1. **PURPOSE OF THE XPERT MTB/RIF ASSESSMENT CHECKLIST FOR TESTING SITES (ACTS)**

Many countries have given considerable effort and resources to expand and decentralize the Xpert MTB/RIF testing so that testing can be done at both traditional laboratories and point of care sites. A continuous and systematic approach is needed to implement and monitor quality assurance activities in all testing sites to ensure that:

* Testing is performed in a safe and functional working environment
* Testing sites are able to provide accurate, reliable, and timely Xpert MTB/RIF results

The Xpert MTB/RIF ACTS sets minimum standards for quality assurance (QA) for all Xpert MTB/RIF testing sites. ACTS was designed to use for:

* Baseline assessments of Xpert MTB/RIF testing sites;
* Follow-up supervisory visits, with assessments conducted at least once per year

Assessments will help identify poorly performing sites where supportive supervisory visits are needed the most. Using the ACTS, testing sites will be able to identify areas where improvement is needed, develop and implement a work plan to address gaps, and monitor progress to maintain quality.

The assessment checklist, together with the users’ guide, may also be used as a self-assessment tool for testing sites as it provides information on best practices and an opportunity to improve practices as needed.

1. **PURPOSE OF THE XPERT MTB/RIF ACTS USERS’ GUIDE**

The users’ guide was developed to provide assessors with instructions on how to implement the ACTS in an accurate and standardized way. The rationale for each standard or checklist question and the methods that should be used to assess them are explained in this users’ guide (See Section VI).

The basis for those standards should also provide the testing site staff with a clear indication of the requirements for compliance and some direction on the assessor’s expectations.

It is recognized that some of the questions may be outside the purview of the testing site management and staff. However, the data collected from these assessments will be used for advocacy and decision making at higher level.

1. **STEPS AND REQUIREMENTS OF THE ASSESSMENT**

**Pre-assessment. Before the assessment visit, the assessor will:**

* Work with the NTP or QA focal person to identify and prioritize sites
* Notify testing sites and agree on the assessment date
* Convey the purpose of the assessment and the estimated time to complete the assessment (≈ 1 day)
* Provide the site with a copy of the assessment checklist and users’ guide
* Familiarize yourself with the assessment checklist and the users’ guide
* Print the assessment checklist to use during the assessment
* Gather other resources as needed (e.g., electronic copy of the national TB diagnostic algorithm, SOPs, and forms related to Xpert MTB/RIF testing, if available) to give to the testing site if needed. Familiarize yourself with the contents of these documents.

**Assessment. During site visit, the assessor will:**

* Introduce assessment team to site management and staff
* Discuss the assessment process
* Conduct the assessment using the standardized checklist (Xpert MTB/RIF ACTS)
* Complete the checklist including the summary of findings and recommendations

**Post-assessment. After the assessment, the assessor will:**

* Review findings and recommendation with testing site management and staff
* Agree on findings, recommendations and on actions to be taken to address the gaps
* Work with the testing site and management to prepare the action plan, implementation timelines, and to identify a point of contact (POC) for follow-up actions.

*Note:* The person in-charge of the testing site (or higher-level management) should sign and date the action plan. The assessor and testing site will keep a copy of the signed action plan.

* Provide testing site with a copy of the completed (signed) checklist including the summary of findings
* Submit completed assessment checklist, action plan, and documents and records collected from the testing site to the NTP or Xpert focal person within the set timeframe.

1. **TIPS ON HOW TO CONDUCT AN ASSESSMENT**

**Assessment of the site should include discussions with GeneXpert users and testing site management, review of Xpert MTB/RIF test site documentation, and observation of Xpert MTB/RIF testing and site operations.**

**Follow a specimen through the Xpert MTB/RIF testing process** from specimen collection through accessioning, testing, recording and reporting of test results, and post-analytic handling of specimens to determine the strength of the site’s systems and operations.

