UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN

STANDARD MEDICAL LABORATORY EQUIPMENT GUIDELINE (SMLEG)

MARCH 2018

Foreword

The Maputo Declaration on Strengthening of Laboratory Systems called on governments to take leadership in harmonizing tiered laboratory networks and standardizing testing services. The development of this Standard Medical Laboratory Equipment Guideline (SMLEG) is a significant step in the implementation of laboratory equipment and reagents standardization. This follows a key recommendation from the Holistic Supply Chain Review and the Dissemination Meeting involving MOHCDGEC, the Global Fund, USAID and other Stakeholders to harmonize and standardize laboratory equipment at each level of the tiered laboratory system in Tanzania.

Standardization is a lengthy process and requires a phased implementation plan, addressing high priority items first and reviewing the current situation before making policy decisions. This guideline provides a basis to harmonize and standardize medical laboratory equipment and provides a clear framework for the recommended approach. The governance structures are a critical aspect of standardization, and it is important that all relevant stakeholders are included in the appropriate structures. These stakeholders include: clinical experts, development partners (DPs), implementing partners (IPs), procurement and legislative bodies.

This guideline shall be used in conjunction with medical laboratory policies, regulations, guidelines and manuals that are available at the MOHCDGEC electronically and as hardcopies. These include the National Standard for Medical Laboratories (NSML), Standard Medical Laboratory Equipment List (SMLEL), Standard Treatment Guidelines & National Essential Medicines List, as well as relevant legislation and procurement policies.

The MOHCDGEC would like to acknowledge the participation of various institutions and expert opinions from all those who participated in one or another way in developing this guideline. Your contributions are well noted as the MOHCDGEC implements Laboratory Equipment and Reagents Standardization to improve medical laboratory services in Tanzania.

Dr Mpoki M. Ulisubisya
Permanent Secretary

Acknowledgements

This Standard Medical Laboratory Equipment Guideline (SMLEG) is a product of dedicated efforts and contributions of Government, Implementing Partners, Non-Government Organizations, Institutions, Programmes and Individuals towards improving the quality of health service delivery through medical laboratories in Tanzania. The Ministry of Health, Community Development, Gender, Elderly and Children (MOHCDGEC) is very grateful for their financial support and technical assistance towards developing this Guideline.

In particular, the Ministry would like to thank The Global Fund for the financial and technical support through external consultants to improve health service delivery in medical laboratories by supporting equipment and reagent standardization. Special thanks are extended to technical experts and individuals for their active participation and constructive input and comments provided in reviewing this Guideline.

Our appreciations go to the laboratory technical team who played a pivotal role in the development of this Guideline by participating in the consultation workshops, providing relevant information and offering their expert advice when consulted. A list of the workshop participants is provided in Appendix G and a list of the technical team in Appendix H.

Prof. Muhammad B. Kambi
Chief Medical Officer

Executive Summary

Tanzania was an active participant in a Consensus Meeting on Clinical Laboratory Testing Harmonization and Standardization in Maputo in 2008. The meeting sought to address laboratory challenges that limit the scale–up of services for tuberculosis (TB), malaria and HIV diagnosis and care through harmonization and standardization of laboratory equipment and reagents. Tanzania has consistently been a strong proponent of the subsequent Maputo Declaration. However, the introduction of equipment and numerous interventions by Development Partners to assist in reducing the disease burden of the main epidemics, although beneficial, has resulted in a diversity of equipment that has thwarted standardization. This in turn has led to difficulties in long term planning and equipment maintenance, in forecasting and budgeting for reagents, and precluded cost effectiveness as a result of economies of scale.

The methodology to develop this guideline included two consultation workshops with key role-players to ensure alignment of the future expectations of the laboratory service with international best practice, optimization of existing structures and processes, and developing a clear roadmap towards harmonization and standardization of laboratory equipment. The workshops were complemented by: desktop and in-country research; a number of meetings with key stakeholders and visits to individual laboratories to gain a better understanding of the situation on the ground.

The current status of laboratory equipment was established via a questionnaire based on the ATLAS tool and revealed a wide diversity of analyzer equipment, creating complexity for maintenance as well as supply chain management. Through harmonization and standardization efforts outlined in this guideline, equipment diversity will be drastically reduced and the necessary structures and processes implemented, to ensure that equipment standardization is sustained in the long term.

Test menus and methodologies have been updated according to tiered levels and disciplines to appropriately support the clinical service at each level. The laboratory service is responsive to new technologies which will be adopted in a considered manner with due regard to financial constraints and the potential impact on service delivery.

With the updated test menus and methodologies as a basis, a framework to harmonize and

standardize equipment has been developed. In addition to actual harmonization and standardization processes, the framework includes the relevant governance structures, an implementation plan, as well as a monitoring and evaluation framework. Development Partners form an important part of this process and the need to integrate their programmes appropriately into the laboratory system has been highlighted and addressed.

The harmonization approach involves adopting a reduced range of equipment over an average period of 3 years in a staggered fashion to minimize any impact on service delivery. This will be followed by the standardization of equipment, which will be attained through formal procurement processes, based on international practices, over an average of 5 year cycles.

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Acronyms and Abbreviations

ADDS	Assistant Director Diagnostic Services
AIDS	Acquired Immunodeficiency Syndrome
ASLM	African Society for Laboratory Medicine
CDC	Centre for Disease Control and Prevention
CP	Chief Pharmacist
CMO	Chief Medical Officer
DCS	Department of Curative Services
DHQA	Director of Health Quality Assurance
DHS	Director of Health Services
DHSWNS	Department of Health, Social Welfare and Nutrition Services
DP	Development Partner
DPS	Department of Preventive Services
DPS(H)	Depute Permanent Secretary for Health
DSS	Diagnostic Services Section
EAPHLN	East Africa Public Health Laboratory Network
EQA	External Quality Assessment
FPMS	Forensic Pathology and Mortuary Services
HCTS	Health Care Technical Services
HIV	Human Immunodeficiency Virus
HSHSP	Health Sector HIV and AIDS Strategic Plan
HLS	Head Laboratory Services
IDSR	Integrated Disease Surveillance and Response
IP	Implementing Partner
ISO	International Organization for Standardization
LEC	Laboratory Equipment Committee
LMS	Logistics Management Service
M&E	Monitoring and Evaluation
MEC	Monitoring & Evaluation Committee
MOHCDGEC	Ministry of Health Community Development, Gender, Elderly, and Children
MSD	Medical Stores Department
NBTS	National Blood Transfusion Services
NEMLIT	National Essential Medicine List for Tanzania
NHLS	National Health Laboratory Service

NHLSP	National Health Laboratory Strategic Plan
NHLSSL	National Health Laboratory Service Supplies List
NRL	National Reference Laboratory
PMU	Procurement Management Unit
PORALG	President's Office, Regional Administration and Local Government
PS	Permanent Secretary
PSU	Pharmaceutical Services Unit
QA	Quality Assurance
RIS	Radiology and Imaging Services
SCMS	Supply Chain Management System
SMLEG	Standard Medical Laboratory Equipment Guideline
SMLEL	Standard Medical Laboratory Equipment List
STG	Standard Treatment Guidelines
TAT	Turnaround Time
TB	Tuberculosis
TAEL	TFDA Approved Equipment List
TMDA	Tanzania Medicine and Drugs Authority
TOT	Training of the Trainers
TSC	Tier Specific Committee(s)
TWG	Technical Working Group
QMS	Quality Management System
USAID	United States Agency for International Development
WHO	World Health Organization

1.0 Introduction

In 2017, the MOHCDGEC, in collaboration with the Global Fund and USAID financial support, conducted a Holistic Supply Chain System Review for Health Commodities, including health laboratory equipment, reagents and consumables. Among the recommendations of this Holistic Review were: 1) To standardize and harmonize health laboratory equipment and reagents; and 2) Diagnostic Services Section to centrally coordinate quantification and forecasting of laboratory reagents and consumables. These recommendations resulted in this exercise to reintroduce harmonization and standardization through the development of the Standard Medical Laboratory Equipment Guideline (SMLEG).

1.1 The need for harmonization and standardization of laboratory equipment

On an international level, health systems, including laboratory services, are undergoing major reviews with the aim of optimization of resources, improving quality and ensuring a more affordable and sustainable service. The need is simply a better, faster, cheaper and more accessible service delivered through the right people with the right skills, underpinned by a clinically acceptable diagnostic pathology model on a national basis – in a structured, standardized manner to all health facilities – vested in good laboratory practice and improved quality.

Expanding health care services for Human Immunodeficiency Virus (HIV), tuberculosis (TB), Malaria, and non- communicable diseases (e.g. diabetes and hypertension) has increased the demand for affordable and reliable laboratory diagnostics in resource-limited countries. Many countries, including Tanzania, are responding by upgrading their public laboratories and introducing new technology to provide expanded testing services into more regions. This expansion carries the risk of increasing the diversity of an already highly diverse technology and testing platform landscape, making it more difficult to manage laboratory networks across different levels of the health care system. To address this challenge, the Ministry has developed this guideline to standardize test menus, technology, platforms, and commodities across multiple laboratories.

The USAID (United States Agency for International Development) Deliver project report (USAID 2010) defines a standardized laboratory system as one in which each laboratory at the same level of the network will offer the same testing menus, using the same techniques and equipment. Guidelines and manuals are developed at national levels to guide managers, supervisors, and trainers in maintaining quality services. Clinicians can be certain that the health facility they are working at will provide a consistent level of laboratory testing services, and if patients are transferred between facilities, their results can be accessible and comparable. Laboratory professionals can also easily be transferred between facilities because they are familiar with the techniques and equipment used at all facilities. Moreover, generalized refresher training courses can be provided for all staff members. In addition, commodities can be managed through a central logistics system, thus rationalizing resources and benefiting from economies of scale.

1.1.1 The Maputo Declaration

The objectives as outlined in The Maputo Declaration (2008) on Strengthening of Laboratory Systems, are clear and transparent. These objectives are:

i. To review and agree on a list of supplies and tests needed at each level of an integrated tiered laboratory network;
ii. To develop a consensus to guide standardization of laboratory equipment at each level of the laboratory network;
iii. To develop a consensus on key considerations to guide maintenance and service contracts for equipment at various levels of the laboratory network.

Despite these clear objectives, their implementation in a resource-limited setting such as Tanzania remains challenging. Historically, the comprehensive management of disease-specific programs like HIV and AIDS were performed at the single National Reference Laboratory (NRL). As the demand for these testing services increased, testing could not be confined to the NRL alone and were extended to other laboratories. During this expansion, coupled with global technology changes and the introduction of near patient testing, the absence of a standardized approach to laboratory testing at peripheral laboratories has resulted in a proliferation of different tests, techniques, and equipment – including the required commodities – across laboratories.

1.1.2 Context in Tanzania

While infrastructure and the provision of services in Tanzania's decentralized health system have seen improvement, important opportunities remain for further advancement. Implementation of national laboratory plans towards quality laboratory services has initially focused on high level laboratories (e.g. regional and higher) and the challenge is to continue with implementation at lower levels.

It should be noted that the Tanzania Medicine and Drug Authority (TMDA) has made substantial progress towards the implementation of a comprehensive regulatory framework for medical devices and the organization is perceived to be ahead of its peers in Africa.

1.1.3 Benefits of harmonization and standardization

The benefits of standardization include rational prioritization of resources for capacity development and more efficient supply chain management through volume-based price discounts for reagents and analyzer equipment service. Procurement procedures, including specification, prequalification, and contract negotiation, need to align with the standardization policies for maximum benefit. Standardization should be adhered to irrespective of whether procurement is centralized or decentralized or whether carried out by national bodies or development partners. (Trevor F. Peter 2009)

The benefits of standardization are far-reaching. Programmatically, having a greater number of the same equipment and reagents results in economies of scale for procurement, which provides leverage to national laboratory programs in negotiating service and maintenance contracts. Additionally, having a smaller range of equipment and techniques facilitates simplified training of staff members. Finally, fewer products flowing through the supply chain enhance the agility, efficiency, and manageability of the national laboratory logistics system. For example, when facilities at the same level use the same techniques and equipment to conduct the same menu of tests, the correlated commodities are also the same. Alternatively, if analyzer equipment break-down or if a sudden change in consumption occurs, commodities can be redistributed to other facilities, thereby reducing the risk of expiries and stock outs.

Standardization does, however, present some risks, such as supplier monopoly, dependency and the subsequent disruption of services in the event of major supplier challenges. It is important to ensure that the process followed mitigates these potential disadvantages and enhances a fair competitive supplier environment.

1.2 Approach to harmonization and standardization

A two-phase method to develop an adequate harmonization and standardization approach was proposed by Williams in 2016 (Williams, et al. 2016). Although standardization has multiple supply chain benefits, it will have limited effect if it focuses only on the supply chain. Therefore, throughout the process, one must consider the policy, service delivery, programmatic, clinical, and supply chain considerations. The standardization process should focus on meeting the needs of those accessing laboratory services and those delivering high-quality testing services in a way that maximizes limited resources. Figure 1-1 reflects a highly proposed approach, the detail of which will be dealt with in further sections.

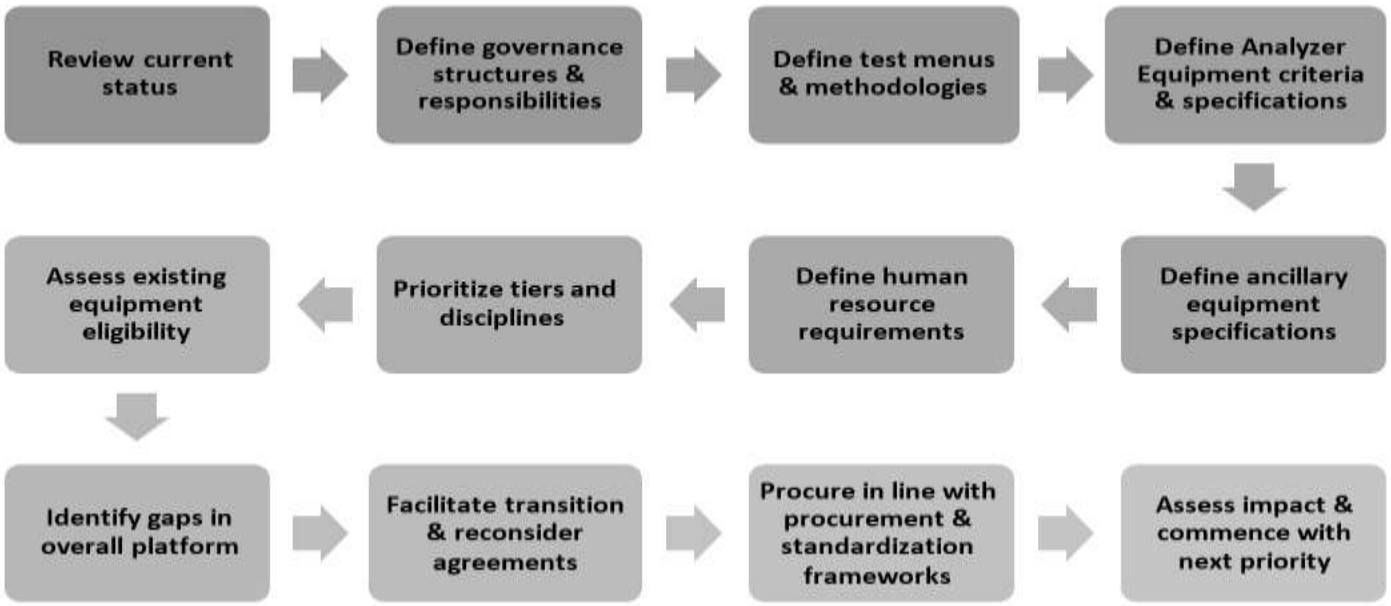

Figure 1-1 High level approach to harmonization and standardization

2.0 Current Status

The departure point for standardization is a review of the current status. Aspects to consider are highlighted in Figure 2-1.

