




# TB SCREENING AND TESTING STANDARD OPERATING PROCEDURE



health

Department:  
Health  
REPUBLIC OF SOUTH AFRICA



<b>Document Name</b>	TB Screening and Testing Standard Operating Procedure
<b>Date of this Version</b>	June 2022
<b>Date of review</b>	May 2023
<b>Contact details for enquiries</b>	Dr L Mvusi <i>Lindiwe.Mvusi@health.gov.za</i>
<b>Signature</b>	

## Table of Contents

---

Table of Contents.....	<b>Error! Bookmark not defined.</b>
Abbreviations .....	4
Definitions .....	4
Background.....	5
Purpose.....	6
Scope .....	7
Objectives .....	7
Applicable Legislation, Policies and Guidelines.....	7
Target Population.....	7
Settings for implementation .....	8
Values and safety precautions.....	8
Roles and responsibilities .....	8
Screening for TB symptoms .....	9
Testing for TB .....	17
Chest x-ray screening.....	12
TB Testing.....	<b>Error! Bookmark not defined.</b>
Monitoring and evaluation.....	<b>Error! Bookmark not defined.</b>
Annexures.....	<b>Error! Bookmark not defined.</b>
Annexure A:.....	<b>Error! Bookmark not defined.</b> 6
Annexure B: .....	17

## Abbreviations

---

ANC	Ante Natal Care
ART	Anti-Retroviral Treatment
CHW	Community Health Worker
CXR	Chest X-ray
DS-TB	Drug Susceptible Tuberculosis
DST	Drug Susceptibility Testing
DR-TB	Drug Resistant Tuberculosis
EN	Enrolled nurse
HIV	Human Immunodeficiency Virus
HTS	HIV Testing Services
IPC	Infection Prevention and Control
LPA	Line Probe Assay
NHLS	National Health Laboratory Services
OTL	Outreach Team Leader
PHC	Primary Health Care
PHLIV	People Living with HIV/AIDS
PN	Professional nurse
PPE	Personal Protective Equipment
QI	Quality Improvement
TB	Tuberculosis
TPT	Tuberculosis Preventive Treatment
WBOT	Ward-Based Outreach Teams
WHO	World Health Organisation

## Definitions

---

**Systematic screening:** Screening for TB disease in a systematic way to identify people with active TB disease, using a standardised questionnaire, procedures, or tests such as Xpert MTB RIF Ultra assay, chest x-rays etc.

**Household contact:** A person who shared the same enclosed living space for one or more nights or for frequent or extended periods of up to 8 hours during the day with the index patient, during the 3 months before the start of current treatment episode.

**Close contact:** A person who shared an enclosed space, such as a social gathering place, workplace or congregate setting, more than 15 minutes over a period of 24 hours with the index patient, during the 3 months before commencement of the current treatment episode.

**Outreach team leader:** A person (Nurse) appointed to lead the ward-based outreach team. This person is responsible for ensuring that the work of the WBOT is linked to service delivery targets and that team members are adequately supported and supervised to meet these.

**Ward-based Outreach Teams:** are teams comprising community health workers and a team leader. They are linked to PHC facilities and provide integrated primary health care services to households and individuals within its catchment area.

**Community health worker:** Refers to any worker who is selected, trained, and works in the community. They are the first line of support between the community and various health and social development services. Their role is to empower community members to make informed choices about their health and psychosocial wellbeing and to provide ongoing care and support to individuals and families.

## Background

South Africa is one of eight countries that collectively account for two thirds of the world TB disease burden. The annual TB incidence in 2019 was estimated to be 615/100 000. The TB prevalence in the country was estimated to be 737 per 100 000 and that 58% of people who had confirmed TB had abnormal chest x-rays. Based on the TB prevalence estimate, the notification gap was 154 348 (missing persons with TB) which could be attributed to underreporting and underdiagnosis.

The TB cascade analysis based on 2018 data showed that only 86% of people were reached with TB testing services, 93% of those tested were diagnosed with TB and 76% of those diagnosed with TB were started on treatment<sup>1</sup>. The “Finding the missing TB patients” strategy, developed to find additional people with TB by strengthening TB screening and testing of patients in PHC facilities has not resulted in increased TB notifications.

A Targeted Universal TB Testing (TUTT) study<sup>2</sup> conducted in the country showed that universal TB testing for patients at high risk for TB using Xpert and culture irrespective of the presence of TB symptoms resulted in a 6% overall yield in laboratory confirmed TB. The Table 1 below summarises the findings of this study.

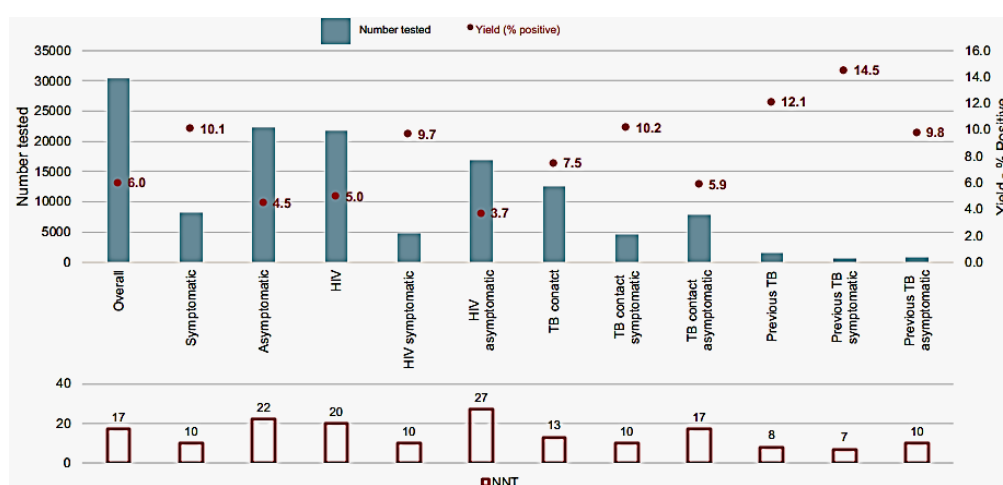


Table 1: TB yield by risk factor and symptoms & NNT

Targeted universal testing for TB in clinics in South Africa: A cluster randomized trial, N Martinson, L Lebina et al

This SOP aims to simplify the implementation of the administrative controls of TB infection prevention and control<sup>3</sup> using the FAST approach. FAST which stands for **F**inding people with TB **A**ctively, **S**eparate safely, and **T**reating effectively, is a quality improvement intervention aimed at preventing the spread of TB in congregate settings.

<sup>1</sup> 2018 TB Cascade Analysis, P Naidoo et al

<sup>2</sup> Targeted universal testing for TB in clinics in South Africa: A cluster randomized trial, N Martinson, L Lebina et al

<sup>3</sup> National Infection Prevention and Control Guidelines for TB, MDR AND XDR-TB, NDOH.2015

The key activities addressed under the administrative controls of TB-IPC include:

- screening for TB,
- cough hygiene/etiquette,
- separation and isolation,
- fast tracking of patients with symptoms of TB
- investigating patients with symptoms of TB,
- prompt treatment
- clear discharge plan (in hospitals)

The WHO recommendations on systematic TB screening<sup>4</sup> are summarised below:

- Systematic screening for TB disease in the general population and among people with risk factors, household and close contacts, inmates, PLHIV, people exposed to silica in workplaces in areas with a high TB prevalence.
- Use of symptom screen, chest X-ray or molecular WHO-recommended rapid diagnostic tests, alone or in combination to screen for TB disease in people 15 years and older
  - Use of the four-symptom screen and chest x-ray as a screening tool in adults and adolescents living with HIV. With those who report any one of the symptoms of current cough, fever, weight loss or night sweats evaluated for TB.
  - Use of TB symptom screen including any one of current cough, fever, poor weight gain or close contact with a TB patient in children <10 years living with HIV
  - Use of symptom screen including any one of cough, fever or poor weight gain; or chest radiography; or both in children < 15 years who are close contacts of a person with TB
  - Use of molecular WHO-recommended rapid diagnostic tests to screen for TB disease in adults and adolescents living with HIV
  - Use of digital chest x-rays with computer-aided detection software programmes as a screening tool in people aged 15 years and older

## Purpose

---

The purpose of this document is to outline the process and procedure for quality TB screening and early identification of patients who require TB testing to minimize avoidable delays in diagnosis and treatment thus reducing TB transmission.

