



QUALITY ASSURANCE OF THE XPERT MTB/RIF (ULTRA)

Facilitator Guide (FG1)

SUMMARY OF MODULE AT A GLANCE

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| Purpose of module: | 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 | |
| Total time of module | 3 hours 5 minutes | |
| CONTENT OUTLINE | | |
| Power point: TB Diagnostics Global Policies and Strategies | <p>Aim: 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</p> <p>Learning objectives:</p> <ul style="list-style-type: none"> Understand essential elements of a QA programme at testing site level Describe the requirements for each QA component at the testing site level Understand how to meet the requirements for each QA component at your testing site | 2 hours |
| Discussion Questions | <ol style="list-style-type: none"> Which QA activities are recommended for Xpert MTB/RIF (Ultra) at testing site level? List the criteria for choosing a staff to attend GeneXpert user training? List three activities to ensure quality reagents are used for Xpert MTB/RIF (Ultra) testing? | 15 minutes |
| Exercise 1: QA Scenarios | <p>Aim: The objective of this exercise is to review scenarios in which Xpert MTB/RIF QA is compromised, and suggest actions to address these challenges</p> | 50 minutes |
| Handout and exercise/practicals in module | <ol style="list-style-type: none"> Worksheet (W1:M6): QA Scenarios | |
| Additional resources or references: | <ul style="list-style-type: none"> GLI stepwise process towards TB laboratory accreditation. http://gliquality.org ISO 15189 Quality Management System Implementation: Look Before You Leap. TB CARE I. | |

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

http://www.challengetb.org/publications/tools/lab/ISO15189_QMS_Implementation.pdf

- Laboratory Quality Management System Training Toolkit. Geneva, World Health Organization. 2014. http://www.who.int/ihr/training/laboratory_quality/doc/en/

MODULE NOTES

Slide 1-13 Introduce the participants to the concepts of QA. Emphasize that QA is broader than quality control testing and that affects all activities required to produce a quality result

Slide 6 & 7 These slides display lists of the QA recommendations for Xpert MTB/RIF (Ultra) test and Programmatic and testing site level. Refer to Programme Module 4 (PM4): How to Plan and Implement a Quality Assurance Programme

Slide 8-31 The QA recommendations introduced in the previous slide are discussed, with suggestions on how these may be implemented. Slide 11 should be adapted to reflect training in-country practices

EXERCISE: QA SCENERIOS

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| Purpose of exercise: | To review Xpert MTB/RIF QA results and suggest actions to address the situations presented |
| Preparation: | <ul style="list-style-type: none"> Work in groups of four Worksheet- Performance Indicators (W1:M5) |
| Materials required: | Full list of materials participants need: <ul style="list-style-type: none"> Pens (Red and black / blue) Worksheet- Performance Indicators (W1:M5) |
| Total time of exercise: | 50 minutes |
| Feedback expected: | Select a someone to report your findings & suggestions |

CONDUCTING THE EXERCISE

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| Read out instructions (shown above in “preparation”) | 1 minutes |
| Break into groups, give worksheet to each group (one scenario per group), and then groups should allot roles presenter for end of exercise | 2 minutes |
| Discussion in groups | 10 minutes |
| Report back to full group. Project the slide for each scenario | 20 minutes |
| Discussion questions posed to the group | 16 minutes |

DEBRIEFING EXERCISE/PRACTICAL

Select key messages from each groups presentation. Summarize by emphasizing QA affects all activities required to produce a quality result in the laboratory

Worksheet (W1:M4)

Time: 50 minutes

Instructions: Work in groups. Each group reviews one scenario on the worksheet provided. Select a spokesperson and share your findings with the group

Scenario 1

You notice that only one staff member performs Xpert MTB/RIF PT. In fact, the PT was not performed in the last round of testing because that staff member was on leave. When you questioned the other staff members they explained they are uncomfortable performing the PT.

During the same discussion, you discover that in the previous round tested, the laboratory results were unsatisfactory (< 80%).

- ▶ How should you handle Xpert MTB/RIF PT at your facility?
- ▶ What should you do if your laboratory receives unsatisfactory Xpert MTB/RIF PT results?

Scenario 2

You recently updated a safety policy to prevent the reoccurrence of a serious issue. Later in the month, the same situation occurred again resulting in a serious injury to one of the staff. When you questioned the staff member, you discovered he/she only had access to the old version of the policy that did not reflect the updated changes. You realize there are several copies of this policy, but you cannot recall where they are all located.

- ▶ What actions can you take in managing your documents and records?

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Scenario 3

You walk into the store room and see 25 GeneXpert cartridges ready to expire next week. You know from the last order and physical inventory that this should not be the case. When you check the cartridges in use in the TB laboratory, you see that their expiration date is six months from now. After reviewing the reagent log, you realize that the lot number with the longer expiration date has been used for the past several months.

- ▶ How will you handle the current situation?
- ▶ What steps will you take to prevent this situation from reoccurring?
- ▶ How will you monitor future inventory cycling of stock to ensure the corrective action is effective?

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Scenario 4:

Upon monthly review of the maintenance records for the GeneXpert instrument, it appears documentation was missed on most days.

How will you address:

- ▶ The staff member who is responsible for performing and documenting the activities?
- ▶ The staff member who says they forgot or did not know it was expected?
- ▶ The staff member who explains that at the beginning of the month, the past month's are in the file and the new month's records are not available?

MODULE ANSWERS

1. Which QA activities are recommended for Xpert MTB/RIF (Ultra) at testing site level?

Make the testing site safe and functional

Conduct training

Standardize policies and documentation

Maintain and service equipment

Ensure adequate supplies and reagents

Test quality samples

Monitor performance indicators

Report accurate results

Implement PT

2. List the criteria for choosing a staff to attend GeneXpert user training?

- Select at least 1-2 staff per testing site for basic user training
- Candidates must have basic computer literacy and knowledge of laboratory registers
- Candidates must be those who will perform the GeneXpert testing on a regular basis

3. List three activities to ensure quality reagents are used for Xpert MTB/RIF (Ultra) testing?

- Accurately forecasting Xpert MTB/RIF (Ultra) test supply needs
- Plan the procurement of reagents based on actual test consumption data
- Regularly monitor cartridge consumption and stock in hand at site
- Rotate stock to ensure that oldest reagents are used first