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Quick Guide to Quality Assurance of Xpert MTB/RIF Testing

Quick Guide to Quality Assurance of Xpert MTB/RIF Testing

Contents

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Lead writers: André Trollip and Heidi Albert (FIND, Cape Town, South Africa). Reviewers: Heather Alexander, Kyle DeGruy, Patricia Hall, Peter Minchella, Bill Coggin (CDC), Daniela Cirillo, Elisa Tagliani (San Raffaele Scientific Institute, Milan, Italy), Martina Casenghi (Médecins Sans Frontières-Access Campaign, Geneva, Switzerland), Kekeletso Kao, Jesse Wambugu (FIND, Geneva, Switzerland).

Revision and finalization of the guide: led by Thomas Shinnick (independent consultant), Heidi Albert (FIND, South Africa) and Josephine San Pedro (CDC) with technical contributions from Andre Trollip (FIND, South Africa), Kyle de Gruy and Patricia Hall (CDC). Critical review was provided by members of the Global Laboratory Initiative (GLI) Core Group, including Lice Gonzalez Angulo, Maka Akhalaia, Kathleen England, Marguerite Massinga Loembe, Alaine Umubyeyi Nyaruhirira and Abiola Tubi. Copy editing: Beatrice Gordis (FIND, Switzerland)

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Acronyms and Abbreviations

CDC	U.S. Centers for Disease Control and Prevention
CQI	Continuous quality improvement
EQA	External Quality Assurance / Assessment
GLI	Global Laboratory Initiative
M&E	Monitoring and evaluation
MDR-TB	Multidrug-resistant tuberculosis
NTP	National TB Programme
NTRL	National TB Reference Laboratory
PPE	Personal protective equipment
PT	Proficiency testing
QA	Quality assurance
QC	Quality control
RIF	Rifampicin
SOP	Standard operating procedure
TB	Tuberculosis
TOT	Training of Trainers
WHO	World Health Organization

About this guide

This quick guide provides an overview of the processes and tools to establish and implement a quality assurance (QA) system for the Xpert MTB/RIF test across the diagnostic network and summarizes the detailed practical guidance found in the *Practical Guide to Implementing a Quality Assurance System for Xpert MTB/RIF Testing*[1].

The QA system is designed to ensure the following are in place and sustained:

- All testing is done in compliance with national testing algorithms and SOPs;
- A cadre of competent users are available to perform the test;
- Testing sites provide uninterrupted diagnostic and testing services unaffected by stock-outs and module failures;
- Samples of optimum quality and quantity are collected
- Xpert MTB/RIF test results are reported in a timely manner to avoid delay in treatment;
- Technical assistance, guidance and on-site supportive supervision and training are provided to testing sites, particularly where needed;
- The TB diagnostic network is monitored, using electronic systems where possible, and the data collected are analysed, evaluated and used for decision-making.

The strategies and approaches described in this document are not unique to the Xpert MTB/RIF test. This guide can therefore be used to inform development of a quality improvement approach for other tests using the GeneXpert platform, as well as other molecular near point-of-care and point-of-care instrument-based diagnostic tests or platforms.

Target audience

This guide is intended for implementers of the Xpert MTB/RIF test and quality assurance managers across the laboratory diagnostic network. Specifically, this guide is intended to inform Ministry of Health officials, National TB Programme officials, National TB Reference Laboratory personnel, donors, implementing partners, quality assurance unit personnel, programme managers, testing site managers, supervisory staff and GeneXpert users at national, regional or testing site level on how to implement activities to assure the quality of Xpert MTB/RIF results.

Note: In this guide, the term 'testing sites' is used to denote a site where the Xpert MTB/RIF test is being performed and includes both traditional laboratories and point-of-care or other clinical testing sites where the Xpert MTB/RIF test is being performed. Furthermore, to ensure the quality of the overall diagnostic process, some of the QA processes (e.g., use of SOPs, participation in supervisory visits, monitoring performance indicators, training, etc.) target activities at participating clinical sites (e.g., specimen collection sites, sample referral centers, and clinics).