---

<sup>4</sup> WHO Consolidated Guidelines on Systematic Screening for TB disease, 2021

## Scope

---

This SOP details screening and testing processes for TB, describes the procedures for triaging patients to testing and linking them to treatment in health facilities and at community levels.

## Objectives

---

The objectives of this document are to:

- To improve the quality of TB symptom screening services
- To provide guidance on the universal TB testing of high-risk groups
- To provide health care workers with operational information on delivery of TB screening and testing services.

## Applicable Legislation, Policies and Guidelines

---

- National Health Act 61 of 2003 as amended, and regulations issued in terms of the Act
- The National TB Management Guidelines, 2014
- Guidelines for the Management of TB in Children, 2013
- Management of Rifampicin-Resistant TB Booklet, 2019 V6
- Policy Framework and Strategy for Ward based Outreach Teams 2018/19 - 2023/24
- Ideal Clinic Framework and Manual, April 2020
- Integrated Clinical Services Management, 2016
- National Infection Prevention and Control Strategic Framework, 2020
- Policy framework on decentralized management of MDR-TB, May 2019
- National Prevention and Control Guidelines for TB, MDR-TB and XDR-TB, 2015
- National Health Laboratory Service Act (37 of 2000)
- National Health Laboratory Service Amendment Bill (1093 of 2015)

## Target Population

---

The intended audience for this SOP includes the management and operational staff of clinical and community outreach settings who will be conducting the screening, testing. These include the following:

- Doctors
- Nurses
- Community Health Workers
- Outreach Team Leaders
- TB and HIV Managers
- District support/ implementing partners
- Civil society partners
- Community representatives

## Settings for implementation

This SOP is for implementation in health facilities and at community level, the settings include:

- Hospitals
- Community Health Centers
- Clinics (including mobile clinics)
- Community sites (including households)

## Values and safety precautions

The following values must be upheld when providing TB screening and testing services:

- Courtesy and with consideration of patients' rights
- Privacy
- Confidentiality
- Respect
- Dignity

Infection control practices must be always adhered to.

Appropriate PPE should be used

A dedicated safe and private sputum collection area must be identified in all settings.

## Roles and responsibilities

The table below outlines the roles and responsibilities of key personnel in providing TB screening and testing services.

Table 1: Roles and Responsibilities of staff, managers and partners

Staff category	Roles and responsibilities
Medical Officer/ Nurse	<ul style="list-style-type: none"><li>• Conduct TB screening of patients.</li><li>• Clinical assessment of patients</li><li>• Collect specimens from all eligible patients for TB testing.</li><li>• Ensure all specimens collected are correctly labelled.</li><li>• Complete the laboratory request forms.</li><li>• Ensure the patient is given the next appointment date for follow up</li><li>• Follow up patient results.</li><li>• Ensure follow up of patients who miss appointments.</li><li>• Complete patient clinical records, PHC Tick and TB Identification registers</li></ul>
HTS Counsellors	<ul style="list-style-type: none"><li>• Conduct TB screening of patients.</li><li>• Collect specimens from all patients for testing.</li><li>• Refer and actively link patients to services</li><li>• Complete the HTS register</li></ul>



Staff category	Roles and responsibilities
CHW	<ul style="list-style-type: none"> <li>• Conduct TB screening of patients.</li> <li>• Collect specimens from all eligible patients for TB testing.</li> <li>• Ensure all specimens collected are correctly labelled</li> <li>• Follow up patient results.</li> <li>• Trace and refer patients for results.</li> <li>• Complete the community outreach forms and registers</li> </ul>
Data Capturer	<ul style="list-style-type: none"> <li>• Capture data on the electronic TB information system and other related systems</li> <li>• Ensure completeness of data.</li> <li>• Print out patient appointment list daily</li> <li>• Print out outstanding laboratory results line list daily</li> <li>• Print out facility reports weekly for analysis and actioning.</li> </ul>
Sub/ District TB Manager	<ul style="list-style-type: none"> <li>• Plan and conduct social mobilisation and awareness campaigns, health promotion and educational campaigns on TB screening and testing.</li> <li>• Develop and distribute relevant IEC (information, education and communication) materials on TB screening and testing in local language.</li> <li>• Coordinate training and mentoring for facility staff.</li> <li>• Coordinate laboratory services and communication with laboratories</li> <li>• Conduct support visits to health facilities to monitor implementation.</li> <li>• Ensure reporting by all facilities.</li> <li>• Collate and validate health facility data</li> </ul>
Civil society partners and community leaders	<ul style="list-style-type: none"> <li>• Demand creation through community education</li> <li>• Educating communities on rights and addressing TB stigma and myths.</li> </ul>
Facility Managers	<ul style="list-style-type: none"> <li>• Ensure TB screening is conducted effectively in the facility.</li> <li>• Review patient flow processes to allow for TB screening and specimen collection.</li> <li>• Ensure training of all facility staff on TB clinical management.</li> <li>• Ensure training of all facility staff on TB Infection Control</li> <li>• Ensure completeness of data</li> <li>• Conduct monthly data reviews</li> <li>• Ensure that remedial interventions are implemented to improve service delivery where the data shows inadequate performance</li> </ul>

## TB symptom screening

TB symptom screening must be conducted for all patients seen in health facilities and in targeted community settings.

### 1. Facility level screening

This applies to screening conducted in health facilities – clinics (fixed, mobile), and community health centers.

## Preparation

1. Introduce yourself to the client.
2. Explain the purpose and the actual screening process to the patients.
3. Explain that the screening will take approximately five minutes to conduct.
4. Patients should be offered the option to self-screen by completing the screening form or use the TBCheck platform.
  - 4.1 For patients who opt for self-screening:
    - The screening tool should be made available in local languages for patients who prefer self-screening
    - The self-screening form must be provided to the health care provider,
    - The health care provider must go through the responses, ask clarity seeking questions where required, communicate the results based on the patient's responses and advise on the follow up action.
  - 4.2 For patients who opt for screening by the health care provider:
    - The health care provider should administer the questionnaire in patient's preferred language and complete the form
    - The health care provider must communicate the results based on the patient's responses and advise on the follow up action.

## Facility Level Tools for data collection

- Integrated TB and Covid-19 Screening form
- Patient Clinic Record
- TB Identification Register
- PHC Tick Register
- TIER.Net

## 2. Community Level Screening

This applies to screening conducted at community level as part of outreach programmes. This includes household contact tracing, door to door campaigns and wellness campaigns – Checka Impilo.

### Preparation

1. Introduce yourself to the person undergoing screening
2. Explain the purpose and the actual screening process.
3. Explain that the screening will take approximately five minutes to conduct.
4. The community health worker should administer the questionnaire in the patient's preferred language and complete the screening form.

5. The community health worker must communicate the results based on the patient's responses and advise on the follow up action.

### **Community level tools for data collection**

- Integrated TB and Covid-19 Screening form
- WBOT Register
- WBOT Referral forms

## **3. Hospital level screening**

This applies to screening in hospital outpatient departments and wards (including mental health facilities, excluding TB hospitals). Routinely asking patients about TB symptoms and triaging them to urgent testing by laboratory whilst patients are waiting in the OPD clinics will result in early TB detection and reduce risk of transmission in these settings. Emergency and casualty patients who end up in the wards must be screened for TB once their condition has stabilized.

Patients with TB symptoms must be educated on cough hygiene which should include the importance of using masks and separation. They must be provided with surgical masks and take their position in the waiting area or where feasible they can wait in a separate adequately ventilated waiting area.

In the wards patients with TB symptoms must be isolated in a side ward or provided with a surgical mask where separation is not feasible.

