workflow

(5) Sample handling

- The sample is stored in an ice pack or refrigerator prior to testing or shipment to the lab.

(6) Conduct test and diagnosis

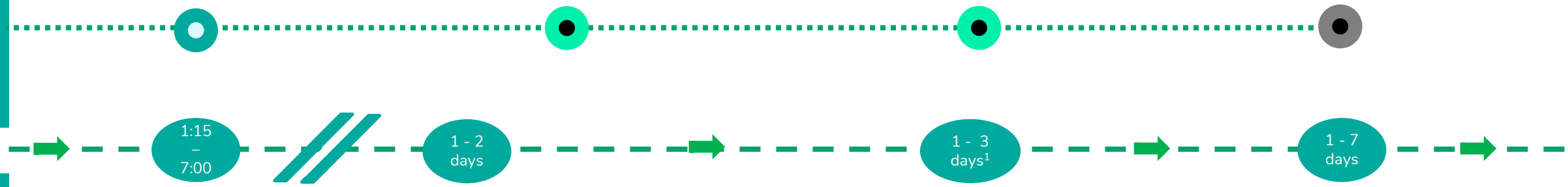
- The laboratory technician conducts the test using a NAAT test (e.g., GeneXpert) in an onsite or offsite laboratory.

(7) Report test results

- Lab reports results to provider via SMS, patient portal, and/or hard copies.
- Providers call or SMS patients to return for result; CHWs follow up if unreachable.

(8) Initiate treatment and TB management

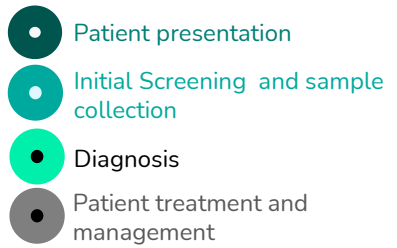
- If positive, initiate Drug Sensitive TB Rx
- If RIF resistant initiated Drug Resistant TB Rx
- If neg, investigate further or start TPT



Future Workflow

(7) Initiate treatment and TB management

New step: Start TB treatment and TB preventive treatment (TPT) immediately, assuming same-day test results.
New step: Collect sputum samples for resistance testing (proceed to step 4 for the current workflow).



GH+Labs ADVISORS

1. The longest delay was 3 – 4 months due to lab backlog

Workflow Integration Recommendations

Triage Integration 	• NAATOS testing should be incorporated into the triage process for early identification of potential TB cases, aligning with current symptom screening practices to minimize transmission risks while the client is waiting in the clinic to be seen by the nurse. • Provides opportunity for NAATOS testing BEFORE clinic assessment, enabling quicker more efficient clinical decisions to be made with the NAATOS result already available.
Device Placement 	• Placing a single NAATOS device centrally in high-traffic areas (e.g., triage or observation rooms) would be more cost-effective than placing them in individual nurse rooms.
Pre-Test Instructions 	• WHO recommends abstaining from food and drink 30 minutes before testing. Usability testing should assess the impact of this waiting period on clinic workflows and patient compliance.
Sample Handling 	• Proper training on sample handling is crucial to minimize contamination risks. Observations included practices like placing tubes on their sides when open. Design modifications (e.g., wider base for sample tubes) could reduce spillage risks.
Resistance Testing 	• If NAATOS is positive, this would require sputum collection for resistance testing. Suggest this incorporated into the quick reference guides and product inserts

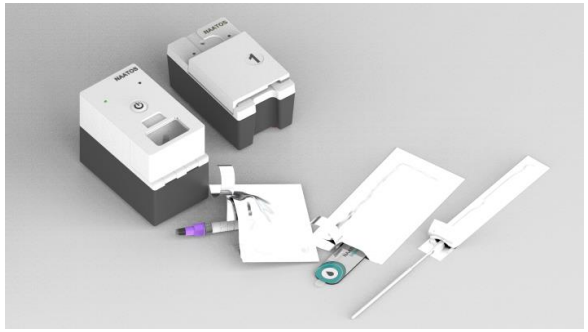
Contents

We interviewed 18 participants to better understand potential user profiles and gather usability insights

PROVIDER	COMMUNITY HEALTH WORKER (N = 6)	NURSE (N = 9) AND CLINICAL OFFICER (N = 2)	DISTRICT LABORATORY COORDINATOR (N = 1)
ABOUT	• 2 males and 4 females • From Kenya (1) and South Africa (5) • Ages between of 25-54 • Completed secondary school (3) or post-secondary education (3)	• 3 males and 8 females • From Kenya (5) and South Africa (6) • Ages between 25-64 • Completed post-secondary (8), bachelors (1) or master's degree (1) programs (note: data missing from 1 nurse)	• 1 female participant from South Africa • Age between 55 - 64 • Completed masters degree program.
TESTING EXPERIENCE	• Ranges from no testing experience and use of simple rapid tests • TB LAM	• Includes use of simple rapid tests and TB LAM	• BD Max and chemistry analyzers
RESPONSIBILITIES	• Community-based screening and education • Assistance with sputum sample collection • Patient referral to clinics • Patient follow-up (missed appointments and results) • Patient data reporting.	• Facility-based screening and assessment • Assistance with sputum (or urine) sample collection • Referral for testing • Result notification (via phone calls and in-person) • Treatment initiation and patient management.	• Laboratory logistics • Cost management • Quality control and monitoring the effectiveness of testing devices. • Training providers
FRUSTRATIONS AND NEEDS	• Concerns about sample stability in the field • Preference for storing swab samples in tubes over sheets for better handling during field testing.	• Competing interests - manages multiple responsibilities and patients • Preference for less paperwork and patient charting • Timely access to test results • Challenges contacting patients for test results	• Quality concerns - whether design and handling of consumables prevents spillage and contamination.

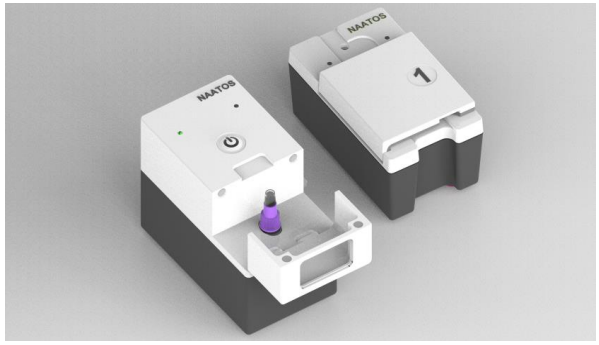
Participants completed 6 tasks in the NAATOS TB test workflow

Task 1: Open and label consumables - sample tube and test device

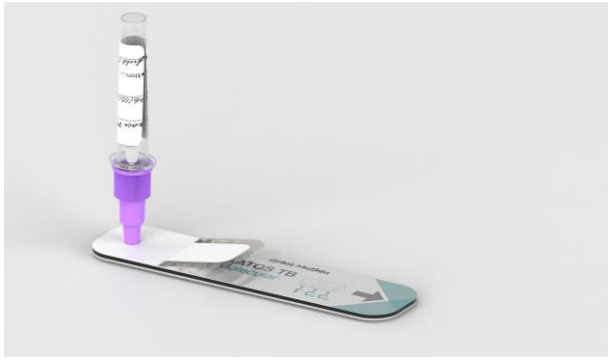


Task 2: Collect the tongue swab from the patient, break off the swab head directly into the sample tube, and close the tube