Note: In this guide, the term Xpert MTB/RIF test is used to denote either the Xpert MTB/RIF test or the Xpert MTB/RIF Ultra test. When the two tests differ (e.g., whether or not a 'trace' result is generated), the tests will be described separately.

[1] Available at: http://www.stoptb.org/wg/gli/xpertqaguide.asp

Background

Failure to provide a quality Xpert MTB/RIF result can result in either under- or over-diagnosis of TB. Under-diagnosis can lead to worsening of disease and can contribute to the spread of TB (and drug-resistant TB) in the community (Bailey, 2011)[2]. Over-diagnosis may result in unnecessary patient treatment and stigma. Failure to get accurate results can undermine confidence in laboratory testing leading to under-utilization of services and over-reliance on clinical diagnosis.

A laboratory test is just one part of the diagnostic process, which starts with the patient experiencing symptoms and seeking care (passive case finding), or a health care worker identifying a person to be evaluated for TB (active case finding), then continues to a test being ordered by the health care worker, referral of the specimen to the laboratory for testing, receipt of the test results by the health care worker, initiation of appropriate treatment, and finally to monitoring of response to therapy. Lack of quality or delays in any of these steps can reduce the clinical and public health impact of laboratory testing. As such, a system to ensure the quality of laboratory testing must address all the relevant parts of the diagnostic cascade, not just what happens in the laboratory.

Standards and key activities for assuring quality

Quality standards are requirements that must be fulfilled to assure quality Xpert MTB/RIF testing. Standards that were developed to measure the performance of the TB diagnostic network form the basis of the benchmarks used for the Xpert MTB/RIF QA system. They are based on standards developed by the Global Laboratory Initiative (GLI) for ensuring the quality of AFB smear microscopy[3], by the African Society of Laboratory Medicine and Association of Public Health Laboratories for evaluating diagnostic networks[4], and by USAID and partners for evaluating TB diagnostic networks in Nigeria and India[5]. The QA activities associated with each standard are shown in Table 1 and are discussed in subsequent sections in this document. Note that the number of each QA element (e.g., Element 1) corresponds to a subsequent section in this quick guide as well as to the corresponding section in the full QA Implementation Guide.

From standards and procedures to implementation

This quick guide provides an overview of the practical steps to be taken at the national level and at the testing sites for the implementation of a system for ensuring the quality of Xpert MTB/RIF testing at all levels of the TB diagnostic network. At the national and supervisory levels, the QA activities focus on the processes and systems needed to ensure quality testing in all facilities and includes developing national policies and procedures; monitoring and evaluating performance indicators; conducting External Quality Assurance (EQA) and Proficiency testing (PT) programs; and providing supportive supervision. At the individual testing site, the QA system focuses on the processes and procedures to ensure the quality and reliability of each test performed in the laboratory and a well-functioning laboratory-clinical interface to ensure efficient referral for testing, prompt reporting and linkage to care of diagnosed patients.

The key steps required to accomplish each of the individual QA elements shown in Table 1 are briefly described in the subsequent sections. More details and specific practical guidance on accomplishing the activities are available in the full Xpert QA Guide.

[2] Bailey S.L. et al. 2011. Missed opportunities for tuberculosis diagnosis. Int J Tuberc Lung Dis 15: 205-10
[3] TB Microscopy Network Accreditation. An assessment tool. Global Laboratory Initiative. 2013. http://www.stoptb.org/wg/gli/assets/documents/TB-Microscopy_Network_Accreditation_Web.pdf
[4] Ondoa, P. et al. A new matrix for scoring the functionality of national laboratory networks in Africa: introducing the LABNET scorecard. African Journal of Laboratory Medicine, 5, Oct. 2016. http://www.ajlmonline.org/index.php/ajlm/article/view/498/712
[5] Albert, H. Essential standards for a TB diagnostic network. ASLM2016

