GLI TRAINING PACKAGE: TECHNICAL MODULES FOR XPERT MTB/RIF (ULTRA)

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ACRONYMS

AIDS	Acquired Immunodeficiency Syndrome
CDC	US Centers for Disease Control and Prevention
DST	Drug susceptibility test
EQA	External quality assessment
FIND	Foundation for Innovative New Diagnostics
GLI	Global Laboratory Initiative
HIV	Human Immunodeficiency Virus
LED FM	Light-emitting diode fluorescence microscopy
LPA	Line probe assay
M&E	Monitoring and evaluation
MDR-TB	Multidrug-resistant tuberculosis
MOH	Ministry of Health
MTB	*Mycobacterium tuberculosis*
PEPFAR	US President's Emergency Plan for AIDS Relief
PLHIV	People living with HIV/AIDS
PT	Proficiency testing
QA	Quality assurance
QC	Quality control
RIF	Rifampicin
SOP	Standard Operating Procedure
TB	Tuberculosis
TWG	Technical Working Group
USAID	US Agency for International Development
WHO	World Health Organization
XDR-TB	Extensively drug-resistant tuberculosis

ACKNOWLEDGEMENTS

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Key updates and revisions to the original training package were made, as well as development of a new set of training modules for programme planning and implementation.

The development of this revised training package was led by Heidi Albert and André Trollip (FIND South Africa) and Wayne van Gemert (GDF).

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GLI TRAINING PACKAGE: TECHNICAL MODULES FOR XPERT MTB/RIF (ULTRA)*

BACKGROUND AND RATIONALE

Elimination of tuberculosis (TB) is a major global health priority. Multidrug-resistant tuberculosis (MDR-TB) and HIV-associated TB pose enormous challenges to health systems due to the complexity of diagnosis and treatment. The current landscape for TB response underscores the urgent need for rapid diagnosis of TB, especially in resource- limited settings.

In 2010, the World Health Organization (WHO) endorsed a real-time PCR-based molecular test, the Xpert MTB/RIF assay, which Cepheid developed to detect *Mycobacterium tuberculosis* complex (MTB) and rifampicin resistance (WHO, 2010). This automated, fully-integrated system enables molecular testing in lower levels of health systems, providing results within 90 minutes. With its ease of use, this system can be adopted in district and sub-district settings, where the impact of testing on the clinical decision-making process is greatest. Based on analysis of the body of evidence generated following the initial roll-out of Xpert MTB/RIF, WHO issued updated Xpert MTB/RIF policy recommendations in 2013. Updated policy guidelines include the strong recommendation for use of Xpert MTB/RIF as an initial diagnostic for TB and rifampicin resistance in adults and children suspected of having MDR-TB or HIV-associated TB, and the conditional recommendations that Xpert MTB/RIF is used as the initial diagnostic for all adults and children suspected of having TB (WHO, 2014).

In 2015, the introduction of the End TB Strategy outlined the global strategy and targets for tuberculosis prevention, care and control beyond 2015. Milestones for 2025 include a 75% reduction in the number of TB deaths compared to 2015; a 50% reduction in TB incidence rate compared with 2015 and zero TB affected families facing catastrophic costs due to TB. By 2035, the targets are to reduce the number of TB deaths by 95% compared to 2015, and the incidence rate by 90% compared to 2015. The ambitious aims of the End TB Strategy highlight the need for: expanding the reach and scope of interventions; engaging the whole health system, both public and private, to best benefit from all systems; and pursuing new scientific innovations in TB prevention and care. In this strategy, WHO also calls for early diagnosis of TB and makes a new recommendation for universal drug susceptibility testing. The need for continued roll-out and scale-up of molecular technologies including Xpert MTB/RIF to increase testing coverage and to detect cases rapidly and accurately, and to provide universal drug susceptibility testing for all cases at risk has never been clearer.

*Refers to Xpert MTB/RIF and Xpert MTB/RIF Ultra

THE GLI TRAINING PACKAGE

The GLI Training Package provides a comprehensive management and technical training resource to support the implementation of Xpert technologies (including Xpert® MTB/RIF and Xpert® MTB/RIF Ultra using the GeneXpert® platform) for the diagnosis and drug susceptibility testing of samples for tuberculous (TB).

