

# Preventive and Routine Maintenance Curriculum and Plan for Tuberculosis Laboratory Equipment

Version I.0





INFECTIOUS DISEASE DETECTION AND SURVEILLANCE (IDDS)

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## List of Abbreviations

BI	Biological indicator	
BSC	Biological safety cabinet	
DR TB	Drug resistant TB	
ELI	European TB Laboratory Initiative	
HEPA	High-efficiency particulate air	
HIV	Human immunodeficiency virus	
LMP	Laboratory maintenance plan	
MDR TB	Multidrug-resistant TB	
MGIT	Mycobacteria growth indicator tube	
NTP	National TB Control Programme	
NTRL	National TB Reference Laboratory	
SOP	Standard operating procedure	
SRL	Supranational Reference Laboratory	
ТВ	Tuberculosis	
UV	Ultraviolet	
UVGI	Ultraviolet germicidal irradiation	
WHO	World Health Organization	
XDR TB	Extensively drug-resistant TB	

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### **Background**

Over the past decade, tuberculosis (TB) has become a major public health threat globally, including in Bangladesh. This situation has been further complicated by the need to expand laboratory services to address the challenges posed by the human immunodeficiency virus (HIV) epidemic, the emergence of multidrug-resistant TB (MDR TB) and extensively drug-resistant TB (XDR TB), and more recently, the COVID-19 pandemic.

Many National TB Control Programs (NTPs) have been in existence for nearly three decades. While treatment programs have been provided through NTP services, TB laboratory services have often been neglected. In the past few years this situation has changed. Investment in TB laboratories has increased due to increasing recognition of the critical role of the laboratory in TB control and in identifying and managing drug-resistant TB (DR TB). In 2007, the Global Laboratory Initiative was established by the Stop TB Partnership to accelerate and expand access to quality assured laboratory services in response to TB and DR TB diagnostic challenges. If TB laboratory services are to support NTPs effectively through TB diagnosis and monitoring, they need to provide reliable, valid, and timely results. High-quality equipment and reliable supplies are essential for quality-assured laboratory services.

Equipment management is an essential element of a quality management system program for any laboratory. Routine maintenance, calibration, and repairs require formal documentation and regular monitoring to ensure quality performance and optimize the lifespan of each piece of equipment (1-4). In addition, proper equipment installation, verification, and validation will ensure that routine test results produced for patient diagnosis and management are reliable, accurate and timely. A customer-support plan and maintenance contracts should be available for all items of capital equipment. Maintenance contracts are essential for all automated equipment and biosafety equipment and adequate budget needs to be allocated for this.

### **Preventive Maintenance**

Apart from maintenance by the manufacturer or their service engineer, preventive maintenance by laboratory staff or biomedical engineers is important to retain the correct functioning of equipment. Preventive maintenance includes measures such as systematic and routine cleaning, adjustment and replacement of equipment parts at scheduled intervals. Manufacturers generally recommend a set of equipment maintenance tasks that should be performed at regular intervals: daily, weekly, monthly, quarterly, or annually. Following these recommendations will ensure the equipment performs at maximum efficiency and will increase the lifespan of the equipment. This will also help to prevent:

- Inaccurate test results due to equipment failure
- Delays in reporting results
- Low productivity
- Large repair costs

### **Roles and Responsibilities for Equipment Maintenance**

A number of documents referenced provide a detailed description of the different steps necessary for facility and equipment maintenance (1-8). This document describes the roles of the key personnel groups which can vary based on the context and organizational structure within a TB program, required to design and enforce proper strategies and protocols necessary to sustain equipment performance. The key personnel groups are:

- National TB Program manager
- Laboratory manager
- Laboratory technical staff
- Biomedical engineer
- Equipment officer
- Quality officer
- Safety Officer

These key personnel groups are responsible for systematically organizing and managing the proper maintenance of all key laboratory equipment used in a TB clinical laboratory in a cost-efficient and sustainable manner. This is achieved by addressing four major questions listed below, which are further illustrated in

Figure 1, from the European Tuberculosis Laboratory Initiative's a proposed laboratory maintenance plan:

- 1. Which pieces of equipment need to be maintained?
- 2. When and how frequently (time interval) should the maintenance be performed?
- 3. Who is responsible for maintenance (i.e. most qualified and most appropriate)?
- 4. What type of maintenance task or work is to be completed?

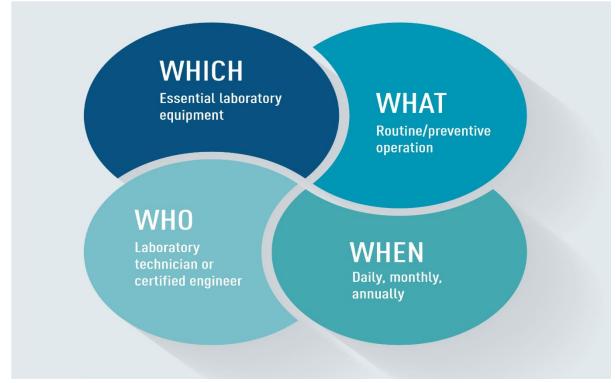


Figure I. European Tuberculosis Laboratory Initiative's proposed laboratory maintenance plan

### **Equipment Maintenance Plan**

A maintenance plan will include preventive maintenance procedures as well as provision for inventory, troubleshooting, and repair of equipment. When implementing an equipment maintenance program, some of the initial steps will include:

- Assigning responsibility for providing oversight
- Developing written policies and procedures for maintaining equipment, including routine maintenance plans for each piece of equipment that specifies the frequency with which all maintenance tasks are performed
- Developing the format for records, creating logs and forms, and establishing the processes to maintain records
- Training staff on the use and maintenance of the equipment, and ensuring that staff understand their specific responsibilities

If a piece of equipment malfunctions, users should:

- Check the manufacturer's instructions
- Determine the source(s) of the problem
- Make one change at a time, to attempt to diagnose the source of the problem
- Arrange for an engineer to visit if the problem cannot be resolved

Cleaning of equipment and regular maintenance are important for keeping equipment in good working order. Staff shall keep specific maintenance logs for all equipment, refer to the manufacturer's operational manual for recommended equipment scheduled maintenance, repair, and/or adjustments and keep adequate equipment maintenance records.

This document outlines two approaches to designing a proper laboratory maintenance plan (LMP). The plan illustrated in Figure 2 covers areas of maintenance which include both equipment and infrastructure (y-axis) by frequency (time interval; x-axis) and the person responsible for completing the task (indicated by color coding). This outline can be used to determine staff work load and when specialists or certified engineers, the NTP and/or the National TB Reference Laboratory (NTRL) managers are needed. From this LMP, the level of additional budget necessary to sustain maintenance practices (i.e. whether and how often a certified engineer is needed) can be determined.

		Laboratory Maintenance Plan						
		Time table and responsible person						
		Equipment	Daily/per procedure	Weekly	Monthly	Every 6 months	Yearly	As needed
c)	men							
nance	Equipment							
Area of Maintenance								
of Ma								
Area								
	ure							
	Infrastructure							
	ıfras							
	-							

Figure 2: First version of the LMP, as proposed by the European Tuberculosis Laboratory Initiative

Implementing a maintenance program for laboratory equipment requires the following steps (1-5)

- Assigning responsibility based on the LMP;
- Ensuring that manufacturer's instructions and operations manuals are on site;
- Developing a verification and validation protocol (for use after installation or repair);
- Calibrating equipment (as recommended by the manufacturer);
- Developing a written protocol to ensure proper equipment calibration, inspection or troubleshooting, and routine performance checks;
- Creating recording and reporting templates, logs or registers;
- Archiving documentation; and
- Providing well-documented staff training and refresher training programs.

## **Equipment Inventory**

All laboratories should have an inventory logbook created for all laboratory equipment (large and small). The log should be updated with information on new equipment and include documentation of when old equipment is retired. For each piece of equipment, the inventory logbook should have a record of the following(1-5):

- Equipment name and manufacturer
- Instrument type and/or model number
- Serial number
- Important specifications (e.g. voltage, hertz, capacity, size)
- Location in the laboratory
- Laboratory inventory number
- Date of purchase and date received
- Whether it was purchased new, used or reconditioned
- Date of installation
- Date of calibration
- Date of validation
- Date of entry into routine service
- Date retired
- Contact information for the manufacturer and vendor
- Verification that the manufacturer's operating instructions or manual are available on site
- Warranty (note expiration date)
- List of spare parts included in shipment (and their location).

