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Strategic Plan for Laboratory Scientist and Director Certification within Africa Union Member States

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Abstract

Strategic Plan for Laboratory Scientist and Director Certification
within Africa Union Member States
By Varsha Kumar

Background: Laboratory scientists and directors are essential to the healthcare workforce. However, inadequate training programs and competency assessment, plus underdeveloped laboratory infrastructure contribute to the lack of a qualified laboratory workforce in Africa Union (AU) Member States (MS). Laboratory staff assessments prior to entry in the workforce is fragmented and varies substantially. This stems directly from the lack of laboratory certification integrated into national regulation.

Purpose: Our goal was to outline competencies that laboratory scientists and directors require with an implementation plan for AU MS.

Methods: Formal and grey literature were reviewed to develop the laboratory scientist and director competencies and guidelines. Each AU MS laboratory sciences regulatory website was explored to identify certification or licensing guidelines and processes. University bachelor and master's degree programs were reviewed to understand the skills and knowledge gaps in laboratory education. Global stakeholders in laboratory sciences (e.g., WHO, U.S. CDC, Association of Public Health Laboratories, American Society of Microbiology, Africa Society of Laboratory Medicine) were reviewed for laboratory sciences, staff competencies, and assessment processes. Competencies were established for laboratory staff certification. Successful laboratory regulation and staff certification in other countries were used to create the proposed certification system and implementation plan.

Results: A comprehensive set of laboratory scientist and director competencies were adopted targeting AU MS. They were divided by area and skill level (i.e., novice, competent, proficient), with 8 competency areas for laboratory scientists and 11 for laboratory directors. Deliverables included intended audience, means of verification, and application process for certification.

Discussion: Laboratory sciences should be regulated to ensure a competent workforce. We provided competencies to assess laboratory and leadership staff and proposed implementation as part of a certification system. Certification provides national verification of a laboratory scientist or director's qualification to work in MS laboratories The ultimate impact is the certification of a qualified AU MS laboratory workforce.

Strategic Plan for Laboratory Scientist and Director Certification within African Union Member States

By

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Abbreviations

AABB	American Association of Blood Bankers
APHL	Association for Public Health Laboratories
APTT	Partial Thromboplastin Time
ASC	Association of Clinical Scientists
ASCP	American Society of Clinical Pathology
ASLM	Africa Society for Laboratory Medicine
AU	African Union
BOC	Board of Certification
CSMLS	Canadian Society for Medical Laboratory Sciences
CBC	Complete Blood Count
CDC	Centers for Disease Control and Prevention
ECDC	European Centers for Disease Control and Prevention
EU	European Union
FELTP	Field Epidemiology and Laboratory Training Programs
FFP	Fresh Frozen Plasma
GLLP	Global Laboratory Leadership Program
HCPC	HCPC
HDN	Hemolytic Disease of the Newborn
INR	International Normalized Ratio
IVD	In Vitro Diagnostics
MoH	Ministry of Health
MS	Member State
PT	Prothrombin Time
RBC	Red Blood Cell
SLIPTA	Stepwise Laboratory Improvement Process Towards Accreditation
SLMTA	Strengthening Laboratory Management Toward Accreditation
SOP	Standard Operating Procedure
WBC	White Blood Cell
WHO	World Health Organization
WHO-AFRO	World Health Organization Regional Office for Africa

USAID United States Agency for International Development

Chapter One: Introduction

Problem

There is a scarcity of qualified laboratory personnel within African Union (AU) Member States (MS). A majority of countries have laboratory staffing levels of <0.1 per 1,000 inhabitants, with a range of 0.01 – 1.3 per 1,000 [1]. In comparison, developed countries such as the United States and Britain have staffing rates of 0.34 and 2.15 per 1,000, respectively, despite higher levels of automation requiring fewer technicians [1]. A poorly qualified workforce can be traced to inadequate laboratory scientist training programs, varied job descriptions and responsibilities, high staff turnover rates, and overworked staff within laboratories [2]. Laboratory director positions are often filled by individuals who often lack the proper qualifications [3]. In many cases these leaders are not equipped to effectively manage laboratory operations or personnel [4]. They are also often ill prepared to advocate for the needs of laboratories to national policymakers and facility leadership [3].

The direct impact of incompetent laboratory staff is a lack of quality testing performed for patient care [5]. This results in the lack of faith in laboratory capacity, as well as low rates of laboratory staff job satisfaction [5]. Job dissatisfaction contributes to a phenomenon called “brain drain” where health professionals leave their home country to pursue better job opportunities [6]. This leads to a shortage of competent laboratory professionals and fewer funds being allocated to laboratory scientist training programs. Ultimately this feeds a vicious cycle of de-valuation of the laboratory workforce (Figure 1) [6].

Problem Statement

Laboratory scientist certification is the process of assessing the ability to work in a diagnostic, reference, clinical or other laboratory. The scientist must demonstrate competency in all areas considered for *certification*. Competency is assessed by a national regulatory agency (e.g., American Society of Clinical Pathology (ASCP) in the United States). Within the AU there are not yet many certification programs or recommendations for national regulation.

Among African nations, attempts at reform of government policy to structure and define laboratory staff competencies and career ladders have been ineffective [1]. While most countries have established national strategic plans to strengthen laboratory infrastructure, few have policies or initiatives regarding workforce development or assessment [7]. Many have health profession councils charged with regulating and registering healthcare workers and training programs [8]. However, within the councils there is a lack of leadership for laboratory sciences and laboratory training. A majority of the 4-year university training program curricula vary both within and between nations. Few MS have standards for laboratory staff certification; those that do are often inadequate. Among countries with policy, requirements for laboratory scientist certification and training vary considerably [8].

Inconsistences in laboratory training can be attributed to a lack of international-level regulation. Although, there are no pan-African standards outlining laboratory scientist or director competencies for national laboratory regulators to reference, standards for laboratory staff assessment are available in the literature [8]. In 2015, the U.S. Centers for Disease Control and Prevention (CDC) and the Association for Public Health Laboratories (APHL) created standards to evaluate the skills of laboratory

scientists working in public health state laboratories [9]. Similarly, the WHO published laboratory leadership guidelines in 2019 that outline the competencies needed for laboratory management [10]. These were designed for use by a variety of laboratory leadership roles (e.g., policy makers, regulators, and facility-level stakeholders) and should not be directly applied to laboratory staff certification.

In addition to these guidelines, there are documents outlining skills needed for laboratory staff from ASCP, the European Centers for Disease Control and Prevention (ECDC), and the American Association of Blood Bankers (AABB) [11-13]. Almost always designed for the laboratory infrastructure and workforce of western nations, they cannot be directly applied to the AU. Most documents also focus on a specific area of the laboratory such as quality control or microbiology as opposed to providing comprehensive guidelines for staff certification.

Plan Objectives

This thesis will address the lack of qualified laboratory staff within AU MS by proposing standards for laboratory scientist and laboratory director certification, along with a plan for implementation. The standards were broken down by competency area and then further stratified by specific skill. They include the personnel who may apply for certification, as well as competency verification and certification guidelines. This plan was designed for implementation within national MS laboratory regulation agencies.

Research Questions

1) What are current methods used for assessing and strengthening laboratory infrastructure, and how can they be applied to laboratory workforce development in the AU?
2) What literature exists for assessing laboratory scientist and director competency and how has this literature been applied to the laboratory workforce?
3) What is the current level of leadership dedicated to laboratory workforce training within AU MS, and what are their existing mechanisms for laboratory scientist assessment and certification?
4) How can a sustainable system for laboratory scientist and director certification be implemented and institutionalized within MS?

Significance Statement

Within the AU, standards for laboratory scientist and director certification are virtually non-existent. This thesis provides a set of laboratory director and scientist competencies along with a plan to implement a standardized certification system. Certification of laboratory scientists and directors provides verification of their qualification to work in MS laboratories. The desired impact of the strategic plan is the certification of a qualified laboratory workforce within the AU.

Chapter Two: Literature Review

Africa Laboratory Science Background

Sub-Saharan Africa has made remarkable progress since the Maputo Declaration in 2008 where Africa Union (AU) Member States (MS) vowed to prioritize laboratory infrastructure development through national policy and procedure creation [14]. International partnership establishment, including the World Health Organization Regional Office for Africa (WHO-AFRO), Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA), the Strengthening Laboratory Management Toward Accreditation (SLMTA), and the creation of African Society for Laboratory Medicine (ASLM) all served as laboratory infrastructure strengthening catalysts [15]. However, there is significant development yet to be made for laboratory scientist training, increased workforce retention, and upward career mobility [16].

Although strides have been made, laboratory scientist training programs suffer from shortages of qualified faculty, funding, and facilities. The underdeveloped infrastructure contributes to minimal hands-on-training, limited new automated testing exposure, and poor laboratory operations comprehension [2]. Laboratory scientists face numerous challenges within the workforce including inadequate salaries, limited training and promotional opportunities, and poor workplace safety [6]. Clinicians and healthcare leadership often do not recognize laboratory testing and personnel's importance [1]. There is little job qualification standardization, salary structure, and workplace training at MS national levels [1]. Few higher education opportunities exist for laboratory personnel as well as adequate pay and defined career ladders [4]. These issues all contribute to

brain drain, where skilled laboratory professionals leave their home nation for countries with more opportunities and competitive pay schemes [2].

The direct repercussion of *brain drain* at the scientist and supervisory levels is subpar testing services [2]. This negatively impacts patient care leading to increased misdiagnosis, longer hospital stays, and higher patient mortality [17]. Within public health laboratories this results in poor surveillance and outbreak/emergency response as well as inadequate public health interventions [18]. High staff turnover rates results in periods of understaffing and greater workloads for the remaining employees who are then more likely to ignore good quality laboratory practices [2]. Laboratory managers and supervisors face similar issues resulting in laboratory mismanagement as well as inadequate representation at facility and policy levels [10]. Poor service provision causes clinicians and public health leadership lose faith in laboratory diagnostics [1]. This completes the vicious cycle of laboratory scientists losing motivation due to lack of faith in their profession [1].

Laboratory Scientist Certification Systems

A certified or licensed laboratory professional is someone who has met the qualifications necessary to work within the laboratories of a particular country. The certification process includes meeting the competencies set by a national regulator through education or experience, passing the in-country certification exam, and gaining a certificate or license that is periodically renewed. National regulators have sets of competencies or core functions that laboratory professionals should be able to perform in that country's laboratories. To apply for certification laboratory scientists must confirm they have met the competencies for that country by either graduating from a certified

laboratory science program, or having a degree in a relevant scientific field with years of laboratory experience [11, 19]. Criteria for laboratory director assessment had varied requirements depending on the level of education, type of degree, and years of laboratory experience [11].

Certification steps vary depending on if there is a certification exam or not [11, 19]. For example, the United States has a certification exam titled the Board of Certification (BOC) that laboratory scientists must take. To sit for the exam, an applicant must submit an application stating they have met the competencies set by ASCP. After verification of the application by ASCP, the applicant is approved to take the BOC. If the applicant passes the exam they will be considered a certified laboratory scientist and issued a license that is valid for three years [20]. If the applicant fails the exam, they must wait three months to retake the exam. After laboratory scientists are certified their certification status lasts a few years before they must apply for recertification [21]. There are certain activities titled “continuing education” that laboratory scientists are required to complete in order to fulfill requirements for recertification [21].

In the United Kingdom where standards are set by the Association of Clinical Scientists (ASC), there is no certification exam [22]. Instead applicants must complete training at an accredited institution along with a minimum of three years of clinical science training. The applicant then submits a portfolio of evidence to the ASC as evidence of training and competency mastery. If the application is approved the scientist is rewarded a certificate of attainment [22].

Since competencies, assessment systems, and licensing titles vary among countries, laboratory professionals are required to become recertified if they move to a

different country [11]. Re-certification may involve providing documentation of laboratory experience, re-taking the country's certification exam if there is one, even repeating parts of laboratory scientist education depending on the requirements of the specific country and where the professional has moved from [23].

Although there is an international laboratory leadership organization titled the International Federation of Biomedical Laboratory Sciences that promotes competencies for biomedical scientists, they along with other global laboratory stakeholders do not directly certify laboratory staff [24]. There are also continent level laboratory leadership organizations such as ASLM, the Asia Association for Medical Laboratory Sciences, the European Federation of Clinical Chemistry and Laboratory Medicine, and the Latin American Association of Medical Pathology and Laboratory Medicine [25-28]. These organizations support the development and competence assessment of laboratory professionals within member countries but do not provide certification or licensing. The processes for laboratory scientist certification in comparison to licensing are fairly similar between countries.

Within countries, laboratory sciences certification can be provided by an independent scientific organization such as the Canadian Society for Medical Laboratory Sciences (CSMLS) or ASCP in the United States [23]. Certification is required for laboratory personnel to work in state, clinical, and reference laboratories within their country. These organizations are run by laboratory leaders in the field. The other common regulator is certification through a Ministry of Health (MoH) department or another governmental body. This is the case in Japan and most other Asian countries [23]. In the European Union (EU), 24 out of 28 nations has some form of a competency

assessment system [20]. Laboratory scientist competencies in a few cases were set by a scientific organization, but certification is provided by a general health professions council that assesses and maintains a registry of all types of healthcare workers including doctors, nurses, and laboratorians. An example of this in the United Kingdom, where laboratory staff competencies are set by the ASC but a registry of proficient laboratory staff is maintained by the Health and Care professions Council (HCPC) [22, 29]. Laboratory staff must earn a certificate of attainment from ASC prior to applying to the HCPC [22].