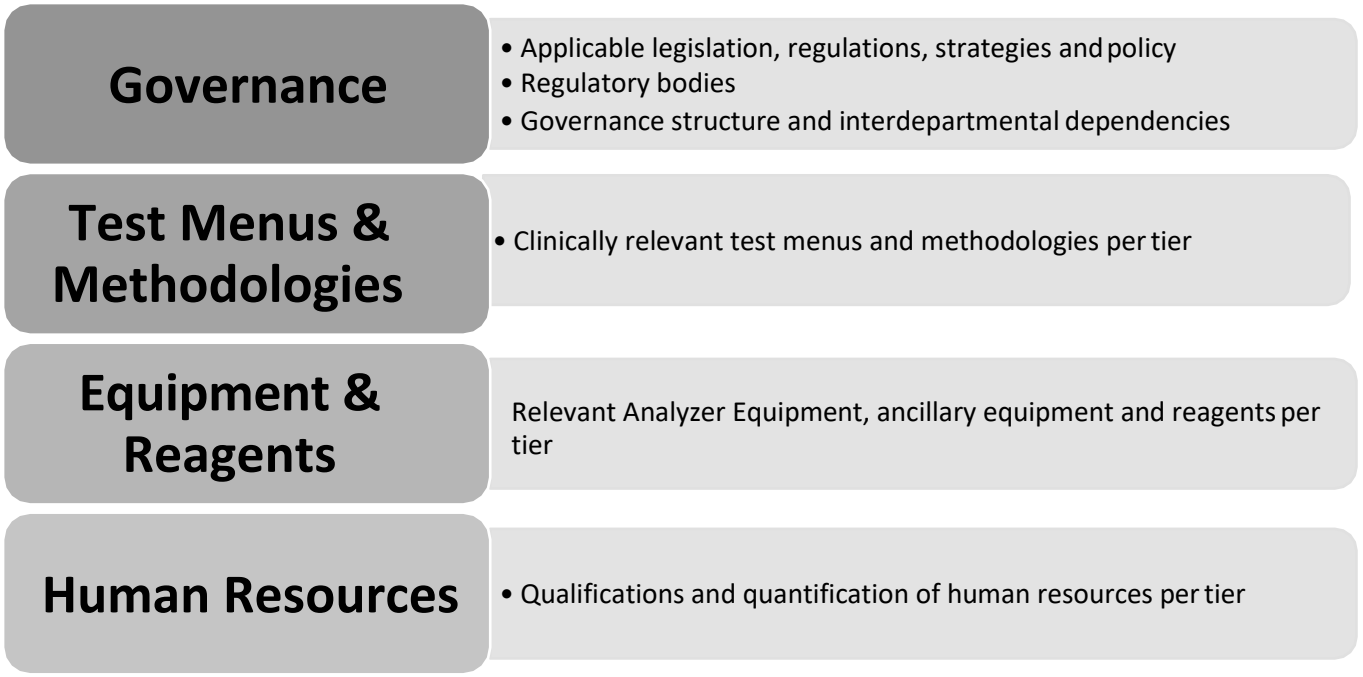

Figure 2-1 Aspects for consideration in current status review

2.1 Governance

A number of key stakeholders have a direct impact on laboratory services in Tanzania, all of which are primarily integrated into, or closely related to the MOHCDGEC. While the impact and role of all key stakeholders are duly acknowledged, the focus is on those selected few who directly impact the extent of the project.

The Diagnostic Services Section (DSS) is one of five sections in the larger Department of Curative Services (DCS), one of seven such departments in the MOHCDGEC. DSS's scope of responsibility includes Clinical Laboratories, Public Health Laboratories, National Blood Transfusion Service (NBTS), Health Care Technical Services (HCTS), Forensic Pathology and Mortuary Services (FPMS), and Radiology and Imaging Services (RIS). DSS is primarily responsible for setting the overarching strategy, annual performance plans and national policies for laboratory services. The Section is headed by the Assistant Director, Diagnostic Services (ADDS). HCTS has a wide range of equipment maintenance and service responsibilities, ranging from guideline implementation to inception testing and service contract function. Public Health Laboratories are responsible for disease surveillance and outbreak investigations, using Integrated Disease Surveillance and Response (IDSR) and other guidelines.

The Chief Pharmacist (CP) oversees all medicines, medical supplies, laboratory equipment and reagents.

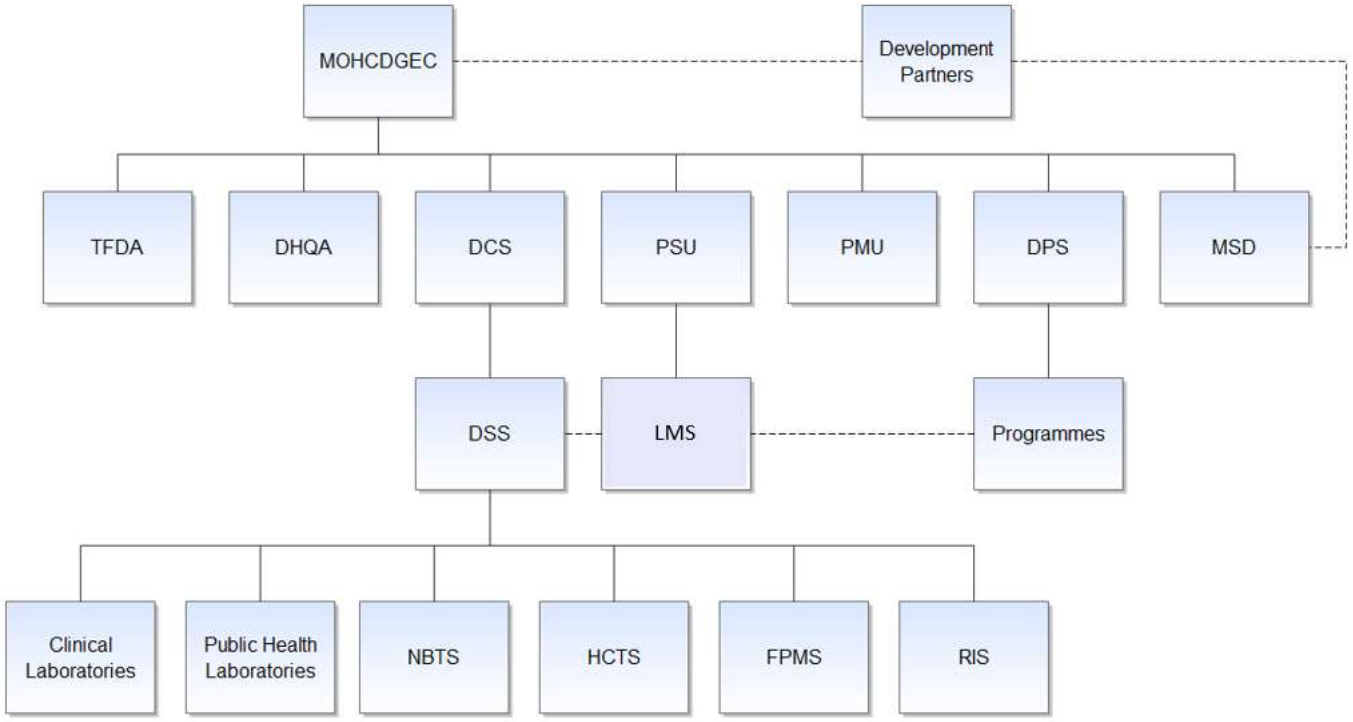

Figure 2-2 Organogram of relevant governance structures in the MOHCDGEC

The Medical Stores Department (MSD) was established under the MSD Act Number 13 of 1993, is governed by an autonomous Board and reports directly to the Permanent Secretary (PS). MSD is overall responsible for procurement, storage and distribution of health commodities.

The Tanzania Food and Drugs Authority (TFDA) was established under the TFDA and Cosmetics Act Number 1 of 2003, is governed by an autonomous Board and reports directly to the Permanent Secretary (PS). The TFDA is the executive agency responsible for the regulation of quality, safety and performance of medical devices, including diagnostics equipment, among others.

Expectations from the clinical platform and end-users of laboratory services are central to any strategy developed for laboratory services. The service platform and baskets of services offered at any tier should be set by knowledgeable experienced clinicians and other health professionals, based on reliable health economic information such as burden of disease, detailed workforce planning and a targeted understanding of infrastructure status and planning. The clinical model should dictate the laboratory service model and not vice versa. For this reason, it is critical to have an integrated relationship between the clinical and laboratory services on every level of the healthcare system.

The provision of laboratory equipment in Tanzania is to a degree dependent on external funding through Development Partners (DP). As such, DPs play a substantial role in the operational, procurement and maintenance functions within the laboratory services, subsequently contributing to shaping the structure of service delivery. These Partners provide expertise as well as funding to

support Laboratory services by providing equipment and supplementing reagents and training. Whilst individual projects may provide benefits to the system beyond their own outputs, they may equally create unwitting problems as equipment may not suit the local environment or, if left after project closure, there may be no mechanism to obtain consumables or maintain or repair the equipment. As a consequence of the varied programmes, a variety of equipment and consumables were introduced into laboratories.

Table 2-1 summarizes the key strengths and challenges as it relates to the role of governance in laboratory equipment and standardization and makes some recommendations on possible improvements.

Table 2-1 Governance: Strengths, challenges and recommendations

STRENGTHS	**CHALLENGES**
Strong commitment by the Government of Tanzania and all key role-players. Apparent strong collaborative relationship between some stakeholders. A number of key pieces of legislation and regulatory frameworks are in place, e.g. Public Procurement Act; Cap 410 of 2011 as amended in 2016 and TFDA and Cosmetics Act 1 of 2003. A number of key strategy and policy documents have been developed and are providing substantive frameworks to underpin standardization. These include: - NHLSP II - HSHSP III	Varying degrees of disconnect between some key stakeholders for laboratory services, which may result in non-optimized engagement between them. Funding doesn't appear to always follow function, e.g. bulk of budget for equipment, reagents and consumables lies with MSD, while DSS has no budget for management of those, e.g. Inventory management, planned preventive maintenance, and monitoring and evaluation. No fully integrated governance framework towards harmonization and standardization. No fully integrated coherent governance structure, allowing for joint accountability and clear responsibilities, to facilitate buy-in and comprehensive execution of strategies.

RECOMMENDATIONS

1. Establish a fully integrated comprehensive governance structure, defined by a clear Terms of Reference, to allow for structural responsibilities and accountability, with due consideration of:
    a) Membership for all key stakeholders.
    b) Engagement opportunity for all other relevant stakeholders.
    c) Appropriate different committee structures to make provision for all aspects ranging from policy decisions to execution and Monitoring and Evaluation (M&E).
2. Review existing mandates and structures to ensure absolute clarity of roles.
3. Ensure compliance with agreed implementation timelines.

2.2 Test Menus & Methodologies

The diagnosis and treatment of disease without the support of a functioning laboratory service to guide clinical decision-making can lead to poor patient outcomes and impact negatively on public health, such as the emergence of drug resistant organisms. In line with strengthening of laboratory systems, laboratory services in Tanzania are already structured in a hierarchical tiered laboratory network.

The six tiers, starting at Dispensary laboratory level, offer tests of increasing complexity to meet the needs of the corresponding clinical services that is patient-centered and dynamic. For example, a number (approximately 187 out of >500) of Health Centers are being scaled up to offer emergency obstetric care. The laboratory test menus at these centers may need to be extended to meet these needs.

Laboratories in Tanzania Mainland have been mapped and charted in a hub and spoke model. In standardizing the test menu and methodologies, test results from different laboratories within the network can be compared and interpreted against results from different laboratories. This also facilitates referral of samples without the need to duplicate testing.

In order to impact favourably on clinical care, test results must not only be of acceptable quality, but must also be received timeously by clinicians to impact on clinical management. Therefore, quality test results delivered within clinically acceptable turnaround times add value.

Table 2-2 Test Menus & Testing Methodologies: Strengths, challenges and recommendations

STRENGTHS	**CHALLENGES**
Updated test menu approved (National Standard for Medical Laboratories 2017) Test menu is differentiated into laboratory tiers up to district hospital level. Test menu is aligned with clinical practice (Standard Treatment Guidelines 2017) The test menu is responsive to new technologies (e.g. newly developed point of care tests, molecular biology and genetic sequencing) The recently approved tiered test menu ensures that tests offered are appropriate to the level of skill of laboratory personnel operating at that level.	Financial constraints require adoption of tests to be prioritized (e.g. chlamydia rapid diagnostic test will be placed in high prevalence areas initially). To remain effective, the test menu needs to be reviewed periodically and adjustments made to reflect advances in technology and changes in practice.
RECOMMENDATIONS 1. Expand profiles to detail constituent tests to facilitate quantification (e.g. components of liver function tests). 2. Establish clinically relevant turnaround times, starting with the national priority programmes. 3. Review and update test menus on an annual or biennial basis.	

2.3 Equipment and Reagents

At present, there is a diversity of analyzer equipment in clinical laboratories, whether donated or government acquired (Refer to section 3.3.1.1 Current Analyzer Equipment Status for detail). In Tanzania, most analyzer equipment are acquired one at a time or in small quantities, foregoing the leveraging of large numbers of items. Having the same analyzer equipment enables central procurement to negotiate better reagent costs, service and maintenance contracts. Impediments to service delivery include non-functioning analyzer equipment due to reagent stock-outs and a lack of planned preventative maintenance. Standardization of equipment will assist in addressing these challenges.

Programme specific analyzer equipment introduced into the system have resulted in a plethora of analyzer equipment and consumables at each level. Furthermore, when a specific programme is not meeting targets, different additional analyzer equipment may be brought in to resolve the immediate problem, without consideration to the additional complexities this causes.

