STANDARD OPERATING PROCEDURE

1. **TITLE**

Xpert MTB/RIF Proficiency Testing

1. **PURPOSE**
2. Proficiency testing (PT) is an essential element of the testing site quality assurance.
3. PT schemes are inter-laboratory comparisons that are organized regularly to assess the performance of analytical laboratories and the competence of the analytical personnel.
4. Performance on PT has been found to be an indicator of the quality of patient testing.
5. **SCOPE**
6. This procedure provides instructions to testing sites for proper handling and analysis of Xpert MTB/RIF PT samples, and reporting and review of proficiency testing results.
7. In this SOP, “testing site” includes both traditional laboratories and point of care or other clinical testing sites where the Xpert MTB/RIF is being performed.
8. **RESPONSIBILITIES**
9. Testing Site Staff
10. Participate in proficiency testing activities of the testing site.
11. Comply with instructions outlined in this SOP.
12. Review Participant’s Evaluation Report from PT provider.
13. Comply with remedial or corrective action as necessary to ensure quality results.
14. Testing Site Supervisor
15. For the purposes of this SOP, the laboratory supervisor refers to person(s) who direct and manage the activities, and with authority over a testing site.
16. Ensure that the testing site participates in a proficiency testing program.
17. Ensure all staff involved are trained and competent in performing this procedure.
18. Ensure that all testing personnel are given the opportunity to analyze PT samples.
19. Ensure that PT materials are processed and reported in a timely manner.
20. Oversee testing of PT samples.
21. Review PT sample results prior to submission to the PT provider.
22. Review and sign PT Participant’s Evaluation Report and provide feedback to the staff.
23. Investigate PT failures and institute remedial or corrective action as necessary.
24. Prepare Annual Summary of PT Results.
25. Ensure that all PT reports and other related documents are properly filed and managed.
26. Assign a designee as necessary to support PT testing and results review.
27. Ensure that this SOP and other related documents are updated, reviewed, and available to the end user.
28. **MATERIALS**
29. Xpert MTB/RIF PT Samples
30. Refer to Xpert MTB/RIF Testing SOP for list of reagents, equipment, and supplies
31. **SAFETY PRECAUTIONS**
32. All testing personnel must receive appropriate safety training prior to working with patient specimens and PT samples.
33. Xpert MTB/RIF PT samples are presumed infectious and must be handled using universal precautions.
34. Wear appropriate personal protective equipment (laboratory gown and disposable gloves) when handling PT samples
35. Wash hands thoroughly after handling samples and test reagents.
36. Use proper technique to minimize aerosols when working with any sample.
37. Do not shake specimens vigorously
38. Do not process grossly leaking specimens
39. Manipulate specimens with care
40. Work space must have adequate ventilation.
41. Waste management
42. Immerse used transfer pipettes and sticks in discard container containing dilution of appropriate disinfectant, placed on the work station.
43. Discard empty specimen containers in infectious waste container.
44. Discard used MTB/RIF cartridges in infectious waste container.
45. Contaminated wastes (e.g., pipettes, specimens, cartridges) should be removed from the testing site in sealed disposal bags.
46. Discard wastes according to the testing site’s waste management SOP.
47. Clean work bench with paper towels soaked with appropriate disinfectant before starting and after completing work.
48. Clean spills with appropriate disinfectant according to the testing site’s SOP for handling spills.
49. Strict adherence to safety precautions is required at all times. In the event of workplace safety incident, follow the testing site’s SOP.
50. **QUALITY CONTROL**
51. Each Xpert MTB/RIF test includes a Sample Processing Control (SPC) and Probe Check Control (PCC). Refer to Xpert MTB/Rif testing SOP for the purpose of each control and interpretation of results.
52. External controls should be used in accordance with local or national requirements as applicable.
53. **PROCEDURE**

This section provides instructions for receiving and handling PT samples, testing, and recording and reporting PT results.