AU MS Laboratory Leadership and Certification

A large part of the laboratory training gap stems from lack of regulatory oversight. MS laboratory science is regulated by a department within the Ministry of Health (MoH) or a collaborating organization (Table 1). These governing bodies are responsible for developing standards and accreditation processes for laboratory scientist training programs, certification process for laboratory scientists including a final competency assessment, registration of certified laboratory scientists, and continuing professional development opportunities (Table 1). In a review of MS laboratory strategic plans (published in 2017), only four of 55 countries addressed oversight of laboratory systems through a specific laboratory directorate under the MoH [7]. Additionally, 11 MS delegated laboratory service to a specific branch and seven fragmented laboratory oversight among various health ministry agencies [7, 30]. Out of the 55 MS, eight had a regulatory organization independent of the government that set competencies for laboratory scientists (Table 1). Twelve MS had a laboratory leadership organization separate from the government charged with education and promotion of the profession, as

well as continuing professional development. No regulatory body or leadership within the MoH was found for 23 MS (Table 1).

Well-formed laboratory regulation at the MS level, information regarding laboratory scientist competency requirements, certification processes, and continuing education was difficult to find. We found no comprehensive list of competencies for laboratory scientists or director's certification or qualifications to work in laboratories for any MS. Within MS laboratory leadership websites with accessible information on a certification process, there were few requirements beyond completing a 4-year bachelor's degree. Although few laboratory science regulatory websites maintained a registered list of laboratory scientists the only qualification necessary to apply was completing a bachelor's degree in lab sciences and passing the certification exam.

Most applications for registration were paper based and difficult to find on the websites (Table 1). There were no certification or registration processes for laboratory leadership found in regulatory websites. Many countries had some form of final competency assessment for laboratory scientists in addition to the completion of an MLS program in the form of an exam. Little information was found on the exam format, topics covered, and the process for applying for examination. In Kenya, the final exams were oral and span multiple days. Regulatory websites contained little information regarding laboratory leadership competencies or opportunities for professional development.

State of Laboratory Education within the AU MS.

Although information was available about laboratory scientist courses on university websites, coursework varied among universities at both the national and

international levels (Table 2). MS universities offered 4-year degree programs where individuals could earn a Bachelor's of Science in medical laboratory sciences. The standard curriculum consisted of two years of basic science coursework in subjects such as biology, chemistry, and microbiology as well as skills such as communication and mathematics (Table 2). These courses are taught through a mixture of lectures, applied class or laboratory, self-directed study, and workshops or seminars [31]. For the final two years students focus on clinical subjects such as hematology, clinical chemistry, virology, and blood transfusion (Figure 2). Additionally, students have experiences called "attachment" or "rotation" that are composed of shadowing in clinical laboratories, observing senior medical laboratory scientists, and practicing laboratory techniques (Figure 2). Students were assessed throughout the duration of the program through a combination of tests, assignments, practical exams, and final assessments [31]. Laboratory scientists graduating from the 4-year programs are considered eligible to work in a variety of clinical settings such as hospitals, health centers, research centers, or academia [32-34].

University websites contained minimal information outside of the 4-year curricula on the skills laboratory students gained through the duration of the program as well as skill assessment methods. There was also very little information available on how MS university laboratory science programs were accredited.

Similar to laboratory scientist training, there was limited information regarding laboratory director education among MS. As there were few higher education degree programs for laboratory managers, many laboratory leaders have not had formal training or organizational leadership experience [4]. While there are opportunities for further

studies in a specific area of laboratory sciences such as a masters in microbiology or immunology, MS do not offer laboratory leadership training programs [35].

Global laboratory leadership training programs are usually created for audiences within western nations and are fee based and do not assess core laboratory functions [4]. They are also usually only offered online leading to a lack of direct mentorship. As an alternative to university coursework there are also 2-year leadership training programs administered by the U.S. CDC for laboratory scientists to be trained in field epidemiology and public health laboratory management titled Field Epidemiology and Laboratory Training Programs (FELTP) [36]. However, FELTP programs are focused on outbreak investigation and response as opposed to laboratory management [37]. Other laboratory leadership development programs have been disease specific such as HIV programming with the United States Agency for International Development (USAID), providing non-generalizable skill sets [38].

Guidelines for Laboratory Scientist and Laboratory Manager Certification

There are currently no AU MS sets of international guidelines to assess laboratory scientists or director competencies. However, stakeholders have developed numerous competency lists to evaluate laboratory scientists abilities to perform testing in the core laboratory areas: chemistry, hematology, microbiology, and blood banking [11]. Competencies were developed by organizations in specific laboratory operations including: biosafety, biosecurity, quality assurance, quality control, and data management [9, 10, 39]. Other relevant areas discussed in literature included communication and laboratory ethics. Competencies were developed for public health areas such as surveillance and emergency response [9, 12].

One example is the list of the skills developed by the U.S. CDC and APHL for laboratory scientists working in public health laboratories [9]. This document contains 122 competencies and 519 sub competencies within 15 domain areas divided into the following levels of proficiency: beginner, competent, proficient, and expert [9]. The guidelines were created to supplement workforce development efforts for public health laboratory scientists within developing and developed countries.

There is a similar comprehensive manual developed by APHL, U.S. CDC, ECDC, the Food and Agriculture Organization of the United Nations, the World Organization for Animal Health, and WHO targeted toward laboratory leadership titled *The Laboratory Leadership Competency Program (GLLP)*. Organizations collaborated to identify nine competency areas which are divided into three levels of proficiency: developing, skilled, and expert. The guidelines were intended for a variety of purposes including workforce development, job description creation, and policy. While the framework offers holistic standards on the public health, personal, and laboratory operation skills public health management should possess, there is little information on how the guidelines were developed and no mention of a validation process.

Many countries regulatory websites contain certification or licensing competency lists laboratory scientists need to fulfill. ASCP has one such requirements list that U.S. laboratory scientists should meet for certification [11]. The guidelines specifically outline biomedical testing procedures laboratory scientists should be able to perform and focuses on methodology as opposed to specific technology, since technology can vary substantially across laboratories [11]. They also include information on the qualifications necessary apply for certification and the verification process of those qualifications [11].

However, U.S. laboratory education curriculums are also structured differently compared to African nations. U.S. students either earn a bachelor's degree or learn basic science testing for three years and then complete a "clinical year" where they rotate through the core areas of a clinical laboratory and learn how to perform testing [11]. Among AU MS the standard curriculum is two years of basic science coursework and two years of rotation (Table 2). Therefore, the qualification and verification of those processes cannot be directly adopted from the ASCP guidelines.

Another example of comprehensive laboratory manager competencies is the U.S. CDC's SMLTA program. The program consists of a three workshop series where laboratory managers are taught 66 laboratory management tasks through 45 hands on activities [40]. The ultimate goal of SMLTA is to train laboratory managers to strengthen laboratory infrastructure for accreditation through SLIPTA. SLMTA standards were specifically developed for laboratory management in low resource settings and have been initiated in 47 countries throughout Africa and South America. The program has helped 10 laboratories achieve ISO accreditation and empowered, motivated, and increased the commitment of laboratory personnel towards reporting quality results. SMLTA's laboratory management tasks are broken down by four levels: Community, District, Regional/provincial, and National. The management tasks are limited to lists of manager job activities within clinical laboratories and do not include areas of individual development such as communication or leadership. Also, the indicator assessed is laboratory infrastructure, which is evaluated at the beginning and end of the program using the SLIPTA checklists. Since the change in laboratory management competency is

not directly assessed it is more difficult to evaluate the importance of the 66 laboratory management tasks in assessing competency.

Along with the examples of guidelines listed above, various organizations have published numerous area specific guidelines for laboratory staff competency assessment. The ECDC published a set of guidelines for the EU's microbiology fellowship programs [12]. The guidelines included microbiology skills, public health activity concepts, and laboratory operations. The document does a thorough job of outlining the specific competencies necessary for microbiologists performing bench science and laboratory functions as well as public health skills such as outbreak response and surveillance. Within the competency framework there is no breakdown based on the level of mastery such as novice/competent/proficient. AABB also had a list of skills laboratory scientists need to competently perform blood-banking related functions.

In addition to the literature listed above, researchers and laboratory leadership organizations such as APHL, the International Federation for Clinical Chemistry, and the Clinical Laboratory Improvement Amendments created competency lists [13, 41-44]. However, a majority of the guidelines target laboratory staff within western nations. Some competencies may not be applicable to AU MS due the differences in scientist training, laboratory infrastructure, and regulation. Many of these guidelines, while providing an overview of laboratory scientist and laboratory leadership skills, lack implementation recommendations. It is difficult to find competency uptake and utilization literature. These guidelines are broadly designed for a variety of laboratory settings and can assess a workforce with varied laboratory training levels. Additionally,

guideline uptake may be difficult depending on the resources available and leadership support.

Laboratory Operations Guidelines

There is a wealth of laboratory operations assessment and certification processes in addition to staff competencies. SLIPTA is once such program designed to address the lack of accredited laboratories within Sub-Saharan Africa [45]. The guidelines are based on International Organization for Standardization's standard 15189/17025 which outlines the quality management system of the laboratory and is widely recognized as the gold standard of laboratory assessment [45]. The report includes key areas of laboratory systems broken down by competency along with elements of the quality improvement process. SLIPTA includes a well-designed framework for implementation outlining the responsibilities of various stakeholders including WHO, Country-level-Ministries of health, and national/international level regulatory agencies. MS laboratory infrastructure has evolved since the checklist was published in 2009, evolved and some of the guidelines are outdated. Although there are comprehensive sections on essential laboratory functions such as safety, quality control, and record keeping, there is no information regarding specific testing procedures that should be followed for accreditation.

The second edition of the list of essential diagnostic testing is another document that encompass 46 general in-vitro diagnostics (IVD), 69 disease specific IVDS for detection, diagnosis, and monitoring, as well as seven test categories for blood donation screening. The guidelines outline the essential testing for each of the four tiers of laboratories: primary care; district hospital/laboratory; regional/provincial/specialized

laboratories; and national reference laboratories. The guidelines contain valuable information on specific testing methodology for common disease conditions seen in low resource settings. Each disease is broken down by essential laboratory method(s), testing format, and specimen type. The WHO assumed that laboratory technologists are trained to perform the IVD testing listed. Similar to the IVD list, national and regional network strengthening recommendations were published to respond to global health threats within the country [46]. The guidelines contain testing, laboratory operations, and staffing necessary to strengthen laboratory infrastructure [46].

International organizations have also developed area-specific laboratory operation guidelines. WHO published a manual on how to mitigate biosecurity risks in 2006 that outlined how to develop a biorisk plan and prepare laboratory staff for a potential incident [47]. Another research article by Astuto-Gribble created technical guidelines for assessing biosecurity and biosafety risks within clinical laboratories [48]. The WHO office in South Asia also developed and piloted a manual in Thailand on setting and implementing quality control standards. The manual includes a comprehensive checklist of quality control standards, laboratory personnel quality control skills, and the program's hospital implementation program results [49]. It is considered the laboratory quality control gold standard for implementation by WHO [50, 51]. Organizations such as the U.S. CDC and APHL also created technical guidelines outlining public health laboratory core functions including outbreak response and surveillance [52].

Outcomes of Strengthened Laboratory Regulation

International organization partnerships have been shown to strengthen laboratory infrastructure at the country level. The WHO European Region launched the *Better Labs*

for the Better Health program aimed at providing timely and accurate laboratory results along with early detection of acute public health events to improve the overall health of the population [53]. Within a 5-year window five European Region countries developed an action plan that included infrastructure development, quality management systems, and a framework for training and retaining laboratory workers as well as career development [53]. This national policy's creation strengthened the local laboratory systems. The establishment of ASLM is another such instance. Its creation there has increased country support for national capacity building, greater output of laboratory research within Africa, and increased international laboratory development communication between stakeholders [15]. Similarly WHO and national laboratory leadership partnerships for the SLIPTA and SMALTA programs have resulted in many African nations changing their national laboratory frameworks [54]. The WHO-AFRO stepwise accreditation initiative has also increased the number of laboratories partaking in the accreditation process [55]. Overall, international organization partnerships have proven to be a critical tool in creating sustainable support and investment in national laboratory sectors [15].

Following the Maputo declaration there has been a MS call for creating national plans, policies, and strengthening laboratory oversight [17]. National laboratory policy empowers the government to develop and monitor laboratory networks that meet the public's healthcare needs [46]. Uganda is one of the countries that demonstrated the benefits of creating a strong national laboratory policy [56]. The strengthened laboratory leadership has resulted in increased laboratory performance, evaluation and rectification of problem areas, evaluation of training activities, standardization of techniques, and

superior communication between laboratory staff and healthcare stakeholders [56]. Another example of this is South Africa, which had 312 of 340 accredited laboratories in Africa in 2012 [15]. This is attributed to South Africa's National Accreditation System which advocates for the benefits of laboratory accreditation and aids South African labs in strengthening their laboratory for accreditation. The in-country leadership demonstrates how strong national regulation can contribute to quality system improvement and laboratory accreditation [15]. Within Sierra Leone a National Health Sector Strategic Plan and laboratory government leadership development created functional laboratory systems post-ebola [57]. Although, there is little national laboratory scientist certification policy implementation literature, there is evidence demonstrating how national policy and regulation strengthens laboratory infrastructure.

Chapter Three: Methods

Prior to the development of laboratory scientist and director competencies and a certification system, white and grey literature was explored to determine the extent of information on the topic. A preliminary search was conducted to identify and evaluate laboratory scientist and director competencies, certification systems, and regulation within AU MS. First, a literature review was conducted by entering the terms "Laboratory Scientist License", "Laboratory Scientist Certification", "Laboratory Director License", "Laboratory Direction Certification", and "Laboratory staff certification system" into PubMed and no relevant published literature could be found on this topic. The search was then expanded to laboratory systems outside of the AU and one systematic review paper was found that contained information on the laboratory scientist certification systems in Asia, as well as how ASCP's BOC is used to certify scientists in countries outside of the United States. Due to the lack of published information on this topic, we conducted a literature search within laboratory regulatory websites.

Laboratory Regulation and Certification Systems

We determined that certification systems are established by national regulatory bodies within MS. A regulatory agency was defined as a national body charged with setting and enforcing standards for laboratory sciences. Regulatory bodies were difficult to identify as they varied from an independent organization, the country's MoH, or another branch of government across the AU. In some cases we found both a laboratory leadership organization and a regulatory body. These organizations were separate from national laboratory regulators and do not provide certification or licensing. A laboratory leadership organization was defined as a group that provides advocacy, personal

development, and education opportunities to laboratory professionals. Laboratory leadership organizations were explored for material related to laboratory scientist training, skill assessments, job satisfaction, leadership, and higher education.

