**National and Supervisory-Level Xpert MTB/RIF Quality Assurance Situational Analysis Checklist**

This checklist is used to assess the current status of the Xpert MTB/RIF quality assurance system. This part assesses the status of the QA system at the national and supervisory levels. A similar checklist is used to assess the status at the testing site.

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 |

**Country name: Assessor name:**

**Assessor contact details:**

**Date of assessment:**

### 

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| **General** | | |
| How many testing sites are providing Xpert MTB/RIF testing? |  |
| How many GeneXpert instruments have been placed in-country:   1. For diagnostic purposes? 2. For research purposes? |  |
| Are additional instruments planned, and if so how many? |  |
| What is the distribution of the current GeneXpert instruments  (list per region or district)? |  |

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. Is there a national regulatory body to approve the use of diagnostic testing? | 😐, ? | Y | N | P |  | |
| b. Is there a National Technical Working Group responsible for providing guidance on TB laboratories? | 😐, ? | Y | N | P |  | |
| c. Does a Technical Working Group assist the NTP in identifying and reviewing TB testing strategies and algorithms? | 😐, ? | Y | N | P |  | |
| d. Is there a GeneXpert Focal Person or equivalent to oversee the implementation of the Xpert MTB/RIF test? | 😐, ? | Y | N | P |  | |
| i. If Yes, are they responsible for QA oversight? If no, who is responsible and do they liaise regularly with the GeneXpert focal person on QA issues? | 😐, ? | Y | N | P |  | |
| e. Is there a National QA Unit within MOH/NTP to oversee QA of the Xpert MTB/RIF testing? | 😐, ? | Y | N | P |  | |
| f. Is there a regional QA officer responsible for the oversight of Xpert MTB/ RIF test EQA/PT? | 😐, ? | Y | N | P |  | |

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|  |  | **Yes** | **No** | **Partial** | **Comments** |
| **2. Strategic Planning, Policies, and Resources** | | | | | |

Are the following national guidelines and policies in place (i.e., approved, accessible and implemented at the national and regional levels):