Table 2-3 Equipment & Reagents: Strengths, challenges and recommendations

<table>
<tr>
<td><u>STRENGTHS</u>
A comprehensive, updated list of reagents is available (NHLSSL)

A minimum equipment list has been compiled for each tier up to district level (National Standard for Medical Laboratories 2017)

Standardized laboratory floor plans for dispensary, health care center and district laboratories have been published. These plans are a template to standardize new laboratory facilities, and where possible, upgrade existing ones. This, in turn will simplify installation of standardized equipment across the platform.

Optimal test methodologies are being introduced in a considered manner, mindful of resource constraints e.g. LED microscopes for detection of Mycobacteria; molecular identification of MTB/RIF</td>
<td><u>CHALLENGES</u>
Diversity of equipment as individual programmes import, and place own equipment puts pressure on MSD, supply chain and staff who must manage a diverse number of reagents.

More than one type of analyzer equipment for the same purpose in a laboratory leads to duplication of controls, reagents and SOPs – resulting in reduced efficiency and additional work for staff.

The Ministry and Medical Stores Department are not always informed of equipment being introduced by Development Partners.

Although safe disposal of non-functioning equipment is the responsibility of Laboratory Management, it has no mandate to dispose of any equipment.

MSD is required to supply reagents when they are no longer purchased by Development Partners, regardless of whether provision has been made for purchase of these reagents.

Issued supplies ordered from MSD are sometimes not complete.

Reagents with a short shelf life often result in expired stock.

Holding a large range of reagents puts pressure on limited space at zonal stores.

There is a shortage of biomedical engineers and technicians, both in numbers and in skills to maintain and repair equipment.

Laboratory staff may not be informed of preventative maintenance contracts and therefore do not alert management if conditions are not met.

Unawareness of warranty conditions may lead to not repairing or replacing defective equipment at the manufacturer/supplier’s cost when still under cover.</td>
</tr>
<tr>
<td colspan="2"><u>RECOMMENDATIONS</u>
1. The Ministry must require Development Partners and funders to work within the Ministry’s stated framework of standardized equipment.
2. A small range of laboratory equipment should be identified in order to reduce the large range of reagents that must be managed.
Reagent rental is the recommended method of equipment ownership for analyzers.</td>
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2.4 Human Resources

There are benefits to standardization with respect to training and management of staff. Standardization achieves greater efficiency when the same analyzer equipment and techniques are used at each level of the system. Training programmes can be uniform and simplified. Refresher courses can be designed and rolled out more efficiently.

Standard laboratory practice enables personnel to be more easily deployed to different facilities.

Performance can more easily be measured and managed if staff are performing the same tests on the same analyzer equipment throughout a laboratory tier. EQA can be compared between laboratories and outliers identified and corrective and preventative action initiated.

Workforce requirements in standardized laboratories can be more accurately estimated and provide a template for staffing levels within a tier.

Table 2-4 Human Resources: Strengths, challenges and recommendations

STRENGTHS	**CHALLENGES**
An increase in number of training facilities. The workforce requirement for technical laboratory staff up to district laboratory level has been published in the National Standard for Medical Laboratories 2017 Laboratory technologists (part-time) have been assigned to dispensary laboratories to oversee full-time laboratory assistants in the private sector laboratories that cannot employ a full-time laboratory technologist. Commitment to increasing training of mentors and internal auditors towards continuous improvement of Quality Management System (QMS) in laboratories. A pool of expertise is provided by a total of 136 pathologists: (Anatomical pathologists 34; Haematologists 19; Clinical Chemistry 14; Microbiologists 44 and Parasitologists 25). Competent staff with potential for advancement.	Insufficient numbers of laboratory personnel and biomedical engineers and technicians are recruited. Budget allocation is required to increase training numbers of biomedical engineers and technicians. Present staff constraints make it difficult to allocate staff to assist in training. There are insufficient pathologists for the country's needs and doctors need to be encouraged to specialize in pathology. Insufficient managerial and leadership skills in health laboratories.
RECOMMENDATIONS 1. Develop advocacy programmes to attract personnel into careers in laboratory services. 2. Increase numbers of qualified biomedical engineering personnel. 3. Identify laboratory personnel for management and leadership skills development.	

3.0 Laboratory Equipment Harmonization and Standardization

3.1 Governance

3.1.1 Governance Principles

With due consideration of the assessment in section 2.1 and subsequent recommendations:

1. Establish a fully integrated comprehensive governance structure, defined by a clear Terms of Reference, to allow for structural responsibilities and accountability, with due consideration of:
    a) Membership for all key stakeholders.
    b) Engagement opportunity for all other relevant stakeholders.
    c) Appropriate different committee structures to make provision for all aspects ranging from policy decisions to execution, and Monitoring and Evaluation (M&E).
2. Review existing mandates and structures to ensure absolute clarity of roles. In this regard specifically:
    a) The process and responsibility towards the regulation of new platform introduction should reside with TFDA, measured against the TFDA regulatory framework and quality standards. In essence, TFDA must maintain and update one national TFDA Approved Equipment List (TAEL), compiled following a rigorous assessment process (yet with due acknowledgement of international regulatory bodies' approval, e.g. FDA). The structures responsible for operational roll out, whether public or private, must then select equipment from the TAEL in line with the proper procurement processes. The MOHCDGEC, DSS and MSD should manage the operational roll out through the Laboratory Equipment Committee (LEC) and Tier Specific Committees (TSCs).
    b) It is imperative that DPs' planning and procurement activities are fully aligned to the guideline.
    c) It is further essential to ensure funding follows functions and that there are no unfunded mandates or operational mandates without an allocated operational budget.
3. Ensure compliance with agreed implementation timelines, monitored through an Implementation M&E framework.

3.1.2 Governance Structure

It is essential that the governance structure adequately addresses the expectations towards the execution of this guideline while being as agile and streamlined as possible. Harmonization and standardization should not be bogged down by administrative processes, but requires timeous and considered decision-making. With due consideration of the extent of responsibilities expected from the various governance levels, the minimum governance structure is outlined in Table 3-1.

Table 3-1 Governance Structure Committees

Committee	Composition	Responsibilities
Technical Working Group (TWG)	DCS: - ADDS - HLS - HCTS - NBTS - D-NHLQATC DHSWNS: (DHS) DHQA (ADHQA) DPS (Programme Managers) CP: - H-PSU H-LMS DPMU (PSO) TMDA (Medical Devices) MSD (Quality Officer) DPs: - Global Fund - CDC - USAID	Based at National level Set strategic and policy direction for standardization and harmonization. Constitute further committees and direct their Terms of Reference. Enable participation by all stakeholders. Prioritize steps in the staggered approach, i.e. what happens in which order. Review existing structures and make recommendations on streamlining. Ensure national compliance. Develop Delegation of Authority framework for standardization and harmonization. Monitor overall progress through M&E Framework. Any other function as deemed appropriate by the committee. Reports to Minister, PS-MOHCDGEC and DPS (H)-PO RALG.
Laboratory Equipment Committee (LEC)	Technical/ discipline experts QA experts End-user representatives from all levels (e.g. Laboratory Manager) SCM coordinators and experts LMS experts Biomedical engineers and technicians DP representatives IP representatives	Based at National level Make recommendations to TWG on: - Implementation priorities. - Transition of existing equipment. - Technical specifications. - M&E framework. Provide detailed technical and discipline recommendations. Finalize tier specific specifications. Develop technical specifications. Develop, implement and coordinate M&E framework. Develop and oversee implementation of overall roll out and validation processes. Develop standardization and harmonization training manual and ensure Training of the Trainers (TOT). Any other function as deemed appropriate by the TWG. Reports to TWG.

Tier specific committees (TSC): **1. Dispensary & Health Centers** **2. District & Regional** **3. Zonal & National**	Discipline representatives QA End-user representatives	Based at facility level Make recommendations to LEC on: - Implementation priorities. - Transition of existing equipment. - Tier specific specifications. Provide detailed technical and discipline recommendations. Drive tier specific transition of existing equipment. Implement overall roll out and validation process. Comply with and report on M&E framework. Roll out of training. Any other function as deemed appropriate by the LEC. Reports to LEC.

Figure 3-1 below depicts the governance structure organogram.

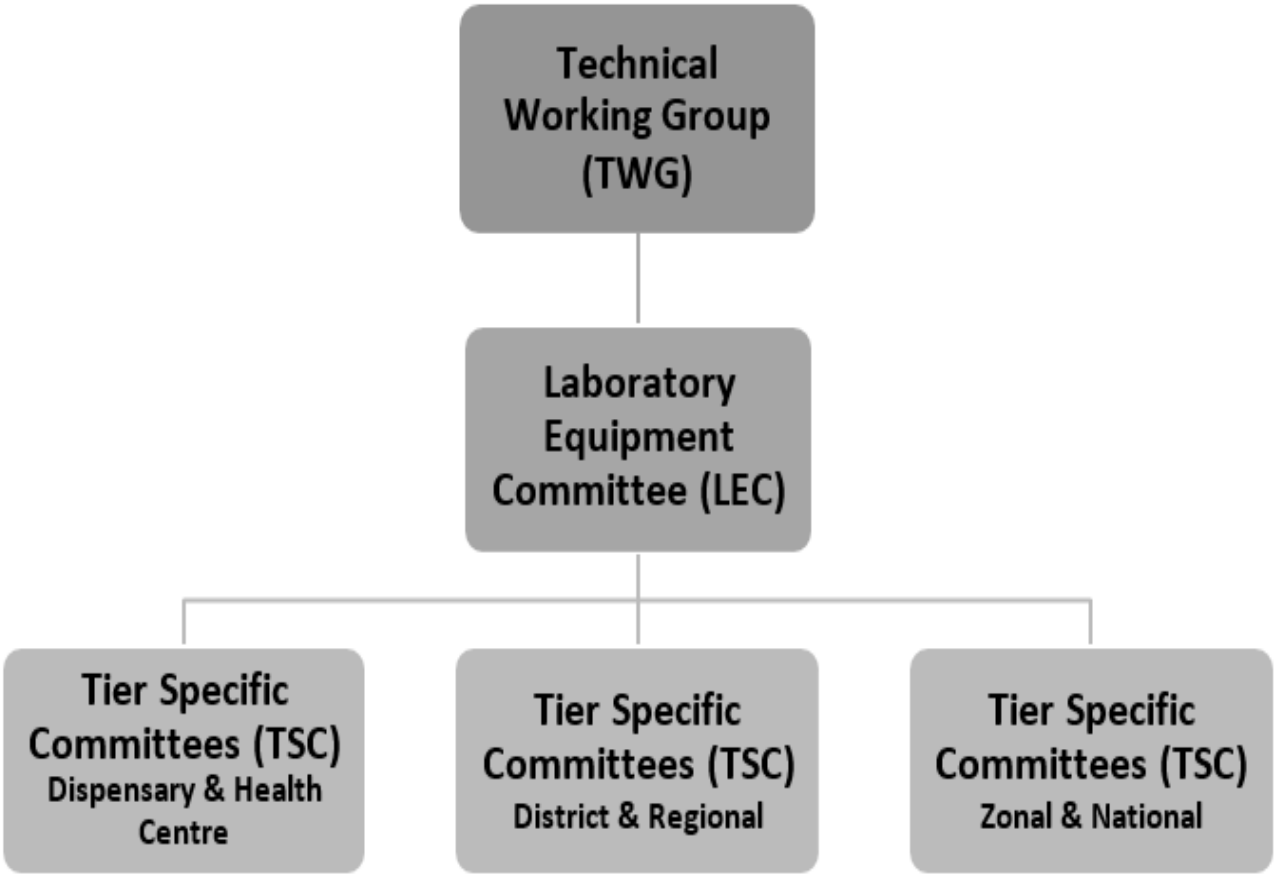

Figure 3-1 Governance structure organogram

3.1.3 Development Partners

It is imperative that DPs' planning and procurement activities are fully aligned to the guideline:

1. As DPs are key stakeholders they must be involved in harmonization and standardization approach from the outset to guarantee an integrated approach and optimal use of resources.
2. DPs should not procure or negotiate in isolation of the TWG and LEC. In this regard:
    a. No new platforms should be introduced by DPs until the current analyzer equipment have been harmonized.
    b. DPs must follow the harmonization approach outlined in Section 4.3.
    c. Any new instruments introduced by DPs must be on the TAEL.
    d. Any new instruments introduced by DPs must be in line with the national standardization strategy.
    e. With due consideration of the national oversight and integration functions performed by the LEC and TWG, any planned DP procurement initiatives should be tabled to the LEC (for consideration) and TWG (for approval).
    f. Once approved, DP initiatives should be rolled out through DSS and MSD processes.
3. It is essential that any negotiations with suppliers and must take place on a national level, in consultation with the TWG, with due cognizance of the comprehensive analyzer equipment asset inventory, to ensure economies of scale and the best possible financial solutions going forward.

3.2 Test Menus & Methodologies

Having due regard for the extensive work already undertaken towards updating the test menus as reflected in the National Standard for Medical Laboratories, 2017, the following should take place:

1. Review and update test menus annually or biennially, with regards to new technologies being introduced, particularly at lower level tiers.
2. Assess the cost/benefit when introducing new tests.

The updated test menus and methodologies can be found in Appendix A as well as an alternative view of Test Menus per Discipline per Tier in Appendix B.

3.3 Equipment and Reagents

3.3.1 Harmonization

There are a number of definitions of harmonization of laboratory services within the literature and the term is often used interchangeably with standardization. For the purpose of this report, harmonization is defined as "a process of coordinating host country governments and stakeholders in the procurement and placement of laboratory products within a defined tiered laboratory network" (Williams, et al. 2016). This particularly relates to the transitional period of moving a national laboratory system towards standardization.

In order to prioritize harmonization efforts, it is important to have access to relevant data in relation to current equipment. This will assist in focusing standardization efforts on areas that have the greatest opportunities to improve.

3.3.1.1 Current Analyzer Equipment Status

Analyzer equipment is defined as a medical laboratory instrument designed to measure different chemicals and other characteristics in a number of biological samples, with minimal human assistance. Analyzer equipment requires reagents to produce test results.

3.3.1.1.1 Data Collection Tool

Understanding the baseline information is an important input into a standardization guideline. For the purposes of harmonization and standardization in Tanzania, The Assessment Tool for Laboratory Services was developed to gather relevant laboratory data at relevant levels. This tool is based on the well-known ATLAS tool and has three levels:

a. Central Administrative Level: Aimed at the central administration function fulfilled by the Ministry of Health.
b. Intermediate Administrative Level: Aimed at the intermediate administration function, typically Regions/Councils.
c. Facility Level: Aimed at the individual facilities – from National Reference down to Dispensary level.

