**Competency Assessment for GeneXpert Users**

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| **First Name:** | **Last Name:** |
| **Home institution:** | **Country:** |
| **Evaluator:** | **Date GX user training course completed:** |

Test observation

* Ask the user to perform the Xpert MTB/RIF test on four sputum samples according to the SOP.
* Observe the test being performed, scoring one point for each correct item.

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| **Questions** | | **Answered Correctly** | |
| **Sample preparation** | 1. Did the operator add the correct volume of SR? (compared to the reference material sputum cups) | Yes | No |
| 2. Did the operator shake the sample mix 2 times before the end of incubation time? | Yes | No |
| 3. Was the incubation time 15 minutes? | Yes | No |
| 4. Was the input volume transferred to the cartridge correct? Were the sample numbers checked to prevent mix-ups? | Yes | No |
| **Xpert test** | 5. Did the operator start each new test in the GeneXpert without any problem? | Yes | No |
| **Bleach** | 6. Did the operator clean the work bench with fresh bleach before and after performing the Xpert™ MTB/RIF assay? | Yes | No |
| **Storage** | 7. Are new/unopened Xpert™ MTB/RIF kits stored in a clean and dry place? | Yes | No |
| **Waste** | 8. Are used Xpert™ MTB/RIF reagents sealed in a plastic bag before discarding? | Yes | No |
| 9. Are all infectious materials (sputum cups, pipettes) properly disposed of? (as per local guides for hazardous materials) | Yes | No |
| **Lab setup** | 10. Is the workflow in the lab correctly set up to avoid DNA cross-contamination? (Unidirectional workflow from sample preparation area to DNA amplification area) | Yes | No |
| **PART A: SCORE / NUMBER OF CORRECT ITEMS** | |  |  |

* Ask the user the following questions. Score one point for each correct answer.

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| **Questions** | **Answered Correctly** | |
| 1. Which are the acceptable ranges for SR and input volume? | Yes | No |
| 2. For how long is the sample mix (sputum + SR) stable and can you batch samples? | Yes | No |
| 3. What would you do if you have started a test and realize that you did not enter the sample ID? | Yes | No |
| 4. What would you do if you drop sputum on the bench and other containers when transferring it to the cartridge? | Yes | No |
| 5. What would you do if you drop SR and splashed on hands, face and eyes? | Yes | No |
| 6. What would you do if you dropped a cartridge containing sample mix while transporting it from the sample preparation area to the GeneXpert? | Yes | No |
| 7. What would you do if the Xpert result is “invalid” or “no result”? | Yes | No |
| 8. Which are the biosafety requirements for the Xpert sample preparation step? | Yes | No |
| 9. What would you do if you receive an error message or if a run is aborted by GeneXpert? | Yes | No |
| 10. How often do you have to check the calibration of the GeneXpert modules? | Yes | No |
| **PART B: SCORE / NUMBER OF CORRECT QUESTIONS** |  |  |

**Using the software**

* After the observation and questionnaire components of the competency assessment have been completed, ask the user to perform the following tasks.
* Observe the tasks being performed, scoring one point for each correct item.

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| **Task** | **Done Correctly** | |
| 1. Create a test, enter all the information requested by the software to start a new run | Yes | No |
| 2. Enter information manually (in case the barcode reader does not work) | Yes | No |
| 3. Edit the test information (i.e. change the sample ID for a given sample result) | Yes | No |
| 4. Display test results for a given ID | Yes | No |
| 5. Archive .gxx files | Yes | No |
| 6. Retrieve .gxx files | Yes | No |
| 7. Export test results into a .csv file | Yes | No |
| 8. Install a new Assay Definition File | Yes | No |
| 9. Create reports: assay definition report and installation qualification | Yes | No |
| 10.Maintenance - perform exterior, module, and plunger rod disinfection, valve maintenance and self-test | Yes | No |
| **PART C: SCORE / NUMBER OF CORRECT TASKS** |  |  |

#### Appraisal

* Evaluate the level of confidence shown by the user while performing Xpert MTB/RIF test.

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| **Appraisal**  1  (Not confident) | 2 | 3 | 4 | 5  (Very confident) |

#### Interpretation

Users are deemed to have shown an acceptable level of procedural competency at the Xpert MTB/RIF test if:

* The individual scores of A, B, & C are ≥ 8; and
* The overall appraisal of the operator’s confidence to perform Xpert MTB/RIF test (Part D) is ≥ 4.

If performance targets are not met, the user must undergo additional training. Users may not perform the Xpert MTB/RIF test until they have demonstrated an acceptable level of competency.