This current release includes updates to the technical modules of the Xpert MTB/RIF Training Package. These technical modules supplement the training modules developed by Cepheid and are used in conjunction with the eight Programmatic Modules (Table 1). The GLI Training Package can be accessed at:

http://www.stoptb.org/wg/gli/trainingpackages.asp

The Cepheid developed training modules can be accessed at:

https://drive.google.com/open?id=1e1MSPhRGIsJC5exT63-hPC4tDikxfF7w

https://drive.google.com/open?id=0B5BEDNbsSBMWfjZ4XzViVU5PNXRtdjFmN3BYOW1nRFhSS29WNlBYaEZRaE1tY0NMVDM2YUE

Table 1. GLI Training Package modules

Programmatic Modules	Technical Modules	Cepheid Modules
▪ PM1: TB Diagnostics – Global Policies & Strategies ▪ PM2: Implementing TB Diagnostics – Practical Considerations ▪ PM3: Plan and Establish a Sample Referral Network for TB Diagnosis ▪ PM4: How to Plan and Implement a Quality Assurance Program ▪ PM5: How to Plan and Implement Connectivity Solutions ▪ PM6: How to Monitor and Evaluate your Programme ▪ PM7: Funding your Programme ▪ PM8: Plan an Integrated Diagnostic Approach	▪ M1: TB Biosafety ▪ M2: Specimen Collection & Referral ▪ M3: Procurement and Inventory Management ▪ M4: Recording & Reporting Results ▪ M5: Monitoring Quality Indicators ▪ M6: Quality Assurance of the Xpert MTB/RIF (Ultra) ▪ M7: External Quality Assurance ▪ M8: Clinical Guide to Xpert MTB/RIF (Ultra)	▪ Introduction to Cepheid HBDC ▪ PCR Basics I ▪ PCR Basics II ▪ Technology of the GeneXpert ▪ Installation of the GeneXpert ▪ Xpert HIV-1 Viral Load ▪ HIV-1 Qual ▪ Xpert MTB/RIF Ultra ▪ GeneXpert Maintenance ▪ Getting Technical assistance - Technical Support

WHO NEEDS TO USE THIS PACKAGE AND WHY

The GLI Training Package: Technical Modules for Xpert MTB/RIF (Ultra) is intended to be used by a variety of audiences for managers and staff currently or preparing to work in TB testing facilities using Xpert technologies.

POLICY MAKERS

Stakeholders at the ministry level and individuals involved in national and global policy should be aware of the training package so they can make it available to programme and facility managers.

QUALITY ASSURANCE (QA) OFFICERS

QA officers responsible for organising QA schemes, post-market surveillance, training and supervision will require training using programmatic and technical modules.

CLINICAL MANAGERS AND STAFF

Together with public health programme managers, clinical managers and staff (including physicians, nurses, and clinic and community health workers) play a critical role in providing TB testing services. The Clinical Guide module will provide clarity on the use of the Xpert MTB/RIF (Ultra) test in clinical settings, clinical algorithms and the important role these stakeholders play in the clinical / laboratory interface.

LABORATORY MANAGERS AND STAFF

Laboratory managers, who must advocate for the required resources to support TB testing services and ensure service delivery at the facility, will benefit from both programmatic and technical modules. The technical modules will ensure they have a good understanding of the processes required to ensure quality and efficiency at the bench.

PARTNERS AND DONORS

Partners and donors include stakeholders invested in Xpert technologies such as national ministry officials, private sector leaders, multi-lateral organisation officers, non-governmental organisation staff and internal governmental organisations. This group of stakeholders is responsible for the review, dissemination, delivery and continual evaluation of this training package.

HOW THIS PACKAGE CAN BE USED

This training package was designed using a modular approach, thus, while there are linkages between modules, modules can stand alone and be combined in a variety of ways to best suit the intended audience. Suggested module combinations for specific participants are presented in the section, "Different Sets of Training Workshops."

Each module includes, at a minimum, a PowerPoint presentation and a Facilitator's Guide. The Facilitator's Guide includes detailed information on module content, flow and timing of the training session, important points to be made, directions for any practical exercises, and discussion questions with answers. Any module that includes an exercise will also have a worksheet to be given to each participant that provides directions for the activity and space for the participant's work. Some exercises will have well-defined answers (e.g. mathematical calculations). In these cases, a handout with activity answers will be provided for distribution to participants at the end of the session. For exercises without clear answers, key points for discussion during the exercise will be included in the Facilitator Guide. All materials included in each module are described in the specific module sections below.