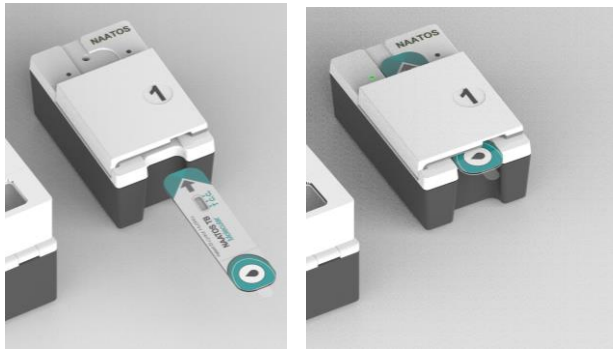
Task 3: Place sample tube into sample prep module and press "start" to process sample



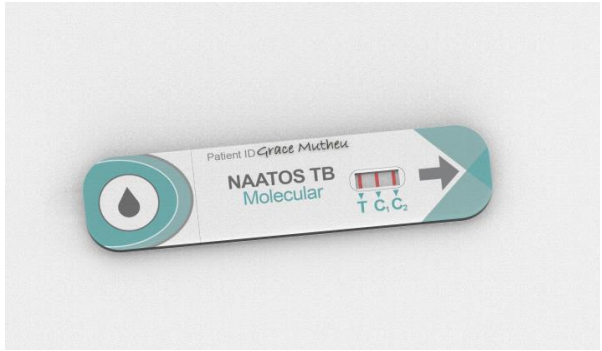
Task 4: Transfer the processed sample into the NAATOS test device and peel the sticker to seal



Task 5: Slide the loaded NAATOS test device into the power module and initiate testing



Task 6: When the power module indicates testing is complete, remove the test device, read the test results, and report



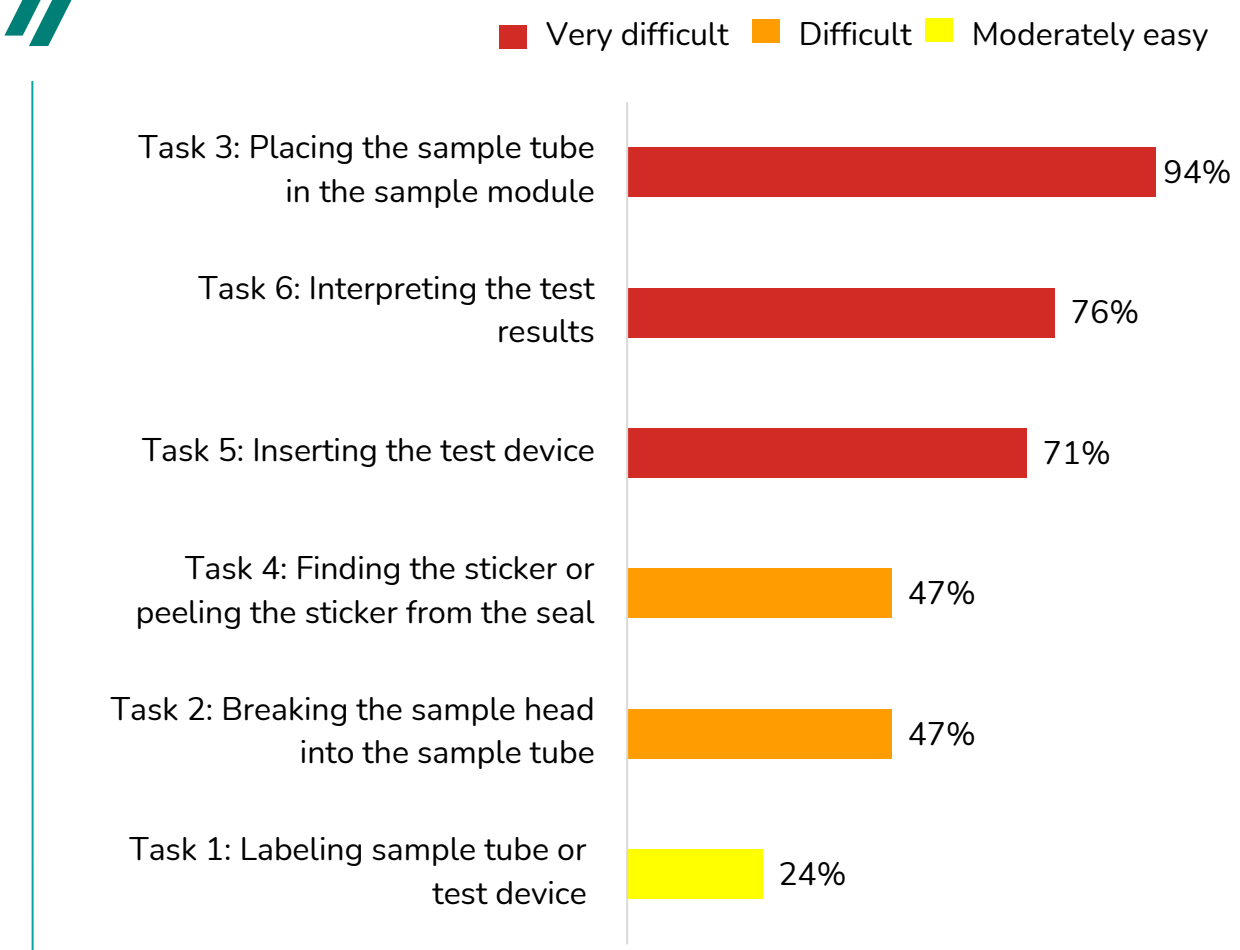
Overall, participants expressed enthusiasm and recognized the potential of NAATOS in their settings

Feature	Benefit	Quote
Workflow	• Appreciation of paperwork-free solutions	• "This is a lovely idea. It's really a good thing. I think the fact that there's no paperwork, it's good. It's a good idea." ***~29-year-old female nurse from South Africa***
Sample Type	• Breakthrough solution for pediatric testing	• "This one will come handy when it comes to the pediatric population for sure...this is really...this is a breakthrough" : **~25 – 34-year-old female clinical officer from Kenya**
Turnaround time	• Early results for immediate treatment and prevention	• "We have to do proper sensitization to our clients to tell them this is the new thing and it'll be the best thing. At least you'll know your results before leaving the facility and you start, you're starting on treatment before spreading to others." ***~ 32-year-old female nurse from Kenya***
Ease of Use	• Anticipation for an easy-to-use solution	• "Yes. I cannot wait for this and the fact that is easily understandable, at least it's not difficult." ***~ 51-year-old female nurse from South Africa***

Participants struggled most with placing the sample tube in the sample module, inserting the test device into the power module, and interpreting results

Difficulty Level	Task
Very Difficult (>70%)	**Task 3:** Finding the sample module lid (76%) **Task 3:** Placing the sample tube in the sample module (94%) **Task 6:** Interpreting the test results (76%)
Difficult (30% - 70%)	**Task 2:** Breaking the sample head into the sample tube (47%) **Task 3:** Remembering to close the lid before pressing start (53%) **Task 4:** Finding the sticker or peeling the sticker from the seal (47%) **Task 5:** Inserting the test device (71%) **Task 5:** Finding the front of the power module (41%)
Moderately Easy (1% - 29%)	**Task 1:** Labelling sample tube or test device (24%) **Task 4:** Dispensing the sample into the well (29%) **Task 4:** Remembering to put the cap back on after dispensing the sample (18%) **Task 3:** Finding the start button (12%)
Easy (0%)	**N/A**

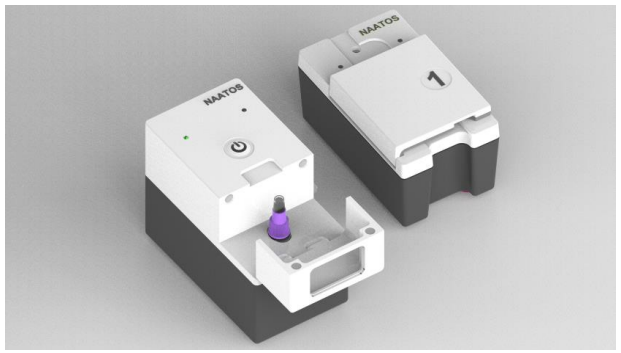
% of participants with usability challenges



Theme #1: Most participants had challenges using the sample module

Task 1: Open and label consumables - sample tube and test device

Task 2: Collect the tongue swab from the patient, break off the swab head directly into the sample tube, and close the tube.