Each of the 55 AU MS names were entered into Google along with the key words "Laboratory Scientist Certification", "Laboratory Technician Certification", "Laboratory Scientist Competency", "Medical Laboratory Scientist", "Medical Laboratory Science", "Medical Laboratory Technologist", and "Clinical Laboratory Science". If there were no results the key words were generalized to "laboratory science", "clinical laboratories", and "laboratory regulation" with the country's name. If no relevant information appeared through the search, MS status was determined as unknown. Outside of the AU, western nations regulatory websites such as ASCP, ASC, and CSMLS were also explored using the search process outlined above.

Information within Regulatory Websites

Each regulatory website was searched for webpage and documents containing information pertinent to 1) laboratory scientist competency guidelines; 2) a registry with laboratory scientists; 3) literature on a certification exam; 4) documents regarding the process for laboratory scientist registration and certification; and 5) laboratory scientist training competencies. The information found was used to outline the steps needed for a laboratory staff certification system.

Competencies and Guidelines

We explored a variety of literature regarding laboratory staff and laboratory operation assessment to develop the laboratory scientist and laboratory director

competencies. A literature search was conducted through PubMed, as well as websites including WHO, CDC, USAID, APHL, and ASM. Key words that were entered into the databases for information on general competencies were “Laboratory Scientist Competencies”, “Public Health Laboratory Scientist Competencies”, “Laboratory Scientist Certification”, “Laboratory Scientist Training”, “laboratory Scientist Assessment” and “Laboratory Scientist Education”. To identify general laboratory supervisor competency literature, the search terms were “Laboratory Leadership Competencies”, “Laboratory Supervisor Competencies”, “Laboratory Manager Competencies”, “Laboratory Leadership Qualifications”, “Laboratory Supervisor Qualifications”, “Laboratory Manager Education”, and “Laboratory Leadership Training”. We reviewed literature that contained guidelines, skills, and/or competencies used to train or assess the performance of laboratory staff or laboratory operations.

Laboratory Scientist and Director Training Curriculums

Along with regulatory bodies, the laboratory scientist training programs we identified during the literature review were examined in depth through website analyses. Universities were identified from search terms “medical laboratory scientist” and “clinical laboratory scientist” as entered into university websites and scanned for information pertaining to laboratory scientist curricula, methods of skill evaluation, final exams, and skills/knowledge gained.

We searched for laboratory director training curricula in AU universities; no programs were identified. A PubMed search using the key terms “Laboratory Director Training”, “Laboratory Manager Training”, and “Laboratory Director Education” was

performed and articles relevant to laboratory director training programs were identified. Articles were analyzed for information regarding program structure and topics covered.

AU Laboratory Infrastructure

Background literature was also explored to understand the current state of laboratory infrastructure in AU MS, validate the competency framework, and develop implementation recommendations. We searched the African Journal of Laboratory Medicine, the African Journals Online database, PubMed, and WHO regional laboratory policy and strategy document websites through the search terms “medical laboratory science”, “clinical laboratory science”, “medical laboratory scientist”, “laboratory science”, and “laboratory leadership”. Articles that did not pertain to MS were excluded from the review. Papers were assessed for relevance by discussion of laboratory infrastructure, laboratory workforce, laboratory policy and regulation, and laboratory diagnostics.

Competency Framework Development

Once the review of comprehensive laboratory scientist and supervisor guidelines as well as assessment of laboratory education and regulation in African MS was completed, the competency framework was developed. Competency areas were established based on literature on core laboratory operations, laboratory scientist and director training curriculums, and recurring themes in assessment and certification guidelines. For laboratory scientists and directors 12 and 9 competency areas were established respectively. The framework is structured by competency area such as Hematology or Biosafety, broken down by competency and further stratified by activities

We based the framework on the evaluation of existing manuals such as the GLLP and CDC and APHL's *Competency Guidelines for Public Health Laboratory Professionals* which utilized similar structures.

We established competency area specific competencies and activities through a review of the comprehensive laboratory staff guidelines identified in the earlier search. Each competency and activity that was included was assessed for relevance based on information found regarding AU MS laboratory infrastructure and education. The framework was then supplemented by a search for competency area specific literature. Each of the areas were entered into the search boxes of PubMed and stakeholder websites along with the key words "laboratory sciences". Pertinent literature found was included in the relevant competency area.

Chapter Four: Deliverables

Applicant Qualifications

This section describes the educational and work experience requirements laboratory personnel must meet to apply for certification. Application requirements differed between laboratory scientists and directors. The requirements below only apply to laboratory personnel seeking certification in the country they were trained or have worked in. For example, if Chad implemented the certification system, only applicants educated in Chad or have laboratory experience in Chad are eligible for certification. Laboratory scientists and directors from a variety of backgrounds are encouraged to apply, however they must meet all the requirements of one of the options described below. The work experience requirements must have been fulfilled a maximum of five years ago.

Laboratory Scientist [11, 19, 20]

- An entry-level laboratorian who graduated from an accredited laboratory science or laboratory technology program in the AU and passed the certification exam within their country
- A laboratory scientist that graduated from an accredited laboratory scientist certificate program within the AU (the individual should have at least four years of full time acceptable clinical laboratory experience in blood banking, chemistry, hematology, microbiology, immunology, and urinalysis/body fluids within a laboratory over the last five years).
- A scientist that graduated from an accredited college or university within the AU with a major that required:

a. 16 semester hours (24 quarter hours) of biological sciences with one semester in microbiology
b. 16 semester hours (24 quarter hours) of chemistry with one semester in organic or biochemistry

The individual should also have at least two years of full time acceptable clinical laboratory experience in blood banking, chemistry, hematology, microbiology, immunology, and urinalysis/body fluids in a laboratory within the last five years.

Laboratory Directors [11, 19, 20]

- Graduated with a management-related master's degree such as an MBA or MHA from an accredited university within the AU. Had at least two years of full-time acceptable experience in clinical laboratory supervision or management in an AU MS.
- Graduated with a master's level degree from an accredited university within the AU. Graduated from a bachelors or certificate program in laboratory sciences. Had at least two years of full-time acceptable experience in laboratory supervision or management in an AU MS.
- Graduated from an accredited university within the AU with a bachelor's degree or certificate in medical laboratory sciences. Had at least four years of full-time acceptable experience in laboratory supervision or management in an AU MS.
- Graduated from an accredited doctorate in medicine, chemistry, biology, immunology, microbiology, allied health, medical laboratory science or other

related field program. Had at least two year of full-time acceptable experience in laboratory supervision or management within an AU MS.

- Finished a laboratory leadership program such as FTELP. Graduated from an accredited university within the AU with a bachelor's degree in laboratory sciences or a relevant physical science field. Had at least two years of full-time acceptable experience in laboratory supervision or management within an AU MS.
- Graduated from an accredited university within the AU with a bachelor's degree in laboratory sciences or a relevant physical science field. Had at least five years of full-time acceptable experience in laboratory supervision or management within an AU MS.

Competency Framework

The framework consists of 12 competency areas for laboratory scientists which are General Requirements, Research, Biosafety, Biosecurity, Quality Assurance, Quality Control, Hematology and Coagulation, Chemistry, Virology, Microbiology/Mycology/Parasitology, Genomics and Molecular Biology, and Blood Banking and Blood Transfusion. The 9 laboratory director competency areas are Research and Communication, Leadership, Emergency Preparedness and Outbreak Investigation, Laboratory Systems, Human Resource Management, Financial Resource Management, Biosafety and Biosecurity, and Quality Systems. Each competency area contains competencies broken down by performance activities used to evaluate a laboratory scientist concept mastery. A scientist will be rated as novice, competent, or proficient for each activity.

Proficiency Levels:

- Novice: Able to define and describe the principles and procedures encompassing a competency through education, training, or on the job experience [10]. Individual is able to perform competency with supervision, mentorship, or coaching [58]. We used words such as define, describe, identify and list to assess novice, meaning the applicant must be able to determine the meaning of, identify, or highlight the important parts of various competencies.
- Competent**:** Able to clearly articulate the methodologies, concepts, and components of a competency [10]. Independently able to satisfactorily apply competencies attained through education, training, or work experience to

laboratory work [58]. We used the verbs explain, analyze, apply, or demonstrate for applicant proficiency assessment. The applicant should be able to take existing literature and apply it, or explain and/or demonstrate the principle of a certain competency.

- Proficient: Clear mastery of the methodologies, concepts, and components encompassing a competency demonstrated through repeated successful application of competency within the laboratory environment [10]. Is able to apply critical thinking and problem solving methodology to complete, evaluate, and critique the competency. Can effectively teach the competency and take on a leadership role in mentoring or supervising application of concept [59]. We used the verbs create, develop, evaluate, and perform for applicant assessment at the proficient level. The applicant must be able to satisfactorily demonstrate their ability to routinely perform testing.

Laboratory Scientist Competencies

1. **General Requirements:** Core knowledge regarding the laboratory systems including customer service, ethics, and organizations

1.1 Laboratory Services [9]	
Novice	Identify the laboratory's internal and external customers and the customer services provided
Competent	Explain the laboratory's internal and external customers and describe the customer services provided
Proficient	Evaluate the laboratory's internal and external customers and the customer services provided

1.2 Regulation and Accreditation [10, 60]	
Novice	List the national bodies within your MS and international organizations that perform laboratory accreditation and regulation
Competent	Explain the national bodies and outline their functions within your MS and international organizations that perform laboratory accreditation and regulation
Proficient	Evaluate the national bodies and their functions within your MS and international organizations that perform laboratory accreditation and regulation

1.3 Scientific Integrity [9]	
Novice	Describe methods to verify the scientific integrity of laboratory test results and findings
Competent	Explain verification methodology of scientific integrity of laboratory test results and findings
Proficient	Perform verification of the scientific integrity of laboratory test results and findings

1.4 Ethics [9]	
Novice	Outline how to apply ethics and rules of conduct to the workplace
Competent	Demonstrate how to apply ethics and rules of conduct to the workplace
Proficient	Evaluate how to apply ethics and rules of conduct to the workplace

1.5 Statistics and Math [9]	
Novice	Describe the basic statistical analysis and mathematical calculations necessary for laboratory operations
Competent	Apply basic statistical analysis and mathematical calculations to laboratory operations
Proficient	Perform the basic statistical analysis and mathematical calculations necessary for laboratory operations

1.6 Units of Measurement [61]	
Novice	Define the common units of the metric system such as milli, micro, nano and how to convert between units
Competent	Explain how to convert between common units of the metric system such as milli, micro, nano and apply concepts to laboratory operations
Proficient	Perform conversions between the common units of the metric system such as milli, micro, nano for appropriate laboratory operations

2. Virology: Laboratory diagnostics used to identify viral infections

2.1 Human Immunodeficiency Virus (HIV) [62, 63]	
Novice	Outline HIV diagnostic methods including viral load, immunoassay, and CD-4 count
Competent	Explain HIV diagnostic methods including viral load, immunoassay, and CD-4 count
Proficient	Perform HIV diagnostic methods including viral load, immunoassay, and CD-4 count

2.2 Serology [12, 62]	
Novice	List common manual and automated serological testing methods and the viral illnesses they are frequently used to identify or monitor
Competent	Demonstrate common manual and automated serological testing and explain the viral illnesses they are frequently used to identify or monitor
Proficient	Perform manual and automated serological testing and evaluate the results

2.3 Immunoassay [61]	
Novice	Describe manual and automated immunological testing methods for common conditions including syphilis, hepatitis, and HIV
Competent	Demonstrate manual and automated immunological testing methods for common conditions including syphilis, hepatitis, and HIV
Proficient	Perform manual and automated immunological testing methods for common conditions including syphilis, hepatitis, and HIV

2.4 Viral Culture [63]	
Novice	Outline viral culture procedures and be able to identify common conditions through microscopy
Competent	Analyze viral culture procedures and demonstrate ability to identify common conditions through microscopy
Proficient	Perform viral culture procedures and identify common conditions through microscopy

3. **Research:** The clinical, epidemiological, behavioral, and health service studies designed to produce information that furthers understanding of human disease, prevention and treatment of illness, and health promotion within the field of public health [64]

3.1 Information Search [9, 60]	
Novice	List sources to conduct basic information searches using databases, literature, and the internet
Competent	Conduct basic information searches using databases, literature, and the internet
Proficient	Conduct information searches and prioritize material by relevance using databases, literature, and the internet

3.2 Critical Thinking [61]	
Novice	Process and describe scientific literature
Competent	Apply critical thinking skills to the analysis and interpretation of scientific literature
Proficient	Critically evaluate, analyze, and interpret scientific literature

3.3 Laboratory Experimentation [65]	
Novice	Outline and describe components of a laboratory experiment
Competent	Plan and execute laboratory experiments with supervision
Proficient	Create and independently execute laboratory experiments

3.4 Educational Communication [60]	
Novice	Identify modern teaching methods such as objectives development and case studies to communicate scientific concepts to peers and other personnel
Competent	Apply modern teaching methods such as objectives and case studies to communicate scientific concepts to peers and other personnel
Proficient	Develop modern teaching methods such as objectives and case studies and use them to communicate scientific concepts to peers and other personnel

3.5 General Communication [61]	
Novice	List methods of effective communication and collaboration within interprofessional environments
Competent	Apply effective communication and collaboration methods within interprofessional environments
Proficient	Consistently use effective communication and collaboration skills within interprofessional environments

4. <u>Hematology and Coagulation:</u> Diagnostic methods relating to blood and its components

4.1 Hemoglobin [63]	
Novice	Describe automated and manual hemoglobin testing
Competent	Demonstrate automated and manual hemoglobin testing and explain its role in evaluation of disease states
Proficient	Perform automated and manual hemoglobin testing and interpret the results in relation to disease states