### **Preparation**

1. Introduce yourself to the client.
2. Explain the purpose and the actual screening process to the patients.
3. Explain that the screening will take approximately five minutes to conduct.
4. Patients should be offered the option to self-screen by completing the screening form or use the TBCheck platform.
  - 4.1 For patients who opt for self-screening:
    - The screening tool should be made available in local languages for patients who prefer self-screening
    - The self-screening form must be provided to the health care provider,
    - The health care provider must go through the responses, ask clarity seeking questions where required, communicate the results based on the patient's responses and advise on the follow up action.

4.2 For patients who opt for screening by the health care provider:

- The health care provider should administer the questionnaire in patient’s preferred language and complete the form
- The health care provider must communicate the results based on the patient’s responses and advise on the follow up action.

### Facility Level Tools for data collection

- Integrated TB and Covid-19 Screening form
- Patient Clinic Record
- TB Identification Register
- TIER.Net

### TB and Covid-19 Symptoms

The Table 2, below demonstrates the overlap of symptoms between the two diseases hence the need for integrating for integrating screening and testing services. Examples of screening tools that can be used are in Annexure A.

Table 2: Symptoms of TB and Covid-19

TB symptoms in Adolescents and Adults	TB Symptoms in Children
<ul style="list-style-type: none"> <li>– Cough of any duration</li> <li>– Fever more than 2 weeks</li> <li>– Loss of weight (&gt;1.5kg in a month)</li> <li>– Drenching night sweats</li> </ul>	<ul style="list-style-type: none"> <li>– Cough of any duration</li> <li>– Fever</li> <li>– Documented weight loss/ failure to thrive</li> <li>– Fatigue</li> </ul>
Covid-19 symptoms	
<ul style="list-style-type: none"> <li>– Cough</li> <li>– Fever</li> <li>– Fatigue</li> <li>– Shortness of breath</li> <li>– Sore throat</li> <li>– Headache</li> <li>– Chills</li> <li>– Loss of smell/ taste</li> <li>– Arthralgia/ myalgia</li> </ul>	

### Chest x-ray screening

Digital chest x-rays with computer aided diagnosis are recommended for screening purposes. The following groups of people should be considered for chest x-ray screening, irrespective of HIV status:

- People who do not present with TB symptoms especially in high TB settings.
- People with TB symptoms other than cough.
- Symptomatic clients with a dry cough and cannot produce a sputum specimen.
- Current and former mineworkers with silica exposures.
- Symptomatic clients with a history of chronic lung disease

**Refer to the chest x-ray screening guide for further information.**



Note: Chest x-rays are NOT recommended for screening in children below the age of 15 years



Note: Chest x-ray screening should not act as a barrier to testing. Patients should not be referred to the next level of care for chest x-ray screening.



All people presenting with any TB symptom must be tested for TB



All people presenting with an abnormal chest x-ray suggestive of TB must be tested for TB