Responses were collected via one of three methods, namely:

a. Online submission
    i. This is the preferred method of data collection due to the ability easily and rapidly evaluate results.
    ii. Data collectors were emailed a web link to a Survey Monkey questionnaire which has been intuitively designed to ensure that users provide value-adding information.
b. Electronic submission
    i. This method makes use of email and MS Excel spreadsheets.
    ii. Data collectors were emailed the spreadsheet and were able to complete the information before emailing it back.
c. Manual submission
    i. This method makes use of printed documentation.
    ii. Data collectors were provided with a printed document which could be completed by hand and returned. The completed documents could also be scanned before being emailed back

3.3.1.1.2 Data collection results received

Understandably, not all data was submitted via the online submission. Electronic and manual submissions were also received, although some of them had incomplete responses. A summary of the responses received is summarized in Table 3-2 below:

Table 3-2 valid responses per survey level

Levels	Valid Responses
Central	8
Intermediate	65
Facility	46

3.3.1.1.1 Additional data received

In addition to survey responses, a number of equipment lists were received, which in some instances covered an entire region. This information has been incorporated into the analysis, increasing the total number of facilities with basic equipment information to 254.

Table 3-3 Number of facilities with equipment data

Tier Level	No. of Facilities
National	2
Zonal	6
Regional	28
District	164
Health Centre	25
Dispensary	15
*Not specified	14

3.3.1.1.2 Analysis of results

The focus of the analysis is on analyzer equipment per tier and as indicated in Table 3-3, the tiers with the most information on equipment are both Regional and District. The following analyzer equipment were specifically addressed:

i. Haematology
ii. Chemistry
iii. CD4
iv. Viral Load
v. TB

Table 3-4 Analyzer Equipment diversity: Pre-standardization

Current Analyzer Equipment diversity: Pre-standardization			
Discipline	**District**	**Regional**	**Zonal & National**
Haematology	14	14	13
Chemistry	17	15	13
CD4	5	4	6
Viral Load	N/A	2	2
TB	1	1	1

3.3.1.2 Recommended Analyzer Equipment for Harmonization

In order to harmonize the current analyzer equipment, consideration must be given to the current proportion of analyzer equipment per tier, as well as their adherence to relevant analyzer equipment criteria. It is clear from Table 3-4 that there are a large variety of Haematology and Chemistry analyzer equipment. It is recommended that the number of analyzer equipment models are harmonized as per Table 3-5.

Table 3-5 Analyzer Equipment Diversity: Post-standardization

Proposed Analyzer Equipment diversity: Post-standardization		
Discipline	**Dispensary to District Level**	**Regional to National Level**
Haematology	4	2
Chemistry	4	2
CD4	4	2
Viral Load	N/A	2
TB	2	2

3.3.1.2.1 Analyzer Equipment Selection Criteria

Analyzer equipment should be evaluated against the following criteria:

i. Mandatory Requirements
   a) FDA Approve/ISO Compliant
   b) Surge Protection
   c) UPS with >30min working time
   d) System must be interfaceable with LIS systems
   e) Power Source and voltage

ii. General Requirements
   a) Technical support and backup in Tanzania
   b) Remote access troubleshooting
   c) Current analyzer equipment presence in Tanzania and evidence of acceptable performance

iii. Test Volumes (According to laboratory tier)
   a) Low to moderate volume (Dispensary & Health Centre)
   b) Mid to high volume (District & Regional)
   c) High volume (Zonal & National)

iv. Test Menus (According to laboratory tier)
   a) Manual or Semi-automation (Dispensary)
   b) Semi to full automation (Health Centre & District)
   c) Full automation (Regional to National)

v. Costs
   a) Equipment purchase cost / Reagent Rental cost
   b) Reagent and consumable cost
   c) Planned preventative maintenance cost
   d) Running costs (Overhead cost)

vi. Contract options
   a) Equipment Service Contract
   b) Reagent Rental Contract
   c) Reagent bundle service contract

vii. Registration
   a) Registration by regulatory authority
   b) Listed by Regulatory authority responsible institution or program

3.3.1.1.1 Harmonized Analyzer Equipment

With due consideration to the current proportion of analyzer equipment per tier, as well as adherence to the analyzer equipment criteria, the following analyzer equipment is recommended, as per Table 3-6:

Table 3-6 Recommended Analyzer Equipment per Tier

Recommended Analyzer Equipment per Tier			
Discipline	**Dispensary & Health Centre**	**District & Regional**	**Zonal & National***
Haematology	- POC - Manual to Semi-automated - Low to Moderate Volume	- Analyzer - Semi to fully automated - Moderate to High Volume	- Analyzer - Fully Automated - High Volume
Chemistry	- POC - Manual to Semi-automated - Low to Moderate Volume	- Analyzer - Semi to fully automated - Moderate to High Volume	- Analyzer - Fully Automated - High Volume
CD4	- POC - Manual to Semi-automated - Low to Moderate Volume	- Analyzer - Semi to fully automated - Moderate to High Volume	- Analyzer - Fully Automated - High Volume
Viral Load	N/A	- POC - Low Volume	- Fully Automated - High Volume
EID	N/A	- Fully Automated - Moderate to High Volume	- Fully Automated - High Volume
TB	N/A	- POC - Low Volume	- Fully Automated - High Volume

* Specialized hospitals fall under this category

3.3.2 Standardization

The purpose of equipment standardization is to acquire appropriate equipment of a high standard at each level. Limiting the range of laboratory equipment enables greater efficiencies of procurement and maintenance. It also allows adoption of standard practice across different laboratories, thereby increasing operational efficiencies. These efficiencies should reduce overall costs to the health system.

Standardization of equipment is an important, yet complex task, requiring substantial planning efforts and may take a number of years to fully implement. The process of standardization is described in the following section.

3.3.2.1 Policy Decision

Standardization is driven by a policy decision which should be informed by an identified need such as an understanding of the diversity of analyzer equipment at a specific tier level. This policy decision must be approved by management through the TWG and then passed on to the LEC.

3.3.2.2 Technical Specifications for Analyzer Equipment

a. Following the policy decision, the LEC must compile the appropriate specifications – appropriate for tendering purposes, considering general criteria (WHO Guidance for procurement of in vitro diagnostics 2017), such as:

   i. Laboratory Infrastructure
   ii. Environmental conditions
   iii. Safety
   iv. Staff skills and training
   v. Simplicity of operation
   vi. Maintenance and calibration requirements
   vii. Supplier/vendor support
   viii. Total cost of ownership

b. Equipment specifications vary substantially and may include the following headings (WHO Manual for procurement 2013):

   i. General Description
   ii. Intended Use
   iii. Performance Specifications
   iv. Operational Specifications
   v. Required Accessories
   vi. Installation and Training
   vii. Service and Maintenance
   viii. Quality Standards[1]

c. Additional points for consideration during the tender process:
   i. Request proof of prior implementation and acceptable performance in Africa
   ii. Compulsory site meeting for large analyzer equipment
   iii. Suppliers often provide large amounts of equipment documentation which is difficult to evaluate against the set criteria and specifications. It is therefore recommended to require the supplier to indicate where in the documents provided the supporting information may be found. (e.g. page numbers noted against each point and tags placed in documentation)

d. Examples of equipment specifications are included in Appendix D and E, and further detail can also be found in the applicable WHO documents: *Guidance for procurement of in vitro diagnostics and related laboratory items and equipment (2017)*, as well as the *Manual for procurement of diagnostics and related laboratory items and equipment (2013).*

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1 *Quality standards may be challenging for laboratory personnel to specify and therefore reliance should be placed on other organizations' quality standards, such as TFDA, WHO prequalification (http://www.who.int/diagnostics_laboratory/evaluations/en/) and other internationally recognized regulatory authorities such as ISO, FDA or CE/CE IVD Mark.

3.3.2.3 Mandatory Requirements and Weighting

The LEC must specify mandatory requirements which if not met, disqualify the item. The non-mandatory requirements should then be weighted according to level of importance. This weighting is for tender evaluation purposes and should not be distributed to suppliers. An example of a weighting has been included in Appendix F.

3.3.2.4 Technical Evaluation of Tenders

When standardizing, a small range of equipment is being proposed. Therefore, it is crucial that the technical evaluation of tenders ensures that the selected equipment meets technical requirements and standardization criteria.

a. The technical group evaluates each tender submission against the specifications and scores the submission according to whether requirements have been met. Suppliers must provide evidence of compliance or they will be scored as non-compliant.
b. These scores are handed back to procurement

3.3.3 Ancillary Equipment

Ancillary equipment is defined as equipment that does not directly produce a test result, but rather supports the process of obtaining a result (e.g. autoclave, microscope, and refrigerator). The detailed list of ancillary equipment is included in Appendix C.

3.3.4 Equipment ownership

Equipment ownership is an important consideration and standardization provides an opportune time to implement the appropriate ownership strategy. There are three different types of ownership to consider:

i. Purchase
ii. Lease/Placement
iii. Reagent Bundle
iv. Reagent Rental

The recommended type of ownership for laboratory analyzer equipment is reagent rental. This is for a number of reasons including: minimum initial capital expenditure; less dependence on the resource-constrained biomedical engineers and technicians; minimized risk of being caught with outdated technologies; improved quality of service and support from the supplier (refer to Table 3-8). It should be clearly stated in the tender specification that all-in costs are provided, these include insurance, controls, calibrators and any other expenses that may be encountered.

In Tanzania, the majority of analyzer equipment has been purchased. Therefore, it is recommended that reagent bundle service contracts are negotiated. This will assist in ensuring planned equipment maintenance and limit reagent stock-outs.

It is recommended that most ancillary equipment is purchased, and suppliers will typically only

offer this option. It is important to also include, where relevant, maintenance service plan when purchasing ancillary equipment.

Consideration should be put on using local biomedical engineers for servicing ancillary equipment. Therefore, equipment installation and on-site training should be included in the tendering process; and local biomedical engineers should be involved during installation and on-site training.

Table 3-7 recommended ownership model by equipment category

EQUIPMENT CATEGORY	RECOMMENDED OWNERSHIP MODEL
Analyzer Equipment	Reagent Rental
Analyzer Equipment (already purchased)	Reagent Bundle
Point-of-Care/Handheld Analyzers	Purchase
Ancillary Equipment	Purchase

Note: It is important to clearly state the intended type of ownership in the tender specification. There is also an option to request costing for both purchase and reagent rental in order to determine which option is more cost effective.

A summary of important considerations for equipment ownership is included in Table 3-8 (WHO Manual for procurement 2013).

Table 3-8 Considerations for equipment ownership

PURCHASE	LEASE/PLACEMENT	REAGENT BUNDLE	REAGENT RENTAL
Requires initial cash outlay. Can result in discounted price	Requires minimum initial cash outlay, but total cost will be higher. A buy out option may exist at the end of the leasing period.	Initial cash outlay has already occurred	Requires minimum initial cash outlay. Cost of equipment is factored into reagent costs. Total cost will be higher than purchase. A buy out option may exist.
Reagent cost must be negotiated considering the capital outlay for equipment purchase	Consider this option when no or few reagents are involved. Any reagent costs must be negotiated separately from the lease, based on volumes – or purchased independently	Cost is negotiated to include both the reagent and maintenance.	Reagent costs are higher as cost of equipment and service is included in the reagent cost. This requires accurate forecasting of volumes and reagent costs per test may increase with reduced volumes (vendors give different cost options based on volumes.

Equipment cannot be upgraded.	Equipment can be upgraded for a new model, usually after completion of the current lease period and with a new leasing agreement	Equipment could be upgraded depending on the contract.	Equipment can be upgraded for a new model, even during the contract period
Risk of obsolescence in 5-7 years	Risk of obsolescence is less, as it is unlikely to be a problem within the leasing period, which is usually no longer than 5 years	Risk of obsolescence is less, due to the supplier involvement.	Risk of obsolescence is less, as reagent rental period is usually no greater than 5 years. Most desirable for changing technologies and high cost systems.
Equipment must be disposed of at some point.	Owner (supplier) is responsible for disposal. Laboratory is responsible for decontamination of equipment, if required.	Equipment must	Owner (supplier) is responsible for disposal. Laboratory is responsible for decontamination of equipment, if required.
Less incentive for supplier to resolve problems of equipment downtime.	The owner (supplier) has a responsibility to maintain equipment in working order.	It is in the suppliers' interest to ensure equipment is in working order.	It is in the owner's (suppliers') interest to ensure equipment is in working order.

3.4 **Human Resources**

Standardization results in a large number of the same equipment and this enables improved utilization of laboratory staff. The following benefits will result:

i. The biomedical engineering personnel will be able focus their skills on a smaller range of equipment
ii. Partnership with vendors to ensure a continuous quality service.
iii. Vendor assistance in the establishment training programmers to equip laboratory staff to perform first line troubleshooting and maintenance of equipment.
iv. Vendors to provide technical assistance, thus releasing staff for other activities.
v. Reporting of equipment performance can be monitored by the LIS, thus releasing staff for other activities.

4.0 Implementation Plan

4.1 Objective

The objective of this chapter is to outline the proposed approach towards implementation of a standardized equipment framework, with due consideration of the activities outlined in Chapter 3. It deals with the specific steps to be undertaken within allocated timeframes and defines proposed process performance indicators in M&E framework.

4.2 Key Departure Points for Implementation

This section makes provision for pivotal principles in the harmonization and standardization approach and should be duly considered during the implementation:

1. The central assumption and departure point to the harmonization approach is that there are no contracts attached to current analyzer equipment. This applies to specific reagent deals, and maintenance and service agreements.
2. Where there are any contractual agreements in place (reagents, service, maintenance or any other), it is essential that the legal and financial impact of any substantive change be considered before taking any action. These agreements must be reviewed on a case by case basis and provision should be made for a number of possible outcomes, such as reviewed or extended agreements, replacement and subsequent reagent deals or termination – either immediately or over an agreed period. It is imperative that these negotiations take note of the overall approach towards harmonization and standardization, and every effort must be made to ensure that the approach is adhered to.
3. Ensure that all stakeholders are involved from the outset to guarantee a constructive approach, optimal use of resources and as little disruption as possible to service delivery.
4. Any new platforms should adhere to the list of standardized equipment.
5. It is essential that any negotiations with suppliers and development partners must take place on a national level, with due cognizance of the comprehensive analyzer equipment asset inventory, to ensure economies of scale and the best possible financial solutions going forward.
6. It is strongly recommended that the harmonization phase do not exceed three years in total, to ensure a consistent cycle of review, consideration of new technologies and to create opportunities for new improved deals.

4.3 Harmonization approach

As for the current equipment harmonization approach, it is essential to follow an iterative, staggered approach with due consideration of the potential impact on service delivery. In this regard:

1. Detailed analyzer equipment types per discipline and tier must be agreed to before any harmonization activities are implemented. This must be done using the process outlined in Section 3.3.1.2.

2. All analyzer equipment types per laboratory must be confirmed, together with any contractual agreements.
3. Equipment which has been found to be obsolete should be properly decommissioned and disposed of.
4. Where the current analyzer equipment comply with the recommended standardized equipment(s):
    a) Decommission and remove obsolete analyzer equipment.
    b) Review contractual agreements and engage with suppliers to conclude agreements on reagents, maintenance and service (reagent bundle). It is strongly recommended that "new" agreements on current analyzer equipment do not exceed three years. This timeframe is relevant to the placement of new analyzer equipment during the harmonization phase (e.g. the replacement of obsolete analyzer equipment) as well.
    c) This exercise should be completed within 6 months.