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| --- | --- | --- | --- | --- | --- |
| a. National Health Strategic Plan | 🕮 | Y | N |  |  |
| b. National TB Strategic Plan | 🕮 | Y | N |  |  |
| c. National TB Laboratory Strategic Plan | 🕮 | Y | N |  |  |
| d. Xpert MTB/RIF Implementation Plan | 🕮 | Y | N |  |  |
| e. Are QA activities for Xpert MTB/RIF test referenced in the available guidelines? | 🕮 | Y | N |  |  |
| f. If Yes, do they include specific QA measures including | 🕮 | 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 |  |
| g. Does MOH engage key partners (e.g., WHO, implementing partners, etc.) in policy development for TB testing? | 😐, ? | Y | N | P |  | |
| h. Does MOH engage other disease programs who are using Xpert in policy development for TB testing? | 😐, ? | Y | N | P |  | |
| i. Are resources (e.g., funding, staff, laboratory infrastructures, etc.) available at the national and regional levels to support Xpert MTB/RIF: | 😐, ? | Y | N | P |  | |
| * QA-related documentation activities? | 😐, ? | Y | N |  |
| * Training according to the national plan for the current year? | 😐, ? | Y | N |  |
| * On-site supervisory visits? | 😐, ? | Y | N |  |
| * Proficiency testing activities? | 😐, ? | Y | N |  |
| * Monitoring and evaluation activities | 😐, ? | Y | N |  |
| * Analysis of quality and performance indicators? | 😐, ? | Y | N |  |
| * Procurement activities? | 😐, ? | Y | N |  |
| j. Does a current costing plan exists for GeneXpert implementation? If yes,   * 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 | 🕮 | Y | N | P |  | |
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|  |  | | **Yes** | **No** | **Partial** | **Comments** | | |
| **3. Quality procedures and documentation** | | | | | | | | |
| a. Is the use of standardized documents, records and forms described in the national laboratory policy, or other national policies? | | 🕮 | Y | | N | P |  |
| 1. Are the following site-level standardized documents, records and forms available, approved, and disseminated to testing sites? | | 🕮 | Y | | N | P |  |
| * TB diagnostic algorithm | |  | Y | | N |  | |
| * Document control SOP | |  | Y | | N |  | |
| * Test requisition SOP and form | |  | Y | | N |  | |
| * Sample collection and transport SOP | |  | Y | | N |  | |
| * Laboratory register | |  | Y | | N |  | |
| * Xpert MTB/RIF maintenance log | |  | Y | | N |  | |
| * Xpert MTB/RIF test SOP | |  | Y | | N |  | |
| * Xpert MTB/RIF Ultra test SOP | |  | Y | | N |  | |
| * Proficiency Testing (PT) SOP | |  | Y | | N |  | |
| * Waste management SOP | |  | Y | | N |  | |
| * Spill management SOP | |  | Y | | N |  | |
| * Stock cards | |  | Y | | N |  | |
| * Temperature monitoring records | |  | Y | | N |  | |
| * Nonconformity and corrective action log | |  | Y | | N |  | |
| * Training records forms | |  | Y | | N |  | |
| * Xpert MTB/RIF WHO reporting codes | |  | Y | | N |  | |
| * Xpert MTB/RIF performance indicator reporting form | |  | Y | | N |  | |
| * Xpert MTB/RIF test reporting SOP and form | |  | Y | | N |  | |
| * PT results form & failure follow-up form | |  | Y | | N |  | |
| 1. Are the following supervisory-level standardized documents, records and forms available, approved, and accessible at supervisory laboratories? | | 🕮 | Y | | N | P |  |
| * TB diagnostic algorithm | | 🕮 | Y | | N |  | |
| * Document control SOP | | 🕮 | Y | | N |  | |
| * SOP for Proficiency Testing programme | | 🕮 | Y | | N |  | |
| * SOP for producing PT panels | | 🕮 | Y | | N |  | |
| * Form for reporting PT results and providing feedback | | 🕮 | Y | | N |  | |
| * SOP for conducting on-site supervision | | 🕮 | Y | | N |  | |
| * Checklists for supervisory assessments | | 🕮 | Y | | N |  | |
| * Form for providing supervisory feedback to testing sites | | 🕮 | Y | | N |  | |
| * Form for follow-up of corrective actions | | 🕮 | Y | | N |  | |
| * SOP for quality indicator monitoring and data analysis | | 🕮 | Y | | N |  | |
| * Xpert MTB/RIF performance indicator reporting form | | 🕮 | Y | | N |  | |
| * Diagnostic cascade quality indicator reporting form | | 🕮 | Y | | N |  | |
| * QA system quality indicator form | | 🕮 | Y | | N |  | |
| d. Is there a mechanism to review, update and disseminate standardized documentation from the central-level to testing sites? | | 🕮 | Y | | N | P |  |

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|  |  | **Yes** | **No** | **Partial** | **Comments** | |
| **4. Training, competency assessment and certification** | | | | | | |
| a. Is a national, approved standardized training available for:   * GeneXpert users? * GeneXpert advanced users? * Clinicians and healthcare workers? | 🕮 | Y | N | P |  |
|  | Y | N | P |
|  | Y | N | P |
|  | Y | N | P |
| b. Is there an Xpert MTB/RIF standardized training for ‘training of trainers’ (TOT)? for each type of training:   * GeneXpert users? * GeneXpert advanced users? * Clinicians and healthcare workers? | 🕮 | Y | N | P |  |
|  | Y | N | P |
|  | Y | N | P |
|  | Y | N | P |
| c. What proportion of each type of user is being trained using approved training?   * GeneXpert users? * GeneXpert advanced users? * Clinicians and healthcare workers? | 🕮,? |  | | |  |
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| d. Is there a current national level database of all Xpert MTB/RIF testing personnel? | 🕮 | Y | N | P |  |
| e. Are there criteria for assessing competency for:   * GeneXpert users? * GeneXpert advanced users? * Clinicians and healthcare workers? | 🕮 | Y | N | P |  |
|  | Y | N | P |
|  | Y | N | P |
|  | Y | N | P |
| f. Are competency assessments for users and advanced users conducted annually and bi-annually respectively? | 🕮 | Y | N | P |  |
| g. Is there a programme for training supervisors to conduct supervisory visits? | 🕮 | Y | N | P |  |
| h. Are records of trainings kept centrally? | 🕮 | Y | N | P |  |
| i. Are records of training reported to MOH/NTP? | 🕮 | Y | N | P |  |
| j. Is there a national annual training plan? | 🕮 | Y | N | P |  |

