THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

National Tuberculosis and Leprosy Control Programme
Tuberculosis Specimen Referral System

Clinician Handbook

Version 7.0

RD 001
Aug 2026

Disclaimer: This clinician handbook supersedes the previous version 6.0

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Approval

	Name	Signature	Date
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Approved changes

Brief description of the change

Biennial Changes and Reviews

Name of reviser	Changes compared to previous version
Mary Akumu 10-June-2026	1. Section – Abbreviations and Acronyms, Added new ones 2. Section 2.0– Included NTRL's Twitter handle 3. Section 1.1– Included Leprosy diagnostics available at NTRL. 4. Section 3.3 Added new Diagnostics introduced by NTRL 5. Section 3.5: Revised to include TAT for new diagnostic tests. Revised the TAT of Genome Sequencing 6. Section 3.6 – Added the new Proficiency Test Schemes 7. Section 4.0 – Revised section to include indications (guide to when to order) for the new tests. 8. Section 6.0 –Included a statement on use of the online NTRL TBLIS Hospital Access interface for requesting of tests from NTRL 9. Section 7.0 –Deleted the use of Posta vans and added NSRTN Vans for sample transport. 10. Section 11.2 – Added the use of the online NTRL TBLIS Hospital Access interface for results reporting 11. Section 13.0 Added the online PT Portal as an avenue for submitting complaints 12. Appendix 1- Updated to include the current version of the GeneXpert diagnostic algorithm 13. Appendix 5- Updated the results report comments section to include new comments

Acknowledgement of reading and understanding this Clinician Handbook

Name	Signature	Date

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ABBREVIATIONS AND ACRONYMS

AFB	Acid Fast bacilli
DST	Drug Susceptibility Testing
FM	Fluorescent Microscopy
HIV	Human Immuno deficiency Virus
KCCA	Kampala Capital City Authority
LJ	Lowenstein Jensen
LPA	Line Probe Assay
MDR	Multi Drug Resistance
MGIT	Mycobacterium Growth Indicator Tube
NIN	National Identification number
NTLP	National Tuberculosis and Leprosy control Programme
NHLDS	National Health Laboratory and Diagnostic services
NTRL	National Tuberculosis Reference Laboratory
QA	Quality assurance
QM	Quality manual
RIF	Rifampicin
SOP	Standard operating procedure
TAT	Turnaround Time
TB	Tuberculosis
ISRS	Integrated specimen referral system
XDR	Extensive Drug resistance
ZN	Zeihl Neelsen
TB LAMP	Loop Mediated Isothermal Amplification Test for *M.tuberculosis* detection

LF LAM	Lateral flow Lipoarabinomannan assay
RR	Rifampicin resistant
mWRDs	Molecular WHO Recommended Rapid Diagnostics
DR TB	Drug Resistant Tuberculosis
LQMS	Laboratory Quality Management systems
LIMS	Laboratory Information Management systems
IACET	International Accreditation for Continuous Education and Training
PCR	Polymerase Chain Reaction
SOS	Simple One Step Technique
PBC	Pulmonary Bacteriologically Confirmed Tuberculosis
IRRDS	Integrated Request and Results Dispatch System
7H11 DST`	7H11 Drug Susceptibility Test
NSRTN	National Sample and Results Transport Network

GLOSSARY OF TERMS

Multidrug Resistance Tuberculosis: Tuberculosis that is resistant to at least the following first line anti TB drugs; Isoniazid and Rifampicin.

Pre-XDR TB: is defined as disease caused by M. tuberculosis strains that are resistant to isoniazid, rifampicin, and any fluoroquinolone.

Extensively Drug-Resistant TB (XDR-TB): defined as TB caused by Mycobacterium tuberculosis strains that are resistant to isoniazid, rifampicin, any fluoroquinolone, and either bedaquiline or linezolid (or both)
Final Laboratory Results Report: Has all test results for the tests requested by the clinician.

Preliminary Laboratory Results Report: Does not have results for all the tests requested for by the clinician

Turnaround Time: refers to the maximum time from the date of sample reception at the NTRL to the date of dispatch of results.

PREFACE

The programmatic management of Drug resistant TB (PMDT) in Uganda started in 2012. The estimated Drug resistant burden as per the 2010 DR TB survey was 1.4% and 12.1% among new and re-treatment patients respectively. .

During the year of 2024/25, the proportion of PBCs that accessed a mWRD test for Rifampicin susceptibility testing was 84%. Additionally, in 2024, 1,300 RR/MDR TB patients were expected but only 810 were notified. This implies that the NTLP still misses about 37 of the expected cases annually. All stakeholders are therefore called upon to intensify case detection strategies at all levels of service delivery and also scale up the use of TB diagnostic technologies available within the TB laboratory network. This client handbook details the services available at the National TB Reference Laboratory and provides a guide on their utilization to enable access and effective use of these quality assured services as a means of increasing DR TB case detection and improving treatment monitoring.

ACKNOWLEDGEMENTS

The development of this clinician handbook was made possible by input of various members of the National TB Reference Laboratory and stakeholder institutions that individually, collectively and severely discussed, formulated and/or reviewed this document. It would have never been possible to develop and finalize this document without their undeterred commitment.

1.0 INTRODUCTION

1.1 Background

The National Tuberculosis Reference Laboratory (NTRL) under the NHLDS is the laboratory technical arm for the NTLP and is responsible for delivery of specialized quality Tuberculosis and leprosy laboratory services in Uganda. It has a mandate to provide laboratory services for TB and leprosy diagnosis, DR TB and leprosy surveillance and DR TB treatment monitoring. It achieves this through laboratory testing and provision of professional and technical advice as such contributing to TB and leprosy patient care in Uganda. The testing is provided in the fields of TB and Leprosy Microscopy, PCR for *M.leprae*, TB Culture, TB phenotypic Drug susceptibility testing and a number of mWRDs for TB including Gene Xpert, Truenat, TB LAMP, Line Probe Assay, DNA sequencing among others.

1.2 Vision

Tuberculosis and Leprosy diseases are controlled until they are no longer a public health problem in Uganda

1.3 Mission

To provide quality laboratory services and to strengthen the national tuberculosis laboratory diagnostic network through leadership and expert guidance in support of the national tuberculosis and leprosy control program to reduce the burden of tuberculosis and leprosy in Uganda.

1.4 Quality Policy

The quality policy of NTRL aims at improvement of customer focus of the organization. In addition, NTRL wants to maintain and strengthen its position as an (inter) nationally operating, competent and reliable partner in the field of tuberculosis. The quality policy of NTRL is primarily focused on:

- Control and improvement of its technical services (= product quality),
- Control and improvement of transparency and efficiency of the organization (=process quality)
- Control and improvement of the quality of the customer service (=customer orientation).

1.5 Services provided

- Technical services for TB detection, identification and drug sensitivity testing
- Leadership, support and supervision to the national tuberculosis laboratory network
- Surveillance and (operational) research linked to NTLP

2.0 GENERAL INFORMATION

2.1 Name of Laboratory and contact persons

National Tuberculosis Reference Laboratory (NTRL)
Laboratory Director and Laboratory Manager.

2.2 Legal Entity

The laboratory belongs to the Department of National Health Laboratories and Diagnostic services of the Ministry of Health

2.3 Physical address

National Tuberculosis and Leprosy Control Program
National Tuberculosis Reference Laboratory
Plot 106-1062, Butabika Road, Luzira
Opposite Butabika Hospital

2.4 Postal Address

National Tuberculosis Reference Laboratory
P.O. Box 16041
Wandegeya, Uganda

2.5 Laboratory Telephone, Email and Website

Phone #: +256 414 236 250
Toll Free #: 0800111133
Email: info@ntrl.or.ug
Website: Ntrl.or.ug
Twitter: @NTRLUg

2.5.1 Training Department email address

training@ntrl.or.ug

2.5.2 Proficiency Testing department Email address and Website

Email: pt@ntrl.or.ug
Website: Srlugpt.com

2.6 Opening hours

- Monday to Friday : 8:00am to 5:00pm
- Saturday, Sunday and Public holidays : Closed

3.0 LABORATORY TESTS/SERVICES AND THEIR TURNAROUND TIME

The list below gives the full name of the test/procedure and in brackets are the most commonly used abbreviations on specimen laboratory request forms and test report copies.

