Republic of Zambia
Ministry of Health

CHEST DISEASES LABORATORY

LABORATORY CLIENT HANDBOOK

Information for users on the effective utilisation of our laboratory services

July 2020 | Version 2

CHEST DISEASES LABORATORY
LABORATORY CLIENT HANDBOOK

Chest Diseases Laboratory (July 2020)

History of Review:

Date of Review	Changes Made	Version Number	Name
20/05/2020	*Preparation and review for initial release*	1	Taurai Musonda Mutende Mwamba Jonathan Mwenya John Muzyamba Samuel Mwabafu
15/07/2020	• *Review of turnaround time for Line Probe Assay* • *Review of time between specimen collection and transportation* • *Inclusion of Microscopy turn around time*	2	Taurai Musonda Mutende Mwamba Jonathan Mwenya John Muzyamba

APPROVED BY:

Mutende Mwamba
Laboratory Manager
10th July 2020

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i. Contact Details

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ii. Glossary of terms

Chain of Custody – Each sequential participant in the act of collecting and transporting a specimen from the patient to the laboratory. The effective documentation of this chain provides a valid audit trail for the specimen for accreditation and regulatory purposes.

Examination – laboratory assays or tests

Specimen Collection – Producing a specimen from a patient for laboratory analysis.

Specimen/sample – For simplicity, the terms ‘specimen’ and ‘sample’ in this handbook are used interchangeably to indicate the discrete biological material of whatever size sent to the laboratory for examination.

Urgent - Requiring immediate action or attention. It is important that if a specimen requires urgent analysis that this status is effectively indicated on the requisition form and conveyed to the participants in the ‘chain of custody’ from specimen collection to the laboratory. The abuse or overuse of this status overloads the process and devalues the term when there is a truly urgent situation; it must not be used lightly.

iii. Abbreviations

AFB:	Acid Fast Bacilli
CDL:	Chest Diseases Laboratory
DST:	Drug Susceptibility Testing
EQA:	External Quality Assurance
FM:	Fluorescent Microscopy
ID:	Identification
INH:	Isoniazid
IQC:	Internal Quality Control
ISO:	International Standardization Organization
LAB:	Laboratory
LJ:	Lowenstein Jensen
LQMS	Laboratory Quality Management Systems
MGIT:	Mycobacterium Growth Indicator Tube
MOH:	Ministry of Health
MOTT:	Mycobacterium Other Than Tuberculosis
MTB:	Mycobacterium Tuberculosis
MTBC:	Mycobacterium Tuberculosis Complex
NISIR:	National Institute for Scientific and Industrial Research
NTRL:	National Tuberculosis Reference Laboratory
PCR:	Polymerase Chain Reaction
PZA:	Pyrazinamide
QMS:	Quality Management Systems
RIF:	Rifampicin
SIRE:	Streptomycin. Isoniazid, Rifampicin, Ethambutol,
TB:	Tuberculosis
WHO:	World Health Organization
ZN:	Ziehl Neelsen

1. Introduction

Thank you for your interest in accessing the services of Chest Diseases Laboratory (CDL). CDL is the National Tuberculosis Reference Laboratory which provides clinical diagnostic testing services for patients with presumptive tuberculosis (TB) and drug resistant TB. It is also involved in conducting research in the area of Tuberculosis.

CDL staff is committed to providing the highest quality of service to all our clients to ensure excellent patient care and management. We continue to improve and upgrade systems and policies to ensure that the quality of our services is always assured. This Client Handbook provides you with all the relevant information on the services of the CDL including safe specimen collection, courier system, turnaround time of results and any other information required by the user of our Laboratory services.

Quality Policy

The CDL management is committed to satisfying the needs of its customers by implementing a quality management system that conforms to the ISO 15189 and all relevant national and international regulations. Our quality policy is to:

- ◊ Provide laboratory examinations that are reliable, affordable, of high quality and fit for intended purpose;
- ◊ Adhere to the professional code of ethics in our interactions with clients and fellow staff;
- ◊ Satisfy the needs of our customers through continually improving the quality of laboratory services provided;
- ◊ Ensure that all laboratory personnel are competent for assigned tasks;
- ◊ Continually improve our quality management system to adapt to latest technologies, relevant standards, regulations and accreditation requirements;
- ◊ Ensure a safe environment for all laboratory personnel and clients.

2. Operating hours

Monday to Friday	Saturday and Sunday	Public Holidays
08:00 – 17:00 hrs	*Closed*	*Closed*

3. Turnaround times (TAT) of laboratory tests

Test	TAT
Microscopy	48 hrs
Culture/DST	Up to 66 days
Detection of MTBC and Rif resistance (GeneXpert/MTBC)	48 hrs
Line probe assay (LPA)	7 days

We do not provide urgent testing.

