CENTRE FOR TUBERCULOSIS RESEARCH
MICROBIOLOGY DEPARTMENT
NIGERIAN INSTITUTE OF MEDICAL RESEARCH

LABORATORY CLIENT HANDBOOK

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REVISION RECORD

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Version 1	**To meet SLIPTA requirements/ annual update**	**January 2012**
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PREFACE

Dear Colleague,

Thank you for your interest in accessing the services of The Centre for Tuberculosis Research, NIMR.

The Centre for Tuberculosis Research at NIMR provides clinical diagnostic testing services for patients suspected of Tuberculosis diseases. This laboratory is also involved in performing Research in the area of Tuberculosis as stated in the Institute Mission statement.

The staff of the Reference Laboratory is committed to providing the highest quality service to you our clients and as such we have instituted and will continue to upgrade systems and policies to ensure that the quality of our services is assured at all times.

We hope that this Client Handbook will provide the necessary information to facilitate access to our services and we welcome the opportunity to serve you.

BACKGROUND

The Centre for Tuberculosis Research (CTBR) is located in the Nigeria Institute of Medical Research (NIMR) compound, Yaba, Lagos. This laboratory was established by the Federal Military Government through the Research Institute order 1977, pursuant to the National Science and Technology Development Agency Decree (No 5) of 1977. The NTBRL was initially established for research on tuberculosis infection in order to meet the Institute's mandate. From 2005, the scope of services rendered gradually increased and the laboratory was included as one of the DOTS diagnostic centres. In 2007, the CTBR was expanded and renovated to meet up with the organization's policy and standard of providing quality services to the private and public sectors. The laboratory was commissioned as a National Reference Laboratory by the Honourable Minister Prof (Mrs) Grange in February, 2008. The services provided at the CTBR are outlined in detail in this handbook.

Our Vision

"To be the foremost tuberculosis research and diagnostic laboratory in Nigeria, committed to providing effective and efficient clinical diagnosis and research in Tuberculosis"

Our Mission

- To carry out innovative research on tuberculosis infections and disseminate the findings through publications, meetings and presentations.
- To render accurate, reliable and quality clinical diagnostic services for the timely management of patients affected by tuberculosis.
- To keep our staff motivated so that they can provide services in a conducive working environment.

LOCATION AND CONTACT INFORMATION

The NIMR Centre for Tuberculosis CTBR is situated at:

6, Edmund Crescent, (Off Murtala Mohammed Way)

P.M.B. 2013, Yaba, Lagos - Nigeria

Telephone: 08097009975

E-mail: ctbr@nimr.gov.ng

Website: www.nimr.gov.ng

LABORATORY CONTACT INFORMATION

Centre for Tuberculosis Research,

Office Phone No.: 09093845605

Mrs Kunle-Ope Chioma (Head, CTBR)

Phone No.: 08036808878;

NOTE: For Enquiry /Complaint please call the numbers above.

LABORATORY BUSINESS SCHEDULE

The NIMR Centre for Tuberculosis research is open from Monday to Friday during the hours of 8:00 a.m. to 4:00 p.m. except for Public Holidays.

The declared public holidays in the Nigeria are as follows:

HOLIDAY	MONTH	DAY
New Year's Day	**January**	**01**
Mohlud Nabbiya*		
Good Friday*		
Easter Sunday*		
Easter Monday*		
Workers Day	**May**	**01**
Democracy Day	**June**	**12**
Ramadan *		
Eid-el-Fitri *		
National (Independence) Day	**October**	**01**
Eid-el-Addha *		
Christmas Day	**December**	**25**
Boxing Day	**December**	**26**

Public Holiday that is movable

INSTRUCTIONS FOR SPECIMEN COLLECTION

SPUTUM:

Patients are advised to collect specimen as follows:

- Remove dentures and rinse mouth with water
- Take labelled specimen container and go out to an open space [Designated place]
- Open lid of specimen container
- Take a deep breath and cough deeply
- Spit out material into the specimen container
- Continue this process until the required amount of material (3-5ml) is collected into a 50ml translucent container
- Replace lid on the container
- Bring container with specimen to the Clinic which will then be forwarded to the laboratory

NOTE: A designated personnel is available at the DOTs Clinic to assist in collection, labelling and sorting of specimens from patients.

