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| **Xpert MTB/RIF Continuous Quality Improvement (Xpert CQI)** |

Before completing the checklist questions, please provide the relevant information in the tables in Part A and Part B below.

**PART A. TESTING SITE INFORMATION**

|  |  |  |
| --- | --- | --- |
| 1. Name of Testing Facility: | | 2. Testing Site ID Number (if applicable): |
| 3. Location of Testing Site (address): | | |
| 4. Testing Site Level (circle one): National Regional/Province District Health Center Other: | | |
| 5. Name of Contact Person (POC) at testing Site: | | 6. POC Phone number: |
| 7. POC E-mail: |
| 8. Total number of staff trained to perform Xpert MTB/RIF testing: | 8a. Number of trained users: | 9. Number of staff currently doing  Xpert MTB/RIF testing: |
| 8b. Number of trained Advanced users: |
| 10. Number of supervisory visits the site received the last 12 months: | | 11. When was the last supervisory visit? |
| 12. Onsite internet is available (Yes/No):  13. Onsite internet is stable: (Yes/No): | | 13. Number of Xpert MTB/RIF tests performed in the last 3 months:  Total = \_\_\_\_\_\_\_\_\_\_\_\_ Average= \_\_\_\_\_\_\_\_ |

**PART B. GENEXPERT INSTRUMENT INFORMATION**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Instrument #1 | Instrument #2 | Instrument #3 |
| How many modules does the GeneXpert instrument at this site have? |  |  |  |
| What is the serial number of the GeneXpert instrument? |  |  |  |
| What is the installation date of the GeneXpert instrument? |  |  |  |
| Is the latest software installed on the computer? Indicate version #. |  |  |  |
| 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? |  |  |  |
| Is the instrument connected to a data connectivity solution? Specify |  |  |  |

**PART C. CHECKLIST QUESTIONS**

Mark each question as “**Yes”, “No”, or “Partial”**.

Provide comments for each **“Partial”** or **“No”** response to explain why this item was not fulfilled (what was the missing element?).

Mark **“Yes”** only when **all** the elements are satisfactorily present. Some questions will not have all the elements listed in the checklist.

The assessor should refer to the ACTS User’s Guide for details of the required elements (User’s Guide Section V1: What to ask for and what to look for when conducting an assessment).