5. Where the current analyzer equipment do not comply with the recommended standardized equipment(s):
    a) Decommission and remove obsolete analyzer equipment.
    b) Engage with suppliers to agree on a transition period. Such a period should ideally not exceed six months.
    c) Simultaneously, initiate a closed tender process for recommended analyzer equipment suppliers. This process should be executed in line with the process outlined in Chapter 3. This process should not exceed six months from tender initiation to analyzer equipment verification in the facility, to ensure uninterrupted service delivery.
6. The harmonization approach should be staggered with differentiation between disciplines and tiers (Refer to the Implementation Gantt Chart in Appendix I). It is recommended that the stages be as follows, with the next stage starting three months after the commencement of the previous stage:
    a) Month 1 – 6 CD4 & Viral Load: Regional & Zonal Laboratories
    b) Month 4 – 9 CD4 & Viral Load: Health Centre & District Laboratories
    c) Month 7 – 12 Haematology: Regional & Zonal Laboratories
    d) Month 10 – 15 Chemistry: Regional & Zonal Laboratories
    e) Month 13 – 18 Haematology: Health Centre & District Laboratories
    f) Month 16 – 21 Chemistry: Health Centre & District Laboratories
    g) Any other equipment
7. Due to the specialized nature of tests offered and specific equipment required at a national level, it is recommended that harmonization only takes place where the LEC deems it appropriate. The same harmonization process should still be followed.

4.4 Standardization approach

Once the three-year harmonization process as outlined above nears its end, (for each of the differentiated tiers and disciplines respectively) the new procurement cycle should commence, as outlined in Chapter 3. This process should ideally begin at least 9 months before the three years expire.

4.5 Implementation Steps

The steps towards implementation are outlined in Table 4-1 and should be read in conjunction with the activities outlined in the previous chapter. It is reflected in Gantt chart format in Appendix H, considering **21 March 2018** as the starting date.

Table 4-1 Implementation Steps

No	Category	Activities	Responsibility	Timeline
1.	Governance	Approval of the SMLEG	PS/CMO	0.5 weeks
2.	Standardization	Finalize detailed analyzer equipment types per discipline and tier in line with Section 3.3.1.2 - Refer to Analyzer Equipment Evaluation spreadsheet	MSD LEC, TSC	2 weeks
3.	Governance	Printing of SMLEG	CP	1 week
4.	Governance	Launch of SMLEG	Honourable Minister	0.5 weeks
5.	Governance	Dissemination of SMLEG	CP	3 months
6.	Governance	Convene inaugural TWG meeting to finalize its structure, with due consideration of the recommendations made and including as a minimum in the Terms of Reference for all committees: i. Clearly defined objectives ii. Membership iii. Specific activities iv. Meeting format and frequency v. Reporting hierarchy vi. Reporting expectations	CP	2 weeks
7.	Governance	Finalize governance structure, including LEC and TSCs, with due consideration of the recommendations made and including as a minimum in the Terms of Reference for all committees:	TWG	1 month

		i. Clearly defined objectives ii. Membership iii. Specific activities iv. Meeting format and frequency v. Reporting hierarchy vi. Reporting expectations		
8.	Governance	Review and streamline existing structures/entities (e.g. roles of TFDA & MSD) with a specific focus on ensuring that: i. Mandates are clearly differentiated, formalized and communicated ii. Allocated and dedicated functions are aligned to a single, standardized decision-making, funding and procurement process iii. Engagement between the stakeholders are integrated and constructive	TWG	1 month
9.	Standardization	Engage with all role-players, including Development Partners, on the proposed harmonization to agree on the phased harmonization approach.	LEC TWG	1 month
10.	Governance	Develop and implement a Delegation of Authority framework down to laboratory level and in line with organizational hierarchy, to guide the harmonization and standardization processes going forward, outlining: i. Expected action/ activities ii. Recommendation and Approval hierarchy iii. Financial limits	TWG	1 month
11.	Governance	Develop and implement a detailed operational M&E framework, subject to prioritization, specifications and reporting expectations over the medium to long term. This framework needs to consider tier and laboratory specific KPIs.	LEC TWG	1 year
12.	Training	Develop training material and training plan, which should address as a minimum: i. Policy approach to harmonization and standardization ii. Roles and responsibilities of key stakeholders	LEC	1 month

		iii. Governance Structure iv. Delegation of Authority v. M&E Framework, including compliance expectations Technical evaluation framework		
13.	Training	Roll out training to all relevant personnel (TWG, LEC, TSC and laboratory management)	TSCs LEC	3 months
14.	Standardization	Implement Harmonization approach: CD4 & Viral Load: Regional & Zonal Laboratories	TSCs LEC	6 months
15.	Standardization	Implement Harmonization approach: CD4 & Viral Load: Health Centre & District Laboratories	TSCs LEC	6 months
16.	Standardization	Review and update of standard medical laboratory equipment list and specifications (Annually or biennially)	TSCs LEC	1 month
17.	Standardization	Implement Harmonization approach: Haematology: Regional & Zonal Laboratories	TSCs LEC	6 months
18.	Standardization	Implement Harmonization approach: Chemistry: Regional & Zonal Laboratories	TSCs LEC	6 months
19.	Standardization	Implement Harmonization approach: Haematology: Health Centre & District Laboratories	TSCs LEC	6 months
20.	Standardization	Implement Harmonization approach: Chemistry: Health Centers & District Laboratories	TSCs LEC	6 months
21.	Standardization	Implement Harmonization approach: Any other equipment	TSCs LEC	6 months
22.	Standardization	Implement 5-year cycles of standardization	All	5 years

4.6 Monitoring & Evaluation Framework

The implementation steps are expanded into an Implementation M&E framework captured in Table 4-2. Note that this framework has been developed to support implementation and does not replace the operational M&E framework required over the medium to long term. Reference is made to the operational M&E framework in the Implementation Steps.

Table 4-2 Monitoring and Evaluation Framework

Objective/ Goal	Outcome	Indicator	Baseline	Target	Timeframe	Responsibility
Governance						
To establish a Governance Structure for the standardization and harmonization of laboratory equipment within 1 month	Effective oversight of the standardization and harmonization process.	Documented Governance structure for TWG, LEC and TSC, complete with approved Terms of Reference for all committees	New	Established Governance Structure within 1 month	• At outset (1 month) • Comprehensive structure review on an annual basis	CP TWG
To establish mandates and functions of key stakeholders in the laboratory harmonization and standardization process within 1 month	Efficient communication and collaboration between stakeholders	Documented mandates and functions of the key stakeholders.	New	Established mandates and functions of the key stakeholders within 1 month	• At outset (1 month) • Review every 5 years	TWG
To allocate clear responsibilities and accountability across the standardization organizational structures within 1 month (refer to Figure 2-2)	Efficient implementation processes	Documented responsibilities and accountabilities across the standardization organizational structure.	New	Clear responsibilities and accountabilities allocated across the standardization organizational structures within 1 month	• At outset (1 month) • Comprehensive framework review on an annual basis	TWG

Objective/ Goal	Outcome	Indicator	Baseline	Target	Timeframe	Responsibility

To develop and utilize an operational M&E framework within 1 month, to drive tier Specific Standardization and harmonization	Effective decision-making based on programme data.	Operational M&E framework available and in use, with:
		• Goals/ Objectives
		• Expected Outcomes
		• Indicators (KPIs) with:
		  ○ Baselines
		  ○ Targets
		  ○ Timeframes
		  ○ Responsibilities
			New	Operational M&E framework developed and utilized within 1 month	• At outset (1 month)
					• Comprehensive framework review on an annual basis
						LEC
						
						TWG

Standardization						
To review and update the test menus, methodologies, and equipment list annually or biennially	All procurement is aligned with the standardization process.	Updated list of test menu, methodologies, and equipment available	New	Test menu, methodologies and equipment list reviewed and updated annually or biennially	• Review annually or biennially	TSC s LEC
To develop a Technical Evaluation Framework within1 month to support the procurement process	The procurement process is compliant with the technical framework	Documented Technical Evaluation Framework	New	Technical Evaluation Framework developed within 1 month	• At outset (1 month) • Review on an annual basis	LEC
To harmonize and standardize existing equipment over a 3-year period.	Harmonized and standardized laboratory equipment.	The planned proportion of standardized laboratory equipment	New	100% of planned existing equipment standardized	3 years (measured quarterly)	TSC s LEC

Objective/ Goal	Outcome	Indicator	Baseline	Target	Timeframe	Responsibility
			Training			
Transfer knowledge with regard to process of Equipment standardization to TWG, LEC, TSC and Laboratory Management.	Increased competency in standardization process	Number of personnel trained and declared competent	New	Knowledge of equipment standardization process transferred to all TWG, LEC, TSC and Laboratory Management personnel.	• At outset (3 months) • Review 3 yearly	TSCs LEC

Appendix A – Test Menus & Methodologies per Tier

Sections	Specimen	Test	Methodology	Tier
Blood Transfusion	blood	ABO grouping and Rhesus factor	tube method- forward and reverse grouping - ABOD grouping sera (blend IgM and IgG Anti D)	Dispensary and above
Chemistry	blood	glucose (POC)	POC glucometer	Dispensary and above
Chemistry	blood	CRP (POC)	RDT	Dispensary and above
Chemistry	urine	urinalysis for glucose and protein	strip test	Dispensary and above
Chemistry	urine	urine pregnancy test	RDT	Dispensary and above
Haematology	blood	WBC total count	manual - Turks	Dispensary and above
Haematology	blood	WBC differential count	manual- Leishman	Dispensary and above
Haematology	blood	sickle cell screening test	slide - sodium metabisulphite	Dispensary and above
Haematology	blood	Haemoglobin	POC haemoglobinometer	Dispensary and above
Microbiology	sputum	AFB for TB	microscopy (auramine O /AAFB)	Dispensary and above
Microbiology	vaginal /urethral swab	yeast, Trichomonas	microscopy-saline	Dispensary and above
Microbiology	exudates	AFB for TB	microscopy (auramine O /AAFB)	Dispensary and above
Microbiology	skin smear	AFB for leprosy	microscopy-AFB	Dispensary and above
Microbiology	skin scraping	fungal elements	microscopy - KOH	Dispensary and above
Microbiology	DBS for EID	EID	prepare DBS and refer to higher levels	Dispensary and above
Microbiology	plasma	HVL	prepare plasma and refer to higher levels	Dispensary and above
Parasitology	blood	Blood film for haemoparasites	microscopy (Giemsa)	Dispensary and above
Parasitology	urine	Sediment	microscopy-saline	Dispensary and above
Parasitology	stool	Sediment for cells	microscopy - saline, iodine	Dispensary and above
Parasitology	stool	Ova, cysts, protozoa, larvae	microscopy - saline, iodine	Dispensary and above
Parasitology	Skin snip	Onchocerciasis	microscopy- saline	Dispensary and above
Serology	blood	Malaria	RDT	Dispensary and above
Serology	blood	Syphilis	RDT	Dispensary and above
Serology	blood	HIV	RDT	Dispensary and above
Serology	blood	Chlamydia	RDT	Dispensary and above
IDSR	Outbreak specimens for public health events of international concern (PHEIC)	collect samples appropriate to outbreak (blood, rectal, nasopharyngeal, swabs, serum, aspirates)	place samples in relevant transport medium, package and refer to higher level	Dispensary and above
Chemistry	serum	Liver Profile-total protein, albumin, ALT, AST/SGOT, bilirubin total and direct)	chemistry analyzer	Health Centre and above
Chemistry	serum	total protein	chemistry analyzer	Health Centre and above

Sections	Specimen	Test	Methodology	Tier
Chemistry	serum	albumin	chemistry analyzer	Health Centre and above
Chemistry	serum	alanine transaminase (ALT)	chemistry analyzer	Health Centre and above
Chemistry	serum	aspartate transaminase (AST/SGOT)	chemistry analyzer	Health Centre and above
Chemistry	serum	total bilirubin	chemistry analyzer	Health Centre and above
Chemistry	serum	conjugated (direct) bilirubin	chemistry analyzer	Health Centre and above
Chemistry	serum	creatinine	chemistry analyzer	Health Centre and above
Chemistry	serum	Urea	chemistry analyzer	Health Centre and above
Haematology	blood	FBC with 3-part differential count	Haematology analyzer- semi automated	Health Centre and above
Haematology	blood	Coomb's test (indirect antiglobulin test IAT)	tube-indirect antiglobulin	Health Centre and above
Haematology	blood	bleeding time	Ivy - on patient	Health Centre and above
Haematology	blood	clotting time	Lee and White	Health Centre and above
Haematology	blood	INR (POC)	POC automated	Health Centre and above
Haematology	blood	antibody screening (IAT & DAT)	antenatal screening - tube method	Health Centre and above
Haematology	blood	CD4 cell count	flow cytometer	Health Centre and above
Microbiology	skin smear	AFB - microscopy	microscopy	Health Centre and above
Microbiology	Bubo aspirate	Microscopy for *Y. pestis* (plague)	microscopy -Wayson stain	Health Centre and above
Serology	serum	Brucella abortus	agglutination	Health Centre and above
Serology	blood	Hepatitis B	RDT	Health Centre and above
Serology	blood	Hepatitis C	RDT	Health Centre and above
Serology	blood	Dengue Haemorrhagic fever	RDT	Health Centre and above
Serology	stool	*Helicobacter pylori* ag. test (POC)	RDT	Health Centre and above
Anatomical Path	seminal fluid	semen analysis	microscopy	Health Centre and above
Chemistry	stool	occult blood	colorimetric	District and above
Chemistry	serum	uric acid	chemistry analyzer	District and above
Chemistry	serum	amylase/lipase	chemistry analyzer	District and above
Chemistry	blood	glycosylated haemoglobin	POC device, chemistry analyzer	District and above
Chemistry	serum	Rheumatoid factor	agglutination	District and above
Chemistry	blood	Glucose	chemistry analyzer	District and above
Chemistry	serum	potassium	chemistry analyzer	District and above
Chemistry	serum	Sodium	chemistry analyzer	District and above
Chemistry	serum	chloride	chemistry analyzer	District and above
Chemistry	serum	Calcium	chemistry analyzer	Zonal and above
Chemistry	serum	total cholesterol	chemistry analyzer	District and above
Chemistry	serum	triglyceride	chemistry analyzer	District and above