3.1 Microscopy

3.1.1 Ziehl-Neelsen Smear Microscopy (ZN Microscopy)
3.1.2 Fluorescence Microscopy (FM)

3.2 Tuberculosis Culture Methods

3.2.1 Löweinsten-Jensen solid Media Method (LJ Culture)
3.2.2 Mycobacterial Growth Indicator Tube (MGIT) method

3.3 Phenotypic Drug Susceptibility Testing (DST) Methods

3.3.1 Löweinsten-Jensen DST (LJ DST)
3.3.2 Mycobacterial Growth Indicator Tube (MGIT DST)
3.3.3 Multiplexing kit for DST (MKIT DST)
3.3.4 Micro Broth Dilution DST
3.3.1 Seven-H11 DST (7H11 DST)

3.4 Genotypic DST Methods

3.4.1 First and Second Line Probe Assays (LPA/HAIN test)
3.4.2 DNA Whole and Targeted Genome Sequencing
3.4.1 GeneXpert MTB/RIF Ultra Assay
3.4.2 Xpert MTB/XDR Assay

3.5 Laboratory Diagnostics for Leprosy disease

3.5.1 Microscopic analysis for Leprosy
3.5.2 PCR test for *M. Leprae*

3.5 Expected maximum TAT

Test method	**Expected maximum TAT**
Microscopy	2 working days
LJ culture	63 days/9 weeks
MGIT culture	49 days/7 weeks
First and Second line LPA	4 days *from receipt of sample*
LJ DST	7 weeks *after LJ culture positive*
Seven H11 DST	5 weeks *after LJ culture positive*
Gene Xpert MTB/Rif Ultra Assay and Xpert MTB/XDR Assay	2 working days
DNA Targeted Genome Sequencing	7 Days from date of sample receipt

DNA Whole Genome Sequencing	14 days from date of culture positivity
MGIT DST	3 weeks after MGIT culture positive with the exception of Pyrazinamide which will take 4 weeks from positive culture
MKIT DST	5 weeks from date of culture positivity
Micro Broth Dilution DST	21 working days
M.leprae PCR	21 working days
Slit-skin smear for leprosy	2 working days

3.6 Other Services offered

3.6.1 Proficiency testing Schemes

The NTRL operates Proficiency testing (PT) schemes for Microscopy, Gene Xpert MTB/Rif Assay, Truenat, LF LAM, TB LAMP, MTB Pulse Life, XPERT MTB XDR, SARS- COV2 PCR and Antigen test, TB Culture, Line Probe Assay, and Phenotypic DST. Proficiency test materials are sent to all TB laboratories in the network based on their TB test menu to assess their proficiency in provision of the different TB laboratory services. Below is the PT annual plan.

EQA panels category	Frequency/ year	Sending out Month	Quantity	Expected TAT (from date of dispatch)
Microscopy	Biannual	February and August	10 slides/round	44 days
Culture	Annual	August	10 isolates/round	91 days
LPA	Biannual	February and August	10 isolates/ round	44 days
Gene Xpert MTB/Rif Ultra	Biannual	Feb and Aug	05 isolates/ round	44 days
DST	Annual	August	20 isolates/ round	116 days for phenotypic DST
SARS- COV2	Biannual	February and August	05 panels/ round	44 days
Truenat	Biann ual	February and August	05 isolates/ round	44 days
TB LAM	Biann ual	February and August	05 DTS/round	44 days
Gene Xpert MTB XDR	Biannual	Feb and Aug	05 isolates/ round	44 days
MTB Pulse Life	Biannual	Feb and Aug	05 isolates/ round	44 days

Note 1: Refer to the PT website for list of additional schemes that may be added on after release of this version of the client handbook

Note 2: Laboratories being fast tracked for ISO 15189 international accreditation within Uganda are enrolled onto the TB microscopy scheme.

TB Microscopy Blinded Rechecking EQA services

The NTRL coordinates and oversees TB microscopy blinded rechecking EQA activities in the TB laboratory network. TB smears examined for AFBs by peripheral laboratories each quarter are sampled and rechecked at two levels i.e district and regional/national levels for accuracy in TB testing. NTRL ensures that laboratories with performance gaps are offered technical assistance following the slide rechecking process. NTRL requires that atleast 95% of laboratories in each district participate in EQA each quarter and that TB EQA slides for second control are delivered to the NTRL or regional laboratories (where EQA processes are decentralized) within one month after the end of the quarter. This enables timeliness of feedback reports and allows for follow up of laboratories with errors before start of the next quarter.

NTRL's Training Program

NTRL offers training to laboratory personnel in TB diagnostic techniques and other laboratory related training packages such as LQMS, LIMS, Proficiency test preparation and management of PT schemes, Writing of Laboratory strategic plans, setting up and management of integrated sample referral systems among others.

Uganda NTRL/SRL is an IACET accredited training provider. Our trainings comply with the ANSI/IACET standard which is recognized internationally as a standard of excellence in institutional practice and we are authorized to issue the IACET CEU.

Note:

All services provided by NTRL are free of charge for NTRL clients within Uganda. Charges may apply for international clients. The fees for the different services can be obtained upon request by contacting the Uganda SRL through the laboratory's official communication channels.

4.0 GUIDE FOR SELECTION OF TESTS AND THEIR INDICATIONS

4.1 Microscopy

4.1.1 Ziehl-Neelsen Smear Microscopy (ZN Microscopy)

4.1.2 Fluorescence Microscopy (FM)

4.2 TB LAMP

TB Microscopy and TB LAMP are indicated for the diagnosis of TB among presumptive TB cases

4.3 Culture Methods

4.3.1 Löweinsten-Jensen Solid Media Method (LJ Culture)

Indicated for the diagnosis of presumptive TB cases, TB smear negatives (but clinically suggestive of TB) and Extra-pulmonary samples (often smear negatives). Used as a prior test to DST and a follow-up test for MDR TB patients (culture conversion). Also indicated for clients with Gene Xpert Rifampicin indeterminates results as a prior test to DST and Patients started on treatment as a result of a Gene Xpert MTB Detected Trace result.

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4.3.2 Mycobacterial Growth Indicator Tube (MGIT) method

More sensitive than solid culture methods and very vital for improved detection of TB
Used alongside LJ culture to increase sensitivity to TB Detection.

Note: For DR TB patients, samples should be referred to NTRL monthly for culture to monitor effectiveness of treatment.

4.4 Drug Susceptibility Testing (DST)

4.4.1 Löweinsten-Jensen (LJ) (Solid Media) Method

Indicated for drug resistant TB patients where both first line and second line DST profiles are required i.e. Isoniazid, Rifampicin, Ethambutol, Amikacin, Levofloxacin Moxifloxacin

4.4.2 Mycobacteria Growth Indicator Tube (MGIT) Liquid Method

Indicated for drug resistant TB patients where both first line and second line DST profiles are required i.e. Isoniazid, Rifampin, Ethambutol, Moxifloxacin and Leveofloxacin. (Other drugs such as Pyrazinamide, Cycloserin, Linezolid, Bedaquiline, Clofazimine and Delamanid etc can be set on MGIT DST as required by the clinician whenever drug powders are available).