It is recommended that a label is attached to the equipment indicating when the next maintenance or service should be performed and the calibration status (if applicable).

An inventory process should be implemented, and this can be done room by room. For example, conduct an inventory of equipment in the reception area, then the sample collection area etc. During the inventory, the condition of the equipment should be documented as functional, partially functional, or nonfunctional. Equipment that is not functioning needs to be evaluated as to whether or not it can be repaired. Non-repairable equipment should be retired, and work should be scheduled for equipment needing repair.

### **Inventory of Spare Parts**

To ensure that the laboratory does not run out of spare parts, an inventory record of those used most frequently should be kept for each piece of equipment. The record should include:

- Part name and number
- Average use of the part, and the minimum to keep on hand
- Cost
- Date when the part is placed into storage and when it is used (in and out stock log)
- Quantity of each part remaining in the inventory

## **Equipment Standard Operating Procedures (SOP)**

A SOP should be developed for each piece of equipment. SOPs may be based on templates recommended by the World Health Organization (6), but should be customized according to the manufacturer's instruction for each piece of equipment and include:

- General procedure for routine use
- Routine maintenance activities (based on the LMP)
- Function and safety checks
- Calibration protocols
- Troubleshooting information
- Manufacturer's service information.

Each piece of equipment should have a dedicated folder containing the manufacturer's instruction guide or manual, a SOP on the use and maintenance, concise operator instructions (quick guide), and a logbook for

recording data on routine calibrations, maintenance activities, error reports, service and repairs, and function checks. These records must be kept for the lifespan of the equipment; hence, they comprise the "book of life" for each piece of equipment.

All problems in equipment function should be recorded in the dedicated logbook, including:

- Date the problem occurred
- Date the equipment was removed from service
- Reason for the breakdown or failure (error codes or a description of what occurred when the equipment stopped normal operations, i.e. sounds, leaks, vibrations)
- Troubleshooting reports
- Whether decontamination was needed
- Date the service provider was contacted (if needed)
- Date the service provider responded
- Corrective actions taken
- Engineer reports of service and repair work performed
- Results of re-calibrations and verifications
- Date of return to use
- Changes to maintenance or function checks.

### **Retiring Equipment**

Equipment should be retired and removed from the laboratory when it is no longer functional and cannot be repaired. Questions to ask in terms of retiring equipment include the following:

- When should the equipment be retired?
- This might occur when experts indicate that an item cannot be repaired or is out-of-date and should be replaced with a new model.
- Why should an item be retired?
- Reasons might be to avoid issuing inaccurate test results, to free up valuable space, and to reduce hazards.
- How should an item be retired?
- A useful approach is to salvage any usable parts, taking into account any biohazards, and then follow safety disposal procedures for any parts that cannot be reused.

Laboratories should follow their institutional procedures regarding what approvals are required for retirement and disposal of laboratory equipment.

### **General laboratory equipment\***

\*All maintenance and service procedures must be recorded in the respective logs.

The maintenance process of laboratory equipment and responsibilities of the designated person are described below; and though this is indicated in the tables below, laboratories can determine the exact responsibilities based on local position titles and staff responsibilities.

#### Autoclaves

Autoclaves play a key role in sterilizing and decontaminating infectious materials (e.g. objects, media, waste) in laboratories. Maintenance of this equipment involves seven daily and weekly procedures that can be done by laboratory technicians, three monthly procedures that need the involvement or supervision of the biosafety officer, and seven annual or biannual procedures that can only be done by a qualified engineer. Refer to Table I for a description of each procedure.

Whi	ch	What	When	Who
Equipment	Task No.	Procedure	Time Interval	Responsible Person
		Temperature control for each sterilization cycle (autoclave tape test and sterilization report printout check)	Daily	Operating laboratory technician, supervised by equipment officer
		Bowie–Dick testing (air removal inside chamber control)	Daily	Operating laboratory technician, supervised by equipment officer
		Cleaning the front of the autoclave, controls, indicators and handles with a damp cloth	Daily	Operating laboratory technician, supervised by equipment officer
ω		Cleaning the sterilization chamber and drainage filter with non- chlorine/noncorrosive disinfectants	Weekly	Operating laboratory technician, supervised by equipment officer
Autoclave		Cleaning external rust-proof surfaces with a mild detergent	Weekly	Operating laboratory technician, supervised by equipment officer
۹		Lubricating the rubber O-ring	Weekly	Operating laboratory technician, supervised by equipment officer
		Draining the vapor generator	Weekly	Operating laboratory technician, supervised by equipment officer
		Replacing paper in the printer and checking ink levels in the recorder	As needed	Operating laboratory technician, supervised by equipment officer
		Checking for adequate functioning using a biological or chemical indicator	Weekly	Biosafety officer or operating laboratory technicians under direct supervision of the biosafety officer, in coordination with equipment officer
		Checking the temperature using chemical test strips	Weekly	Biosafety officer or operating laboratory technicians under direct supervision of the biosafety

Table I.	Maintenance p	plan for	autoclaves
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		officer, in coordination with equipment officer
Checking indicator lights; comparing temperature & pressure gauges with recordings	Monthly	Biosafety officer or operating laboratory technicians under direct supervision of the biosafety officer, in coordination with equipment officer
Checking the function of manometers	Every 6 months	Qualified and certified engineer or manufacturer service provider if the equipment is still under warranty or where applicable
Manually activating the safety valves	Every 6 months	Qualified and certified engineer or manufacturer service provider if the equipment is still under warranty or where applicable
Lubricating the door gasket	Every 6 months	Qualified and certified engineer or manufacturer service provider if the equipment is still under warranty or where applicable
Checking the seals of safety valves	Every 6 months	Qualified and certified engineer or manufacturer service provider if the equipment is still under warranty or where applicable
Calibrating the control unit	Annually	Qualified and certified engineer or manufacturer service provider if the equipment is still under warranty or where applicable
Maintaining and/or replacing filters	As needed	Qualified and certified engineer or manufacturer service provider if the equipment is still under warranty or where applicable
Maintaining solenoid valves	As needed	Qualified and certified engineer or manufacturer service provider if the equipment is still under warranty or where applicable

For general maintenance information, consult the Maintenance manual for laboratory equipment, 2nd edition (8), Chapter 12, Autoclave (pp. 81–92) and SOP module 11: use and maintenance of an autoclave (6). For information on safe management of waste from health-care activities, consult the second WHO document on safe management of wastes from health-care activities (7).

Success of the sterilization process should be routinely monitored using mechanical, chemical and biological indicators, as explained below.

- **Mechanical indicators**. For monitoring sterilization, the cycle time, temperature and pressure of sterilization equipment are recorded daily in the logbook by the instrument operator.
- Chemical indicators (internal and external). Sensitive chemicals are used to assess physical conditions such as temperature (autoclave tape, steam chemical process indicators) or steam penetration (Bowie–Dick test) during the sterilization process (following the manufacturers guidelines). Chemical indicators are heat sensitive (i.e. temperature-dependent color change). An internal chemical indicator should be placed in every sterilization package, and external indicators should be used when the internal indicator cannot be seen from outside the package. Single-parameter internal indicators measure provide information on only one sterilization parameter; multiparameter internal indicators measure

two to three parameters and can provide a more reliable indication that sterilization conditions have been met (e.g. autoclave test strips with time, steam and temperature control). Consult the manufacturer's instructions for the proper use and placement of chemical indicators.

• **Biological indicators (BIs)**. Bls are the most accepted method of monitoring the sterilization process because they directly determine whether the most resistant endospore-forming microorganisms (i.e. Geobacillus or Bacillus species) are viable after the sterilization cycle. Correct functioning of sterilization cycles should be verified for each sterilizer via the periodic (at least weekly) use of Bls. Follow the manufacturer's instructions on the most appropriate placement of the Bl in the sterilizer.