1. **Receiving and Handling Proficiency Testing Samples (Pre-analytical)**
2. The testing staff are responsible for receiving PT samples.
3. Note the date of receipt of your shipment.
4. Immediately inspect and reconcile the contents of the shipment with the accompanying paperwork.
5. Are the PT samples and accompanying documents (e.g. Kit instructions, Report Form) complete?
6. Was there delay in transport?
7. Are the quality and appearance of the specimens acceptable?
8. Notify supervisor of any shipment or specimen problems. The supervisor will contact the PT provider for resolution of the problem.
9. Note the due date of the results.
10. Log-in PT sample in the assigned register (or computer). Each PT sample must be assigned a separate specimen number.
11. Label PT samples with the specimen number.
12. Store PT samples until testing. Refer to PT Kit Instructions for storage and stability information.
13. **Testing of PT Samples (Analytical)**
14. The supervisor will assign the staff to perform testing of the PT samples.
15. PT samples are assigned to the testing staff on a rotation basis.
16. PT samples are tested by the same personnel who routinely perform the procedure.
17. PT samples are tested and reported by trained and competent staff.
18. PT samples are tested in the same space and using the same PPE and other biosafety precautions for testing patient samples.
19. Complete PT sample testing and submit results within the timeframe given by the PT program.
20. Integrate PT samples into the routine workflow and test in the same manner as patient specimens using the same method (Xpert MTB/RIF Assay).
21. Always refer to the PT provider’s PT Kit Instructions for sample rehydration and special testing instructions.
22. Analyze specimens at correct temperature. If shipment was stored in the refrigerator, samples may need to come to room temperature before testing.
23. If there are more than one primary instrument used for testing patient samples, testing of PT samples can be rotated among primary instruments for different PT rounds or events.
24. There is no need to order multiple PT kits for the purpose of Xpert MTB/RIF testing on multiple instruments.
25. Do not refer PT samples to a reference laboratory or other testing site for testing.
26. PT panels from other testing sites are never accepted for testing.
27. There should be no inter-laboratory (testing site) communication regarding PT samples and results prior to the date of submission of results.
28. **Recording and Reporting PT Results (Post-analytical)**
29. The testing staff is responsible for recording PT result.
30. As soon as testing is completed, record results on the specimen register and on the PT Result Form, following PT provider’s instructions.
31. The supervisor and another individual will review results on the register, instrument print-out, and the PT Result Form for accuracy, completion, and clerical errors.
32. The supervisor and staff who processed or tested the PT samples should sign and date the Attestation Statement on the PT Result Form.
33. The supervisor or designee will send the report to the PT provider according to the PT provider’s instructions.
34. Retain a copy of the completed PT Results Form.
35. Retain specimens until the Participant’s Evaluation Report from the PT provider is received in the laboratory, for investigation of unacceptable PT results, if any.
36. PT records must not be shared with and should not be accessible to personnel of other testing sites until after the deadline for submission of results.
37. **REVIEW OF PT EVALUATION REPORTS**
38. The testing site supervisor is responsible for reviewing PT reports (PT Participant’s Evaluation) and discussing the results with the testing site staff in a timely manner.
39. Review PT results within 10 days of receipt of results from the provider.
40. Review PT results with the staff, which may be done during scheduled staff meetings.
41. Review the accompanying commentaries that will provide continuing education to the staff.
42. Document discussions of PT evaluation reports in the staff meeting minutes or on the PT Participant’s Evaluation Report.
43. The testing site supervisor will ensure that unacceptable PT results are investigated.
44. Each PT result is evaluated to be “acceptable” or “unacceptable” as scored against peer groups by the PT provider.
45. A failed PT event or round is a less than 80% performance for Xpert MTB/RIF assay.
46. Investigate any unacceptable result even if considered a successful event, as this may detect system problems (See Section 10)**.**
47. Ungraded PT results
48. PT challenges may not be graded for many reasons including lack of consensus, late or lack of submission of results, and incorrect completion of results form.
49. Identify the PT result with an ungraded response and review all participant statistics for any explanatory information.
50. Investigate ungraded results determined to be unacceptable upon review in the same manner as graded unacceptable results.
51. **PROFICIENCY TESTING FAILURES OR UNACCEPTABLE RESULTS**