4.2 Cell Count [63]	
Novice	Outline manual and automated white blood cell (WBC), red blood cell (RBC), platelet, and complete blood count (CBC) testing procedures
Competent	Demonstrate manual and automated white blood cell, red blood cell, platelet, and complete blood count testing
Proficient	Perform manual and automated white blood cell, red blood cell, platelet, and complete blood count testing

4.3 Coagulation [63]	
Novice	Describe principle of automated and manual routine coagulation testing including prothrombin time (PT), partial thromboplastin time (APTT), D-dimer, and international normalized ratio (INR)
Competent	Demonstrate automated coagulation testing including PT, APTT, D-dimer, and INR (demonstrate manual testing if automated unavailable)
Proficient	Perform automated and manual routine coagulation testing including PT, APTT, D-dimer, and INR

4.4 White Blood Cell Differential [61]	
Novice	Define blood smear differential count and identify common healthy and disease state white cell morphologies
Competent	Demonstrate blood smear differential counts and explain the white cell morphologies seen in relation to disease states
Proficient	Perform blood smear differential counts and evaluate the results in relation to disease states

4.5 Blood Smear Preparation [61]	
Novice	Define blood smear procedure and identify appropriate staining procedures
Competent	Demonstrate quality blood smear procedure and explain appropriate staining procedures
Proficient	Create quality blood smears and perform appropriate staining procedures

4.6 Flow Cytometry [66]	
Novice	List common markers (CD3, CD4, CD8, CD19/20, CD 34, CD45) and define CD45/bright/dim markers and forward/side scatter gating techniques
Competent	Explain the use of common markers (CD3, CD4, CD8, CD19/20, CD 34, CD45) and CD45/bright/dim markers and forward/side scatter gating techniques to identify common disease states
Proficient	Apply knowledge of common markers (CD3, CD4, CD8, CD19/20, CD 34, CD45) and CD45/bright/dim markers and forward/side scatter gating techniques to identify common disease states

5. Biosafety: A set of procedures, regulations, and policies implemented to prevent the unintended exposure to biological materials and toxins or manage their accidental release [48]

5.1 Biosafety Levels [9]	
Novice	Define the 4 biosafety levels (BSL)
Competent	Explain the purpose of each of the 4 biosafety levels (BSL)
Proficient	Apply the protective uses of the 4 biosafety levels (BSL) to pathogens

5.2 Decontamination [67]	
Novice	List the routine cleaning, disinfection, and sterilization procedures within the laboratory
Competent	Explain the routine cleaning, disinfection, and sterilization procedures within the laboratory
Proficient	Perform the routine cleaning, disinfection, and sterilization procedures within the laboratory

5.3 Signage [67]	
Novice	Identify laboratory signage and describe appropriate actions and precautions
Competent	Explain laboratory signage and describe in appropriate actions and precautions
Proficient	Evaluate laboratory signage and engage in appropriate actions and precautions

5.4 Health Hazards [68]	
Novice	List procedures designed to minimize exposure to health hazards within the laboratory
Competent	Explain procedures designed to minimize exposure to health hazards within the laboratory
Proficient	Perform procedures designed to minimize exposure to health hazards within the laboratory

5.5 Personal Protective Equipment [69]	
Novice	List personal protective measures including gloves, lab coats, face masks, and close toed shoes within the laboratory
Competent	Explain personal protective measures including gloves, lab coats, face masks, and close toed shoes within the laboratory
Proficient	Utilize personal protective measures including gloves, lab coats, face masks, and close toed shoes within the laboratory

5.6 Waste Management [9]	
Novice	Define waste management activities in compliance with laboratory policies and procedures
Competent	Explain waste management activities in compliance with laboratory policies and procedures
Proficient	Perform waste management activities in compliance with laboratory policies and procedures

5.7 Biosafety Incident Reporting [10]	
Novice	Define a biosafety incident and describe how to manage it based on established laboratory biosafety principles
Competent	Explain a biosafety incident and demonstrate how to manage it based on established laboratory biosafety principles
Proficient	Manage and report a biosafety incident based on established laboratory biosafety principles

6. <u>Biosecurity:</u> Regulations and procedures designed to prevent the intentional unauthorized release, theft, or misuse of valuable biological materials through protection, control, and accountability measures [48]

6.1 Biosecurity Incident [10]	
Novice	Define a laboratory biosecurity incident and describe how to report it
Competent	Explain how to manage, document, and report a laboratory biosecurity incident
Proficient	Manage, document, and report a laboratory biosecurity incident

6.2 Bioterrorism Threat Reporting [47]	
Novice	List pathogens considered potential bioterrorism threats through appropriate systems
Competent	Explain pathogens considered potential bioterrorism threats through appropriate systems
Proficient	Report pathogens considered potential bioterrorism threats through appropriate systems

6.3 Bioterrorism Risk Minimization [67]	
Novice	Outline safety protocols to minimize the risk of infection from potential bioterrorism threats
Competent	Apply safety protocols to minimize the risk of infection from potential bioterrorism threats
Proficient	Minimize risk of infection from potential bioterrorism threats by compliance with safety protocols

7. <u>Quality Control:</u> Techniques pertaining to the laboratory testing processes to monitor the accuracy and precision of laboratory results reported [10]

7.1 Westguard Rules [42]	
Novice	Outline Westguard rules as a quality control measure
Competent	Apply Westguard rules as a quality control measure and explain how to troubleshoot non-compliant laboratory results
Proficient	Interpret Westguard rules as a quality control measure and troubleshoot non-compliant laboratory results

7.2 Non-compliant Quality Control [49]	
Novice	Define non-compliant quality control and list remedial actions taken according to laboratory protocol
Competent	Explain non-compliant quality control and remedial actions taken according to laboratory protocol
Proficient	Report non-compliant quality control and perform remedial actions according to laboratory protocol

7.3 Quality Control isolate/Specimen Collection [12]	
Novice	List isolates/specimens needed for external and internal quality control programs
Competent	Explain isolates/specimens as needed for external and internal quality control programs
Proficient	Collect isolates/specimens as needed for external and internal quality control programs

7.4 Internal and External Quality Control [12]	
Novice	Describe results of internal and external quality control programs
Competent	Analyze and explain results of internal and external quality control programs
Proficient	Perform testing and evaluate results of internal and external quality control programs

7.5 Quality Control Documentation [41]	
Novice	Outline procedures for documentation and maintenance of laboratory quality control records
Competent	Explain procedures for documentation and maintenance of laboratory quality control records
Proficient	Perform laboratory quality control documentation and record maintenance

7.6 Specimen Viability [41]	
Novice	List recommended time frames for specimen testing and storage
Competent	Demonstrate knowledge of recommended time frames for specimen testing and storage
Proficient	Evaluate specimen viability based on knowledge of recommended testing and storage time frames

8. **<u>Quality Assurance:</u>** The systematic processes within the laboratory's quality system to monitor the accuracy and precision of specimen testing and result reporting [50]

8.1 Standard Operating Procedures [10]	
Novice	Define laboratory equipment standard operating procedures (SOP)
Competent	Describe laboratory equipment SOPs
Proficient	Perform testing in accordance with laboratory equipment SOPs

8.2 New Sample Accession [10]	
Novice	Describe the accession process for new samples into the LIS
Competent	Explain the accession process for new samples into the LIS
Proficient	Process and accession new samples into the LIS

8.3 Quality Assurance Record Maintenance [45]	
Novice	Outline maintenance procedures specimen testing records within the LIS
Competent	Explain maintenance procedures for specimen testing records within the LIS
Proficient	Maintain specimen testing records within the LIS

8.4 Equipment Validation [10]	
Novice	Outline validation procedures of laboratory testing equipment for analytic accuracy
Competent	Explain validation and verification procedures of laboratory testing equipment for analytic accuracy
Proficient	Validate and verify laboratory testing equipment for analytic accuracy

8.5 Equipment Maintenance [10]	
Novice	Outline laboratory equipment maintenance, service, troubleshoot, and repair procedures
Competent	Describe laboratory equipment maintenance, service, troubleshoot, and repair procedures
Proficient	Perform maintenance, service, troubleshoot, and repair laboratory equipment according to established procedures

8.6 Specimen Transport [68]	
Novice	List quality system specimen packaging regulations for inter-and intra-facility transport
Competent	Explain quality system specimen packaging regulations for inter-and intra-facility transport
Proficient	Perform quality system specimen packaging regulations for inter-and intra-facility transport

8.7 Specimen Management [10]	
Novice	Outline the laboratory's specimen referral, retention, chain of custody, and disposal protocols
Competent	Apply the laboratory's specimen referral, retention, chain of custody, and disposal protocols
Proficient	Perform the laboratory's specimen referral, retention, chain of custody, and disposal protocols

8.8 Specimen Storage [10]	
Novice	Outline the processes, and procedures for sample storage in compliance with the biobanking /repository policies
Competent	Explain the processes, and procedures for sample storage in compliance with the biobanking /repository policy,
Proficient	Store samples in compliance with the biobanking /repository policy, processes, and procedures

8.9 Quality Assurance Documentation [49]	
Novice	Outline documentation and record maintenance procedures for laboratory quality assurance
Competent	Explain documentation and record maintenance procedures for laboratory quality assurance
Proficient	Document and maintain records of laboratory quality assurance

8.10 Information Protection	
Novice	List information protection measures to sensitive and directly/indirectly identifiable patient information [10]
Competent	explain information protection measures to sensitive and directly/indirectly identifiable patient information [10]
Proficient	Apply information protection measures to sensitive and directly/indirectly identifiable patient information [10]

9. Chemistry: Diagnostic methods to evaluate the chemical components within the body and relate them to disease states

9.1 Proteins [11]	
Novice	Identify protein testing methods and the common conditions they are used to diagnose and monitor
Competent	Explain protein testing methods and the common conditions they are used to diagnose and monitor
Proficient	Perform protein testing and evaluate results for the common conditions they are used to diagnose and monitor

9.2 Electrophoresis [11]	
Novice	Identify electrophoresis testing methods and the common conditions they are used for
Competent	Explain electrophoresis testing methods and apply results to common conditions they are used to diagnose and monitor
Proficient	Run electrophoresis and evaluate results for common conditions they are used to diagnose and monitor

9.3 Carbohydrates [11]	
Novice	Identify carbohydrate testing methods and the common conditions they are used for
Competent	Explain carbohydrate testing methods and apply results for common conditions they are used to diagnose and monitor
Proficient	Perform carbohydrate testing and evaluate results for common conditions they are used to diagnose and monitor

9.4 Hematology Compounds [11]	
Novice	Identify hematological compound testing methods and the common conditions they are used for
Competent	Explain hematological compound testing methods and apply results for common conditions they are used to diagnose and monitor
Proficient	Perform hematological compound testing and evaluate results for common conditions they are used to diagnose and monitor

9.5 Acetate [63]	
Novice	Identify acetate testing methods and the common conditions they are used for
Competent	Explain acetate testing methods and apply results for common conditions they are used to diagnose and monitor
Proficient	Perform acetate testing and evaluate results for common conditions they are used to diagnose and monitor

9.6 Hormones and Vitamins [63]	
Novice	Identify hormone and vitamin testing methods and the common conditions they are used for
Competent	Explain hormone and vitamin testing methods and apply results for common conditions they are used to diagnose and monitor
Proficient	Perform hormone and vitamin testing and evaluate results for common conditions they are used to diagnose and monitor

9.7 Enzymes [63]	
Novice	Identify enzyme testing methods and the common conditions they are used for
Competent	Explain enzyme testing methods and apply results for common conditions they are used to diagnose and monitor
Proficient	Perform enzyme testing and evaluate results for common conditions they are used to diagnose and monitor

9.8 Blood Gases [63]	
Novice	Identify blood gases testing methods and the common conditions they are used for
Competent	Explain blood gases testing methods and apply results for common conditions they are used to diagnose and monitor
Proficient	Perform blood gases testing and evaluate results for common conditions they are used to diagnose an d monitor

9.9 Non-protein Nitrogen Compounds [11]	
Novice	Identify non-protein nitrogen compound testing methods and the common conditions they are used for
Competent	Explain non-protein nitrogen compound testing methods and apply results for common conditions they are used to diagnose and monitor
Proficient	Perform non-protein nitrogen compound gases testing and evaluate results for common conditions they are used to diagnose and monitor

9.10 Electrolyte Panel [63]	
Novice	Identify electrolyte testing methods and the common conditions they are used for
Competent	Explain electrolyte testing methods and apply results for common conditions they are used to diagnose and monitor
Proficient	Perform electrolyte testing and evaluate results for common conditions they are used to diagnose and monitor

9.11 Lipids/Lipoprotein Panels [63]	
Novice	Identify lipid and lipoprotein testing methods and the common conditions they are used for
Competent	Explain lipid and lipoprotein testing methods and apply results for common conditions they are used to diagnose and monitor
Proficient	Perform lipid and lipoprotein testing and evaluate results for common conditions they are used to diagnose and monitor

9.12 Immunochemicals [11]	
Novice	Identify immunochemical testing methods and the common conditions they are used for
Competent	Explain immunochemical testing methods and apply results for common conditions they are used to diagnose and monitor
Proficient	Perform immunochemical testing and evaluate results for common conditions they are used to diagnose and monitor

9.13 Point of Care [11]	
Novice	Identify point of care testing methods and the common conditions they are used for
Competent	Explain point of care testing methods and apply results for common conditions they are used to diagnose and monitor
Proficient	Perform point of care testing and evaluate results for common conditions they are used to diagnose and monitor

9.14 Therapeutic Drug Monitoring [11]	
Novice	Identify therapeutic drug monitoring laboratory methods and the common drugs they are used for
Competent	Explain therapeutic drug monitoring laboratory methods and apply methodology to common drugs they are used to monitor
Proficient	Perform therapeutic drug monitoring laboratory methods and evaluate results for the common drugs they are used to monitor

