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# Technical Brief: Laboratory Systems Strengthening

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# 1. Introduction and Rationale

## 1.1 Introduction

The purpose of this technical brief is to guide countries preparing Global Fund funding requests that include interventions related to laboratory systems strengthening. It outlines the Global Fund's approach, the general principles that underpin Global Fund's investments, the different types of investments that may be supported, and how interventions should vary according to country context.

Applicants, including country stakeholders, members of the Country Coordinating Mechanism (CCM), technical assistance providers and writing teams, are encouraged to review this document in parallel with the resources available for this allocation cycle, including the HIV, TB, Malaria and RSSH Information Notes, related technical briefs, and the Global Fund Applicant's Handbook.

Efficient and reliable health laboratory systems are an essential component of any resilient health system and are central to achieving the core mission of the Global Fund. Laboratory diagnostic capacity is critical towards reaching the global targets to end AIDS, Tuberculosis (TB) Malaria. The UNAIDS targets of ensuring that 90% of people know their HIV status, 90% of those testing positives are receiving optimized treatment regimens and 90% of those on treatment are virally suppressed (90-90-90) by 2020 rely heavily on adequate laboratory services. Similarly, the laboratory will play a critical role in achieving the Global Plan to End TB's target of reaching 90% of all people who need TB treatment and achieving at least 90% treatment success. The Global Technical Strategy for Malaria 2016-2030 aims to accelerate progress toward malaria elimination based on three pillars: ensuring universal access to malaria prevention, diagnosis and treatment; accelerating efforts toward elimination and attainment of malaria-free status; and transforming malaria surveillance into a core intervention. This strategy, too, relies heavily on strong laboratory diagnostic capacity and systems to support diagnosis, surveillance and detection of drug resistance.

Disease surveillance, diagnosis, prevention, treatment and health promotion all require sound and reliable laboratory services, and, under the revised International Health Regulations (IHR), countries are required to develop capacity to detect, investigate and report potential public health emergencies of international concern, such as disease outbreaks to WHO. The availability of laboratory services capable of producing reliable results in a timely manner is the cornerstone of any country's capacity to detect such outbreaks.

## 1.2 Rationale for Investments in Laboratory Systems

There have been significant efforts to strengthen laboratory systems over the past decade, and the continued need for support is reflected in the Global Fund's 2017-2022 Strategy 'Investing to End Epidemics.' However, numerous challenges remain, with a reliance on empirical patient care leading to misdiagnosis and inappropriate treatment, and subsequent increases in the risk of poor

patient outcomes, drug resistance and waste of already scarce resources. Challenges include: dilapidated infrastructure; lack of funding for developing and implementing national policies and strategic planning; poorly funded and implemented quality management systems; unlinked referral and reporting services; inadequate human resources; lack of, or limited equipment maintenance; weak specimen referral networks; lack of or limited laboratory information systems (LIS); and weak linkages to care.

Very few countries have clearly defined the role of laboratory services at each level of the health care system. Many countries are not aware of what laboratory services are being offered to the population in terms of types of tests and the quality of testing offered per facility, and national planning for laboratory systems is weak. Data on access to health laboratory services is scarce and is not integrated into other systems. This lack of an informed strategic approach is an important challenge to be addressed. Laboratory priorities should be established jointly with other public health priorities at all levels of the health system.

A final challenge is how to advocate for representation of laboratory services at the highest decision-making levels. In many Ministries of Health there is no dedicated directorate of laboratory services or this key service delivery area is positioned too low in the organization structure to be effective. Often, more attention is given to essential medicines rather than essential diagnostics or laboratory services. Therefore, the establishment of strong national laboratory leadership is necessary to ensure that the laboratory agenda is seen as a critical component of national health systems. A strong national laboratory directorate can help provide the leadership and coordination to ensure better integration and efficiency of services. The creation of a decentralized and coordinated structure led by the national laboratory directorate is key to improving national laboratory services, enabling them to play a significant role in disease control and prevention.