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|  |  | **Yes** | **No** | **Partial** | **Comments** |
| **5. Data Connectivity and remote monitoring** | | | | | |
| a. Has an in-country assessment of existing diagnostics connectivity systems and infrastructure (both laboratory and connectivity) for GeneXpert been conducted? | 😐 ? | Y | N | P |  |
| b. Are national guidelines and policies in place for diagnostics connectivity and remote monitoring that address: | 🕮 | Y | N | P |  |
| * Which diagnostics connectivity system will be used? |  | Y | N |  |
| * If the diagnostics connectivity solution will be specific for GeneXpert or if it will be integrated across diseases? |  | Y | N |  |
| * If integrated, are integration issues addressed (software compatibility, shared infrastructure, human resources, data access, IT support etc.)? |  | Y | N |  |
| * Who will have access to the data? |  | Y | N |  |
| * What training will be required for access the system? |  | Y | N |  |
| * How data will be secured? |  | Y | N |  |
| * How, and at what frequency, will the system backed-up? |  | Y | N |  |
| * Who will be responsible for remote monitoring |  | Y | N |  |
| * Who is responsible for technical support, IT-support and updates |  | Y | N |  |
| c. Does a current costing plan exist for implementation of diagnostics connectivity? | 🕮 | Y | N | P |  |
| d. If yes, does the implementation plan address: | 🕮 | Y | N | P |  |
| * Installing and maintaining hardware and software at each testing site? |  | Y | N |  |
| * Setting up the connectivity solution at each site? |  | Y | N |  |
| * Training for new users and refresher training for existing users? |  | Y | N |  |
| * Providing operational costs of the system? |  | Y | N |  |
| * Establishing and maintaining units at the national, regional and local level to monitor data systematically on a weekly or biweekly basis |  | Y | N |  |
| * Developing and disseminating SOPs for access, reporting, data entry, data security and data back-up |  | Y | N |  |
| e. Have SOPs for access, reporting, data entry, data security and data back-up been developed, approved, and disseminated to testing sites? | 🕮 ? | Y | N | P |  |
| f. Have SOPs for remote monitoring and data analysis been developed, approved, and disseminated to monitoring units? | 🕮 ? | Y | N | P |  |
| g. Are a sufficient number of appropriately trained staff available for remote monitoring and data analysis at monitoring sites? | 😐 ? | Y | N | P |  |
| * How many persons are trained in remote monitoring and data analysis? |  |  | | |  |
| * How frequently do staff login to the remote monitoring system? |  |  | | |  |
| * For what purposes do staff access the system (e.g., monitor cartridge use, module functioning, performance indicators, etc.)? |  |  | | |  |
| h. Are a sufficient number of appropriately trained staff available for remote monitoring and data analysis at testing sites?   * How many persons are trained in remote monitoring and data analysis? * How frequently do staff login to the remote monitoring system? * For what purposes do staff access the system (e.g., monitor cartridge use or module functioning, analyse performance indicators, etc.)? | 😐 ? | Y | N | P |  |
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|  |  | **Yes** | **No** | **Partial** | **Comments** |
| **6. A safe and functional testing site** | | | | | |
| a. Is there a mechanism for assessing each testing site for readiness? | 🕮 ? | Y | N | P |  |
| b. If yes, is a standardized checklist such as the FIND Xpert pre-installation checklist used? | 🕮 ? | Y | N | P |  |
| c. Is there a mechanism for upgrading facilities as needed to create a safe functional work environment? | 🕮 ? | Y | N | P |  |