4. Advisory services

Advisory services are provided by the Laboratory Head, scientists and technologists as appropriate to the inquiry. If you need advice on any of the following aspects, contact the laboratory:

- ◊ choice of examinations and use of our services;
- ◊ specimen requirements and follow-up frequency
- ◊ scientific and logistical judgements on sample requirements;
- ◊ interpretations of results of examinations;
- ◊ effective utilisation of our services.

5. Confidentiality and protection of personal information

5.1. Confidentiality of patient information

Our laboratory is committed to protecting the confidentiality of our clients and has implemented the Confidentiality Procedure (CDL-TB-MGT-021). All public service employees working in the CDL have signed the Confidentiality Agreement Form (CDL-TB-F-036) which is kept in their personnel files. The laboratory management also ensures that other individuals who are not CDL's employees (e.g. students, volunteers, etc.) and have access to patient information sign the Confidentiality Agreement Form upon arrival when reporting to the Laboratory Head for

placement in the laboratory.

5.2. Control of access to patient records

Further, access to areas where patient records are kept is restricted to authorised personnel to safeguard against tempering or loss. This is achieved by locking areas where information is kept and protecting electronic data with usernames and passwords

6. Requesting an examination

All requests for laboratory tests should be made on the approved request form for TB Culture and Drug Susceptibility Testing (DST), see Appendix 1.

The table below summarizes the **minimum** information required when requesting a test:

Patient data item	Request form	Specimen container
Surname	✓	✓
First name (***not just initials***)	✓	✓
Date of Birth or Age	✓	✓
Gender	✓	✓
File number	✓	
Location (Ward/clinic)	✓	
Requester's name	✓	
Person collecting the specimen	✓	
Relevant clinical details and drug history*	✓	
Date of collection	✓	
Time of collection*	✓	
Requested examinations (tests)	✓	
Specimen type (& site if appropriate)	✓	

!!! IMPORTANT NOTES ABOUT FILLING THE REQUEST FORM

* Please ensure that you indicate reason for examination i.e. whether the request is for diagnosis or follow-up with months of follow-up clearly indicated. Omission of these details can lead to a specimen being rejected.

****Time of collection** is extremely important as it allows the laboratory to:

- ◊ Assess the suitability of a sample for tests
- ◊ Audit specimen turnaround times and identify where delays may be taking place so as to improve the services

The laboratory **does not** have the authority to amend details on a specimen or request form if incorrectly given. *The laboratory reserves the right to **reject** specimens received with incompletely or incorrectly filled-in request forms.*

6.1. Making verbal requests

Clinicians can make 'verbal requests' for additional testing on a specimen *previously submitted* to the CDL. This is in order to avoid collecting another specimen when the one previously submitted could still be used for further testing. However, the specimen must be within stability time for the requested additional tests. We have a procedure for Verbal Requests (CDL-TB-MGT-017) and it's summarized here:

Step	Action
1.	By phone, the authorised patient care provider should request the addition of test procedures to specimens already received by CDL
2.	The laboratory member of staff receiving the request will complete a Verbal Request Form (CDL-TB-F-041).
3.	The laboratory staff receiving the verbal request will perform a "read back" of the verbal request to confirm the patient details and the requested test.
4.	The staff receiving the request then locates the original specimen and checks for appropriateness of the additional test request and verifies if the specimen meets the acceptability requirements for the test.

5.	If it is established that the additional testing can be performed, the test is added to the original specimen number.
6.	If additional testing cannot be performed, the requester is notified and the reason for not performing the test is recorded on the Verbal Request Form (CDL-TB-F-041).
7.	Results of added tests are reported the same way as those previously received with a filled in request.
8.	**Note:** Results of additional tests are not released until confirmation of a verbal request is received by way of a duly filled/in request form within the stipulated turnaround time of the requested test. See Section 3 for turnaround times of tests.