It is often not necessary to ask all the questions in the checklist verbatim. In some instances, a simple observation may be sufficient to assess whether or not there is compliance. Questions should be asked for clarification**.**

**Ask open-ended questions** to clarify documentations seen and observations made. Ask questions like “show me how…” or “tell me about…”. An experienced assessor can often learn to answer multiple questions through open-ended questions with the staff.

**Use the assessment process as an opportunity to mentor and motivate the staff to correct non-compliances in a timely fashion and to initiate quality improvement.**

During the assessment, the assessor may assist the staff to correct some of the “easy to fix” checklist non-compliances instead of waiting until the corrective action plan is prepared at the end of the assessment.

*Example 1*. You noticed the bottle of disinfectant solution on the bench had the incorrect concentration (question 2.7). You can explain the optimal working concentration so that the staff can prepare and change the solution that day and affix the correct label.

*Example 2*. You were checking the storage area for stock Xpert MTB/RIF test kits (question 4.4); you noticed that the kits were not labeled with the receive date. You can explain to the staff the importance of writing the receive date and ask them to start labeling while you are doing the assessment.

Mention the corrective actions that were implemented (in examples 1 and 2) in your summary of findings and during the post-assessment discussions to educate other staff members and to inform the management so that appropriate changes can be made in their SOPs.

1. **STRUCTURE OF THE XPERT MTB/RIF ACTS**

**The checklist has five parts (A-E).** The assessor must complete all the information by following the instructions provided below. Read additional instructions in the checklist. Do not leave any space blank.

**Part A. Testing Site Information**

Part A is a summary table that gathers general information on the testing site to be assessed.

1. Provide the official name of the facility.
2. Some countries have a listing of the facilities with unique ID assigned; provide the number if available. If not available, write NA in this box.
3. Provide the complete location or physical address of the testing facility.
4. Circle the type of testing site. If not listed, specify under “other”. Countries will need to customize this classification of sites to reflect current tiered-structure of the Xpert/MTB RIF network
5. Provide the name of the contact person (e.g., testing site manager or QA officer) who may be contacted for follow-up actions or other QA-related information.
6. Provide phone number of the contact person.
7. Provide email address of the contact person.
8. Provide the total number of staff that have been trained to perform Xpert MTB/RIF testing, both users and advanced users.

8a. Provide the number of users.

8b. Provide the number of advanced users.

1. Provide the number of staff currently performing Xpert MTB/RIF testing, both trained and untrained.
2. Provide the number of supervisory visits in the last 12 months.
3. Provide the date of last supervisory visit (dd/mm/yyyy).
4. Write “Yes” if internet is available at the testing site.
5. Write “Yes” if the onsite internet connection is stable.
6. Review the testing site’s specimen register and count the total number of Xpert MTB/RIF tests performed the last 3 months (a). Do not include repeat testing. Provide the total number and average number of tests performed per month (a/3). *Note:* If the testing site is monitoring this number, you may just request for these numbers from the testing site’s record.

**Part B. GeneXpert Instrument Information**

Part B is a summary table that gathers information about the GeneXpert instruments available at the testing site. Include both functioning and non-functioning instruments and explain why instrument is non-functional, if any. The space provided can accommodate three instruments. List the instrument on the space below this table if the number of GeneXpert instruments exceeds three.

**Part C. Checklist Questions**

Part C contains questions divided into 5 sections.

* Section 1. Personnel Training and Competency
* Section 2. Physical Facilities and Safety
* Section 3. Xpert MTB/RIF testing: Pre-testing, Testing, and Post Testing Phases
* Section 4. Supplies, Reagent, and Equipment
* Section 5. Monitoring Quality

For each of the checklist questions, circle “Y”, “P”, or “N”, according to the scoring criteria.

Write your comments in the space provided for each question.

Write the score (1, 0.5, 0) in the space provided for each question.

**Part D. Summary of Findings and Recommendations**

Part D contains the summary of the assessment scores obtained and performance level by the testing site and summarizes the assessor’s comments with recommended corrective action.

Complete all the information in Table1.

* Assessment round refers to the number of times the testing site was assessed, as of the day of assessment. If not available, review past assessment records to determine this round number.