4.4.3 First and Second Line LPA

First Line LPA is indicated for diagnosis of Rifampin and Isoniazid resistance but it is only 80% sensitive for Isoniazid.
Second Line LPA (for Fluoroquinolones and Injectable/Aminoglycosides) is available and is indicated for screening of XDR TB among GeneXpert Rifampicin Resistance cases.
Note: NTRL still maintains LPA as one of the molecular DST techniques on its test menu. This will serve as a backup test for the new Xpert MTB/XDR Assay

4.2.1 Multiplexing DST KIT (MKIT)

Just like LJ DST above, Indicated for drug resistant TB patients where both first line and second line DST profiles are required i.e. First line, second line and newer drug regimen like Linezolid.

4.2.2 Seven H11 DST(7H11 DST)

Just like LJ DST above, Indicated for drug resistant TB patients where both first line and second line DST profiles are required i.e. First line, second line and newer drug regimen like Linezolid, Bedaquiline and Delamanid.

4.2.3 **Micro Broth Dilution DST**

Indicated for drug resistant TB patients where first line, second line DST and newer/ repurposed drug profiles are required.

4.2.4 **Whole Genome and Targeted Next Generation Sequencing**

Indicated for determining extended DST profiles in the following category of patients;

- Patients on DR TB treatment who do not culture convert
- Patients with discordant genotypic (LPA, Xpert XDR TB test) and phenotypic DST results
- Routine DR TB suveillance (both first and second line anti TB DST testing)

Whole genome sequencing is also used during TB drug surveys for quality assurance purposes i.e rechecking of DST results obtained using LPA and Gene Xpert.

4.2.5 GeneXpert MTB/RIF Ultra Assay

Indicated for rapid diagnosis of MTB and rifampicin resistance among all presumptive TB cases. *(See Appendix 1 for Algorithm for TB Screening, Diagnosis and Management)*

4.2.6 Xpert MTB/XDR Assay

Used for detection of Resistance to INH, Fluroquinolones, ethionamide and injectables such as Amikacin in clients with pulmonary TB and Rifampicin resistant TB.

4.2 **Slit-skin smear and PCR for Leprosy**

The slit-skin smear in current practice is one of the three cardinal signs to diagnose leprosy. A slit-skin smear is used to diagnose leprosy by detecting the presence of acid-fast bacilli. In-house PCR is used to detect the DNA of *M. leprae* on slit-skin smear or biopsy specimens.

NOTE: NTRL keeps processed sediments from from the primary samples for up to 2 months. Therefore, clinicians can request for additional TB tests on the same sample when need arises within the 2 months period.

5.0 TYPE OF PATIENTS WHOSE SAMPLES QUALIFY FOR REFERRAL

5.1 Referral from peripheral facilities to Gene Xpert and Truenat sites

- All presumptive TB clients
- Patients with a positive smear at month 2, 5 or 6 of category one TB treatment.

NOTE: Always provide the phone number of the clinician and patient on the TB request form to enable SMS result reporting through the LabXpert DS Platform.

Utilize the Integrated Request and Results Despatch system when referring samples to GeneXpert sites

5.2 Referral from peripheral facilities to NTRL

- TB Patients on Drug resistant TB (DR TB) treatment
- TB Patients with a Gene Xpert Rifampicin resistant result
- TB Patients with repeat Gene Xpert MTB positive, Rifampicin resistance indeterminate result
- Patients started on anti TB treatment as a result of an MTB Detected Trace result obtained with a GeneXpert MTB test
- Patients in whom laboratory diagnosis of leprosy is required
- Leprosy patients that require AMR testing.

6.0 LABORATORY REQUEST FORM AND COMPLETION

Samples to be referred for any TB diagnostic test should be accompanied by a completed TB laboratory request form (HMIS TB 002) The TB laboratory request form captures the following information; (***See Appendix 2***)

Clinicians section

- The Health facility or research organization requesting examinations.
- The name, sex, age, NIN of the patient from whom the sample was collected.
- Address of the patient
- Clinical history of the patient (on chemotherapy or not etc.)
- Patient category and patient risk group
- Reasons for Request
- Laboratory procedure(s) being requested for.
- Type of sample collected or the site from where the sample was collected
- Date and time of sample collection
- Name, Signature and contact of person requesting for laboratory investigation and date.

Note:
Other shorter versions of the request form may be accepted as is the case with big batches of samples referred during surveys for laboratory analysis.
Requests for *M.leprea e*xaminations may be made using the same HMIS 002 request form

- Requests can be made through the online NTRL TBLIS Hospital Access interface

. This does not replace the sending of print versions of the request forms along with the samples. For lower facilities not yet configured onto the NTRL TBLIS Hospital Access interface, endeavour to indicate/provide the email addresses of clinicians in addition to their phone numbers on the request forms to enable seamless report despatch.

6.1 Completing the laboratory request form

The laboratory request form must be completed fully at all times. This is key in ensuring that the sample is traceable to the patient , the right examinations are offered, informed clinical and

technical advice, and clinical interpretation is provided and that results are sent back to right requester.
Each specimen sent to the NTRL or other GeneXpert sites must have a separate request form.

7.0 COLLECTION OF PRIMARY SPECIMENS

7.1 Sputum collection

Mycobacterium has capacity to affect all organs of the body but most cases of tuberculosis in Uganda are still pulmonary, requiring sputum specimen for diagnosis.

- **Patient preparation**

No special preparation of patient is required but patient may be advised to rinse his/her mouth thoroughly with water before coughing out sputum for laboratory examination.

- **Sample collection timing**

The early morning sputum collected within two hours after the patient rises from bed is the best. However, on-spot collection of sputum is also acceptable

- **Specimen/sample containers**

Wide mouthed screw-capped leak-proof conical shaped 50 ml graduated disposable plastic containers should be used.

- **Informed consent**

Consent to provide a sample need not to be obtained from the patient whose samples are going to be used in their care and management. It is generally agreed that the patient who voluntarily moves to the laboratory to provide a sample has already consented.
NTRL may use received diagnostic patient samples for internal research purpose, quality control and quality assurance and where possible for epidemiological and surveillance of DR and MDR TB. The patient details shall remain confidential.
In the event that samples are to be obtained by invasive procedures such as Gastric Lavage, clinicians need to offer detailed explanations about the examination procedure to the patient to enable informed consent.
If the sample is to be used for research purposes as is the case in clinical trials, it is the responsibility of the principal investigator to ensure that informed consent is obtained from all participants.

SAFETY PRECAUTION:

DO NOT COLLECT SPUTUM SAMPLES IN THE LABORTORY, CLINIC EXAMINATION ROOMS OR IN THE PATIENT/CLIENT WAITING AREA. ALWAYS

INSTRUCT PATIENT TO GO OUTSIDE IN OPEN AIR (OR UNDER A TREE) AWAY FROM OTHER PERSONS TO MINIMISE RISK OF TRANSMISSION AND INFECTION OF OTHERS.

- Give the patient instructions and demonstrate how she or he can produce and collect good sputum; do up to three deep inhalations and exhalations and on the third exhalation or when a strong cough reflex arises, accompany it with a cough from deep inside the chest as much as possible

- Tell patient to move to an outdoor area exposed to sunshine then coughs 3-5 ml of sputum into the 50ml falcon tube (***primary receptacle***), tighten lid and return the tube.

- The patient should take care not to spit on the outer walls of the container. Early morning sputum is preferred but a good spot sputum sample is acceptable.

- Tighten the lid. Disinfect the container walls with Lysol 5%, or 70% ethanol or 1% Sodium hypochlorite (JIK).

- Dispose off any other material used in collecting and handling the sample such as gloves according to the facility's procedure on disposal of infectious wastes.

- Label the sputum container with the **patient's name, sex**, **age** and **Health facility name**.

- Record the sputum specimen in the health facility lab register and give the usual serial No., which must be indicated on the TB lab request form.

- Fill in the TB laboratory request form. Fill all spaces accurately.

Note: Specimens for TB diagnosis, Culture and DST should never be collected in any preservative.