## 2. Guiding Principles for Investing in Health Laboratory Systems

### 2.1 Integration of Laboratory Services and Systems

There is a need to integrate laboratory services across programs and sectors, both public and private. While international funding has increased for disease-specific programming, many of these programs are often organized as silos. Although vertical approaches have improved disease-specific responses, in some cases they have also resulted in the fragmentation of laboratory services and duplication of efforts. In addition, they have often left important gaps in the capacity of individual countries to perform crucial clinical and disease surveillance functions in a coordinated manner. Therefore, it is imperative to change the thinking around laboratory investments and move towards securing the establishment of integrated national laboratory services, networks and systems. An integrated approach allows both programs and clinicians to use more comprehensive information that can lead to more informed clinical decision-making and more effective patient care.

Integrating diagnostic services for different diseases within the same facility avoids duplication of investments in infrastructure/space, equipment and laboratory support systems, such as human resources, specimen transport, results delivery, supply chain management and data management under a unified information system. An integrated approach can also help ensure standardization of core laboratory systems, such as quality assurance and standard operating procedures, as well as more efficient delivery of training. Further, with the current decline in qualified laboratory specialists, integration allows for cross-training providing staff with multi-disciplined skillset expanding their utility in the workforce. Integrated laboratory services optimize quality, efficiency and cost-effectiveness for all its core functions.

## **2.2 Country Ownership**

Country ownership is a fundamental principle of the Global Fund model, in conjunction with performance-based financing and partnerships. Laboratory system improvements should be built on a common vision, which has been articulated in a costed national laboratory strategic plan with investments of partners and aligned to an implementation plan that has clearly defined milestones and objectives. The vision should be coupled with strong leadership to ensure that the laboratory agenda is included in the national health sector priorities and budgeted within the overall strategic plan. Excessive dependence on donor and partner funding creates inadequate country-level ownership and will lead to unsustainable laboratory services for both routine clinical work and epidemic response. Lack of ownership and leadership in some countries limits opportunities for resource mobilization and financing. Global Fund contributions should be complementary to domestic and other donors' investments and should be framed within a national strategic vision.

## **2.3 Partnerships**

There is a proverb "If you want to go fast, go alone; but if you want to go far, walk together." It is recognized that partnerships are essential to achieve the common goal of strengthening laboratory systems and services. It is evident that no single entity can work in isolation in laboratory system strengthening. This service delivery area is a cross cutting intervention, requiring coordinated and harmonized activities.

Strengthening of national laboratory services and systems depends on partnerships beyond the laboratory facility itself, with technical and clinical professionals, healthcare managers at the community, regional and national levels, and public health programs. Private services and non-government laboratories play a significant role in the delivery of services and are becoming a major part of the network of national laboratories. Private labs are key to building national capacity, as well as public-private partnership models that increase access to diagnostic services and patient care. Countries are encouraged to think about ways to build and strengthen partnerships with private sector providers and contract out services where appropriate. The relationship between public/private health clinics and laboratories (including research laboratories, where feasible) should be defined in a national laboratory plan. This should define the relationship between the different levels in a tiered system, the roles and responsibilities at each level and the populations served.

## **2.4 Efficient and quality laboratory service delivery**

The demand for laboratory services to meet the diagnostic and treatment needs for HIV and TB, has helped drive investments in new or renovated infrastructure and advanced technologies. This

expansion and investment in laboratory capacity should be harnessed and optimized to serve the needs of other diseases of public health and national importance for both clinical diagnosis and disease surveillance. For example, an integrated laboratory tiered network should be capable to provide all primary diagnostic services and referral of specimens without requiring patients to go to different laboratories for specific tests. The network should focus on providing quality-assured basic laboratory testing, common specimen transport systems and polyvalent diagnostic platforms that can be used across diseases within the same facility.

Polyvalent molecular platforms and other testing technologies can be used to rapidly detect a wide range of viral and bacterial pathogens. Their strategic placement requires careful planning of the anticipated numbers of different types of samples based on the testing of different patient populations, and planning of procurement and supply chain system to match available machine throughput. For example, an instrument with capacity for TB detection as well as early infant detection of HIV should have adequate daily capacity to test all the sputum specimens received from patients suspected of having TB at that site and in the referral network, as well as test all the blood specimens received from newborn infants at risk of HIV.

