Situational Analysis of Quality Assurance Activities at Testing Sites**[[1]](#footnote-2)**

This checklist is used to assess the current status of the Xpert MTB/RIF quality assurance system at the testing site. The numbering of the sections in this checklist corresponds with the numbering of the sections in the CQI manual. Most questions are to be answered with a ‘Yes’ (achieved), ‘No’ (not achieved) or ‘Partial’ (partially achieved). Some questions (e.g., how many instruments?) will be answered by providing numbers) and some (e.g., who is responsible for …?) will have text answers. Space is provided to provide comments for the responses for each question. To aid in the assessment, a suggested approach to assessment is provided for each question.

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| **Symbol** | **Approach** |
| 🕮 | Review applicable documents, e.g., policies, SOPs, guidelines, and data |
| ? | Ask staff members or clients for their views or level of understanding |
| 😐 | Objective observations or conclusion |
| ☟ | Test the functionality of the equipment or system |

This situational analysis checklist is more detailed than a checklist that would be used for a supervisory visit. A supervisory checklist has been developed (the Assessment Checklist for Testing Sites or ACTS). Each of the ACTS questions is incorporated in the situational analysis checklist. These questions are identified by the presence of a ‘scorebox’ in the comments section. The number in the scorebox corresponds to the number of the question in the ACTS. Assessors may enter a score for each of the questions in the scorebox and thereby generate a baseline score for the testing site which would be useful for tracking progress during subsequent supervisory visits.

**Country name:**

**District:**

**Testing site:**

**Assessor name:**

**Assessor contact details:**

**Date of assessment:**

In addition to noting the presence of documentation, assessors must collect, where possible, a copy of the policy, document, SOP or form.

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|  |  | **Yes** | **No** | **Partial** | **Comments** |
| **1. Governance** | | | | | |
| a. Has a quality officer (part-time or full-time) responsible for overseeing the Xpert MTB/RIF QA processes been appointed and trained? If yes, | 😐, ? | Y | N | P |  |
| * Has the quality officer been empowered to implement and enforce the QA programme? | 😐, ? | Y | N | P |  |
| * Does the quality officer report directly to the head of the laboratory? | 😐, ? | Y | N | P |  |
| If no, who is responsible for implementing and enforcing the QA program? |  | | | |  |
| b. Has a quality assurance or quality improvement officers been appointed at participating clinical sites to oversee the quality of the clinical and diagnostic services? | 😐, ? | Y | N | P |  |