As well as in routine monitoring, BI's should be used under the following conditions:

- Whenever a new type of packaging material or tray is used
- After training new sterilization personnel
- After a sterilizer has been repaired
- After any change in sterilizer loading procedures.

#### Air displacement pipettes

Pipettes are devices used for measuring or transferring small volumes of liquid with great precision. Pipettes are widely used when performing most TB laboratory tests, and their functionality is very important. A dedicated logbook for leakage control and calibration of pipettes should contain records of these parameters. Four maintenance procedures can be performed by the responsible laboratory technician under the supervision of the Equipment Officer and Quality Officer and three procedures should be done only by the Equipment Officer.

Which		What	When	Who
Equipment	Task No	Procedure	Time Interval	Responsible Person
		Inspecting the integrity and adjusting the mechanism	Daily or per procedure	Operating laboratory technician under the supervision of the equipment officer
		Testing leakage control by putting on a tip and filling it with distilled water	Daily or per procedure	Operating laboratory technician under the supervision of the equipment officer
ettes		Disassembling and cleaning all pipette parts	Biannually	Service Engineer
ent pip		Calibrating pipette using a standardized procedure	Biannually	Service Engineer
Air displacement pipettes		External cleaning and decontamination with a mild detergent	As needed	Operating laboratory technician under the supervision of the equipment officer
		Sterilizing the pipette according to the manufacturer's instructions	As needed	Equipment officer or responsible Laboratory staff <sup>1</sup>
		After using harmful substances, complete decontamination is needed Plan the maintenance and calibration of all the pieces of	As needed	Equipment Officer or as assigned

Table 2. Maintenance plan for air displacement pipettes

<sup>&</sup>lt;sup>1</sup> Position title is dependent on the organizational structure, context and the availability of resources. In some instances, equipment officer and lab staff could be the same person.

equipment present in the laboratory. Make a yearly schedule in which the planned maintenance/calibration is shown.
Arrange for sufficient funding with the laboratory manager Start adhering to this schedule.

For general maintenance information, consult Chapter 16, Pipettes (pp. 119–26), in the Maintenance manual for laboratory equipment, 2nd edition (8).

### **Biological safety cabinet**

Biological safety cabinets (BSCs) are the most important items of safety equipment for working with air-borne infectious substances. The proper functioning of BSCs ensures safety for workers who are handling potentially infectious substances and so this equipment must be adequately monitored and maintained.

- All internal and external surfaces of the safety cabinet should be visually examined to ensure that there are no surface defects or other damage.
- Smoke test for down flow and inflow visualization should be performed based on the corresponding standard relevant to the specific BSC with reference to the manufacturer's instructions.
- The downflow and inflow air velocity must be checked in accordance with the manufacturer's requirements and adjusted if necessary.
- An aerosol leakage test should be performed for the HEPA filters using a particle counter or photometer. Each filter should be tested independently.
- The alarm indicators should be checked according to the manufacturer's specifications. The alarm device should be calibrated, if necessary.
- The extraction duct system should be visually inspected to ensure that it is free from defects, cracks and other damage, and that it is clearly labelled.

A spare set of suitable HEPA filters should be available in the laboratory in case the filter leaks but filters must only be replaced by a service engineer.

Whic	h	What	When	Who
Equipment	uipment Task no Procedure		Time Interval	Responsible Person
		Disinfecting internal working parts with 70% alcohol or equivalent before and after use	Daily (before and after usage)	Responsible laboratory technician
ų		Visually examine internal and external surfaces to ensure that there are no surface defects or other damage	Daily (before and after usage)	Responsible laboratory technician
Class II BSC		Check alarm indicators according to the manufacturer's specifications	Daily or as specified by the manufacturer's specifications.	Responsible laboratory technician
Ū		Checking the airflow conditions on the display and checking the inward air velocity using a vaneometer	Daily (before usage)	Responsible laboratory technician
		Switching on the built-in UV lamp (if installed) after use	Daily (after usage for 30 min if the time is not regulated	Responsible laboratory technician

Table 3. Maintenance plan for class II biosafety cabinets

		automatically by the BSC)	
	Air sampling on agar plates for BSC product protection testing	Every 6 months	Responsible laboratory technician
	Visually examining airflow (inflow and downflow) using smoke test tubes and inspecting extraction duct system to ensure that it is free from defects, cracks and other damage	Monthly	Responsible laboratory technician
	Disinfecting and cleaning external parts with a general cleaner	Monthly	Responsible laboratory staff
	Disinfecting and cleaning internal parts with a general cleaner	Quarterly	Responsible laboratory staff
	Installation testing	At installation and relocation, before beginning of operation	Qualified engineer/ technician
	Field testing and certifying each BSC as per corresponding standard (EN 12469, NSF/ANSI 49 or other)	Annually	Qualified engineer/ technician
	Replacing HEPA filters (with recalibration and recertification)	As needed according to the engineer's report	Qualified engineer/ technician
BSC MAINTENECE EQUIPMENT	Calibration	Annually	Qualified body (ISO 17025 accredited)

A dedicated logbook should be created for recording maintenance procedures. Most maintenance procedures can be done by the responsible laboratory technician however, annual certification, and if necessary changing the high-efficiency particulate air (HEPA) filters (and subsequent recertification), must be performed only by authorized engineers based on the corresponding standards (EN 12469, NSF 49 or others).

Class II BSC procedures I–7 can be performed by an operating laboratory technician under the supervision of the Equipment Officer and Safety Officer. BSC maintenance equipment procedure I should ideally be done yearly by an ISO 17025 accredited organization. The following should be part of the routine preventive maintenance and use procedures:

- Daily airflow readings (of actual values or signals) of the BSC display and measured values using a vanometer (for qualitative indication of velocity, containment and turbulence) should be recorded in the daily BSC maintenance log. If the reading is below the threshold based on the manufacturer's manual or shows a warning signal, the BSC should not be used and the head of the laboratory alerted to initiate the testing of the BSC by a qualified engineer/technician.
- Qualitative checks across the entire width of the BSC opening should be performed with a smoke generator. The smoke test is an indicator of airflow direction, not of velocity, as suggested manufacturer guidelines.
- Air sampling (passive) is used to check for product protection only. This test cannot be used to assess personal protection provided by the BSC and it does not replace the annual field testing and

certification by a specialist. A negative air sampling result (no growth on the test plates and negative control) cannot lead to the conclusion that the BSC is functioning properly. The annual BSC field testing needs to be performed on schedule.

For the air sampling test (in accordance to EN 12469, NSF/ANSI 49 standard or equivalent) the entire BSC workspace is covered with suitable agar plates (e.g., blood or nutrient agar) during laboratory operating times. All test agar plates should be exposed without lids for 30 min in the BSC. In addition, two agar plates are used for the negative control, the first one incubated without being placed inside the BSC (no exposure) and the second one placed inside the BSC with the others but the lid of the agar plate is not removed (no exposure). The agar plate for the positive control is one where one agar plate is placed on a laboratory bench outside of the BSC and the lid removed for 30 minutes; this allows bacteria in the air to settle onto the agar plate. Subsequently all plates, including the positive and negative controls are incubated at  $36\pm 1^{\circ}$ C for 24h and 48h at which times the plates are read for any microbial growth. Interpretation of results:

- Acceptable performance of the BSC:
- No growth on the plates placed in the BSC with lids removed
- Growth on the positive control plate
- No growth on the negative control plates
- Unacceptable performance of the BSC:
- Growth on the plates placed in the BSC with lids removed
- Growth on the positive control plate
- No growth on the negative control plates

If unacceptable BSC performance is noted, it should not be used and be checked by a qualified engineer/technician.

Class II BSC procedures 8 and 10 can be only performed by an authorized engineer in the presence of the Equipment Officer and Safety Officer. Obligatory annual certification of each BSC unit should be performed in accordance with the corresponding standard (EN 12469, NSF/ANSI 49 or other).

For general maintenance information, consult Chapter 6, Biological safety cabinet (pp. 35–44), in the *Maintenance manual for laboratory equipment, 2nd edition*, and SOP module 10: use and maintenance of class I and class II biological safety cabinets ). **(6)**.