Task 3: Place sample tube into sample prep module and press "start" to process sample

- 13 of the 18 participants had difficulty finding the sample module lid
- 16 of the 18 participants had challenges placing the sample tube into the sample module
- 9 of the 18 participants did not close the lid before pressing start
- 3 of the 18 participants had trouble finding the start button

"You must make this thing (sample module) just like this black here, white here, so that we can see. Now it's all black. I don't see anything...this thing man needs to be two colors. I can't see that there was a door"

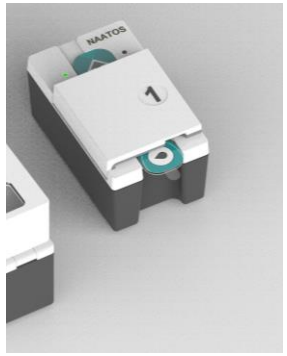
~ 52-year-old female nursing assistant from South Africa

"I struggle in inserting it. I thought that was the end of it, but again, if I press it down, it went again deeper. That is the only challenge. And then I was also struggling because I've not learned about the machine. I was struggling to open and see where to put the sample tube, but later on I found the path about it"

~35-year-old male nurse from Kenya

Theme #2: Many participants had challenges using the power module

Task 4: Transfer the processed sample into the NAATOS test device and peel the sticker to seal.



Task 5: Slide the loaded NAATOS test device into the power module and initiate testing.

- 7 of the 17 participants had difficulty finding the front of the power module
- 13 of the 17 participants did not fully insert the test device or were unsure of how far to insert the test device, with one participant inserting it the wrong way.
- Participants suggested clear guidance for using the device by adding labels or markers to identify the front of the power module and where to insert the test device, as well as specifying how far to insert the test device.

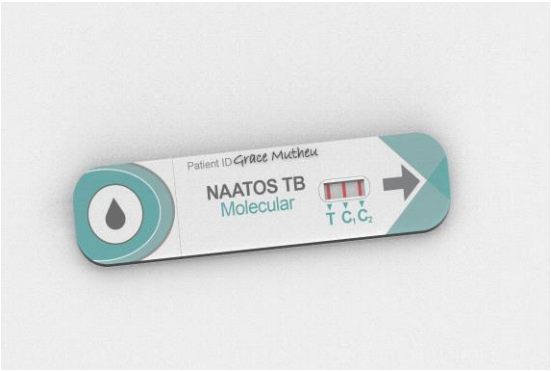
"Okay. This is the arrow. I assume I turn it (power module)...does it (test device) go here? I'm really not sure. Definitely not. Or does it open? It doesn't. I'm not sure about this one guys."

~ 29-year-old professional nurse from South Africa

"The power module, there is no that labeling to show you where to put the test device after doing the heating. So I found challenge finding a place to insert my test device."

~35-year-old male nurse from Kenya

Theme #3: Many participants had challenges understanding what a positive, negative, or invalid result looked like on the test device.



Task 6: When the power module indicates testing is complete, remove the test device, read the test results, and report.

- Of the 17 participants, 13 (including **5 of 6 community health workers** and **8 of 10 nurses or clinical officers**) faced challenges interpreting the test results, primarily due to difficulty in understanding the meaning of the test lines.
- For example, 9 participants said that 2 lines (regardless of it being T, C1 or C2), indicated a positive result, in some cases attributing this reasoning to how they have been trained in interpreting other test results (e.g., HIV or pregnancy tests).
- Some participants expressed that they did not know what any of the lines meant or did not know what C or T represented.

"I usually know when it's two line is positive and then when it's one line it's negative, but I don't know how this one is going.."

~ 31-year-old female community health worker from South Africa

"Oh, now there comes the part of the test results, which I do not understand...because there are three, T, C1, C2. With HIV and pregnancy testing, there's normally two lines, T and C. So here it's kinda like too many things to explain...Ooh, this is gonna confuse people...why are we having two lines when it's negative? That's where the problem would start."

~ 52-year-old female nursing assistant from South Africa

Usability Recommendations

Sample Module	• Sample Module Lid: Redesign the sample module lid to be easier to locate and open, possibly with visual cues or ergonomic design improvements • Tube Insertion Guidance: Implement a mechanism or visual guide to ensure users insert the tube fully, allowing the sample prep module to close properly
Power Module	• Test Device Insertion Point: Redesign the interface to make the insertion point for the test device more intuitive and easier to locate. • Correct Test Device Insertion: Implement a mechanism or visual guide to ensure the test device is inserted correctly to prevent incorrect insertion.
Test Device Interpretation	• Control Lines Understanding: Provide clear quick reference guides and basic training to help non-laboratory users confidently interpret the two control lines and one test line. • Visual Guidance for Control Lines: Explore options to visually guide users to read both control lines as one, such as minimizing the space between C1 and C2 or using a wash-away design.
Impact of Alcohol / Drug Use	• There were concerns about alcohol and drug use potentially affecting test accuracy, and further investigation is recommended during the usability testing phase.
User Cadre	• Nurses, clinical officers, community health workers and lab technicians, were all able to run the test with independence. These professionals often manage multiple responsibilities and face challenges, such as sample handling and a lack of timely access to test results.

Contents

Key Recommendations | NAATOS Requirements (1/2)

Thematic Area	Description
NAATOS System (Device, Modules & Consumables)	• **Temperature conditions variable and uncontrolled:** Sample prep tube contents, device & modules must be robust enough to handle varying and undocumented temperatures in Africa temperature settings. • **Module configuration needs:** Single and two-test module systems would be sufficient for clinics visited. • **Battery operated devices:** Rechargeable battery solutions essential since there is limited back-up power and on the odd occasion, long periods of power outages. • **Module battery life indicator:** Add a clear battery life indicator (battery icon) to keep users informed about remaining power levels. • **Module instrument labeling:** require clear labeling of lights & user-friendly solution influenced by UI/UX design. • **Securing devices in facilities:** With the potential for theft, the instruments should have an ability to be secured to a counter or table within the clinic environment. • **Quick turnaround time** is crucial to ensure testing is completed within the same clinical encounter, reducing patient wait times, improving TB case follow-up, and minimizing the need for additional modules to support high-traffic urban clinics.
Test Device	• **Control Lines Understanding**: Explore options to visually guide users to read both control lines as one, such as minimizing the space between C1 and C2 or using a wash-away design. Provide clear quick reference guides and basic training to help non-laboratory users confidently interpret the two control lines and one test line. • **Contamination risks:** NAATOS cartridges need a secure design to prevent contamination during disposal, due to potential incineration or off-site dumping. • **Interfering substance:** There were concerns about alcohol and drug use potentially affecting test accuracy, and further investigation is recommended during the usability testing phase. • **Abstaining from food and drink:** WHO recommends abstaining from food and drink 30 minutes before testing. Usability testing should assess the impact of this waiting period on clinic workflows and patient compliance.