Write “1” if this is the first Xpert MTB/RIF assessment

* If more than one assessor, provide the name of the second assessor
* Provide the title of the assessor and the organization affiliated with

Perform the necessary computations and provide the testing score in Table 2.

* Determine the performance level (0-4) achieved by the testing site based on the % score obtained.

|  |  |  |
| --- | --- | --- |
| **Performance levels** | **% Score** | **Recommendation** |
| Level 0 | Less than 40% | Testing sites with performance level 0-2 may be targeted for more frequent supervisory visits (e.g., 3-4 times per year) to follow up and assist in the implementation of the corrective action plans. In contrast, sites with performance level 3-4 may need less supervisory visits (e.g., 1-2 per year) to ensure compliance with QA standards is sustained. |
| Level 1 | 40% - 59% |
| Level 2 | 60% – 79% |
| Level 3 | 80% - 89% |
| Level 4 | 90% or higher |

Complete all the information in Table 3. Summarize all your assessment comments for each checklist questions section and provide appropriate recommendations to correct the deficiency.

Review the findings and recommendations with the person in-charge of the testing site and the staff. The person in-charge and the assessor (s) should sign on the space provided. The testing site and the assessor should each keep a signed copy of the completed assessment checklist with the summary report. Assist the site in preparing a binder at the testing site to organize all assessment-related documents for the site’s reference.

1. **WHAT TO ASK FOR AND WHAT TO LOOK FOR WHEN CONDUCTING THE ASSESSMENT**

This section provides the assessor with instructions to complete each section of ACTS Part C (Section 1-5) in a systematic and efficient manner.

Remember to follow the tips on how to conduct an assessment (Users’ Guide Section IV).

Read the Xpert MTB/RIF QA Guide for additional information. Generic SOPs and forms (e.g., competency assessment, GeneXpert maintenance, and performance indicator reporting form) are available in the Xpert MTB/RIF QA Guide and in the suggested references.

1. **PERSONNEL TRAINING AND COMPETENCY**

This portion of the checklist involves review of SOPs and related forms and training and competency assessment records. Request the testing site to bring all the necessary documents and records in an office or conference room.

1. **Review** the document control and retention log. **Verify** that the log lists all SOPs, each with unique ID number and version, location, and schedule of document review and retention.

**Review** the master copy of each SOP (a-g) and associated forms. **Verify** that the authorized person has approved the SOPs, they are up-to-date (reviewed every 2 years), contents aligned with national guidelines and best practices, and related forms linked to specific SOP. **Verify** that SOPs are filed systematically (e.g. according to SOP number) and organized in binders. **Verify** that obsolete SOPs and Forms are labeled “retired”, have been removed from circulation, and retained for at least 2 years or according to national policy.

**Review** records documenting that staff have read and understood the SOPs. **Review** the list of staff with their assigned duties and responsibilities. Using the two documents, **verify** that staff have read and understand the SOPs that relate to their responsibilities.

**Ask** to see the authorized bench copies of the SOPs (a-g) to determine if they are readily accessible to the staff. **Verify** that the copies are the latest version of the SOP by comparing with the master copy.

1. **Review** the national TB diagnostic algorithm available at the testing site. **Verify** that the version is current. **Review** records documenting that all staff have read and understood the algorithm. **Verify** that all testers have signed the review and understand document.
2. **Review** staff training records and **verify** that staff are trained on assigned tasks (a-d). **Verify** that a standardized training checklist is used describing specific skills to be mastered and covers all the elements contained in the SOPs. **Verify** training contents include hands-on sessions.
3. **Review** Xpert MTB/RIF testers’ competency assessment records and verify that all testers are certified as competent according to national or testing site guidelines. **Verify** that all testers are assessed twice on the first year of hire and at least annually thereafter. Records should show which skills were assessed (Xpert MTB/RIF testing), how skills were measured, and who performed the assessment (the assessor must be competent in Xpert MTB/RIF testing). Competency testing techniques include direct observation of routine test performance, direct observation of instrument maintenance and function checks, proficiency testing samples, problem solving, and review of reports. If competency assessment is unsatisfactory, **review** records to verify that staff retraining and reassessment was conducted. **Verify** testers’ signatures on the Xpert MTB/RIF register to confirm that only certified competent testers are performing testing.
4. **PHYSICAL FACILITIES AND SAFETY**