Sections	Specimen	Test	Methodology	Tier
Chemistry	serum	HDL cholesterol	chemistry analyzer	District and above
Chemistry	serum	LDL cholesterol	chemistry analyzer	District and above
Chemistry	serum	alkaline phosphatase (ALP)	chemistry analyzer	District and above
Chemistry	urine	qualitative chemistry (protein, sugar, ketones, blood, bilirubin, urobilinogen)	test strip	District and above
Haematology	blood	bleeding indices	haematology analyzer	District and above
Haematology	blood	reticulocyte count	haematology analyzer	District and above
Haematology	blood	partial thromboplastin time (PTT)	manual - tubes & waterbath/automated	District and above
Haematology	blood	sickling test	manual	District and above
Microbiology	blood	culture, identification and sensitivity	manual	District and above
Microbiology	stool	culture, identification and sensitivity	manual	District and above
Microbiology	urine	culture, identification and sensitivity	manual	District and above
Microbiology	pus/exudates/swabs	culture, identification and sensitivity	manual	District and above
Microbiology	body fluids/CSF	culture, identification and sensitivity	manual	District and above
Microbiology	yeast	culture & identification	manual	District and above
Microbiology	fungal isolation (Aspergillus)	culture & identification	manual	District and above
Microbiology	plasma	HVL	automated POC	District and above
Microbiology	CSF	India Ink	microscopy	District and above
Microbiology	serum/CSF	Cryptococcal antigen	RDT	District and above
Parasitology	stool	stool concentration	Formal ether	District and above
Serology	serum	TPHA	manual/automated	District and above
Serology	serum	ASOT	manual	District and above
Serology	serum	Human Papilloma Virus	RDT	District and above
Blood Transfusion	blood	Hb estimation	copper II sulphate POC	NBTS collection sites
Haematology	blood	INR	automated	Regional and above
Chemistry	blood	glucose tolerance test	chemistry analyzer	Regional and above
Chemistry	serum	lactate dehydrogenase	chemistry analyzer	Regional and above
Chemistry	serum	TSH	immuno analyzer	Regional and above
Chemistry	serum	Free T4	immuno analyzer	Regional and above
Chemistry	serum	Free T3	immuno analyzer	Regional and above
Chemistry	serum	CK, CK-MB and/or troponin	immuno analyzer	Regional and above
Chemistry	serum	PSA	immuno analyzer	Regional and above
Microbiology	blood	culture, identification and sensitivity	automated	Regional and above
Microbiology	blood	HIV confirmatory test	EIA	Regional and above

Sections	Specimen	Test	Methodology	Tier
Microbiology	sputum	*M.tuberculosis* rifampicin resistance	nucleic acid technology	Regional and above
Microbiology	plasma	HVL	nucleic acid technology	Regional and above
Microbiology	Dried blood spot	EID	DBS nucleic acid technology	Regional and above
Microbiology	CSF	CSF protein and glucose	chemistry analyzer	Regional and above
Microbiology	CSF	cell count	manual / automated	Regional and above
Serology	serum	Salm.Typhi O	manual / semi-automated	Regional and above
Serology	serum	Salm. Typhi H	manual / semi-automated	Regional and above
Serology	serum	Brucella abortus	manual / semi-automated	Regional and above
Serology	serum	Proteus OX19	manual / semi-automated	Regional and above
Chemistry	serum	phosphate	chemistry analyzer	Zonal and above
Anatomical Path	tissue	histological examination	histological examination	Zonal and above
Anatomical Path	smear/ fluids	cytological examination	cytological examination	Zonal and above
Chemistry	serum	parathyroid hormone (PTH)	immuno analyzer	Zonal and above
Chemistry	serum	Gamma-glutaryl transferase (GGT)	chemistry analyzer	Zonal and above
Chemistry	serum	albumin/globulin ratio	chemistry analyzer	Zonal and above
Chemistry	serum	gentamycin	chemistry analyzer	Zonal and above
Chemistry	serum	vancomycin	chemistry analyzer	Zonal and above
Chemistry	serum	digoxin	chemistry analyzer	Zonal and above
Chemistry	serum	FSH	immuno analyzer (CLIA)	Zonal and above
Chemistry	serum	LH	immuno analyzer (CLIA)	Zonal and above
Chemistry	serum	prolactin	immuno analyzer (CLIA)	Zonal and above
Chemistry	serum	progesterone	immuno analyzer (CLIA)	Zonal and above
Chemistry	serum	estrogen	immuno analyzer (CLIA)	Zonal and above
Chemistry	serum	testosterone	immuno analyzer (CLIA)	Zonal and above
Chemistry	serum	Beta HCG	immuno analyzer (CLIA)	Zonal and above
Chemistry	serum	gonadotrophin	immuno analyzer (CLIA)	Zonal and above
Chemistry	serum	alpha foetoprotein	immuno analyzer (CLIA)	Zonal and above
Haematology	blood	Hb variants	gel electrophoresis, HPLC, capillary electrophoresis	Zonal and above
Haematology	blood	FBC with 5-part differential count	haematology analyzer - automated	Zonal and above
Microbiology	Sputum. other	line probe assay	nucleic acid technology	Zonal and above
Microbiology	Sputum. other	TB culture	automated liquid culture & LJ	Zonal and above
Serology	serum	Hepatitis B surface antigen	immuno analyzer (CLIA)	Zonal and above
Serology	serum	Hepatitis B core antigen	immuno analyzer (CLIA)	Zonal and above
Serology	serum	Hepatitis B surface antibody	immuno analyzer (CLIA)	Zonal and above

Sections	Specimen	Test	Methodology	Tier
Serology	serum	Hepatitis C antibody	immuno analyzer (CLIA)	Zonal and above
Serology	serum	Hepatitis A Virus antibody	immuno analyzer (CLIA)	Zonal and above
Serology	serum	Toxoplasma IgM	immuno analyzer (CLIA)	Zonal and above
Serology	serum	Toxoplasma IgG	immuno analyzer (CLIA)	Zonal and above
Serology	serum	Rubella IgM	immuno analyzer (CLIA)	Zonal and above
Serology	serum	Rubella IgG	immuno analyzer (CLIA)	Zonal and above
Serology	serum	Cytomegalovirus (CMVg, CMVm)	immuno analyzer (CLIA)	Zonal and above
Blood Transfusion	blood	transfusion transmissible infections (TTIs)	ELISA / CLIA / automation	NBTS laboratories
Blood Transfusion	blood/serum	ABO and Rh(D) grouping	tube / gel cards / microtitre plate/ automation	NBTS laboratories
Blood Transfusion	serum	antibody screening	tube/ gel cards / microtitre plate /automation/ IAT	NBTS laboratories
Blood Transfusion	blood	high titre test for group O donation	tube / microtitre plate/ automation	NBTS laboratories
Blood Transfusion	blood	component production	manual/ automated / apheresis	NBTS laboratories
Chemistry	serum	magnesium	chemistry analyzer	Zonal and above
Chemistry	serum	zinc	chemistry analyzer	Zonal and above
Haematology	blood	G6PD	methaemoglobin reduction/manual	Zonal and above
Chemistry	serum	vitamin B12	immuno analyzer	National
Chemistry	serum	folate	chemistry analyzer	National
Chemistry	serum	iron	chemistry analyzer	National
Chemistry	serum	ferritin	immuno analyzer	National
Chemistry	serum	transferrin	immuno analyzer	National
Chemistry	serum	% saturation (iron)	immuno analyzer	National
Chemistry	serum	cyclosporine	immuno analyzer	National
Chemistry	serum	tacrolimus	immuno analyzer	National
Chemistry	serum	CEA	immuno analyzer	National
Chemistry	serum	CA-125	immuno analyzer	National
Chemistry	serum	CA 19-9, CA 15-3, CA 27-29	automated	National
Chemistry	serum	protein electrophoresis	electrophoresis	National
Chemistry	serum	brain natriuretic peptide (BNP)	CLIA	National
Chemistry	serum	immunoglobulin (G,E,A,M)	CLIA	National
Chemistry	serum	adenosine deaminase (ADA)	CLIA	National
Chemistry	serum	Cortisol	CLIA	National
Chemistry	serum	C-peptide	CLIA	National
Chemistry	serum	D-dimer	CLIA	National
Chemistry	serum	Insulin	CLIA	National

Sections	Specimen	Test	Methodology	Tier
Chemistry	serum	growth hormone	CLIA	National
Chemistry	serum	Bicarbonate	chemistry analyzer	National
Chemistry	serum	thyroglobulin,	CLIA	National
Chemistry	serum	Calcitonin	CLIA	National
Microbiology		sequencing and genotyping	sequencing and genotyping	National
Haematology	tissue/aspirate	bone marrow	microscopy	National
Serology	serum	Rotavirus	antibody detection	National
Serology	serum	Measles	antibody detection	National
IDSR	throat swab	Influenza virus investigation	Real time PCR	National
IDSR	CSF	cerebral spinal meningitis	Gram (other) stains, culture, sensitivity, latex slide agglutination	National
IDSR	stool/rectal swab	cholera investigation	direct microscopy, culture, identification, sensitivity	National
IDSR	aspirate, blood, sputum, throat swab	*Y. pestis* identification (plague)	microscopy, culture, sensitivity, RT PCR	National
IDSR	serum	*Y. pestis* serology (plague)	antibody testing	National
IDSR	stool	bacillary dysentery investigation	culture, identification, sensitivity	National
IDSR	serum	Measles serology	antibody testing	National
IDSR	blood, stool	Typhoid diagnosis	culture, identification, sensitivity	National
IDSR	blood smear	malaria: species identification in epidemics	microscopy	National
IDSR	brain tissue, CSF, saliva, skin	Rabies diagnosis	virus isolation, PCR, antigen detection	National
IDSR	serum	Rabies antibody detection	fluorescent antibody test	National
IDSR	sputum, pleural fluid, blood	Pneumonia investigation	microscopy, culture, sensitivity	National
IDSR	stool	acute flaccid paralysis investigation	culture of Poliomyelitis virus (types 1-3)	National
IDSR	tissue post mortem (liver)	Yellow fever investigation	virus detection (PCR)	National
IDSR	serum	Yellow fever investigation -serology	IgM antibody detection	National
IDSR	tissue post mortem (liver)	Viral haemorrhagic fever investigation	virus detection (PCR)	National
IDSR	serum	Yellow fever investigation -serology	IgM and IgG detection	National
IDSR	serum	Anthrax, brucellosis	PCR	National
Anatomical Path	tissue	immunohistochemistry	manual	National and specialized hospitals

Anatomical Path	fluid	fine needle cytology	manual	National and specialized hospitals
Anatomical Path	seminal fluid	seminalysis	manual	National and specialized hospitals
Anatomical Path	fluid	exfoliative cytology	manual	National and specialized hospitals
Anatomical Path	tissue	histology	semi-automated	National and specialized hospitals

NOTE 1: For tests recommended at regional referral laboratories and above; installation at the hospital laboratory level will be optional, depending on personnel, equipment and infrastructure

NOTE 2: IDSR investigations may require additional tests depending on the outbreak being investigated

Appendix B – Test Menus per Discipline per Tier

CHEMISTRY					
Dispensary	**Health Centre (including all tests at Dispensary Level)**	**District (including all tests at Health Centre Level)**	**Regional (including all tests at District Level)**	**Zonal (including all tests at Regional Level)**	**National (including all tests at Zonal Level)**
Glucose (POC)	total protein	occult blood	glucose tolerance test	PTH	vitamin B12
CRP (POC)	albumin	uric acid	LDH	GGT	folate
urine: glucose, protein	ALT	amylase/lipase	TSH	alb/globulin ratio	iron
urine pregnancy test	AST (SGOT)	glycosylated Hb	Free T4	gentamycin	ferritin
	total bilirubin	Rheumatoid factor	Free T3	vancomycin	transferrin
	conjugated (direct) bilirubin	phosphate	CK, CK-MB / troponin	digoxin	% saturation (iron)
	creatinine	glucose	PSA	FSH	cyclosporine
	urea	potassium		LH	tacrolimus
		sodium		prolactin	CEA
		chloride		progesterone	CA-125
		total cholesterol		estrogen	CA 19-9, CA 15-3, CA 27-29
		triglyceride		testosterone	protein electrophoresis
		HDL cholesterol		Beta HCG	BNP
		LDL cholesterol		gonadotrophin	immunoglobulin (G,E,A,M)
		ALP		alpha foetoprotein	ADA
		urine qualit. chemistry (protein, sugar, ketones, blood, bilirubin, urobilinogen)		magnesium	cortisol
				calcium	C-peptide
				phosphate	D-dimer
				zinc	insulin
				bicarbonate	growth hormone
					magnesium
					thyroglobulin
					calcitonin

MICROBIOLOGY					
Dispensary	**Health Centre (including all tests at Dispensary Level)**	**District (including all tests at Health Centre Level)**	**Regional (including all tests at District Level)**	**Zonal (including all tests at Regional Level)**	**National (including all tests at Zonal Level)**
sputum, exudate: AAFB for TB	micro: Y pestis	micro: Gram stain	automated blood culture	TB line probe assay	sequencing and genotyping
HVS: saline wet prep - yeast, Trichomonas		culture, identification, sensitivity	HIV confirmation (EIA)	TB culture	
AFB for TB		Fungus (Aspergillus), yeast: culture & identification	M.tuberculosis rifampicin resistance		
smear: AFB for leprosy		HIVL (POC)	HVL		
fungal elements (KOH)		CSF: India Ink	EID		
EID: prepare & refer DBS		Cryptococcocal antigen test	CSF protein, glucose		
HVL: prepare & refer plasma			CSF cell count		

HAEMATOLOGY					
Dispensary	**Health Centre (including all tests at Dispensary Level)**	**District (including all tests at Health Centre Level)**	**Regional (including all tests at District Level)**	**Zonal (including all tests at Regional Level)**	**National (including all tests at Zonal Level)**
WBC differential count	FBC (3-part diff. count)	reticulocyte count	FBC (5-part diff. count)	Hb variants	bone marrow
sickle cell screening test	Coomb's test (IAT)	PTT	coagulation factors	G6PD	
haemoglobin	bleeding time	sickling test			
	clotting time				
	INR (POC)				
	antibody screening (IAT & DAT)				
	CD4 cell count				

PARASITOLOGY					
Dispensary	**Health Centre (including all tests at Dispensary Level)**	**District (including all tests at Health Centre Level)**	**Regional (including all tests at District Level)**	**Zonal (including all tests at Regional Level)**	**National (including all tests at Zonal Level)**
micro: haemoparasites		stool concentration			
micro: urine sediment					
micro: stools					
micro: skin snip					

SEROLOGY					
Dispensary	**Health Centre (including all tests at Dispensary Level)**	**District (including all tests at Health Centre Level)**	**Regional (including all tests at District Level)**	**Zonal (including all tests at Regional Level)**	**National (including all tests at Zonal Level)**
Malaria	Brucella	TPHA	Salm typhi	Hepatitis B S ag	Rotavirus
Syphilis	Hepatitis B	ASOT	B. abortus	Hepatitis B S ab	Measles
HIV	Hepatitis C	HPV		Hepatitis B core ag	
Chlamydia	Dengue			Hepatitis C ag	
	H pylori ag			Hepatitis A ab	
				Toxoplasma (IgM,G)	
				Rubella (M,G)	
				Cytomegalovirus (M,G)	