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|  | |  | **Yes** | | **No** | **Partial** | **Comments** | | | | | |
| **2. Strategic planning, policies and resources** | | | | | | | | | | | | |
| a. Are the following national guidelines and policies accessible at the testing site: | | 🕮 | Y | | N | P |  | | | | | |
| * Use of standardized documents, records and forms at all testing sites? | |  | Y | | N |  |
| * Maintenance, servicing and verification of GeneXpert instruments? | |  | Y | | N |  |
| * Training and competency assessments? | |  | Y | | N |  |
| * Participation in proficiency testing program? | |  | Y | | N |  |
| * Conducting supervisory visits at testing sites? | |  | Y | | N |  |
| * Procurement & supply of diagnostic reagents? | |  | Y | | N |  |
| * Monitoring & evaluation? | |  | Y | | N |  |
| b. Are resources (e.g., funding, staff, laboratory infrastructures, etc.) available to support Xpert MTB/RIF QA activities including: | | 😐, ? | Y | | N | P |  | | | | | |
| * QA-related documentation activities? | |  | Y | | N | P |
| * Training according to the national plan for the current year? | |  | Y | | N | P |
| * On-site supervisory visits? | |  | Y | | N | P |
| * Proficiency testing activities? | |  | Y | | N | P |
| * Monitoring and evaluation activities? | |  | Y | | N | P |
| * Analysis of quality and performance indicators? | |  | Y | | N | P |
| * Procurement activities? | |  | Y | | N | P |
| c. Are a sufficient number of qualified staff available for Xpert MTB/RIF diagnostic testing? | |  | Y | | N | P |  | | | | | |
| d. Have testing services been interrupted for longer than 24 hours due to lack of personnel in the last 3 months? | | 🕮 ? | Y | | N | P |  | Score 4.7 | | | | |
| e. Is an adequate budget for Xpert MTB/RIF diagnostic testing available? | |  | Y | | N | P |  | | | | | |
| f. Does a current costing plan exists for GeneXpert implementation in the laboratory? If yes, | | 🕮 | Y | | N | P |  | | | | | |
| * Proportion of planned implementation for next year for which funding is secured | |  | | | | |
| * Number of months’ worth of reagents/supplies that are in stock, or on order or with secured funding | |  | | | | |
|  |  | | **Yes** | **No** | | **Partial** | **Comments** | | | | |
| **3. Quality procedures and documentation** | | | | | | | | | | |
| a. Are all of the needed standardized documents, records and forms readily accessible to all staff?  (see Table 12 in manual for a complete list) | 🕮 | | Y | N | | P |  | |  |
| * Document control: document master file, identification, access and availability, forms, job aids, controlled document system, creation/revision, read and sign, and archiving | 🕮 | | Y | N | | P |  | | Score  1.1a |
| * Specimen management: specimen collection, labeling, storage, transport, receiving and accessioning at the testing site, and rejection criteria with corrective action | 🕮 | | Y | N | | P |  | | Score  1.1b |
| * Operation and maintenance of the GeneXpert instrument | 🕮 | | Y | N | | P |  | | Score  1.1c |
| * Xpert MTB/RIF testing procedure: specific safety precautions, sample requirements, quality control, step-by-step procedure, interpretation, recording and reporting, and sample retention. | 🕮 | | Y | N | | P |  | | Score  1.1d |
| * Safety: standard safety practices, use of PPEs, handling spills, waste management, preparation and labeling of disinfectants | 🕮 | |  |  | | P |  | | Score  1.1e |
| * Supplies: procurement, acceptance criteria, labeling with receive date, inventory, proper storage (FEFO/FIFO) | 🕮 | | Y | N | | P |  | | Score  1.1f |
| * EQA/PT: sample receiving and handling, testing, recording and reporting, review, and investigation PT failures | 🕮 | | Y | N | | P |  | | Score  1.1g |
| b. Is a copy of the current national TB diagnostic algorithm available at the testing site, with documented review and understanding by the testing staff? | 🕮 ? | | Y | N | | P |  | | Score  1.2 | |
| c. Does the testing site perform an annual review of all SOPs, documents and forms? | 🕮 | | Y | N | | P |  | | | |
| d. Does the testing site withdraw redundant documentation and archive them in accordance with their policies? | 🕮 | | Y | N | | P |  | | | |
| e. Is there evidence that all SOPs, documents and forms have been read by the personnel? | 🕮 | | Y | N | | P |  | | | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Yes** | **No** | **Partial** | | **Comments** | | |
| **4. Training, competency assessment and certification** | | | | | | | | |
| a. Are records in place documenting that all staff have been trained on assigned work processes, procedures, and tasks? | 🕮 | Y | N | P | |  | |  |
| * Specimen management | 🕮 | Y | N | P | |  | | Score  1.3a |
| * Operation and maintenance of the GeneXpert instrument | 🕮 | Y | N | P | |  | | Score  1.3b |
| * Safety and safe working practices | 🕮 | Y | N | P | |  | | Score  1.3c |
| * EQA/Proficiency Testing | 🕮 | Y | N | P | |  | | Score  1.3d |
| b. Are at least two users trained in the operation of the GeneXpert instrument & Xpert MTB/RIF test at this testing site? | 😐, ? | Y | N | P | |  | | |
| c. Does the testing site perform competency assessments for users (annually) and advanced users (bi- annually)? | 😐, ? | Y | N | P | |  | | |
| d. Are records in place documenting that GeneXpert users and advanced users are assessed for competency? | 🕮 | Y | N | P | |  | | Score  1.4 |
| e. Does the site provide Xpert MTB/RIF training for clinicians, nurses and healthcare workers on: | 😐, ? | Y | N | | P | |  | |
| Diagnostic algorithm? |  | Y | N | |  | |
| Ordering tests? |  | Y | N | |  | |
| Sample requirements |  |  |  | |  | |
| Sample transport? |  | Y | N | |  | |
| Result interpretation? |  | Y | N | |  | |