7.2 Collection of other types of specimens

7.2.1 Stool Samples for SOS Technique

- Stool collection should be done by the caregivers or the patients, depending on the age of the child.
- Obtaining a specimen on demand is often challenging; therefore, stool can be collected at home and the patient or caregiver needs to return to the facility for specimen submission.
- Collect the stool sample during the first daily bowel movement. If possible, first empty the bladder, to avoid mixing urine with the stool sample.

- Put a clean plastic sheeting (wrap) on the spot where the stool will be dropped, to ensure the collection of a clean sample. Avoid contamination of the plastic with soil, detergent or disinfectant from the toilet.
- If the stool sample needs to be collected from a child that uses a diaper (i.e. a nappy), then either collect the stool directly from the diaper as soon as possible after defecation, or put a plastic sheet/wrap in the diaper to avoid (prolonged) contact between the stool and the surface of the diaper (diapers may contain substances that inhibit the test).
- Use a sterile stool container with a small spoon attached to the screw cap to collect atleast 3-5g of stool (2g is sufficient for both testing and retesting if the first test is unsuccessful).
- As soon as the stool sample has been collected, store the stool container in a clean, cool place (e.g., in a fridge if possible), avoiding exposure to direct sunlight. Do not freeze the sample.
- For transport and storage of stool samples, the same conditions apply as for transport and storage of sputum samples for Xpert testing (section 7.0 and 8.0 below).
- Take the plastic bag containing the stool container to the laboratory facility, preferably on the same day that you collected the stool sample

Note: Collected stool can be kept at maximum of 35^{o}C for up to 3 days, or a maximum of 7 days at 2-8 ^{o}C before testing. However, samples should always be tested timely to ensure timely initiation of treatment.

7.2.2 Collection of slit-skin smear and skin biopsy for Leprosy Examination

7.2.2.1 Collection of Slit-skin smear (SSS)

- Use new slide for each patient.
- Label with date, name of patient (initials), registration number.
- Enter details in request form in the register.
- Wipe the blade of a sharp scalpel with a piece of cotton soaked in Methylated spirit then pass the blade gently on top of the spirit lamp. Do not over heat. Put it on a flat surface so that the cutting edge does not touch anything.
- Allow the blade to cool off.
- Seat the patient comfortably. Explain procedure to the patient.
- Select the site and rub firmly with cotton wool soaked in spirit (or 70% ethanol). Let dry.
- Keep a small piece of dry cotton wool between the 4th and 5th finger on the back of left hand, for wiping away blood if necessary.
- Take the fold of the skin to be smeared firmly between thumb and forefinger and maintain the pressure until the skin becomes pale (bloodless).

- Make a cut in the skin about 5mm long and 2-3mm deep. Turn the blade until it is at right angles (90^0) to the incision and scrap some tissue material from the sides and bottom of the cut. Scrap firmly 2 or 3 times then maintain pressure of the fingers until there is no bleeding.
- Make smear (5-7 mm is ideal). 1^{st} smear should be near the names (initials).
- Wipe the blade with cotton wool soaked in Methylated spirit before next smear. If you observe bleeding, apply a piece of dry cotton to the wound.
- Apply a piece of adhesive to the incision. Do not let the patient leave until the bleeding has stopped.
- Single slit-skin smear examination performed reliably and accurately from the most affected lesion is enough

7.2.2.2 Collection of Skin biopsies

Skin biopsies are taken from the patient lesion cleaned with any suitable disinfectant.

Sampling is done at the limit of the lesion; half in the lesion and half in the healthy skin (since most of the bacteria can be found in this area) using a disposable clean 3 to 5 mm dermal punch. Suture is then performed.

The skin biopsy is collected and cut in two pieces (please see Figure 1) using a clean disposable blade and then each part is transferred into a 2mL tube.

Each tube is labeled with the a) patient unique identifier, b) date of collection using a sharpie pen or a pre-labeled sticker. From skin biopsies, DNA can be extracted to study the host or pathogen genetics, or histopathology can also be performed.

Storage for shipment to NTRL, add 1mL of 70% ethanol to all tubes containing half of the skin biopsy, close the tube and store at -20°C until shipment or DNA extraction in the NTRL. Once in ethanol, skin biopsies are very stable and are stored at +4°C for short term storage (two weeks post collection) or -20°C to avoid temperature variation during long term storage (>1 month) but skin biopsies can be shipped at room temperature to NTRL.

Prior to shipment, tubes should be para-filmed to avoid leaking.

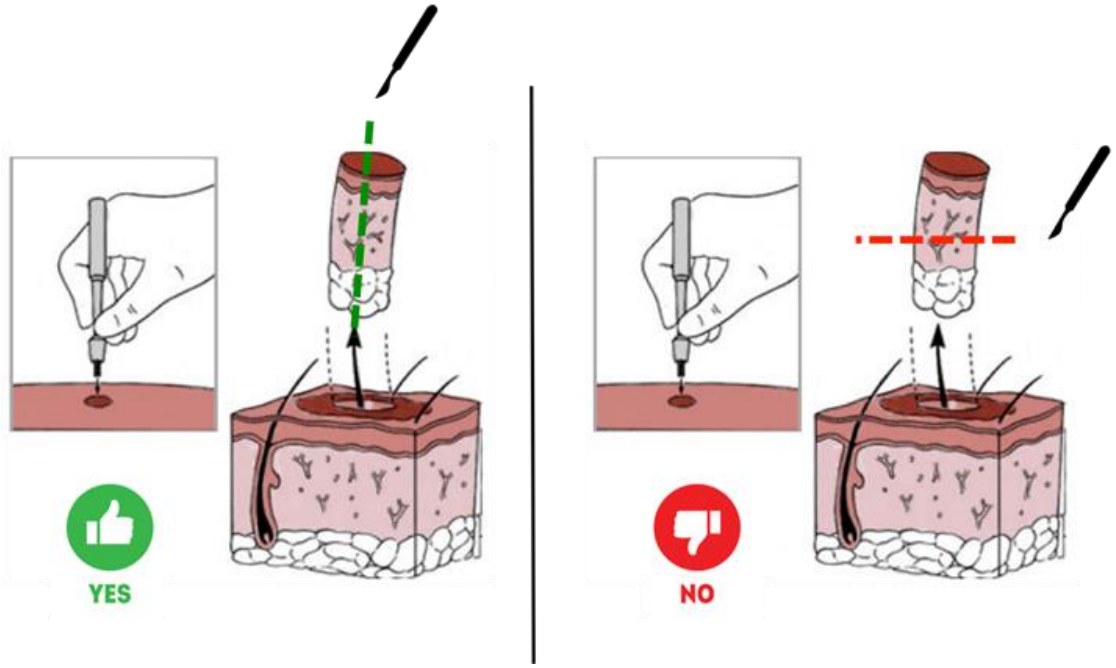


Figure 1: Method to cut the biopsy after collection –The correct method is the transverse cut (left image) with a separation along the epidermis to the subcutaneous tissue. The longitudinal cut (right) should be avoided.

7.2.3 Gastric lavage

Gastric lavages are indicated for children who cannot be able to produce sputum.

- Make the collection early in the morning, when the patient has an empty stomach.
- Neutralize the specimen by adding 100mg of sodium bicarbonate to the gastric aspirate and transport it immediately to the laboratory.

7.2.4 Extra-pulmonary specimens

These specimens may be broadly divided into two groups:

1. **Aseptically collected specimens'** e.g. spinal fluid which is usually free from contaminating flora.

- All fluid specimens should be collected in sterile glass containers without using any preservative.
- Specimens can be collected directly into sterile containers or the usual 50ml specimen containers
- Specimens must be transported to the laboratory immediately or kept at 2–6 ºC.