Key Recommendations | NAATOS Requirements (2/2)

Thematic Area	Description
Sample Preparation Module	• **Sample Module Lid:** Redesign the sample module lid to be easier to locate and open, possibly with visual cues or ergonomic design improvements • **Tube Insertion Guidance:** Implement a mechanism or visual guide to ensure users insert the tube fully, allowing the sample prep module to close properly
Power Module	• **Test Device Insertion Point:** Redesign the interface to make the insertion point for the test device more intuitive and easier to locate. • **Correct Test Device Insertion:** Implement a mechanism or visual guide to ensure the test device is inserted correctly to prevent incorrect insertion.
Connectivity	• **Connectivity an add-on feature:** With majority of data management being paperwork for the clinic, but there being a strong element of electronic record keeping for monthly national reporting, connectivity should be a supplementary feature, with integration into national TB programs and centralized lab data systems. • **Consider alternative communication strategies:** Connectivity solutions would work well where results can be shared via SMS to facilitate robust client communication and ownership of their own results.
Sample Collection Kit	• **Contamination risks:** Design modifications (e.g., wider base for sample tubes) could reduce spillage risks. Proper training on sample handling is crucial to minimize contamination risks. Observations included practices like placing tubes on their sides when open.

Key Recommendations | Placement and Users of NAATOS (1/2)

Thematic Area	Description
Recommended Clinic Level Placement	• The NAATOS device is ideally suited for Level 2 & 3 facilities in Kenya and PHC and CHC facilities in South Africa, which typically handle moderate patient volumes and are equipped with trained healthcare workers capable of operating diagnostic equipment. • These facilities provide a balance between resource availability and high patient need. • This will help reduce the reliance on sample logistics for TB tests that enable same day linkage to care.
Placement Location within Facilities	• **Triage/Observation/Vitals Room**: Placing the device in the triage room ensures early TB testing as soon as TB symptom screening questionnaire is done with the client, aligning with current symptom assessments and helping reduce transmission risk • For centralized access, a dedicated testing area within the facility would enable nurses or clinical officers to efficiently manage testing away from patient traffic, facilitating a smoother workflow.
Primary Users of NAATOS	• **Primary Users:** Nurses, clinical officers, community health workers, and in rare cases, lab technicians, will be the main users of the device. These professionals often manage multiple responsibilities and face challenges, such as sample handling and a lack of timely access to test results. • **User Needs:** – **Ease of Use:** Users prefer minimal setup and simple instructions, particularly in facilities where multiple staff share responsibility for TB testing. – **Quick Results:** Faster testing and result turnaround are critical to prevent patients from needing multiple clinic visits, which affects adherence and follow-up. – **Training and Support:** Users need training on device operation and sample handling to avoid common errors observed during the usability study, such as difficulty with the sample module

Key Recommendations | Placement and Users of NAATOS (2/2)

Recommendation	Description
Target Population for testing with NAATOS	• **TB patients and symptomatic individuals:** visiting primary care centers in high TB-burden areas, especially those with limited access to rapid testing. • **PLHIV** and others who can't produce sputum • **Children:** at each facility children were mentioned as an important population that the tongue swab TB test would help considerably. It is traumatic to for the child and parent to collect samples via gastric aspirate or bronchial lavage, and how they avoided the procedure as much as possible. • **Household contacts:** all community health workers asked about using the test for household contacts and taking NAATOS into the community. More would need to be done to explore the feasibility and performance capability for this use case. • **Benefit to the Target Population:** By minimizing turnaround time and patient wait periods, NAATOS could significantly reduce delays in diagnosis, ensuring same day access to treatment and improving the overall patient experience. NAATOS also helps reduce the risk of transmission in waiting areas.

Next Steps

Key next steps

1. **Revise product specifications:** Considering findings from usability and interview feedback from facilities visited.
2. **Conduct Pilot Implementation**: Launch a pilot at selected facilities to gather additional real-world data and feedback.
3. **Refine Training Programs**: Develop and roll out tailored training for healthcare workers on NAATOS use, sample handling, and error prevention.
4. **Implement Follow-Up Mechanisms:** Establish a robust system for monitoring test results and patient follow-ups, especially for rural clinics with low connectivity.
5. **Advocacy:** Engage iteratively with the TB Programs by providing regular updates and seeking their feedback after implementing changes to the product.

Potential Partners

1. **Ministries of Health:** For nationwide implementation, regulatory guidance, and integration with national TB programs.
2. **Local TB Implementation Science Groups:** For data generation implementation and outcomes research to help inform policy and guidelines (e.g. HE2RO, WITS RHI)
3. **Community Health Networks:** For outreach, education, and follow-up, especially in rural areas.
4. **Technology Partners:** To address connectivity challenges and integrate NAATOS with health information systems, allowing seamless data reporting and result relay.

Thank you to our local collaborators

We are deeply grateful to Dr. Immaculate Kathure and Prof Norbert Ndjeka for allowing this work to be done to ensure NAATOS TB meets the needs of the TB Program in Kenya and South Africa. Special thanks to Dr. Stephen Macharia, whose dedication and expertise have been invaluable in advancing our efforts. His commitment to improving healthcare outcomes in Kenya is truly inspiring. We also wish to acknowledge the coordination by the sub-county coordinators – Simon Were, Moses Otieno, Nellie Motanya, and Meshack Mungai. We also wish to acknowledge the NHLS team – Shaheed Omar and Pinkie Moipolai – for their laboratory insights and the coordination by the provisional and district TB directors and coordinators – Zuki Mwanda, Mncedisi Madlavu, Boitumelo Fanampe, Leole Setilhare, Sabata Makatane, and Thato Lion, Noor Zakhura, Sheila Katz, Jean Volgraff, Mavis Malelane, Vincent Blaar – whose dedication and expertise have been invaluable.

Most importantly, we are grateful to the contributions of the clinical officers, nurses, laboratory technicians, and community health promotors and all team members who worked to ensure the success of this initiative. Their enthusiasm and collaboration are greatly appreciated.

South Africa's **National Department of Health - National TB Control & Management Cluster**

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

Kenya's **National Tuberculosis, Leprosy and Lung Disease Program**

REPUBLIC OF KENYA
MINISTRY OF HEALTH
NATIONAL TUBERCULOSIS,LEPROSY AND LUNG DISEASE PROGRAM

Contents

Acronyms

ACF - Active Case Finding
CAD - Computer-Aided Detection
CHC - Community Health Center
CHW - Community Health Worker
DR-TB - Drug-Resistant Tuberculosis
DS-TB - Drug-Sensitive Tuberculosis
EHR - Electronic health records
GH Labs - Global Health Labs
IPC - Infection Prevention and Control
LFA - Lateral Flow Assay
LF-LAM - Lateral Flow Lipoarabinomannan Assay
NAAT - Nucleic Acid Amplification Technology
NHLS - National Health Laboratory Service
PHC - Primary Health Care
PLHIV - People Living with HIV
PoC - Point of Care
RDT - Rapid Diagnostic Test
RIF - Rifampicin
TB - Tuberculosis
TPP - Target Product Profile
TPT - Tuberculosis Preventive Therapy
TUTT - Tuberculosis Unit Testing Tool
WHO - World Health Organization