9.15 Toxicology [11]	
Novice	Identify clinical toxicology testing methods and the common conditions they are used for
Competent	Explain clinical toxicology testing methods and apply results for common conditions they are used to diagnose and monitor
Proficient	Perform clinical toxicology testing and evaluate results for common conditions they are used to diagnose and monitor

9.16 Urine Dipstick [60]	
Novice	Outline the procedure for urine testing via dipstick and conditions it is used to evaluate
Competent	Explain the procedure for urine testing via dipstick and interpret results for common conditions it is used to diagnose
Proficient	Perform urine dipstick testing and evaluate results evaluate results for common conditions it is used to diagnose and monitor

9.17 Body Fluids [60]	
Novice	Identify blood gases testing methods and the common conditions they are used for
Competent	Explain blood gases testing methods and apply results for common conditions they are used to diagnose and monitor
Proficient	Perform blood gases testing and evaluate results for common conditions they are used to diagnose and monitor

10. Microbiology/Mycology/Parasitology: The field related to the identification and monitoring of microorganisms

10.1 Culture Media [9]	
Novice	Outline the steps for culture media preparation
Competent	Explain the process for culture media preparation
Proficient	Perform culture media preparation

10.2 Aseptic Technique [9]	
Novice	Define and outline the procedure for aseptic technique
Competent	Explain how to inoculate media for culture using aseptic technique
Proficient	Inoculate media for culture using aseptic technique

10.3 Media Selection [9]	
Novice	List common media used for culture and describe their uses
Competent	Explain various types of media for culture and their uses
Proficient	Selection of appropriate media for microorganism culture

10.4 Plate Streaking [70]	
Novice	List common plate streaking identification and quantification techniques such as quadrant and spread plating
Competent	Describe common plate streaking identification and quantification techniques such as quadrant and spread plating
Proficient	Streak plates utilizing identification and quantification techniques such as quadrant and spread plating

10.5 Microbiology Microscopy [9]	
Novice	List common morphological characteristics of microorganisms identified through microscopy
Competent	Describe morphological characteristics of microorganisms identified through microscopic techniques
Proficient	Perform microscopic examination of microorganisms and identify morphological characteristics

10.6 Microorganism Quantification [65]	
Novice	Outline how to calculate number of microorganisms in a sample by colony forming units
Competent	Describe calculation of number of microorganisms in a sample by colony forming units
Proficient	Calculate number of microorganisms in a sample by colony forming units

10.7 Morphology Interpretation [65]	
Novice	List gram stain and plate morphological characteristics used to identify follow up testing for microorganism identification
Competent	Explain gram stain and plate morphological characteristics used to identify follow up testing for microorganism identification
Proficient	Interpret gram stain and plate morphology and identify follow up testing for microorganism identification

10.8 Antigens [9, 71, 72]	
Novice	Outline procedures for agent specific antigen detection testing including immunoassays, agglutination, and enzyme linked immunosorbent assay (also used for viral identification)
Competent	Explain testing procedures for agent specific antigen detection including immunoassays, agglutination, and enzyme linked immunosorbent assay (also used for viral identification)
Proficient	Perform agent specific antigen detection testing including immunoassays, agglutination, and enzyme linked immunosorbent assay (also used for viral identification)

10.9 Antimicrobial Susceptibility [63, 73]	
Novice	Outline procedures for antimicrobial susceptibility testing including broth dilution, antimicrobial gradient diffusion, disk diffusion, and automated methods
Competent	Explain antimicrobial susceptibility testing procedures including broth dilution, antimicrobial gradient diffusion, disk diffusion, and automated methods
Proficient	Perform antimicrobial susceptibility testing including broth dilution, antimicrobial gradient diffusion, disk diffusion, and automated methods

10.10 Infectious Agents [9]	
Novice	Identify pathogens that have the potential to cause outbreaks or laboratory infect personnel
Competent	Explain pathogens that have the potential to cause outbreaks or infect personnel and their mechanisms for transmission
Proficient	Evaluate pathogens that have the potential to cause outbreaks or infect personnel and require epidemiological notification and consultation

10.11 Public Health Microbiology [9]	
Novice	List the ways in which the laboratory contributes to public health surveillance, outbreak investigation, and applied research
Competent	Explain how the laboratory contributes to public health surveillance, outbreak investigation, and applied research
Proficient	Explain how the laboratory contributes to public health surveillance, outbreak investigation, and applied research

10.12 Mycobacterium Tuberculosis [14]	
Novice	Identify *Mycobacterium tuberculosis* laboratory testing methods including culture, nucleic acid amplification, and acid fast base smear
Competent	Explain *Mycobacterium tuberculosis* laboratory testing methods including culture, nucleic acid amplification, and acid fast base smear
Proficient	Perform and interpret *Mycobacterium tuberculosis* laboratory testing methods including culture, nucleic acid amplification, and acid fast base smear

10.13 Fungi Identification [60]	
Novice	List common plate growth and microscopic morphology characteristics of fungal illness
Competent	Explain fungal plate growth and microscopic morphology characteristics of common fungal illnesses
Proficient	Correlate fungal plate growth and microscopic morphology with common fungal illnesses

10.14 Parasite Identification [74]	
Novice	Describe manual and automated methods for common parasite identification including thick and thin smears, staining, and serology
Competent	Explain manual and automated testing methods for common parasite identification including thick and thin smears, staining, and serology
Proficient	Perform manual and automated testing methods for common parasite identification including thick and thin smears, staining, and serology

10.15 Malaria [74]	
Novice	List the morphological characteristics and diagnostic methods of the four most common Malaria species (*Plasmodium falciparum, Plasmodium vivax, Plasmodium ovale, Plasmodium malariae)*
Competent	Explain the morphological characteristics and diagnostic methods of the four most common Malaria species (*Plasmodium falciparum, Plasmodium vivax, Plasmodium ovale, Plasmodium malariae)*
Proficient	Evaluate the morphological characteristics and perform diagnostic methods for identification of the four most common Malaria species (*Plasmodium falciparum, Plasmodium vivax, Plasmodium ovale, Plasmodium malariae)*

11. <u>Blood Banking/Blood Transfusion:</u> The science of blood and blood related products and its application to storage and transfusion medicine

11.1 Blood Typing [11, 13]	
Novice	Outline procedure for ABO and Rh typing
Competent	Explain procedure for ABO and Rh
Proficient	Perform ABO and Rh typing

11.2 Antiglobulins [11, 13]	
Novice	Outline procedure for direct/indirect antiglobulin testing
Competent	Explain procedure for direct/indirect antiglobulin testing
Proficient	Perform direct/indirect antiglobulin testing

11.3 Antibodies [11]	
Novice	Outline procedures for antibody detection and identification
Competent	Explain procedures for antibody detection and identification
Proficient	Perform antibody detection and identification

11.4 Crossmatching [11, 13]	
Novice	Outline procedure for blood product crossmatching
Competent	Explain procedure for blood product crossmatching
Proficient	Perform crossmatching

11.5 Transfusion Reactions [11]	
Novice	Outline steps for the management and documentation of transfusion reactions
Competent	Explain procedures for the management and documentation of transfusion reactions
Proficient	Manage and document transfusion reactions

11.6 Immune Hemolytic Anemias [11]	
Novice	Outline procedure for immune hemolytic anemia testing
Competent	Explain procedure for immune hemolytic anemia testing
Proficient	Perform immune hemolytic anemia testing

11.7 Newborn Testing [11]	
Novice	Outline procedure for hemolytic disease of the newborn (HDN) and newborn testing
Competent	Explain procedure for HDN and newborn testing
Proficient	Perform HDN and newborn testing

11.8 Rh [9]	
Novice	Outline procedure for Rh immune globulin studies
Competent	Explain procedure for Rh immune globulin studies
Proficient	Perform Rh immune globulin studies

11.9 Transfusion [11, 75]	
Novice	List indications for transfusion of various blood products including RBCs, platelets, fresh frozen plasma (FFP), and cryoprecipitate (CRYO)
Competent	Explain disease states requiring transfusion of various blood products including RBCs, platelets, FFP, and cryoprecipitate CRYO
Proficient	Evaluate disease states requiring the transfusion of various blood products including RBCs, platelets, FFP, and CRYO

11.10 Blood Products [75, 76]	
Novice	List preparation, storage, and transport procedures for commonly transfused blood products including RBCs, platelets, FFP, and CRYO
Competent	Explain the preparation, storage, and transport procedures for commonly transfused blood products including RBCs, platelets, FFP, and CRYO
Proficient	Perform preparation, storage, and transport procedures for commonly transfused blood products including RBCs, platelets, FFP, and CRYO

11.11 Blood Donation [76]	
Novice	List national requirements for an individual to be eligible for blood donation, donation process, and pre/post donation testing
Competent	Explain national requirements for an individual to be eligible for blood donation, donation process, and pre/post donation testing
Proficient	Evaluate donor eligibility based on national requirements, oversee donation, and perform pre/post donation testing

12. Genomics/Molecular Biology: The branch of biology that applies molecular techniques to the genetic mapping and DNA sequencing of organisms [77]

12.1 Genomics [11]	
Novice	List common genetic/genomic analysis methods including genotyping, pharmacogenomics, and genome-wide analysis
Competent	Explain genetic/genomic analysis methods including genotyping, pharmacogenomics, and genome-wide analysis
Proficient	Perform genetic/genomic analysis including genotyping, genetic disorders, pharmacogenomics, and genome-wide analysis

12.2 Oncology [11]	
Novice	Define common oncologic genetic testing methods such as hematologic lymphoid neoplasms/neoplasia, and solid tumor gene markers
Competent	Explain common oncologic genetic testing methods such as hematologic lymphoid neoplasms/neoplasia, and solid tumor gene markers
Proficient	Perform oncologic genetic testing such as hematologic lymphoid neoplasms/neoplasia, and solid tumor gene markers

12.3 Histocompatibility [11]	
Novice	Outline histocompatibility testing (DNA-based) procedures
Competent	Explain histocompatibility testing (DNA-based) procedures
Proficient	Run histocompatibility testing (DNA-based)

12.4 Molecular Testing [11]	
Novice	Identify common molecular DNA testing methods for infectious disease (bacteriology/virology) identification
Competent	Explain common molecular DNA testing methods for infectious disease identification
Proficient	Run common molecular DNA testing for infectious disease identification

Laboratory Director Competencies

1. **Research/Communication:** The clinical, epidemiological, behavioral, and health service studies designed to produce information that furthers understanding of human disease, prevention and treatment of illness, and health promotion [64]

1.1 Grant Proposal [10]	
Novice	Outline the grant proposal writing process for laboratory development
Competent	Explain the grant proposal writing process and analyze grant proposals for laboratory development
Proficient	Write and evaluate grant proposals for laboratory development

1.2 Scientific Methodology [78]	
Novice	Identify laboratory operation and research related problem solving techniques, statistical analysis skills, and scientific principles
Competent	Apply problem-solving techniques, statistical analysis skills, and scientific principles to laboratory operations and research
Proficient	Perform problem-solving techniques, statistical analysis skills, and scientific principles for laboratory operations and research

1.3 Ethics [10]	
Novice	Identify ethical principles concerning human, animal, and environmental welfare and relating to study design, research, and testing
Competent	Explain ethical principles concerning human, animal, and environmental welfare and apply them to study design, research, and testing
Proficient	Prioritize ethical principles concerning human, animal, and environmental welfare when evaluating study design, performing research and testing, and reporting findings

1.4 Needs Assessment [78]	
Novice	Describe needs assessments and identify laboratory programming to address performance gaps
Competent	Explain needs assessments and implement laboratory programming to address performance gaps
Proficient	Perform needs assessments and develop laboratory programming to address performance gaps

1.5 Research Law and Regulation [10]	
Novice	List relevant laboratory laws and regulations regarding research and operational data collection, management, and dissemination
Competent	Apply laboratory laws and regulations regarding research and operational data collection, management, and dissemination
Proficient	Ensure laboratory compliance with laws and regulations regarding research and operational data collection, management, and dissemination

2. **<u>Leadership:</u>** The act of uniting people towards a common goal through motivation and inspiration [10]

2.1 Motivation and Empowerment [10]	
Novice	Outline motivational and empowerment theory principles relevant to the laboratory workforce
Competent	Apply motivational and empowerment theory principles to appropriately delegate work, communicate clear directions, and demonstrate confidence in laboratory staff
Proficient	Create channels to appropriately delegate work, communicate clear directions, and demonstrate confidence in laboratory staff based on motivational and empowerment theory principles

2.2 Critical Thinking [10]	
Novice	Outline problem solving and critical thinking principles to improve work processes
Competent	Apply problem solving and critical thinking principles to improve work processes
Proficient	Perform problem solving and critical thinking principles to improve work processes

2.3 Collaboration [10]	
Novice	Identify opportunities for collaboration between the laboratory and internal/external partners and stakeholders
Competent	Implement collaborations between the laboratory and internal/external partners and stakeholders
Proficient	Evaluate opportunities for collaboration between the laboratory and internal/external partners and stakeholders

2.4 Partnership [10]	
Novice	Identify community partnerships to enhance laboratory operations and communication channels
Competent	apply community partnerships to enhance laboratory operations and communication channels
Proficient	Create community partnerships to enhance laboratory operations and communication channels

2.5 Professionalism [10]	
Novice	Outline a professional code of conduct for laboratory staff
Competent	Implement a professional code of conduct for laboratory staff
Proficient	Develop a professional code of conduct and advocate for staff compliance

3. Emergency Preparedness/Outbreak Investigation: The organizational and resource capabilities of a laboratory to anticipate, respond to and recover from emergency situations as well as control a disease outbreak affecting humans, animals, or the environment [10]

3.1 Emergency Preparedness and Response Guidelines [79]	
Novice	Implement guidelines for emergency laboratory preparedness and response
Competent	Apply guidelines for emergency laboratory preparedness and response
Proficient	Create and evaluate guidelines for emergency laboratory preparedness and response

3.2 Emergency Operations Plan [79]	
Novice	Outline the components of an emergency operations plan
Competent	Apply a laboratory emergency operations plan
Proficient	Develop and implement a laboratory emergency operations plan