2. **Specimens with resident or contamination flora**

- A urine specimen should consist of a single, early-morning, midstream sample, collected in a wide-mouthed sterile vessel (of at least 200 ml capacity)
- Seminal and prostate secretions are sent without any additions.
- Menstrual bloody samples should be discouraged

- Stool samples should be discouraged

Note:

- The minimum volume of samples other than stool sent to NTRL for TB examination should be 0.5ml.
- Verification of the identity of the patient from whom a primary sample is to be collected should be done prior to sample collection. This ensures that the sample is collected from the right client.
- In case of any doubt about the collection procedure of a sample, please call the Toll-free line or refer to other available medical literature.

7.3 Labeling of the Primary Sample

- Specimen container must be identified with at least a patient's name and date of collection.
- Patient's name may be replaced by a unique numerical study or clinic Patient Identification Number (PIN). These parameters must at all times be 100% identical to the ones written on the laboratory request form accordingly, the specimen may otherwise be rejected.

7.4 Sample Rejection

NTRL shall reject specimens in the event that there is a deviation in the collection procedure and a potential negative risk or impact to the patients outcomes is likely to exist when such specimens are processed...

Sample Rejection Criteria

A sample will be rejected if it meets one or more of the following criteria;

- Sample container is broken, damaged, or leaking.
- Sample container is not labeled or there is not enough information on the container to match with the laboratory request form.
- Information on laboratory request form does not match sample label.
- Sample was not accompanied by a request form.
- Request form sent without a sample
- Sample collected in an inappropriate container (antibiotic bottles or narrow-necked bottle)
- Sample volume is too little (<0.5ml) and container appears empty.
- Wrong sample is delivered for the test

Note.

Under such circumstances, the potential risk or impact to the patient outcomes with accepting such samples will be recorded and the client advised to provide another sample.

In the event that the compromised sample is clinically critical or irreplaceable and the risk or impact on rejection is high to the patient, the sample will be accepted and advisory caution when interpreting provided on the report

Laboratory or clinical personnel involved in sample collection should adhere to the the instructions in this document to enable safe, accurate and clinically appropriate sample collection and pre-examination storage. Failure to adhere to pre-examination processes described in this document can negatively influence the outcome of intended examinations.

7.5 Advisory Service

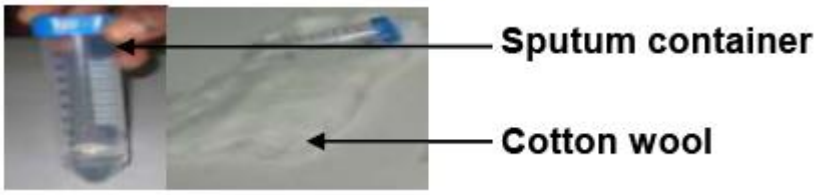
Authorized personnel provide clients with advice and/or training regarding required types of samples, choice of examinations, repeat frequency and interpretation of results

8.0 SPUTUM PACKAGING

1. The Triple packaging system is used. Primary receptacle (falcon tube), secondary receptacle (a ziplock bag) and a tertiary receptacle (safety box)

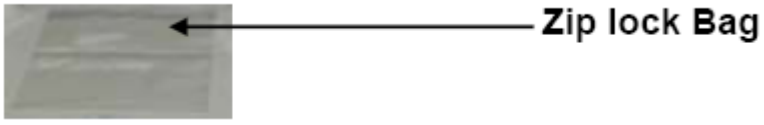
i. A **primary receptacle(s)** – The tube should be wide-mouthed, screw-capped and leak-proof. A 50 ml falcon tube is thus ideal. When the sample is coughed into the tube and after tightening the lid, label the tube with the patient name, age, sex and health facility name, then wrap the tube with absorbent material e.g cotton in sufficient quantity to absorb the entire contents in case of leakage.

Figure 2:



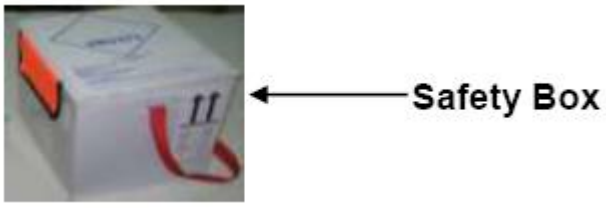
ii. A **secondary packaging**: Is the zip lock or biohazard bag. Place the wrapped tube inside the zip lock bag and zip it up.

Figure 3:



iii. **Tertiary receptacle**: In this manual, this is referred to as the **safety box**. Place the Ziploc bag and its contents into the safety box.

Figure 4:



2. On top of the safety box is an area printed with words '**To consignee'** (s*ee fig 2).* This area is already labeled with the address of the NTRL where the sample is being sent.

3. Above this is an area where the name and contacts of the shipper are written. Please fill that area with your name, address and 24-hour phone contact.

4. The safety box also displays the UN symbol and number, plus the words **"BIOLOGICAL SUBSTANCE, CATEGORY B".** All these refer to the hazard category of sputum.

5. Take the sealed safety box to the post office within 2 hours after collection, to reach there not later than 3pm of same day. In case of delay of more than 2hrs, keep at 2-8^{o}C

Summary:

Figure 5: ***Left:*** an open safety box; ***Middle***: after inserting the sputum container; ***Right:*** after sealing the box.

Note:

- Endeavor to put the accompanying request form in the shipment box either in a separate zip lock pack bag or in the side porch of the zip lock containing the sample if provision is available on the zip lock bag.
- The request form should never be placed together with the sample inside the same zip lock.
- Not two samples from different patients should be packaged in the same zip lock bag.
- Other types of samples submitted for diagnosis of TB and Leprosy should also be triple packaged as illustrated above.

8.1 Sample runner delivering directly to NTRL

For packages that are directly delivered to NTRL by sample runners, the following procedure may be followed.

- A double packaging system may be used. i.e with primary container (50 ml falcon tube) and secondary container (safety box).
- The primary container must carefully be put into the secondary container in an upright direction.
- The request forms must not be stack into the secondary container, hence they should be carried separately.

- The packages must arrive at the NTRL before 4:30pm of every working day.

9.0 TRANSPORT OF SPECIMEN PACKAGES

- For KCCA TB health region, once specimen packages are ready, call the sample runners serving the different divisions on their telephone numbers to collect the sample. In cases where the sample runner is inaccessible, NTRL should be informed on its toll free line.

- For other health regions, samples will be shipped using the Hub transport system. These samples should be handed over to the Hub sample transporters for shipment to the hub laboratory. Samples that require GeneXpert or Truenat testing will be tested at the hubs.

- Samples for *M.leprae* examinations or TB culture and DST can be delivered to the NTRL through NSRTN vans that visit the facilities.

Note:

- If pick up by the NSRTN vans is to be delayed for more than 2 hours, keep the specimen in a refrigerator at 2 – 8 º C.
- TB samples may be transported without ice packs, however ice packs can be used if available.
- Samples for TB culture and DST should be delivered to NTRL within 3 Days from the time of collection. This prevents overgrowth of contaminants that could be present in the sample and potential loss of mycobacterial viability due to unfavorable environmental conditions.
- NTRL evaluates the adequacy of sample transportation on a weekly basis. In the event of delays of samples in transit (Beyond 3 Days from time of collection), the parties involved in the transportation of the affected samples are notified and actions taken to prevent recurrence.