HOW TO ACCESS THIS TRAINING PACKAGE

This document provides an overview of each module. The training package can be accessed at:

http://www.stoptb.org/wg/gli/trainingpackages.asp

TECHNICAL MODULES FOR XPERT MTB/RIF (ULTRA)

The GLI Training Package: Technical Modules for Xpert MTB/RIF (Ultra) is designed to equip managers at the testing site level with the knowledge to plan, implement, monitor and evaluate the use of WHO-approved technologies as part of a TB diagnostic network. The GLI Training Package: Technical Modules for Xpert MTB/RIF (Ultra) also contains a module for sensitization of clinicians and other healthcare workers on the Xpert MTB/RIF (Ultra) tests.

Intended Audience	Learning Objectives
▪ Quality Assurance Officers ▪ Laboratory managers and staff ▪ Implementation partners ▪ Regional stakeholders (e.g. supervising and support staff from supranational laboratories) ▪ Basic users performing Xpert MTB/RIF (Ultra) testing ▪ Clinicians	▪ Inform Quality Assurance Officers, Laboratory managers, Implementation partners and regional stakeholders on technical requirements for implementing Xpert MTB/RIF (Ultra) testing at the laboratory level ▪ Train basic users on the requirements for performing Xpert MTB/RIF (Ultra) testing ▪ Sensitive clinicians and other healthcare workers on the use of the Xpert MTB/RIF (Ultra) test in clinical settings

MODULE M1: TB BIOSAFETY

MODULE M1 SYNOPSIS

To provide participants with an overview of key considerations for implementing Biosafety in the TB laboratory

MODULE M1 LEARNING OBJECTIVES

By the end of the module, participants should be able to:

- Understand the safety risks in laboratories using various methods
- Describe the risk associated with Xpert MTB/RIF (Ultra)* testing
- Explain what precautions should be taken to safely use Xpert MTB/RIF (Ultra) tests
- Create a spill kit for your laboratory
- Know how to safely clean up a spill outside or within the Biosafety Cabinet (BSC)

MODULE M1 CONTENT

This module includes four components:

1. PowerPoint set of 43 slides (**1 hour**)
2. Group discussion framed by questions found on slide 41
3. Exercise 1: Layout of the TB laboratory. To design the optimal layout of a TB laboratory performing smear and Xpert MTB/RIF (Ultra) testing (**50 minutes**)
4. Exercise 2: Preparing disinfectants. The aim is to revise solution calculations. This is a quick exercise to calculate the volume of stock solution required for GeneXpert disinfection during routine cleaning of the instrument (**10 minutes**)

Additional Materials:

- Facilitators guide (FG1)
- Exercise 1: Layout of the TB laboratory worksheets (W1&2:M1)
- Exercise 2: Preparing disinfectants worksheet (W3:M1) & handout (H1:M1)

MODULE M1 ADDITIONAL RESOURCES

1. World Health Organization. (2004). Laboratory Biosafety Manual (3rd Edition). www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf
2. World Health Organization. (2012). Tuberculosis Laboratory Biosafety Manual. www.who.int/tb/publications/2012/tb_biosafety/en/
3. FIND Biosafety online training. http://finddiagnostics-training.org/moodle/

MODULE M2: SPECIMEN COLLECTION & REFERRAL

MODULE M2 SYNOPSIS

To provide participants with an overview of specimen referral networks and the sample requirements for Xpert MTB/RIF (Ultra)

MODULE M2 LEARNING OBJECTIVES

At the end of this module, participants should be able to:

1. Understand the principles of specimen referral systems
2. List the TB-specific considerations and recommendations for specimen collection, storage, packaging and transport
3. Describe the specimen collection, storage & transport processes
4. Tabulate quality indicators for monitoring the specimen referral system

MODULE M2 CONTENT

This module is comprised of three parts:

1. PowerPoint presentation of 41 slides (**1hour**)
2. Guided discussion (**15 minutes**)
3. Exercise 1: Properly filling NTP requisition form. The objective of this exercise is to complete a Laboratory Request Form with the information provided (30 minutes)

Additional Materials

- Facilitators guide (FG2)
- Exercise 1: Properly filling NTP requisition form (W1:M2)

MODULE M2 ADDITIONAL RESOURCES

1. GLI Guide to TB Specimen Referral Systems. (2017). www.stoptb.org/wg/gli/assets/documents/GLI_Guide_specimens_web_ready.pdf

MODULE M3: PROCUREMENT AND INVENTORY MANAGEMENT

MODULE M3 SYNOPSIS

To provide participants with an overview of procurement and inventory management of consumables for the Xpert MTB/RIF (Ultra) tests

MODULE M3 LEARNING OBJECTIVES

At the end of this module, participants will be able to:

1. List all supplies required for performing the Xpert MTB/RIF (Ultra) tests
2. Forecast supplies needed based on the number of tests performed during a specific period
3. Describe the procurement processes
4. Explain the use and importance of the stock log book in maintaining an adequate inventory
5. Explain storage and shelf life requirements of Xpert MTB/RIF (Ultra) kits

MODULE M3 CONTENT

This module includes three components:

1. PowerPoint set of 55 slides (**2 hours**)
2. Group discussion framed by questions found on slide 52
3. Exercise 1: Forecasting. To correctly forecast reagent testing requirements for Xpert MTB/RIF (Ultra) (**30 minutes**)

Additional materials:

- Facilitators guide (FG3)
- Exercise 1: Forecasting worksheets and handouts (W1-3:M3) & (H1-3:M3)

MODULE M3 ADDITIONAL RESOURCES

1. Logistics supply management tool. TB CARE I. www.tbcare1.org/publications/toolbox/lsm/
2. Guidance for countries on the specifications for managing TB laboratory equipment and supplies. Geneva, World Health Organisation. 2011. http://whqlibdoc.who.int/publications/2011/9789241503068_eng.pdf
3. Guidelines for Managing the Laboratory Supply Chain: Version 2. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 1 2008. http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/GuidManaLabSC_v2.pdf

MODULE M4: RECORDING & REPORTING RESULTS

MODULE M4 SYNOPSIS

To provide participants with an overview of recording and reporting Xpert MTB/RIF (Ultra) results

MODULE M4 LEARNING OBJECTIVES

By the end of this module, participants should be able to:

1. Understand the principles of specimen referral systems
2. List the TB-specific considerations and recommendations for specimen collection, storage, packaging and transport
3. Describe the specimen collection, storage & transport processes
4. Tabulate quality indicators for monitoring the specimen referral system

MODULE M4 CONTENT

This module is comprised of three components:

1. PowerPoint presentation of 21 slides (**1 hours**)
2. Guided discussion on slide 19 (**15 minutes**)
3. Exercise 1: Recording. Practice reporting results on the correct TB forms and registers using the WHO reporting codes (**15 minutes**)

Additional Materials:

- Facilitators guide (FG4)
- Exercise 1: Recording worksheets (W1:M4) & handouts (H1:M4)

MODULE M4 ADDITIONAL RESOURCES

1. Definitions and reporting framework for tuberculosis – 2013 revision. Geneva, World Health Organization. 2013. (WHO/HTM/TB/2013.2). http://www.who.int/tb/publications/definitions

MODULE M5: MONITORING QUALITY INDICATORS

MODULE M5 SYNOPSIS

To provide participants with an overview of quality (performance) indicator monitoring at the testing site, data analysis and performing root cause analysis for unexpected results or if targets are not met

MODULE M5 LEARNING OBJECTIVES

By the end of this module participants should be able to:

1. Understand the importance of quality indicator monitoring
2. List quality indicators that are needed to monitor the quality of TB laboratory tests
3. List the quality indicators that should be collected for Xpert MTB/RIF (Ultra)*
4. Describe the process of analysing and reporting quality indicators

MODULE M5 CONTENT

This module is comprised of three components:

1. PowerPoint Presentation of 24 slides (**1 hour**)
2. Guided discussion on slide 22 **(15 minutes)**
3. Exercise 1: Reviewing quality indicators. The objective of this exercise is to review quality indicator graph and to identify the problem(s), and list possible root causes of the problem(s). (**15 minutes**)

Additional materials:

- Facilitators guide (FG5)
- Functionality of a data connectivity solution worksheets (W1:M5)

MODULE M5 ADDITIONAL RESOURCES

1. Framework of indicators and targets for laboratory strengthening under the End TB Strategy. Geneva, World Health Organization. 2016. (WHO/HTM/TB/2016.18). http://www.who.int/tb/publications/labindicators/en/
2. GLI Quick Guide to TB Diagnostics Connectivity Solutions. Global Laboratory Initiative. 2016. http://stoptb.org/wg/gli/assets/documents/gli_connectivity_guide.pdf

MODULE M6: QUALITY ASSURANCE OF THE XPERT MTB/RIF (ULTRA)

MODULE M6 SYNOPSIS

To provide participants with an understanding of the essential elements of a quality assurance (QA) programme at testing site level, including the requirements for Xpert MTB/RIF (Ultra)* test QA

MODULE M6 LEARNING OBJECTIVES

At the end of this module, participants should be able to:

1. Understand essential elements of a QA programme at testing site level
2. Describe the requirements for each QA component at the testing site level
3. Understand how to meet the requirements for each QA component at your testing site

MODULE M6 CONTENT

This module is comprised of four components:

1. PowerPoint Presentation of 39 slides **(2 hours)**
2. Guided discussion on slide 37 **(15 minutes)**
3. Exercise 1: The objective of this exercise is to review scenarios in which Xpert MTB/RIF QA is compromised, and suggest actions to address these challenges **(50 minutes)**

Additional Materials:

- Facilitators guide (FG6)
- QA Scenarios (W1:M6)

MODULE M6 ADDITIONAL RESOURCES

1. GLI stepwise process towards TB laboratory accreditation. http://gliquality.org
2. ISO 15189 Quality Management System Implementation: Look Before You Leap. TB CARE I. http://www.challengetb.org/publications/tools/lab/ISO15189_QMS_Implementation.pdf
3. Laboratory Quality Management System Training Toolkit. Geneva, World Health Organization. 2014. http://www.who.int/ihr/training/laboratory_quality/doc/en/

MODULE M7: EXTERNAL QUALITY ASSURANCE

MODULE M7 SYNOPSIS

To provide participants with an overview of external quality assessment (EQA), proficiency testing (PT), on-site supervision and their role in ensuring quality of testing

MODULE M7 LEARNING OBJECTIVES

By the end of this module, participants should be able to:

1. Define sources of funding for TB programmes and diagnostic services
2. Define key cost items that should be included in TB diagnostic services budgets
3. Identify steps required in development of budgets for TB diagnostic services
4. Understand how to use available tools to develop a comprehensive budget for TB diagnostic services

MODULE M7 CONTENT

This module includes four components:

1. PowerPoint presentation of 43 slides (**1 hour**)
2. Group discussion framed by question on Slide 20 & 41 (**15 minutes each**)
3. PT Report Analysis: The objective of this exercise is to review a PT report and to identify the PT the problem(s), and list possible causes of the problem(s). Participants must also suggest possible corrective actions to address the problem(s), and how these corrective actions can be monitored (**25 minutes**)
4. On-site supervision checklist: The objective of this exercise is to develop a checklist of items that should be considered by a supervisor when planning, conducting and reporting an onsite supervision visit (**25 minutes**)

Additional materials:

- Facilitators guide (FG7)
- PT Report Analysis worksheets (W1:M7)
- On-site supervision checklist (W2:M7)

MODULE M7 ADDITIONAL RESOURCES

1. External Quality Assessment for AFB Smear Microscopy. https://www.aphl.org/.../External_Quality_Assessment_for_AFB_Smear_Microscopy.pdf

MODULE M8: CLINICAL GUIDE

MODULE M8 SYNOPSIS

To provide clinicians with sensitization training for the Xpert MTB/RIF and Xpert MTB/RIF Ultra tests

MODULE M8 LEARNING OBJECTIVES

By the end of this module, participants should be able to:

1. Describe the role of Xpert MTB/RIF (Ultra) testing in diagnosis of TB and MDR-TB
2. Explain and discuss your country TB diagnostic algorithm (or the WHO preferred algorithms) for diagnosis and management of TB and MDR-TB
3. Understand the use of the WHO reporting codes for Xpert MTB/RIF (Ultra)

MODULE M8 CONTENT

This module includes three components:

1. PowerPoint presentation of 34 slides (1 hour)
2. Exercise: Clinical Case Studies (50 minutes)

Additional materials:

- Facilitators guide (FG8)
- Worksheet: Clinical Case Studies (W1:M8)

MODULE M8 ADDITIONAL RESOURCES

1. World Health Organization. Global Tuberculosis Programme. http://www.who.int/tb
2. World Health Organization. (2016). Framework of indicators and targets for laboratory strengthening under the End TB Strategy http://www.who.int/tb/publications/labindicators/en/
3. World Health Organization. (2015). Implementing tuberculosis diagnostics: A policy framework http://www.who.int/tb/publications/implementing_TB_diagnostics/en/
4. Global Laboratory Initiative, Stop TB Partnership. (2017). GLI Model TB Diagnostic Algorithms. http://stoptb.org/wg/gli/assets/documents/GLI_algorithms.pdf
5. World Health Organization. (2015). WHO End TB Strategy http://www.who.int/tb/post2015_strategy/en/