# Screening Algorithms

---

Figure 1: Health Facility TB Screening Algorithm

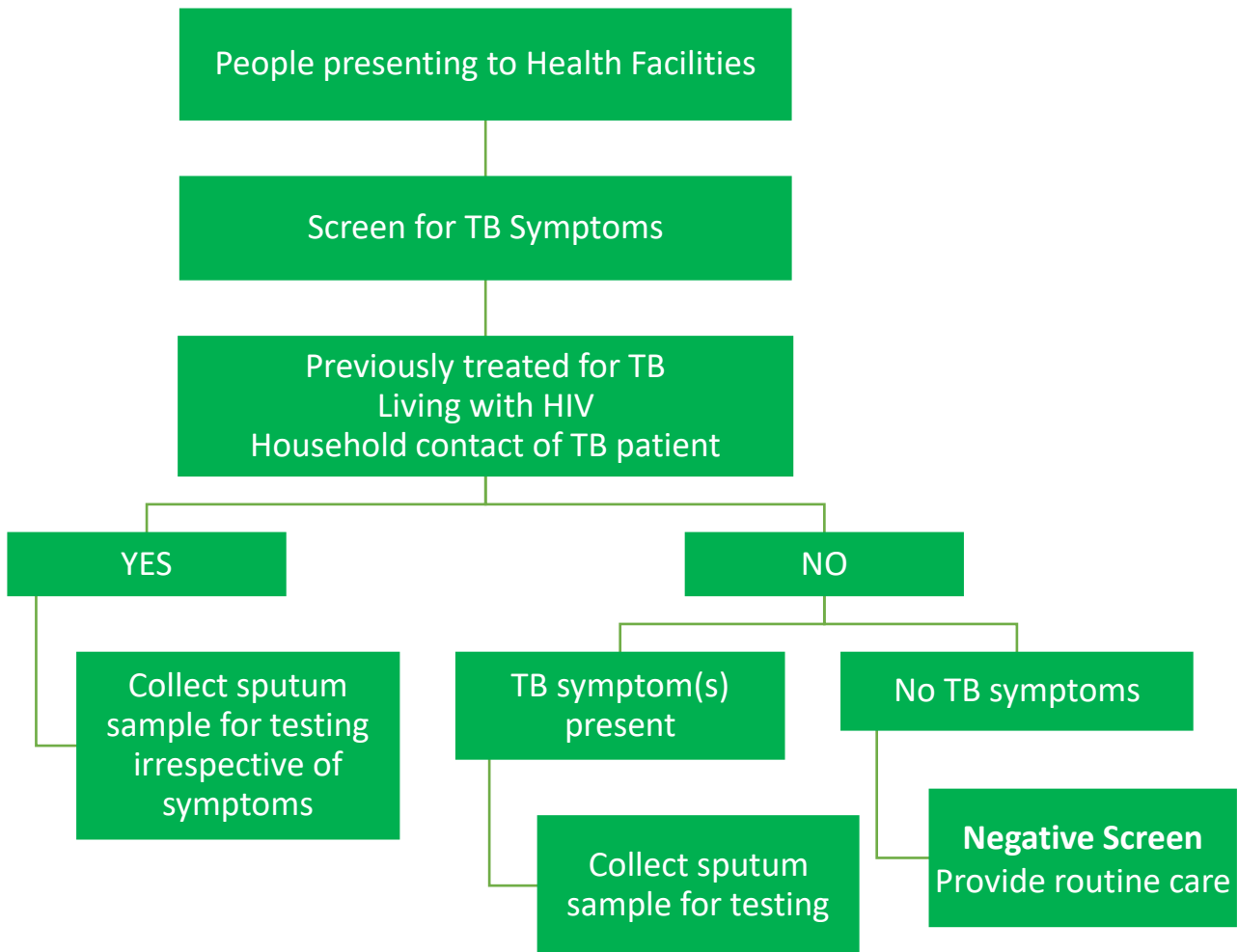


Figure 2: Community TB Screening Algorithm

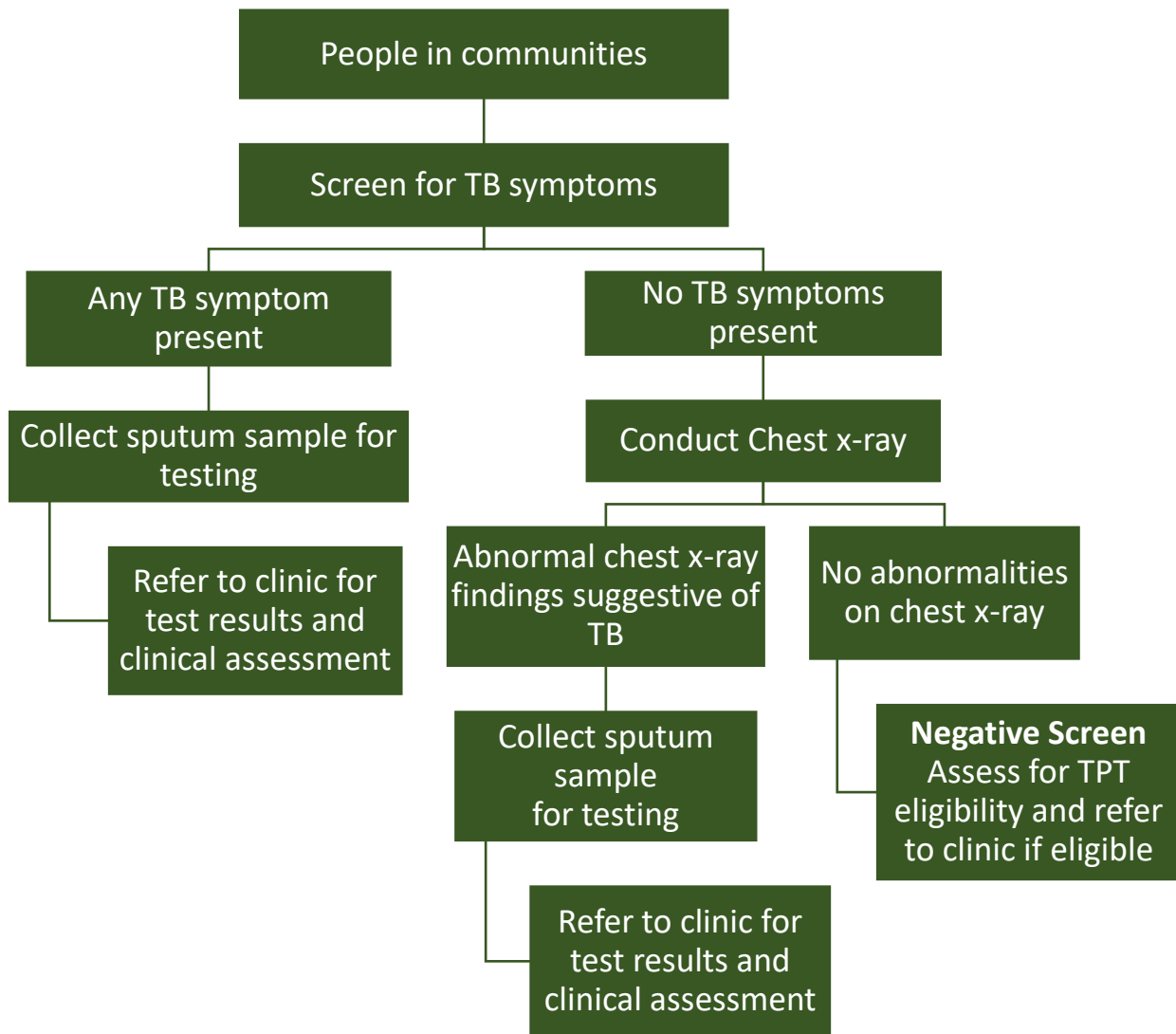
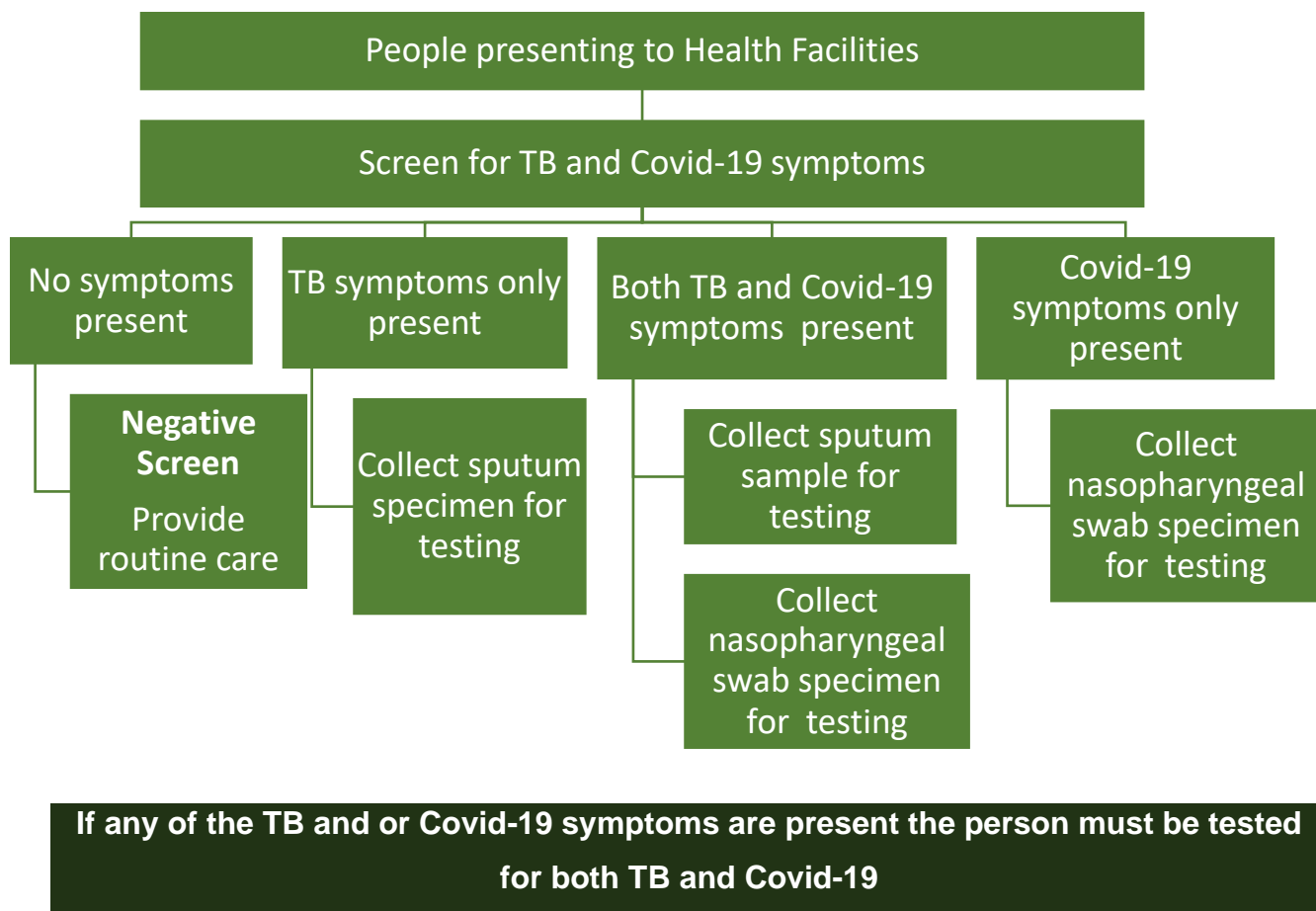


Figure 3: Integrated TB and Covid-19 Screening Algorithm



## Risk Assessment

To assess the patient's risk of developing TB, medical history must be obtained from the patient or guardian (in children), this should include the following:

1. Chronic medical conditions
  - HIV status
  - Diabetes
  - Chronic lung disease including Silicosis
2. History of previous TB disease
  - Has patient had TB (DS or DR) disease in the past 2 years?
3. History of close contact with a person who was diagnosed with TB disease/ on TB treatment in the past
4. Smoking and alcohol use
  - people with alcohol use disorder are at high risk of TB
5. Assessment for under nutrition
  - people with a body mass index (BMI)  $\leq 18$  are at high risk of TB



## Testing for TB

---

### Who must be tested for TB?

A specimen must be collected for TB testing in the following groups:

- People (children, adolescents, and adults) with any one of the TB symptoms
- People who have been in close contact with a person diagnosed with TB or TB treatment in the past year irrespective of TB symptoms
- People who have been treated and completed TB treatment in the past two years irrespective of TB symptoms.
- Newly diagnosed PLHIV irrespective of symptoms

### Frequency of testing

1. General population
  - Only when they present with any TB symptom or chest x-ray changes suggestive of TB
2. People living with HIV
  - At the time of HIV diagnosis
  - On enrolment in Antenatal care for pregnant women
  - Annually for PLHIV on treatment linked to VL monitoring follow up visits
3. Household contacts of people diagnosed with TB
  - After each exposure to a person with a confirmed TB diagnosis
4. People previously treated for TB
  - Annually for a period of two years