Note: Listed below are the factors that may affect performance of the examination or interpretation of results

- Insufficient sample volumes e.g. less than 0.5ml, Stool samples for SOS <0.8g or thumbnail.
- Poor quality sample i.e. salivary
- Delay in transit i.e. samples that arrive at referral lab beyond 3 days from collection date
- Use of preservative when collecting samples

10.0 VERBAL REQUESTS

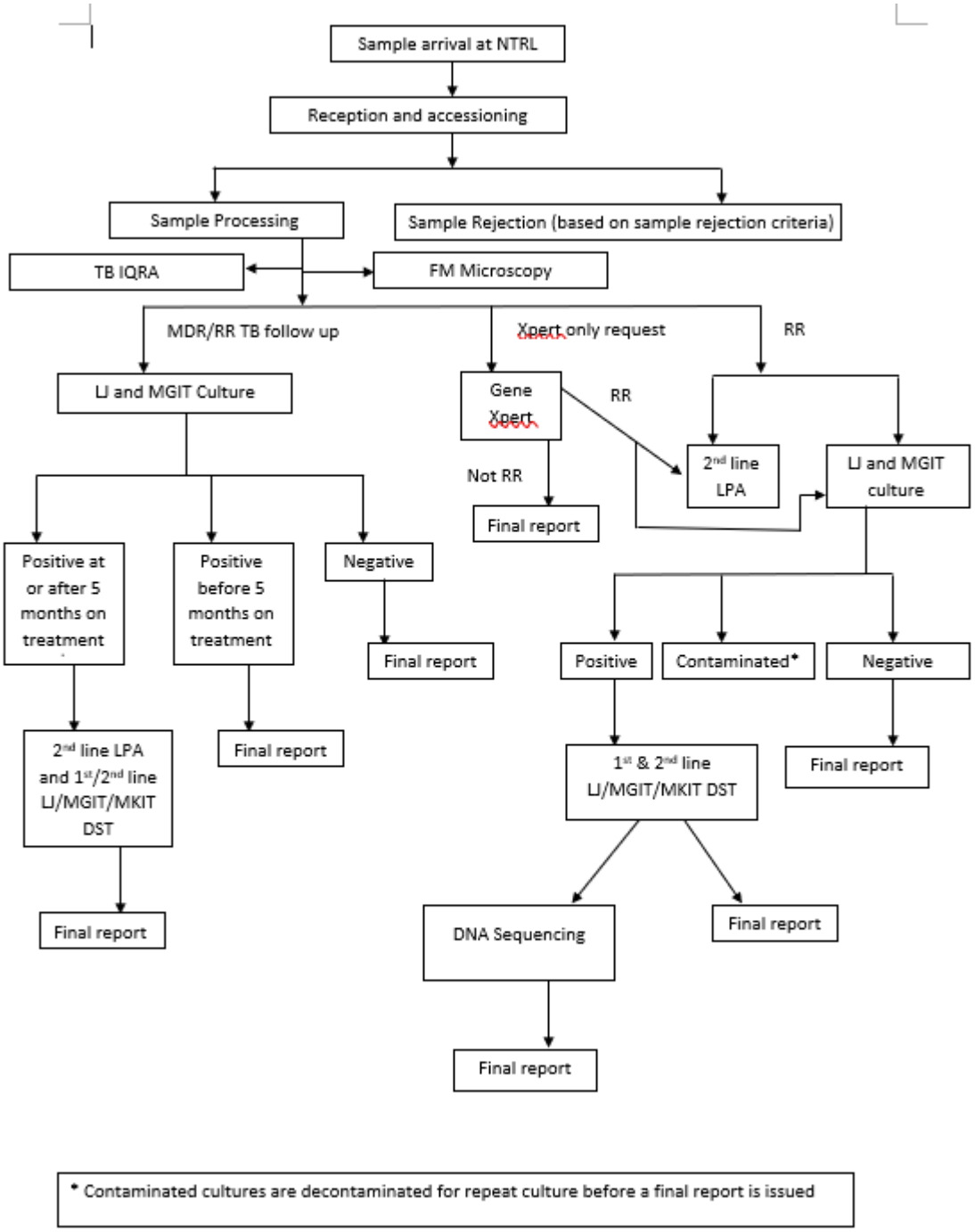
When a sample is delivered to NTRL without a request form, the patient/sample bearer is asked to fill in the request form in the presence of an NTRL staff in consultation with the requesting physician.

11.0 RESULTS REPORTING

The NTRL, upon testing the received sample issues out a laboratory test report. Reports can be preliminary or final depending on the tests requested for and the category of the patient. Preliminary implies that there are additional results to be reported later and final reports bear all the expected results for that particular patient's sample.

The testing is done following the algorithm below in Figure 3;

Figure 6: NTRL internal testing algorithm



11.1 Report forms format

Each report form includes (where relevant) (***See Appendix 3 and 4***)

- Patient unique identifier and address
- Name and address of the client/Health facility,
- Sample quality, Date/time collected and received in the laboratory
- Name and address of the laboratory
- Clear and concise results of tests analyses
- Date of test results
- Report Print date and time
- Review and approval dates
- Comment section (***see Appendix 5*** for list of possible comments).
- Signature of the reviewer and Lab manager or any other designee
- Section with interpretive comments

11.2 Result dispatch

- Reports for samples received from peripheral health facilities are mainly transmitted to requestors electronically through the online NTRL TBLIS Hospital Access interface
- Recipients of all soft copy reports sent via email must acknowledge receipt of the electronic reports.

11.3 Release of results directly to patients

Under normal circumstances, the laboratory is not supposed to release results directly to the patients except in situations where the patient has delivered the specimen and request form in person. If need arises the case will be handled by the lab manager or designee.

11.4 Quality Control

- **Laboratory test results**

i. All test results and test validity are checked by test operator in conjunction with the section reviewer.

ii. All the equipment and procedures are validated before use.

- **Report forms**

i. 100% of reports are checked for accuracy of data and patient's information before results are sent out.

11.5 Notification of Critical Values (MDR/XDR)

The Critical values are MDR, pre-XDR and XDR TB.

The laboratory will notify the requesting clinician of these critical values.

11.6 Notification of delayed examination to requester

The laboratory shall communicate delay of results that may significantly compromise patient care by notifying the requester giving reason/s for delay and the probable results date.

11.7 Results distributed by Telephone

- It is not a policy of NTRL to report results using telephone except those classified as critical values to authorized personnel.
- In the event that this has occurred, the lab will follow up the verbal result with an official test report even in cases of critical values.

11.8 Alteration of reports

In case of an erroneous report, the laboratory will re-call the results by communicating to the client the erroneous report and the correct result after which a corrected test report is issued. Documentation of this communication is kept at the laboratory for record purposes.

12.0 POLICY ON PROTECTION OF PERSONAL INFORMATION

- NTRL has a policy in place to ensure that no personal information provided by clinicians is released to unauthorized persons. Its electronic data base is password protected and hard copy files containing patient's information are kept under lock and key. Access to such files can only be authorized by the NTRL data manager.

- NTRL will only release information about patients to third parties in circumstances when the third parties are authorized to receive it by law. In such instances, the patients will be notified unless prohibited by law. These may include results of culture and DST testing among other confidential information.

13.0 NTRL'S COMPLAINTS PROCEDURE

Complaints to NTRL can be made by making a phone call to the laboratory on its Toll Free line, Twitter handle, online PT portal or using any other possible means of communication (outlined on Page 11). All complaints received will be substantiated, recorded, investigated and addressed by the responsible department in the shortest time possible after which feedback will be made to the complainant on phone or email or any other communication channel.