Overall, there is a growing demand within the global health community for improved access to robust, quality-assured diagnostics in resource-limited settings. Manufacturers have slowly engaged, resulting in the emergence of a range of new technologies and a dynamic pipeline. These include easy-to-manipulate POC technologies and polyvalent platforms, suitable to respond to the needs of different levels of care, along with improvements in sample transport and device and data connectivity networks. Determining the optimal mix of centralized, high-volume diagnostics and POC diagnostics based on each country's unique needs is a challenge, as is assuring the quality. Improved coordination and appropriate planning involving all stakeholders and the Ministry of Health is required to ensure that the introduction of POC platforms does not disrupt the functioning of existing standard testing platforms. An in-country platform or instrument mapping exercise can be done to determine gaps and to ascertain where POC platforms can be placed to add value to the national program. POC platforms should not be replacements for standard platforms; they are complimentary and should be placed only where absolutely needed and supported with data on gaps in service delivery. While preparing funding requests, challenges associated with POC rollout and sustainability should be considered.

Finally, it is important to note that health promotion to increase demand for services in the community as well as community laboratory systems capacity also plays an important role in facilitating disease detection. A combination of improved sample transport and simple rapid point of care testing can provide greater access to quality testing in decentralized settings. The Global Fund supports cross-cutting laboratory system investments that maximize impact against the three diseases and support the development of integrated and tiered national laboratory services (that include hematology, chemistry, and microbiology laboratories). This may include strengthening and integrating specimen transport and data networks; building effective public–private partnerships to scale up laboratory services, increase coverage and improve quality of care; introducing new innovations and polyvalent technologies.

## **2.5 Based on country context and need**

Maximizing the impact of investments in laboratory systems, as a pillar of resilient and sustainable systems for health, requires taking into consideration the country context. As countries have

different laboratory system maturity levels, the type of interventions and investments will vary depending on the situation. In challenging operating environments, maintaining or developing essential service delivery capacity that includes diagnostics is important; this can include strengthening the sample transport system to facilitate access to diagnostic services. In acute emergency contexts and where risks are deemed high, service delivery might be temporarily delegated to service providers that are equipped for such activities. In more stable countries, developing or reviewing an integrated laboratory system strategy might be a critical investment for the future. In transitioning countries, the gap analysis combined with a sustainability analysis should guide Global Fund investments in laboratory systems.

In all contexts, it is critical that proposed laboratory system interventions address identified gaps in the laboratory system. To do this, a gap analysis should be done that considers various factors, including the country's vision and the maturity of its laboratory systems strategy, synergies with partners at the global and country level, and funding availability.

It is also important that funding requests make clear how proposed improvements will be measured and how baselines will be established. Where possible, assessments should be part of, and informed by a country's national health information system. Resulting investments should be assessed based upon evidence showing how specific weaknesses, gaps or bottlenecks in the targeted laboratory system components have been reduced because of the supported interventions.

### 3. Scope of Global Fund Investments in Laboratory System Strengthening

#### 3.1 Introduction to what Global Fund can support

The Global Fund can support the following interventions detailed below. These are the same interventions as those listed under the laboratory systems module in the [Modular Framework Handbook](#), as well as other RSSH interventions (for example for HRH). For each intervention, information is provided on what it is, why it is important and the types of activities that can be funded. More general guidance on how to develop a funding request for the Global Fund is provided in the Global Fund [Applicant Handbook](#).

When requesting laboratory development and system strengthening funds, countries must demonstrate how they will support a national integrated laboratory policy and strategic plan. Specifically, investments should help reach the following objectives:

- Build the capacity of laboratory systems to scale-up integrated service delivery models and improve quality, equity, efficiency, effectiveness and sustainability of the laboratory services, particularly in hard-to-reach areas and those targeting key affected and underserved populations;
- Improve the managerial capacity across the laboratory network and systems through: support to procurement and supply chain management, integrated laboratory information

systems, monitoring and evaluation systems, human resources training and supervision, quality management systems, and biosafety/biosecurity and financial management systems;

- Support the selection of equipment balancing access and cost analyses, and context-appropriate contractual arrangements with providers;
- Utilize existing laboratory equipment more efficiently;

Although countries are usually the major investors in their own laboratory systems, other partners may also contribute, including the private sector. Therefore, it is essential that investments align with the national vision and are well coordinated.