OTHER SPECIMENS:

For collection of other specimens such as plural fluid, biopsies and bronchial washes, please contact the Clinician at the DOTS Centre.

SPECIMEN COLLECTION / ACCEPTANCE / REJECTION CRITERIA

SPECIMEN ACCEPTANCE CRITERIA
All specimens being sent for laboratory investigation must be ***clearly labelled*** with the following information on the container: • Patient identification and Laboratory serial number • Date and time of collection • Required volume of specimen is 3-5ml
All specimens must be accompanied by ***patient documentation (specimen request form)***. Information required for each specimen is as follows: • Name of Health Unit, • Date/Time of request • Patient's information (i.e., name, sex, age, address, e.t.c.) • Sputum ID No/ Patients LGA TB No • Reason for examination (e.g., diagnosis or follow-up) • Specimen identification number • Month of treatment (follow-up/Diagnosis) • Signature of person requesting examination • All specimen collected from other facilities should be transported in a cold chain (at temp 2 to 8^0C) using a cold box • Please ensure legibility of patients' information.

REJECTED SPECIMENS AND FURTHER ACTIONS

SPECIMEN REJECTION CRITERIA	FURTHER ACTION
• Unlabeled or mislabeled specimen	• Specimen will be discarded and client notified
• Specimens with insufficient volume • Leaking specimen • Contaminated specimen • Salivary specimen • Bloody sputum sample (rejected only for GeneXpert assay) carry out AFB on the sample.	A new sample will be requested Inform requesting facility/Clinician.
• Specimens without request form	• Hold specimen, advice DOTs Clinic to send form. If no form is sent within 24 hrs, discard specimen and send out specimen rejection form.
• Samples brought to the lab without ice pack	• Such samples are rejected, then educate the facility on proper sample handling and transportation
• Samples are expected to get to the laboratory by 2:30pm	• Educate facilities on the need for proper documentation before close of work

Sample storage/ Transportation

Samples for culture should be sent immediately to the lab in a cold chain at the temperature 2^0-8^0C. but if the samples cannot be sent to the lab immediately, it must be kept in the temperature between 2^0-8^0C (temperature of refrigerator).

Sputum specimen must be transported in cold chain using triple packing. This is necessary to ensure that bacilli remain viable while on transit. The procedure for triple packing is as follows:

- Sputum should be collected in a well labelled transparent container (primary container)
- Each container should be wrapped with an absorbent material and placed in a ziplock bag (secondary container)
- The packaged ziplock bags should be placed in a sputum transport box with ice pack place at the bottom and top of the container (tertiary container)
- The transport box should be sealed and labelled "BIOHAZARD".

Specimen Transportation

The most important factors are the use of a triple packaging system to prevent damage and cross-contamination, storage (in a fridge for a maximum of one week), and transportation conditions.

The triple packaging method is used to pack specimens for transportation:

1. Leakproof primary receptacle:

This receptacle contains specimens, e.g., test tubes, Petri dishes, urine vial etc.

For liquid specimens, absorbent material (hi-tech polymer) is supplied in a quantity sufficient to retain the content of the primary receptacle and to wrap every primary receptacle, so they are individually separated.

2. Secondary Packaging:

Several primary receptacles can be housed in it for transport. It is capable of withstanding, without leakage, an internal pressure of 95 kPa (0.95 bar). The secondary packaging can be rigid (a canister with screw-on cap) or flexible (a two-pocket tray-sealed specimen bag, being the second one designed in order to protect information).

3. Outer Packaging:

The Outer Packaging made of 100% recyclable polypropylene ecopolymer is leakproof and strong enough to withstand usual shocks, loadings and accidents during transportation. Three secondary packaging can be set using Medimail/Cooler.

Medimail is yellow and all necessary marking is displayed on its external surface, including a security label to avoid unauthorized use

Factors that affect GeneXpert testing
Bloody samples
Samples with food particles

Tests available, Accreditation Status, Test Method, Frequency of Testing and Turn Around Times (TAT)