Kenya: Facility Characteristics

Facility Name	Electricity (Source)	Backup Power	Electricity available in past 7 days	Waste disposal	Connectivity	Records Management	Estimated Patient No's at Facility	Temperature recording
Riruta Health Centre	• Yes (central supply of electricity)	• No backup power	• Often available	• Removed offsite	• No internet	• Paper based records	• 600 - 700	• None
Baraka Health Centre	• Yes (Central supply of electricity)	• Generator	• Sometimes available (frequent or prolonged interruptions of more than 2 hours per day)	• Removed offsite	• Wireless (Wi-Fi)	• Electronic health records	• Not provided	• Daily
Kuoyo Kaila Dispensary	• Yes (Central supply of electricity)	• No backup sources	• Sometimes available (frequent or prolonged interruptions of more than 2 hours per day)	• Open burning	• · Wired (ethernet) • · Mobile data	• Electronic health records • Paper based records	• 25 - 70	• Twice daily
Asat Beach Dispensary	• Not provided	• Not provided	• Not provided	• Not provided	• Not provided	• Not provided	• Not provided	• Not provided
Rhodes Chest Clinic	• Yes (central supply of electricity)	• No backup sources	• Always available	• Removed offsite	• · Wired (ethernet) • · Wireless (Wi-Fi)	• Paper based	• 40 - 80	• Automatic temperature monitor
Marimani CDF Dispensary	• Yes (central supply of electricity)	• No backup sources	• Monthly power cut of 24 hours	• Open burning • Removed offsite • Sputum in placenta pit	• Mobile data	• Electronic health records • Paper based records	• 30 - 50	• None
Kongowea Health Centre	• Not provided	• Not provided	• Not provided	• Not provided	• Not provided	• Electronic health records • Paper based records	• Not provided	• Not provided

Note: Insights captured as 'not provided' were in instances where there was insufficient time at the clinic to collect these data points.

Kenya: TB Clinic Services

Facility Name	Days/hours of TB service	TB services available at facility	How TB NAAT testing is conducted	Where samples are sent for testing	How samples sent to offsite lab	Types of on-site TB test	Where testing is conducted in facility	Estimated turnaround time
Riruta Health Centre	Monday to Friday: 8:00AM – 5:00PM TB service always open	· Onsite lab testing · Offsite testing for TB · Prescribe & dispense TB Rx · TB Rx follow-up	Onsite	Culture sent to National TB reference lab	Not provided	· Smear microscopy • NAAT · Chest radiography · LF-LAM	Lab	• 2 Hours • 24 Hours
Baraka Health Centre	Monday to Friday: 8:00AM – 5:00PM	· POC Onsite testing · Offsite testing for TB · Prescribe & dispense TB Rx · TB Rx follow-up	Offsite	· Mathare North Health Centre · NTRL	Facility motorbike or “boda-boda” or public transport, daily at 11am	· Smear microscopy · LF-LAM	Lab	• AFB – 24 Hours • Xpert – 48 Hours
Kuoyo Kaila Dispensary	Monday to Friday: 8:00AM – 5:00PM	· Offsite testing for TB · Prescribe & dispense TB Rx · TB Rx follow-up	Offsite	· Sputum sent to Koneywa · Cultures sent to KEMRI	· Samples sent once a day. · Samples with ice box	Not provided	Not provided	• 48 Hours
Asat Beach Dispensary	Monday to Thursday	· Offsite testing for TB · Prescribe & dispense TB Rx · TB Rx follow-up	Offsite	• Kongowea • Bode • Simea	Not provided	Not provided	Not provided	Not provided
Rhodes Chest Clinic	Monday to Friday: 8:00AM – 5:00PM	· Onsite lab testing · Offsite testing for TB · Prescribe & dispense TB Rx · TB Rx follow-up	Onsite	Cultures set to KEMRI	Not provided	· Smear microscopy • NAAT · Chest radiography	Lab	• 24 Hours
Marimani CDF Dispensary	Monday to Friday: 8:00AM – 4:00PM	· Offsite testing for TB · Prescribe & dispense TB Rx · TB Rx follow-up	Offsite	Mlaleo Lab	Sent by motorbike rider	Not provided	Not provided	Not provided
Kongowea Health Centre	N/A	· Offsite testing for TB · Prescribe & dispense TB Rx · TB Rx follow-up	Offsite	• Mlaleo Lab • Coast General	Patient goes to lab	N/A	N/A	• Minimum 24 Hours • Maximum 48 hours • Culture: 6 – 8 weeks

Note: Insights captured as ‘not provided’ were in instances where there was insufficient time at the clinic to collect these data points.

South Africa: Facility Characteristics

Facility Name	Electricity (Source)	Backup Power	Electricity available in past 7 days	Waste disposal	Connectivity	Records Management	Estimated Patient No's at Facility	Times temperature is recorded in lab
Motherwell CHC	Yes (Central supply of electricity)	Yes (Generator)	Always available (no interruptions)	Removed offsite	Yes - Wireless (Wi-Fi)	• Paper- based records	150 - 200	Daily
Walmer Clinic	Yes (Central supply of electricity)	No backup sources	Always available	Removed offsite	Wired (Ethernet)	• Paper-based records • Electronic records	101 - 220	Twice daily
Heidedal CHC	Yes (central supply of electricity)	Generator	Always available	Removed offside	Mobile data	• Paper based records	600 - 700	N/A
Batho Clinic	Yes (central supply of electricity)	Generator	Often available (interruptions of less than 2 hours per day)	Removed offsite	· Wired (ethernet) · Wireless (Wi-Fi)	• Paper based records	500 - 1000	Once a day
Warrenvale Clinic	Yes (central supply of electricity)	No backup sources	Sometimes available (frequent or prolonged interruptions of more than 2 hours per day)	Removed offsite	Mobile data	• Electronic health records • Paper based records	30	Once daily
Kimberley City Clinic	Yes (central supply of electricity)	No backup sources	Often available (interruptions of less than 2 hours per day)	Removed offsite	Wireless (Wi-Fi)	• Paper based records	180 - 200	N/A

Note: Insights captured as 'not provided' were in instances where there was insufficient time at the clinic to collect these data points.

South Africa: TB Clinic Services

Facility Name	Days/hours of TB service	TB services available at facility	How TB NAAT testing is conducted	Where samples are sent for testing	How samples sent to offsite lab	Types of on-site TB test	Where testing is conducted in facility	Estimated turnaround time
Motherwell CHC	Monday to Friday: 7:30AM – 4:00PM	· POC Onsite testing · Offsite testing for TB · Prescribe & dispense TB Rx · TB Rx follow-up	Offsite	Sent to the lab in Port Elizabeth	Picked up by a driver 3 times a day	· Chest radiography · LF-LAM · Skin test for under 5-year old's	· Nurse room · TB room · Dr. consulting room	• 24 Hours • Culture takes 6 weeks
Walmer Clinic	Monday to Friday: 7:30AM – 4:00PM TB services always open	· POC Onsite testing · Offsite testing for TB · Prescribe & dispense TB Rx · TB Rx follow-up	Offsite	Sent to provincial NHLS (Port Elizabeth Provincial Hospital)	Transported 2 times a day	· LF-LAM	· TB room · Doctors room	• Minimum 24 hours • Maximum 48 hours
Heidedal CHC	Monday to Friday: 7:00AM – 4:00PM	· POC Onsite testing · Offsite testing for TB · Prescribe & dispense TB Rx · TB Rx follow-up	Onsite	NHLS lab	· NHLS lab · Lab picks up samples 3 times a day	· Smear microscopy • NAAT · Chest radiography · LF-LAM	Onsite lab in the hospital grounds, not part of the CHC	• 48 hours
Batho Clinic	Monday to Thursday: 7:00AM – 4:00PM Fridays - follow ups	· POC Onsite testing · Offsite testing for TB · Prescribe & dispense TB Rx · TB Rx follow-up	Offsite	Pelonomi	· NHLS driver · Samples picked up 2 times a day	· LF-LAM	LF LAM conducted in room within the facility	• 48 hours
Warrenvale Clinic	Monday to Friday: 7:30AM – 4:00PM	· POC Onsite testing · Offsite testing for TB · Prescribe & dispense TB Rx · TB Rx follow-up	Offsite	· Kimberly Hospital · National NHLS	Sent to lab once a day	· Chest radiography · LF-LAM	Vitals room	• Minimum 24 Hours • Maximum 48 Hours
Kimberley City Clinic	Monday to Friday: 7:00AM – 4:00PM	· POC Onsite testing · Offsite testing for TB · Prescribe & dispense TB Rx · TB Rx follow-up	Offsite	Kimberly Hospital	Sent to lab twice a day by driver	• LF-LAM	• TB focal • Acute care	• Minimum 24 hours • Maximum 48 hours