### **3.2 Human resources for laboratory systems**

In many countries the human resources crisis within the laboratory system is acute, with an inadequate number of staff and inadequate skill sets. Many countries have limited laboratory education programs, with only basic training for technicians producing graduates with limited skill sets who are unable to operate modern sophisticated technologies. This has the effect of limiting the technology that they can use. New and diverse skill sets (lab informatics, molecular lab skills, sequencing skills, cost effectiveness skills etc.) are needed to operate laboratories. Retention in the public sector is also a challenge because well-trained laboratory specialists often leave the country or migrate to better-paid positions within the country, for example in the private sector or in research institutes.

Activities that may be supported by the Global Fund include those that are aimed at improving the equitable distribution and retention of a skilled laboratory workforce, especially in hard-to-reach areas and those serving marginalized populations. HRH interventions related to laboratories should be included under the HRH or laboratory systems module, as relevant (instructions can be found in the [Modular Framework handbook](#)). Activities can include:

- Support for recruitment, retention strategies and leadership development, with clear career pathways, incentives and the potential for advancement as laboratory professionals;
- Laboratory educational interventions that promote the enrollment of students with various (especially rural) backgrounds and support the expansion of the laboratory education infrastructure, including curriculum revisions and special laboratory internships in training programs;
- Regulatory interventions such as enabling the implementation of task-shifting, introducing laboratory professional cadres with specific professional profiles and strategies to increase retention;
- Financial interventions that provide financial and non-financial incentives for retraining laboratory specialists at the various levels;
- Personal and professional support for safe and supportive working environment, outreach support, career development programs, professional networks and public recognition measures;
- Support for curriculum revision and implementation to align the required skills with testing needs and technologies;
- Support to national regulatory councils/authorities, including capacity-building of regulatory bodies and professional associations.

### 3.3 National Laboratory Governance and Management Structures

Strong laboratory governance ensures that the laboratory is a central component of national health systems. However, in many cases, weak institutionalized laboratory leadership and poor coordination has resulted in duplication at all levels, and unsupervised district and peripheral laboratories with dubious quality of testing. With several different donors, implementers and technical partners involved across many programs, strong coordination mechanisms need to be in place to ensure that efforts and funding align with national laboratory strategic plan.

A national laboratory policy should focus on the following: laboratory leadership and organization, structure and coordination; staff retention; quality management systems; integration of services; facilities; waste management; and biosafety and biosecurity. Decisions to classify laboratory services in the tiered network and choice of technologies should be based on testing complexity, cost, throughput, specimen referral linkages, program need, and the patient population being served.

To address these governance concerns, activities that may be supported include:

- Laboratory governance support to establish national lab directorate for better coordination of laboratory services and development of comprehensive national laboratory policies and costed strategic plans including support to operational management and technical assistance;
- Support to “Three One’s”— one national strategic plan, one coordination system, one monitoring and evaluation plan – this will enable countries to better manage and coordinate the efforts of multiple different partners contributing to national laboratory network and systems. Development of comprehensive national laboratory policies and plans, including support to operational management and technical assistance;
- Establishment of a national laboratory network that includes all disease programs coordinated by the Ministry of Health;
- Coordination mechanisms and mapping of partners’ contributions;
- Legal, regulatory and policy reforms;
- Support organization and communication between the different tiers of the laboratory system within the context of tiered laboratory networks compatible with the Maputo declaration. Labs should be integrated across diseases and based on national laboratory strategic plans that are informed by strong technical guidelines and national standards; they should also be consistent with international standards as defined by WHO or ISO accrediting bodies.
- National policies and guidelines on biosafety and biosecurity and respective standard operating procedures.

### 3.4 Infrastructure and equipment management systems

#### *Infrastructure*

Appropriate building space and equipment are essential to deliver safe and effective services, as laboratories must be fit for purpose. The infrastructure of a laboratory should ideally be designed to maintain appropriate biosafety standards and ensure quality delivery of results. The minimum number of rooms and their requirements according to function and equipment should be defined, noting requirements for molecular laboratories. Global Fund investments may be used for

interventions aimed at supporting the scale-up of laboratory services according to tiered level, whether facility-based or community-based. Such interventions may include:

- upgrading infrastructure, including refurbishing facilities to comply with international recommendations;
- equipment and development of reliable power sources, including innovations in renewable energy, such as solar panels;
- information communication technology (ICT), including connectivity for POC technologies.