Test	Accreditation Status	Method	Testing Frequency	Turn Around Time	Comments
Microscopy for acid fast bacilli (AFB) detection	SANAS Accredited	Zeihl Neelsen Stain/ Fluorescent Microscopy	Daily (Mon – Fri)	24 to 48 hrs. after specimen receipt	Direct smear on clinical specimens
GeneXpert MTB/RIF Assay	SANAS Accredited	GeneXpert	Daily (Mon – Fri)	24 to 48 hrs. after specimen receipt	Now used as entry point for TB presumptive cases.
Primary Culture	SANAS Accredited	Solid culture using LJ slants, MGIT 960	Daily (Mon – Fri)	Usually available 4-6 weeks after specimen receipt. Negative cultures are reported after 6-8 weeks 2-6 weeks	Results for specimens that are contaminated are communicated to the facility to collect and resend a fresh sample.
Species Identification	On-going	**MPT64 TB test** Biochemicals Line probe assays	**Daily** Twice weekly (Monday and Thursday)	**48 hrs.** 1-14 days depending on method employed	Additional phenotypic and molecular methods may be required for some strains
Drug Susceptibility Testing to first- and Second-line drugs	On-going	Line probe assay (MTBDR*plus*) MGIT 960	As the samples are available.	5 days 3-4 weeks	Line probe assay – RIF and INH Fluoroquinolone, Injectables MGIT 960 and Proportion – SIRE, PZA

		Proportion method		4-6 weeks	**Proportion method - RIF, INH and EMB Fluoroquinolone and Injectables**

RIF – Rifampicin, SIRE – Streptomycin. Isoniazid, Rifampicin, Ethambutol, INH – Isoniazid, PZA – Pyrazinamide, EMB – Ethambutol

REPORTING OF RESULTS

Initial Report on specimens

Microscopy results: Direct / Concentrated/Culture smears

For Negative Smears:

- No Acid-Fast Bacilli seen (No AFB Seen)

For Positive Smears:

Microscopy results: Direct

Results are reported depending on number of bacilli seen on the smear and results can be as follows:

- (1) actual numbers
- (2) 1+
- (3) 2+
- (4) 3+

New positive results of AFB microscopy are telephoned as soon as they become available if clients request for it, usually within 48 hours. Written reports are issued within 2 working days from receipt of specimen.

Initial Reports on Positive Cultures

Culture positive, Mycobacterium species (after ZN is done and AFB seen on smear)

Final Report on Cultures after identification is performed

- Report species either as MTB Complex or NTM (when CM is done most NTMs can be identified), report species and clinical significance (if appropriate)
- If AFB seen and cannot be identified – report as mycobacteria species – unable to further identify
- If no growth was seen report at the end of 6 or 8 weeks – No growth seen after 6-8 weeks of incubation

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Molecular Line Probe Assay

- Report as MTBC, Sensitive or Resistant to Rifampicin and/or Isoniazid
- Report as MTBC, Sensitive or Resistant to fluoroquinolones and/or injectables

GeneXpert Assay

- Report as MTB detected
- MTB not detected
- RIF resistance detected
- RIF resistance not detected

Drug Susceptibility: Proportion Method

- Report Sensitive or Resistant to the first line drugs (include drug concentration used)

Cumulative reports

Cumulative results on a patient with positive results will be sent out at the end of the test

Delay in release of results

A delay in release of results is communicated through phone call, email or submission of a form to the Client requesting the test.

Other Services:

Research:

Research in various areas of Tuberculosis is conducted by the staff and Research Fellows attached to the centre for Tuberculosis research [CTBR]. For details on areas of research, please contact the Laboratory Director/Manager.

Training:

Training in various areas of TB diagnostics is conducted by the staff of the Centre for Tuberculosis Research, both for in-house staff as well as other institutions.

Confidentiality of Patient Information

Patient information as contained in all laboratory records and medical records are treated with utmost confidentiality. Towards this end, the NIMR, TB Reference Laboratory has a procedure in place to ensure patient confidentiality and to ensure that records of patient results are accessible only by authorized personnel.

a. Patient samples are given a unique identifier on receipt and this is used throughout the testing process
b. Employees are made to sign a confidentiality statement which is placed in their personnel file.
c. The confidentiality statement states that patient results will not be discussed with any third party, non-employees, friends or family
d. Employees will not discuss patient results in public or within the vicinity of other patients

e. Notebooks and registers containing patient results are kept in a lockable cabinet to prevent unauthorized access.

f. Telephone calls to patients will ensure that the patient is identified before results are given

g. Electronic records stored in computers are pass-worded to enhance access control.

h. For research projects, names and identity of patient will not be disclosed and published.

Distributions

#1 Clinicians

#2 Patients

#3 CTBR Website

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