#### Centrifuge

The centrifuge is used for concentrating specimens after decontamination procedures. Centrifugation at the correct speed and temperature is important for preserving viable mycobacteria in specimens. These parameters should be recorded in a dedicated logbook for each procedure and use.

Which		What	When	Who
Equipment	Task no	Procedure	Time Interval	Responsible Person
ω		Drying condensed water in the rotor chamber after use	Daily	Responsible laboratory staff under the supervision of the Equipment Officer
Centrifuge		Balancing buckets before spinning	Each time of use	Responsible laboratory staff under the supervision of the Equipment Officer
0		Disinfecting the centrifuge chamber and rotor buckets	Weekly	Responsible laboratory staff under the supervision of the Equipment Officer

Table 4. Maintenance plan for centrifuges

Lubricating rotor trunnions	Monthly	Responsible laboratory staff under the supervision of the Equipment Officer
Cleaning external surfaces with a general-purpose cleaner	Monthly	Responsible laboratory staff under the supervision of the Equipment Officer
Disinfecting after spillage	As needed	Responsible laboratory staff under the supervision of the Equipment Officer and Safety Officer
Checking and calibration	Annually	Qualified engineer/ technician under the supervision of the Equipment Officer.

For general maintenance information, consult Chapter 7, Centrifuge (pp. 45–52), in the Maintenance manual for laboratory equipment, 2nd edition (8), and SOP module 13: use and maintenance of a centrifuge (6).

#### **Drying oven**

In the laboratory, drying ovens (also known as hot air ovens) are used for drying and sterilizing glass and metal containers. The operating temperature is between room temperature and 350°C.

Which	1	What	When	Who
Equipment	Task no	Procedure	Time Interval	Responsible Person
		Checking temperature	Daily	Responsible laboratory staff
g Oven		Cleaning surfaces with 70% alcohol	Weekly	Responsible laboratory staff
Drying		Servicing	Annually or as needed	Qualified engineer/ technician in the presence of the Equipment Officer

Table 5. Maintenance plan for drying ovens

For general maintenance information, consult Chapter 13, Drying oven (pp. 93–8), in the Maintenance manual for laboratory equipment, 2nd edition (8).

#### Freezer/refrigerator/ultralow freezer

Refrigerators and freezers are among the most important pieces of laboratory equipment. They maintain a temperature controlled (refrigerated or frozen) environment for storing various liquids, reagents and specimens. Different kinds of refrigerators and freezers are used in the laboratory, and temperature logs should be kept for each. If the laboratory uses combined refrigerators/freezers, then thermometers should be placed in both compartments and temperatures taken and recorded from both. Maintenance procedures can be performed by the responsible laboratory technician under the supervision of the Equipment Officer and Quality Officer. As shown in Table 6, one of the procedures for the ultralow freezer (Freezer, Task I) should be performed only by a qualified engineer.

Table 6. Maintenance	plan	for freezers	/refrigerators
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Whick	า	What When		Who
Equipment	Task no	Procedure	Time Interval	Responsible Person

	Checking temperature control (display and	Daily	Responsible laboratory staff under the supervision of the
	thermometer)		Equipment Officer
	Cleaning internal and external surfaces	Monthly	Responsible laboratory staff under the supervision of the Equipment Officer
	Checking gasket seals	Monthly	Responsible laboratory staff under the supervision of the Equipment Officer
	Checking blower fan for proper operation	Monthly	Responsible laboratory staff under the supervision of the Equipment Officer
Refrigerator	Checking hot air vents with cooling fans near the bottom, cleaning with vacuum	Monthly	Responsible laboratory staff under the supervision of the Equipment Officer
	Cleaning filters, washing with general purpose disinfectant	Monthly	Responsible laboratory staff under the supervision of the Equipment Officer
	Defrosting	Every 6 months	Responsible laboratory staff under the supervision of the Equipment Officer
	Cleaning the condenser	Every 6 months	Responsible laboratory staff under the supervision of the Equipment Officer
	Verifying the door gasket is functional	Every 6 months	Responsible laboratory staff under the supervision of the Equipment Officer
zer	Maintaining the alarm system battery (if installed)	Biannually	Qualified engineer/ technician
Freezer	If the frost thickness is > 8 mm, defrosting and cleaning/disinfecting	As needed	Responsible laboratory staff

For general maintenance information, consult Chapter 18, Refrigerators and freezers (pp. 131–42), in the *Maintenance manual for laboratory equipment, 2nd edition* (8), SOP module 14: use and maintenance of a freezer and module 15: use and maintenance of a refrigerator **(6)**.

#### Incubator

An incubator is a chamber with controlled temperature, atmosphere and humidity; it is used for maintaining live organisms in a suitable growth environment. Some incubators have  $CO_2$  injection for achieving specific atmospheric conditions to support the growth of *Mycobacterium tuberculosis* in specific medium. Temperature logs should be updated daily for each incubator. All maintenance procedures except for servicing can be performed by the responsible laboratory technician under the supervision of the Equipment Officer.

 Table 7. Maintenance plan for incubators

Whie	ch	What	When	Who
Equipment	Task No.	Procedure	Time interval	Responsible person
		Checking temperature controls (display and thermometer)	Daily	Responsible laboratory staff under the supervision of the Equipment Officer
ncubator		sinfecting internal and external surfaces	Monthly	Responsible laboratory staff under the supervision of the Equipment Officer
lncub		Full cleaning, removing old cultures, disinfecting internal surfaces and cleaning fan filter vents (if present)	Annually	Responsible laboratory staff under the supervision of the Equipment Officer
		Servicing	As needed	Qualified engineer/ technician under the supervision of the Equipment Officer

For general maintenance information, consult Chapter 14, Incubator (pp. 99–104), in the Maintenance manual for laboratory equipment, 2nd edition (8), and SOP module 16: use and maintenance of an incubator (6).

#### Microscope

In TB laboratories, microscopes are used for sputum smear acid-fast bacilli microscopy. Two types of microscopes are used for TB diagnostics: clear field optical microscopes and fluorescence optical microscopes. Routine maintenance can be performed by responsible laboratory staff under the supervision of the Equipment Officer. Basic adjustments and cleaning can be done by the Equipment Officer. Specialized servicing tasks should be done only by a qualified engineer.

Which		What	When	Who
Equipment	Task No	Procedure	Time interval	Responsible person
Microscope		Cleaning the objective lens, removing residual oil	Daily	Responsible laboratory staff under the supervision of the Equipment Officer
		Covering the microscope with a dust cover	Daily	Responsible laboratory staff under the supervision of the Equipment Officer
		Removing dust particles from eyepieces, objectives and condenser with a rubber bulb air blower	Monthly	Responsible laboratory staff under the supervision of the Equipment Officer

Table 8. Maintenance plan for microscopes

Removing the slide holder mechanism, cleaning carefully and reinstalling, and circling the optics	Monthly	Responsible laboratory staff under the supervision of the Equipment Officer
Verifying that good ventilation conditions, temperature and humidity control are in place	Every 6 months	Responsible laboratory staff under the supervision of the Equipment Officer
Testing the quality of the electrical system of the microscope	Every 6 months	Responsible laboratory staff under the supervision of the Equipment Officer
Servicing	As needed	Qualified engineer/ technician in presence of the Equipment Officer

Procedures 1–6: All troubleshooting procedures described in the manufacturer's manual should be performed by the Equipment Officer.

For general maintenance information, consult Chapter 15, Microscope (pp. 105–18), in the Maintenance manual for laboratory equipment, 2nd edition (8), and SOP module 18: use and maintenance of a light microscope (6).

#### pH meter

The pH meter is used to determine the concentration of hydrogen ions,  $[H^+]$ , in a solution by measuring the difference in electrical potential between the pH electrode and a reference electrode. pH meters are also called pH analyzers, pH monitors or potentiometers. All maintenance procedures can be done by responsible laboratory staff under the supervision of the Equipment Officer.