**In-between the annual testing, PLHIV and people previously treated for TB must be screened for TB symptoms and tested only if symptomatic.**

## Procedure for collecting quality sputum sample

---

### 1. Equipment and Materials Instruments and supplies required

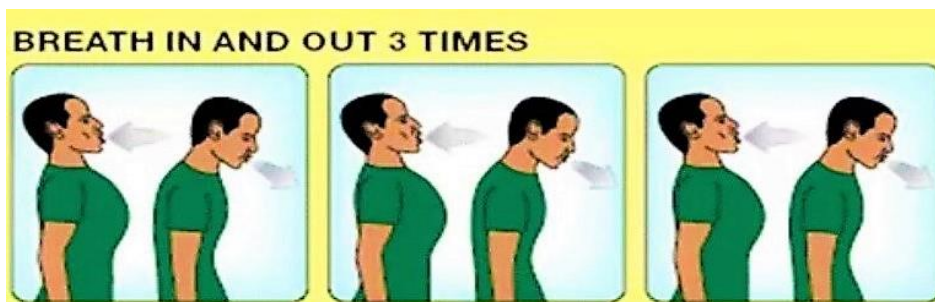
- Sterile specimen jars
- Laboratory Request Form
- Specimen Bags
- Laboratory Bar code stickers
- Disposable plastic gloves
- Respirator masks
- Sterile, filtered water or normal saline (150-250 mL)

- Box of tissues/ wiping paper
- A hand-held nebulizer with mouthpiece
- 15 mL vial of 3% saline
- Pen
- Cooler box and ice packs for specimen storage

## 2. Pre sputum sample collection procedure

### 2.1 Expectoration

- Explain the procedure for sputum sample collection to the patient
- Give the patient the container and explain how to open and close the lid
- Rinse your mouth with water
- Open the container without touching the inside of the lid and container
- Take a deep breath and exhale two times
- On the third time, cough deeply from your chest



- Place the open sterile specimen jar close to your mouth and spit into the container without contaminating the outside
- Spit into the container without contaminating the outside
- Repeat steps 2 and 3 times until at least 5 - 10ml (1 – 2 Tablespoons) of specimen is obtained
- Advise patient to make sure the container is tightly closed and to wipe the outside of the container to clean any spillages
- Direct the patient to the designated sputum collection area. This should be an area that is well ventilated and offers the patient some privacy
- Advise the patient on what to do with the specimen after collection based on facility process flow
- Advise patient to wash or sanitise hands after sample collection.

## 2.2 Nebulized sputum induction and collection

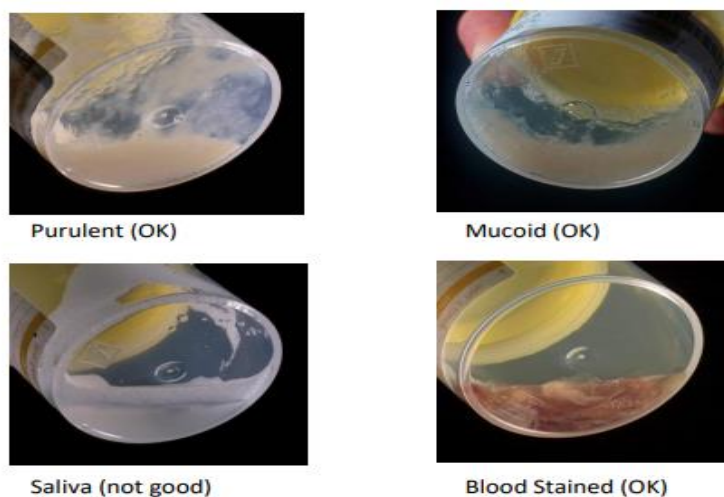
Nebulisation is recommended for patients who have dry, non-productive cough.

- A N95/ FFP2 respirator masks must worn by healthcare personnel for cough-producing procedures.
- Place approximately 5 mL of 3% saline into the hand-held nebulizer.
- Set the flow at 6-8 L/min and nebulize saline for 7-10 minutes or until sputum is expectorated.
- The maximum nebulization time is 20 minutes. Note: More saline may be added to the nebulizer if more than 10 minutes is needed to produce an adequate cough.
- Ask the patient to inhale the nebulized 3% saline deeply 2-3 times followed by a vigorous cough. This will assist in expectorating quality sputum.
- Collect the sputum into a sterile specimen container. Repeat until a minimum of 5ml of sputum is collected.
- Document the procedure in the patient's medical record.

## 3. Post sputum collection

- Put on gloves.
- Check if the sample is adequate and that the container is tightly closed. At least 5ml of sputum must be collected if less request the patient to produce more.

Figure 4: Illustration of acceptable sputum quality



- Peel-off one of the pre-printed barcoded labels from the Laboratory request form and place horizontally on the specimen container
- Complete the laboratory request form. Ensure all information is completed, if there is any missing information in patient folder verify with patient.
- Place the specimen container and request form in the appropriate compartment of the specimen plastic bag.

- If more than one specimen is collected from a patient, all the specimens should be placed in one bag with the relevant request form/s.
- Inform the patient on estimated date of results and how these will be communicated.
- Provide a follow up appointment date for TB results.

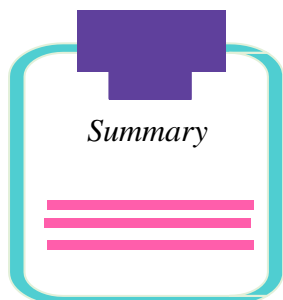
## **TB tests conducted.**

---

The following laboratory tests are available:

1. Nucleic Acid Amplification tests (NAATs)
  - Xpert MTB/RIF Ultra
  - Line Probe Assays (LPAs) such as First-line LPAs (FL-LPAs) e.g., GenoType MTBDR*plus* and Second-line Line Probe Assays (SL-LPAs) e.g., GenoTypeDR*s*/
2. Culture
  - Using liquid media e.g., automated BACTEC™ MGIT™ 960 TB System
3. Smear Microscopy

All people must be tested using the Xpert MTB RIF Ultra as a first line test. People diagnosed with RR-TB must be tested for first and second-line DST. Previously treated patients must be tested using TB Culture and DST/1<sup>st</sup> Line LPA. Smear microscopy is used as a baseline test following a positive RS-TB test result and as a monitoring test at 7 and 23 weeks. The TB Culture test is used if the RIF testing on Xpert MTB RIF Ultra is unsuccessful, in PLHIV with a negative Xpert MTB RIF Ultra test result, and when DST is required.



- All clients entering the health facility must be screened for symptoms of TB and Covid-19
- Where available, a chest x-ray may be conducted for people without TB symptoms to screen for TB
- People who present with any of the TB symptoms or who have an abnormal chest x-ray suggestive of TB must have a sputum sample collected for Xpert MTB RIF testing
- People living with HIV must have a sputum sample collected for Xpert MTB RIF Ultra testing, irrespective of TB symptoms
- People who are close contacts of TB patients must have a sputum sample collected for Xpert MTB RIF Ultra testing, irrespective of TB symptoms
- People who have been previously treated for TB must have a sputum sample collected for Xpert MTB RIF Ultra testing irrespective of TB symptoms
- Patients must be requested to return for test results in two days
- Always offer an HIV test to people who do not know their HIV status and those who tested negative more than 3 months ago