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| --- | --- | --- | --- | --- | --- |
|  |  | **Yes** | **No** | **Partial** | **Comments** |
| **5. Data Connectivity and remote monitoring** | | | | | |
| a. Has a diagnostics connectivity system for GeneXpert been installed in the laboratory? | 😐 ? | Y | N | P |  |
| b. If yes   * What proportion of the time is the system available (i.e., how many days last month did it work)? * How frequently do staff login to the data connectivity system? * For what purposes do staff access the system (e.g., monitor cartridge use or module functioning, analyse performance indicators, etc.)? |  | | | |  |
|  | | | |  |
|  | | | |  |
| c. If no,   * Has the site been assessed for connectivity? | 😐 ? | Y | N | P |  |
| Is there a costed plan for implementing a connectivity solution that includes: | 🕮 ? | Y | N | P |  |
| Installing and maintaining hardware and software? |  | Y | N |  |
| Setting up the connectivity solution? |  | Y | N |  |
| Training for users? |  | Y | N |  |
| Providing operational costs of the system? |  | Y | N |  |
| Is there an adequate budget available for implementing connectivity solution? | 🕮 ? | Y | N | P |  |
| d. Are a sufficient number of appropriately trained staff available for data connectivity at the testing site?   * How many persons are trained in using the data connectivity system? | 😐 ? | Y | N | P |  |
|  | | | |  |
| e. Are SOPs for access, reporting, data entry, data security and data back-up available and implemented? | 🕮 ? | Y | N | P |  |
| f. Has the testing site put measures in place to prevent the unauthorized access to Xpert MTB/RIF test data? | 😐 ? | Y | N | P |  |
| Restricted access to paper or electronic records |  | Y | N |  |
| Paper and electronic records with patient information are secured (e.g., kept in a locked cabinet) |  | Y | N |  |
| Electronic files and systems are password protected |  | Y | N |  |
| Unique passwords for each user |  | Y | N |  |
| g. Is an adequate budget for data connectivity available? | 🕮 | Y | N | P |  |

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|  |  | **Yes** | **No** | **Comments** | |
| **6. A safe and functional testing site** | | | | | |
| a. Is the physical facility of sufficient space and design to enable safe working practices? | 😐 | Y | N |  | Score  2.1 |
| b. Is the GeneXpert instrument placed correctly in the laboratory? | 😐 | Y | N |  | Score  2.2 |
| c. Is the GeneXpert instrument and computer safe from theft? | 😐 | Y | N |  | Score  2.3 |
| d. Is the Xpert MTB/RIF workstation clean, free of clutter, and organized for efficient operation? | 😐 | Y | N |  | Score 2.4 |
| e. Is there sufficient, secured, and organized storage space for reagent kits and supplies? | 😐 | Y | N |  | Score  2.5 |
| f. Is there documented monitoring and review of environmental temperatures at the testing and storage areas? | 😐 | Y | N |  | 1Score  2.6 |
| g. Does the testing site use appropriate disinfectants and are they prepared correctly? | 😐 | Y | N |  | Score  2.7 |
| h. Is an uninterrupted power supply in use? | 😐 | Y | N |  | |
| i. Does the testing site ensure an optimal working temperature for the GeneXpert instrument? | 😐 | Y | N |  | |
| j. Does the testing site perform regular risk assessments? | 😐 | Y | N |  | |
| k. Does the testing site provide sufficient ventilation for Xpert MTB/RIF testing procedures? | 😐 | Y | N |  | |
| l. Is suitable personal protective equipment (PPE) provided at the testing site, and are staff trained in its correct use? | 😐 | Y | N |  | |
| m. Does the testing site segregate waste and dispose of it by incineration or as per national regulations or guidelines? | 😐 | Y | N |  | Score  2.9 |