#### *Equipment management systems*

The availability and maintenance of laboratory equipment remains challenging. For example, a recent survey that examined lab use for TB and HIV programs revealed major weaknesses in managing and utilizing existing lab equipment, including lack of reagents, lack of installation and deployment of equipment, poor maintenance and no staff training on techniques and equipment. These challenges led to a striking disconnect between capacity and utilization. It also showed that most machines were not covered by maintenance contracts and were not receiving the recommended service.

Maintenance should be done on a preventive basis rather than a corrective basis, and any equipment procured should come with a maintenance contract. Basic training is essential for laboratory technologists to operate laboratory equipment and perform preventive maintenance. In addition, countries should build internal capacity for preventative maintenance, and if possible, secure reagent rental agreements that include service and maintenance for major equipment rather than outright purchases. Connectivity through equipment-based testing devices are now widely available and such solutions should be harnessed to monitor consumption, quality and functionality of lab equipment.

To address these common weaknesses, activities that may be supported by the Global Fund include the following:

- Equipment management systems including planning and negotiation of maintenance contracts, bundled maintenance agreements and reagent rental agreement;
- Training of biomedical engineers;
- Training of users of equipment;
- Support to calibration and maintenance contracts;
- Connectivity solutions for laboratory equipment.

### **3.5 Quality Management Systems and Accreditation**

Quality assurance (QA) is the foundation of any laboratory management program. It aims to ensure that the results produced by the laboratory are truly representative and reliable. The QA process ensures greater consistency and trustworthiness of results. However, in many countries, QA in laboratory medicine has been severely neglected and has become a serious impediment to effective healthcare delivery and disease surveillance. Due to a lack of confidence in laboratory test results, physicians often rely solely on patient history and physical examination for patient management. There is now a greater recognition for quality performance of testing and many countries are currently making great strides in implementing quality management systems (QMS) leading to laboratory accreditation in accordance to global standards. Implementation of a QMS is

one of the core indicators of the WHO Framework of Indicators and Targets for Laboratory Strengthening under the End TB Strategy.

Over the past decade, quality performance-enablers have been developed to guide the implementation of a sustainable QMS leading to accreditation. These include: The Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA), the WHO Laboratory Quality Stepwise Implementation tool (LQSI tool), the Caribbean Laboratory Quality Management System – Stepwise Improvement Process (LQMS-SIP) towards Accreditation, and the Laboratory Quality System Handbook. It is recommended that countries adapt and implement laboratory international standards, comprehensive quality systems and goals for accreditation in their plans for future development. Countries are encouraged to develop and implement accreditation programs, including country-specific standards and monitoring systems. Mentorship should be incorporated into laboratory quality improvement and management training programs to accelerate the progress of laboratories towards achieving accreditation. Although considerable resources are needed for quality improvement towards accreditation, these costs are much less than the costs of the adverse consequences of poor quality in terms of misdiagnosis, repeating tests, lost time and ultimately poorer health outcomes.

Activities that may be supported by the Global Fund include:

- Support to the establishment and implementation of national continuous quality programs for laboratory systems including quality management systems towards accreditation, for example, SLMTA/SLIPTA; participation in EQA (external Quality Assurance schemes);
- Support to national regulatory bodies, frameworks and minimum licensing requirements for laboratory systems;
- Support to development of national quality standards for laboratory systems.

### **3.6 Information systems and integrated specimen transport networks**

The laboratory core business is to produce information for clinicians and for public health disease surveillance. A well-functioning LIS ensures the production, analysis, dissemination and use of reliable and timely information. Investments in laboratory information systems (LIS) must be interoperable with the electronic medical records (EMRs) and national health management information system (HMIS). With advances in information communication, technology (ICT) significant opportunities exist to harness the power of ICT, as is widely done in the private sector. For example, mobile technologies can be used to track specimens, the return of lab results, and to send results to the patients' local clinics. The use of healthcare system wide individual unique identifiers will also improve the quality and coordination of service provision with individual longitudinal service records, as well as improve the effectiveness, efficiency, equity and acceptability of these services through ongoing monitoring and evaluation.