Table 3: Interpretation of Xpert MTB RIF Ultra test results

Result	Meaning	Comment
<i>Mycobacterium tuberculosis</i> (MTB) complex detected. RIF resistance NOT detected	MTB DNA was detected in the specimen; therefore, the patient has bacteriologically confirmed TB. Rifampicin resistance was not detected; therefore, patient has RS-TB.	<b>This patient has Rifampicin susceptible TB</b> A second specimen for baseline microscopy should be submitted if this has not been done already.
<i>Mycobacterium tuberculosis</i> (MTB) complex detected. RIF resistance detected	MTB DNA was detected in the specimen therefore the patient has bacteriologically confirmed TB. Rifampicin resistance was detected, therefore patient has RR-TB	<b>This patient has Rifampicin Resistant TB.</b> Refer URGENTLY to an appropriate treatment facility and refer to the Drug Resistant TB management guidelines.
<i>Mycobacterium tuberculosis</i> (MTB) complex detected. RIF unsuccessful	MTB DNA was detected in the specimen therefore the patient has bacteriologically confirmed TB, however testing for rifampicin was unsuccessful.	<b>This patient has TB.</b> The rifampicin testing was unsuccessful. Another specimen should be submitted for culture and LPA (if not done already). Start first line TB therapy and monitor response to treatment. Follow up result of culture and LPA
<i>Mycobacterium tuberculosis</i> (MTB) complex NOT detected.	MTB DNA was not detected in the specimen.	A negative MTB result by Xpert Ultra does not always exclude TB in patients with paucibacillary disease i.e. children, HIV-positive patients with PTB and patients with EPTB. The sensitivity of Xpert may be low in smear negative, culture positive patients. This result therefore means that TB disease could not be confirmed bacteriologically. Further investigations are required to confirm TB in these patients if TB remains to be a possible diagnosis.
MTB Trace detected. RIF unsuccessful	A very low amount of MTB DNA was detected in the specimen.	<i>Mycobacterium tuberculosis</i> DNA detected at the lowest limit (trace). The rifampicin testing was unsuccessful. Refer to the TB management guidelines and the “trace” flow diagram
Unsuccessful	The test was unsuccessful. This may be due to poor quality specimen or technical causes. The test should be repeated on a newly collected specimen	The GeneXpert MTB/RIF Ultra assay was unsuccessful. Please submit a second specimen for repeat GeneXpert testing.

**NOTE:**

- PLHIV present with pauci-bacillary PTB or EPTB therefore a negative Xpert MTB RIF result must be followed by clinical assessment, chest x-ray and culture and DST to confirm the diagnosis of TB.
- People who are asymptomatic but test positive on Xpert MTB RIF must be clinically assessed for TB (including proper history taking), chest x-rays, culture and DST or other tests must be conducted to confirm TB.
- In people who completed TB treatment in the past two years, a “Positive” or “Trace” Xpert MTB RIF test result may indicate presence of live (active TB disease) or dead (left over from previous TB episode) bacilli or DNA. Therefore, the test result must be considered along with the clinical findings before treatment initiation and a TB culture conducted to confirm active TB disease.