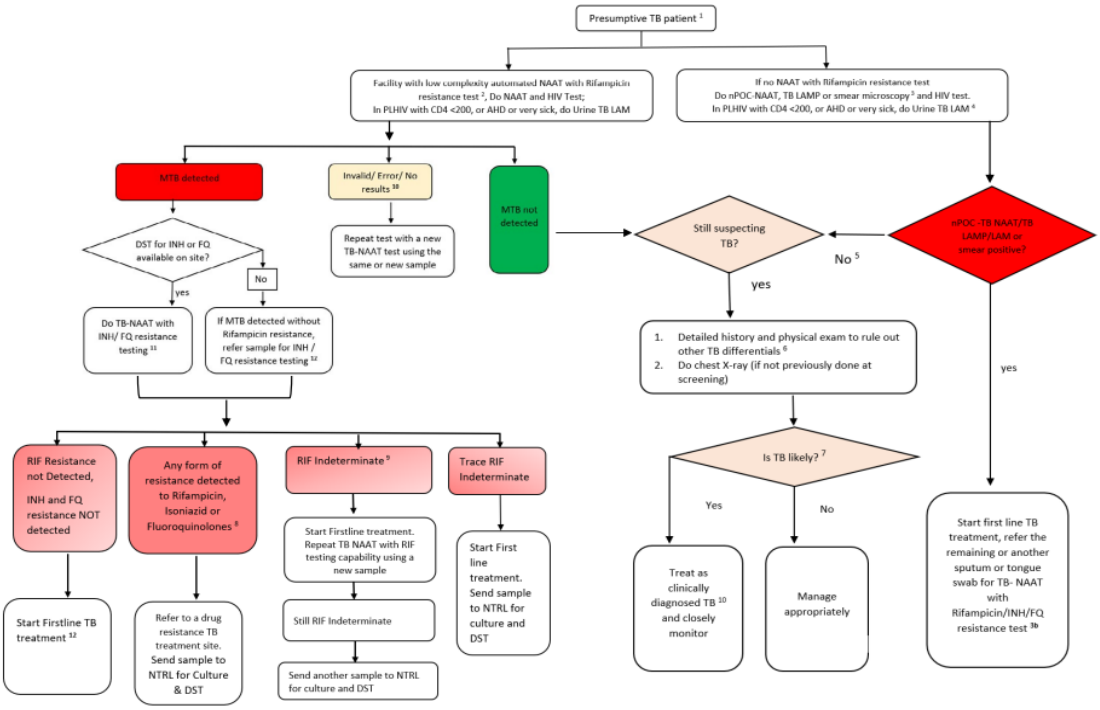
NOTE

THIS CLINICIAN HANDBOOK OUTLINES THE MINIMUM GUIDELINES AND REQUIREMENTS THAT WILL HELP THE NTRL PROVIDE QUALITY RESULTS, HENCE THEY HAVE TO BE ADHERED TO BY ALL OUR CLIENTS

Appendix 1: TB DIAGNOSTIC ALGORITHM

1.9 TB Diagnostic algorithm

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



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

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

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

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

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

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

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

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

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

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

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

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

Figure 1: TB Diagnostic algorithm

Appendix 2: Request form for TB Specimen Examination

MINISTRY OF HEALTH

HMIS TB 002: TB SPECIMEN EXAMINATION REQUEST AND RESULTS FORM

Name of Health Facility: .....District..... Date: .....

Name of Patient: ..... Age: ..... Sex: F ☐ M☐

Presumptive TB No..... Unit TB No.....DR-TB No: .....

A. Address of Patient:

District: ..... Nearest Health Unit: .....

Sub-County: ..... Tel No.: .....

Parish: ..... NIN: | | | | | | | | | | | | | | |

Village: ..... Next of Kin: ..... Tel No.: .....

B1. Type of Patient:

☐ Presumed TB
☐ New
☐ Previously Treated (R,F,LTF,THU)

B2. HIV STATUS:

☐ New POS
☐ Known POS
☐ NEG
☐ Unknown

C. Entry points

☐ OPD ☐ MAT ☐ TB clinic ☐ FP
☐ ART ☐ PNC ☐ Nutrition ☐ IPD
☐ ANC ☐ Contact tracing ☐ Community ☐ POE(Border point)

Entry point No.: .....

D. Reason for Examination:

☐ Diagnosis
☐ Baseline Tests
☐ Follow-up Treatment (Month):.....

E. Examination Request:

NAAT(☐ Genexpert ☐ Truenat ☐ TB LAMP)
LBTI Tests (☐ IGRA ☐ TBST ☐ TST) ☐ C-RP
☐ Microscopy ☐ LPA** ☐ TB LAM
☐ Culture** ☐ DST** ☐ Others (specify):.....

F. Specimen Details: Type of Specimen: ..... Date of Collection: .....Time of collection: .....

Clinical notes:

Requester's Name & Signature: ..... Tel. No. ..... Email: .....

LABORATORY RESULTS

Lab No.: .....
Date Received: .....Time Received:.....

Receivers Name and Signature: .....
Specimen Appearance: .....
Volume: ..... Mls.

NAAT: ☐

Tick option that applies :

☐ T = MTB detected, rifampicin resistance not detected;
☐ RR = MTB detected, rifampicin resistance detected;
☐ TI = MTB detected, rifampicin resistance indeterminate;
☐ TT = MTB Trace Detected RR indeterminate;
☐ N = MTB not detected;
☐ I = invalid / no result / error

Microscopy	Date	Specimen No.	Result					
			No AFB.	Exact No.	+	++	+++	
		1						
		2						
TB LAM:			Positive:		Negative:		Invalid	
CRP:			Value:					

Examined by (signature): ..... Date: .....Telephone: .....
Reviewed by (signature): ..... Date: ..... Telephone: .....
Result Dispatch Date: ..... Time: .....By(Lab Name):.....

***Results can be printed on a separate form*

Page 1 of 1

(Print Version July 2024)

Appendix 3 and 4: NTRL Results Report format (INSERT PRELIMARY AND FINAL REPORTS

NATIONAL TUBERCULOSIS REFERENCE LABORATORY, KAMPALA
Plot 1062-106 Butabika Road, Luzira Opp. Butabika National Mental Referral Hospital
P.O. Box 16041, Wandegeya, Kampala, Uganda. Toll Free Line: 0800111133

PRELIMINARY LABORATORY RESULTS REPORT **LAB No: 128885-QC**

REPORT FOR: QUALITY CONTROL PANELS **CONTACT:** CHRISTINE KORSAH - 0777014898
HEALTH FACILITY: **LUGOBA HC IV** DISTRICT: **WAKISO** NTLP REGION: **SOUTH CENTRAL**

PATIENT DETAILS

NTRL Patient No: NTRL/39959
Patient Names: 2/22/34
TB Patient Category: New Patient
Age (Years): 39
Sex: Female

HC Patient ID: 2/22/34
Reason for Request: Initial Culture & DST.
District of Residence: Kampala
LC1/Zone: Kazo

SPECIMEN DETAILS

Specimen Type: Sputum
Appearance: Salivary
Volume: 5 ml

Collected: 29-Nov-22 06:00:00
Received: 01-Dec-22 09:00:00
Requested by: DR. RASHID M 0777797979

MICROSCOPY RESULTS

Auramine/FM	NEGATIVE - No AFBs seen	05-Dec-22

CULTURE RESULTS

LJ Culture	NEGATIVE	24-Jan-23

SUSCEPTIBILITY RESULTS

COMMENTS:

For questions concerning this report, contact the Lab at this Toll Free Line: 0800111133

Report Review:
By Winfred Penny on 27/01/2023

NATIONAL T.B REFERENCE LAB (MOH) 27 JAN 2023 P.O. BOX 16041, BUTABIKA UGANDA

Report Authorisation:
By Smith Stone on 27/01/2023

MTBC = Mycobacterium tuberculosis complex, DST = Drug Susceptibility Testing,LJ= Lowenstein-Jensen, MDR = Multi-Drug Restant TB Strain, XDR= Extensively Drug Resistant TB Strain, MGIT = Mycobacterium Growth Index Tube, NTM = Non-TB Mycobacterium, ZN = Ziehl-Neelsen, 1-100 = Absolute colony counts on solid media. Smear Microscopy Grading: 1-9/100 fields = absolute number of AFBs seen per 100 fields; 1+= 1-100/100 fields; 2+ = 1-9 AFBs/field; 3+ = 10+ AFBs/field, FM=Fluorescent Microscopy, Negative=Zero AFBs/1 Length, Scanty= 1-29 AFB/l Length, 1+= 30-299 AFB/1 Length, 2+ = 10-100 AFB/1 Field on average, 3+ = > 100 AFB/1 Field on average, LPA= Line Probe Assay, NP=Not Provided, FLQ=Fluoroquinolones(Ofloxacin,Moxifloxacin), EMB=Ethambutol, AG/CP=Injectible antibiotics(Kanamycin, Amikacin/Capreomycin, Viomycin), PAS=Para-Aminosalicylic Acid, (CB) = Critical Breakpoint. Critical Breakpoint Concentration applies to high-dose Moxifloxacin, IGRA = Interferon-Gamma Release Assay, IGRA Positive = M.tuberculosis infection likely, IGRA Negative = M.tuberculosis NOT likely, IGRA Indeterminate = Likelihood of M.tuberculosis infection cannot be determined