DURATION OF TRAINING SESSIONS PER MODULES

Name of Module	Time Required
M1: TB Biosafety	Total: 2h 15min Lecture: 1h Discussion: 15min Exercise 1: 50min Exercise 2: 10min
M2: Specimen Collection & Referral	Total: 1h 45min Lecture: 1h Discussion: 15min Exercise 1: 30min
M3: Procurement and Inventory Management	Total: 2h 45min Lecture: 2h Discussion: 15min Exercise 1: 30min
M4: Recording & Reporting Results	Total: 1h 30min Lecture: 1h Discussion: 15min Exercise 1: 15min
M5: Monitoring Quality Indicators	Total: 1h 30min Lecture: 1h Discussion: 15min Exercise 1: 15min
M6: Quality Assurance of the Xpert MTB/RIF (Ultra)	Total: 3h 5min Lecture: 2h Discussion: 15min Exercise 1: 50min
M7: External Quality Assurance	Total: 2h 20min Lecture: 1h Discussion: 15min + 15min Exercise 1: 25min Exercise 1: 25min
M8: Clinical Guide to Xpert MTB/RIF (Ultra)	Total: 1h 50min Lecture: 1h Exercise: 50 min

DIFFERENT SETS OF TRAINING WORKSHOPS

A variety of different training courses can be created from the materials in the Xpert TB Training Package, depending on the intended audience. Different audiences that may be targeted include:

- Laboratory Managers and Quality Assurance Officers and higher-level stakeholders involved in policymaking
- Trainers (TOT course)
- Basic users performing Xpert MTB/RIF (Ultra) testing
- Clinicians

Suggested full training courses for various groups of participants are outlined in the table below.

Laboratory Managers and Quality Assurance Officers	Advanced Users/Supervisors
▪ M1: TB Biosafety ▪ M2: Specimen Collection & Referral ▪ M3: Procurement and Inventory Management ▪ M4: Recording & Reporting Results ▪ M5: Monitoring Quality Indicators ▪ M6: Quality Assurance of the Xpert MTB/RIF (Ultra) ▪ M7: External Quality Assurance	▪ M7: External Quality Assurance
Basic Users	**Clinicians**
▪ M1: TB Biosafety ▪ M2: Specimen Referral ▪ M3: Procurement and Inventory Management ▪ M4: Recording & Reporting Results ▪ M5: Monitoring Quality Indicators ▪ M6: Quality Assurance of the Xpert MTB/RIF (Ultra) ▪ M7: External Quality Assurance	▪ M8: Clinical Guide to Xpert MTB/RIF (Ultra)

TRAINING SCHEDULES

The theoretical and practical sessions of the GLI Training Package: Technical Modules for Xpert MTB/RIF (Ultra) workshop is designed to be delivered in 3-4 days depending on whether the Cepheid training modules are used. The clinical training can be completed in a morning. Below are draft timetables given as an example, which should be adapted to your needs and setting. When planning your own agenda, please refer to the above section, "Duration of Training Sessions per Module".

DAY 1:

Start Time	End Time	Duration	Description	Faculty
08:30	09:00	30min	Registration	
09:00	09:30	30min	Welcome & Introductions, Workshop Goals, Objectives	
09:30	10:00	30min	Pre-assessment	
10:00	11:00	1h	M1: TB Biosafety (Lecture)	
11:00	11:15	15min	*Break*	
11:15	12:30	75min	M1: TB Biosafety (Exercise & Discussion)	
12:30	13:30	1h	*Lunch*	
13:30	14:30	1h	M2: Specimen Referral (Lecture)	
14:30	14:45	15min	*Break*	
14:45	16:30	45min	M2: Specimen Referral (Exercise & Discussion)	
16:30	17:00	30min	Daily Evaluation	

DAY 2:

Start Time	End Time	Duration	Description	Faculty
09:00	11:00	2h	M3: Procurement and Inventory Management (Lecture)	
11:00	11:15	15min	*Break*	
11:15	12:00	45min	M3: Procurement and Inventory Management (Exercise 2 & Discussion)	
12:00	13:00	1h	M4: Recording & Reporting Results (Lecture)	
13:00	14:00	1h	*Lunch*	
14:00	14:30	30min	M4: Recording & Reporting Results (Exercise 2 & Discussion)	
14:30	15:30	1h	M5: Monitoring Quality Indicators (Lecture)	
15:30	15:45	15min	*Break*	
15:45	16:15	30min	M5: Monitoring Quality Indicators (Exercise 2 & Discussion)	
16:15	17:15	30min	Post-assessment	

DAY 3:

Start Time	End Time	Duration	Description	Faculty
09:00	11:00	2h	M6: Quality Assurance of the Xpert MTB/RIF (Ultra) (Lecture)	
11:00	11:15	15min	*Break*	
11:15	12:20	1h 5min	M6: Quality Assurance of the Xpert MTB/RIF (Ultra) (Exercise 2 & Discussion)	
12:20	13:30	1h 10min	*Lunch*	
13:30	14:30	1h	M7: External Quality Assurance (Lecture)	
14:30	15:35	1h 5min	M7: External Quality Assurance (Exercise 2 & Discussion)	
15:35	16:00	25min	Daily Evaluation	

CLINICAL TRAINING:

Start Time	End Time	Duration	Description	Faculty
09:00	10:00	1h	M8: Clinical Guide to Xpert MTB/RIF (Ultra) (Lecture)	
10:00	10:15	15min	*Break*	
10:15	11:05	50min	M8: Clinical Guide to Xpert MTB/RIF (Ultra) (Exercise 2 & Discussion)	
11:05	11:30	25min	Daily evaluation	

BEFORE THE TRAINING

CUSTOMIZATION OF SLIDE SETS

Certain modules include slides with data that should be customized based on national/regional context. Slides for customization are marked with this symbol. These slides should be updated ahead of the training, and the trainer should make sure they are familiar with these country-specific statistics or information. Specific slides to be customized can be found in the table below:

Module	Slides to be customized
M1: TB Biosafety	**Slide 9 - 11: Risk assessment** **Slide 20-22:** Personal Protective Equipment (PPE) **Slide 25-27:** Disinfectants **Slide 38:** Waste disposal
M2: Specimen Collection & Referral	**Slide 9:** Sputum specimen collection: container specifications **Slide 15:** Request Form **Slide 20:** Specimen transport guidelines **Slide 33:** Sample rejection criteria Xpert MTB/RIF (Ultra) **Slides 39-40:** Quality Indicator Monitoring
M3: Procurement and Inventory Management	**Slide 9:** Supply Management System **Slide 11:** Information needed for forecasting of GeneXpert supplies
M4: Recording & Reporting Results	**Slide 4:** Laboratory Record Keeping Documents **Slides 5 & 6:** Request Form **Slide 7:** Laboratory Record Keeping Documents **Slide 9:** Report Form **Slides 11&12:** Laboratory Register **Slides 15&16:** Reporting Results
M5: Monitoring Quality Indicators	**Slide 6:** Quality indicator monitoring
M6: Quality Assurance of the Xpert MTB/RIF (Ultra)	**Slide 11:** Conduct training
M7: External Quality Assurance	**Slides 7 & 15:** PT testing **Slides 24-39:** Conducting onsite supervision visits
M8: Clinical Guide to Xpert MTB/RIF (Ultra)	**Slide 8:** Country algorithm **Slide 15:** Country algorithm (Ultra) **Slides 21-22:** Laboratory Request Form **Slide 23-28:** Xpert MTB/RIF Ultra

CLASSROOM

To provide an optimal learning experience, a classroom should be made available for the lectures, discussions, and exercises associated with each module. The classroom should be comfortable, distraction-free and include: 1) tables and chairs, and 2) conveniently-located outlets for a computer and projection monitor. Windows in the room should have curtains, or be easily darkened when necessary, to provide appropriate conditions for LCD projection. To facilitate discussion and interaction amongst participants, the tables should be arranged in a semi-circle or classroom style, giving all participants and unobstructed view of the projection monitor. It is necessary to make sure that all trainees, trainers, guests and observers (if any) are comfortably accommodated in the classroom. Overcrowding should be avoided. Bottled water and glasses should be made available on each table.

The classroom should have:

- 2 flip charts with easel
- Markers (different colours, for flipcharts)
- Laptop computer
- Projection monitor (LCD, compatible with computer)
- White screen or whiteboard for LCD projection
- Extension cords and adaptors
- Wastebasket
- Laser printer

Classroom supplies:

- Marking pens
- Masking tape for posting flip chart pages
- Note pads
- Pens, pencils and erasers
- Calculators (one per participant, as necessary)
- Stapler and staples
- Puncher

PRINTING MATERIALS / HANDOUTS FOR PARTICIPANTS

The workshop facilitator or trainer should ensure that appropriate materials are available to each participant at the start of the workshop. Printed materials include:

- Pre-course and post-course tests
- Daily evaluation questionnaire
- Post workshop evaluation
- Handouts (texts, exercises and supplementary materials as stated per module)
- Name tents
- Name badges

INSTRUCTIONS ON HOW TO ARRANGE THE PARTICIPANT MANUAL

Taking into consideration the complexity of the training content as well as the need for flexibility when compiling training materials, it is recommended to arrange the Participant Manual in a binder that allows for printed materials to be inserted as and when needed.