3.3 Mobilization of Laboratory Resources [10]	
Novice	Identify processes for mobilizing laboratory resources and personnel during emergency situations
Competent	Apply processes for mobilizing laboratory resources and personnel during emergency situations
Proficient	Create, implement, and monitor processes for mobilizing laboratory resources and personnel during emergency situations

3.4 Post Emergency Assessment [10]	
Novice	Identify strategies for assessing the situational post-emergency resources necessary and develop strategies for rebuilding and/or reopening the laboratory
Competent	Describe strategies for assessing the situational post-emergency resources necessary and develop strategies for rebuilding and/or reopening the laboratory
Proficient	Develop processes for assessing the situational post-emergency resources necessary and develop strategies for rebuilding and/or reopening the laboratory

3.5 Outbreak Surveillance [10]	
Novice	List the laboratory's activities that contribute to the surveillance, outbreak investigation, and response to rare/emerging disease
Competent	Explain the laboratory's activities that contribute to the surveillance, outbreak investigation, and response to rare/emerging disease
Proficient	Demonstrate and evaluate the laboratory's performance in contributing to surveillance, outbreak investigation, and response to rare/emerging disease

3.6 Outbreak Data Collection [10]	
Novice	Describe laboratory sample and data collection methodology for public health surveillance in daily and outbreak situations
Competent	Apply laboratory sample and data collection methodology for public health surveillance in daily and outbreak situations
Proficient	Create and evaluate laboratory sample and data collection methodology for public health surveillance in daily and outbreak situations

3.7 Outbreak Testing [10]	
Novice	Describe procedures for appropriate sample processing, testing, and result turnaround time in outbreak situations
Competent	Apply procedures for appropriate sample processing, testing, and result turnaround time to outbreak situations
Proficient	Create and implement procedures for appropriate sample processing, testing, and result turnaround time in outbreak situations

3.8 Outbreak Communication [10]	
Novice	Identify channels for outbreak/emergency related communication between the laboratory and other stakeholders
Competent	Implement channels for outbreak/emergency related communication between the laboratory and other stakeholders
Proficient	Develop and utilize channels for outbreak/emergency related communication between the laboratory and other stakeholders

4. <u>Laboratory System:</u> A set of networks, procedures, and processes that encompass the operations, services, and activities of a functioning laboratory

4.1 Law [80]	
Novice	Describe national and international healthcare laws that pertain to the laboratory
Competent	Implement laboratory operations in compliance with national and international healthcare laws
Proficient	Evaluate laboratory adherence to national and international healthcare laws

4.2 Qualification for Operation [11]	
Novice	Outline relevant registration, licensure, certification, and accreditation processes needed for laboratory operation
Competent	Implement relevant registration, licensure, certification, and accreditation processes to ensure laboratory's qualifications to operate
Proficient	Evaluate laboratory's qualifications to operate through relevant registration, licensure, certification, and accreditation processes

4.3 Regulation [11]	
Novice	Outline strategies for laboratory compliance with national policies and laboratory regulatory bodies
Competent	Implement processes for laboratory compliance with national policies and laboratory regulatory bodies
Proficient	Evaluate laboratory compliance with national policies and laboratory regulatory bodies

4.4 Data Management [49]	
Novice	Outline policies defining who may access patient data including who is authorized to enter and change patient results, correct billing, or modify computer programs.
Competent	Apply policies defining who may access patient data including who is authorized to enter and change patient results, correct billing, or modify computer programs.
Proficient	Implement and establish policies defining who may access patient data including who is authorized to enter and change patient results, correct billing, or modify computer programs.

4.5 Information Management [79]	
Novice	Identify appropriate laboratory information management systems based on laboratory needs
Competent	Analyze and select information management systems based on laboratory needs
Proficient	Evaluate and implement the appropriate laboratory information management systems

4.6 Documentation and Records [10]	
Novice	Describe the national health information system requirements for laboratory operations and identify compliant documentation and record systems
Competent	Implement documentation and record systems that comply with the national health information system requirements for laboratory operations
Proficient	Develop and utilize documentation and record systems that comply with the national health information system requirements for laboratory operations

4.7 Activity Reports [78]	
Novice	Outline the steps for preparation and maintenance of laboratory reports summarizing laboratory activities, accomplishments, and needs
Competent	Apply a process for the preparation and maintenance of laboratory reports summarizing laboratory activities, accomplishments, and needs
Proficient	Implement and evaluate a process for the preparation and maintenance of laboratory reports summarizing laboratory activities, accomplishments, and needs

4.8 Role and Function [10]	
Novice	Outline the roles and functions of reference, public health, clinical, ect. within regional /national /multinational /international laboratory networks
Competent	Explain the roles and functions of reference, public health, clinical, ect. within regional /national /multinational /international laboratory networks
Proficient	Evaluate the roles and functions of reference, public health, clinical, ect. within regional /national /multinational /international laboratory networks

4.9 Information Sharing [10]	
Novice	Identify processes for sharing laboratory information with relevant sectors and stakeholders
Competent	Analyze and apply processes for sharing laboratory information with relevant sectors and stakeholders
Proficient	Implement and utilize processes for sharing laboratory information with relevant sectors and stakeholders

4.10 Standard Operating Procedures [81]	
Novice	Outline standard operating procedures for laboratory activities
Competent	Apply standard operating procedures to laboratory activities
Proficient	Create and evaluate standard operating procedures for laboratory activities

5. Human Resource Management: Activities relating to the employees of an organization including hiring, orientation, retention, and management [82]

5.1 Mentorship [78]	
Novice	Identify the mentoring skills necessary to provide workforce development opportunities
Competent	Apply the mentoring skills to provide workforce development opportunities in response to trends and initiatives within the healthcare field
Proficient	Develop the mentoring skills to implement workforce development opportunities in response to trends and initiatives within the healthcare field

5.2 Hiring [78]	
Novice	Outline decision policies needed to make hiring recommendations and decisions for the laboratory
Competent	Apply decision making policies to hiring recommendations and decisions regarding for the laboratory
Proficient	Perform hiring recommendations and decisions for the laboratory

5.3 Talent Management [10]	
Novice	Identify strategies for education, training, recruitment, deployment and retention of laboratory talent
Competent	Apply strategies for laboratory talent management including education, training, recruitment, deployment and retention
Proficient	Development and implement strategies for laboratory talent management including education, training, recruitment, deployment and retention

5.4 Conflict Management [78]	
Novice	Outline organizational policies to mitigate employee grievances and settle interpersonal disputes within the laboratory
Competent	Describe organizational policies and apply them to mitigate employee grievances and settle interpersonal disputes within the laboratory
Proficient	Create and disseminate organizational policies to mitigate employee grievances and settle interpersonal disputes within the laboratory

6. <u>Financial Resource Management:</u> Activities relating to the management of laboratory finances including purchasing, budgeting, inventory, and cost-analysis

6.1 Inventory [10]	
Novice	Outline components needed for laboratory's inventory system based on equipment and supplies
Competent	Analyze and identify optimal inventory systems for laboratory equipment and supplies
Proficient	Implement and maintain an inventory system for laboratory equipment and supplies

6.2 Instrumentation [80]	
Novice	Identify necessary laboratory instrumentation based on the financial and workflow needs of the laboratory
Competent	Analyze the financial and workflow needs of the laboratory and identify appropriate laboratory instrumentation
Proficient	Select and purchase the optimal laboratory instrumentation based on the financial and workflow needs of the laboratory

6.3 Budget [78]	
Novice	Outline the components of a laboratory budget
Competent	Analyze laboratory operations and needs for the development of a laboratory budget
Proficient	Develop and periodically evaluate the laboratory budget

6.4 Budget Evaluation [78]	
Novice	Apply economic analysis principles such as utility, cost-benefit, and effectiveness to the evaluation of laboratory activities
Competent	Apply economic analysis principles such as utility, cost-benefit, and effectiveness to the evaluation of laboratory activities for budget adjustments
Proficient	Evaluate laboratory activities based on utility, cost-benefit, and effectiveness and adjust the laboratory budget accordingly

6.5 Wages and Salary [11]	
Novice	Define laboratory wage rates and salary administration
Competent	Analyze and evaluate laboratory finances for the development of wage rates
Proficient	Create laboratory wage rates and oversee salary administration

6.6 Equipment Maintenance [10]	
Novice	Outline the components of a maintenance program for laboratory equipment
Competent	Apply maintenance procedures for laboratory equipment
Proficient	Create a maintenance program for laboratory equipment

7. Biosafety: A set of procedures, regulations, and policies implemented to prevent the unintended exposure to biological materials and toxins or manage their accidental release [48]

7.1 Biosafety Program [10]	
Novice	Identify the necessary components of a comprehensive laboratory biosafety program, including a biosafety operations manual
Competent	Apply biosafety principles to the development of a comprehensive laboratory biosafety program, including the creation of an operations manual
Proficient	Design and implement a comprehensive laboratory biosafety program, including the creation of a biosafety manual

7.2 Hazard Protocols [39]	
Novice	Identify relevant laboratory hazard communication protocols and signage
Competent	Apply appropriate hazard communication protocols and signage within the laboratory
Proficient	Develop and implement hazard communication protocols and signage

7.3 Risk Assessment [39]	
Novice	Outline risk assessment and management procedures for biological and non-biological substances including medical-legal issues
Competent	Apply risk assessment and management procedures to the handling biological and non-biological substances including medical-legal issues
Proficient	Develop and evaluate risk assessment and management procedures for biological and non-biological substances including medical-legal issues

7.4 Waste Management [47]	
Novice	Outline the necessary components of a laboratory waste management system
Competent	Apply handling, storage, transport, documentation, and disposal procedures of biological and laboratory waste materials
Proficient	Create a system for the handling, storage, transport, documentation, and disposal procedures of biological and laboratory waste materials

7.5 Biosafety Training [10]	
Novice	Identify the components necessary for a comprehensive biosafety training program for all laboratory staff
Competent	Apply biosafety procedures including incident response and reporting within the laboratory
Proficient	Create a biosafety training program for all laboratory staff including procedures for biosafety incident response and reporting

8. **Biosecurity:** Prevent the intentional unauthorized release, theft, or misuse of valuable biological materials through protection, control, and accountability measures [48]

8.1 Biosecurity Training [47]	
Novice	Identify the components necessary for a comprehensive biosecurity training program for all laboratory staff
Competent	Apply biosecurity procedures including incident response and reporting within the laboratory
Proficient	Implement and periodically evaluate a biosecurity training program for all employees

8.2 Biosecurity Plan [47]	
Novice	Identify the components necessary for a comprehensive biosecurity plan in the laboratory
Competent	Apply biosecurity procedures including preparedness, incident management, reporting procedures within the laboratory
Proficient	Implement and periodically evaluate plan for biosecurity including preparedness, incident management, reporting procedures

8.3 Area Access [49]	
Novice	Define who may access areas within the laboratory
Competent	Implement policies that define who may access areas within the laboratory
Proficient	Create clear procedures defining who may access areas within the laboratory

8.4 Materials Access [49]	
Novice	Describe authorization procedures for access to infectious agents and hazardous materials
Competent	Apply authorization procedures relevant to the access to infectious agents and hazardous materials
Proficient	Create specific authorization procedures for access to infectious agents and hazardous materials

8.5 Sensitive Information Management [10]	
Novice	Define sensitive information and identify management procedures of sensitive information, agents, and technology
Competent	Apply guidelines to the management of sensitive information, agents, and technology
Proficient	Develop guidelines for management of sensitive information, agents, and technology and ensure staff compliance

9. <u>Quality Systems:</u> The overall framework of policies, practices, and resources to improve the overall quality of laboratory results reported through quality control and quality assurance procedures [83]

9.1 Quality Systems Training [84]	
Novice	Describe new personnel training and evaluation procedures on testing, quality control, and laboratory safety
Competent	Apply educational testing, quality control, and laboratory safety procedures to new personnel training and evaluation
Proficient	Institute programs for new personnel training and evaluation on testing, quality control, and laboratory safety

9.2 Competency Assessments [84]	
Novice	Describe a laboratory staff recurring competency assessment
Competent	Adapt laboratory scientist competencies to the assessment of laboratory staff
Proficient	Create and implement recurring competency assessments for laboratory staff

9.3 Quality Documentation [41]	
Novice	Outline policies and documentation systems for quality assurance and quality control procedures and describe laboratory regulatory standards
Competent	Apply policies and documentation systems to laboratory quality assurance and quality control procedures in compliance with laboratory regulatory standards
Proficient	Create policies and documentation systems for quality assurance and quality control procedures in compliance with laboratory regulatory standards

9.4 Nonconforming Events [10]	
Novice	Define quality control related nonconforming events and describe documentation systems
Competent	Analyze quality control related nonconforming events and apply appropriate documentation systems
Proficient	Evaluate quality control related nonconforming events and create appropriate documentation systems

9.5 Performance Indicators [49]	
Novice	Describe quality indicators used to monitor and evaluate laboratory performance
Competent	Analyze quality indicators and demonstrate their uses for monitoring and evaluating laboratory performance
Proficient	Implement quality indicators to systematically monitor and evaluate laboratory performance

9.6 Maintenance [14]	
Novice	Outline policies for equipment maintenance, documentation, and supervisory review
Competent	Apply maintenance policies, documentation systems, and supervisory review procedures of maintenance performed within the laboratory
Proficient	Create maintenance policies, documentation systems, and routinely evaluate maintenance performed

9.7 Equipment Donations [14]	
Novice	Describe potential guidelines for acceptable equipment donations
Competent	Analyze relevant information relating to acceptable equipment donations
Proficient	Develop and maintain guidelines for acceptable equipment donations

9.8 Quality Assessment [49]	
Novice	Outline a framework for internal and external quality assessment
Competent	Analyze internal and external quality assessments and their impact on laboratory testing quality
Proficient	Design and routinely perform internal and external quality assessment

9.9 Equipment [84]	
Novice	Describe manufacturer guidelines on laboratory equipment calibration, testing, service, troubleshooting, repair, and decommissioning
Competent	Apply laboratory equipment calibration, testing, service, troubleshooting, repair, and decommissioning procedures
Proficient	Implement laboratory equipment calibration, testing, service, troubleshooting, repair, and decommissioning procedures based on manufacturer guidelines

9.10 Internal Audit [10]	
Novice	Describe the components of an internal audit process
Competent	Implement an internal audit process
Proficient	Evaluate internal audit processes

9.11 External Audit [10]	
Novice	Identify external audit procedures set by accreditation bodies and national regulators
Competent	Describe and apply external audit procedures set by accreditation bodies and national regulators
Proficient	Comply with external audit procedures set by accreditation bodies and national regulators

Means of Verification

This section outlines the necessary materials for verification that the laboratory scientist or director met the competency requirements for certification. Education, work experience, and certification exam results must all be from the MS in which the applicant is applying for certification. The laboratory scientist or director must upload all documents pertaining to education, certification exam, and work to the certification portal.

