



# ***QUALITY ASSURANCE OF THE XPRT MTB/RIF (ULTRA)***

Worksheet (W1:M6)

## EXERCISE 1: QA SCENERIOS (W1:M6)

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?

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### 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?

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