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|  |  | **Yes** | **No** | **Partial** | **Comments** |
| **7. Equipment and supplies** | | | | | |
| **7.1. Equipment service and maintenance** | | | | | |
| a. Are policies in place requiring testing sites to maintain and service GeneXpert instruments? | 🕮 | Y | N | P |  |
| b. Is there a mechanism in place to monitor which testing sites are performing maintenance and servicing of the GeneXpert instrument? | 😐, ? | Y | N | P |  |
| c. Is there a mechanism in place to monitor GeneXpert instrument repairs at testing sites? | 😐, ? | Y | N | P |  |
| d. Is there a mechanism in place to monitor GeneXpert instrument verification at testing sites? | 😐, ? | Y | N | P |  |
| e. Is there a mechanism in place to know how many modules are in service and out of service at a given time? | 😐, ? | Y | N | P |  |
| **7.2. Procurement & supply chain** | | | | | |
| a. Is there a national policy in place for procurement of GeneXpert instruments and reagents? | 🕮 | Y | N | P |  |
| b. Is procurement of GeneXpert instruments and reagents managed centrally (e.g., NTRL, Central Pharmacy, Central Medical Store etc.)? | 😐,? | Y | N | P |  |
| c. Is there a mechanism to provide Xpert MTB/RIF test consumption data to inform procurement practices? | 😐, ? | Y | N | P |  |
| d. Is there a policy in place for quality verification of new Xpert MTB/RIF test lots coming into your country? | 🕮 | Y | N | P |  |
| e. Is there a practice in place to quality check new lots of test kits coming into your country? | 😐, ? | Y | N | P |  |
| f. Is there a policy and practice in place to that failed lots of Xpert MTB/RIF tests (out of established and acceptable ranges) are not used? | 🕮 | Y | N | P |  |

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|  | |  | | **Yes** | | **No** | | **Partial** | | **Comments** |
| **8. External quality assessment (EQA)** | | | | | | | | | | |
| **8.1. On-site supervisory visits** | | | | | | | | | | |
| a. Are there national policies requiring on-site supervisory visits to all testing sites? | | 🕮 | | Y | | N | | P | |  |
| b. Does the policy indicate the minimum frequency of visits?  (if yes, state frequency in comments) | | 🕮 | | Y | | N | | P | |  |
| c. Is there documented evidence of regular on-site supervisory visits to testing sites? | | 🕮 | | Y | | N | | P | |  |
| d. Are supervisory visits conducted by trained supervisors?  If no, who conducts the supervisory visits? | |  | | Y | | N | | P | |  |
| e. Is there a database of trained supervisors?   * How many supervisors are trained to conduct supervisory visits? * How many are available for conducting visits? * How many conducted visits in the past year? | | 🕮 | | Y | | N | | P | |  |
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| f. Are all testing sites covered by current supervisory activities?  (If yes, what is the frequency of visits?) | | ? | | Y | | N | | P | |  |
| g. Are approved standardized checklists available for conducting Xpert MTB/ RIF test supervisory visits?  (If yes, what proportion of visits use standardized checklists?) | | 🕮, ? | | Y | | N | | P | |  |
| h. Is there a mechanism to provide feedback to testing sites following an Xpert MTB/RIF test supervisory visit? | | ? | | Y | | N | | P | |  |
| i. Are the outcomes of Xpert MTB/RIF test supervisory visits reviewed at the central or regional level? | | ? | | Y | | N | | P | |  |
| j. Are the outcomes of Xpert MTB/RIF test supervisory visits reported to MOH/NTP? | | ? | | Y | | N | | P | |  |
| **8.2. Proficiency testing (PT)** | | | | | | | | | | |
| a. Is there a national policy in place requiring participation of all testing sites in Xpert MTB/RIF PT? | 🕮 | | Y | | N | | P | |  | |
| b. How many and what proportion of Xpert MTB/RIF testing sites are currently participating in a PT programme for Xpert MTB/RIF? | ? | |  | | | | | |  | |
| c. Are there sufficient skilled staff to analyse PT program data and generate reports for timely feedback and corrective actions to the testing sites? | 😐, ? | | Y | | N | | P | |  | |
| d. Does the NTRL or designee provide oversight of the PT programme and performance of testing sites? | 😐, ? | | Y | | N | | P | |  | |
| e. Are adequate logistics (e.g., result reporting paper-based, computer based, phone, fax, local courier, etc.) available for PT data collection and feedback to sites? | 😐, ? | | Y | | N | | P | |  | |
| f. Are mechanisms in place to follow- up with testing sites that produce incorrect PT results? | 😐, ? | | Y | | N | | P | |  | |
| g. Does the NTP produce its own Xpert MTB/RIF PT panels? Or is it planned? | 😐, ? | | Y | | N | | P | |  | |
| h. If Yes, does the NTRL or a regional TB culture laboratory have sufficient | 😐, ? | | Y | | N | | P | |  | |
| * Funding to produce PT panels? |  | | Y | | N | | P | |
| * Trained competent staff to produce PT panels? |  | | Y | | N | | P | |
| * Laboratory infrastructure to produce PT panels? |  | | Y | | N | | P | |
| * Capacity to distribute panels and PT results? |  | | Y | | N | | P | |
| * Experience producing other PT panels (e.g., for smear microscopy)? |  | | Y | | N | | P | |