Materials Needed

- Education: Official transcripts must be sent from all colleges or universities where relevant coursework was completed. If multiple institutions were attended, transcripts from all institutions should be provided. No alternate documents may be submitted in place of an official transcript.
- Certification Exam: If the country the applicant graduated from had a licensing, certification, or other final exam set by the MoH or national laboratory regulators to be considered a licensed medical laboratory scientist, evidence that the individual applied for certification and passed should be submitted as well. If there were multiple attempts to pass the certification exam, only the most recent one needs to be submitted.
- Work Experience: Work experience that happened a maximum of 5 years from the time of application may be submitted to fulfill the requirements for application. A detailed summary of departments worked, job description, and job duties must be submitted along with a letter from a supervisor or manager verifying employment. Qualifications to be considered a supervisor or

manager are the same as those listed for the competency verification below. If multiple jobs were worked, documentation from each individual establishment should be submitted.

Competency Evaluation

Along with the materials listed in the means of verification section above, documentation must be submitted by eligible personnel verifying that the applicant met the competencies outlined about for certification. This section lists the personnel who are qualified to assess the applicant's mastery of the competencies provided above. Both coursework and laboratory experience can be used to fulfill a competency requirement. Since many of the competencies are broad a variety of projects and experiences may be used to evaluate a laboratory scientist or director's skill. It is at the discretion of the verifier to determine if an activity is adequate to asses competency. Along with the competencies document a letter of authenticity should be provided and signed by the individual completing the form, verifying the accuracy of the form [11].

Eligible Personnel

- A general supervisor or professor with a Bachelor's/Master's/Doctorate in medical laboratory science, chemistry, or other physical/biological science, or medicine in addition to one year of training and experience in a high complexity testing environment is eligible to fill out the verification form [13].
- A supervisor or professor with an associate's degree in Medical Laboratory Technology along with two years of laboratory training/experience.
- The years of laboratory training or experience can be met through experiences such as an internship with a medical laboratory, a year of experience performing testing as a generalist or particular specialty within a clinical lab or experience performing testing as a research scientist [13].

Certification System Process

The laboratory certification system is designed to assess a laboratory personnel's competency to work in a variety of laboratories such as clinical, reference and public health. The components of the deliverables section outline the step by step process from educational requirements to competency verification needed to certify laboratory scientists and directors. The certification process a laboratory personnel applying for certification will follow is broken up into the five different steps below (Figure 2).

1) Meet Certification Requirements

First laboratory personnel must identify if they are eligible to apply for certification. The criteria for this can be found within the first section of Chapter 3: Deliverables titled Applicant Qualifications. For laboratory scientists they must either have graduated from an accredited laboratory scientist training program or graduated degree in a biological science with laboratory experience. Similarly laboratory directors should have the relevant combination of education and leadership experience. If laboratory personnel are unsure if they meet the qualifications for certification they should reach out to the regulatory organization.

2) Identify Personnel for Competency Evaluation

Laboratory personnel should identify qualified evaluators to complete their competency assessment. The desired qualifications of an evaluator are listed in the deliverable section titled Personnel Eligible for Evaluation.

3) Apply for Certification

Laboratory personnel should apply for certification using the web-based portal, ideally located on a MS MoH or Independent regulatory organization depending on the country's leadership structure. The application will contain: 1) information on the applicant's demographics 2) education 3) certification exam scores (if the country has an exam) 4) competency assessments 5) competency evaluator information 6) letters of authenticity from the evaluators. Applicants will receive a notification through email that their application has successfully been submitted for review.

4) Review of Application by Committee

A committee within the national regulators will review the application to ensure the applicant has met all the necessary qualifications for certification. Applicants should have earned a competent or proficient in at least 75% of each competency area. The review process can take up to six weeks before applicants are notified of their certification status. Applicants will be able to check their application status through the portal. Their application status while the committee is evaluating their application will display "under review".

5) Certification Status Determined

The applicant will be notified of their certification status through email. The portal will either display "certification granted", "certification denied", or "additional materials needed". "Certification granted" indicates the applicant has successfully met the requirements necessary for certification. The applicant will then be issued an official certificate stating that they are qualified to work within the laboratories of the MS they applied for certification in. "Certification denied" means the applicant was denied from

certification either though ineligibility for certification or some requirement for certification not being met. “Additional materials needed” indicates that more information is needed to determine if the applicant is qualified to be certified. The additional information needed will be listed on the application portal. The applicant should gather the necessary information and resubmit the application for certification. The committee will then review the application again and come to a decision about their certification status.

Chapter Five: Discussion

The Strategic Plan for Laboratory Scientist and Director Certification was designed to outline the components needed for laboratory staff certification. The intended use of the plan is to aid MS laboratory leadership in the development and implementation of their own certification systems. The system verifies laboratory scientists and directors ability to work in a variety of laboratory settings including diagnostic, reference, and public health laboratories. The program implementation's desired impact is qualified laboratory workforce certification.

Public Health and Policy Implications

Post implementation, certification of qualified laboratory scientists would increase output of accurate laboratory results, decrease staff turnover, increase clinician faith in laboratory personnel in traditional diagnostic labs [6]. Competent laboratory directors would effectively advocate for laboratory needs, improve workflow processes, and improve relations with healthcare stakeholders [1]. However, it is important to acknowledge that a laboratory scientist certification system's implementation does not directly lead to qualified laboratory workforce certification. The outcomes of the plan are contingent on stakeholder investment and adequate regulatory infrastructure.

Historically laboratory science development programs have been a low priority and received little funding within MS [1]. A majority of MS strategic plans mentioned laboratory scientist education and competency assessment [7]. However, since laboratory scientist training and assessment has been ignored among African nations, it is difficult to gauge the interest MS leadership will have in certification systems [15]. The cost of integrating the laboratory certification system into existing guidelines and disseminating

them at the regional level may be too great or be seen as poor resource application. When applying for external funding, international donors may have their own programs and agendas for laboratory scientist certification and securing implementation funding may be difficult.

Process implementation requires strong laboratory leadership that may not be present in all MS (Table 1). It may be necessary to invest resources in national leadership establishment before adding a certification system. Within MS that already have laboratory certification procedures, the plan may be modified to strengthen the existing system.

Post-implementation, the benefits of a laboratory scientist or director certification system have never been directly evaluated. Due to this lack of information, it is difficult to assess the impact this system will have within AU MS. However, a comparison can be made between a laboratory staff certification system and laboratory operations accreditation processes. The successful accreditation processes utilization in various MS has resulted in laboratory infrastructure strengthening [56]. Although laboratory accreditation focuses on infrastructure as opposed to training, parallels can be made between how increased regulation results in better laboratories.

Strengths and Limitations

The main system strength is that it provides a tangible way to verify that laboratory scientists and directors possess the skills needed to staff AU MS laboratories. The competencies are comprehensively designed to assess laboratorians skills to work in a variety of settings including public health, clinical, and reference laboratories. This is especially important as a majority of laboratory development is focused on infrastructure, while laboratory workforce development is often neglected. These were the first competencies created for AU laboratory professional certification. Other competency literature targets laboratory staff education or on the job assessment. Certification provides tangible recognition of laboratory staff skill sets as well as sets scientist and director competency standards for laboratories and training programs. Many published laboratory standards are also designed for broad modification and use within countries but have never been specific assessment through a national system. This plan aims to mitigate that barrier by providing competencies within a certification system along with recommendations for adoption by a MS.

Although the plan provides a unique system for assessing laboratory staff competency, limitations within the context may hinder utilization of these guidelines as intended. Due to the lack of accessible information on MS laboratory training programs, certification exams, and certification qualifications the guidelines may be incomplete. The information unavailability on laboratory technology and testing performed within AU, some of the standards may not be applicable. To ensure contextual appropriateness, we recommend the competencies be validated by implementing MS experts.

Additionally, the applicant qualifications section of the deliverables also includes graduation from an “accredited” institution for both laboratory scientists and directors. In MS there are not always accreditation processes for laboratory staff training programs and in those that do, institutions do not always apply for accreditation. This could exclude a proportion of competent scientists from applying who did not graduate from an accredited institution.

This is the first set of competencies developed to encompass the qualifications necessary to work in all types of labs in AU MS and therefore some standards are not generalizable. Since the system is designed to encompass clinical and public health laboratory scientist competencies, some general testing skills such as hematology or blood banking are not applicable to those working in public health laboratories. As these guidelines cover all possible areas of laboratory sciences, scientists without a degree in medical laboratory sciences who only worked one specialty such as chemistry cannot meet the competency requirements for certification. Depending on the MS laboratory workforce structure, the certification system should expand to include specialty certifications assessing laboratory personnel competency within a certain lab area, including public health.

These guidelines also do not contain information on how a laboratory scientist or director that has moved from another country should apply for certification. Since laboratory certifications are not valid across countries, processes for immigrant certification should be developed. In the future, the system should be modified to include a process for international laboratory professional certification.

Many laboratory directors are usually laboratory scientists or technicians promoted with little formal training or experience, therefore competency assessment may be difficult. As there are few established laboratory leadership training programs, directors may find it difficult to gain the necessary certification skills. Within smaller or more rural laboratories, directors may be unable to gain all the relevant competency experience. It may also be challenging for laboratory directors to demonstrate their competence with softer skills such as fostering collaborations between laboratory and internal/external stakeholders. This could be addressed by connecting interested but underqualified laboratory directors with appropriate mentorship and higher education programs to gain the competencies necessary for certification.

Aside from the competencies themselves, there is flexibility for interpretation throughout the verification process of the competencies as there are multiple ways to demonstrate expertise in a certain skill. For example, there are numerous ways to demonstrate ability to use problem solving and critical thinking principles to improve work processes. There is also inherent bias across what activities various verifiers deem as relevant problem-solving experience and what activities are acceptable. There will always be some variation within the skill levels of certified laboratory directors. The criteria for personnel eligible for competency verification in the verification section was designed to help mitigate this. Post pilot of this program in a few MS supplementary documents should be developed detailing examples of suitable activities for each skill level to ensure more accurate assessments of laboratory staff skills.

Recommendations for Implementation

The purpose of the Strategic Plan for Laboratory Scientist and Director Certification was to outline the components for a national laboratory staff assessment system. The plan's intended use was to become a tool maintained by an international leadership such as ASLM or Africa CDC. International-level leadership will both contribute to the sustainability of certification systems as well as the institutionalization of the certification systems. international leadership was shown to harmonize and prioritize laboratory infrastructure, among AU MS strategic plans [7]. International leadership has been shown to facilitate program implementation and sharing within AU states [7]. Part of international regulators responsibility is to advocate for the importance of laboratory staff certification to MS and help them understand the benefits of an institutionalized system. A successful international-member state partnership example was the WHO-Afro SLIPTA. The projects substantially strengthened laboratory operations through structured accreditation processes and demonstrates how international oversight of the implementation process can help MS achieve certification of a qualified laboratory workforce.

The successful MS addition of a laboratory staff certification system will involve a commitment from laboratory leadership, country-specific validation, identification of funding sources, and the creation of an integration plan within existing infrastructure (Figure 3). These components are vital to ensuring adequate personnel and resources are available for the implementation of a contextually appropriate certification system in a MS. The desired outcome is the institutionalization of a sustainable system, that will ultimately certify a qualified laboratory workforce within the MS (Figure 3).

Implementation Inputs

The strategic plan was developed based on material from international organizations and western certification systems because of the laboratory scientist competencies and certification information shortage. There are numerous differences in laboratory infrastructure, staff education, and regulation within AU MS (Table 1). To account for these discrepancies, the competencies should be validated for the specific MS prior to implementation. Documents such as the CDC and APHL's Competency Guidelines for Public Health Laboratory Professionals, have guidelines that were developed and validated through an extensive review by 170 domain specific experts identified by the CDC and APHL[9]. The strategic plan should be evaluated by a similar process where specific areas are reviewed by experts in a certain competency area such as biosafety or blood banking. To ensure the guidelines are contextually appropriate for the target audience, a majority of the expert reviewers should be from the implementing MS and the AU.

Another essential input for the implementation of a certification system is the commitment of laboratory leadership. Laboratory science in the AU is regulated within by a department within the MoH or an independent organization [85]. Within these departments there are personnel who oversee the certification and training of laboratory staff. Their buy in to the benefits of a certification system is critical for guideline adoption along with the sustainability, and institutionalization of the certification systems (Figure 3). For laboratory programming within the AU, stakeholder acceptance is key to advocating the need and importance of laboratory development [86]. Committed leadership results in support from development partners, laboratory strengthening, and professional

development [56]. Although stakeholder commitment has been shown to improve program implementation and sustainability, there are a few assumptions the output is contingent. Stakeholders must be available and willing to dedicate time for the entirety of the implementation process as well as secure the necessary resources for the program. Stakeholder commitment to laboratory staff certification will aid in adoption and contribute to the sustainability and institutionalization of the system (Figure 3).