Table 1: Diagnostic Network Standards and Key QA Activities

Diagnostic Network Standards	Key QA Activities
Structures & policies are in place that enable continuous, country-wide availability of free, quality assured diagnosis according to the national guidelines.	**Governance (Element 1):** Establish a governance structure with clearly defined roles, responsibilities & linkages **Planning (Element 2):** Conduct a situational analysis, strategic planning, and develop a prioritized, budgeted action plan for phased implementation of the QA activities
A minimum package of tests & quality standards is defined for each level of the TB diagnostic network.	**QA documentation (Element 3):** Develop & disseminate the SOPs, bench aids, forms, documents & records that will be needed to ensure the quality of testing
Adequate numbers of competent, well-trained & motivated technical & managerial staff are available at all levels of the diagnostic network.	**Training & certification (Element 4):** Develop & implement a training, competency assessment & certification program to ensure the availability of qualified laboratory staff
Inter-operable & inter-connected electronic recording & reporting systems are in place that generate reliable data that are monitored & analysed in real time.	**Data connectivity & remote monitoring (Element 5):** Utilize remote monitoring systems to collect & analyse data relating to performance indicators, QA and procurement
Testing is performed in a manner & in facilities that ensure safety for the staff, the customers, the community & the environment.	**A safe and functional testing site (Element 6):** Create & maintain safe & functional testing sites
Testing is performed with state-of-the-art and well-maintained equipment and an uninterrupted supply of quality reagents & consumables.	**Equipment & supplies (Element 7):** Ensure well-functioning equipment & a reliable supply of reagents
Continuous quality improvement (CQI) targets all facilities within the network and includes quality indicator monitoring, external quality assurance & regular on-site supervision.	**Proficiency testing (PT) & supportive supervision (Element 8):** Develop and implement an external quality assessment (EQA) program that includes quality indicator monitoring, PT, on-site supportive supervision and timely feedback and corrective actions **Monitoring & evaluation (Element 9):** Monitor & evaluate the performance of Xpert MTB/RIF testing & of the QA/CQI system
An efficient diagnostic-clinical interface allows for appropriate diagnostic tests to be ordered & performed & ensures the timely linkage of diagnosed patients to appropriate care &treatment.	**Strengthen the clinical-laboratory interface & the diagnostic cascade (Element 10):** Strengthen the clinical-laboratory interface to ensure that national testing algorithms are followed, the correct test is ordered, quality samples are collected, accurate results are reported, results are correctly interpreted & patients are placed on appropriate therapy

Key Quality Assurance Activities

Element 1. Governance

It is important to note that while these guidelines focus on Xpert MTB/RIF QA and CQI programs, governance structures may already exist for other programs such as HIV, TB, QA and biosafety of laboratory services. Xpert MTB/RIF QA and CQI activities should be incorporated wherever possible into existing governance structures with clear lines of communication and reporting.

The governance structure at the national and supervisory level will likely vary by country. In many countries, implementation of national policies and procedures are coordinated at the central level by the Ministry of Health, national TB programme (NTP) or national TB reference laboratory (NTRL). In some settings, particularly in large countries, these activities may be decentralized to the regional level. Commonly, the central level provides policies, guidance and tools for standardized QA activities, while the regional and district levels operationalize and supervise the QA activities and monitor the adherence to the procedures. In turn, data collected at the testing sites are reviewed regionally and centrally and used to inform and update policies and procedures, thereby closing the CQI cycle.

Activities at a glance	
National, Regional, and District Level	**Testing site level**
☐ Establish a governance structure ☐ Establish a National QA Office or Coordination Team with a National Laboratory QA Officer ☐ Establish lines of communication across the diagnostic network	☐ Establish a governance structure ☐ Appoint, train and empower a QA officer

Element 2. Strategic planning

The strategic planning process is typically conducted at the national level with input from other levels and should include 1) a situational analysis to determine the current status of Xpert MTB/RIF QA activities, 2) design of a QA system customized to the country's situation, 3) development of a costed prioritized action plan for phased implementation of the required QA activities with targets and a time line, and 4) allocation of an adequate budget and resources for the implementation and annual operation of QA activities.