To complete this portion of the checklist**, reques**t a staff to take you around the testing site facility. Specifically, **ask** to see the specimen receiving area, Xpert MTB/RIF testing area, area where paperwork is completed, storage area for Xpert MTB/RIF kits and other supplies, and autoclave room or incinerator. **Observe** staff perform their daily work while going around the testing site.

1. **Verify** that testing site space is adequate, secured, clean and well organized, well ventilated, adequately lit, and within acceptable temperature ranges.

**Verify** that the testing site is set up correctly (i.e., unidirectional workflow from sample preparation area to DNA amplification area). **Identify** unsafe conditions and practices and **note** for problems that contribute to inefficient workflow.

**Verify** that the place is not cluttered with expired reagents, non-functioning equipment, and outdated files. **Verify** sinks are functional with a faucet and that soap and running water are available**.**

**Look** for safety signage: “Authorized Personnel Only” or “Visitors not Allowed” on entrance doors and “No Food or Drinks Allowed” on refrigerators for specimen storage. **Observe** if staff and visitors comply with the policy.

1. **Verify** that GeneXpert instruments, computers and printers are placed on a stable bench, away from vents and air handling units, and from thoroughfares where it may easily be bumped. **Verify** thatthe GeneXpert instrument is protected from dust.
2. **Verify** that GeneXpert instruments are protected from theft by security lock or door without impairing general safety (e.g. blocking fire exits).
3. **Verify** that the Xpert MTB/RIF workstation is clean and free of clutter. **Verify** if minimum supplies and documents required to perform daily tasks are available and accessible for a more efficient operation - disinfectant dispenser, bucket with disinfectant for used pipettes, markers for labeling, disposable gloves, waste bins with biohazard bag, GeneXpert operator manual, SOPs, Forms, and the national TB diagnostic algorithm.
4. **Verify** storage space for reagents kits and supplies is sufficient, accessible, secured, and organized. **Verify** that stocks are not too close to the ceiling, away from direct sunlight. Ideally, storage shelves (including the refrigerator) should be appropriately labeled to improve efficiency.
5. **Ask** where thermometers for room temperature monitoring are located. **Verify** temperature is within acceptable limit of 15oC-30oC. **Ask** for the room temperature records for the last 3 months to **verify** daily room temperature monitoring and monthly review of records by the person in charge. **Ask** for documentation to v**e**rify if out-of-range readings are investigated and corrective action is taken in a timely manner.
6. **Ask** the staff what disinfectant is used in the facility and how it is prepared. **Review** the SOP on preparation of disinfectants to verify that optimal concentration is used and prepared correctly. **Inspect** disinfectant bottles to check it is properly labeled with the disinfectant name and concentration, date prepared, and expiry date.
7. **Observe** if waste is segregated. **Look** at waste bins to check if potentially infectious materials (used cartridges, specimen containers, and pipettes) are placed in labeled biohazard bags. **Verify** that waste containers are not over-filled. **Verify** that infectious wastes are double-bagged and sealed (tied) before transporting for autoclaving or incineration.
8. **XPERT MTB/RIF: PRE-TESTING, TESTING, AND POST-TESTING PHASE**

This portion of the checklist involves review of records (registers, logbooks or electronic files, Xpert MTB /RIF reports, test request forms) and visiting the area where records are archived. The assessor will also observe the testers perform Xpert MTB/RIF testing. You will observe the tester receive the specimen for Xpert MTB/RIF testing, process and test the specimen, and record and report results.