**Scoring**: **“Yes”** (1 point); **“Partial”** (0.5 point); **“No”** (0 point).

The overall total points obtained by the testing site will be weighed to correspond to a specific performance level (0-4)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **SECTION** | | | **YES** | | **NO** | | **Partial** | | **COMMENTS** | | **SCORE** | | |
| **1.0 Personnel Training and Competency**  ***Ensure GeneXpert users are trained in accordance with national/sub-national/testing site guidelines, policies and regulations.*** | | | | | | | | | | | **13** | | |
| 1.1 | Are written policies and procedures (SOP) available at the testing site, up-to-date, accurate and relevant, reviewed by staff, and readily accessible to authorized users? |  | |  | |  | |  | |  | |
| 1. Document control: document master file, document identification, access and availability, forms, job aids, controlled document system, creation/revision, read and sign, and archiving | Y | | N | | P | |  | |  | |
| 1. Specimen management: specimen collection, labeling, storage, transport, receiving and accessioning at the testing site, and rejection criteria with corrective action | Y | | N | | P | |  | |  | |
| 1. Operation and maintenance of the GeneXpert instrument | Y | | N | | P | |  | |  | |
| 1. 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 | |  | |  | |
| 1. Safety: standard safety practices, use of PPEs, handling spills, waste management, preparation and labeling of disinfectants | Y | | N | | P | |  | |  | |
| 1. Supplies: procurement, acceptance criteria, labeling with receive date and open date, inventory, proper storage (FEFO/FIFO) | Y | | N | | P | |  | |  | |
| 1. EQA/PT: sample receiving and handling, testing, recording and reporting, review, and investigation of PT failures | Y | | N | | P | |  | |  | |
| 1.2 | 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 | |  | |  | |
| 1.3 | Are records in place documenting that all staff have been trained on assigned work processes, procedures, and tasks? |  | |  | |  | |  | |  | |
| 1. Specimen management | Y | | N | | P | |  | |  | |
| 1. Operation and maintenance of the GeneXpert instrument and Xpert MTB/RIF testing | Y | | N | | P | |  | |  | |
| 1. Safety | Y | | N | | P | |  | |  | |
| 1. EQA/Proficiency Testing | Y | | N | | P | |  | |  | |
| 1.4 | Are records in place documenting that GeneXpert users and advanced users are assessed for competency (annual/semi-annual)? | Y | | N | | P | |  | |  | |
| **2.0 Physical Facilities and Safety**  ***Make the testing site safe and functional.*** | | | | | | | | | | | **8** | | |
| 2.1 | Is the physical facility of sufficient space and design to enable safe working practices and efficient operation? | Y | | N | | P | |  | |  | |
| 2.2 | Is the GeneXpert instrument placed on a stable bench top with at least 5 cm of clearance on either side, free of clutter to enable access, and protected from dust? | Y | | N | | P | |  | |  | |
| 2.3 | Is the GeneXpert instrument and computer safe from theft? | Y | | N | | P | |  | |  | |
| 2.4 | Is the Xpert MTB/RIF workstation clean, free of clutter, and set up for efficient operation? | Y | | N | | P | |  | |  | |
| 2.5 | Is there sufficient, secured, and organized storage space for reagent kits and supplies? | Y | | N | | P | |  | |  | |
| 2.6 | Is there documented monitoring and review of environmental temperatures (15-30oC) at the testing and storage areas, with corrective action taken on out-of-range readings? | Y | | N | | P | | . | |  | |
| 2.7 | Does the testing site use appropriate disinfectants? Are they prepared correctly and container properly labeled? Note in the comment field the disinfectant used at the site. | Y | | N | | P | |  | |  | |
| 2.8 | Does the testing site segregate waste and dispose of it by incineration? | Y | | N | | P | |  | |  | |
| **3.0 Xpert MTB/RIF: Pre-testing, Testing, Post-testing Phases**  ***Test quality samples correctly and safely and report accurate results*** | | | | | | | | | | | **13** | | |
| 3.1 | Does the testing site inform healthcare workers on sample requirements for testing? | Y | | N | | P | |  | |  | |
| 3.2 | Does the testing site ensure patients are instructed in good sputum collection technique? | Y | | N | | P | |  | |  | |
| 3.3 | Are standardized forms/registers/logbooks or electronic files for recording **patient and specimen information** available at the testing site? | Y | | N | | P | |  | |  | |
| 3.4 | Are standardized registers/logbooks or electronic files for recording **Xpert MTB/RIF results** available at the testing site? | Y | | N | | P | |  | |  | |
| 3.5 | Are all forms/registers/logbooks or electronic files complete and legible? | Y | | N | | P | |  | |  | |
| 3.6 | Are all forms/registers/logbooks or electronic files properly labeled, organized, and kept in a secure location? | Y | | N | | P | |  | |  | |
| 3.7 | Are Xpert MTB/RIF results recorded properly in an appropriate register in a timely manner? | Y | | N | | P | |  | |  | |
| 3.8 | Are Xpert MTB/RIF results reported in a standard format and sent out according to national policy? Note how reports are sent out (e.g., SMS, email, courier, LIMS) in the Comment field | Y | | N | | P | |  | |  | |
| 3.9 | Are the GeneXpert operator manual and Xpert MTB/RIF package insert available and accessible to all testing staff (hard or soft copy)? | Y | | N | | P | |  | |  | |
| 3.10 | Are Xpert MTB/RIF procedures being adequately followed (direct observation)? |  | |  | |  | |  | |  | |
| 1. Pre-testing (analytical) | Y | | N | | P | |  | |  | |
| 1. Testing (analytical) | Y | | N | | P | |  | |  | |
| 1. Post-testing (post-analytical) | Y | | N | | P | |  | |  | |
| 1. Correct safety practices and procedures being adequately followed | Y | | N | | P | |  | |  | |