The situational analysis informs the implementation of QA activities at central, regional, testing site and participating clinical site level. Some QA components may have already been implemented to varying degrees. The phased implementation plan and time line should focus on providing the appropriate structures (e.g., quality teams, data monitoring units), support (e.g., training, supportive supervision, constructive feedback) and monitoring and evaluation processes (e.g., collection and regular analysis of key performance data) needed to implement a functioning QA process. For example, implementing a proficiency testing (PT) program without implementing a corresponding system of timely feedback, corrective actions and supervisory visits will greatly limit the usefulness and impact of the PT program on the quality of testing.

Depending on available human resources and funding, countries may decide to prioritize implementation of certain activities that could rapidly produce improvements in the quality of testing with a limited investment. That is, certain activities (e.g., monitoring and evaluating quality indicators) require limited resources to implement and maintain, beyond initial development of data collection tools and training of staff.

Countries may focus on implementing all QA components and monitoring all indicators at a selected number of sites initially, and once successfully implemented, a scale up plan will be developed for all sites. Alternatively, countries may work on establishing a selection of QA activities at all sites, then expanding the range of QA activities once the initial implementation has been completed. Either way, an important focus should be on the quality of the entire diagnostic cascade including clinical, programmatic and laboratory services. Monitoring the progress of implementation will help identify challenges that could affect the outcome. Addressing these challenges will greatly improve the chances of successful rollout of the QA activities.

Activities at a glance

National, Regional, and District Level	Testing site level
☐ Assemble the team	☐ Participate in a situational analysis
☐ Define roles and responsibilities	☐ Assist with the development of an action plan
☐ Conduct situational analysis	☐ Assist with the development of a QA budget
☐ Develop a strategic plan to implement and sustain the QA system	
☐ Set the budget and time line	

Element 3. Quality procedures and documentation

Without accurate and complete documentation, the quality of Xpert MTB/RIF test results may be compromised. The documentation must address activities throughout the diagnostic cascade including documentation for clinical and programmatic activities (e.g., specimen collection and referral, reporting) as well as laboratory activities.

- Standardized documents, records and forms should be developed at the national level and distributed to all testing and participating clinical sites to assure conformity.
- Standardizing documents, records and forms will take time. Therefore, plan the implementation of standardized documentation in a systematic manner.
- SOPs, forms, documents and records must be up-to-date, accurate, and readily accessible at all testing and participating clinical sites.
- A document control system is needed to ensure regular review of quality documents (e.g., SOPs) and the correctness of the documentation that supports laboratory testing.

Activities at a glance	
National, Regional, and District Level	**Testing site level**
☐ Generate QA documents ☐ Disseminate QA documents ☐ Implement document control system	☐ Receive documents from supervisory or national level ☐ Customize documents by adding testing site specific information ☐ Implement a document control system ☐ Ensure users read and understand the QA documents

Element 4. Training, competency assessment and certification

Training, competency assessment and certification are critical components of providing quality assured Xpert MTB/RIF test results. The implementation of the Xpert MTB/RIF test in a quality assured manner requires training beyond the steps required to carry out the test. Manufacturer-supplied on-site training following installation is often too short to cover QA activities. The testing site manager must ensure that GeneXpert users are trained in the operation of the GeneXpert instrument, correct performance of the Xpert MTB/RIF test and carrying out the associated QA activities.

Competency assessments should be performed after training and periodically (e.g., annually). Assessment of skills of staff performing on-site supervision, training and mentoring should be included, as well as competency assessment for performing the test. Templates for conducting and recording the results of a competency assessment can be found in the Xpert QA Guide.

Activities at a glance	
National, Regional, and District Level	**Testing site level**
☐ Customize training package ☐ Conduct training ☐ Perform competency assessments	☐ Train users in the operation of the GeneXpert instrument, Xpert MTB/RIF test and QA activities ☐ Assess users for competency

Element 5. Data connectivity and remote monitoring

Diagnostics connectivity refers to the ability to connect diagnostic test devices that produce results in a digital format, such as GeneXpert instruments, in such a way as to transmit data reliably to a variety of users. Key features of the systems are the ability to remotely monitor performance, conduct QA and manage inventory. With remote monitoring, designated persons can use any internet-enabled computer to access the software platform, providing them with an overview of the facilities, devices and commodities in their network. Software can track consumption and inventory to avoid stock-outs and expiring cartridges, as well as identify commodity lots or specific instruments with poor performance or abnormal error rates for QA purposes. This can provide a highly cost-effective way to ensure proper functioning of a diagnostic device network.