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|  |  | **Yes** | **No** | **Partial** | **Comments** | |
| **7. Equipment and supplies** | | | | | | |
| **7.1. Equipment service and maintenance** | | | | | | |
| a. Was the GeneXpert instrument verified on site prior to routine use for patient testing? | 🕮 | Y | N | P |  | Score  4.9 |
| b. Is the GeneXpert maintained and in good working condition? | 😐, ? | Y | N | P |  | |
| c. Are all modules functional? | 😐, ? | Y | N | P |  | |
| d. Have testing services been interrupted for longer than 24 hours due to instrument failure in the past 3 months? | 🕮 ? | Y | N | P |  | Score  4.6 |
| e. Does the testing site perform and document Xpert MTB/RIF preventative maintenance as required? | 🕮 ? | Y | N | P |  | |
| f. Is there an SOP in place to obtain repairs or service for the GeneXpert instrument? | 🕮 ? | Y | N | P |  | |
| g. Are all Xpert MTB/RIF warranties and service contracts in place and adhered to? | 😐, ? | Y | N | P |  | |
| h. Is preventive maintenance (annual calibration) of the GeneXpert instrument performed and documented? | 🕮 ? | Y | N | P |  | Score  4.10 |
| i. Are the GeneXpert instrument routine maintenance (daily, weekly, and monthly) performed and recorded? | 🕮 ? | Y | N | P |  | Score  4.11 |
| j. Are the GeneXpert instrument maintenance records reviewed regularly (at least monthly) by the supervisor or designee with root cause analysis conducted following equipment malfunction, and corrective action taken? | 😐, ? | Y | N | P |  | Score  4.12 |
| k. Are records in place documenting that instrument maintenance and servicing needs are routinely communicated to upper management? | 🕮 ? | Y | N | P |  | Score  4.13 |
| **7.2. Quality supplies** | | | | | | |
| a. Does the testing site forecast how many Xpert MTB/RIF cartridges are required before placing an order? | 😐,? | Y | N | P |  | |
| b. Does the testing site monitor Xpert MTB/RIF cartridge consumption? | 😐, ? | Y | N | P |  | |
| c. Are Xpert MTB/RIF test kits available at the testing site, are in-date, labeled with receive date, organized and stored at recommended storage conditions (2-30oC)? | 😐, ? | Y | N | P |  | Score  4.2 |
| d. Is quality control testing (QC) performed on new lots of Xpert MTB/RIF kits prior to their use for testing patient samples to ensure that they perform as expected? | 🕮 ? | Y | N | P |  | Score  4.3 |
| e. Are Xpert MTB/RIF kits and other supplies inventoried (physical count) at least monthly? | 🕮 ? | Y | N | P |  | Score 4.4 |
| f. Have testing services been interrupted for longer than 24 hours due to Xpert MTB/RIF reagent kit stock-out in the past 3 months? | 🕮 ? | Y | N | P |  | Score  4.5 |
| g. Does the testing site adequately store Xpert MTB/RIF cartridges? | 😐, ? | Y | N | P |  | |
| h. Does the testing site use appropriate disinfectants and are they prepared correctly? | 😐, ? | Y | N | P |  | |
| i. Is there a designated person at the testing site that is responsible for forecasting and procurement? | ? | Y | N | P |  | |
| If yes, who at the testing site is responsible? |  | | | |  | |
| If no, who or what organization is responsible? |  | | | |  | |
| Who controls the budget? |  | | | |  | |
| j. Are specimen collection and safety equipment and supplies available at the testing site? | 😐, ? | Y | N | P |  | Score 4.1 |
| k. Are records in place documenting notification to clients regarding delays or interruptions in Xpert MTB/RIF testing (due to equipment failure, stock outs, staffing level, etc.)? | 🕮 ? | Y | N | P |  | Score 4.8 |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | | **Yes** | **No** | | **Partial** | | | **Comments** | |
| **8. External quality assessment (EQA)** | | | | | | | | | | |
| **8.1. On-site supervisory visits** | | | | | | | | | | |
| a. Does the laboratory receive regular supervisory visits from a higher-level laboratory? | 😐, ? | | Y | N | | P | | |  | |
| If yes, when was the last visit? |  | | | | | | | |  | |
| b. Are supervision reports available at the laboratory? | 🕮 | | Y | N | | P | | |  | |
| c. Is there evidence of corrective action and follow-up in case supervision reports show deficiencies? | 😐, ? | | Y | N | | P | | |  | |
| **8.2. Proficiency testing (PT)** | | | | | | | | | | |
| a. Is the testing site enrolled in an Xpert MTB/RIF PT programme? If yes: | | 🕮, ? | Y | | N | | P |  | | Score 5.2 |
| * Does the testing site perform PT as required? | | 😐, ? | Y | | N | | P |  | | |
| * Does the testing site analyse the PT reports? | | 😐, ? | Y | | N | | P |  | | |
| * Does the testing site troubleshoot unexpected PT results and identify corrective actions? | | 😐, ? | Y | | N | | P |  | | Score5.4 |
| * When was the last PT panel tested and results submitted? | | 😐, ? 🕮 |  | | | | |  | | |
| * What was the score? (request a copy of the PT evaluation report for the last round copy) | | 😐, ? 🕮 |  | | | | |  | | Score 5.3 |