Note: Insights captured as 'not provided' were in instances where there was insufficient time at the clinic to collect these data points.

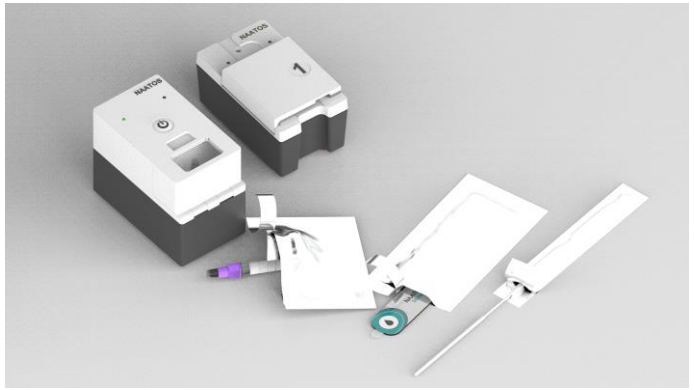
Task 1: Open and label consumables - sample tube and test device

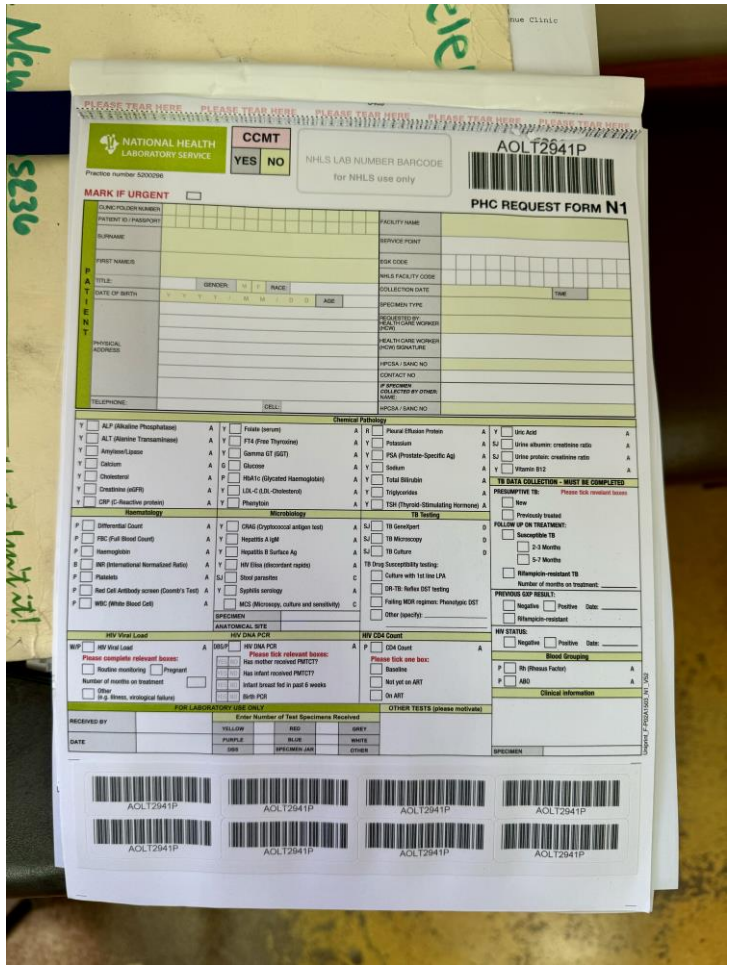
Learnings:

- Labeling (name, ID, initial, birth year, etc.) requirements differed at the country, district, clinic, and staff level (e.g., first name, full name, date of birth, patient ID number)
- RDTs are not labeled
- TB Sputum samples have a designated barcode from the
- Consensus that labeling with a pen works

Next steps:

- Ensure sample tube labeling is unaffected by sample processing (e.g., exposure to heat)
- Introduce a standardized labelling approach and develop training to ensure consistency.





Task 2: Collect the tongue swab from the patient, break off the swab head directly into the sample tube, and close the tube

Learnings:

- Tongue swab is a preferred sample type
- Excitement on potential impact for pediatric population
- Concern for people with substance abuse
- Difficulty with finding break off point at first
- Users consistently inserted swab fully into the tube, searching for the break-off point instead of breaking off the swab head and letting it fall into the tube
- No concern with holding the tube while taking the sample
- No users spilt the tube, as they saw the tube was pre-filled with liquid and handled with care
- Preference for swab in sheets versus tubes

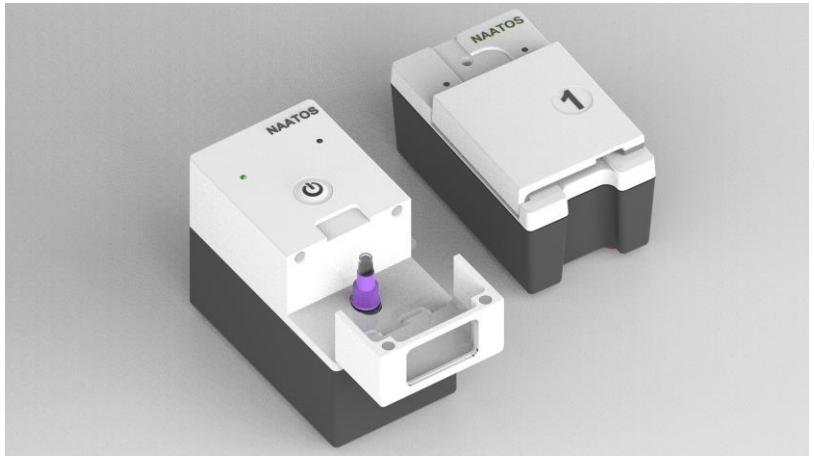
Next Steps:

- Consider swab options with breakoff point clearly marked

Task 3: Place sample tube into sample prep module and press "start" to process sample.