Data can also be transmitted automatically to 1) clinicians and patients which allows for faster patient follow-up, 2) laboratory information management systems or electronic registers, reducing staff time and the chance of transcription errors, and greatly facilitating monitoring and evaluation processes, and 3) the NTP to assist with surveillance of disease trends or resistance patterns, as well as enhance the capacity of the NTP to generate the data needed for several of the performance indicators of the End TB Strategy.

Detailed information on the design and implementation of a diagnostics connectivity solution may be found in the *GLI Quick Guide to TB Diagnostics Connectivity Solutions*.[6]

Activities at a glance

National, Regional, and District Level	Testing site level
☐ Select a data connectivity solution	☐ Work with national level to determine which diagnostic connectivity system will be used
☐ Connect all GeneXpert instruments	☐ Obtain and install all needed hardware and equipment
☐ Prepare SOPs and train users	☐ Identify and train users
	☐ Implement SOPs
	☐ Establish lines of communication

[6] GLI Quick Guide to TB Diagnostics Connectivity Solutions. 2016. http://www.stoptb.org/wg/gli/gat.asp.

Element 6. A safe and functional testing site

In a functional testing site, the GeneXpert instrument will be properly positioned in a clean, secure location and placed on a vibration free bench (not directly under an air conditioning unit). In addition, there should be an uninterrupted supply of power and appropriate working and storage conditions (humidity and temperature controlled). In a safe environment, WHO biosafety recommendations for conducting the Xpert MTB/RIF test will be followed with adequate ventilation, appropriate personal protective equipment (PPE) will be used, and biologic waste will be disposed of safely and in accordance with regulations. Failure to provide a safe and functional work environment can impact the quality of testing in several ways, including:

- An unsafe testing site is a hazard to staff, patients and the environment
- In an unsecure testing site, test results may be delayed if there is equipment failure or theft
- Testing sites that do not maintain uninterrupted power, optimal working temperature, and a clean environment can have equipment failures and high error rates that delay reporting and waste reagents

The selection of which sites will conduct Xpert MTB/RIF testing is usually determined by the NTP or NTRL and is based on factors such as TB epidemiology, geographic considerations, testing workload, efficiency of referral networks, and patient access to services. The Xpert MTB/RIF testing sites may be located in a peripheral clinic, district laboratory, or a high-throughput reference laboratory. Each testing site should be evaluated for readiness using a standardized checklist prior to the testing of clinical specimens. In addition, existing testing sites should be regularly assessed for safety and operational functionality.

Activities at a glance

National, Regional, and District Level	Testing site level
☐ Assess each testing site for readiness	☐ Place the GeneXpert instrument correctly and secure from theft
☐ Upgrade facilities as needed to create a safe functional work environment	☐ Ensure an uninterrupted power supply
☐ Regularly assess existing testing sites for safety and functionality	☐ Ensure an optimal working temperature
	☐ Perform a risk assessment
	☐ Ensure sufficient ventilation for testing procedures
	☐ Provide suitable PPE and train staff in its correct use
	☐ Discard waste as recommended
	☐ Use appropriate disinfectant and prepare correctly

Element 7. Equipment and supplies

The GeneXpert is a precision instrument that requires regular maintenance as described by the manufacturer to ensure that it provides accurate and precise results. A robust inventory system is required to monitor Xpert MTB/RIF cartridge consumption. Accurately forecasting Xpert MTB/RIF test supply needs reduces the risk of service interruption due to shortage of cartridges and testing materials. Failure to maintain an adequate, uninterrupted supply of quality-assured reagents can affect quality because 1) stock-outs result in delayed testing and delayed reporting of results and 2) use of poor quality or expired reagents can result in high error rates and inaccurate test results. New lot testing, also known as lot-to-lot verification, should be performed (at least at the national level) on new batches of cartridges to ensure their fitness for use.