IDSR					
Dispensary	**Health Centre (including all tests at Dispensary Level)**	**District (including all tests at Health Centre Level)**	**Regional (including all tests at District Level)**	**Zonal (including all tests at Regional Level)**	**National (including all tests at Zonal Level)**
collect, package and refer outbreak samples					virus culture
					PCR, RT PCR
					Influenza virus
					cerebral spinal meningitis
					cholera
					Y. pestis
					bacillary dysentery
					Measles
					Typhoid
					malaria: species identification
					Rabies
					pneumonia investigation
					acute flaccid paralysis
					Yellow fever
					Viral haemorrhagic fever
					Anthrax, brucellosis

BLOOD TRANSFUSION					
Dispensary	**Health Centre (including all tests at Dispensary Level)**	**District (including all tests at Health Centre Level)**	**Regional (including all tests at District Level)**	**Zonal (including all tests at Regional Level)****	**National (including all tests at Zonal Level)**
ABO grouping and Rhesus Factor		Hb estimation*		TTI'S	
				ABO and Rh(D) grouping	
				antibody screening	
				high titre test for group O donation	
				component production	
***NBTS collection sites**					
****NBTS laboratories**					

ANATOMICAL PATHOLOGY					
Dispensary	**Health Centre (including all tests at Dispensary Level)**	**District (including all tests at Health Centre Level)**	**Regional (including all tests at District Level)**	**Zonal (including all tests at Regional Level)**	**National (including all tests at Zonal Level)**
	semen analysis			histological examination	
				cytological examination	
				immunohistochemistry	
				fine needle cytology	
				seminalysis	
				exfoliative cytology	
				histology -staining	
				histology- embedding	

Appendix C – List of Equipment per Tier

Equipment	Dispensary	Health Centre	District	Regional	Zonal	National
Analyzer chemistry (semi-automated)		☐	☐	☐		
Analyzer chemistry (automated)				☐	☐	☐
Analyzer coagulation				☐	☐	☐
Analyzer haematology (semi-automated)		☐	☐	☐		
Analyzer haematology (automated)				☐	☐	☐
Analyzer immunology				☐	☐	☐
Analyzer urine chemistry (POC)	☐	☐	☐	☐	☐	☐
Viral Load Machine (POC)				☐		
Viral Load Machine				☐	☐	☐
Analyzer CD4 (POC)		☐	☐			
Analyzer CD4 (automated)				☐	☐	☐
Analyzer cartridge NAT (MTB-RIF)			☐	☐	☐	☐
Analyzer EID				☐	☐	☐
Autoclave/pressure cooker	☐	☐	☐	☐	☐	☐
Biological safety cabinet			☐	☐	☐	☐
Blood culture automated system				☐	☐	☐
Centrifuge	☐	☐	☐	☐	☐	☐
Centrifuge - micro				☐	☐	☐
Centrifuge - refrigerated				☐	☐	☐
Containers - anaerobic organisms				☐	☐	☐
Counter- differential count	☐	☐	☐	☐	☐	☐
Counter- Tally	☐	☐	☐	☐	☐	☐
CRP (POC) reader		☐	☐	☐	☐	☐
Electrical voltage stabilizer for analyzers			☐	☐	☐	☐

ELISA reader				☐	☐	☐
ELISA washer				☐	☐	☐
Freezer (-20)				☐	☐	☐
Freezer (-80)				☐*	☐	☐
Glucometer	☐	☐	☐	☐	☐	☐
Glycosylated Hb reader		☐	☐	☐	☐	☐
Haemoglobinometer	☐	☐	☐	☐	☐	☐
Hot air oven	☐	☐	☐	☐	☐	☐
Hot plate	☐	☐	☐	☐	☐	☐
Incubator (5% CO_2)				☐	☐	☐
Incubator aerobic			☐	☐	☐	☐
INR (POC) device		✓ **	☐			
Line probe assay equipment					☐	☐
Magnetic stirrer with hotplate		☐	☐	☐	☐	☐
Meter pH	☐	☐	☐	☐	☐	☐
Microplate viewer			☐	☐	☐	☐
Microscope (fluorescent)		☐	☐	☐	☐	☐
Microscope (ordinary light)	☐	☐	☐	☐	☐	☐
Mixer roller (blood)		☐	☐	☐	☐	☐
Mixer vortex		☐	☐	☐	☐	☐
PCR machine					☐	☐
Refrigerator	☐	☐	☐	☐	☐	☐
Refrigerator with freezer compartment	☐	☐	☐	☐	☐	☐
Shaker (horizontal)			☐	☐	☐	☐
Shaker VDRL			☐	☐	☐	☐
Staining rack	☐	☐	☐	☐	☐	☐
TB automated culture system					☐	☐
Thermometer (max-min)	☐	☐	☐	☐	☐	☐
Timer digital	☐	☐	☐	☐	☐	☐
Water bath		☐	☐	☐	☐	☐
Water distiller			☐	☐	☐	☐

Weighing scale - analytical			☐	☐	☐	☐
Weighing scale (donor)		☐	☐	☐	☐	☐
Grossing kit					☐	☐
Grossing station					☐	☐
Microtome					☐	☐
Storage cabinet - blocks and slides					☐	☐
Tissue embedder					☐	☐
Tissue processor					☐	☐
Tissue stainer					☐	☐
Vacuum infiltration processors					☐	☐
Real time PCR equipment					☐	☐
Sequencer & genetic analyzer						☐
Liquid nitrogen storage system						☐
Inspissator						☐
Automated Plasma extractor/ Apheresis machine						☐
Plasma extractor - manual						☐
Blood Tubing Sealers						☐
Platelets Agitator (22-24 °C)						☐
Barcode Product Label Printer						☐
Centrifuge - microplate						☐
Microplate reader						☐
Incinerator						☐

* Only public health satellite laboratories.

** Only health centers that perform operations.

NOTE:

- NBTS equipment placed at NBTS laboratories
- EID POC: Consider using existing cartridge-based equipment

Appendix D – Example of Equipment Specification (Analyzer)

REQUEST FOR PROPOSAL: PLACEMENT OF CHEMISTRY ANALYZERS (GENERAL CHEMISTRY AND THERAPEUTIC DRUGS)- SMALL AND MEDIUM LABORATORIES -NATIONAL

Medium Laboratories: 15 000 to 50 000 tests per month

Small Laboratories: < 15 000 tests per month

NB: National and Regional pricing structures Must be proposed for both 3 year and 5-year terms.

Cost Impact
All-in costs per tests provided (include costs of reagents, all consumables including those in the kit, leasing of the equipment, insurance, including controls, calibrators and any other expenses that may be encountered)

Mandatory Requirements:
• The product must be FDA approved or ISO compliant
• Surge protection – voltage regulator
• UPS must be supplied with > 30 minutes of working time.
• Random access / discreet / batch analysis as required
• System must be interfaceable with LIS

Sample Management:
• State throughput of tests per hour as test stats provided (small and medium: 400; large: 800) specs must include list of analytes and historic quantities of each per month and projected increases.
• Analyzer Equipment must have continuous loading of reagents and samples with routine and stat capabilities for laboratories
• Average time spent by staff in daily, weekly and monthly maintenance (buyer may suggest what each should be no more than)
• Projected response time for unscheduled breakdown or repairs (urban/rural)

• Number of Analyzer Equipment technician / engineer available in the Region
• 24-hour service and backup to be available
• Remote access troubleshooting
• Provide preventative maintenance requirements for the Analyzer Equipment (must be included in total costing)
• Provide the following: frequency of calibration / priming / warm up time after Analyzer Equipment shut down (Note: if calibration specified too frequently, will be too costly)
• Analyzer Equipment must have sample barcode reader and be capable of being linked to the host computer & LIS including Primary tube sampling
• Availability of Sample checks using level and clot detection, including haemolysis, icteric sample and lipaemic detection
• Post dilution of sample and Automatic re-run of sample (Should be able to revise rules to prevent unnecessary reruns.)
• Sample type: serum, plasma, urine, CSF, fluids
• Provide Minimum sample volume required.
• Availability of a dedicated paediatric sample cup required?

QA Functions
• Analyzer Equipment must have a cumulative automated QC module which maintains all data and graphs
• The system must have bi-directional with total query mode (between Analyzer Equipment and LIS. (If LIS down, must be able to send batch results when LIS back up)
• Software upgrade
• Reagent tracking and refrigeration
• Provide on board stability of reagents per repertoire of tests
• QC results automatically transferred to LIS (additional QC rules to be added if wanted e.g. what samples to reject)
• Data archive, including test counter and report
• Provide Water purification system with electronic readings. (Indicate wastage of system)
• Provide user training on site with competency certificates provided (stipulate number of users)
• Availability of equipment and reagent upgrades as technology improves

Technical Specification
• Methodologies compliant to standards (e.g. IFCC, FDA European standards)
• Applications for user defined reagents (Does buyer want an open system? – may be beneficial for certain tests)
• Availability of different reagent pack sizes
• Provide details of the control regimen used for costing (different Analyzer Equipment have different specs depending on assay and volume of tests)
• State maximum and minimum environmental operating temperatures (e.g. Analyzer Equipment should be able to operate in a 30C room temp environment)
• Provision of acceptable published evaluation data (e.g. CV% per test and acceptable EQA/ proficiency performance (90%) of internationally acceptable programme – this should be standard information)
• Provide maximum number of reagent on board (depends on number of analytes required to be run. High volume tests may require two channels depending on volume of container and volume of tests)
• The availability of the Analyzer Equipment malfunction alarm
• Cuvettes: disposal or washable cuvettes
• Test repertoire as per specification (specify test repertoire and numbers of each analyte and projected volume increase over tender period)
• Is the system used elsewhere in country?
• OHS and environmental safety compliant
• State method of waste disposal- on board container or direct sewer plumbing (frame question for yes/no answer depending on bylaws of municipality)
• Provide footprint of Analyzer Equipment (state dimensions of space that it must fit into and weight and any structural requirements. Note: if need infrastructure and environmental changes e.g. adequate structural support and increased air conditioning
• Provide Power requirement acceptable for available supply (lab states what is available e.g. I phase or 3 phase - or supplier may have to upgrade electricity supply, which is generally difficult /expensive to do)
• Ability of supplier to have a call centre with service tracking and quarterly service report (history of repairs and preventative maintenance).

Appendix E – Example of Equipment Specification (Ancillary)

Generic Specification: Biological Specimen Containers		
	Requirement	**Evidence to be provided by supplier**
Description	Specimen Containers	Instructions for use/manual
Intended Use	Multipurpose specimen containers are designed for the collection and transport of sputum, urine and other biological specimens.	
Performance Characteristics		
36 x60 Container with lid for Sputum samples Volume max 40ml	Required	
Asceptically manufactured	Required	
The lid to have an "O"ring moulded into the lid	Required	
	Required	
Manufactured from ultra-clear polypropylene	Required	
Excellent temperature and chemical resistance	Required	
Deep threaded cap to ensure sample containment	Required	
(3 & 1/2 Turn to close properly)	Required	
Size Approx.	Required	
Diameter bottom 36 w/lid	Required	
Diameter Top 40 w/lid	Required	
Height w/lid 60	Required	
Operational Characteristics	N/A	
Required Accessories	N/A	
Installation and Training	N/A	
Service and Maintenance	N/A	
Quality Standards		Copy of certificate / assessment report
Supplier: ISO 9001	Required	
Manufacturer: ISO 9001	Required	
Manufacturer: ISO 13485, if applicable	Required	
Leak tested in accordance with EN14254	Required	
EN 14254 Medical Specimen Containers for Microbiology Annex D.	Required	
Regulatory Approval		
CE marked in accordance with the European Directive 93/42/EC	Required	
Other Regulatory Authorities	Optional	

Appendix F – Example of Weighting

REQUIRED SPECIFICATIONS for the PLACEMENT of Point of care Troponin	
Ratings given to the RESPONSES are as follows:	
Matches expectations = full score	
Matches expectations to a large extent, though not completely = 80% of full score	
Matches expectations partially = 50% of full score	
does not match specifications at all = no points awarded	
Mandatory Requirements:	
The product must be FDA /CE approved or ISO compliant	
OHS and environmental safety compliant	
Surge protection and voltage regulator	
Evidence of previous acceptable performance in Evaluation studies performed within the organization	
Clinical usable imprecision (i.e. CV of </=20%) at 99th percentile	
Cost Impact	
All-in costs per tests provided (include costs of reagents, all consumables including those in the kit, leasing of the equipment, servicing/PM of the equipment, insurance, including controls, calibrators and other expenses that may be encountered) Costs may be calculated on a projected average of 50-100 tests per month	
QA Functions	**WEIGHTING**
Availability of cumulative automated QC module that maintains all data and graphs	4
software is upgradable	2
Unacceptable IQC flagging and subsequent prevention of sample analysis	5
availability of patient result and QC data archive & the facility to easily download and retrieve this data	3
Total QA	
Technical Specifications:	
Ability to process whole blood, plasma and serum specimen for Troponin	4
Analyzer Equipment dimensions should be compatible with a point of care analyzer and should be mobile	4

Power supply requirements compatible with placement lab facilities	4
Back up battery power to allow for mobility of analyzer	4
Internal quality control material available	3
Environmental operating temperatures between 15 - 30 degrees Celsius	2
Availability of customer call center and service tracking facility	2
Availability of loan of analyzer when in house analyzer taken off site for repair	4
Number of Analyzer Equipment technicians / engineers = 2 or more available in region	3
On site response time for breakdown or repairs maximum of 12 hours	3
Availability of equipment and reagent upgrades as technology improves	2
Average time spent by staff in daily, weekly and monthly maintenance should not be more than 15 min for daily/weekly an 1 hours for monthly	3
Availability of Analyzer Equipment access control with password per user	4
Stated frequency of calibration / priming functions if applicable / warm up time after Analyzer Equipment shut down	2
expected total downtime during preventative maintenance if applicable (maximum 2 hrs)	1
Availability of end-user on-site training (with provision of certificates) and post-training technical competency testing (with certificates)	4
Facility for interfacing with LIS (TRAK) and provide details (e.g. uni/bidirectional, host query/down load mode etc)	4
Availability of bar-code reader facility	4
Availability of sample/patient identification	4
Availability of different reagent pack sizes	2
On board stability of reagent cartridge (“in-use life”) (< 1 week =1 ;1-2 weeks =2 point; >2-3 weeks =3 points; > 3-4 week = 4 points > 4 weeks=5)	4
Notification of onboard expiry of reagent/cartridge and lot expiration as applicable	3
Facility for reagent lot tracking	2
availability of calibration error flagging and subsequent prevention of sample analysis	2
calibration traceability (i.e. evidence of assay harmonization/standardization)	3
Facility to record lot-specific calibration data and in-use expiry dates	2
availability of evaluation data (both published and unpublished)	2
Reference Intervals available from supplier (details of reference ranges studies should be available on request)	2
Time to result for sample analysis <25 minutes	3