1. **Ask** for documentation to verify that healthcare workers are informed on sample requirements for Xpert MTB/RIF testing. This could be the document control log or any similar document to prove that collection sites were provided with SOP on specimen volume and quality, proper labeling, storage, and transport, policy on rejection of samples, and completion of test request forms.
2. If sputum collection is not done at the site**, ask** for documentation to verify healthcare workers are trained to ensure patients are instructed in good sputum collection technique. **Ask** to see a copy of the instructions on proper sputum collection handed out to patients, to verify that it is available- **ask** for documentation to verify these are distributed to the collection sites. If sputum is collected at the site, **ask** to observe the process.
3. **Review** the Xpert MTB/RIF test request form to verify it is aligned with national guidelines. **Verify** that the standard test request form accompanies all specimens received in the laboratory.

**Ask** to see the **specimen** registers/logbooks or electronic files to record patient and specimen information. **Verify** they capture all key information including patient unique ID, specimen accession number, specimen type, date and time of collection and others according to national policy. **Ask** what unique patient identifier is used and record in the comment field of the assessment checklist. **Verify** that rejected specimens are logged and corrective actions are documented.

1. **Ask** to see the **Xpert MTB/RIF** registers/logbooks or electronic files to record Xpert MTB/RIF test results. **Verify** they capture all key patient and specimen information and Xpert MTB/RIF test results, date tested, name of the tester, date of reporting, and others according to national policy. In some testing sites, the specimen register may also be the Xpert MTB/RIF register.
2. **Review** entries on the registers for the past 30 days (or up to 100 entries/samples if number of tests is small). **Verify** all the fields are accuratelycompleted and readable. If you notice some missing data, ask the staff to explain the reason why and what action was taken.
3. **Ask** the staff to describe where registers or logbooks and other testing documents are kept when they are not testing (e.g. staff on short breaks, when testing is completed for the day) and **ask** to seethe location where registers are stored to ensure they are secure. **Verify** that records are kept out of view of other patients and unauthorized staff**.**

**Ask** to describe the procedure how test request forms and registers are archived once they are full. **Ask** to see the archiving locationto verify that they are organized, properly labeled, and easily retrievable (good filing system).

**Verify** that measures are in place to protect patient data and results in the GeneXpert computer from unauthorized access such as use of strong passwords, use of firewall, and updating antivirus software.

1. **Review** entries on the Xpert MTB/RIF register for the past 30 days (or up to 100 entries/samples if number of tests is small). **Verify** that Xpert MTB/RIF testers record results on the logbook on the day of testing. **Verify** that testers record invalid, error, and repeat testing. **Verify** that testers record all results in standard format every time, based on country guidelines.
2. **Review** copies of test reports issued the past 30 days. **Verify** that all results are reported in a standard format based on national guidelines.
3. **Verify** that the GeneXpert operator manual, Xpert MTB/RIF product inserts, and procedure SOPs are available at the GeneXpert workstation, easily accessible to the staff.
4. **Ask** to observe the scheduled testers (check staff duty roster) to perform Xpert MTB/RIF testing (maximum of four specimens) from specimen receiving, testing, and after testing.

**Observe** processes and techniques. **Ask** questions or consult the site’s SOP, when needed for clarification, during the observation.

**Note**: Make sure you are familiar with Xpert MTB/RIF testing procedure, standard reporting of Xpert MTB/RIF results, specimen requirements, and the national TB diagnostic algorithm to be able to assess if there are deviations.

* **Pre-testing phase. Verify** thattester checks the following: specimen acceptability (i.e., volume, quality, transport delay, testing delay etc.); test request form was properly completed; specimen container is properly labeled; the correct test was ordered; the national testing algorithm is followed; test request form match with the specimen; and specimen is logged and labeled with unique specimen ID.
* **Testing phase:** **Verify** that all needed materials are available on the workstation prior to testing. **Verify** thatthe in-use box of MTB/RIF kit is in date and labeled with the open date and new expiry date based on manufacturer’s recommendation.

**Verify** tha**t** Xpert MTB/RIF testing procedure is done correctly from sample reagent addition, shaking, incubation, and inoculation of cartridge. **Verify** cartridge is labeled with the sample number and matched with specimen number prior to inoculation.