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|  |  | **Yes** | **No** | **Partial** | **Comments** |
| **9. Monitor performance of Xpert MTB/RIF testing and of the QA/CQI system** | | | | | |
| **9.1 Establish an M&E framework** | | | | | |
| a. Is there a national policy in place requiring the collection of performance indicators? | 🕮 | Y | N | P |  |
| b. Does the NTP collect, analyse and use performance indicators (see below) for decision making including:   * Xpert MTB/RIF Testing Quality Indicators * Diagnostic Cascade Quality Indicators * QA System Process Indicators | 😐, ? | Y | N | P |  |
|  | Y | N | P |
|  | Y | N | P |
|  | Y | N | P |
| c. Are the following Xpert MTB/RIF Testing Quality indicators monitored and analysed by the Xpert MTB/RIF testing site and reported to the supervisory laboratory monthly: | 😐, ? | Y | N | P |  |
| * Number of specimens tested with Xpert MTB/RIF (Disaggregated 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 |  |
| d. Are the following QA System Process Indicators monitored and analysed at the regional or national level at least annually | 😐, ? | Y | N | P |  |
| * Proportion of specimens collected for Xpert MTB/RIF testing for which a result was received within the specified target time |  | Y | N |  |
| * Number and proportion of diagnostic testing sites that are covered by a functional national system of performance indicator monitoring and EQA |  | Y | N |  |
| * Number and proportion of testing sites using a WRD at which a data connectivity system has been established that transmits results electronically to clinicians and to an information management system |  | Y | N |  |
| * Number and proportion of testing sites enrolled in a PT programme |  | Y | N |  |
| * Number and proportion of testing sites participating in a PT programme |  | Y | N |  |
| * Number and proportion of testing sites participating in a PT programme that successfully passed |  | Y | N |  |
| * Number and proportion of testing sites covered by a system of supportive supervision |  | Y | N |  |
| * Number and proportion of testing sites that have supervisory visits at least yearly |  | Y | N |  |
| * Number and proportion of testing sites that monitor and evaluate key performance indicators (KPIs)at least monthly |  | Y | N |  |
| * Number and proportion of testing sites reporting KPIs monthly to supervisory laboratory |  | Y | N |  |
| * Number and proportion of testing sites with standardized, competency-based job descriptions for all positions |  | Y | N |  |
| * Number and proportion of testing sites that have internal quality controls in place for Xpert MTB/RIF |  | Y | N |  |
| * Number and proportion of testing sites that have a document control system in place |  | Y | N |  |
| * Number and proportion of testing sites that have all of (and adhere to) the necessary SOPs in place |  | Y | N |  |
| * Number and proportion of testing sites with complete quality documentation |  | Y | N |  |
| e. Are the following Diagnostic Cascade Quality Indicators monitored and analysed by the supervisory or regional level (or national level) and reported to national level at least annually: | 😐, ? | Y | N | P |  |
| * Number and proportion of presumptive TB patients tested with Xpert MTB/RIF |  | Y | N |  |
| * Percentage of notified new and relapse TB cases tested with a WRD as the initial diagnostic test |  | Y | N |  |
| * Percentage of notified new and relapse TB cases with bacteriological confirmation |  | Y | N |  |
| * Number and proportion of bacteriologically confirmed patients who were initiated on treatment according to the national algorithm |  | Y | N |  |
| * Percentage of testing sites using a WRD at which a data connectivity system has been established that transmits results electronically to clinicians and to an information management system |  | Y | N |  |
| * Number and proportion of Xpert MTB/RIF test results reported to clinicians using electronic systems |  | Y | N |  |
| * Number and proportion of TB patients detected by Xpert MTB/RIF that were reported to the TB control program, TB or MDR TB treatment focal person |  | Y | N |  |
| * Percentage of notified bacteriologically confirmed TB cases with DST results for rifampicin |  | Y | N |  |
| * Percentage of notified rifampicin-resistant TB cases with DST results for fluoroquinolones and second-line injectable agents |  | Y | N |  |
| * Number and proportion of patients with RIF-resistant TB identified by Xpert MTB/RIF testing referred for second-line DST |  | Y | N |  |
| * Proportion of specimens collected for Xpert MTB/RIF testing for which a result was received within the specified target time (i.e., time from collection of a specimen to receipt of results) |  | Y | N |  |
| * Proportion of specimens referred for DST for which a result was received within the specified target time |  | Y | N |  |
| f. Are key patient-centered turnaround times in the diagnostic cascade monitored and evaluated (a survey or special study may be required to obtain the data) | 😐, ? | Y | N | P |  |
| * Time from patient presentation (visit 1) to initiation of treatment, drug- resistant TB patients [mean, median, 95% range] |  | Y | N |  |
| * Time from specimen collection to initiation of treatment, drug-resistant TB patients [mean, median, 95% range] |  | Y | N |  |
| * Time from patient presentation (visit 1)  to initiation of treatment, drug- susceptible TB patients [mean, median, 95% range] |  | Y | N |  |
| * Time from specimen collection to initiation of treatment, drug- susceptible TB patients [mean, median, 95% range] |  | Y | N |  |