One of the most critical inputs is a plan for implementation of the certification system. Implementation will outline integration of the competencies with any existing competency requirements within the MS along with a timeline. Although there are numerous components that should be included in a plan for implementation there are a few key areas to be considered. The plan should contain a process for the modification of the application and uploading of the web-based portal to the MS regulatory website. If the country already had a certification process, the plan should outline integration of the competencies with the existing infrastructure. Similarly, if the MS has established re-certification and continuing professional development programs, those processes should be continued with the integration of the new system. A committee must also be established charged with reviewing and updating the status of certification applications. Depending on the laboratory leadership structure within the MS the committee can be part of the ministry of health or an independent organization (Table 1). Another component of the implementation plan should outline funding for system implementation and maintenance to ensure sustainability. Western countries charge a fee while application for certification and is something to be considered when developing a plan for funding [11, 20]. Post-implementation indicators for assessing the utilization, sustainability, and

institutionalization of the program should be developed as well. A concrete plan outlining competency integration, personnel recruitment, funding, and dissemination must be developed prior to certification system addition.

Outputs

Expert validation of the laboratory staff certification system will result in a contextually appropriate process. Along with system validation, stakeholder commitment to the implementation process will translate to personnel willing to oversee the country's certification system adoption. These personnel are essential for system integration, development, and dissemination oversight. The last output necessary for MS system adoption is a clear process for implementation that MS personnel will utilize. The process will include a timeline for addition, necessary system integration resources and personnel, and clear funding mechanisms.

Outcomes

The desired plan outcome is the adoption and institutionalization of the certification system within a MS. The more stakeholders are committed to the plan's adoption the higher institutionalization and sustainability probability. This is because laboratory leadership will be able to advocate for the continued use and expansion of the system post-implementation [56]. The general competency contextualization outlined in the plan will also contribute to system sustainability [87]. The plan's sustainable practices include a long term funding source and dissemination systems to encourage laboratory staff application, if implemented correctly will add to the longevity of the system [1].

Implementation

Upon implementation, the plan's desired impact is the certification of a qualified laboratory workforce within the MS. As stated earlier, the implementation of a certification system does not directly translate to laboratory staff certification. There are numerous political and infrastructural reasons why the system is not utilized. To address this, the assumption is that laboratory stakeholders overseeing implementation, disseminate the guidelines widely enough that laboratory scientists and directors are motivated to apply for certification. Dissemination involves raising awareness at the laboratory facility and institution levels about the benefits of the certification process. This will theoretically increase laboratory's willingness to hire certified staff and, personnel's interest in applying for certification.

Conclusion

Laboratory development has always a neglected area within health systems strengthening. Although progress has been made with landmark programs such ASLM and SLIPTA/SLMTA establishment, laboratory workforce development remains a neglected area. The strategic plan for laboratory staff outlines the components of a laboratory staff competency assessment system. The plan was created specifically for implementation in AU MS. Currently poorly structure training programs, inadequate regulation, and resource deficiencies contribute to trained laboratory staff shortages among African Nations. Ultimately there were 11 and 8 competency areas identified for laboratory scientists and directors respectively broken down by competencies and activities. A certification system will provide official verification of laboratory personnel qualifications to work in MS laboratories and help set competencies across the field. The strategic plan's longterm desired impact, is the certification of a qualified laboratory workforce across MS.

Glossary

Accreditation	The process in which an organization is publicly notified of meeting the competence and credibility standards for a service or product. Accreditation is achieve though national regulators that adhere to international standards or national recognition of laboratory quality [88]
Audit	A methodical examination and review of a process or procedure performed both within laboratories and by national regulators [89]
Biobank	A storage area for biological samples (such as human tissue, blood, or DNA) that may be used, especially for future medical research [89].
Certification	A procedure by which a third party provides assurance that a product, process, individual, or service conforms to specific requirements [10].
Clinical laboratory	A facility that performs laboratory testing on specimens obtained from humans for the purpose of providing information for health assessment, diagnosis, prevention, or treatment of disease [90].
Critical results	A test result that was generated by a section within a laboratory that met a laboratory's local threshold for a critical result and must be rapidly communicated [91].

Competency	A combination of knowledge, skills, and abilities necessary to effectively perform a task [10].
Core laboratory functions	The essential roles assumed by a laboratory that underlie the laboratory's ability to support health [52].
Health hazard	A danger or source of danger that has the potential to cause harm to the health of an individual [47].
Laboratory director	An individual with sufficient experience and expertise to direct or supervise a public health laboratory in one or more laboratory specialties [92]. Responsibilities include creating, supervising, and consulting on laboratory testing, services, and operations within public health laboratories [80].
Laboratory information system	A data management system, most often computer based that aids in the management of aspects of a medical laboratory including specimen inputting, processing, and quality control [93].
Laboratory scientist	An individual able to perform moderate-high complex public health laboratory testing that protects humans against public health threats from infectious diseases, environmental hazards, hereditary disorders, and human and natural emergencies [92]. Synonyms or similarly qualified personnel titles include medical technology, medical laboratory scientist, and medical technician.

Licensure	The granting of permission by a competent authority to an organization or individual to engage in a practice or activity [50].
Nonconforming event	A quality control result that does not align with the quality control standards of the laboratory [50].
Public health laboratory	A laboratory that provides laboratory services for the public health system including clinical diagnostic testing, disease surveillance, and advanced skills in laboratory practice [94].
Reference laboratory	A laboratory that laboratories refer specimens to for testing. Synonyms include national reference laboratory and national reference center [88].
Regulation	A standard for a process or activity set by a governmental or authoritative body [50].
Risk Assessment	Assessing the potential failure points, severity of consequences, probability of adverse event occurrence, and detection of a system to determine essential control points [50].
Sensitive information	Directly and indirectly identifiable information pertaining to an individual or an organization that should not be made public in order to maintain information security [93]
Stakeholder	A person or organization that can be effected by, affect, or has

	interest or concern regarding a decision or action [8].
Standard	An established rule, guideline, or characteristic for activities or their outcomes that were set by an established consensus and approved by a recognized body with the goal of achieving optimum practice in a given context [10].
Waste management	The management and disposal activities of hazardous, clinical, biological, and electrical waste material generated in a laboratory [48]
Westguard rules	A set of statistical procedures established by James O. Westguard that are used by laboratories for quality control activities [42]

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Appendix

Figure 1: The Cyclic Nature of a Poorly-trained Laboratory Workforce, 2020

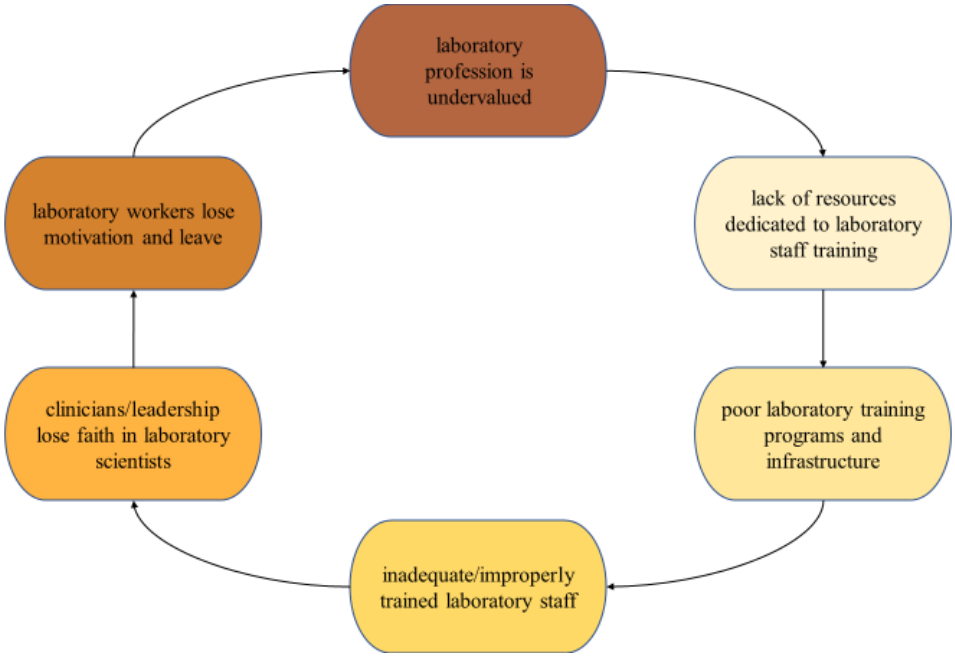

Table 1: Laboratory Regulation within African Union Member States, 2020

Country	Laboratory Leadership Organization	Regulatory Organization	Governmental Department
Republic of Benin			Department Responsible for Laboratory and Other Sectors [7]
Republic of Botswana	Botswana Institute for Clinical Laboratory Professionals [1]	Botswana Health Professions Council [1]	
Burkina Faso			Department of Laboratories [7]
Republic of Burundi			Department Responsible for Laboratory and Other Sectors [7]
Republic of Cameroon	Cameroon Association for Medical Laboratory Scientists [7]		Department Responsible for Laboratory and Other Sectors [7]
Central African Republic			Department Responsible for Laboratory and Other Sectors [7]
Republic of the Cote d'Ivoire			Department Responsible for Laboratory and Other Sectors [7]
Arab Republic of Egypt	Egyptian Society of Laboratory Medicine [95]		
Federal Democratic Republic of Ethiopia	Ethiopian Medical Laboratory Association [1]		Federal Ministry of Education-Medical and Health Science Training Institution [1]
Republic of the Gambia			Department Responsible for Laboratory and Other Sectors [7]
Republic of Ghana	Ghana Association of Biomedical Laboratory Scientists [1]	Allied Health Professions Regulatory Council [1]	
Republic of Guinea			Department Responsible for Laboratory and Other Sectors [7]
Republic of Kenya	Association of Kenya Medical Laboratory Scientific Officers [85]	Kenya Medical Laboratory Technicians and Technologists Board [1]	Multiple Departments within the Ministry of Health [7]
Republic of Liberia			Multiple Departments within the Ministry of Health [7]
Republic of Madagascar			Department Responsible for Laboratory and Other Sectors [7]
Republic of Malawi		Medical Council of Malawi [1]	
Republic of Mauritania			Department Responsible for Laboratory and Other Sectors [7]
Republic of Mozambique			Multiple Departments within Ministry of Health [7]
Republic of Namibia			Multiple Departments within the Ministry of Health [7]
Republic of Niger			Department Responsible for Laboratory and Other Sectors [7]
Federal Republic of Nigeria	Association of Medical Laboratory Scientists of Nigeria [96]	Medical Laboratory Sciences Council of Nigeria [1]	
Republic of Rwanda	Rwanda Association of Biomedical Laboratory Technologists [97]		
Saharawi Arab Democratic Republic			
Republic of Senegal			Laboratory Directorate [7]
Republic of Sierra Leone			Laboratory Directorate [7]
Republic of South Africa	Society of Medical Laboratory Technology of South Africa [98]		
Republic of South Sudan			Ministry of Health [7]
Kingdom of Swaziland			Multiple Departments within the Ministry of Health [7]
United Republic of Tanzania	Medical Laboratory Scientists Association of Tanzania [99]	Health Laboratory Practitioners Council and Private Health Laboratories Board [1]	
Republic of Uganda	Uganda Medical Laboratory Technology Association [100]	Allied Health Professions Council [1]	
Republic of Zambia	Biomedical Society of Zambia [101]		Multiple departments within Ministry of Health [7]
Republic of Zimbabwe		Medical Laboratory and Clinical Scientists Council of Zimbabwe [102]	

[1] No regulatory bodies found for Tunisian Republic, Togolese Republic, Sudan, Republic of Seychelles, Democratic Republic of Sao Tome and Principe, Republic of Mauritius, Kingdom of Morocco, Republic of Mali, Libya, Kingdom of Lestho, Republic of Guinea Bassau, Gabonese Republic, Republic of Equatorial Guinea, State of Eritrea, Democratic Republic of Congo, Republic Of Djibouti, The Republic of Chad, Union of the Comoros, Republic of the Congo, Republic of Cabo Verde, People's Democratic of Algeria, Republic of Angola, Somali Republic

Table 2: African Union Laboratory Scientist 4-Yr Curriculum, 2020

Year	First Semester	Second Semester
Yr 1	Communication and Counseling Skills Computer applications Behavioral Science Principles of Ethics and Integrity Applied Biology Applied Mathematics Applied Physics Applied Chemistry Entrepreneurship Introduction to Medical Laboratory Sciences	Human Anatomy I Medical Physiology I Biochemistry I Basic Immunology Bioinstrumentation and Principles of Quality Assurance Introduction to Community and Community Diagnosis Principles of Epidemiology I Principles of Nursing and First Aid Skills Biostatistics Research Methods
Yr 2	Human Anatomy II Medical Physiology II Biochemistry II Pharmaceutical Microbiology Basic Pharmacology Clinical/Applied Immunology Basic Parasitology and Entomology Genetics	Histopathology I Hematology I Clinical Chemistry I Laboratory Construction and Management Principles of Molecular Biology, Biotechnology, and Bioinformatics Experimental Animal Science Public Health Microbiology Systemic Pharmacology Principles of Epidemiology II
Yr 3	Immunopathology Parasitology I Microbiology I Clinical Chemistry II Histopathology II Hematology and Blood Transfusion II Chemotherapy and Therapeutics Practical Placement/Internship I	Microbiology II Parasitology II Clinical Chemistry III Hematology Blood Transfusion III Project Management General and Systemic Pathology Practical Placement II Health Management & Health Economics Research Methods II Internship I
Yr 4	Microbiology III Histopathology IV Parasitology III Clinical Chemistry IV Hematology and Blood Transfusion IV Toxicology and Forensic Medicine Practical Placement III Research Project Proposal	Microbiology V Hematology Blood Transfusion V Clinical Chemistry V Histopathology IV Human Molecular Genetics and DNA Technology Education Methods Laboratory Ethics and Medico-legal Issues Project Report

Figure 2: Example Laboratory Personnel Application Process for Certification, 2020

Figure 3: Implementation Science Logic Model of Strategic Plan for Laboratory Scientist Certification, 2020