Figure 5: Diagnostic algorithm for Xpert MTB/RIF Ultra Positive result

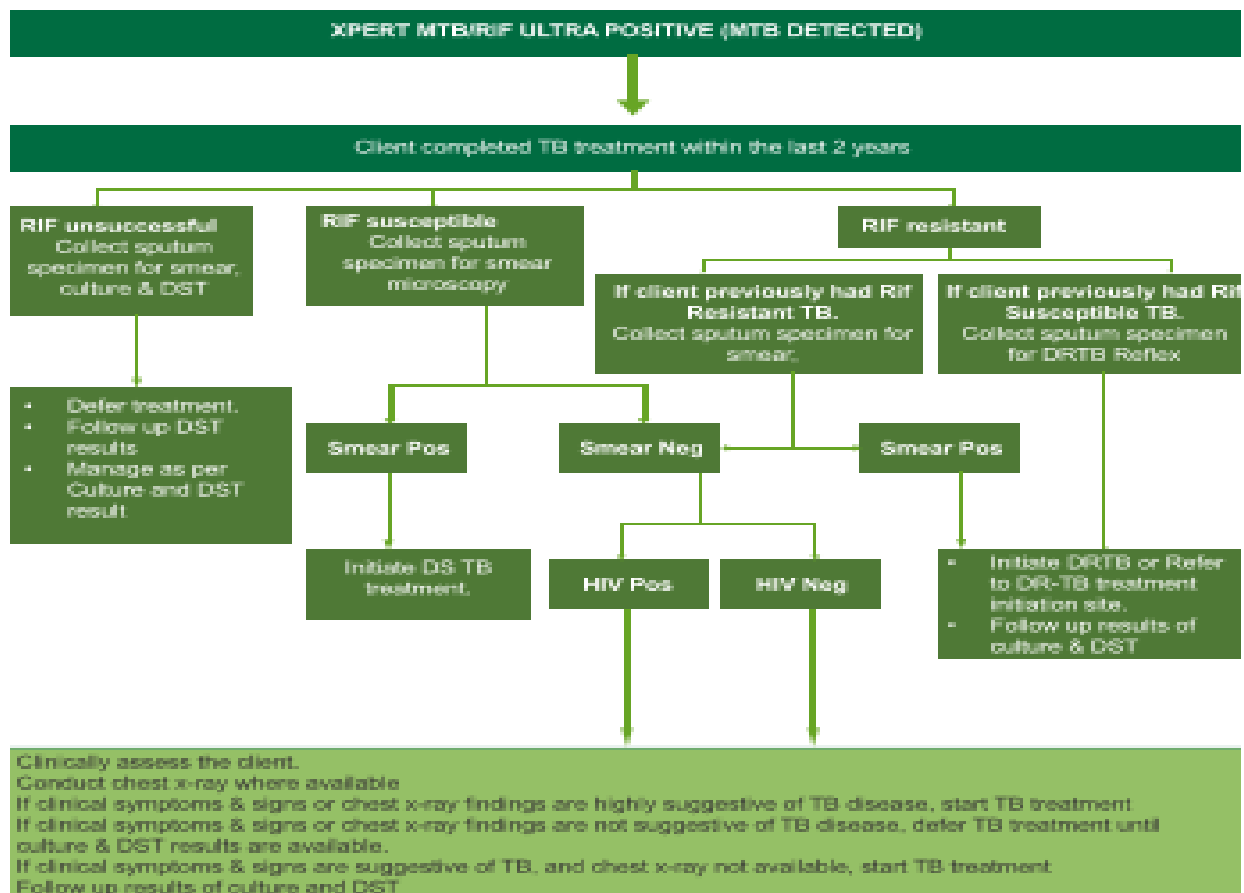




Figure 6: Diagnostic Algorithm for Xpert MTB Ultra Positive Result

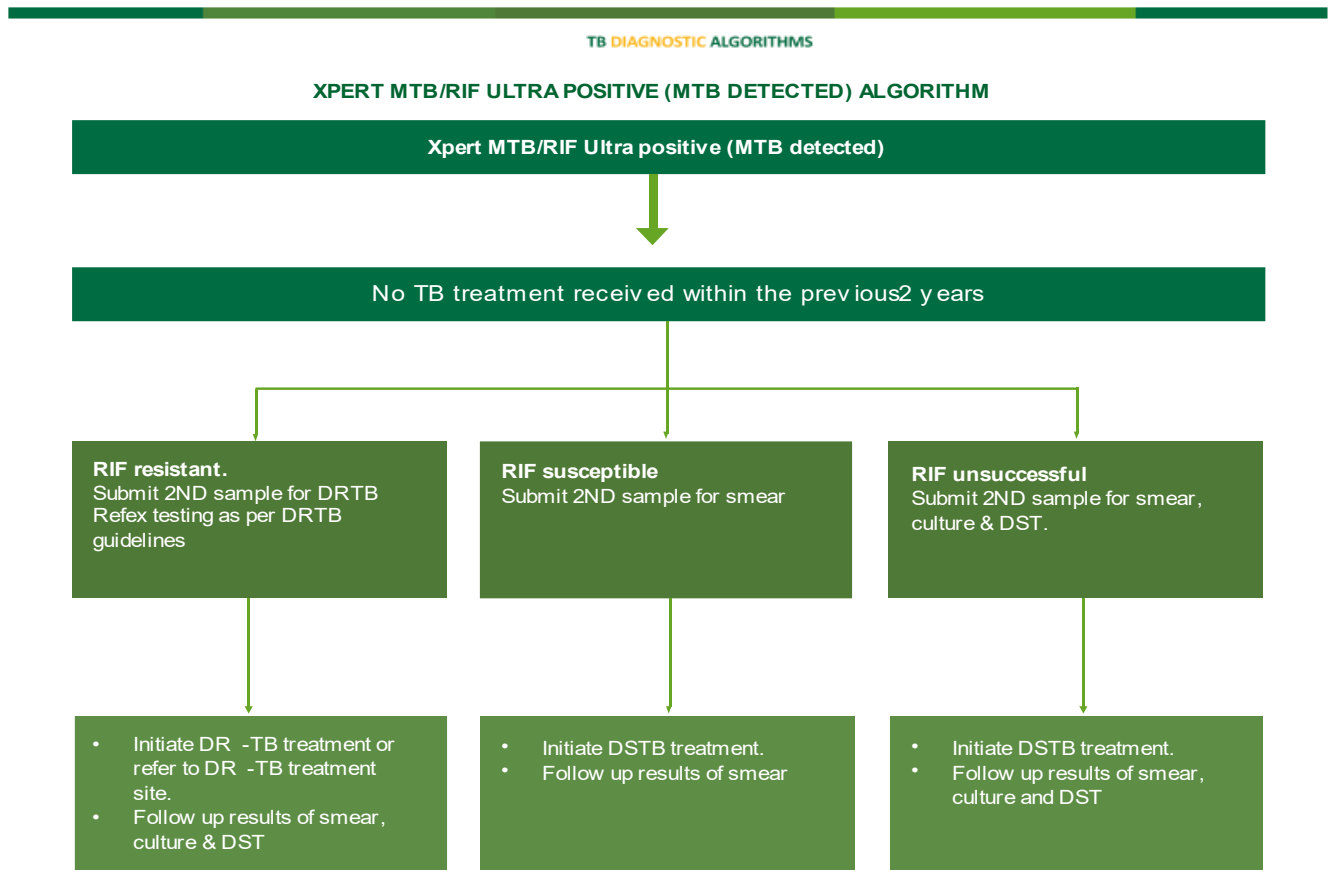


Figure 7: Diagnostic Algorithm for Xpert MTB RIF Ultra Trace result

TB DIAGNOSTIC ALGORITHMS

XPERT ULTRA 'TRACE' FLOW DIAGRAM

A trace result equates to the detection of MTB DNA at the lowest limit. As this can also occur in patients previously diagnosed and/or treated for TB, careful review should be performed before deciding to initiate treatment.