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| **9.2 Monitoring and evaluation of the implementation of Xpert MTB/RIF testing** | | | | | |
| a. Are there national policies and plans in place to monitor and evaluate the implementation of Xpert MTB/RIF testing? | 🕮 | Y | N | P |  |
| b. Are the following implementation indicators monitored and analysed by the national program at least annually | 😐, ? | Y | N | P |  |
| * Total number of Xpert MTB/RIF tests performed (disaggregated by population, e.g., HIV+, children, vulnerable, EPTB) |  | Y | N |  |
| * Number of active testing sites |  | Y | N |  |
| * Proportion of active testing sites relative to projected need |  | Y | N |  |
| * Number of clinical sites (DTCs) with on-site GeneXpert instruments which performed Xpert MTB/RIF tests in the previous 6 month period |  | Y | N |  |
| * Number of clinical sites with access to GeneXpert testing via a functional referral network |  | Y | N |  |
| * Number of clinical sites without access to GeneXpert |  | Y | N |  |
| * Proportion of clinical sites with any access to GeneXpert (on-site plus referral) |  | Y | N |  |
| * Number and proportion of testing sites that experience no interruption in testing services for the past 3 months due to lack of personnel |  | Y | N |  |
| * Number and proportion of testing sites that experience no interruption in testing services for the past 3 months due to stock out of supplies |  | Y | N |  |
| * Number and proportion of testing sites that experienced no interruption in services during the past 3 months due to equipment downtime |  | Y | N |  |
| * Number and proportion of instruments calibrated |  | Y | N |  |
| * Number and proportion of required instrument verifications performed and documented |  | Y | N |  |
| * Proportion of batches received in the country that had new lot testing performed |  | Y | N |  |

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| **9.3. Monitoring and evaluation of data connectivity and remote monitoring** | | | | | |
| a. Are there national policies and plans in place to monitor and evaluate data connectivity and remote monitoring? | 🕮 | Y | N | P |  |
| b. Are the following indicators monitored and analysed by the national program at least annually | 😐, ? | Y | N | P |  |
| * Number and proportion of testing sites that have an operational data connectivity system? |  | Y | N |  |
| * Number and proportion of connected sites that regularly report data |  | Y | N |  |
| * Frequency of data reporting [mean, median, 95% range] |  | Y | N |  |
| * Number and proportion of testing sites that experience no interruption in data connectivity for the past 3 months |  | Y | N |  |
| * Number and proportion of remote monitoring units that routinely monitor and analyse data |  | Y | N |  |
| * Frequency of remote monitoring and data analysis [mean, median, 95% range] |  | Y | N |  |