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| --- | --- | --- | --- | --- | --- | --- |
|  |  | **Yes** | **No** | **Partial** | **Comments** | |
| **9. Monitor performance of Xpert MTB/RIF testing and of the QA/CQI system** | | | | | | |
| a. Are all Xpert MTB/RIF test results regularly reviewed by the testing site supervisor or external monitor? | 😐, ? | Y | N | P |  | Score 5.1 |
| b. Does the testing site collect Xpert MTB/RIF performance indicators? Note: Request for the indicator data for the last 3 months. | 🕮, ? | Y | N | P |  | Score 5.5 |
| c. Does the testing site report Xpert MTB/RIF performance indicator data to the MOH/NTP? | 😐, ? | Y | N | P |  | Score 5.6 |
| d. Does the testing site regularly review performance indicators and troubleshoot unexpected results by identifying corrective actions? | 😐, ? | Y | N | P |  | Score 5.7 |
| e. Are the following implementation indicators monitored at least annually: (check all that apply) | 😐,? | Y | N | P |  | |
| Total number of Xpert MTB/RIF tests performed (disaggregated by population, e.g., HIV+, children, vulnerable, EPTB) |  | Y | N |  |
| * Total and proportion of unsuccessful Xpert MTB/RIF test results in the last year |  | Y | N |  |
| * Total and proportion of Xpert MTB/ RIF rifampicin resistant results in the last year |  | Y | N |  |
| * Number and proportion of required instrument verifications performed and documented |  | Y | N |  |
| * Number and proportion of instruments calibrated annually |  | Y | N |  |
| * Proportion of batches received in the country that had new lot testing performed |  | Y | N |  |
| * Number and proportion of correctly used current revised documents, records and forms |  | Y | N |  |
| * Proportion of personnel who received training using the approved training curricula |  | Y | N |  |
| * Number and proportion of testers who are certified |  | Y | N |  |
| * Number and proportion of batches received that had new lot testing performed |  | Y | N |  |
| * Number of days that the testing site experienced interrupted services in the past 3 months due to lack of personnel |  | Y | N |  |
| * Number of days that the testing sites experienced interrupted services in the past 3 months due to stock-outs |  | Y | N |  |
| * Number of days that the testing sites experienced interrupted services in the past 3 months due to equipment downtime |  | Y | N |  |
| f. Are the following Xpert MTB/RIF Testing Quality indicators monitored by the Xpert MTB/RIF testing site and reported to the supervisory laboratory monthly: (check all that apply) | 😐,? | Y | N | P |  | |
| * Number of specimens tested with Xpert MTB/RIF   (Disaggregate by HIV status, MDR risk, extra-pulmonary TB, pediatric) |  | Y | N |  |
| * Number and proportion of specimens with MTBC detected, rifampicin resistance not detected |  | Y | N |  |
| * Number and proportion of specimens with MTBC detected, rifampicin resistance detected |  | Y | N |  |
| * Number and proportion of specimens with MTBC detected rifampicin indeterminate |  | Y | N |  |
| * Number and proportion of specimens with MTBC detected trace, disaggregated by patient group (Ultra only) |  | Y | N |  |
| * Number and proportion of specimens with MTBC not detected |  | Y | N |  |
| * Number and proportion of specimens with errors |  | Y | N |  |
| * Number and proportion of specimens with invalid results |  | Y | N |  |
| * Number and proportion of specimens with no results |  | Y | N |  |
| * Number and proportion of specimens tested with Xpert MTB/RIF for which a result was reported within 24 hrs |  | Y | N |  |