52. The testing site supervisor will discuss unacceptable PT results with the staff.
53. The testing site should make every effort to find the cause(s) of an unacceptable results and design process improvements to prevent re-occurrences.
54. Identify the cause of the unacceptable result through systematic evaluation of the pre-analytic, analytic, and post-analytic phases of testing.
55. Question the staff who processed the specimen and performed the analysis, and review the PT kit instructions to assure the PT samples were handled correctly.
56. Review all recorded data surrounding the PT event, e.g., PT Result Form, instrument print-outs, specimen register, and PT specimen labels. Look for obvious transcription errors including transposed results.
57. Review instrument calibration records, reagent lot records, and storage temperature logs.
58. Use the PT Failure Investigation Form to ensure that possible critical steps in the investigative process were not overlooked.
59. Remedial or corrective action may need to be considered to remove the cause of unacceptable result.
60. Review and monitor the effectiveness of the preventive action taken.
61. Document results of investigation and action taken on the PT Failure Investigation Form (Appendix A).
62. **DOCUMENTATION**
63. The testing site supervisor and staff will ensure that all PT-related documents and records are filed in a timely manner and organized systematically for easy retrieval and review.
64. Compile all PT documents and records in the PT binder per event or round.
65. Completed (signed) PT Result Form
66. PT Participant Evaluation Report from the PT provider, signed and dated by supervisor.
67. PT Failure Investigation Form, completed and signed, if there are any unacceptable results.
68. Instrument reports print-out, Xpert MTB/RIF worksheets.
69. PT Kit Instructions and other documents from the PT provider.
70. The testing site supervisor is responsible for preparing an annual summary of PT scores using the standard form (Appendix B).
71. The annual summary allows easy “at a glance” review of the site’s PT performance, by the supervisor and external assessors.
72. File the completed annual summary form in the PT binder.
73. The testing site supervisor and staff will ensure that the PT Tracking Form (Appendix C) are updated in a timely manner.
74. File the PT Tracking Form in the PT binder.
75. All PT records must be maintained at the testing site for at least two years.
76. **PROCEDURAL NOTES**
77. In the proficiency testing process, the testing sites receive sample from a PT provider.
78. Testing sites are provided challenge samples at regular interval, typically 2-3 times yearly.
79. The testing sites participating in the program analyze the samples and return their results to the PT provider.
80. Results are evaluated and analyzed by the PT provider, and the testing sites are provided with information (PT Participant’s Evaluation Report) about their performance and how they compared with other participants.
81. The testing sites use the information regarding their performance to make appropriate changes and improvements.
82. The educational purposes of proficiency testing are best served by a rotation that allows testing personnel to be involved in the PT activities.
83. PT records must be retained and can be an important part of the competency and continuing education documentation in the personnel files of the individuals.
84. To be successful, PT instructions must be followed carefully, all paperwork completed accurately, and results submission deadlines are met.
85. PT is valuable only if the information received is directed to improvement at the testing site.
86. PT have some limitations and it is not appropriate to use PT as the only means for evaluating the quality of the testing site.
87. On-site assessment of the testing site (internal/external assessments), using standardized checklist can give a true picture of a testing site’s overall performance, and offer real-time guidance for improvements that are needed.
88. **RELATED DOCUMENTS**
89. SOP: Xpert MTB/RIF Assay
90. Testing Site Safety Manual
91. **REFERENCES**
92. Laboratory Quality Management Systems Handbook, 2011. WHO/CDC/CLSI.
93. Tuberculosis Laboratory Biosafety Manual, 2012. WHO
94. Strengthening Laboratory Management towards Accreditation (SLMTA) training/mentoring toolkit. CDC and ASCP.
95. Medical Laboratories Requirements for Quality and Competence. ISO 15189:2012
96. Cumitech 3B Quality Systems in the Clinical Microbiology Laboratory, 2005. American Society for Microbiology (ASM), Washington D.C., USA.
97. Astles JR, Stang H, Alpasch T. et al. CLI requirements for proficiency testing: the basics for laboratory professionals. *Med Lab Observ*, 2013:45(9):8.
98. Educational Commentary, 2014 2nd Test Event. American Proficiency Institute. Michigan, U.S.A.
99. College of American Pathologists (CAP) All Common Checklist, 2016. Illinois, U.S.A.
100. **APPENDICES**
101. Appendix A. PT Failure Investigation Form
102. Appendix B. Annual Summary of Xpert MTB/RIF PT Result
103. Appendix C. Xpert MTB/RIF PT Tracking Form