**Verify** tester is able to start the test on the GeneXpert and use the software without any problem.

* **Post-testing phase. Verify that** tester review internal control results before reporting. **Verify** result is recorded on the logbook or computer. **Verify** result is reported the same day of testing and in the standard format in an approved report form. **Verify** Xpert MTB/RIF report print-out are filed in a labeled binder according to date or specimen number or archived in the computer.

**Verify** opened Xpert MTB/RIF kit is stored in a clean and dry place and if specimen container is archived or discarded after testing according to site policy.

* **Safety practices. Verify** thattester wears lab gown and gloves during testing and follows good microbiological practices. **Verify** that tester observes site-specific safety precautions based on risk assessment (e.g., some reference labs split samples for culture and MTB/RIF testing in a biologic safety cabinet).

**Verify** bench is cleaned with fresh disinfectant before and after testing; if used transfer pipettes are immersed in disinfectant solution for at least 15 minutes prior to disposal; and production of aerosols is minimized. **Verify** that biologic spill is handled correctly and wastes (specimen containers, pipettes, used cartridges) are discarded according to safety guidelines. **Verify** that tester practices proper handwashing technique.

1. **SUPPLIES, REAGENTS, AND EQUIPMENT**

This portion of the checklist involves review of supplies stock cards and purchasing records, and inspection of the storage locations for Xpert MTB/RIF kits and other supplies (disposable gloves, disinfectant, hand soap, paper towels).

1. **Ask** if there is person designated to manage the stock of test kits and supplies at the testing site. **Ask** that person to describe the process in place to manage the stocks. **Review** stock documents to verify process (e.g., stock cards, order form). **Verify** that stocks are accurately forecasted based on consumption and delivery lead-time, with no over-stocking or under-stocking, to minimize expired reagents and avoid testing service interruptions.
2. **Review** stock cards or inventory records to verify that physical count of Xpert MTB/RIF test kits and other supplies is done at least on a monthly basis. Check that stock cards include the name of item, item number, minimum and maximum, and reorder stock amounts.
3. **Ask** to see the stock of Xpert MTB/RIF test kits. **Check** if quantity of stock meets the minimum stock level with no over-stocking (keep an eye on expired kits by checking kit box labels).

**Ask** to see the stocks of other supplies. **Check** if adequate quantities are available. **Check** if they are labeled with the receive date and stored in an organized manner.

1. **Verify** that Xpert MTB/RIF kits are in-date and are labeled with the receive date. **Check** thermometer reading to verifystorage temperature is at 2-28oC and properly documented. **Check** if Xpert MTB/RIF kits are arranged in shelves according to expiry date and receive date and that stocks are rotated (FEFO, FIFO).
2. **Review** quality control (QC) records to verify that new lots of Xpert MTB/RIF test kits have passed quality control testing prior to their use for patient testing. QC testing may be done at the national level (NTRL) prior to distribution of new lots to peripheral sites. Ideally, QC testing of new lots is also done upon receipt at the regional or testing site level to monitor conditions during transport and storage of cartridges in country. **Check** if kits that passed QC testing are appropriately labeled (“QC passed”/”Ready for use”) to separate them from stocks that have not been QC tested.
3. **Ask** staff if there have been interruptions on Xpert MTB/RIF testing the last 3 months. **Review** Xpert MTB/RIF logbook and look for testing gaps to verify if there were service interruptions. Ask the staff to explain the reason for testing services interruption.
4. **Ask** for the policy on notification of clients regarding service interruptions and how service interruptions are communicated to the clinicians (e.g., memo, e-mail, occurrence management report). A**sk** for documentation to verify clients were notified.
5. **Ask** if the GeneXpert instrument has been verified onsite prior to use for patient testing. **Check** if instrument verification is also conducted after service or calibration, or after moving the GeneXpert instrument. **Ask** for the verification procedure and results to verify results meet established acceptance criteria.
6. **Review** GeneXpert maintenance logs for the last 3 months. **Verify** preventive maintenance are performed consistently (daily weekly, monthly, annual). **Verify** that maintenance activities are according to manufacturer’s recommendations and that trained staff and authorized providers carry out the servicing and repair of the instrument. **Look** for signature and date on the form to verify that the person in charge reviews maintenance records regularly, at least once a month. **Ask** for documentation to verify that the person in charge and the staff investigate instrument failures and implement corrective action in a timely manner.
7. **Ask** for documentation to verify that the person in charge communicates maintenance and servicing needs (e.g. annual calibration), module replacement or repair) to the higher management (e.g., site director, NTP) and followed up until issue is resolved.
8. **MONITORING QUALITY**

