



EXTERNAL QUALITY ASSURANCE

Facilitator Guide (FG1)

SUMMARY OF MODULE AT A GLANCE

Purpose of module:	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	
Total time of module	2 hours 20 minutes	
CONTENT OUTLINE		
Power point: TB Diagnostics Global Policies and Strategies	<p>Aim: 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</p> <p>Learning objectives:</p> <ul style="list-style-type: none">▪ Introduction to External Quality Assurance (EQA) and Proficiency Testing (PT) for Xpert MTB/RIF (Ultra)*▪ PT panel distribution & the PT process▪ Common problems experienced with PT▪ Conducting on-site supervision (Advanced users)	1 hour
Discussion Questions	<ol style="list-style-type: none">1. What are the three components of EQA?2. Why is EQA important?3. What are the responsibilities of the testing site if they receive an incorrect PT result? <p>On-site supervision:</p> <ol style="list-style-type: none">4. Why is it important to contact the testing site before conducting an on-site supervision visit?5. What are the responsibilities of the testing site if problems (non-conformities) are identified during the on-site supervision visit?6. What is the purpose of analysing data from on-site supervision visits at central level (NTP/NTRL)?	15 minutes + 15 minutes
Exercise 1: PT Report analysis	Aim: The objective of this exercise is to review a PT report and to identify problems	25 minutes
Handout and exercise/practicals in module	<ol style="list-style-type: none">1. Worksheet (W1:M7) - External Quality Assurance	

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

Exercise 2: On-site supervision checklist	Aim: The objective of this exercise is to develop a checklist of items to be used during an on-site supervision visit	25 minutes
Handout and exercise/practicals in module	<ul style="list-style-type: none"> Worksheet (W2:M7) - Onsite supervision checklist 	
Additional resources or references:	<ul style="list-style-type: none"> External Quality Assessment for AFB Smear Microscopy. https://www.aphl.org/.../External_Quality_Assessment_for_AFB_Smear_Microscopy.pdf 	

MODULE NOTES

The module should be customized based on the level of participants, the aim for basic users is to familiarize them with what to expect for PT and supervisions, their responsibilities and actions, while advanced users should not only understand the site level PT but also how to carry out activities, collate and review data across a district/region or country. The module should be flexible based on country needs and what has been established before. Additional development of these slides may be necessary. Slides are presented to describe the components of a basic EQA programme which is the minimum of what should be implemented to ensure testing quality in the GeneXpert programme.

Slides 1-19 Introduce participants to the fundamentals of EQA and PT specifically. This section essentially deals with two (but related) concepts. Performing PT (Slides 1-15) & the role of the laboratory as the recipient of an on-site supervision visit (Slides 17-19).

Slide 16 End the first section, with an exercise in identifying problem(s) with PT, and listing possible causes of the problem(s)

Slides 24-39 Introduce participants to the process of conducting an onsite supervision

Slide 40 End the second section, with an exercise to develop a checklist of items that should be considered by a supervisor when planning, conducting and reporting an onsite supervision visit

EXERCISE 1: PT REPORT ANALYSIS

Purpose of exercise:	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
Preparation:	<ul style="list-style-type: none"> Work in groups of four Worksheet- PT report (W1:M7) - External Quality Assurance
Materials required:	Full list of materials participants need: <ul style="list-style-type: none"> Pens (Red and black / blue) Worksheet- PT report (W1:M7) - External Quality Assurance
Total time of exercise:	25 minutes
Feedback expected:	Select a someone to report your findings & suggestions

CONDUCTING THE EXERCISE

Break into groups of four	2 minutes
Review the supplied PT report & answer the questions	8 minutes
Select one group to provide feedback and discuss their findings	15 minutes

DEBRIEFING EXERCISE/PRACTICAL

Discuss the answers and feedback. Do all groups have the same or similar outcomes? What is different?

All sites achieving less than 100% for the PT panel (even if scored a “Pass”) should investigate cause of errors and implement corrective actions.

Worksheet (W1:M7)- External Quality Assurance

XPRT MTB/RIF ASSAY PROFICIENCY TEST PROGRAM PARTICIPANT RESULTS SUMMARY

2015 Panel A

International Laboratory Branch, Division of Global HIV and TB*, Centers for Disease Control and Prevention