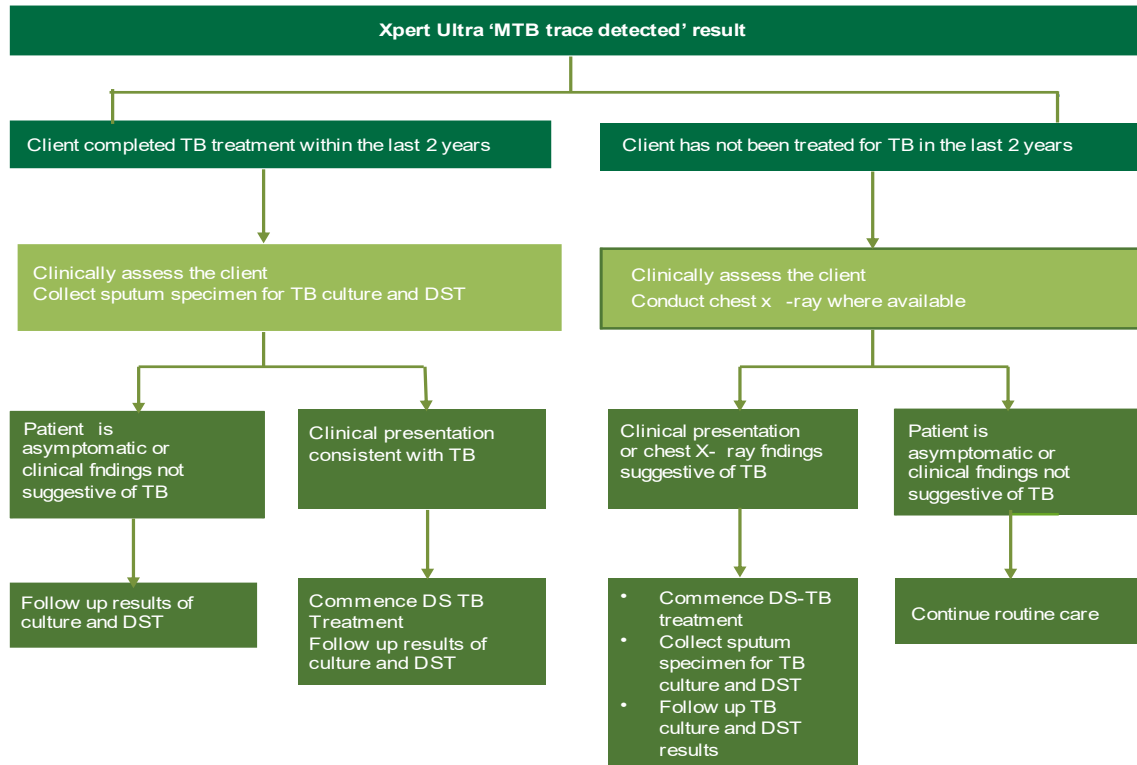


Figure 8: Diagnostic Algorithm for Xpert MTB RIF Ultra Negative result

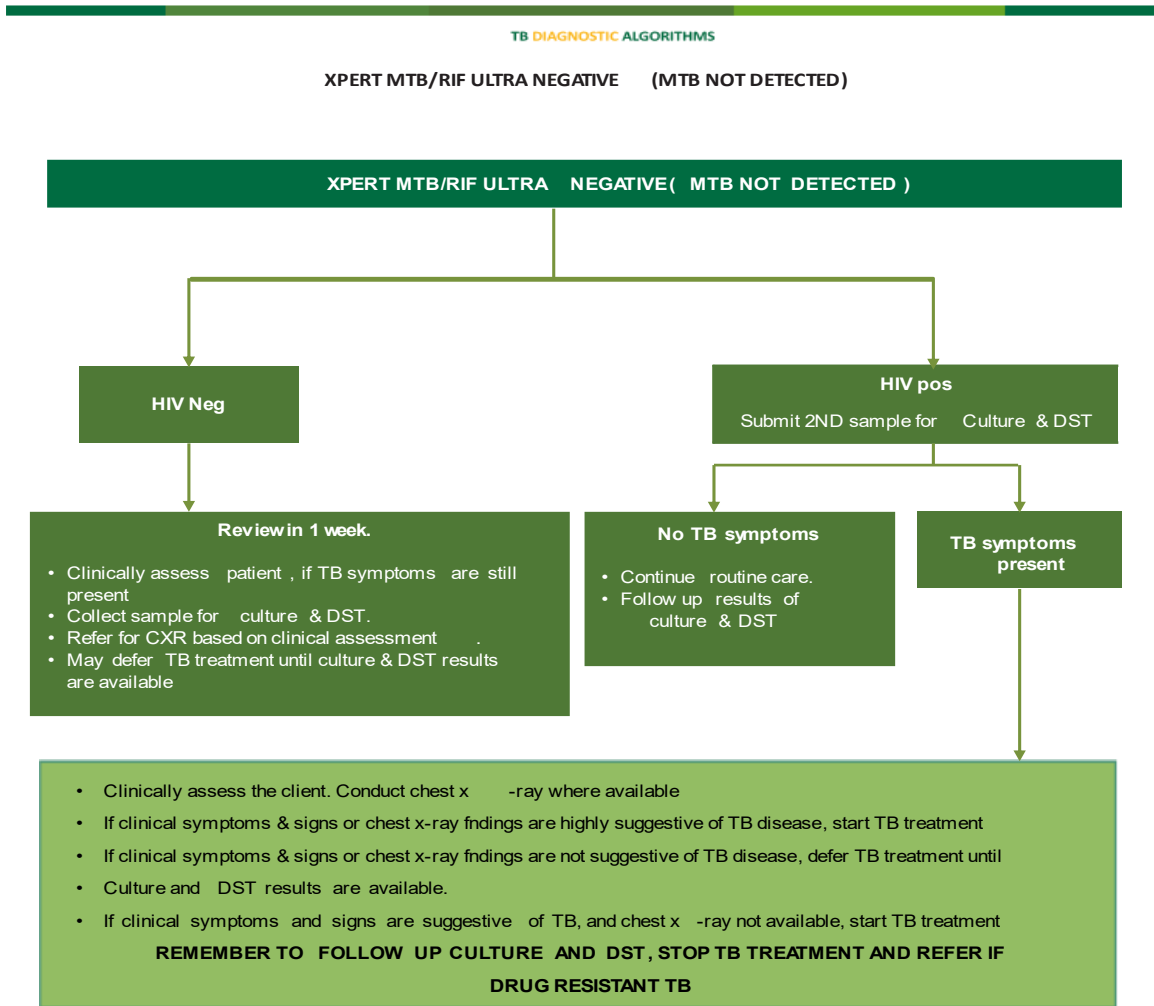



Figure 9: TB and Covid-19 Symptom Screening Tool for self- screening



## TB SYMPTOM SCREENING TOOL

**PATIENT DETAILS**

Surname: \_\_\_\_\_ First Name: \_\_\_\_\_

Physical Address: \_\_\_\_\_ Age: \_\_\_\_\_

\_\_\_\_\_ Gender: \_\_\_\_\_

Telephone Number: \_\_\_\_\_ Patient folder Number: \_\_\_\_\_

**MEDICAL HISTORY (Tick ✓ where applicable)**

Close contact of a person with infectious TB:	Yes	No	Undetermined
What type of TB does the person have?	DIS- TB	BDI TB / XDR- TB	Undetermined
Do you have diabetes?	Yes	No	Undetermined
Do you know your HIV Status? (specify status if known)	Positive	Negative	Undetermined
Do you have a lung disease?	Yes	No	Undetermined
Do you smoke cigarettes or tobacco?	Yes	No	Not Applicable
Do you drink alcohol?	Yes	No	Not Applicable
Have you had TB/ taken TB treatment in the past year?	Yes	No	

**TB SYMPTOM SCREEN**

**1. SYMPTOMS**

(Tick ✓ where applicable)	Yes	No
Do you have a cough?		
When did the cough start?		
Do you/ have you had a fever (high temperature) in the past two weeks		
<b>Additional questions for Adolescents and Adults</b>	<b>Yes</b>	<b>No</b>
Have you been losing weight without trying in the past month?		
Are you sweating a lot at night?		
<b>Additional questions for Children</b>	<b>Yes</b>	<b>No</b>
Is the child less playful or always tired?		
Has the child lost weight?		
Is the child growing well?		

*If "Yes" to one or more of these questions, consider TB.  
Collect sputum specimen and send it for Xpert testing.*

Additional Covid-19 questions	Yes	No
Do you have a sore throat or pain when swallowing		
Shortness of breath or difficulty breathing noticed recently		
Have you noticed any changes in your ability to taste or smell things recently?		
Do you have muscle or joint pains?		
Are you always tired?		
Do you have a headache?		

*If "Yes" to one or more of these questions, consider Covid-19.  
Collect sputum specimen and send it for SARS Cov-2 testing.*

Date of last TB test: \_\_\_\_\_

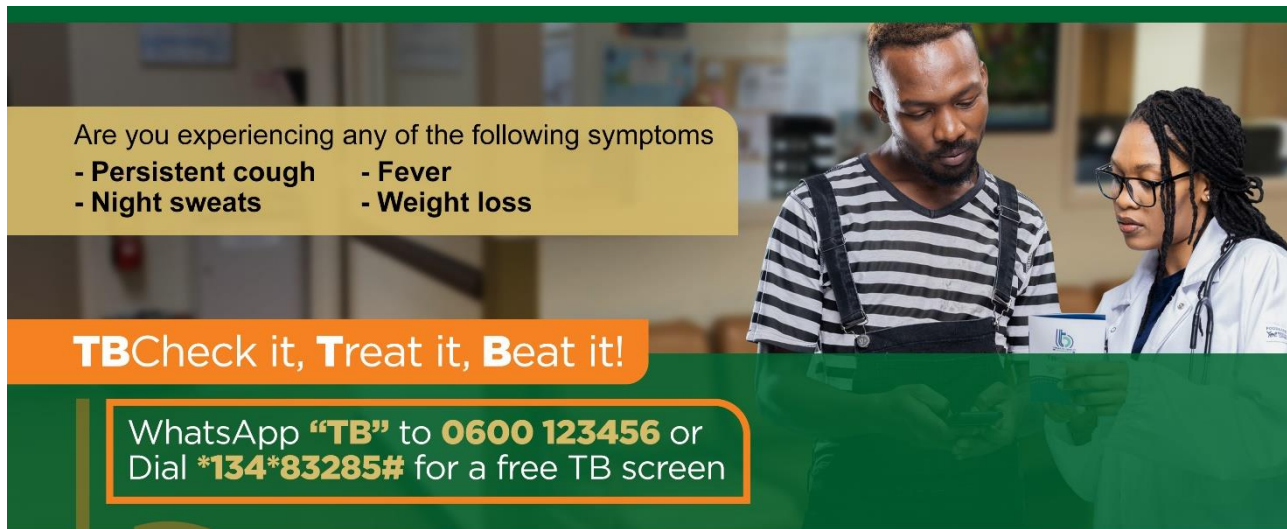
Patient referred for assessment and investigation: Yes No

Sputum specimen collected: \_\_\_\_\_

Date of referral: \_\_\_\_\_ Facility name: \_\_\_\_\_

Name: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Figure 10: TB Check for self-screening



Are you experiencing any of the following symptoms

- Persistent cough
- Night sweats
- Fever
- Weight loss

**TB**Check it, **T**reat it, **B**eat it!

WhatsApp **"TB"** to **0600 123456** or  
Dial **\*134\*83285#** for a free TB screen




health

Department:  
Health  
REPUBLIC OF SOUTH AFRICA

**TB** Check



Figure 11: TB symptom screening tool for use in households and community



health  
Department  
REPUBLIC OF SOUTH AFRICA

**TB SYMPTOM SCREENING TOOL FOR ADULTS AND CHILDREN**

**000001**

**PATIENT DETAILS**

Surname: \_\_\_\_\_ First Name: \_\_\_\_\_

Physical Address: \_\_\_\_\_ Age: \_\_\_\_\_

Telephone Number: \_\_\_\_\_ Patient folder Number: \_\_\_\_\_

**MEDICAL HISTORY**

Close contact of a person with infectious TB: 

Yes	No	Unknown
-----	----	---------

 (Tick v)

Type of index patient: 

DS-TB	RR Resistant TB	MDR-TB or XDR-TB
-------	-----------------	------------------

Diabetic: 

Yes	No	Unknown
-----	----	---------

HIV Status: 

Positive	Negative	Unknown
----------	----------	---------

Other: (Specify) \_\_\_\_\_

**TB SYMPTOM SCREEN**

**1. ADULTS**

Symptoms (Tick v)	Yes	No
Cough of 2 weeks or more OR of any duration if HIV positive		
Persistent fever of more than two weeks		
Unexplained weight loss >1.5kg in a month		
Drenching night sweats		

**2. CHILDREN**

Symptoms (Tick v)	Yes	No
Cough of 2 weeks or more which is not improving on treatment		
Persistent fever of more than two weeks		
Documented weight loss/ failure to thrive (check Road to Health Card)		
Fatigue (less playful/ always tired)		

*if "Yes" to one or more of these questions, consider TB.*  
*if the patient is coughing, collect sputum specimen and send it for Xpert testing.*  
*if the patient is not coughing but has the other symptoms, clinically assess the patient or refer for further investigation.*

Date of last TB test: \_\_\_\_\_

Patient referred for assessment and investigation: 

Yes	No
-----	----

Date of referral: \_\_\_\_\_ Facility name: \_\_\_\_\_