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| --- | --- | --- | --- | --- | --- | --- |
| **9.4. Data analysis** | | | | | | |
| a. Are there national policies and plans in place to monitor and evaluate Xpert MTB/RIF testing? | 🕮 | Y | N | P |  |
| b. Who is responsible for data analysis and review of   * QA System Process Indicators? * Xpert MTB/RIF Testing Quality indicators? * Diagnostic Cascade Quality Indicators? * Implementation of Xpert MTB/RIF testing? * Data connectivity and remote monitoring? | 😐, ? |  | | |  |
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| c. Are mechanisms in place to respond to trends observed when analysing performance indicator data? | 😐, ? | Y | N | P |  |
| d. Is performance indicator data feedback provided to the testing sites? | 😐, ? | Y | N | P |  |
| e. Are performance indicator data trends reported to MOH/NTP? | 😐, ? | Y | N | P |  |
| f. Is remote monitoring of GeneXpert instruments approved by the MOH/ NTP? | 🕮 | Y | N | P |  |
| g. Are quality and performance data reviewed and used to inform decision-making? | 😐, ? | Y | N | P |  |

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|  |  | **Yes** | **No** | **Partial** | **Comments** |
| **10. Clinical-laboratory interface and the diagnostic cascade** | | | | | |
| a. Is a national, approved standardized training available for clinicians, nurses and other healthcare workers on the aspects of the diagnostic cascade that affect the quality of TB testing? | 🕮, ? | Y | N | P |  |
| b. Is there an Xpert MTB/RIF standardized training for ‘training of trainers’ (TOT) for clinicians, nurses and healthcare workers? | 😐, ? | Y | N | P |  |
| c. Has national standardized sensitization content (e.g., algorithm diagrams, brochures, training materials, customer handbook) for healthcare workers involved in the TB diagnostic cascade been developed, approved and disseminated? | 🕮, ? | Y | N | P |  |
| d. Have SOPs for the clinical-laboratory interface been developed, approved and disseminated? | 😐, ? | Y | N | P |  |
| * Ordering Xpert MTB/RIF testing? |  | Y | N |  |
| * Collecting quality samples and submitting them to the testing site along with a properly completed test requisition form? |  | Y | N |  |
| * Packaging and transport of specimens from collecting sites to testing sites? |  | Y | N |  |
| * Reporting results to clinicians and TB programme officials |  | Y | N |  |
| * Flow of information between clinicians, program staff, and laboratorians? |  | Y | N |  |
| e. Have formalized procedures been developed, approved and disseminated to ensure efficient linkage of persons diagnosed with TB and DR-TB to appropriate care and treatment? | 😐, ? | Y | N | P |  |
| f. Have formalized procedures been developed, approved and disseminated to ensure efficient linkage of persons with presumptive TB to TB laboratory testing? | 🕮, ? | Y | N | P |  |
| g. Have guidelines been developed, approved and disseminated promoting regular meetings of laboratory staff, clinical staff, and program staff to discuss issues, troubleshoot problems, and strengthen the clinical-laboratory interface | 🕮, ? | Y | N | P |  |
| h. Are key patient-centered turnaround times in the diagnostic cascade monitored and evaluated (a survey or special study may be required to obtain the data) | 😐, ? | Y | N | P |  |
| * Time from patient presentation (visit 1) to initiation of treatment, drug- resistant TB patients |  | Y | N |  |
| * Time from specimen collection to initiation of treatment, drug-resistant TB patients |  | Y | N |  |
| * Time from patient presentation (visit 1) to initiation of treatment, drug- susceptible TB patients |  | Y | N |  |
| * Time from specimen collection to initiation of treatment, drug- susceptible TB patients |  | Y | N |  |