Like all health information, the development and use of unique identifiers requires balancing the individual's right to privacy and confidentiality with the need for individual-level information to optimize the provision of services to ensure their effectiveness, efficiency, equity and acceptability for both users and providers of those services. Therefore, development and use of these identifiers should be based on the principles of confidentiality and security of health information and compliance with national data protection laws.

To support the development of LIS and integrated transport systems, the following types of activities can be requested:

- Establishment, maintenance and strengthening of national LIS, integrated for all diseases at all levels, including public-sector, private-sector and community-level reporting;
- Capacity building of monitoring and evaluation personnel on key laboratory indicators including support to data analysis and development of laboratory dashboards that are interoperable with national HMIS;
- Development of reporting forms and tools and data-quality assessment methods;
- Training staff at all levels to use data to make informed management and program decisions and monitor program progress;
- Promoting use of technology and electronic systems (e.g. establishment of text messaging/SMS systems of reporting, diagnostic and decision-making algorithms and other innovative applications);
- Integrated specimen transport networks including specimen transport that are disease agnostic, and support for results return.

### **3.7 Laboratory supply chain systems**

Supply chain management is often a weak link within laboratory network systems. Between 15% and 45% of a laboratory's budget is spent on supplies, including a complex combination of reagents, basic equipment and consumables, which are often test-specific. Therefore, careful stewardship of equipment and lab commodities is crucial. Too large a variety of laboratory equipment and reagents in a country complicates procurement, development of specifications and the establishment of service and maintenance contracts. Recent efforts have, therefore, focused on the harmonization and standardization of the minimum package of supplies, tests, and equipment needed at each level of the tiered laboratory network, as well as ensuring alignment with the national policy. This approach requires strong leadership and coordination by local ministries, along with partners and donors. It brings many benefits, such as reduced procurement costs for commodities, easier implementation of quality assurance programs and integration of multi-focused testing that uses shared equipment. In addition, it also allows for harmonized training, equipment maintenance, quality management systems and techniques across diseases. A balance must be struck between standardizing equipment without creating overreliance on a single manufacturer or supplier.

Supply chain and laboratory optimization are critical for service delivery. Countries need to ensure oversight of supply chain operations that are informed by data systems that provide quality data at central, regional and site level facilities. Infrastructure (warehousing/storage) and distribution systems suitable for laboratory commodities need to be in place to consistently serve patients in all areas of the country. Laboratory supply chain systems should be integrated into the national health supply chain system.

In terms of procurement and placement of laboratory equipment, over the past few years there has been an expansion of new near-POC technologies, however there has often been inappropriate placement in isolation of the laboratory networks leading to underutilization and inefficiencies. As countries consider the use of near-POC instruments, they should conduct laboratory network assessments and optimization activities to establish the needs in a tiered laboratory system. They should also ensure appropriate placement of both conventional and near-POC instruments, using the reagent rental or all-inclusive models of service delivery. These business models will lead to improved service delivery and efficiency, ensuring optimization and avoiding over-procurement or the placement of more instruments than are needed. The Global Fund favors reagent rental and

all-inclusive pricing /test models and will continue to discourage outright purchase of laboratory equipment. All instrument acquisition should be through reagent rental/all-inclusive pricing mechanisms which include standardized key performance indicators to monitor suppliers, end users, and instruments.

Future laboratory equipment should be multi-disease diagnostic platforms. These platforms offer technical and financial efficiencies to countries in their disease control efforts, while expanding access to care and saving lives. Given the polyvalent nature of instruments, laboratory costs relating to service maintenance and consumables for this instrument can be apportioned across programs. Testing laboratories should have laboratory information systems (LIS) to ensure connectivity and improved data migration between the laboratories and facilities. Strengthening diagnostic integration within the country's national tiered laboratory network will be essential to ensure accelerated use of currently underutilized instrument fleets.

Support to laboratory procurement and supply chain may include activities such as:

- Mapping and optimizing of networks (to include the private sector). Includes linkages for specimen referral, supply chain and data migration.
- Support to the development of specifications for selection of equipment, reagents, consumables and accessories, balancing cost effectiveness and access;
- Support to standardization and harmonization of tests and technologies;
- Procurement planning, including technical assistance on modalities for reagent rental or leasing, understanding of market dynamics for laboratory items and their impact on lead times needed for different laboratory supplies and supply planning;
- Forecasting and quantification of needs;
- Support to remote monitoring and data connectivity of equipment.