Activities at a glance

National, Regional, and District Level	Testing site level
☐ Develop and implement plans and policies to ensure maintenance and servicing of the GeneXpert instrument	☐ Maintain all testing site equipment in a good working condition
☐ Establish a system to ensure an uninterrupted supply of quality-assured reagents	☐ Perform preventative maintenance
☐ Implement a system for new lot testing of batches of cartridge	☐ Monitor instrument performance and perform on-request maintenance as required
	☐ Ensure warranties and service contracts are in place and adhered to
	☐ Forecast how many cartridges will be used
	☐ Implement a stock control system to manage Xpert MTB/RIF stock
	☐ Store Xpert MTB/RIF cartridges in accordance with manufacturer's recommendations

Element 8. External quality assessment (EQA)

An EQA program includes quality and performance indicator monitoring, PT, regular on-site supportive supervision with timely feedback, corrective actions and follow-up. The Xpert MTB/RIF PT programme is an important tool for communicating with and motivating staff. If used correctly, the PT programme can identify and resolve problems in Xpert MTB/RIF testing. On-site evaluations and supportive supervision can facilitate evaluation of the quality of testing, analyze QA results, identify problems, develop corrective actions, provide initial and refresher training, and document improvements. Failure to implement a comprehensive EQA program is a missed opportunity to identify and correct problems that affect the quality of testing.

Activities at a glance	
National, Regional, and District Level	**Testing site level**
☐ Develop and implement a program for on-site supervision prioritizing poorly performing sites ☐ Develop and implement a PT program	☐ Enroll the testing site in an Xpert MTB/RIF PT programme ☐ Perform PT testing as required. Receive and analyse PT reports ☐ Troubleshoot unexpected PT results and identify corrective actions ☐ Participate in a system of supportive supervision and on-site evaluations

Element 9. Monitor performance of Xpert MTB/RIF testing and the QA/CQI system

Routine monitoring of quality indicators, also known as performance indicators, is a critical element of assuring the quality of any diagnostic test or system and is essential to inform decision-making. Quality indicators should include testing site performance indicators, clinical indicators and programmatic indicators, including those that measure test results, supplies, test performance, PT results and QA processes. The Xpert QA Guide provides detailed descriptions of recommended key performance indicators for monitoring the quality of Xpert MTB/RIF testing and targets for the indicators as well the key indicators for the quality of the diagnostic cascade and the overall QA system that should be monitored at the supervisory or national level.

All laboratories should collect and analyse testing data at least on a monthly basis, using a standardized format. Targets should be set for all indicators monitored, and any unexplained change in quality indicators, such as increase in error rates or a change in MTB positivity or RIF-resistance rate, should be documented and investigated. A standard set of quality indicators should be used for all sites conducting a particular test to allow for comparison. Quality performance indicators should be reviewed by the laboratory manager and must always be linked to corrective actions if any unexpected results or trends are observed. Documentation of corrective actions and subsequent improvement and normalization of laboratory indicators following the corrective actions are critical.

Activities at a glance	
National, Regional, and District Level	**Testing site level**
☐ Establish an M&E framework ☐ Identify key performance and quality indicators ☐ Collect and analyze data ☐ Evaluate progress and identify trends	☐ Implement quality indicator monitoring ☐ Regularly review quality indicators and troubleshoot unexpected results by identifying corrective actions ☐ Report quality indicator data to the NTP/MOH

Element 10. Strengthen the clinical-laboratory interface and the diagnostic cascade

A comprehensive system to ensure the quality of laboratory testing must address all the relevant parts of the diagnostic cascade, not just what happens in the laboratory. Published literature on a variety of laboratory tests highlights that factors that have the largest impact on quality of diagnostic services occur in the pre-pre-analytical phase (choice of test, etc.) and post-post-analytical (interpretation of results and patient management). At the national and supervisory level, efforts should concentrate on training (initial and annual refresher training), developing SOPs and quality assurance systems. At the testing and clinical sites, efforts focus on collecting quality specimens, reporting accurate results, engaging clinicians and ensuring client satisfaction with diagnostic services.