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NATIONAL TUBERCULOSIS REFERENCE LABORATORY, KAMPALA
Plot 1062-106 Butabika Road, Luzira Opp. Butabika National Mental Referral Hospital
P.O. Box 16041, Wandegeya, Kampala, Uganda. Toll Free Line: 0800111133

FINAL LABORATORY RESULTS REPORT **LAB No: 128295-QC**

REPORT FOR: QUALITY CONTROL PANELS **CONTACT:** CHRISTINE KORSAH - 0777014898
HEALTH FACILITY: **LUGOBA HC IV** DISTRICT: **WAKISO** NTLP REGION: **SOUTH CENTRAL**

PATIENT DETAILS

NTRL Patient No: NTRL/39600
Patient Names: 2/22/23
TB Patient Category: New Patient
Age (Years): 49
Sex: Female

HC Patient ID: 2/22/23
Reason for Request: Initial Culture & DST.
District of Residence: Not Provided
LC1/Zone: NP

SPECIMEN DETAILS

Specimen Type: Sputum
Appearance: Mucosalivary
Volume: 4 ml

Collected: 07-Nov-22 08:30:00
Received: 07-Nov-22 11:00:00
Requested by: DR MATOVU

MICROSCOPY RESULTS

Auramine/FM	NEGATIVE - No AFBs seen	09-Nov-22

CULTURE RESULTS

LJ Culture	NEGATIVE	04-Jan-23

SUSCEPTIBILITY RESULTS

LPA 2nd LINE Date: 10-Nov-22
MTBC Not Detected

COMMENTS:

For questions concerning this report, contact the Lab at this Toll Free Line: 0800111133

Report Review:
By Smith Stone on 06/01/2023

NATIONAL T.B REFERENCE LAB (MOH) 06 JAN 2023 P.O. BOX 16041, BUTABIKA UGANDA

Report Authorisation:
By Winfred Penny on 06/01/2023

MTBC = Mycobacterium tuberculosis complex, DST = Drug Susceptibility Testing.LJ= Lowenstein-Jensen, MDR = Multi-Drug Restant TB Strain, XDR= Extensively Drug Resistant TB Strain, MGIT = Mycobacterium Growth Index Tube, NTM = Non-TB Mycobacterium, ZN = Ziehl-Neelsen, 1-100 = Absolute colony counts on solid media. Smear Microscopy Grading: 1-9/100 fields = absolute number of AFBs seen per 100 fields; 1+= 1-100/100 fields; 2+ = 1-9 AFBs/field; 3+ = 10+ AFBs/field, FM=Fluorescent Microscopy, Negative=Zero AFBs/1 Length, Scanty= 1-29 AFB/l Length, 1+= 30-299 AFB/1 Length, 2+ = 10-100 AFB/1 Field on average, 3+ = > 100 AFB/1 Field on average, LPA= Line Probe Assay, NP=Not Provided, FLQ=Fluoroquinolones(Ofloxacin,Moxifloxacin), EMB=Ethambutol, AG/CP=Injectible antibiotics(Kanamycin, Amikacin/Capreomycin, Viomycin), PAS=Para-Aminosalicylic Acid, (CB) = Critical Breakpoint. Critical Breakpoint Concentration applies to high-dose Moxifloxacin, IGRA = Interferon-Gamma Release Assay, IGRA Positive = M.tuberculosis infection likely, IGRA Negative = M.tuberculosis NOT likely, IGRA Indeterminate = Likelihood of M.tuberculosis infection cannot be determined

Print time: Monday, January 30 2026, 09:45 AM ***Page 1 of 1***

Appendix 5: Results Report Comments

COMMENT	SITUATION FOR COMMENT
Complete 1st and 2nd line profile DST results were unable to follow. DST may be provided on subsequent positive culture sample	When 1st and 2nd line DST run was unsuccessful and DST is to be done on another available sample for the patient
Complete 1st and 2nd line profile DST results were unable to follow. If possible, provide another sample	When 1st and 2nd line DST run was unsuccessful and DST cannot be repeated
Complete 1st and 2nd line DST profile results will be provided	When culture is positive and sample qualifies for DST
Gene Xpert results reported after positive culture	When sample is cultured prior to Xpert. In situations where Rif indeterminate sample is referred to NTRL or sample referred to NTRL from a non MDR TB treatment facility without Rifampicin resistance status.
IGRA run was unsuccessful	When plasma cannot be harvested leading to an unsuccessful IGRA run
LJ Culture results acquired after redecontamination	When dispatching re-decontaminated culture result
LJ Culture results acquired after repeat	When initial LJ culture result is withheld and culture repeated
LJ DST 1st line results reported after repeat	When initial LJ DST 1st line result is withheld and DST repeated
LJ DST 2nd line results reported after repeat	When initial LJ DST 2nd line result is withheld and DST repeat
LJ DST results obtained after subculture from MGIT isolate	When MGIT DST results are dispatched following positive LJ results
LPA 1st line results reported after positive culture	When initial LPA 1st line results was indeterminate or negative and another LPA reported after positive culture
LPA 1st line results reported after repeat	When initial LPA 1st line result is withheld and LPA is repeated
LPA 2nd line results reported after positive culture	When initial LPA 2nd line results was indeterminate or negative and another LPA reported after positive culture
LPA 2nd line results reported after repeat	When initial LPA 2nd line result is withheld and LPA is repeated
LPA for 1st line could not be repeated due to stock out of supplies	When initial LPA 1st line result is withheld and LPA cannot be repeated due to stockout of supplies
LPA for 1st line to be repeated following positive culture	When initial LPA 1st line results is indeterminate or negative and LPA is to be repeated following positive culture

LPA for 2nd line could not be repeated due to stock out of supplies	When initial LPA 2nd line result is withheld and LPA cannot be repeated due to stockout of supplies
LPA for 2nd line to be repeated following positive culture	When initial LPA 2nd line results is indeterminate or negative and LPA is to be repeated following positive culture
MGIT Culture results acquired after redecontamination	When dispatching redecontaminated MGIT culture result
MGIT Culture results acquired after repeat	When initial MGIT culture result is withheld and culture repeated
MGIT DST 1st line acquired after repeat	When initial MGIT 1st line result is withheld and DST is repeated
MGIT DST 2nd line acquired after repeat	When initial MGIT 2nd line result is withheld and DST is repeated
Please expect 2nd line DST results	When 1st line DST result is reported before 2nd line DST.
Please provide another sample if possible	When culture is negative or contaminated but DST is expected for the client
Prolonged time (> 3 days) between sample collection and reception may have compromised results	When culture is contaminated or negative but expected to be positive for samples delivered To NTRL beyond 3 days from date of collection
Prolonged time (> 7 days) between sample collection and reception may have compromised results	When culture is contaminated or negative but expected to be positive for samples delivered To NTRL beyond 7 days from date of collection
Salivary sample appearance may have compromised results	When culture is expected to be positive but is negative for a salivary sample
Sequencing could not be performed due to a negative result of the conditional culture result	When Culture turns negative and Whole Genome sequencing cant be done
GeneXpert XDR results to be repeated following positive culture	When GeneXpert XDR test is done on a sputum sediment and it turns negative or indeterminte