Learnings:

- Start button was not intuitive and confusion with the start button and power on as the same button
- Many users required a reminder to close the sample prep module before pressing start
- All participants initially struggled or took longer than expected to find and open the sample module's lid.
- Users consistently did not put the tube all the way in and thus could not close the sample prep module
- Need a battery life indicator to ensure awareness of remaining power levels
- Need for additional notifications (alarm) beyond indicator lights due to the power module ~45 min wait time, but if sample prep stays within ≤ 7 min, then no additional notifications are required
- Indication lights are easy to interpret with instruction, but without them, they require labeling and a more user-friendly solution influenced by UI/UX design



Next Steps:

- Reduce sample prep time to ensure workflow has minimal disruptions from sample processing to result read out
- Need to ensure the power on feature is equivalent for both modules
- Explore alternative power on and start features so that the Start button and power-on are not the same
- Explore options for a battery life indicator and consider measures to prevent theft and ensure both modules are charged simultaneously avoid one being left uncharged
- Explore options to ensure the sample is processed and not removed early or implement a downstream control to confirm successful processing
- Explore grips on the side of the door as an alternative to the current pull-down from the top design
- Explore alternatives for indication lights

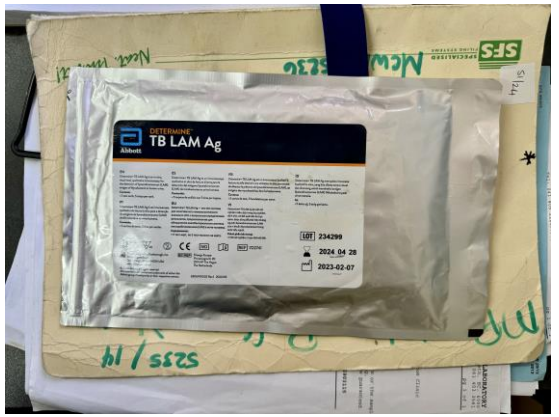
Task 4: Transfer the processed sample into the NAATOS test device and peel the sticker to seal

Learnings:

- Familiarity with RDT at the PHC level instilled confidence
- Introducing the sample required initial instruction
- Sealing the sample well was intuitive
- Appreciation for the visibility of liquid transfer, including potential for color liquid, from the tube into the sample well
- Beyond laboratory technicians, no knowledge of potential for contamination
- Test device labeling and orientation is left-handed
- The shape of the sample well contributed to issues with bubbles

Next Steps:

- Explore changing the orientation to right-handed
- Explore the real risk of contamination and consider additional measures beyond the peel and seal sticker to prevent contamination
- Consider options to keep the sample well transparent to maintain its visibility and options for a colored liquid
- Redesign the sample well



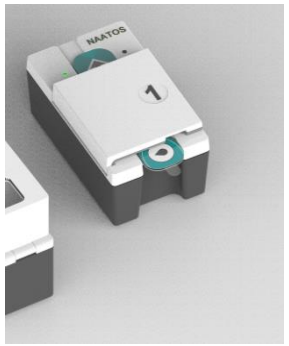
Task 5: Slide the loaded NAATOS test device into the power module and initiate testing

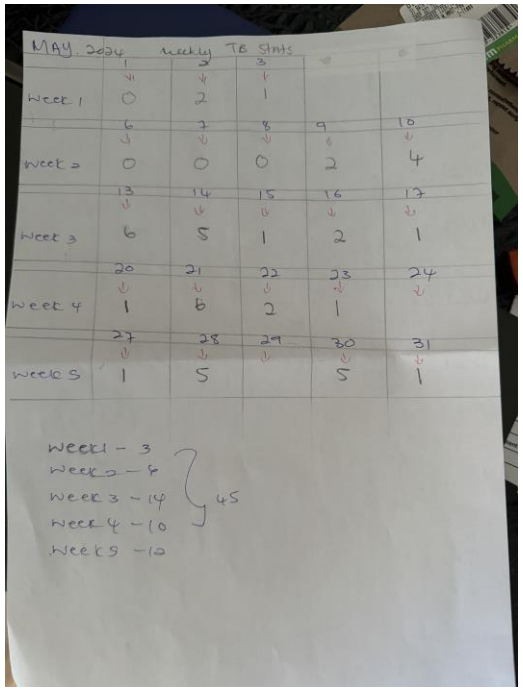
Learnings:

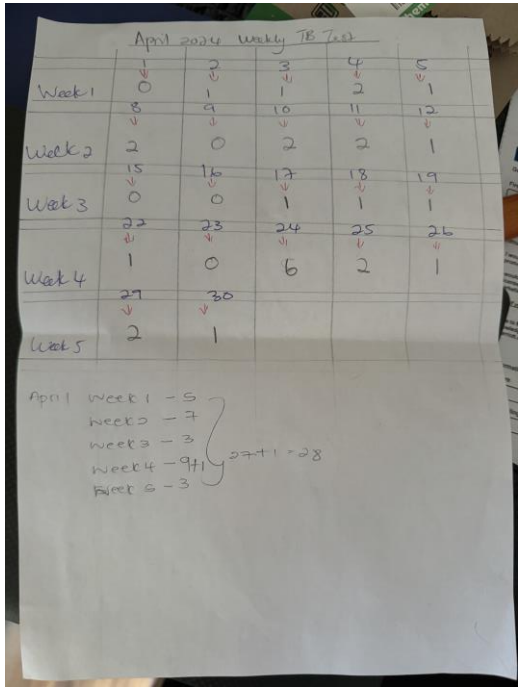
- Simple and intuitive experience, but difficult to find where to insert the test device at first
- Only one user tried to insert the test device the wrong way
- Users called the test device NAATOS TB
- Request for sound notification as a reminder to return to NAATOS if there is an error or if the test is complete
- Needs a battery life indicator to ensure users are aware of remaining power levels
- Indication lights are easy to interpret with instruction, but without them, they require labeling and a more user-friendly solution influenced by UI/UX design
- Current throughput of samples sent for NAAT testing could underestimate the true demand , as it depends on patients with presumptive TB able to produce a sputum sample and on individuals seeking healthcare despite knowing they will not receive results during the same clinical encounter
- Preference for power module configuration that offers random access capability to run parallel analysis of tests due to the time to result exceeding RDTs used today

Next Steps:

- Explore options for a battery life indicator and consider measures to prevent theft and ensure both modules are charged simultaneously avoid one being left uncharged
- Explore options for a sound notification
- Explore design and cost trade-offs for power module configuration to meet expected demand
- Explore alternatives for indication lights from other products found in primary health care
- Explore labeling options for how to insert the test device



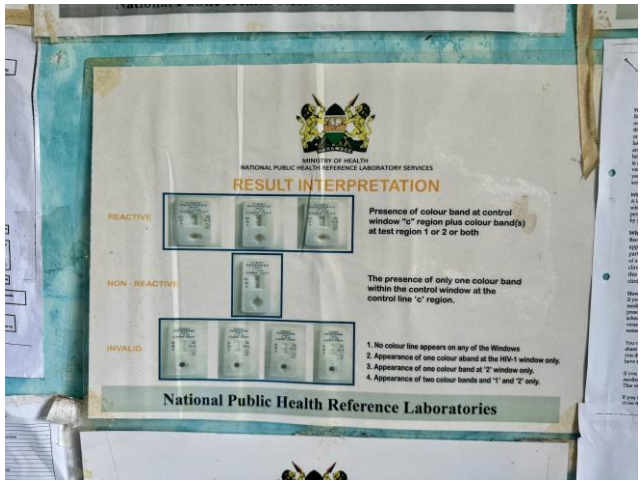




Task 6: When the power module indicates testing is complete, remove the test device, read the test results, and report