Activities at a glance

National, Regional, and District Level	Testing site level
☐ Provide training on the diagnostic cascade to all laboratorians and health care workers	☐ Provide training on the diagnostic cascade to all laboratorians and health care workers
☐ Develop SOPs for the clinical-laboratory interface	☐ Collect and test quality samples
☐ Develop systems to support the flow of information between clinicians, program staff, and laboratorians	☐ Report accurate results
☐ Monitor the performance of the diagnostic cascade	

Additional Resources

Practical Guide to Implementing a Quality Assurance System for Xpert MTB/RIF Testing. This guide provides practical guidance and tools to establish and implement a quality assurance (QA) system for the Xpert MTB/RIF test across the diagnostic network. Part 1 of the guide (national and supervisory Levels) focuses on establishing or integrating Xpert MTB/RIF QA activities into the TB diagnostic network in a country or region and Part 2 (QA at Xpert MTB/RIF Testing Sites) addresses key activities to be carried out at the testing sites to ensure the production of quality Xpert MTB/RIF results. This Quick Guide to Quality Assurance of Xpert MTB/RIF Testing provides a summary of key elements of the full-length guide (*http://www.stoptb.org/wg/gli/xpertqaguide.asp*).

GLI Training Package on Xpert MTB/RIF. The package consists of slide presentations that can be customized and used to train GeneXpert users in all aspects of Xpert MTB/RIF deployment, including related QA procedures. Topics covered include: Overview of TB and diagnostics, biosafety, specimen collection, procurement, installation, Xpert MTB/RIF technology, results interpretation, reporting, troubleshooting, maintenance, a clinical guide, and quality assurance. (*http://stoptb.org/wg/gli/TrainingPackage_XPERT_MTB_RIF.asp*)

FIND TB laboratory strengthening resources Free, generic SOPs, documents and forms and checklists (available in several languages) that can be customized for use at testing sites (*https://www.finddx.org/implementation-resources/#tb*).

GLI Guide on Planning for country transition to Xpert® MTB/RIF Ultra Cartridges (2017). Provides practical guidance to plan and implement a smooth transition from use of Xpert MTB/RIF to Xpert MTB/RIF Ultra cartridges and includes advice on how to develop an actionable implementation plan, from country-level to site-level, for adoption of the Xpert MTB/RIF Ultra cartridge (*http://www.stoptb.org/wg/gli/assets/documents/GLI_ultra.pdf*).

GLI Quick Guide to TB Diagnostics Connectivity Solutions (2016). Provides an overview of diagnostics connectivity solutions, and what is required to establish one and use it effectively *http://www.stoptb.org/wg/gli/gat.asp*. Also contains a link to an online table comparing the functionalities of currently available software (*http://tinyurl.com/gliconnectivity*).

GLI Practical Guide to TB Laboratory Strengthening (2017). Provides practical guidance on implementation of WHO recommendations and international best practices for TB laboratory strengthening. It provides guidance in key technical areas, including quality assurance and quality management systems, specimen collection and registration, procurement and supply-chain management, diagnostics connectivity, biosafety, data management, human resources, strategic planning and other topics (*http://stoptb.org/wg/gli/gat.asp*).

WHO Framework of indicators and targets for laboratory strengthening under the End TB Strategy (2016). Developed as a collaboration between the WHO Global TB Programme and the GLI core group, comprises 12 core indicators that measure countries' capacity to detect TB accurately and rapidly using new diagnostics, provide universal DST, and ensure the quality of testing. (*http://www.who.int/tb/publications/labindicators/en/*).

Guidelines for Managing the Laboratory Supply Chain: Version 2. Arlington, VA.: USAID DELIVER PROJECT, Task Order 1 2008. Provides general guidance for managing a laboratory's commodities and describes planning, coordination, and the well-recognized cycles of selection, procurement, distribution, and use. (*http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/GuidManaLabSC_v2.pdf*)

Notes


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