| **4.0 Supplies, Reagents, and Equipment**  ***Ensure adequate supplies and reagents and maintain GeneXpert instruments.*** | | | | | | | | | | | **14** | | |
| 4.1 | Does the testing site have a stock control system in place to ensure that adequate supplies are available for continuous service without over-stocking or under-stocking? | Y | | N | | P | |  | |  | |
| 4.2 | Are Xpert MTB/RIF kits and other supplies inventoried (physical count) at least monthly? | Y | | N | | P | |  | |  | |
| 4.3 | Are adequate reagents and supplies available at the testing site? |  | |  | |  | |  | |  | |
| 1. Xpert MTB/RIF test kits | Y | | N | | P | |  | |  | |
| 1. Supplies: Laboratory gowns, disposable gloves, hand soap, paper towels, and disinfectant | Y | | N | | P | |  | |  | |
| 4.4 | Are Xpert MTB/RIF test kits in-date, labeled with receive date, stocks organized and stored at 2-28oC? | Y | | N | | P | |  | |  | |
| 4.5 | Are new lots of Xpert MTB/RIF kits tested (QC) to ensure that they perform as expected prior to their use for patient testing? | Y | | N | | P | |  | |  | |
| 4.6 | Has the testing site provided continuous testing services in the past 3 months with no service interruptions for longer than 24 hours due to: |  | |  | |  | |  | |  | |
| 1. Xpert MTB/RIF reagents stock outs? | Y | | N | | P | |  | |  | |
| 1. GeneXpert Instrument or computer failure? | Y | | N | | P | |  | |  | |
| 1. Lack of personnel? | Y | | N | | P | |  | |  | |
| 4.7 | Are records in place documenting notification to clients regarding delays or interruptions in Xpert MTB/RIF testing (due to instrument failure, reagent stock outs, or staffing level, etc.)? | Y | | N | | P | |  | |  | |
| 4.8 | Was the GeneXpert instrument verified on site prior to routine use for patient testing? | Y | | N | | P | |  | |  | |
| 4.9 | Is preventive maintenance of the GeneXpert instrument performed consistently? Are maintenance records reviewed, and GeneXpert malfunction investigated and corrected? |  | |  | |  | |  | |  | |
| 1. Daily, weekly, and monthly maintenance | Y | | N | | P | |  | |  | |
| 1. Annual calibration | Y | | N | | P | |  | |  | |
| 4.10 | Are records in place documenting that GeneXpert instrument maintenance/servicing needs are communicated to upper management? | Y | | N | | P | |  | |  | |
| **5.0 Monitoring Quality**  ***Provide for a quality monitoring system to ensure accurate, reliable, and timely results.*** | | | | | | | | | | | **10** | | |
| 5.1 | Does the testing site supervisor or designee review all Xpert MTB/RIF test results regularly? | Y | | N | | P | |  | |  | |
| 5.2 | Is the testing site enrolled in an EQA/PT program for Xpert MTB/RIF testing? Note: Record the name of PT provider, the number of rounds per year, and number of samples per round. Record the score for the last PT round and request for a copy of the PT report. | Y | | N | | P | |  | |  | |
| 5.3 | Are PT samples handled and tested according to national/international guidelines and assigned to the staff on a rotation basis? | Y | | N | | P | |  | |  | |
| 5.4 | Are EQA/PT feedback report reviewed with the staff in a timely manner, and corrective action taken on unacceptable results? | Y | | N | | P | |  | |  | |
| 5.5 | Does the testing site collect Xpert MTB/RIF key performance indicators (PI) on a monthly basis and report data to the MOH/NTP? Note: Request for a copy of the PI data for the last 3 months. | Y | | N | | P | |  | |  | |
| 5.6 | Does the testing site review and analyze key performance indicators on a regular basis and troubleshoot unexpected results by identifying corrective actions? | Y | | N | | P | |  | |  | |
| 5.7 | Does the testing site meet the Xpert MTB/RIF test report TAT rate of ≤ 24 hours in >90% of Xpert MTB/RIF tests performed?  (See instructions below) | Y | | N | | P | |  | |  | |
| Instructions: Check 20 randomly selected Xpert MTB/RIF results from the previous month. Record the average results turnaround time (TAT) as determined between the date and time the sample was received at the testing site up to the date and time the Xpert MTB/RIF test was reported.  *Note:* The testing site would have these data if the site were monitoring their performance indicators – request for last month’s data from their record instead of checking 20 random samples results).  What is the average TAT at this laboratory (number of hours)? \_\_\_\_\_\_\_\_\_\_\_\_  What percent (%) of cases meet the target TAT of ≤ 24 hours? \_\_\_\_\_\_\_\_\_\_\_\_  Follow-up the same 20 samples and determine the average TAT (in days) from the time report was released from the laboratory to the time the clinic received the report. What was the average TAT (in days)? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | |
| 5.8 | Does the testing site meet the Xpert MTB/RIF test target rate for: (See instructions below) |  | |  | |  | |  | |  | |
|  | “Error” rate is <3% | Y | | N | | P | |  | |  | |
|  | “Invalid” results is <1% | Y | | N | | P | |  | |  | |
|  | “No result” rate is <1% | Y | | N | | P | |  | |  | |
| Instructions: Review the last 100 Xpert MTB/RIF results from the register or computer/ *Note*: The testing site would have these data if the site were monitoring their performance indicators – request for last month’s data from their record instead of reviewing the last 100 results.   1. Total number of tests = \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_      1. Total number of Xpert MTB/RIF test with “Error” results = \_\_\_\_\_\_\_\_\_ “Error” rate (b/a x 100)= \_\_\_\_\_\_\_\_ % 2. Total number of Xpert MTB/RIF test with “Invalid” results = \_\_\_\_\_\_\_\_ “Invalid” results rate (c/a x 100) = \_\_\_\_\_%      1. Total number of Xpert MTB/RIF test with “No result”? \_\_\_\_\_\_\_\_ “No result” rate (d/a x 100) = \_\_\_\_\_\_% | | | | | | | | | | | | |