Country	Testing Site	PT-ID Number

Summary of All Reporting Sites					
	2015-A-1	2015-A-2	2015-A-3	2015-A-4	2015-A-5
Total number of reporting sites	351	351	351	349	349
TB Detection					
Sites detecting TB (%)	3 (0.9)	324 (92.3)	336 (95.7)	8 (2.3)	304 (87.1)
Sites not detecting TB (%)	332 (94.6)	17 (4.8)	7 (2.0)	325 (93.1)	34 (9.7)
Sites reporting uninterpretable TB result* (%)	13 (3.7)	10 (2.8)	8 (2.3)	14 (4.0)	11 (3.2)
Sites not reporting TB detection result (%)	3 (0.9)	0 (0)	0 (0)	2 (0.6)	0 (0)
Rif Detection					
Sites detecting Rif resistance (%)	1 (0.3)	5 (1.4)	3 (0.9)	2 (0.6)	296 (84.8)
Sites not detecting Rif resistance (%)	335 (95.4)	327 (93.2)	335 (95.4)	331 (94.8)	39 (11.2)
Sites reporting indeterminate Rif result (%)	0 (0)	4 (1.1)	0 (0)	0 (0)	3 (0.9)
Sites reporting uninterpretable Rif result* (%)	13 (3.7)	10 (2.8)	8 (2.3)	14 (4.0)	11 (3.2)
Sites not reporting Rif detection result (%)	2 (0.6)	5 (1.4)	5 (1.4)	2 (0.6)	0 (0)

* Uninterpretable result = invalid, error, or no result

Site Results			
	MTB Detected	Rif Resistance	Score
Sample ID: 2015-A-01			
Expected Results	Not Detected	N/A	
All Participants' Consensus Results	Not Detected	N/A	
	Not Detected	N/A	20
Sample ID: 2015-A-02			
Expected Results	Medium	Not Detected	
All Participants' Consensus Results	Low	Not Detected	
	Not Detected	N/A	0
Sample ID: 2015-A-03			
Expected Results	Medium	Not Detected	
All Participants' Consensus Results	Low	Not Detected	
	Very Low	Not Detected	20
Sample ID: 2015-A-04			
Expected Results	Not Detected	N/A	
All Participants' Consensus Results	Not Detected	N/A	
	Not Detected	N/A	20
Sample ID: 2015-A-05			
Expected Results	Low	Detected	
All Participants' Consensus Results	Low	Detected	
	Not Detected	N/A	0
Percentage		Satisfactory/Unsatisfactory	
FINAL SCORE	60%	Unsatisfactory	
Comments			

Identify the PT the problem(s)

List possible causes of the problem(s)

List possible corrective actions to address the problem(s)

How could these corrective actions be monitored?

EXERCISE 2: On-site supervision checklist

Purpose of exercise:	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
Preparation:	<ul style="list-style-type: none"> Work in groups of four Worksheet- On-site supervision checklist (W2:M7)
Materials required:	Full list of materials participants need: <ul style="list-style-type: none"> Pens (Red and black / blue) Worksheet- On-site supervision checklist (W2:M7)
Total time of exercise:	25 minutes
Feedback expected:	Select a someone to report your findings & suggestions


CONDUCTING THE EXERCISE

Break into groups of four	2 minutes
Develop the on-site supervision checklist	13 minutes
Select one group to provide feedback and discuss their findings	10 minutes

DEBRIEFING EXERCISE/PRACTICAL

Discuss the answers and feedback. Do all groups have the same or similar items on the checklists? What is different? (Review slides 32 - 38 for any additional items not mentioned)

Preparation for onsite supervision is important. Preparing for an onsite supervision visit ensures access to people and facilities required to complete the checklist



Worksheet (W2:M7) - On-site supervision

Develop a checklist of items that should be considered by a supervisor when planning, conducting and reporting an onsite supervision visit:

Planning

Conducting

Reporting

MODULE ANSWERS

1. What are the three components of EQA?

Panel testing or Proficiency testing (PT)

On-site supervision

Slide re-checking

2. Why is EQA important?

It can be used to improve performance across the laboratory network

It is an important tool for communicating with and motivating staff

It's designed to identify and resolve serious problems with testing

It can be used to assess the competency of test operators

3. What are the responsibilities of the testing site if they receive an incorrect PT result?

Investigate & implement corrective actions for PT problems

Determine effectiveness of corrective actions

Conducting onsite supervision

4. Why is it important to contact the testing site before conducting an on-site supervision visit?

To ensure that the site is aware of the time and date of visit

To ensure accessibility to testing and clinical facilities

To ensure GeneXpert staff will be available during your visit

5. What are the responsibilities of the testing site if problems (non-conformities) are identified during the on-site supervision visit?

After the visit, perform root cause analysis on the problem(s) identified

Develop action plans, with clear timeframes to address the cause of the problem(s)

Implement the corrective actions

Monitor the effectiveness of the corrective actions

Record & document what was done

Store the report from the supervisor for review at the next onsite supervision visit

6. What is the purpose of analysing data from on-site supervision visits at central level (NTP/NTRL)?

Determine sites which require re-training

Plan for equipment needs

Plan distribution of national documents