Which	า	What	When	Who
Equipment	Task No	Procedure	Time interval	Responsible person
		Rinsing and drying the electrode with deionized water and clean paper towels	Daily	Responsible laboratory staff under the supervision of the Equipment Officer
pH Meter		Calibrating before each use	Daily	Responsible Laboratory Staff under the supervision of the Equipment Officer
		Maintaining and cleaning of the electrode	Every 4 months or as needed	Responsible laboratory staff under the supervision of the Equipment Officer
		Evaluating the general physical condition of the parts: cables, connections, controls, meter, electrode	Every 6 months	Responsible laboratory staff under the supervision of the Equipment Officer

Table 9. Maintenance plan for pH meters

For general maintenance information, consult Chapter 3, pH meter (pp. 13–20), in the Maintenance manual for laboratory equipment, 2nd edition (8), and SOP module 20: use and maintenance of a pH meter (6).

#### Precision and analytical balances

Precision and analytical balances are important for preparing media and reagents. These very sensitive instruments need regular maintenance and periodic calibration. All procedures can be performed by laboratory staff under the supervision of the Equipment Officer or Quality Officer.

Whic	:h	What	When	Who
Equipment	Task No	Procedure	Time interval	Responsible person
Balance (Precision or Analytical)		Cleaning the weighing chamber, externally and internally	Daily or at each time of use	Responsible laboratory staff under the supervision of the Equipment Officer
		Verifying the adjustment mechanisms on the front door (if one is present)	Daily or at each time of use	Responsible laboratory staff under the supervision of the Equipment Officer
		Accuracy checking with externally certified reference weights	Every 6 months	Responsible laboratory staff under the supervision of the Equipment Officer and Quality Officer.
		Internal calibration: drift check performance check measurement uncertainty check	After maintenance, relocation, power failure	Responsible laboratory staff under the supervision of the Equipment Officer and Quality Officer.

Table 10	. Maintenance	plan	for	the	balance
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#### **Reference** weights

Reference weights are calibrated as indicated by the manufacturer. The weight tolerance is equal to ANSI/ASTM E617 Class 0 and exceeds OIML R 111 Class E2. This class is used as a reference standard for calibrating other reference standards and weights and is appropriate for calibrating high-precision analytical balances with scale readability of as low as 0.01 mg (Siddiqi, 2006).

#### **Drift check**

For calculating the drift, 10 measurements for the 10 mg weight should be noted in the performance check log. Variation in the observed weight from the mean value should not exceed  $\pm$  0.2 mg. The 10 mg weight should meet the performance check criteria of the mass value (i.e. 0.1% of actual mass value). For example, for all the 10 measurements of the 10 mg weight, the variation at weighing cannot exceed 0.01 mg.

#### **Performance check**

After autocalibration, add 1 mg, 2 mg, 5 mg, 10 mg and 20 mg weights individually. The measurement should be within the 0.1% of actual mass value of the individual weight as given in the performance check log.

#### Measurement uncertainty check

The measurement uncertainty should be calculated by first determining the mean and standard deviation of 10 measurements of the 10 mg weight and then inserting these values into the following equation: The measurement uncertainty should not be more than 0.001 (Sander, 2016 10). For general maintenance information, consult Chapter 4, Balances (pp. 21-30), in the *Maintenance manual for laboratory equipment, 2nd edition* (8), and SOP module 12: use and maintenance of an electromagnetic balance (6).

### Thermal cycler

The thermal cycler is used for amplifying DNA from samples in the line probe assay. All maintenance procedures, except for servicing, can be performed by responsible laboratory staff under the supervision of the Equipment Officer.

Whic	ch	What	When	Who
Equipment	Task No	Procedure	Time interval	Responsible person
Thermal Cycler		Removing dust from external surfaces with a lint-free cloth and distilled water	Weekly	Responsible laboratory staff under the supervision of the Equipment Officer
		Cleaning the heated lid with a mild detergent	Weekly	Responsible laboratory staff under the supervision of the Equipment Officer
		Checking the temperature inside the heated lid	As needed	Responsible laboratory staff under the supervision of the Equipment Officer
		Cleaning the sealing tape and unit frame with 70% alcohol	Weekly	Responsible laboratory staff under the supervision of the Equipment Officer
		Servicing	Annually or as needed	Qualified engineer/ technician under the supervision of the Equipment Officer

For more information, consult the manufacturer's manual (14).

#### Water-bath and heat block

In the TB laboratory, the water-bath is used for inactivating TB cultures before DNA extraction for the line probe assay or genome sequencing. Water-baths are normally used at between room temperature and 100°C. Water-bath chambers have a capacity of 2–30 l.

Heat blocks are used for a range of procedures, including heat killing mycobacteria during specimen processing for molecular analyses. Routine maintenance procedures can be performed by responsible laboratory staff under the supervision of the Equipment Officer.

Table 12. Maintenance plan for water-baths

Which		What	When	Who
Equipment	Task No	Procedure	Procedure Time interval	
		Lubricating (for water-baths with agitating or circulator unit)	Daily	Responsible laboratory staff under the supervision of the Equipment Officer
Water Bath		Cleaning the tank interior and exterior with a mild detergent and rinsing with clean water	Monthly	Responsible laboratory staff under the supervision of the Equipment Officer

	Periodic inspection: checking the thermometer or temperature controls, recording results in the logbook	Quarterly	Responsible laboratory staff under the supervision of the Equipment Officer
	Cleaning the unit and heating blocks with a mild detergent	Weekly or as needed	Responsible laboratory staff under the supervision of the Equipment Officer
Heat Block	Calibrating	Every 6 months	Responsible laboratory staff under the supervision of the Equipment Officer
	Servicing	As needed	Qualified engineer/ technician

For general maintenance information, consult Chapter 5, Water bath (pp. 31–4), in the Maintenance manual for laboratory equipment, 2nd edition (8), and the generic WHO SOP for water-bath use and maintenance (17).

#### Water distiller

The laboratory water distiller (also called the distillation unit or water still) purifies main water via controlled vaporization and cooling processes. Distilled water is used for preparing culture medium and other reagents. All routine maintenance procedures can be performed by responsible laboratory staff under the supervision of the Equipment Officer.

Which		What	When	Who
Equipment	Task No	Procedure	Time interval	Responsible person
		Inspecting and cleaning the vapor generator tank	Monthly	Responsible laboratory staff under the supervision of the Equipment Officer
Water Distiller		Changing the activated carbon filter	Quarterly	Responsible laboratory staff under the supervision of the Equipment Officer
		Cleaning the condenser	Annually	Responsible laboratory staff under the supervision of the Equipment Officer
		Sterilizing the distilled water storage tank using a chemical process with chlorine-based bleach	As needed	Responsible laboratory staff under the supervision of the Equipment Officer

#### Table 13. Maintenance plan for water distillers

For general maintenance information, consult Chapter 8, Water distiller (pp. 53–8), in the Maintenance manual for laboratory equipment, 2nd edition (8), and SOP module 21: use and maintenance of a water distiller (6).

#### **Specialized instruments**

 The BACTEC MGIT 960 TB system is an automated system for growing Mycobacterium tuberculosis in liquid medium (Middlebrook 7H9 modified broth) using mycobacteria growth indicator tubes (MGIT). This instrument ensures better recovery and faster growth of mycobacteria. Six maintenance procedures can be done by the responsible laboratory technician under the supervision of the Equipment Officer and Quality Officer, and one procedure (annual servicing) should only be done by a Becton Dickinson engineer. For more information, consult the BACTEC MGIT 960 manufacturer's manual (9).

Whic	:h	What	When Who	
Equipment	Task No	Procedure	Time interval	Responsible person
	I	Temperature control and recording	Daily	Responsible laboratory staff under the supervision of the Equipment Officer
		Checking drawer and section light indicators	Daily	Responsible laboratory staff under the supervision of the Equipment Officer
		Cleaning external surfaces with a general-purpose cleaner	Weekly	Responsible laboratory staff under the supervision of the Equipment Officer
BACTEC		Replacing dust filters	Monthly	Responsible laboratory staff under the supervision of the Equipment Officer
MGIT 960 TB system		Archiving the results and saving onto an external hard disk	Monthly	Responsible laboratory staff under the direct supervision of the Quality Officer in coordination with the Equipment Officer
		Changing calibrators	As needed	Responsible laboratory staff under the direct supervision of the Quality Officer in coordination with the Equipment Officer
		Service maintenance	Annually	Qualified engineer/ technician in the presence of the quality officer and Equipment Officer

Table 14. Maintenance plan for the BACTEC MGIT 960

2. The GeneXpert Dx system is a fully integrated and automated on-demand molecular diagnostic system with a mini-polymerase chain reaction laboratory enclosed within each module. All maintenance procedures can be performed by the responsible laboratory technician under the supervision of the Equipment Officer.