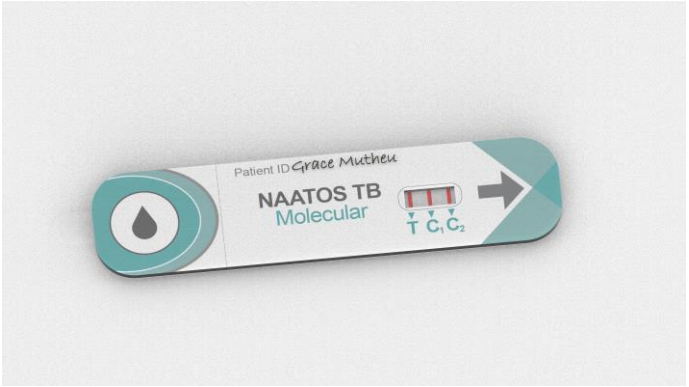
Learnings:

- CHWs and CHPs demonstrated competence with NAATOS TB due to their familiarity with RDTs.
- There was a varying degree of them understanding the two control lines and one test line, but all non-laboratory users expressed that with proper quick reference guides and basic training they would confidently interpret the results.
- All facilities use paper-based capturing of patient records, including results, in the TB registers alongside information systems (e.g., TrackCare, TIER.Net) for NAAT test results from NHLS laboratories.
- No expressed desire for results to connect to the information systems as NAATOS would be the first test in the continuum of care, but drug resistance and treatment monitoring would continue.
- There was positive feedback for the lateral-flow visual readout and interpretation of the results that can be shared with patients during the same clinical encounter, as a patient-centric solution at the point of care.
- Quality assurance oversight could leverage existing external quality assurance from RDTs



Next Steps:

- Explore options for alternative control to address process errors and usability of LFA readout
- Explore options to visually guide users to read both controls as one (e.g., wash away, minimize space between C1 and C2)



Current vs Future Workflow in a TB Clinic

STEPS	CURRENT WORKFLOW	FUTURE WORKFLOW
1. **Patient arrival at clinic**	✓	Improve scheduling to optimize workflow
2. **Take vitals and triage patients**	✓	Prepare patients for testing
3. **Clinical assessment for TB and referral for testing**	✓	Initiate testing process during clinical assessment
4. **Patient preparation**	Patients are given instructions by the nurse, link assistant, or other staff on how to collect a sputum sample.	**New step:** Fasting and oral hygiene required for 30 minutes prior to sample collection.
5. **Sample collection**	Sputum collection by the patient in the designated cough corner (note potential challenges with sputum collection).	Tongue swab collection by the provider, possibly in the consultation room.
6. **Sample storage/transfer**	The sample is stored in an ice pack or refrigerator prior to testing or shipment to the lab.	Sample storage may not be necessary if testing is conducted on the same day.
7. **Conduct test**	The laboratory technician conducts the test using a molecular method (e.g., GeneXpert) in an onsite or offsite laboratory.	**New step:** The provider conducts testing onsite, possibly in the consultation room.
8. **Report test results**	**Results (general and resistance)** are reported to the provider in XX days via SMS, patient portal, and/or hard copies. **Results reported to the patient** in XX days. The provider calls the patient to come in for results, and a CHW follows up if the patient is not reachable.	**New step:** The provider can report results to the patient in person, potentially on the same day, depending on testing volumes.
9. **Initiate treatment and patient management**	**Initiate TB treatment**, including drug-resistant TB treatment if the test is positive. Time to treatment: XX days. **Initiate TB preventive treatment** for negative cases; however, patients typically don't return for follow-up. **Initiate contact tracing** and screen contacts of TB-positive patients.	**New step:** Start TB treatment and TB preventive treatment (TPT) immediately, assuming same-day test results. **New step:** Collect sputum samples for resistance testing (proceed to step 4 for the current workflow).

NAATOS Phase 2 Formative Feedback Learnings for the Sample Prep Module

User Interface and Interaction	• **Separate Power On and Start Functions:** Redesign the interface to have distinct buttons for power on and start to avoid confusion. • **Intuitive Start Button:** Ensure the start button is clearly labeled and intuitive to use • **Sample Module Lid:** Redesign the sample module lid to be easier to locate and open, possibly with visual cues or ergonomic design improvements • **Tube Insertion Guidance:** Implement a mechanism or visual guide to ensure users insert the tube fully, allowing the sample prep module to close properly
Notifications and Indicators	• **Battery Life Indicator:** Add a clear battery life indicator (battery icon) to keep users informed about remaining power levels. • **User-Friendly Indication Lights:** Redesign indication lights to be more user-friendly and self-explanatory without requiring extensive instructions. Consider adding labels or using a more intuitive UI/UX design. Ensure feature is consistent or equivalent for both modules.
Workflow and Efficiency	• **Reduce Sample Prep Time:** Optimize the sample prep process to minimize disruptions and ensure a smooth workflow from sample processing to result readout • **Consistent Power On Feature:** Ensure the power on feature is consistent and equivalent for both modules to avoid user confusion
Design and Ergonomics	• **Alternative Power On and Start Features:** Explore alternative designs for the power on and start features to clearly differentiate them • **Grips on Sample Module Door:** Consider adding grips on the sides of the sample module door as an alternative to the current pull-down design from the to
Security and Maintenance	• **Battery Theft Prevention:** Implement measures to prevent battery theft • **Forced Charging**: Ensure both modules are charged simultaneously to avoid one being left uncharged • **Sample Processing Confirmation:** Develop a downstream control mechanism to confirm successful sample processing and prevent premature removal

NAATOS Phase 2 Formative Feedback Learnings for the Power Module

User Interface and Interaction	• **Test Device Insertion Point:** Redesign the interface to make the insertion point for the test device more intuitive and easier to locate. • **Correct Test Device Insertion:** Implement a mechanism or visual guide to ensure the test device is inserted correctly to prevent incorrect insertion.
Notifications and Indicators	• **Sound Notifications:** Add sound notifications to alert users to return to NAATOS if there is an error or when the test is complete. • **Battery Life Indicator:** Integrate a clear battery life indicator to keep users informed about remaining power levels. • **User-Friendly Indication Lights:** Redesign indication lights to be more user-friendly and self-explanatory without requiring extensive instructions. Consider adding labels or using a more intuitive UI/UX design.
Workflow and Efficiency	• **Sample Throughput Optimization:** Address the potential underestimation of sample throughput by considering the constraints of patients producing sputum samples and the delay in receiving results. Explore ways to streamline the process to better meet true demand.
Design and Ergonomics	• **Random Access Capability:** Configure the power module to offer random access capability, allowing parallel analysis of tests to improve efficiency and reduce wait times compared to current RDTs.
Security and Maintenance	• **Battery Theft Prevention:** Implement measures to prevent battery theft. • **Forced Charging:** Ensure both modules are charged simultaneously to avoid one being left uncharged.

NAATOS Phase 2 Formative Feedback Learnings for the Test Device

User Interface and Interaction	• **Control Lines Understanding:** Provide clear quick reference guides and basic training to help non-laboratory users confidently interpret the two control lines and one test line. • **Visual Guidance for Control Lines:** Explore options to visually guide users to read both control lines as one, such as minimizing the space between C1 and C2 or using a wash-away design.
Notifications and Indicators	• **Lateral-Flow Visual Readout:** Maintain the lateral-flow visual readout for easy interpretation of results, ensuring it remains patient-centric and can be shared during the same clinical encounter.
Workflow and Efficiency	• **Paper-Based Record Keeping:** Ensure compatibility with existing paper-based patient record systems and TB registers, alongside information systems like TrackCare and TIER.Net for NAAT test results.
Design and Ergonomics	• **Alternative Control Options:** Explore alternative control mechanisms to address process errors and improve the usability of the LFA readout.
Security and Maintenance	• **Alternative Control Options:** Explore alternative control mechanisms to address process errors and improve the usability of the LFA readout.