The exercises should NOT be inserted in this binder beforehand. After the exercise, these materials can be stapled and punched for insertion in the Participant Manual by the participants themselves. Handouts with exercise answers should be distributed after the exercise has been completed. Please study the exercise descriptive texts in the module facilitator guides to understand exactly how exercise materials should be distributed.

PRE & POST ASSESSMENTS

Assessments are conducted before & after the training. Pre and post assessment questions are provided in the Question Bank document. An example of a pre & post assessment covering all eight of the programmatic modules is also provided. If the facilitator is not providing training on all the modules, the example can be customized to include more questions from the modules that form part of the training. Ideally the pre & post assessments should consist of 10 - 20 questions. A list of questions (and answers) for all the programmatic modules is provided at the end of the Question Bank.

CRITERIA FOR PARTICIPATION CERTIFICATE

At the end of the workshop, each participant that has met the criteria for successful completion will receive a Certificate of Attendance. The criteria for successful completion of the course include:

- Daily attendance and active participation
- Completed written post-test- Pass mark for the post assessment is 50%.

Prior to the workshop, do not forget to:

- Identify appropriate individuals who will sign the certificate
- Verify spelling of names
- Print certificates

PREPARE TO TRAIN

Know what you are training: This is critical to the success of the training. Even the best of training skills will not hide the fact that a trainer does not know the content. Therefore, it is imperative to:

- Know the goals and objectives of the training
- Know the content of the training
- Know the training activities (i.e. discussions, exercises)

- Know the customized data – Modules that require country/regional customization should be updated and you should be familiar with the data

Know your audience:
Adults require specific training approaches, so special consideration should be made to incorporate adult learning principles and training techniques to fully engage adult learners. Some principles and associated teaching techniques are presented in the table below.

Principle	Training Technique
Adults bring a wealth of knowledge and experience and they want to share their knowledge and experience	Encourage participants to share their knowledge and experiences. Include activities that utilize their knowledge and experience
Adults are decision-makers and self-directed learners.	Include problem-solving activities
Adults have different learning styles that must be respected	Provide multiple ways for participants to learn the material
Adults want to participate rather than just listen to a lecture	Create a participatory learning environment with various types of activities
Adults are motivated by information or tasks that are meaningful and applicable to their jobs.	Relate the content and skills to the participant's jobs
Adults prefer training that focuses on real life problems	Relate content to the types of problems they encounter in their jobs
Adults expect their time during training to be used carefully	Follow a realistic time schedule
Adults feel anxious if participating in a group that makes them look uninformed, either professionally or personally	Avoid criticism. Acknowledge all participant's contributions.
Adults learn best in a positive environment where they feel respected and confident	Create a positive environment by provide positive feedback and showing respect to all participants.
Adults come from different cultures, life-styles, religious preferences, genders, and ages.	Respect all differences and encourage participants to respect each other's differences as well.

Organization: Use effective organizational skills such as:

- Organizing the training logically
- Following a plan
- Using checklists
- Keeping everyone informed

Practice: Practicing your training presentations helps to ensure that the presentations will be successful

- Out loud in front of a mirror (if you will be standing to present, then practice that way)
- With the materials and equipment before the training
- Rehearse in the training room if possible
- Time your presentation

Prepare the Training Space: Before participants arrive, ensure that the training room is set up, all equipment is functioning and all materials are available.

- Check the room before the training (make sure there are enough tables and chairs, and that they are arranged appropriately)
- Make sure all of your materials, supplies and equipment are available
- Test all equipment before the training
- Download files on the computers (if necessary)
- Prepare as much ahead of tome as possible (i.e. flip chart pages, distribute manuals/handouts, arrange things for activities and exercises)

Back-up Plans: Sometimes problems occur so it is best to have a back-up plan for those problems that can be anticipated.

- Have extra materials and supplies available
- Use multiple formats (handouts, slides, flipcharts, etc.). Sometimes the electricity will go out so you will be unable to use the PowerPoint slides. Having handouts available will enable the training to continue.
- Be flexible. Problems often occur so relax and adjust to the situation.
- Make positive situations out of negative ones. For example, when problems occur, make them into a learning situation.