### **3.8 Country Case Study**

#### *The Power of Partnerships and Strong Leadership in Implementing a Laboratory Information System in Kenya*

In Kenya, under the leadership of the National Public Laboratories and in collaboration with other partners, the Global Fund supported the rollout of a LIS (Laboratory Information System). This enabled central servers to host a data warehouse, provided a dashboard to provide data elements for tracking and testing indicators and supported data analysis during specimen collection, rejection, testing and results reporting. Support also included automation of laboratory testing systems, remote ICT solutions and immediate access of results and notification. This resulted in the installation of a customized LIS at central and county level and the expansion of the LIS. The LIS has been tailor-made to fit into both clinical and advanced laboratories requirements to efficiently manage workflow in the laboratory through integration with the hospital electronic medical record systems, automatically receiving lab test requests from health providers and returning the results via a login ward or clinic window, emails and/or an embedded SMS notification to both patients and requesting providers. The system tracks the movement of specimens through pre-analytical, analytical and post-analytical processes providing respective turn-around-times for tests, as well as individual workload monitoring, test reporting and quality control. Consequently, turn-around times have been reduced and patients' confidence in lab services has been boosted. Lab managers use data from the LIS for real time quantification for supply planning and budgeting for reagents and consumables. Collaboration with partners has been key to success for this

collaboration. The Kenyan LIS implementation has been guided by the Association of Public Health Laboratories (APHL) model of LIS implementation in resource constrained settings, and the associated guidelines have helped the country in the planning and implementation of LIS.

## 4. Conclusion

Investments in laboratory systems are critical to the successful delivery of HIV, TB and malaria programs, as well as other health programs. Strengthening laboratory systems in countries requires many programmatic and operational activities under solid national leadership, such as advocating for and fostering government support and investments in laboratory systems, advocating for the inclusion of laboratories in national health policies and strategies, coordinating the different partners involved in laboratory systems, resource mobilization, technical assistance and capacity building of laboratory workforces. Countries are encouraged to ensure that their requests for laboratory system support are strategic and aligned with national policy. Applicants should make full use of the information in this technical brief and other relevant Global Fund documents to ensure that investments in laboratory systems contribute to the building of resilient and sustainable systems for health.

## 5. Laboratory Key Resources

- Laboratory and in vitro diagnostic resources <https://www.who.int/in-vitro-diagnostic/en/>
- Asia Pacific Strategy for Strengthening Health Laboratory Services (2010-2015) [http://apps.searo.who.int/PDS\\_DOCS/B4531.pdf](http://apps.searo.who.int/PDS_DOCS/B4531.pdf)
- Adaption and Use of Multi-Disease Testing Devices in Integrated Laboratory Networks <https://apps.who.int/iris/bitstream/handle/10665/255693/WHO-HTM-TB-2017.06-eng>
- Development of Medical Device Policies [https://www.who.int/medical\\_devices/publications/med-dev-policies/en](https://www.who.int/medical_devices/publications/med-dev-policies/en)
- Development of national health laboratory policy and plan <http://www.who.int/iris/handle/10665/204960>
- First WHO Model List of Essential In Vitro Diagnostics. <https://apps.who.int/iris/bitstream/handle/10665/311567/9789241210263-eng.pdf>
- Guidebook for Implementation of Laboratory Information Systems in Resource-Poor Settings [http://www.aphl.org/MRC/Documents/GH\\_2005October\\_LIS-Guidebook.pdf](http://www.aphl.org/MRC/Documents/GH_2005October_LIS-Guidebook.pdf)
- Laboratory Information System (LIS) High Level Requirements [http://www.aphl.org/MRC/Documents/GH\\_2005October\\_LIS-High-Level-Requirements.pdf](http://www.aphl.org/MRC/Documents/GH_2005October_LIS-High-Level-Requirements.pdf)
- Laboratory Quality Management System Training Toolkit [http://www.who.int/ihr/training/laboratory\\_quality/doc/en/](http://www.who.int/ihr/training/laboratory_quality/doc/en/)
- Laboratory Quality Stepwise Implementation tool <https://extranet.who.int/lqsi/content/homepage>