This portion of the checklist involves review results, Proficiency testing (PT) records, and performance indicator (PI), also known as quality indicator data.

1. **Ask** if there is person designated to review Xpert MTB/RIF test reports. Ask the person the process of reviewing reports (how often, how is the review done, how is review documented. **Ask** for records to verify that the designated person reviews report consistently (e.g., signature and date on reports or register). **Review** register/logbook or computer to **verify** that reviewer follows up test results that need repeat testing and ensures that retesting are done and reports are released in a timely manner. **Review** register/logbook or computer to verify that reviewer follows up specimens with pending results and ensures that there are no missing test reports. **Ask** for documentation to verify that the testing site communicates corrected/amended reports to the client.
2. **Ask** if the testing site is enrolled in Xpert MTB/RIF EQA/PT program. **Ask** who is the PT provider, how many events or rounds per year, and how many samples are received per event, and the score for the last PT round. Record all information in the Comment field of the checklist.
3. **Ask** if there is a person designated to coordinate PT activities at the testing site. **Ask** the person to describe the PT process flow from sample receiving, handling, testing, reporting, review of report, and investigation of PT failures.

**Ask** for the testing site’s PT records. Records include the PT results form, PT evaluation report from the PT provider, GeneXpert test report print out, worksheets. **Check** if PT records are complete and organized in a binder. **Request** for a copy of the PT evaluation report with scores for the last round and reason for any “unacceptable” result.

**Review** PT records for the last 3 rounds. Verify that PT samples are processed onsite and not referred to other testing facilities. **Verify** that testing of PT samples is assigned to the staff on a rotation basis. **Verify** that PT samples are tested by the same personnel who routinely perform Xpert MTB/RIF testing. **Verify** that only trained and competent staff test PT samples. **Verify** that PT results are submitted before the due date established by the PT provider. **Verify** that the management and staff and sign the PT attestation statement.

1. **Review** PT Participant’s Evaluation Report for the last three rounds. **Verify** that the person in charge reviews the report with the staff in a timely manner (preferably within 10 days from date of receipt of the report). To verify, **look** for the signature of the person in charge, date of review, and date of review with the staff on the evaluation report or equivalent form.

**Ask** for documentation to verify that the testing site investigates “unacceptable” PT results in a timely manner and takes corrective action to improve performance. Documentation should show how the site investigated the problem, what was the conclusion, what corrective action was taken (when, and by whom).

1. **Ask** the managementif the testing site collects Xpert MTB/RIF PI data according to national guidelines. **Ask** how the site collect and review PI data. **Ask** or a copy of the PI data for the last 3 months. **Verify** that the testing site report monthly PI data to the MOH, NTP, or NTRL on a regular basis.
2. **Review** the testing site’s PI data for the last three months. **Verify** that target value is set for each indicator monitored, according to national guidelines. **Note** if there are unexpected results or trends.  **Ask** for documentation to verify that the management reviews PI data and takes corrective action on unexpected results. **Verify** if there is subsequent improvement and normalization of the PI data following the corrective action. **Verify** that the management communicates with the higher levels (regional, national) for support to address issues that are more complex.
3. **Follow** instructions on the checklist question to determine the testing site’s Xpert MTB/RIF test results TAT. **Write** the results of the computations on the space provided.
4. **Follow** instructions on the checklist question to determine the testing site’s Xpert MTB/RIF test error, invalid, and No results. Write the results of the computations on the space provided.