| g. Are resources (e.g., funding, staff, laboratory infrastructures, etc.) available to support a collection of performance indicator data? | 😐, ? | Y | N | P |  | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Yes** | **No** | **Partial** | | **Comments** | | | |
| **10. Clinical-laboratory interface and the diagnostic cascade** | | | | | | | | | |
| a. Are healthcare workers involved in the TB diagnostic cascade provided with standardized sensitization content (e.g., algorithm diagrams, brochures, training materials, customer handbook)? | 🕮, ? | Y | N | | P | |  | | |
| b. Does the testing site inform healthcare workers on sample requirements for testing? |  | Y | N | | P | |  | | Score 5.7 |
| c. Do clinical and laboratory staff regularly meet (at least quarterly) to troubleshoot gaps in laboratory-clinical linkages, including specimen referral, interpretation and reporting? If yes, how often do they meet? | 😐, ? | Y | N | | P | |  | | |
|  | | | | | |  | | |
| d. Are the following standardized documents, records and forms for the clinical-laboratory interface available and readily accessible to all staff? | 🕮, ? | Y | N | | P | |  | | |
| * TB diagnostic algorithm | 🕮 | Y | N | |  | |  | | |
| * Test requisition SOP and form | 🕮 | Y | N | |  | |  | | |
| * Sample collection, packaging and transport SOP | 🕮 | Y | N | |  | |  | | |
| * Laboratory registers | 🕮 | Y | N | |  | |  | | |
| * Xpert MTB/RIF WHO reporting codes | 🕮 | Y | N | |  | |  | | |
| * Xpert MTB/RIF test reporting SOP and form | 🕮 | Y | N | |  | |  | | |
| e. Are diagnostic tests ordered according to the diagnostic algorithms and based on national policy and patient factors? | 😐, ? |  |  | |  | |  | | |
| f. Are formalized procedures in place to ensure efficient linkage of persons with presumptive TB to TB laboratory testing? | 🕮, ? |  |  | |  | |  | | |
| g. Does the testing site ensure patients are instructed in good sputum collection technique? | 😐, ? |  |  | |  | |  | Score  3.2 | |
| h. Are specimen containers correctly labeled and accompanying request forms completely and accurately filled? | 😐, ? | Y | N | | P | |  | | |
| i. Are systems in place for referring samples from collection sites to the testing laboratory? If yes:   * Are appropriate containers and materials for packing and transport available and used? * Are specimens properly stored prior to transport? * Do transport conditions comply with international recommendations? * How often and by what means are specimens transported? | 😐, ? | Y | N | | P | |  | | |
| 😐, ? | Y | N | | P | |  | | |
| 😐, ? | Y | N | | P | |  | | |
| 😐, ? | Y | N | | P | |  | | |
|  | | | | | |  | | |
| j. Are there clear policies and procedures for sample rejection? | 🕮 | Y | N | | P | |  | | |
| k. Does the testing site have a log in which it records the number of samples rejected, and the reason for the rejection? | 🕮 | Y | N | | P | |  | | |
| l. Are standardized reporting forms used for all TB tests and have information on interpretation of results included? | 🕮 | Y | N | | P | |  | Score  3.12 | |
| m. Are Xpert MTB/RIF test results reported within 24 hours of sample receipt or as per national guidelines? | 😐, ? | Y | N | | P | |  | | |
| n. Is there an electronic system supporting the reporting of diagnostic data to clinicians for patient management? | 😐, ? | Y | N | | P | |  | | |
| o. Does the testing site sensitize clinicians on the interpretation of Xpert MTB/RIF results | 😐, ? | Y | N | | P | |  | | |
| p. Does the laboratory report the detection of TB cases or drug-resistant TB cases to the local TB control program? | 😐, ? | Y | N | | P | |  | | |
| q. Are formalized procedures in place to ensure efficient linkage of persons diagnosed with TB and DR-TB to appropriate care and treatment? | 🕮, ? | Y | N | | P | |  | | |