Which What		When	Who	
Equipment	Task No	Procedure	Time interval	Responsible person
		Discarding used cartridges	Daily	Responsible laboratory staff under the supervision of the Equipment Officer
		Cleaning the cartridge bay interior	Weekly	Responsible laboratory staff under the supervision of the Equipment Officer
GeneXpert DX		Restarting the system (GeneXpert and computer)	Weekly	Responsible laboratory staff under the supervision of the Equipment Officer
System		Cleaning the syringe plunger rod	Monthly	Responsible laboratory staff under the supervision of the Equipment Officer
		Cleaning instrument surfaces	Monthly	Responsible laboratory staff under the supervision of the Equipment Officer
		Cleaning the optics inside the PCR tube slot with a dry brush	Monthly <sup>a</sup>	Responsible laboratory staff under the supervision of the Equipment Officer
		Cleaning the fan filters with a mild detergent	Monthly	Responsible laboratory staff under the supervision of the Equipment Officer
		Archiving and saving data to an external drive	Monthly	Responsible laboratory staff under the supervision of the Equipment Officer
		Checking the calibration of all modules using manufacturer's procedures (and replacing if necessary)	Annually or after 2000 tests/module	Responsible laboratory staff or service engineer, under the supervision of the Equipment Officer

Table 15. Maintenance plan for the GeneXpert Dx system

Depending on placement – if there are high levels of humidity and dust, this maintenance procedure should be performed weekly. For more information, consult the Cepheid GeneXpert maintenance module (12)

3. The GT-Blot is one of the instruments used for the line probe assay. All maintenance procedures can be performed by the responsible laboratory technician under the supervision of the Equipment Officer.

Wh	ich	What	When Who	
Equipment	Task No	Procedure	Time interval	Responsible person
GT-Blot		Cleaning the GT-Blot trays	procedureunder the supervision of the Equipment OfficereWeeklyResponsible laboratory staff under the supervision of the	
		Cleaning the insert for the internal tray with 70% ethanol and a cotton-tipped applicator stick		
		Washing and rinsing the delivery pipes	y Weekly Responsible laboratory staff under the supervision of the Equipment Officer	
		Cleaning the outside of the instrument with a moist, lint- free cloth	Monthly	Responsible laboratory staff under the supervision of the Equipment Officer

Table 16. Maintenance plan for the GT-Blot

For more information, consult the manufacturer's manual (13).

4. The TwinCubator is used for DNA hybridization in the line probe assay. All maintenance procedures, except of servicing, can be performed by responsible laboratory staff under the supervision of the Equipment Officer.

Whic	Which What Whe		When	Who
Equipment	Task No	Procedure	Time interval	Responsible person
Twincubator			Daily or per procedure	Responsible laboratory staff
		Cleaning with 1% bleach and rinsing with water	Weekly	Responsible laboratory staff
		eaning the unit frame with 70% ethanol	Weekly	Responsible laboratory staff
		Cleaning the wells of the hybridization block after spillage	As needed	Responsible laboratory staff
		Rinsing the plastic trays used for hybridization reactions with distilled water and UV exposure (may be reused several times)	As needed	Responsible laboratory staff
		Prior to each service, cleaning and decontaminating the case (70% ethanol) and wells (1.5% bleach)	As needed	Responsible laboratory staff

Servicing	Annually or as needed	Qualified engineer/ technician
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For more information, consult the manufacturer's reference manual (15) or the SOP (16).

### Laboratory facility\*

\*All maintenance and service procedures must be recorded in the respective logs. Fire extinguishers should be in good working condition and regularly checked for functionality by the Safety Officer.

Which		What	When	Who
Equipment	Task no	Procedure Time interval		Responsible person
	Checking gauge or pressure Monthly indicator for the correct pressure	Safety officer		
		Checking the site and accessibility	Monthly	Safety officer
Fire Extinguisher		Examining thoroughly and repairing, recharging or replacing as necessary (this might reveal the need for hydrostatic testing)	Annually	Service engineer
		Completely discharging, cleaning, inspecting and recharging after each use	As needed	Service engineer

TABLE 18. Maintenance plan for fire extinguishers

More information can be obtained from the Fire Equipment Manufacturers' Association (http://www. femalifesafety.org/types-of-extinguishers.html) and Fire Extinguisher Training (http://www. fireextinguishertraining.com/).

1. Uninterruptable power (UPS) supply is used to support equipment in case of power failure. It should be serviced annually by a qualified engineer.

Table 19. Maintenance plan for uninterruptable power supply

Which	What	When	Who
UPS	Preventive maintenance	Annually	Qualified engineer/ technician

For more information, consult the accompanying manufacturer's manual.

Upper-room UV germicidal irradiation (UVGI) and UV Air-Clean workstations: UVGI lamps are used for room air disinfection as they destroy infectious agents in the air. Exposure to UV radiation damages the nucleic acid of bacteria and viruses, including *M. tuberculosis*, thereby preventing replication. UVGI generally uses a UV wavelength of 253.7 nm (within the UVC, 100 - 280 nm). The lamps should be checked for emission of the appropriate wavelength at least once every six months by a qualified specialist. Other maintenance procedures should be done by responsible laboratory staff under the supervision of the Equipment Officer.

Whic	h	What	When	Who
Equipment	Task No	Procedure	Time interval	Responsible person
		Checking the operation of UV lamps: both external and inside the re-circulator	Daily	Responsible laboratory staff
UV Air-Clean workstations		Cleaning the workstation surface with 70% alcohol, chlorine-based bleach solution or DNA/RNA- removing solution	Daily	Responsible laboratory staff
		Checking the dust filter at both ends of the UV re-circulator with the internal UV lamp; cleaning filters by unclipping the covers, rinsing filters in water, drying and reinstalling in reverse sequence	Monthly	Responsible laboratory staff
		Cleaning with 70% alcohol	Every 2-3 months	Responsible laboratory staff
Upper-room (UVGI)		Checking irradiance effectiveness and safety using a calibrated UV meter	Every 6 months	Qualified engineer/ technician
		Changing the lamp	As needed, according to hours of use	Responsible laboratory staff

Table 20. Maintenance plan for upper-room UVGI and UV AirClean workstations

For more information, see Applications of ultraviolet germicidal irradiation disinfection in health care facilities: Effective adjunct, but not standalone technology (18) and Using ultraviolet radiation and ventilation to control tuberculosis (19).

Ventilation systems, in addition to biosafety cabinets, is one of the most important systems for providing biosafety in TB (and other airborne disease) laboratories undertaking manipulation of infectious material. To ensure safety for laboratory workers, the ventilation system should be properly maintained and serviced. Routine maintenance procedures are performed by the Safety Officer, Equipment Officer and responsible laboratory staff. Servicing, calibration, filter replacement and disinfection should be performed only by a qualified engineer.

Whic	:h	What	When	Who	
Equipment Task No		Procedure Time inter		Responsible person	
Ventilation system		Monitoring and recording air pressure	Daily	Responsible laboratory staff	
		Measuring air direction (exhaust and supply) using a smoke test	Weekly	Responsible laboratory staff	
		Checking <b>BSC</b> exhaust air if a thimble connection is present	Weekly	Responsible laboratory staff	

Table 21. Maintenance plan for ventilation systems

Sampling air on agar dishes during and after use	Monthly	Responsible laboratory staff
Checking the filter	Monthly	Responsible laboratory staff
Changing prefilters at the air intake point	Quarterly <sup>a</sup>	Responsible laboratory staff
Maintaining and servicing the entire ventilation system (checking function, air volume, pressure, filters, control system, safety devices, cooling/ heating/electrical supply system)	Every 6 Qualified engineer/ months technician	
Servicing and calibrating the ventilation system after maintenance	Annually	Qualified engineer/ technician
Replacing filter if the pressure drops below the critical value	As needed	Qualified engineer/ technician
Cleaning and disinfecting	As needed	Qualified engineer/ technician

The following recommendations are aimed to minimize dust pollution in the laboratory and prolong the life of BSC HEPA filters.