7. Specimen Requirements for TB samples

Plain vacutainer	Leak-proof universal container
 **Lid colour:** Red **Additive:** None	 **Lid colour:** Any colour **Additive:** None

Test	Specimen type	Container/volume	Storage/Transportation/ Precautions
Xpert MTB/Rif Line probe assay (LPA)	Sputum	Sterile leak-proof universal container (2-5ml)	**Spot** • For diagnosis, a patient must submit 2 specimens collected as **Spot** • For follow-up, a patient must submit 1 specimen (preferably morning specimen). • Triple packaging must be used for specimens from outside CDL • Cold chain must be maintained.
Microscopy Culture DST	Sputum	sterile leak proof universal container (2-5ml)	
	Lymph node aspirate	Smeared slide (approx. 2 x 3cm in size), plain vacutainer bottle, sterile leak proof universal container (2-5ml)	
	Cerebral spinal fluid, Pleural effusion, Synovial fluid aspirate	Plain vacutainer bottle (2-5ml)	
	Gastric Lavage, Urine, Bronchial lavage	Sterile leak proof universal container (2-5ml)	
	Tissue biopsy	Sterile leak proof container	
	Pus	Swab, smeared slide approx. 2x3cm in size), Plain vacutainer bottle (2-5ml)	

Key: **DST.** Drug Susceptibility Testing; **Rif.** Rifampicin; **LPA.** Line probe assay

NOTE: *If there is delay in bringing the specimen to the laboratory it must be kept refrigerated at 2-8°C for not more than **3 days** before delivery. **Do not freeze.** Factors that might lead to erroneous results include: (i) Anti- TB treatment prior to specimen collection, (ii), not maintaining cold chain transport; (iii) exposure of specimen to direct sunlight*

8. Specimen collection

8.1. Competency of sample collectors

The wards/ clinical areas are responsible for ensuring that persons collecting specimens are competent to perform that procedure. When in doubt on how to collect the specimen, please contact the laboratory.

8.2. Patient identification before sample collection

Persons collecting the specimens are responsible for confirming the identity of the person from whom the specimen is to be collected prior to collection of specimens.

A clinician or nurse is available at the TB corner of the Ministry of Health clinic/hospital to assist in collection, labelling and handling of specimens from patients. Instructions can also be given by Laboratory personnel.

8.3. Informed consent of the patient

For most routine laboratory procedures, consent is assumed when the patient presents himself/herself at the laboratory with a request form and willingly submits to the usual collecting procedure. For more invasive procedures that have a higher chance of complications such as those for collecting body fluids, the person collecting the specimen is responsible for ensuring that consent procedures are followed, including in written form, where required.

8.4. Patient-collected specimens

Staff issuing specimen containers for patient-collected specimens, i.e. sputum and voided urine must label the specimen containers with the patient's details before issuance. Clinical staff are responsible for giving clear instructions to patients on how to collect and handle the specimens as described below:

8.4.1. Sputum

Step	Action
Instruction to the health care provider:	
1.	Explain the procedure and the reason for sputum collection to the patient.
2.	Fill in the approved request form as completely as possible
3.	Label specimen container with patient's first name, surname, sex and age.
4.	Give specimen container to patient with the following instructions (below) on how to collect specimen.
5.	Direct the patient to a well ventilated or open-air area at a distance from the clinic, laboratory and other people.
Instructions to the patient:	
1.	Rinse the mouth with water, but not to brush your teeth or use mouthwash before collecting sputum.
2.	Open the container keeping the cap in your other hand.
3.	Take deep breaths, 3-4 times.
4.	Hold your breath for 3-5 seconds after each inhalation before exhaling.
5.	After the last inhalation, cough deeply to bring up sputum from your lungs.
6.	Spit sputum directly into the container without messing up the outside of the container.
7.	Continue this process until there is about 2-5mls of specimen in the container.
8.	Screw the specimen container tightly
9.	Ensure that the completed request form (from the referring doctor or clinic) is brought with the specimen to the laboratory.
10	Put container in a plastic bag separate from request form and deliver to the laboratory as soon as possible before 10AM.
11.	Contact the laboratory if you have any questions.

8.4.2. Urine specimens

As a routine isolation method, a totally voided early morning urine specimen can be used for mycobacterial culture. Pooled or midstream urine is not recommended for TB culture processes.

8.4.3. Other specimens

Please follow standard medical procedures for the collection of other specimens such as biopsies, pus, bronchial washes, etc.

8.5. Biosafety considerations for specimen collection

All materials used in the collection of specimens must be disposed of in a safe manner. Follow standard precautions when performing specimen collection procedures:

- ◊ Wear gloves and a coat or gown when handling blood/body fluids.
- ◊ Change gloves after each patient or when contaminated.
- ◊ Wash hands frequently.
- ◊ Dispose of specimen collection items in the designated infectious waste containers.
- ◊ Dispose of needles into 'sharps' boxes after use e.g. after the collection of CSF.
- ◊ Do not bend, break, recap, or re-sheath needles to avoid injury or splashes
- ◊ Clean up any spills of infectious material with a disinfectant such as freshly made 0.5% bleach.