**For sites that are already conducting Xpert MTB/RIF testing, also assess technical performance of all phases (pre-analytical, analytical, post-analytical) of Xpert MTB/RIF testing**

|  |  |  |  |
| --- | --- | --- | --- |
| GeneXpert Instrument information | Instrument #1 | Instrument #2 | Instrument #3 |
| How many GeneXpert modules are available at this site? |  |  |  |
| What is the serial number of the GeneXpert instrument(s)? |  |  |  |
| What is the installation date of the GeneXpert instrument(s)? |  |  |  |
| Which software version is installed on the computer? |  |  |  |
| When was the last calibration performed? |  |  |  |
| Are any modules currently malfunctioning? |  |  |  |
| Is the GeneXpert instrument connected to a power supply (UPS/inverter) that provide uninterrupted power for at least 2 hours? If, yes what type of UPS is used? |  |  |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  | **Yes** | **No** | **Partial** | **Comments** | |
| **11. Xpert MTB/RIF TESTING: Pre-testing, Testing, Post-testing Phases** | | | | | | |
| a. Are standardized forms, registers, logbooks or electronic files for recording patient and specimen information available at the testing site? | 🕮 | Y | N | P |  | Score  3.3 |
| b. Are standardized forms, registers, logbooks or electronic files for recording Xpert MTB/RIF results available at the testing site? | 🕮 | Y | N | P |  | Score  3.4 |
| c. Are all forms, registers, logbooks or electronic files complete and legible? | 🕮 | Y | N | P |  | Score  3.5 |
| d. Are all forms/registers/logbooks or electronic files properly labeled, organized, and kept in a secure location? | 🕮 | Y | N | P |  | Score  3.6 |
| e. Are the GeneXpert operator manual and Xpert MTB/RIF package insert available at the testing site and accessible to all testing staff (hard or soft copy)? | 🕮 | Y | N | P |  | Score  3.7 |
| f. Are Xpert MTB/RIF pre-testing (pre-analytical) procedures being adequately followed (direct observation)? | ☟ | Y | N | P |  | Score  3.8 |
| g. Are Xpert MTB/RIF testing (analytical) procedures being adequately followed (direct observation)? | ☟ | Y | N | P |  | Score  3.9 |
| h. Are the correct safety practices and procedures being adequately followed before, during, and after Xpert MTB/RIF testing (direct observation)? | ☟ | Y | N | P |  | Score  3.10 |
| i. Does the testing site monitor performance of internal quality controls? | 😐, ? | Y | N | P |  | |
| j. Are the Xpert MTB/RIF cartridges being used for patient testing in-date and labeled with new expiry date when kit was opened (7 days from opening date)? | 😐, ? | Y | N | P |  | Score  3.11 |
| k. Are Xpert MTB/RIF post-testing (post-analytical) procedures being adequately followed (direct observation)? | ☟ | Y | N | P |  | |
| l. Are Xpert MTB/RIF results recorded in an appropriate register in a timely manner? | 🕮 | Y | N | P | 3 | Score  3.12 |
| m. Has the testing site put measures in place to prevent the unauthorized access to Xpert MTB/RIF test data? |  | Y | N | P |  | |
| n. Does the testing site monitor and meet its target test results turnaround time (TAT) in >80% of the cases in the last 3 months? Note: Write the site’s target test results TAT in the comment field. | 😐, ? | Y | N | P |  | Score  5.8 |

1. It may not be feasible to assess all testing sites. A representative subset can be chosen to reduce the time and cost of performing a situational analysis. This part of the checklist would be completed for each testing site included in the assessment. [↑](#footnote-ref-2)