- Incoming air should be pre-filtered through GI (EUI) and G4 (EU4) type filters for coarse dust and an F9 (EU9) type filter for fine dust. Filters need to be replaced when the pressure drops below the critical value (as specified by the ventilation engineer for each ventilation system). The pressure should be monitored using an inclined tube manometer and documented each month.
- 2. The pipes of the ventilation system should be cleaned (after each prefilter replacement).
- 3. The control unit should be calibrated annually by a qualified engineer.
- 4. Wet cleaning of the laboratory and surrounding rooms should be done every day.
- 5. The windows must be always closed in the biosafety level 3 area. Doors and transfer hatches should have airtight seals.

For more information, consult the Tuberculosis Laboratory Biosafety Manual (20); Chapter 7, Tuberculosis infection control, in the Core curriculum on tuberculosis: what the clinician should know (21) and Using ultraviolet radiation and ventilation to control tuberculosis (19)

## References

- World Health Organization (WHO). (2017). Tuberculosis Laboratory Maintenance Plan (LMP) for preventive and routine maintenance of laboratory equipment Expert opinion of the European Tuberculosis Laboratory Initiative. Europe: WHO.
- World Health Organization (WHO). (2005). Laboratory quality management system (QMS) training toolkit. Geneva: World Health Organization, Retrieved from <u>https://www.who.int/ihr/training/laboratory\_quality/equipment/en/</u>
- 3. Stop TB Partnership. (2017). Activities phase I equipment. In: GLI stepwise process towards TB laboratory accreditation. Geneva, Retrieved from <a href="http://www.gliquality.org/activitiesqse/l/ll">http://www.gliquality.org/activitiesqse/l/ll</a>.
- 4. SLMTA training materials. (2015). Strengthening laboratory management towards accreditation. Retrieved from <a href="https://slmta.org/tool-kit/english">https://slmta.org/tool-kit/english</a>.
- World Health Organization (WHO). (2011). Guidance for countries on the specifications for managing TB laboratory equipment and supplies. Geneva, Retrieved from <u>https://apps.who.int/iris/bitstream/handle/10665/44798/9789241503068\_eng.pdf.?sequence=1</u>
- 6. Stop TB Partnership. (2020) Standard operating procedures. Global Laboratory Initiative training packages. Retrieved from http://www.stoptb.org/wg/gli/documents.asp?xpand=2. http://apps.who.int/iris/bitstream/10665/85349/1/9789241548564\_eng.pdf? ua=1&ua=1
- 7. World Health Organization (WHO). (2014). Safe management of wastes from health-care facilities. Retrieved from <u>https://apps.who.int/iris/bitstream/handle/10665/85349/9789241548564\_eng.pdf;jsessionid=2620EBBE4</u> C6C18646FA7DA698A35B635?sequence=1
- World Health Organization (WHO). (2008). Maintenance manual for laboratory equipment, 2nd edition. Geneva, Retrieved from <u>https://apps.who.int/iris/bitstream/handle/10665/43835/9789241596350\_eng\_low.pdf?sequence=2&isAl\_ lowed=y</u>
- 9. Siddiqi, S., Rüsch-Gerdes, S. (2006). MGIT<sup>™</sup> Procedure Manual. Retrieved from <u>https://www.finddx.org/wp-content/uploads/2016/02/mgit\_manual\_nov2006.pdf</u>
- Sander, L.C. (2016). Use of analytical balances [video]. National Institute of Standards and Technology. Retrieved from <u>https://www.nist.gov/video/use-analytical-balances</u>
- 11. SOP on balance calibration. Gaithersburg (MD): National Institute of Standards and Technology; 2014 <u>https://www.nist.gov/sites/default/files/documents/</u>pml/wmd/labmetrology/SOP\_7\_20140911.pdf
- 12. Cepheid. (2013). Maintenance of GeneXpert. Retrieved from <a href="https://www.ghdonline.org/uploads/10-Maintenance\_of\_GeneXpert.pdf">https://www.ghdonline.org/uploads/10-Maintenance\_of\_GeneXpert.pdf</a>
- 13. FIND. (2013). SOP on use and preventive maintenance of GT-Blot. Geneva: Retrieved from https://www.finddx.org/tb-laboratory-standard-operating-procedures-sops/
- 14. FIND. (2013). SOP on use and preventive maintenance of thermal cycler. Geneva. Retrieved from https://www.finddx.org/tb-laboratory-standard-operating-procedures-sops/
- 15. FIND. (2013). Reference manual: TwinCubator. Nehren, Germany: Hain Lifescience; 2013. https://www.finddx.org/tb-laboratory-standard-operating-procedures-sops/
- 16. FIND. (2013). SOP on use and preventive maintenance of Twincubator. Geneva, Retrieved from https://www.finddx.org/tb-laboratory-standard-operating-procedures-sops/
- 17. FIND (2013). SOP on use and preventive maintenance of water bath. Geneva. Retrieved from https://www.finddx.org/tb-laboratory-standard-operating-procedures-sops/
- 18. Memarzadeh F, Olmsted RN, Bartley JM, et al. (2010). Applications of ultraviolet germicidal irradiation disinfection in health care facilities: Effective adjunct, but not standalone technology. Am J Infect Control. 2010; 38: S13–S24. Retrieved fromhttps://www.orf.od.nih.gov/TechnicalResources/Bioenvironmental/Documents/Applicationsofultra violetgermicidalirradiationdisinfectioninhealthcarefacilities\_508.pdf
- Kizer K.W. (1990). Using ultraviolet radiation and ventilation to control tuberculosis. California Indoor Air Quality Program, Air and Industrial Hygiene Laboratory, and the Tuberculosis Control and Refugee Health Programs Unit, Infectious Disease Branch, Department of Health Services; Sacramento (California). Retrieved from <u>https://www.americanairandwater.com/uv-facts/UV-for-TB-control.pdf</u>

- 20. World Health Organization (WHO). (2012). Tuberculosis laboratory biosafety manual. Geneva. Retrieved from <u>https://apps.who.int/iris/bitstream/handle/10665/77949/9789241504638\_eng.pdf?sequence=1</u>
- 21. Centers for Disease Control and Prevention. (2013). Core curriculum on tuberculosis: what the clinician should know, 6th edition. Atlanta. Retrieved from: https://www.cdc.gov/tb/education/corecurr/pdf/corecurr\_all.pdf

## Annexes

## Annex I. Autoclave logbook

Date:	Time:	Operator's name:				
Type of load:	media 🗆 🛛 glassware 🗆	waste products 🗆				
Presence of bic	hazardous material: YES 🗆	NO 🗆				
Load size (spec	Load size (specify):					
Autoclaving co	nditions: 121 °C (115 kPa)	Time at 121 °C: min				
Check of autoc	lave tape: white 🛛	black 🗆				

	BIOLOGICAL INDICATOR					
(test the biological indicator after every 40 hours of autoclave use, to be scheduled according to the autoclave logbook records, e.g. every 1, 2 or 3 months) Operator's name:						
Autoclave cycle:	Date:	Time:				
Autoclaving conditions:	121 °C (115 kPa)	Time at 121 °C: min				
Growth of spores in the a	Growth of spores in the autoclaved vial: Yes $\Box$ No $\Box$					

## Annex 2. Autoclave maintenance logbook

ITEM IDENTIFICATION					
Equipment: AUTOCLAVE	Brand name:				
Purchase date:	Model/type:				
Location within laboratory: Serial no.					
Warranty expiry date:					
Manufacturer:	Tel:				
Address:					
Contact person:					
Technical service representative:	Tel:				