9. Transporting specimens to the laboratory

Fig 1. Specimen transport cooler box

All samples must be accompanied by a duly completed laboratory request form when transporting specimens. All specimens must be treated as potentially infectious. Therefore, they must never be carried or transported directly in the hand or in a pocket. Specimens must be transported to the laboratory in a manner that ensures timely arrival at the laboratory at a minimal risk to the person transporting the specimen, laboratory and non-laboratory personnel and the environment.

When available, specimens should be placed in plastic sealable bags with a separate pouch for the specimen request form to prevent it from being soiled if there's a spill. Do not wrap laboratory request forms around specimen. Use sturdy, leak-proof cooler boxes and mark them with a **BIOHAZARD** label (or in writing) to prevent accidental exposure by the unsuspecting public (See figure 1)

The packaging and transportation of clinical specimens for TB testing is based on the principle of triple containment (packaging) to prevent exposure to potential infectious hazards. Please follow the instructions below for safe transportation of your specimens:

a. The clinical specimens must be contained within a sealed specimen container – sputum container or other container for extra pulmonary specimens.
b. The specimen container is placed within a sealed plastic specimen bag with sufficient absorbent padding to soak up any fluids should a breakage or leakage occur.
c. This must then be placed with the request form in a cooler box or screw-top plastic specimen carrier in an upright position and the lid secured to form a seal.
d. **NB: the request form must never be in direct contact with the specimen container. To maintain a cold chain, ice packs are placed inside the cooler box.**
e. The request forms can be placed in an envelope and secured to the cooler box.
f. Appropriate address labels for both destination and sender should be attached to this box.
g. Packaging materials will be returned for reuse on request by the courier.
h. Samples must be transported to CDL within 24 hours or otherwise refrigerated AT 2-8°C until the day of transportation.

Note: *As a general guide, ensure that specimens are received at the laboratory within **7 DAYS** after collection.*

10. Delivering specimens

When bringing specimens, please ensure that the specimens are handed over to laboratory staff for traceability/chain of custody. Individuals bringing specimens to the laboratory must also correctly enter the required details into the Specimen Transmittal Sheet (CDL-TB-F-049) which can be accessed from the laboratory. Laboratory staff will sign as evidence of receiving the specimens. **The Laboratory will not accept responsibility for a lost specimen that was not documented as received.**

11. Specimen rejection criteria

In general, the following conditions will lead to rejection of a specimen by the CDL:

- ◊ Specimen label or request form that does not meet the minimum data set required by the CDL. Refer to Section 6 an requesting an examination.
- ◊ Specimen inappropriately handled with respect to temperature, timing, or storage requirements.
- ◊ Unlabeled specimen container
- ◊ Specimens not accompanied by a requisition form
- ◊ Illegible details that cannot be deciphered even after seeking a second opinion from appropriately qualified staff.
- ◊ Insufficient specimen, < 1 ml
- ◊ Mismatched patient identification on the specimen and the request form
- ◊ Specimen submitted in wrong container
- ◊ Specimens in syringes
- ◊ More than 7 days between specimen collection and reception.
- ◊ Leakage

What happens to rejected specimens?

Rejected specimens (except severely leaked) and request forms are still assigned a laboratory number for record purposes. The reasons for rejection are indicated on the Specimen Receipt Register (CDL-TB-F-010). Where possible, the laboratory endeavours to clarify the request form information with the requester before resorting to rejecting the specimen. If the specimen is rejected, the requester or their representative is phoned and the communication documented on the Communication Log (CDL-TB-F-032).The rejected specimen will be disposed of by the laboratory unless the supervisor uses their discretion to retain it for a **limited time** pending confirmation of request form information.

Including your phone number on the request form helps clarify request information more quickly and may reduce instances of specimen rejection.

12. Complaints procedure

CDL handles complaints in accordance with the institutional complaints management policies and procedures. We resolve complaints according to our procedure on Complaints and Customer Feedback (CDL-TB-MGT-005). You can lodge in a complaint using any of the following means:

a) writing on our Customer Feedback Form (CDL-TB-F-021) (see Appendix 2) which is made available upon request, and submitting the form to CDL Laboratory Head or the Quality officer.
b) e-mailing your complaint to chestlab2016@gmail.com

Complaints that cannot be resolved by the CDL management may be directed to the Assistant Director Clinical Care via the Public Relations unit at the Ministry of Health.

The time frame for providing feedback to the complainant is within 30 days while that for closing (resolving) complaints is determined by the gravity of the event and the corrective action required. However, our laboratory endeavors to provide feedback in the shortest possible time.