Appendix G – Workshop Participants

ATTENDANCE SHEET			
ACTIVITY: Consultation Workshop 1: Harmonization and Standardization of Laboratory Equipment			
DATE: 15-17 January 2018			
VENUE: CEEMI Conference Room, Dar es Salaam			
No.	**NAME OF PARTICIPANT**	**ORGANISATION**	**TITLE**
1	DR CHARLES MASSAMBU	MOHCDGEC - DCS	ADDS
2	GOODLUCK KYANDO	AGPAHI	PROGRAM COORDINATOR
3	MICHAEL MWASEKAGA	CDC	CHIEF LAB BRANCH
4	MAVERE TUKAI	GHSC	COP
5	ENG. SAMWEL HHAYUMA	TFDA	MDRO
6	PUPWA RAMADHAN	LMU MTWARA	Lab SCMA
7	ALBERTHO CHENGULA	LMU IRINGA	ZLC
8	MIRIAM MATONYA	NHLQATC	LAB TECH
9	PETER TOROKAA	DRRH	LAB SCIENTIST
10	NEEMA HALLIYE	PHLB	LAB TECH
11	GRACE MLINGI	NBTS	HEAD LABORATORY
12	DR. RESTITUTA B. TENGIO	MOHCDGEC – DCS	NZRHCO
13	DR. JOSEPH CHINTOWA	HJFMRI	TECHNICAL DIRECTOR
14	NANGU JUSTINE	MSD	PHARM D
15	JOSEPH KITUKULU	MSD	SQAO
16	LILIAN SHIJA	CDC	DEPUTY CHIEF LAB BRANCH
17	GRACE M. SHIMWELA	TFDA	MANAGER
18	DAVID TEMBA	MDH	LAB MANAGER
19	DICKSON M. MAJIGE	MOHCDGEC - DCS	HEAD LABORATORY
20	JAFFER SUFI	NHLQATC	LAB MANAGER
21	CHARLES KAGOMA	THPS	STA - LAB
22	ESTHER SHIJA	MOHCDGEC – DCS	LIO
23	MERCY M. MASUKI	MOHCDGEC - HSSU	PSM ADVISOR
24	ANYELWISYE KABUJE	NHLQATC	VIRAL LOAD LAB COORDINATOR
25	JOSEPH A.MZIRAY	NHLQATC	LLO/HEAD OF VIRAL LOAD & EID
26	HAMISI A. BORA	MOHCDGEC - DCS	EHSHPCO
27	VICTOR MUCHUNGUZI	NHLQATC	AG. DIRECTOR
28	MURA NGOI	UMB	LAB ADVISOR
29	THEOPHIL MALIBICHE	MOHCDGEC - HLPC	R-HLPC
30	BAHATI MFAKI	NACP	LAB TECHNOLOGIST
31	RUTH NGOWI	MOHCDGEC - DHQA	LAB SCIENTIST
32	ABDUL MWANJA	MSD	AG.DIRECTOR OF PROCUREMENT
33	AMRI M. KINGALI	NTLP	LAB MANAGER
34	MOHAMED FAZAL	HJFMRI	BIO ENGINEER
35	MAGDALENE LYIMO	NBTS	PROGRAMME MANAGER
36	DAUDI MSASI	MOHCDGEC – PSU	CP
37	MTOROKI MAJALIWA	MOHCDGEC - PSU	H-RMMP

ATTENDANCE SHEET			
ACTIVITY: Consultation Workshop 2: Harmonization and Standardization of Laboratory Equipment			
DATE: 12-13 February 2018			
VENUE: CEEMI Conference Room, Dar es Salaam			
No.	**NAME OF PARTICIPANT**	**ORGANISATION**	**TITLE**
1	DR CHARLES MASSAMBU	MOHCDGEC - DCS	ADDS
2	ABDUL MWANJA	MSD	AG. DIRECTOR OF PROCUREMENT
3	JOSEPH KITUKULU	MSD	SENIOR QUALITY ASSURANCE OFFICER-LAB SUPPLIES
4	DR CATHERINE JOACHIM	MOHCDGEC - HSSU	HSS co
5	THEOPHIL MALIBICHE	MOHCDGEC - HLPC	R-HLPC
6	ENG. VALENTINO MVANGA	MOHCDGEC - DCS	H-HCTS
7	MAGDALENA MICHAEL	NBTS	EQUIPMENT & MAINTANCE OFFICER
8	GRACE MLINGI	NBTS	HEAD LABORATORY
9	ENG. SAMWEL HHAYUMA	TFDA	MDRO
10	DR. LUSASI ABDALLAH	NMCP	SPO
11	VICTOR MUCHUNGUZI	NHLQATC	AG. DIRECTOR
12	PUPWA RAMADHAN	GHSC	Lab-SCMA
13	DICKSON M. MAJIGE	MOHCDGEC - DCS	HEAD LABORATORY
14	EUNIACE BANDIO	CSSC	TCMA SECRETARY
15	JAFFER SUFI	NHLQATC	LAB MANAGER
16	DR EDDA VUHAHULA	MUHAS/MNG	PATHOLOGIST
17	MIRIAM MATONYA	NHLQATC	LAB TECH
18	JOHN R. NYIKA	APHFTA	DEPUTY SEC GENERAL
19	ESTHER SHIJA	MOHCDGEC - DCS	LIO
20	MUSHUBIRA BALINDA	CDC	LAB ADVISOR
21	DR HILTRUDA TEMBA	MOHCDGEC - GFCU	GFCU COORDINATOR
22	MERCY M. MASUKI	MOHCDGEC - HSSU	HSS PSM ADVISOR
23	SELESTINE KATO	NACP	PROGRAMME OFFICER
24	PAVEL MTANGO	NACP	HEAD PLSU
25	WILLIAM M REUBEN	MOHCDGEC – PSU	HEAD LMU
26	DAUDI MSASI	MOHCDGEC – PSU	CP
27	MAVERE TUKAI	GHSC	COP
28	JUSTACE BWIRE	MNH	LAB SCIENTIST
29	GRACE M. SHIMWELA	TFDA	MANAGER
30	JOYCE J CHUWA	MOHCDGEC - GFCU	GFCU PSM ADVISOR
31	CHRISTOPHER MACHANGA	NTLP	DATA TECHNICIAN
32	NICODEM MGINA	NTLP	LAB SCIENTIST
33	RUTH NGOWI	MOHCDGEC - DHQA	LAB SCIENTIST
34	LUBEGA JOSEPH	GHSC	CONSULTANT
35	MAXMILLIAN MSUYA	MOHCDGEC – HSSU	HSS M&E EXPERT
36	ELINEEMA E. KILEO	MOHCDGEC – HSSU	HSS FIN ANALYST

Appendix H – Laboratory Technical Team

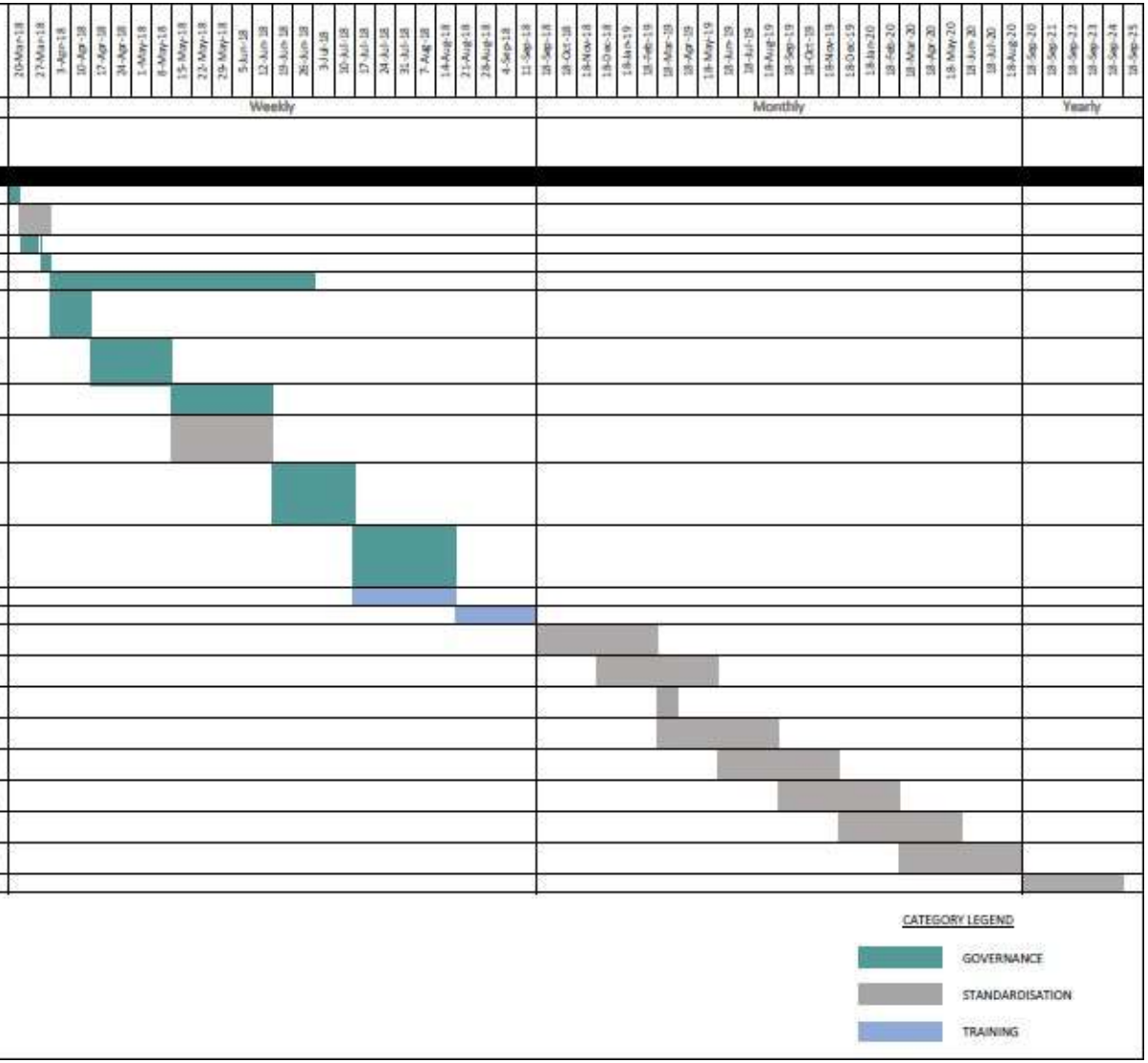
No.	NAME OF PARTICIPANT	ORGANISATION	TITLE
1	DR CHARLES MASSAMBU	MOHCDGEC - DCS	ADDS
2	DICKSON M. MAJIGE	MOHCDGEC - DCS	HEAD LABORATORY
3	THEOPHIL MALIBICHE	MOHCDGEC - HLPC	R-HLPC
4	ABDUL MWANJA	MSD	AG. DIRECTOR OF PROCUREMENT
5	ESTHER SHIJA	MOHCDGEC - DCS	LIO
6	GRACE MLINGI	NBTS	HEAD LABORATORY
7	JUSTACE BWIRE	MNH	LAB SCIENTIST
8	BAHATI MFAKI	NACP	LAB TECHNOLOGIST
9	YAZID KACHWAMBA	PO RALG	SLS – BTS & LABco
10	PETER MWEVILA	ORCI	LAB TECHNOLOGIST
11	JOYCE JOHN	NHLQATC	ICT OFFICER
12	MSAFIRI LISSU	MOHCDGEC - DCS	LIPO
13	VICTOR MUCHUNGUZI	NHLQATC	AG. DIRECTOR

Standard Medical Laboratory Equipment Guideline (SMLEG) - March 2018

IMPLEMENTATION PLAN

Last updated: 2018/03/21

#	ACTIVITY	RESPONSIBILITY	DURATION	PLANNED START	PLANNED END
Implementation steps					
1	Approval of the SMLEG	PS/ CMO	0.5 weeks	21-Mar-18	23-Mar-18
2	Finalise detailed analyser equipment types per discipline and tier in line with Section 3.3.1.2	MSD (LEC, TSC)	2 weeks	22-Mar-18	04-Apr-18
3	Printing of SMLEG	CP	1 week	23-Mar-18	29-Mar-18
4	Launch of SMLEG	Honourable Minister	0.5 weeks	30-Mar-18	02-Apr-18
5	Dissemination of SMLEG	CP	3 months	03-Apr-18	02-Jul-18
6	Convene inaugural TWG meeting to finalise its structure, with due consideration of the recommendations made and including as a minimum in the Terms of Reference for all committees	CP	2 weeks	03-Apr-18	16-Apr-18
7	Finalise governance structure, including LEC and TSCs, with due consideration of the recommendations made and including as a minimum in the Terms of Reference for all committees	TWG	1 month	17-Apr-18	16-May-18
8	Review and streamline existing structures/ entities (e.g. roles of TFDA & MSD)	TWG	1 month	17-May-18	16-Jun-18
9	Engage with all role players, including Development Partners, on the proposed harmonization to agree on the phased harmonization approach	LEC, TWG	1 month	17-May-18	16-Jun-18
10	Develop and implement a Delegation of Authority framework down to laboratory level and in line with organizational hierarchy, to guide the harmonisation and standardisation processes going forward	TWG	1 month	17-Jun-18	16-Jul-18
11	Develop and implement a detailed operational M&E framework, subject to prioritization, specifications and reporting expectations over the medium to long term. This framework needs to consider tier and laboratory specific KPIs	LEC, TWG	1 month	17-Jul-18	16-Aug-18
12	Develop training material and training plan	LEC	1 month	17-Jul-18	16-Aug-18
13	Roll out training to all relevant personnel	TSCs, LEC	1 month	17-Aug-18	16-Sep-18
14	Implement Harmonization approach for CD4 & Viral Load: Regional & Zonal Laboratories	TSCs, LEC	6 months	18-Sep-18	17-Mar-19
15	Implement Harmonization approach for CD4 & Viral Load: Health Centres & District Laboratories	TSCs, LEC	6 months	18-Dec-18	17-Jun-19
16	Review and update of standard medical laboratory equipment list and specifications	TSCs, LEC	1 month	18-Mar-19	17-Apr-19
17	Implement Harmonization approach for Hematology: Regional & Zonal Laboratories	TSCs, LEC	6 months	18-Mar-19	17-Sep-19
18	Implement Harmonization approach for Chemistry: Regional & Zonal Laboratories	TSCs, LEC	6 months	18-Jun-19	17-Dec-19
19	Implement Harmonization approach for Hematology: Health Centres & District Laboratories	TSCs, LEC	6 months	18-Sep-19	17-Mar-20
20	Implement Harmonization approach for Chemistry: Health Centres & District Laboratories	TSCs, LEC	6 months	18-Dec-19	17-Jun-20
21	Implement Harmonization approach for Any other instruments	TSCs, LEC	6 months	18-Mar-20	17-Sep-20
22	Implement 5 year cycles of standardisation	All	5 years	18-Sep-20	17-Sep-25



Appendix I – Implementation Steps Gantt chart

Appendix J - References

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