PERIO	PERIODICITY:					
Date	Maintenance operation	Operator				

FAILUR	FAILURE EVENTS						
Date	Event	Corrective action taken	Operator				

## Annex 3: Balance maintenance logbook

ITEM IDENTIFICATION					
Equipment: BALANCE	Brand name:				
Purchase date:	Model/type:				
Location within the laboratory:	Serial no.				
Warranty expiry date:					
Manufacturer:	Tel:				
Address:					
Contact person:					
Technical service representative:	Tel:				

PERIODIO	PERIODICITY:					
Date	Maintenance operation	Operator				

FAILURE	FAILURE EVENTS					
Date	Event	Corrective action taken	Operator			

## Annex 4: BSC logbook - daily/weekly maintenance Log

Date	Time of use	Cumulative duration of use	Cumulative duration of use of UV lamps	Operator's name	Visual alarm	Sound alarm	Smoke test	Airflow m/s (for class II BSC)	Observations
			Change UV lamps after XXX hours of use (according to manufacturer's recommendations)						

## Annex 5: Centrifuge logbook

Operator's name	Date	Time	RCF = 3000g (tick if correct)	Time = 20 min (tick if correct)	Temp. = 10 °C (tick if correct)	Sediment (tick if correct)	Specify other centrifuge conditions, if any Note observations, if any

## Annex 6: Incubator logbook

Temperature required:

 $36 \pm 1 \degree C$  (acceptable variation)

	Trimester:				Year:			
Month	Temp. °C	Operator (initials)	Month	Temp. °C	Operator (initials)	Month	Temp. °C	Operator (initials)
I			I			I		
2			2			2		
3			3			3		
4			4			4		
5			5			5		
6			6			6		
7			7			7		
8			8			8		
9			9			9		
10			10			10		
П			11			11		
12			12			12		
13			13			13		
14			14			14		
15			15			15		
16			16			16		
17			17			17		
18			18			18		
19			19			19		
20			20			20		
21			21			21		
22			22			22		
23			23			23		
24			24			24		
25			25			25		
26			26			26		
27			27			27	1	
28			28			28	1	
29			29			29		
30			30			30	1	
31			31			31		

## Annex 7: Incubator maintenance logbook

ITEM IDENTIFICATION						
Equipment:	INCUBATOR	Brand name:				
Purchase date:	Purchase date: Model/type:					
Location within laborat	Location within laboratory: Serial no.					
Warranty expiry date:	Warranty expiry date:					
Manufacturer: Tel:			Tel:			
Address:						
Contact person:						
Technical service representative: Tel:				Tel:		

FAILURE EVENTS						
Date	Event	Corrective action taken	Operator			

Disinfection date	
Disinfection reason (regular, spillage)	
Operator's name	
Calibration date	
Calibration reason (temperature correction, power failure, disinfection)	
Operator's name	

Disinfection date	
Disinfection reason (regular, spillage)	
Operator's name	
Calibration date	
Calibration reason (temperature correction, power failure, disinfection)	
Operator's name	

Disinfection date	
Disinfection reason (regular, spillage)	
Operator's name	
Calibration date	
Calibration reason (temperature correction, power failure, disinfection)	
Operator's name	

## Annex 8: Freezer Temperature record form

Equipment: FREEZER	Reference:			
Location:	Installation date:			
<b>Temperature required: –</b> 18 °C ± 2 °C (acceptable variation)				

	Trir	nester:		Year:				
Month	Temp. °C	Operator (initials)	Month	Temp. °C	Operator (initials)	Month	Temp. °C	Operator (initials)
I			I			I		
2			2			2		
3			3			3		
4			4			4		
5			5			5		
6			6			6		
7			7			7		
8			8			8		
9			9			9		
10			10			10		
11			11			11		
12			12			12		
13			13			13		
14			14			14		
15			15			15		
16			16			16		
17			17			17		
18			18			18		
19			19			19		
20			20			20		
21			21			21		
22			22			22		
23			23			23		
24			24			24		
25			25			25		
26			26			26		
27			27			27		
28			28			28		
29			29			29		
30			30			30		

## Annex 9: Freezer Maintenance logbook

ITEM IDENTIFICATION						
Equipment: FREEZER	Brand name:					
Purchase date: Model/type:						
Location within laboratory: Serial no.						
Warranty expiry date:						
Manufacturer: Tel:						
Address:						
Contact person:						
Technical service representative: Tel:						

#### Maintenance card

Date	Maintenance operation	Operator
	Defrosting:	
	Relocation:	
	What/Where:	
	What/Where:	
	What/Where:	
	Refilling:	
Remarks:		
Date	Maintenance operation	Operator
	Defrosting:	
	Relocation:	
	What/Where:	
	What/Where:	
	What/Where:	
	Refilling:	
Remarks:		
Date	Maintenance operation	Operator
	Defrosting:	
	Relocation:	
	What/Where:	
	What/Where:	
	What/Where:	
	Refilling:	

FAILURE EVENTS							
Date	Event	Corrective action taken	Operator				

## Annex 10: Refrigerator Temperature record form

Equipment: REFRIGERATOR	Reference:		
Location:	Installation date:		
<b>Temperature required:</b> +6 °C ± 2 °C (acceptable variation)			

	Trime	ster:				Year:		
Month	Temp.	Operator	Month	Temp.	Operator	Month	Temp.	Operator
	°C	(initials)		°C	(initials)		°C	(initials)
I			I			I		
2			2			2		
3			3			3		
4			4			4		
5			5			5		
6			6			6		
7			7			7		
8			8			8		
9			9			9		
10			10			10		
11			11			11		
12			12			12		
13			13			13		
14			14			14		
15			15			15		
16			16			16		
17			17			17		
18			18			18		
19			19			19		
20			20			20		
21			21			21		
22			22			22		
23			23			23		
24			24			24		
25			25			25		
26			26			26		
27			27			27		
28			28			28		
29			29			29		
30			30			30		
31			31			31		

## Annex II: Refrigerator Maintenance logbook

ITEM IDENTIFICATION					
Equipment:	REFRIGERATOR		Brand name:		
Purchase date:			Model/type:		
Location within laboratory:			Serial no.		
Warranty expiry date:					
Manufacturer:				Tel:	
Address:	Address:				
Contact person:					
Technical service repr	resentative:			Tel:	

#### Maintenance card

Date	Maintenance operation	Operator
	Defrosting:	· · ·
	Relocation:	
	What/Where:	
	What/Where:	
	What/Where:	
	Refilling:	
Remarks:		
Date	Maintenance operation	Operator
	Defrosting:	
	Relocation:	
	What/Where:	
	What/Where:	
	What/Where:	
	Refilling:	
Remarks:		
Date	Maintenance operation	Operator
	Defrosting:	
	Relocation:	
	What/Where:	
	What/Where:	
	What/Where:	
	Refilling:	

FAILURE EVENTS							
Date	Event	Corrective acti taken	Operator				

## Annex 12: Inspissator logbook

Date	Time		Volume of load				Medium type	•		
Date	Time	Operator	(no. of vials/tubes)	LJ	LJ+pyr	Ogawa	LJ INH	LJ RIF	LJ EMB	LJ SM

## Annex 13: pH Meter Maintenance logbook

ITEM IDENTIFICATION					
Equipment: pH METER	Brand name:				
Purchase date:	Model/type:				
Location within the laboratory:	Serial no.				
Warranty expiry date:					
Manufacturer:	Tel:				
Address:					
Contact person:					
Technical service representative:	Tel:				

#### Calibration and record sheet

Date	Temp	Electrode	C	alibratio	on soluti	on	Solution test		
	°C	serial no.	pH 4	рН 7	рН 8	pHI0	Solution/	pH read	Signature
							buffer		

FAILURE EVENTS						
Date	Event	Corrective action taken	Operator			

## Annex 14: Water Distiller Maintenance logbook

ITEM IDENTIFICATION					
Equipment:	WATER DISTILLER	E	Brand name:		
Purchase date:			Model/type:		
Location within the laboratory:			Serial no.		
Warranty expiry date:					
Manufacturer:				Tel:	
Address:					
Contact person:					
Technical service repr	esentative:			Tel:	

CLEANING						
Date	Volume of HCI used	Operator				

FAILURE E	FAILURE EVENTS						
Date	Event	Corrective acti taken	Operator				