9. Reporting of results

Results are available to clients daily during official working hours. Results are sent to the respective requesting facilities through the Provincial Biomedical Scientist and TB focal point Persons via courier service, email or postage. In instances where facilities provide their email addresses results will be sent directly to the requester. Where required, results are phoned to requesting facilities and followed up by hard copy and/or email copies.
Contact the laboratory if you have any inquiries concerning results. Enquiries about results will only be handled during working hours as indicated in Section 2. Only **reviewed** results are issued.

13. References

1. Goering R *et al.* 2012. MIMS Medical Microbiology. 4th Edition. Elsevier. London.
2. ISO 15189: 2012 Medical Laboratories – Requirements for quality and competence

APPENDIX 1. TB Culture And DST Examination Request Form

Request form for TB culture and Drug Susceptibility Testing (DST)

Zambia National Tuberculosis and Leprosy Control Program

Ministry of Health

Patient Details:

Full Name:_____

Sex(circle): Male / Female

Date of Birth: DD/MM/YYYY

Patient NRC:_____

Occupation of Patient: 1. HCW ☐ 2. Miner ☐

3. Ex-Miner ☐ 4. Other (specify)……

Patient File # :_____

Address:_____

Entry point:_____

Contact #:_____

HIV status (Tick): ☐ Pos ☐ Neg ☐ Unknown

Disease type (Tick):
Site: ☐ Pulmonary
☐ Extra pulmonary

History(Tick):
☐ Relapse
☐ New (never treated before≥1 month)
☐ Failure
☐ Lost to follow up
☐ DR Contact
☐ Uncertain

Previous treatment(Tick):
☐ First Line Drugs
☐ Return after default
☐ Second Line Drugs
☐ Chronic excretor
☐ Cat.4 (second-line drugs)
☐ MDR contact

Origin of Request

Facility Name:_____

District :_____

Province :_____

TB Lab Diagnostic Code :_____

Date specimen was collected: DD/MM/YYYY

Date sample referred: DD/MM/YYYY

Local laboratory result: 1st Specimen ……...
2nd Specimen ……..…..

Method used(Tick): ☐ Xpert MTB/RIF
☐ Ziehl-Neelsen
☐ Fluorescence
☐ Other (specify) :_____

Reasons for specimen referral:
☐ Diagnosis
☐ Follow-up at …. Months during treatment
☐ Follow-up at …. Months after treatment

If Follow up: TB Case ID # :_____

Specimen(Tick): ☐ sputum
☐ other specify):_____

Requested tests(Tick):

☐ Xpert MTBRIF

☐ Culture

DST ☐ 1st Line ☐ 2nd Line

Line Probe Assay ☐ 1st Line ☐ 2nd Line

Other (specify)_____

Person requesting examination:
Name:_____

Position:_____ Mobile #:_____

Email:_____

Requestors Signature:_____

Date received in the Reference Laboratory DD/MM/YYYY Reference Laboratory specimen ID: _____

APPENDIX 2: Customer Feedback Form

CHEST DISEASES LABORATORY

CUSTOMER FEEDBACK FORM

Tracking No:	

A. DETAILS *(*Include contact information if you would like us to get back to you)*

Type of Feedback (*tick appropriate*) ☐ Complaint ☐ Compliment: ☐ Suggestion:

Are you a member of staff? ☐ Yes ☐ No (I'm an external client)

Name of person giving feedback: *(optional)**	
Phone Number *(optional)**:	Date:
Physical Address:/ or Facility Name *(optional)**:	
Email *(optional)**:	

B. DESCRIPTION OF COMPLAINT/COMPLIMENT/SUGGESTION

C. FOR OFFICIAL USE ***(to be filled by Laboratory Head/Designee)***

(i) Complaint, is it genuine? (*Tick appropriate*)

☐ **Yes:** fill-out the Nonconformance (NC) Form (CDL-TB-F-017) and attach this form.

☐ **No:** inform the complainant of why the complaint is not genuine and **complete Part D.**

(ii) Compliment or Suggestion): Complete Part D and if there are any further actions needed, write them on the Action Plan and Follow-up Form (CDL-TB-F-011)

D. Description of action taken and feedback provided to the person who made the complaint/compliment/suggestion:

Name:	**Date:**	**Sign:**

Reading, Understanding and Signature Log:

By signing this log, I confirm that I have read this handbook, and have sought clarification where necessary and promise to follow the policies and procedures contained within.

Name	Date	Signature

Chest Diseases Laboratory (July 2020)

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