**PART D. SUMMARY OF FINDINGS AND RECOMMENDATIONS**

**Table 1**.

|  |  |  |
| --- | --- | --- |
| Name of Testing Site: | | Testing Site ID Number: |
| Date of Assessment (dd/mm/yyyy): | Assessment round number: | |
| Name of Assessor1: | Title and Organization of assessor1: | |
| Name of Assessor2: | Title and Organization of Assessor2: | |

**Table 2**.

|  |  |  |  |
| --- | --- | --- | --- |
| **PROVIDE TESTING SITE SCORE:** | **Performance levels** | **% Score** | **Recommendation** |
| **Total score (a):** | Level 0 | Less than 40% | Testing sites with performance level 0-2 need immediate remediation and 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. |
| **Total Possible score (b): 59** | Level 1 | 40% - 59% |
| **% Score (a/b) x 100 =** | Level 2 | 60% – 79% |
| **Performance Level (0-4):** | Level 3 | 80% - 89% |
| Level 4 | 90% or higher |

**Table 3.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Section** | | **Score**  **(a)** | **Possible Score (b)** | **Assessor’s Comments** | **Recommendations** |
| 1 | Personnel Training and Competency |  |  |  |  |
| 2 | Physical Facilities and Safety |  |  |  |  |
| 3 | Xpert MTB/RIF testing |  |  |  |  |
| 4 | Supplies, Reagents, and Equipment |  |  |  |  |
| 5 | Monitoring Quality |  |  |  |  |
| Briefly describe other observations and recommendations that were not covered by the checklist questions: | | | | | |

|  |
| --- |
| Testing Site Manager Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Assessor Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |