World Health Organization

REGIONAL OFFICE FOR Africa

WHO Guide for the Stepwise Laboratory Improvement Process Towards Accreditation in the African Region

(with checklist)

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ABBREVIATIONS

AFENET	African Field Epidemiology Network
AIDS	Acquired Immunodeficiency Syndrome
AMREF	African Medical and Research Foundation
APLAC	Asia Pacific Laboratory Accreditation Cooperation
ASCP	American Society for Clinical Pathology
ASLM	African Society for Laboratory Medicine
CAP	College of American Pathologists
CDC	Centers for Disease Control and Prevention (United States)
CEN	European Committee for Standardization
CGH	Center for Global Health (of CDC)
CHAI	Clinton Health Access Initiative
CLSI	Clinical and Laboratory Standards Institute
CMLF	Caribbean Med Labs Foundation (Trinidad)
EQC	External Quality Control
FEFO	First-Expiry-First-Out
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
IAAC	InterAmerican Accreditation Cooperation
IAG	Independent Advisory Group
IEC	International Electrotechnical Commission
IEG	Independent Evaluating Group
ILAC	International Laboratory Accreditation Cooperation
IQC	Internal Quality Control
ISO	International Organization for Standardization
IST	Intercountry Support Team
IT	Information Technology
KENAS	Kenya Accreditation Service
KIT	Royal Tropical Institute (The Netherlands)
KMTTB	Kenya Medical Laboratory Technicians and Technologists Board

LoA	Letter of Agreement
LQMS	Laboratory Quality Management System
MoH	Ministry of Health
MoPH	Ministry of Public Health
MoU	Memorandum of Understanding
NCCLS	National Committee for Clinical Laboratory Standards (former name of CLSI)
NIH	National Institutes of Health (United States)
PCR	Polymerase Chain Reaction
PPD	Pharmaceutical Product Development
PPE	Personal Protective Equipment
PT	Proficiency Testing
QC	Quality Control
QMS	Quality Management System
QSE	Quality System Essential
RC	Regional Committee
SADCAS	Southern African Development Community Accreditation Service
SANAS	South African National Accreditation System
SLIPTA	Stepwise Laboratory Improvement Process Towards Accreditation
SLMTA	Strengthening Laboratory Management Towards Accreditation
SOP	Standard Operating Procedure
TAT	Turnaround Time
TB	Tuberculosis
ToR	Terms of Reference
UPS	Uninterrupted Power Source
USAID	United States Agency for International Development
WHO	World Health Organization
WHO-AFRO	World Health Organization Regional Office for Africa
WHO-SEARO	World Health Organization Regional Office for South-East Asia
ZINQAP	Zimbabwe National Quality Assurance Programme

FOREWORD

Laboratory services form an essential component of the health services, requiring constant update and strengthening for improved testing, epidemiological surveillance, research and other related activities. Laboratories within the African region need to expand in support of scaling-up disease prevention and control services. However, most laboratories in the region are not only poorly resourced but also operate within a limited capacity.

Cognizant of these weaknesses, the WHO/AFRO strategic direction priorities for 2010–2015 highlighted the importance laboratory quality services through partnerships and harmonization of technical support to countries to accelerate actions on HIV/AIDS, malaria and tuberculosis.

Over the past five years, a number of key resolutions, declarations and initiatives have brought laboratory systems strengthening to the forefront of health systems strengthening. The Resolution AFR/RC58/R2 (2008) called for strengthening of public health laboratories in the African Region. The Maputo Declaration focused on integrated laboratory support for major diseases and urged Member states to develop and implement national laboratory policies and strategic plans.

The WHO AFRO Stepwise Laboratory Accreditation preparedness scheme was launched in Kigali in 2009.

These initiatives led countries to actively invest in strengthening their laboratories. Furthermore they adopted quality assurance and management tools for their readiness for enrollment in the WHO AFRO Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA).

In July 2011, key stakeholders for SLIPTA were brought together in Nairobi, Kenya, to reach consensus on the WHO AFRO SLIPTA Policy Guidance and Checklist documents. This framework for improving quality of public health laboratories in the African region aimed at achieving ISO 15189 standards. Based on the principles of affordability, scalability, measurability, and accessibility, SLIPTA promotes country ownership of the process and sustainability of the improved quality of the laboratories.

It is my pleasure to note that a significant number of laboratories are now enrolled in the process and have started implementing SLIPTA. These SLIPTA-empowered laboratories are making marked improvement in accurate and timely diagnosis of disease and patient care, transforming the landscape of health systems, one laboratory at a time.

We look forward to working with our partners, including the African Society for Laboratory Medicine (ASLM), the Clinton Health Access Initiative, and the US Centers for Disease Control (CDC), to continue to promote WHO AFRO SLIPTA throughout the region and turn the tides on laboratory systems in the Region.

Dr Luis Gomes SAMBO
Regional director

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1. BACKGROUND

1.1 Introduction

Public health systems in sub-Saharan Africa have long remained fragile due to fundamental limitations and lack of prioritization of human, financial and training resources; laboratory infrastructure; and resource and management capacity. Of the 340 accredited laboratories in Africa, only 28 (8.2%) are in sub-Saharan Africa; the other 312 primarily private laboratories are located in South Africa. Sub-Saharan Africa has a population of more than 800 million, the majority of whom rely on government services for health care. The increasing burden of priority diseases such as HIV, tuberculosis and malaria in the Region continues to challenge the weak existing systems. Public health programmes have encountered challenges linked to the lack of reliable laboratory support, disease diagnosis, and management of patient care.

1.2 Purpose, target and structure

The purpose of this document is to provide guidance for using the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA). It describes key elements of the laboratory quality improvement process and details how Member States and partners can implement this initiative for strengthening laboratory systems.

The document is intended for use by policymakers; ministries of health; government and management officials; public health and medical professionals; laboratory technicians; clinicians; technical experts; laboratory and programme managers; and international, regional and local partners.

The World Health Organization Regional Office for Africa (WHO AFRO) will follow the policy and guidelines outlined in this document. The Regional Office will work with the Independent Evaluating Group (IEG) Secretariat, ministries of health (MoH), and other key partners to oversee the management of SLIPTA to strengthen national health laboratory services.

The guidelines contain seven parts. Part 1 includes the background, purpose and scope. It describes the background of public health systems in Africa; defines and clarifies technical terms; and discusses the role of WHO in laboratory quality management strengthening and accreditation. Part 2 describes the origins of the SLIPTA initiative; presents background in the form of WHO key declarations and Regional Committee resolutions on strengthening laboratory quality management systems; and discusses SLIPTA governance and stakeholder roles and responsibilities. Part 3 gives an overview of the SLIPTA audit as well as the SLIPTA tiers of recognition of laboratory quality management. Part 4 describes eligibility and consideration for SLIPTA enrolment and the application process. Part 5 describes the audit visit, evaluation criteria categories and SLIPTA checklist. Part 6 details the decision-making and awarding of recognition; follow-up audit for continued improvement; and the appropriate use of recognition certificates. Part 7 presents SLIPTA operational issues including costs; issues management; monitoring of auditor performance; and release of audit reports.

Bibliographic references that were used to support the preparation of the guidelines are provided in Annex 1.

1.3 DEFINITIONS

For the purpose of this policy, the following definitions are used to clarify terms used herein.

Standard. A standard is an authoritative "document" setting forth criteria for performance and characteristics (RHUD1.7CD/CLSI). Standards may be issued by national, regional, or international standards bodies. The most widely accepted international standards are issued by the International Organization for Standardization (ISO), a federation of national standards bodies from more than 140 countries. ISO standards are formulated by technical committees.

In the case of medical laboratories, the most applicable standard is ISO 15189:2007, "Medical Laboratories—Particular requirements for quality and competence," for use by medical laboratories in developing their quality management systems (QMSs) and assessing their own competence, and for use by accreditation bodies in confirming or recognizing the competence of medical laboratories. Accreditation audit based on ISO 15189 evaluates a laboratory's QMS; technical competence; and ability to provide reliable and accurate test results.

Standardization bodies. Standardization bodies have the authority to develop standards. They can be national or international. The ISO is the world's largest developer of international standards, including the most common standard used by medical laboratories (i.e. ISO 15189), as well as ISO 17025 widely used by food safety or environmental laboratories. ISO is used to compose national standardization bodies. National standardization bodies can develop national standards or adopt international standards with or without modifications. The European Committee for Standardization (CEN) is an example of a regional standardization body with a technical cooperation agreement with ISO.

Licensure. Licensure is the granting of ability to practise. It is most often provided by a governmental agency, and is usually based on demonstrated knowledge, training and skills. Generally when laboratory licensure is used, it is a legal requirement for operation. Licensure criteria often include quality requirements. Licensure is normally a mandatory process described in national laboratory regulations.

Certification. Certification is a procedure by which a third party gives written assurance that a product, process or service conforms to specific requirements. Reference: ISO/IEC 17000:2004. Certification is also often a voluntary process. SLIPTA will certify progress in quality improvement of laboratories.

Certification bodies. Certification bodies are organizations or agencies with the authority to inspect a facility and provide written evidence of its compliance with regards to a standard. In the context of SLIPTA, this is an independent advisory body that will issue certificates recognizing the level of improvement based on audits using the WHO SLIPTA checklist for the African Region aligned with ISO 15189/17025.

Accreditation. Accreditation is a procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks. Reference: ISO 15189.

Laboratory accreditation is a process that employs independent external assessment to determine conformity with recognized standards for quality management systems (QMSs) and competent laboratory practice. Accreditation is a validation process established to ensure that medical laboratories deliver high quality services that meet the needs and requirements of their clients. The intent of the SLIPTA is to improve performance and reliability of laboratories to eventually meet the standards required for application towards accreditation.

The difference between accreditation and certification may be illustrated by a clinical laboratory having a management system that is **certified** as conforming to ISO 9001 while being **accredited** to conduct testing of patient samples by meeting the requirements of ISO 15189.

Accreditation bodies. Accreditation bodies are organizations or agencies with the authority to inspect a facility and provide written evidence of its competence with regards to a standard. Many of them accredit medical laboratories using ISO 15189/17025 standard with or without national adaptation. Accreditation bodies usually require their own accreditation status to ISO 17011:2004 "Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies". This International Standard specifies the general requirements for accreditation bodies.

1.4 WHO ROLE

WHO has a normative role; provides guidance on the appropriate selection and use of standards; and promotes and monitors implementation of standards. WHO has developed standards to accredit specific tests performed by laboratories selected to undertake surveillance of disease-specific activities. In this capacity, WHO acts both as the standardization and accreditation body. However, these WHO standards are very technical and very limited in scope; they do not cover the entire quality management system of the laboratory as described by ISO 15189/17025.

The publication and implementation of ISO 15189/17025 as the gold standard to accredit medical laboratories has dramatically changed the accreditation landscape in the past decade. As a result, many accreditation systems coexist at national level, with a wide range of models and systems.

International organizations like ISO share the same mandate for setting standards or monitoring compliance, and national accreditation bodies often form regional or international bodies such as the Asia Pacific Laboratory Accreditation Cooperation (APLAC), the InterAmerican Accreditation Cooperation (IAAC) or the International Laboratory Accreditation Cooperation (ILAC). These organizations have a significant role in the international recognition of the accreditation of laboratories according to ISO 15189/17025.

In this context, many partners, donors and countries expect WHO to provide some guidance with regards to both accreditation and strengthening quality management. Thus, in 2007, WHO-SEARO published Guidelines on Establishment of Accreditation of Health Laboratories. Also, in 2009, WHO, in cooperation with CDC and CLSI, published a training package on laboratory quality management systems (LQMSs) that has been used by countries for training laboratory managers and other staff in the implementation of quality systems.

2. Origin and Governance

The WHO Guidelines for the Stepwise Laboratory Improvement Process Towards Accreditation in the Africa Region (SLIPTA) provides a framework for countries in their efforts to strengthen national laboratory services through fulfilment of the requirements in the ISO 15189 standard. The SLIPTA guidelines are in accordance with WHO core functions to set standards and norms and to support countries to implement them. This process is intended to encourage, support and recognize the implementation of quality management systems (QMSs) in medical laboratories in the African Region so that laboratories provide safe, timely and accurate results for patient care and public health purposes.

Laboratories working through the programme will progressively develop compliance towards this standard and ultimately be able to apply for accreditation from a nationally, regionally or internationally recognized body.

SLIPTA is a comprehensive approach to strengthen national health laboratory services in a stepwise manner by providing graduated levels of performance recognition towards long-term fulfilment of the ISO 15189 standard. SLIPTA provides a pathway that recognizes conformity over time by breaking down the process into a series of specific implementation-friendly stages. SLIPTA recognizes laboratories where they are in the process of quality improvement; supports them through audits and technical assistance from an independent evaluating group (IEG); and tracks and rewards progress towards obtaining these accreditation standards.

The process is expected to have a catalytic effect by encouraging quality improvement in individual laboratories; incorporating these goals into national strategic and operational plans; sensitizing policy-makers and laboratory staff on accreditation; and nurturing development of laboratories in the African Region.

Laboratories will be audited against laboratory standards outlined in the WHO SLIPTA Checklist for the African Region and will be recognized as operating at one of the levels of performance demonstrated by a star rating. When a laboratory applies for accreditation, the WHO Regional Office and partners will send auditors to inspect that laboratory and advise on any technical measures that need to be implemented in order to improve quality management standards.

2.1 KEY DECLARATIONS AND RESOLUTIONS

The joint conference on laboratory quality management systems (LQMSs) was convened in Lyon, France in April 2008 by WHO and the US Centers for Disease Control and Prevention (CDC). the following statement was issued in support of a stepwise, standards-based process towards internationally-recognized accreditation: “It is recommended that countries with limited resources consider taking a staged approach, where principal requirements for all are stated in the national laboratory standards as a minimum requirement, while more advanced and national reference laboratories are encouraged to aim at meeting internationally accepted standards such as ISO 15189.”

In Kigali, Rwanda, July 2009, the WHO Regional Office for Africa, in collaboration with CDC, the Clinton Health Access Initiative (CHAI), the American Society for Clinical Pathology (ASCP) and other partners, launched SLIPTA in the presence of government health officials from 13 African countries. The Strengthening Laboratory Management Towards Accreditation (SLMTA) training programme was also introduced in Kigali as a preparatory initiative to ready laboratories for SLIPTA. From late 2009 through 2010 SLMTA has been active in nine countries in sub-Saharan Africa.

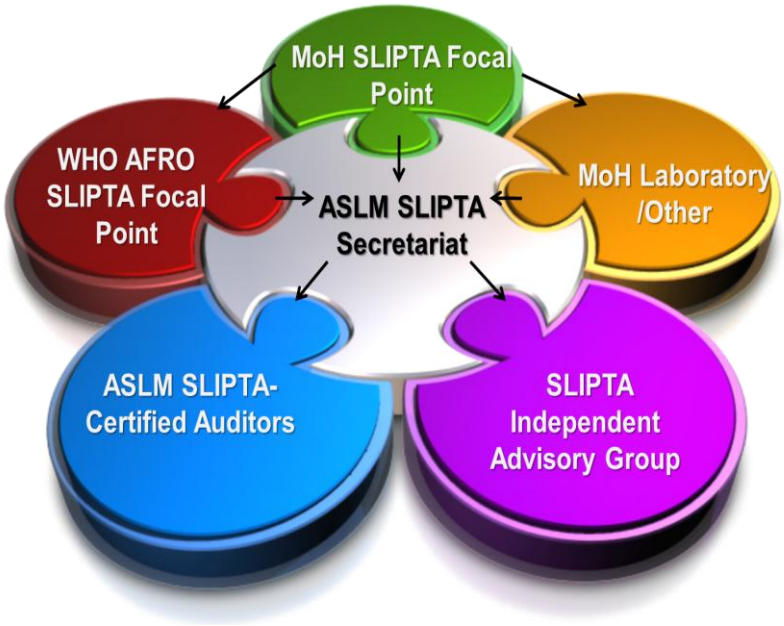
At the Fifty-eighth session of the WHO Regional Committee for Africa (held in Yaounde, Cameroon, September 2008) and the fifty-ninth session (held in Kigali, Rwanda, September 2009) Member States adopted Resolutions AFR/RC58/R2 and AFR/RC59/R4, respectively, calling for capacity strengthening of public health laboratories and centres of excellence to improve disease prevention and control.

2.2 GOVERNANCE

Recognizing that WHO is not an accrediting or implementing body, partner(s) will be identified to implement the Guidelines for SLIPTA. A memorandum of understanding (MOU) will be established between the WHO Regional Office for Africa and the IEG that will allow the IEG to implement the SLIPTA. The IEG will identify a Secretariat and establish a SLIPTA independent advisory group (IAG) comprised of regional and international experts in laboratory quality management systems and accreditation who will oversee the coordination and implementation of the process.

The SLIPTA implementation structure is comprised of the following stakeholders: the WHO Regional Office for Africa, ministries of health and applicant labortories, SLIPTA IEG Secretariat, SLIPTA IEG auditors, SLIPTA IEG IAG, and αdditional partners (see Figure 1).

Figure 1: Stakeholder governance structure



2.3 STAKEHOLDER ROLES AND RESPONSIBILITIES

In order for SLIPTA to be effective, various responsibilities have been assigned as appear in the following lists.

SLIPTA Point of Contact in the WHO Regional Office for Africa:

- Provides guidance on content and implementation as outlined in the SLIPTA Policy and Procedures (initial review and annual review), technical annexes and related documents;
- Reviews and updates the WHO SLIPTA Checklist for the African Region and keeps it closely aligned with appropriate internationally recognized standards;
- Convenes meetings and workshops with stakeholders;
- Oversees the identification of IEG members and coordinates the signing of MoUs between the Regional Office and IEGs;
- Monitors the stepwise process and identifies areas for improvement;
- Contributes to the training of auditors;
- Supports the development of an implementation component for laboratory quality improvement as part of the country's strategic plan;
- Develops and implements a communication strategy that advocates and disseminates information to all countries about the WHO Guidelines for SLIPTA in the African Region.

Ministries of Health:

- Designates a focal point responsible for coordination, information-sharing and implementation;
- Develops an implementation plan for SLIPTA with prioritization of potential applicant laboratories, using care in the selection, orientation and evaluation of the performance of prioritized laboratories;
- Allocates financial and human resources;
- Oversees the implementation of corrective actions outlined in audit reports.

The SLIPTA Independent Evaluating Group Secretariat should be regional or subregional in composition. The IEG Secretariat:

- Oversees the establishment of the SLIPTA IAG utilizing a vetted nomination process;
- Establishes a letter of agreement (LoA) with the MoH;
- Works with professional societies and other stakeholders to i) mobilize resources to support the laboratories for quality improvement; and ii) identify suitable experts to comprise a pool of auditors and sign LoAs with these partners when needed;
- Provides training of auditors to conduct laboratory audits using the WHO SLIPTA Checklist;

- Provides certificates of recognition issued by the SLIPTA IAG;
- Serves as primary point of contact for MoHs seeking further information on SLIPTA as well as MoHs assisting laboratories with applications for enrolment, technical support or monitoring;
- Receives and processes application requests from MoHs;
- Maintains a register of auditors with full contact details, institutional or professional affiliation, and record of past experiences;
- Organizes audit visits;
- Maintains documentation, records and information, and shares them in a timely manner with the Regional Office and MoHs.

SLIPTA auditors comprise a group of experienced laboratory auditors. They must attest that they have no conflict-of-interest in conducting the work for a particular audit and must maintain confidentiality. Their responsibilities are to:

- Conduct laboratory audits using the WHO SLIPTA Checklist for the African Region;
- Provide technical assistance and on-site mentoring to the enroled laboratories;
- Develop audit reports with recommendations.

The Independent Advisory Group (IAG) will be established by the SLIPTA IEG Secretariat. Membership will consist of technical experts from professional bodies such as laboratory associations via a vetted nomination process. Members will be trained by the IEG Secretariat and will serve as a standing board whose individuals are anonymous. IAG will be regional with eventual transition to independent national advisory committees as countries develop national capacity. The IAG:

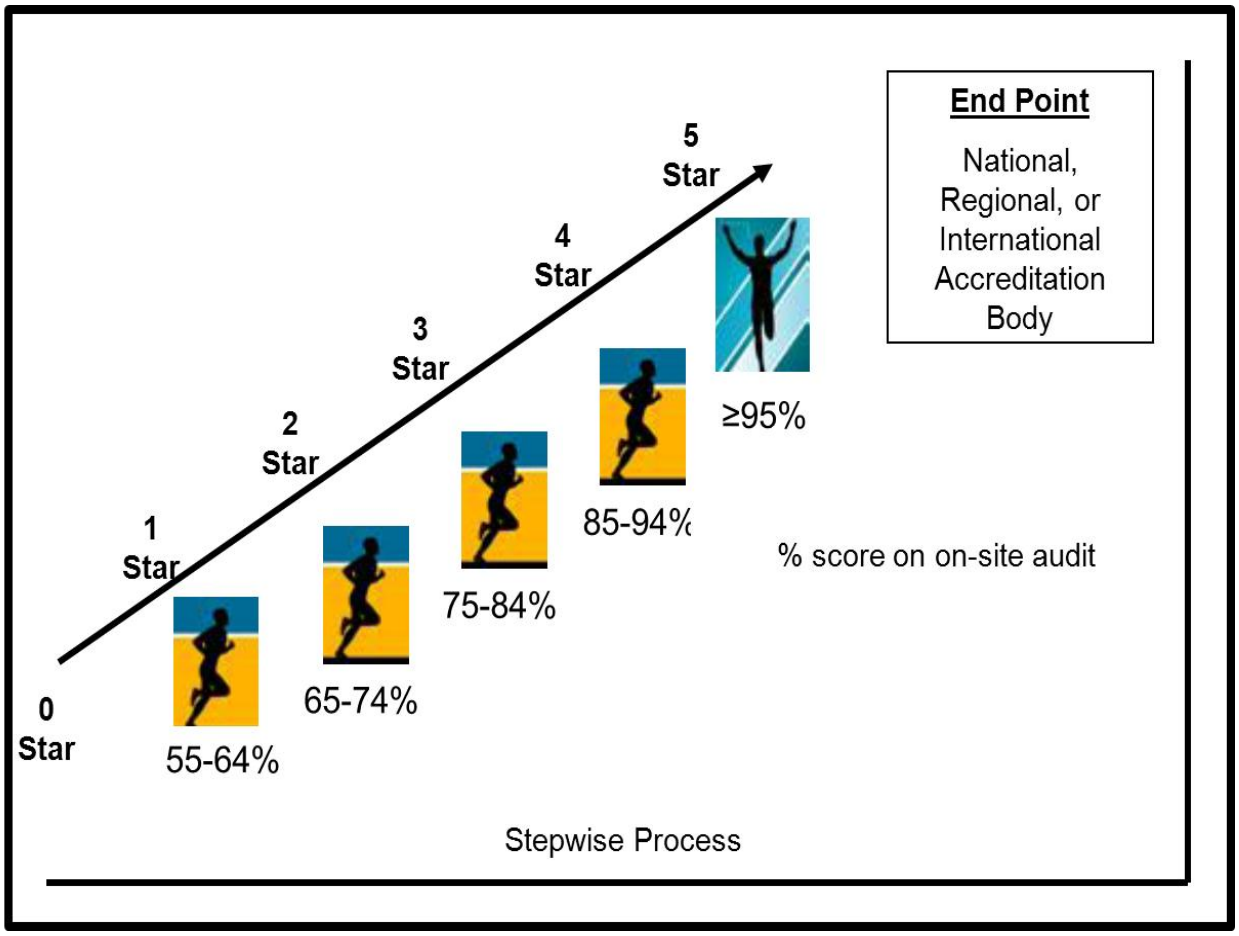
- Ensures specific standards are applied across the board;
- Advises on the resolution of conflicts or complaints from laboratories or other stakeholders;
- Issues Certificates of Recognition to laboratories.

3. The Audit

The Independent Evaluating Group (IEG) provides audits for laboratories that ministries of health (MoHs) in Member States have prioritized for improvement; the IEG also provides stepwise recognition in fulfilment of the ISO 15189/17025 standard. Following an audit, laboratories will be recognized on a zero to five star ascending scale. Laboratories that fail to achieve at least 55% compliance upon audit will not be awarded a star ranking. Laboratories that achieve ≥ 95% upon audit will receive a five star rating.

Once audited, laboratories are expected to maintain their star status and work towards the next star which would be evaluated during the re-audit process. Laboratories that achieve five stars will be strongly encouraged to enrol in an established ISO 15189/17025 accreditation scheme. Figure 2 indicates the tiers of recognition employed in the WHO SLIPTA for the African Region.

Figure 2: SLIPTA tiers of recognition of laboratory quality management



4. Eligibility and Application for Enrolment

4.1 ELIGIBILITY AND CONSIDERATION

All medical, clinical and public health laboratories in Member countries of the WHO African Region are eligible for consideration for accreditation. This presupposes that the Ministry of Health has a strategic plan for implementating laboratory quality improvement. However, the SLIPTA IEG Secretariat only accepts applications submitted by the MoH SLIPTA focal point. MoHs are encouraged to invest in this process in order to support the development of public sector laboratories. All applications received will be reviewed by the SLIPTA IEG Secretariat before laboratories are officially enroled in the SLIPTA and scheduled for audit.

Unless there are special circumstances or instructions from the MoH (see above), enrolment will be done on the basis of the entire laboratory (all sections providing services for patients and/or public health). Therefore, applicant laboratories must declare their full repertoire of tests in the application. All satellite services directly managed by the laboratory must also be declared. Inaccuracies identified during audit may delay the audit process. Only sections of the laboratory that specifically request the audit will be recognized as part of the SLIPTA and on the certificate.

The SLIPTA IEG Secretariat will only accept audit applications from the MoH. Individual laboratories should not apply directly to the SLIPTA IEG Secretariat. MoHs are invited to submit applications for laboratories they have prioritized for accreditation. All communications should be conducted between Ministry of Health laboratory leadership or designated contact person and the SLIPTA IEG Secretariat.

Eligibility is not conditioned by the size of the laboratory. Given the capacity challenges entailed in responding to requests from across the entire Region, applicant MoHs are encouraged to select laboratories in phases. Prioritization should take into account the tiered laboratory network. For example, laboratories that have successfully completed a laboratory quality improvement training course, such as the Strengthening Laboratory Management Towards Accreditation (SLMTA) training programme or structured laboratory mentoring, are likely to be better prepared for SLIPTA enrolment. The current procedure recommends basing the number of proposed laboratories on available resources per country. The request should aim at listing all laboratories to be enroled for the year in order to facilitate the audit mission.

4.2 ENROLMENT

If a laboratory's application meets the SLIPTA enrolment criteria, the SLIPTA IEG Secretariat will send an enrolment letter. The enrolment letter will indicate the date of the laboratory's enrolment, its enrolment number, and suggested timeframes within which an audit might be scheduled. Once an enrolment date has been issued, the laboratory will be considered an "Enroled Laboratory".

The audit of the laboratory must be conducted within a year of the enrolment date. If the laboratory has not been audited within that time period the laboratory will be considered inactive. Table 1 shows the stepwise approach to application.

Table 1: Laboratory status designations for SLIPTA

Applicant Laboratory	Enroled Laboratory	Audited 0 Star	Audited 1 Star	Audited 2 Star	Audited 3 Star	Audited 4 Star	Audited 5 Star	Graduate
Applicant documents received	Application approved; ready to schedule audit							Enroled in ISO 15189 scheme

5. Evaluation and Criteria

5.1 THE AUDIT VISIT

A team of auditors will be sent out to conduct laboratory audits. The composition and size of an audit team is based on the size of the laboratory or laboratory system to be audited and the amount of time required. Audit teams operate under the direction of the designated lead auditor. During an audit visit the lead auditor is the primary contact person for the team. The SLIPTA IEG Secretariat will define the terms of reference (ToR) in collaboration with the WHO Regional Office SLIPTA focal point.

Once a laboratory is enroled, the SLIPTA IEG Secretariat will communicate with the applicant MoH to find suitable dates for the audit visit and coordinate logistics for the audit team. Due to the coordination challenges, any changes in audit dates may result in long rescheduling delays.

If a ministry has successfully enroled more than one laboratory, every effort will be made to schedule audit visits that are of sufficient length to audit multiple laboratories in close proximity of one another.

The length of audit visits will vary based upon four main factors: (i) number of laboratories to be audited, (ii) size of the laboratories to be audited, (iii) number of auditors on the audit team and (iv) logistics and transportation considerations.

The travel logistics for audit visits will be arranged through consultations between the IEG SLIPTA Secretariat and the applicant MoH. Schedules will be confirmed in advance, including whether MoH laboratory leadership will be available for an opening meeting and closing briefing at the beginning and end of the audit visit.

5.2 CRITERIA AND CHECKLIST

There are five audit criteria for evaluation in the SLIPTA. They include:

- Laboratory test results;
- Number of tests annually: defined as total annual volume of tests performed by laboratory;
- Internal quality control procedures implemented for all testing methods used;
- Two most recent proficiency test results for each test performed;
- WHO SLIPTA Checklist for the African Region.

The WHO SLIPTA Checklist (see Annex 2) is compliant with ISO 15189/17025. The Checklist has 334 questions and a possible 258 points. The questions are organized in 12 sections. While the checklist has been constructed to prepare laboratories for international accreditation, the headings are derived from the quality system essentials (QSEs) contained in the quality management system (QMS) of the renowned Clinical and Laboratory Standards Institute (CLSI). Table 2 provides a breakdown of the checklist categories and points.

Table 2: Sections and points in the SLIPTA checklist

Audit Section	Points
Section 1: Documents and Records	25
Section 2: Management Reviews	17
Section 3: Organization and Personnel	20
Section 4: Client Management and Customer Service	8
Section 5: Equipment	30
Section 6: Internal Audit	10
Section 7: Purchasing and Inventory	30
Section 8: Process Control and Internal and External Quality Assessment	33
Section 9: Information Management	18
Section 10: Corrective Action	12
Section 11: Occurrence Management and Process Improvement	12
Section 12: Facilities and Safety	43
TOTAL	**258**

The WHO SLIPTA Checklist for the African Region is available on the Regional Office website which will be updated whenever the Checklist is revised.

6. Recognition and Certification

6.1 DECISION-MAKING AND AWARDING OF RECOGNITION

Within two weeks of completing the audit, the SLIPTA audit team will submit a list of nonconformities to the laboratory and the IEG Secretariat. The laboratory will have six weeks to submit documentation of corrective actions of nonconformities to the audit team for reconsideration. At this stage, the audit team may provide technical assistance and guidance for the laboratory. Corrective action of major nonconformities may require a follow-up audit by the audit team, and this should be conducted within three to six months. The SLIPTA audit team will submit their final report to the IAG via the IEG Secretariat within one week of reconsideration. Within two weeks of receiving the final report, the SLIPTA IAG will make the final determination regarding what level of recognition the laboratory will be awarded. Table 3 indicates the possible recognition tiers to be awarded.

Table 3: SLIPTA tiers of recognition of laboratory quality management

					5 Stars
				4 Stars	
			3 Stars		
		2 Stars			
	1 Star				
0 Stars					
0-141 pts **<55%**	142-166 pts **55-64%**	167-192 pts **65-74%**	193-218 pts **75-84%**	219-243 pts **85-94%**	244-258 pts **≥95%**

The current recognition status of enroled medical laboratories will be made available on the IEG website (www.aslm.org).

6.2 FOLLOW-UP AUDIT FOR CONTINUED IMPROVEMENT

Following audit, successful laboratories will receive a certificate valid for **two years** from the date of issue. Applications for renewal should be submitted six months before the expiration of the certificate.

Since progression to full internationally-recognized accreditation is a key programme goal, laboratories are strongly encouraged to graduate to International Laboratory Accreditation Cooperation (ILAC) recognition level within six years (initial application and up to two renewal applications). This will require that the MoH allocate funding in the country strategic implementation plan for accreditation services in future budgets. In addition, the MoH will need to negotiate with accreditation providers based on the volume of laboratories to be serviced.

Participating laboratories that go on to receive an ILAC-recognized accreditation will be transitioned from the SLIPTA register and their achievement will be recognized on the IEG website.

6.3 APPROPRIATE USE OF RECOGNITION CERTIFICATES

Laboratories are encouraged to display the recognition certificates received from the SLIPTA IEG Secretariat as evidence of their enrolment in the process and achievement as a laboratory.

The Certificate of Recognition will clearly state that the laboratory has achieved a star ranking according to the SLIPTA level of recognition of laboratory quality management (Figure 3). **The Certificate of Recognition is not a certificate of laboratory accreditation.**

Laboratories displaying a SLIPTA recognition certificate should comply with the following provisions:

- Display of certificate does not imply that the IEG or the WHO Regional Office for Africa accepts responsibility for activities carried out under the scope of the level of recognition.
- A certificate may only be displayed at the laboratory to which it was issued. It cannot be transferred to another laboratory or displayed at another facility.
- Certificates cannot be amended or altered in any way.
- Certificates must be removed promptly following expiration.
- Certificates cannot be used in any way that might mislead the reader about the status of the laboratory.
- Laboratories displaying the SLIPTA recognition certificate should notify the SLIPTA Secretariat in the event of a substantial change in staffing test menu, workload, discontinuation of proficiency testing or inter-laboratory comparisons, or two consecutive incidents of poor proficiency testing performance.

An onsite visit may be required. The SLIPTA IAG will make this judgment. Failure to notify the SLIPTA IAG regarding major changes could result in suspension or withdrawal of recognition.

7. Operating Procedures

7.1 COST

The cost will be covered by the MoH and its partners. MoH should mobilize these resources as part of an MoH national strategic implementation plan.

7.2 ISSUES MANAGEMENT

During these processes, circumstances may arise that warrant complaints from laboratories or MoHs. The head officer of the SLIPTA IEG Secretariat and the Chair of the SLIPTA IAG are responsible for ensuring that all complaints are dealt with impartially and objectively.

Complaints must be submitted in writing to the SLIPTA IEG Secretariat. Complaints might refer to inappropriate or unprofessional conduct by staff or auditors; conflicts of interest; or poor quality of services.

Complaints will be logged with acknowledgement of receipt being returned within two weeks. Complaints will be forwarded to the Chair of the SLIPTA IAG for discussion through email communication. Complaints will be investigated and addressed within four weeks. Corrective action will be taken as necessary.

7.3 MONITORING OF AUDITOR PERFORMANCE

SLIPTA IEG Secretariat annually monitors and evaluates the performance of its laboratory auditors to ensure that standards of competence and professionalism are observed. Auditors are bound by confidentiality and must be free of conflicts-of-interest. Findings indicating that a SLIPTA IEG auditor has breached confidentiality or participated in an audit in which there was a conflict-of-interest will be acted upon.

7.4 RELEASE OF AUDIT REPORTS

The name of the enroled laboratory can be made public. Results of the internal audit will be disclosed by the director of each laboratory to the Ministry of Health and IEG Secretariat. The MoH is encouraged to mobilize appropriate resources to help the laboratory rectify any nonconformities found duing the audit.

Results of the external audit should be disclosed by the SLIPTA IEG Secretariat to the director of the laboratory and the Ministry of Health only. The SLIPTA IAG members will access results after signing a confidentiality agreement stating that data cannot be disclosed.

SLIPTA is a process that supports laboratories in the implementation of quality management systems and the development of technical competence. The WHO, the SLIPTA IEG Secretariat, IAG and auditors cannot accept liability for any laboratory testing conducted in facilities enroled in SLIPTA.

Annex 1: References

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Annex 2: Checklist for the Stepwise Laboratory Improvement Process Towards Accreditation

1. Introduction

In accordance with WHO core functions of setting standards and building institutional capacity, the WHO Regional Office for Africa has established the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) to strengthen laboratory systems in Member States of the Region. SLIPTA provides a framework for improving quality of public health laboratories in developing countries to achieve ISO 15189 standards. It is a process that enables laboratories to develop and document their ability to detect, identify, and promptly report all diseases of public health significance that may be present in clinical specimens.

Clinical, public health and reference laboratories participating in SLIPTA are reviewed bi-annually. Recognition is given for the upcoming calendar year based on progress towards meeting requirements set by international standards and on laboratory performance during the 12 months preceding the SLIPTA audit, relying on complete and accurate data, usually from the past 1–13 months to 1 month prior to evaluation.

2. Scope

This checklist specifies requirements for quality and competency aimed at developing and improving laboratory services to raise quality to established international standards. The elements of this checklist are based on ISO standard 15189:2007(E) and, to a lesser extent, CLSI guideline GP26-A4.

Recognition is provided using a five star tiered approach based on a bi-annual on-site audit of laboratory operating procedures, practices and performance.

The inspection checklist score will correspond to the number of stars awarded to a laboratory in the following manner:

No Stars (0–142 pts)	**1 Star** (143–165 pts)	**2 Stars** (166–191 pts)	**3 Stars** (192–217 pts)	**4 Stars** (218–243 pts)	**5 Stars** (244–258 pts)
< 55%	*55–64%*	*65–74%*	*75–84%*	*85–94%*	*≥95%*

A laboratory that achieves less than a passing score on any one of the applicable standards will work with the Regional Office laboratory coordinator to:

- identify areas where improvement is needed;
- develop and implement a workplan;
- monitor laboratory progress;
- conduct re-testing where required;
- continue steps to achieve full accreditation.

3. Parts of the Audit

This laboratory audit checklist consists of three parts:

Part I: Laboratory Profile

Part II: Laboratory Audit
Evaluation of laboratory operating procedures, practices and tables for reporting performance.

Part III: Summary of Audit Findings
Summary of findings of the SLIPTA audit and action planning worksheet.

Part I: Laboratory Profile

Date of Audit				**Date of Last Audit**			
Prior Audit Status	**Not Audited**	**0 Stars**	**1 Star**	**2 Stars**	**3 Stars**	**4 Stars**	**5 Stars**
Name(s) and Affiliation(s) of Auditor(s)							
Laboratory Name						**Laboratory Number**	
Laboratory Address							
Laboratory Telephone		**Fax**			**Email**		
Head of Laboratory				**Telephone** (Head of Laboratory)		Personal / Work	
Laboratory Level (check only one)				**Type of Laboratory/Laboratory Affiliation** (check only one)			
☐ National	☐ Reference	☐ Regional / Provincial		☐ Public	☐ Hospital	☐ Private	
☐ District	☐ Zonal	☐ Field		☐ Research	☐ Non-hospital Outpatient Clinic	☐ Other – Please specify: _____	

Laboratory Staffing Summary

Profession	*Number of Full Time Employees*	*Adequate for facility operations?*
Degree-holding Professional Staff		Yes No Insufficient Data
Diploma-holding Professional Staff		Yes No Insufficient Data
Certificate-holding Professional Staff		Yes No Insufficient Data
Microscopist		Yes No Insufficient Data
Data Clerk		Yes No Insufficient Data
Phlebotomist		Yes No Insufficient Data
Cleaner		Yes No Insufficient Data
Is the cleaner(s) dedicated to the laboratory only? Yes No		*Has the cleaner(s) been trained in safe waste handling*? Yes No
Driver		Yes No Insufficient Data
Is the driver(s) dedicated to the laboratory only? Yes No		*Has the driver(s) been trained in biosafety*? Yes No
Other		Yes No Insufficient Data

If the laboratory has IT specialists, accountants or non-laboratory-trained management staff, this should be indicated in the description of the organizational structure on the following page.

Does the laboratory have sufficient space, equipment, supplies, personnel, infrastructure, etc. to execute the correct and timely performance of each test and maintain the quality management system? If no, please elaborate in the summary and recommendations section at the end of the checklist.		
Sufficient space	**YES**	**NO**
Equipment	**YES**	**NO**
Supplies	**YES**	**NO**
Personnel	**YES**	**NO**
Infrastructure	**YES**	**NO**
Other—Please specify:	**YES**	**NO**

Part II: Laboratory Audit

A laboratory audit is an effective means to i) determine if a laboratory is providing accurate and reliable results; ii) determine if the laboratory is well-managed and is adhering to good laboratory practices; and iii) identify areas for improvement.

Auditors complete this audit using the methods below to evaluate laboratory operations per checklist items and to document findings in detail.

- **Review laboratory records** to verify that the laboratory quality manual, policies, personnel files, equipment maintenance records, audit trails, incident reports, logs, standard operating procedures (SOPs) and other manuals (e.g. safety manual) are complete, current, accurate and annually reviewed.

- **Observe laboratory operations** to ensure:
  - laboratory testing follows written policies and procedures in pre-analytic, analytic and post-analytic phases of laboratory testing;
  - laboratory procedures are appropriate for the testing performed;
  - deficiencies and nonconformities identified are adequately investigated and resolved within the established timeframe.

- **Ask open-ended questions** to clarify documentation seen and observations made. Ask questions like, "show me how…" or "tell me about…" It is often not necessary to ask all the checklist questions verbatim. An experienced auditor can often learn to answer multiple checklist questions through open-ended questions with the laboratory staff.

- **Follow a specimen through the laboratory** from collection through registration, preparation, aliquoting, analysing, result verification, reporting, printing, and post-analytic handling and storing samples to determine the strength of laboratory systems and operations.

- **Confirm that each result or batch can be traced** back to a corresponding internal quality control (IQC) run and that the IQC was passed. Confirm that IQC results are recorded for all IQC runs and reviewed for validation.

- **Confirm PT results** are reviewed and corrective action taken as required.

- **Evaluate the quality and efficiency of supporting work areas** (e.g. phlebotomy, data registration and reception, messengers, drivers, cleaners, IT, etc).

- **Talk to clinicians** to learn the users' perspective on the laboratory's performance. Clinicians often are a good source of information regarding the quality and efficiency of the laboratory. Notable findings can be documented in the Summary and Recommendations section at the end of the checklist.

Audit Scoring

This SLIPTA Checklist contains 111 main sections (a total of 334 questions) for a total of 258 points. Each item has been awarded a value of 2, 3, 4 or 5 points based on relative importance and complexity. Responses to all questions must be, "yes", "partial" or "no".

- Items marked "*yes*" receive the corresponding point value (2, 3, 4 or 5 points). **All** elements of a question must be present when indicating a "yes" response for a given item to receive the corresponding award points.

  NOTE: Items that include "tick lists" must receive all "yes" or "n/a" responses to be marked "yes" for the entire item.

- Items marked "*partial*" receive 1 point.

- Items marked "*no*" receive 0 points.

When marking "partial" or "no", the auditor should write notes in the comments field to explain why the laboratory did not fulfil this item. Such comments will assist the laboratory to address areas of identified need following the audit.

Audit Score Sheet

Section	*Total Points*
Section 1: Documents and Records	**25**
Section 2: Management Reviews	**17**
Section 3: Organization and Personnel	**20**
Section 4: Client Management and Customer Service	**8**
Section 5: Equipment	**30**
Section 6: Internal Audit	**10**
Section 7: Purchasing and Inventory	**30**
Section 8: Process Control and Internal and External Quality Assessment	**33**
Section 9: Information Management	**18**
Section 10: Corrective Action	**12**
Section 11: Occurrence Management and Process Improvement	**12**
Section 12: Facilities and Safety	**43**
TOTAL SCORE	**258**

No Stars (0–142 pts)	**1 Star** (143–165 pts)	**2 Stars** (166–191 pts)	**3 Stars** (192–217 pts)	**4 Stars** (218–243 pts)	**5 Stars** (244–258 pts)
< 55%	*55–64%*	*65–74%*	*75–84%*	*85–94%*	*≥95%*

For each item, please circle Yes (Y), Partial (P) or No (N). All elements of the item must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.

	Y	P	N	Comments	Score
1. DOCUMENTS and RECORDS					
1.1 <u>Laboratory Quality Manual</u> Is there a current laboratory quality manual composed of the quality management system's policies and procedures; has the manual content been communicated to staff, and is the manual understood and implemented by all staff? ***ISO 15189: 4.2.3 , 4.2.4***					4
	Tick for each item				
The quality manual includes the following elements:	**Y**	**N**			
Structure defined per ISO15189, Section 4.2.4					
Quality policy statement that includes scope of service, standard of service, objectives of the quality management system, and management commitment to compliance					
Description of the quality management system and the structure of its documentation					
Reference to supporting procedures, including technical procedures					
Description of the roles and responsibilities of the laboratory manager, quality manager, and other personnel responsible for ensuring compliance					
Documentation of at least annual management review and approval					
Standard: *A quality manual should be available that summarizes the laboratory's quality programme, includes policies that address all areas of the laboratory service, and identifies the goals and objectives of the quality programme. The quality manual should include policies (processes and procedures) for all areas of the laboratory service and should address all of the quality system essentials (QSEs).* ***ISO 15189: 4.2.3, 4.2.4***					
1.2 <u>Document and Information Control System</u> Does the laboratory have a system in place to control all documents and information (internal and external sources)?	**Y**	**P**	**N**		2
Standard: *A document control system should be in place to ensure that records and all copies of policies/procedures are current, read by personnel, authorized by proper authorities, reviewed annually, and immediately prior versions filed separately as per national policy. There must be a procedure/policy on document control. Documents must be uniquely identified to include title, page numbers, and authority of issue, document number, versions, effective date, and author.* *There must be a procedure/policy on document control. Documents must be uniquely identified to include tile, page numbers, and authority of issue, document number, versions, effective date, and author.* ***ISO 15189: 4.3.1, 4.3.2, 4.3.3***					
1.3 <u>Document and Records</u> Are documents and records properly maintained, easily accessible and fully detailed in an up-to-date Master List?	**Y**	**P**	**N**		2

Standard: *An up-to-date Master List that comprehensively details all laboratory documents, policies, and procedures should be readily accessible in either hard copy or electronic form. These should be retrievable in a timely manner. If documents and records are maintained in electronic form they should be stored on compact disks or other media.*

ISO 15189: 4.3.2 (b,c): *"Procedures shall be adopted to ensure that… b) a list, also referred to as a document control log, identifying the current valid revisions and their distribution is maintained; c) only currently authorized versions of appropriate documents are available for active use at relevant locations."*

1.4 Laboratory Policies and Standard Operating Procedures **Are policies and standard operating procedures (SOPs) for laboratory functions current, available and approved by authorized personnel?** ***ISO 15189 4.3.2***	**Y**	**P**	**N**		5
Policies and/or SOPs that:	**Tick for each item**				
	Yes	**No**			
Document and Record Control Defines the writing, checking, authorization, review, identification, amendments, control and communication of revisions to and retention and safe disposal of all documents and records ***ISO15189: 4.3.1, 4.13.1-3***					
Conflict of Interest Defines the systems in place to identify and avoid potential conflicts of interest and commercial, financial, political or other pressures that may affect the quality and integrity of operations ***ISO15189: 4.1***					
Communication Defines the systems in place to ensure effectiveness of the quality management systems ***ISO15189: 4.1.6***					
Review of Contracts (Supplier and Customer) Defines the maintenance of all records, original requests, enquiries, verbal discussions and requests additional examinations, meetings, and meeting minutes ***ISO 15189: 4.4***					
Examination by Referral Laboratories Defines the 1) evaluation, selection, and performance monitoring of referral laboratories, 2) packaging and tracking of referred samples, 3) reporting of results from referral labs ***ISO 15189: 4.5.1***					
Purchasing and Inventory Control Defines the processes for 1) requesting, ordering and receiving supplies, 2) selection of approved suppliers, 3) acceptance/rejection criteria for					

purchased items, 4) safe handling, 5) storage, inventory control system, 6) monitoring and handling of expired consumables ***ISO 15189: 4.6***				
Advisory Services Defines the required qualifications and responsibility for providing advice on: 1) choice of examinations, 2) use of the services, 3) repeat frequency, 4) required type of sample, 5) interpretation of results, 6) maintenance of records of communication with lab users ***ISO 15189: 4.7***				
Resolution of Complaints and Feedback Defines how 1) complaints and feedback shall be recorded, 2) steps to determine whether patient's results have been compromised, 3) investigative and corrective actions taken as required, 4) timeframe for closure and feedback to the complainant ***ISO 15189: 4.8***				
Identification and Control of Nonconformities Defines the 1) types of nonconformities that could be identified, 2) how/where to record, 3) who is responsible for problem resolution, 4) when examinations are to be halted, 5) the recall of released results, 6) person responsible for authorizing release of results after corrective action has been taken ***ISO 15189: 4.9***				
Corrective Action Defines 1) where to record, 2) how to perform root cause analysis, 3) who will be responsible for implementing action plans within the stipulated timeframes, 4) monitoring the effectiveness of these actions in overcoming the identified problems ***ISO 15189: 4.10***				
Preventive Action Defines what tools will be used, where the action plan will be recorded, who will be responsible for ensuring the implementation within an agreed time frame and the monitoring of its effectiveness ***ISO 15189: 4.11***				
Continual Improvement Defines what quality indicators will be used and how action plans for these areas will be recorded, evaluated, and reviewed for effectiveness of improvement ***ISO 15189: 4.12***				
Quality and Technical Records Defines what are quality and technical records, how amendments would be done, traceability,				

storage, retention and accessibility of all hard and electronic records ***ISO 15189: 4.13***				
Internal Audits Defines the internal audit process, including roles and responsibilities, types of audits, frequency of audits, auditing forms to be used, what will be covered, and identification of personnel responsible for ensuring closure of any nonconformities raised within the agreed timeframe and effectiveness of corrective actions implemented ***ISO 15189: 4.14***				
Management Review Defines frequency, agenda (in line with 4.15.2 a-m), key attendees required, and plan that will include goals, objectives, action plans, responsibilities, due dates and how decisions/actions taken will be communicated to the relevant persons ***ISO 15189: 4.15***				
Personnel Records/Files Defines organizational plan, personnel policies, what is required in a personnel file (minimum in line with ISO 15189 Section 5.1.2) and location of personnel files ***ISO 15189: 5.1***				
Personnel Training Defines staff appraisals, staff orientation, initial training, refresher training, continuous education programme, recommended and required training, and recordkeeping of training ***ISO 15189: 5.1.4, 5.1.6, 5.1.9***				
Competency Assessment Defines the methods, ongoing competency testing and training, and criteria used to assess competency of personnel ***ISO 15189: 5.1.11***				
Authorization Defines the level of authorization for all tasks, roles and deputies for all staff ***ISO 15189: 5.1.7***				
Accommodation and Environmental Conditions Defines any specific environmental and accommodation requirements, and the responsibility, monitoring, controlling, and recording of these requirements ***ISO 15189: 5.2.5***				
Equipment Defines what records are to be maintained in equipment file, the minimum information required				

on equipment label, action to be taken for defective equipment and maintenance frequency, and access control ***ISO 15189: 5.3***				
Calibration of Equipment Defines frequency, use of reference standards where applicable, what is required on the calibration label or calibration record and what action to be taken if calibration fails ***ISO 15189: 5.3***				
Pre-examination Procedures (Handbook) Defines specimen collection, sample and volume requirements, unique identification, special handling, minimum requirements for completion of a requisition form, transportation and receipt of samples ***ISO 15189: 5.4.2 , 5.4.3***				
Specimen Storage and Retention Defines pre- and post-sampling storage conditions, stability and retention times ***ISO 15189: 5.7.2***				
Examination SOPs Defines all sub-clauses of *ISO15189 Section 5.5.3 (a-q)* ***ISO 15189: 5.5.3***				
Equipment Validation/Verification Defines methods to be used, how the lab ensures that equipment taken out of the control of the lab is checked and shown to be functioning satisfactorily before being returned to laboratory use, validation/verification acceptance criteria and person responsible for final authorization for intended use ***ISO 15189: 5.5.2***				
Interrupted Services Defines back-up procedures for equipment failure, power failure, unavailability of consumables and other resources				
Examination Validation/Verification Defines methods to be used, acceptance criteria, and person responsible for final authorization for intended use ***ISO 15189: 5.5.2***				
Quality Assurance Defines the use of IQC and EQC, setting up of ranges, monitoring performance and troubleshooting guidelines ***ISO 15189 5.6***				
Reporting of Results				

Defines the standardized format of a report (in line with ISO15189: Section 5.8.3), methods of communication, release of results to authorized persons, alteration of reports and re-issuance of amended reports ***ISO 15189: 5.8***					
Patient Confidentiality Defines the tools used to ensure patient confidentiality and access control to laboratory facilities and records (electronic and paper records) ***ISO 15189: 5.8.13***					
Laboratory Safety or Safety Manual Defines the contents to be included ***ISO 15190: 7.5***					
Standard: *Standard operating procedures (SOPs) should be established and maintained up-to-date for all tasks performed within the laboratory, safety and waste disposal, document control, specimen collection and processing, inventory control, procurement, and quality assurance. SOPs should be reviewed for accuracy and relevance on an annual basis. All policies and procedures should be approved by an authorized person.*					
1.5 Policy and SOPs Accessibility **Are policies and SOPs easily accessible/ available to all staff and written in a language commonly understood by respective staff?**	**Y**	**P**	**N**		2
Standard: *All procedures should be documented and be available at the workstation for relevant staff. Documented procedures and necessary instructions should be available in a language commonly understood by all staff in the laboratory.* ***ISO 15189: 5.5.3, 4.3.2 Part C***					
1.6 Policies and SOPs Communication **Is there documented evidence that all relevant policies and SOPs have been communicated to and are understood and implemented by all staff as related to their responsibilities?**	**Y**	**P**	**N**		2
Standard: *Policies, processes, programmes, procedures and instructions should be documented and communicated to all relevant staff, and management must ensure that these documents are understood by staff and implemented.* ***ISO 15189: 4.2.1***					
1.7 Document Control Log **Are policies and procedures dated to reflect when it was put into effect and when it was discontinued?**	**Y**	**P**	**N**		2
Standard: *The document control log or other documentation should capture the date the policy/procedure went into service, schedule of review, the identity of the reviewers, and the date of discontinuation.* ***ISO 15189: 4.3.1, 4.3.2 Parts (e) and (f): 4.3.2*** *"Procedures shall be adopted to ensure that e) invalid or obsolete documents are promptly removed from all points of use, or otherwise assured against inadvertent use; and f) retained or archived superseded documents are appropriately identified to prevent their inadvertent use."*					
1.8 Discontinued Policies and SOPs **Are invalid or discontinued policies and procedures removed from use and retained or archived for the time period required by lab and/or national policy?**	**Y**	**P**	**N**		2
Standard: *Discontinued policies/procedures should be retained or archived in a separate file or place clearly marked to avoid use for the period of time required by laboratory and/or national policy.* ***ISO 15189: 4.3.1, 4.3.2 Parts (e) and (f);*** *see above.*					
1.9 Data Files **Are test results and technical and**	**Y**	**P**	**N**		2

quality records archived in accordance with national/international guidelines?					
Standard: *Copies or files of results should be archived. The length of time that reported data are retained may vary; however, the reported results shall be retrievable for as long as medically relevant or as required by national, regional or local authorities.* ***ISO 15189: 5.8.6, 4.13.2, 4.13.3***					
1.10 <u>Archived Results Accessibility</u> **Are archived records and results easily retrievable in a timely manner?**	**Y**	**P**	**N**		2
Standard: *Archived patient results must be easily, readily and completely retrievable within a timeframe consistent with patient care needs.* ***ISO 15189: 5.8.6, 4.13.2***					
SECTION 1: DOCUMENTS and RECORDS Subtotal					**25**

For each item, please circle Yes (Y), Partial (P) or No (N). All elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.

	Y	P	N	Comments	Score
2. MANAGEMENT REVIEWS					
2.1 <u>Workplan and Budget</u> **Does management develop and implement a workplan as well as a budget that supports the laboratory's testing operations and maintenance of the quality system?**	**Y**	**P**	**N**		2
Standard: *Laboratories should be involved in the development of the workplan and budget for their activities. The workplan should reflect the findings of management reviews in its goals, objectives and actions. Not all labs will have budgetary authority as higher levels of management may have direct control for budget-making. If the laboratory does not develop these guiding documents itself, it must communicate with upper management effectively about these areas, including providing a forecast of needs.* ***ISO 15189: 4.1.5 Parts (a) and (h) "****Laboratory management shall have responsibility for the design, implementation, maintenance and improvement of the quality management system."*					
2.2 <u>Review of Quality and Technical Records</u> **Does the laboratory supervisor routinely perform a documented review of all quality and technical records?**	**Y**	**P**	**N**		5
	Tick for each item				
Does the supervisor's review include the following?	**Y**	**N**			
Follow-up of action items from previous reviews					
Status of corrective actions taken and required preventive actions					
Reports from personnel					
Changes in volume and type of work the laboratory undertakes					
Changes in suitability of biological reference ranges					
Changes in the client handbook					
Environmental monitoring log sheets					
Specimen rejection logbook					
Equipment calibration and maintenance records					
IQC records across all test areas					
Outcomes of PTs and other forms of inter-laboratory comparisons					
Monitoring of turnaround time					
Quality indicators					

Outcomes from recent internal audit records					
Results of assessment(s) or audits by external bodies					
Customer complaints and feedback					
Occurrence/incidence logs, nonconformities and corrective action reports					
Results of improvement projects					
Operational procedures (for potential sources of non-conformance and opportunities for improvement)					
Evaluation of performance of referral laboratories					
Evaluation of supplier performance					
Document review					
Documentation of review and action planning with staff for resolution and follow-up review					

Standard: *There must be documentation that the laboratory manager/supervisor or a designee reviews the quality programme regularly. The review must ensure that recurrent problems have been addressed, and that new or redesigned activities have been evaluated.*

ISO 15189: 4.15.2 (a) – (m). *Management review shall include 4.15.2. (a) through (m).*

2.3 <u>Annual Review of Quality Management Systems</u> Does the laboratory management annually perform a review of all quality systems at a management review meeting?	**Y**	**P**	**N**		5
Does the management review meeting include the following?	**Tick for each item**				
	Yes	**No**			
Follow-up of action items from previous management reviews					
Status of corrective actions taken and required preventive actions					
Reports from managerial and supervisory personnel					
Changes in volume and type of work the laboratory undertakes					
Changes in the suitability of biological reference ranges					
Changes in the client handbook					
Environmental monitoring log sheets					
Specimen rejection logbook					
Equipment calibration and maintenance records					

IQC records across all test areas					
Outcomes of PTs and other forms of inter-laboratory comparisons					
Turnaround time					
Quality indicators					
Outcomes from recent internal audit records					
Results of assessment(s) or audits by external bodies					
Customer complaints and feedback					
Reports from managerial and supervisory personnel					
Occurrence/incidence logs, nonconformities and corrective action reports					
Results from improvement projects					
Operational procedures (for potential sources of non-conformance and opportunities for improvement)					
Evaluation of performance of referral laboratories					
Evaluation of supplier performance					
Documentation of review and action planning with staff for resolution and follow-up review					
Standard: *There must be documentation that the head of laboratory or a designee reviews the quality programme at least once every 12 months. The review must ensure that recurrent problems have been addressed, and that new or redesigned activities have been evaluated.* ***ISO 15189: 4.15***					
2.4 <u>Quality Management System Improvement Measures</u> Does the laboratory identify and undertake quality improvement projects?	**Y**	**P**	**N**		3
Standard: *The monthly and annual reviews of the quality management system must be used as opportunities for identifying nonconformities and areas for improvement. Action plans for improvement shall be developed, documented and implemented, as appropriate.* ***ISO 15189: 4.12.1***					
2.5 <u>Communications System on Laboratory Operations</u> Does the laboratory communicate with upper management regularly regarding personnel, facility and operational needs?	**Y**	**P**	**N**		2
Standard: *The laboratory must have a system in place for communicating with management regarding laboratory operations and effectiveness of the quality management system. The communication and follow-up must be documented.* ***ISO 15189: 4.1.6***					
SECTION 2: MANAGEMENT REVIEW Subtotal					**17**

For each item, please circle Yes (Y), Partial (P) or No (N). All elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.

	Y	P	N	Comments	Score
3. ORGANIZATION and PERSONNEL					
3.1 Workload, Schedule and Coverage **Do work schedules show task assignments and coordination of work for adequate laboratory staff coverage?**	**Y**	**P**	**N**		2
***Standard**: Work schedules show who is in the laboratory and when they should be available. Work schedules are normally provided to hospital management showing laboratory coverage. There should be enough staff resources adequate to cover the work as required and tasks should be prioritized, organized and coordinated based on personnel skill level, workloads and the task completion timeframe.* ***ISO 15189: 5.1.5** "There shall be staff resources adequate to the undertaking of the work required and the carrying out of other functions of the quality management system."*					
3.2 Duty Roster and Daily Routine **Are daily routine work tasks established, assigned (duty roster and workstation assignments/tasks), monitored and supervised by qualified professional staff, and do they indicate that only authorized personnel perform specific tasks?**	**Y**	**P**	**N**		2
***Standard:** A duty roster designates specific laboratory personnel to specific workstations, and workstation tasks list the tasks associated with a specific workstation, e.g. personnel X assigned to hematology (duty roster) expected to perform specific tasks (workstation tasks). Daily routines should be prioritized, organized and coordinated to achieve optimal service delivery for patients.* ***ISO 15189: 5.1.7** "Laboratory management shall authorize personnel to perform particular tasks such as sampling, examination and operation of particular types of equipment, including use of computers in the laboratory information system."*					
3.3 Organizational Chart and External/Internal Reporting Systems **Are lines of authority and responsibility clearly defined for all laboratory staff, including the designation of a supervisor and deputies for all key functions?**	**Y**	**P**	**N**		2
Standard:** An up-to-date organizational chart and/or narrative description should be available detailing the external and internal reporting relationships for laboratory personnel. The organizational chart or narrative should clearly show how the laboratory is linked to the rest of the hospital and laboratory services where applicable.* ***ISO 15189: 5.1.1, 4.1.5 Parts (e) and (j)					
3.4 Quality Management System Oversight **Is there a quality officer/manager with delegated responsibility to oversee compliance with the quality management system?**	**Y**	**P**	**N**		3
Standard:** There should be a quality manager (however named) with delegated authority to oversee compliance with the requirements of the quality management system. This quality manager should report directly to the level of laboratory management at which decisions are made on laboratory policy and resources.* ***ISO 15189: 4.1.5 Part (i)					
3.5 Personnel Filing System **Are personnel files present?**	**Y**	**P**	**N**		3
If files are present, do they document or contain the following:	**Tick for each item**				
	Yes	**No**	**N/A**		
Employee orientation					
Education and training (e.g. degrees/certificates)					
Previous experience and work history (e.g. CV)					
Written job description with documentation that staff member received and signed a copy of individual job description					

Letter of employment or appointment					
Review of job-relevant SOPs					
Documented review of safety manual, evidence of safety training					
Review of procedure for employees to communicate concerns about test quality and laboratory safety					
Registration with professional board					
Training record documenting training received, vendor training received on-site					
Periodic performance review including observation, competency assessment, coaching /feedback, on-the-job training					
Documentation of employee recognition (i.e. employee of the month, letter of commendation etc)					
Human resource data (vaccination status, accidental exposure during work injuries, accident history, leave days taken, etc)					
Standard: *Personnel files should be maintained for all current staff. Documentation should include job description, qualifications, training, experience, competency assessment records, periodic performance review records, and records of vaccination, injuries, or workplace accidents.* ***ISO 15189: 5.1.2***					
3.6 <u>Staff Competency Assessment and Training</u> Is there a system for competency assessment of personnel (both new hires and existing staff) and does it include planning and documentation of retraining and reassessment, when indicated?	**Y**	**P**	**N**		3
Standard: *Newly hired lab staff should be assessed for competency before performing independent duties and again within six months. All lab staff should be regularly assessed for testing competency at least once a year. Staff assigned to a new section should be assessed before fully assuming independent duties. When deficiencies are noted, retraining and reassessment should be planned and documented. If the employee's competency remains below standard, further action might include supervisory review of work, re-assignment of duties, or other appropriate actions. Records of competency assessments and resulting actions should be retained in personnel files and/or quality records. Records should show which skills were assessed, how those skills were measured, and who performed the assessment.* ***ISO 15189: 5.1.11: "****The competency of each person to perform assigned tasks shall be assessed following training and periodically thereafter. Retraining and reassessment shall occur when necessary."*					
3.7 <u>Laboratory Staff Training</u> Does the laboratory have adequate training policies, procedures, and/or training plans, including cross-training within the laboratory team, one-on-one mentoring, and/or off-site external training?	**Y**	**P**	**N**		2
Standard: *In line with national laboratory training plans, each laboratory should have functional training policies and procedures that meet the needs of laboratory personnel through both internal and external training.* ***ISO 15189: 4.12.5, 5.1.6, 5.1.9***					
3.8 <u>Staff Meetings</u> Are staff meetings held regularly?	**Y**	**P**	**N**		3
Do meetings include the following items?	**Tick for each item**				
	Yes	**No**	**N/A**		
Follow-up of action items from previous staff meetings					
Discussion about problems and complaints					
Review of documentation					

Communication on reviewed/revised/redundant SOPs				
Systemic and or recurrent problems and issues addressed, including actions to prevent recurrence				
Review of results from prior corrective actions				
Discussion and evaluation of improvement topics/projects				
Feedback given by staff that have attended meetings, training, conferences etc.				
Recognition of employees for exemplary performance (i.e. employee of the month, letter of commendation, etc.)				
Relay of reports and updates from laboratory staff attendance at meetings with clinicians (the use of lab services and/or attendance at clinical rounds)				
Recording and monitoring of meeting notes for progress on issues				
Standard: *The laboratory should hold regular staff meetings to ensure communication within the laboratory. Meetings should have recorded notes to facilitate review of progress over time.* ***ISO 15189: 4.1.6*** *"Laboratory management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the quality management system."*				
SECTION 3: ORGANIZATION and PERSONNEL Subtotal				**20**

For each item, please circle Yes (Y), Partial (P) or No (N). All elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.

	Y	P	N	Comments	Score
4. CLIENT MANAGEMENT AND CUSTOMER SERVICE					
4.1 Advice and Training by Qualified Staff **Do staff members with appropriate professional qualifications provide clients with advice and/or training regarding required types of samples, choice of examinations, repeat frequency, and interpretation of results?**	**Y**	**P**	**N**		2
Standard: *Professionally-qualified staff should provide advice on sample type, examination choice, frequency and results interpretation.* ***ISO 15189:4.7; 4.12.5***					
4.2 Laboratory Handbook for Clients **Is there a laboratory handbook for laboratory users that includes information on services offered, quality assurance, laboratory operations, sample collection, transport and agreed turnaround times?**	**Y**	**P**	**N**		2
Standard: *The laboratory should provide its clients with a handbook that outlines the laboratory's hours of operation, available tests, specimen collection instructions, packaging and shipping directions, and expected turnaround times.* ***ISO 15189: 4.7, 4.12.5, 5.5.6***					
4.3 Communication Policy on Delays in Service **Is timely, documented notification provided to customers when the laboratory experiences delays or interruptions in testing (due to equipment failure, stock-outs, staff levels, etc.) or finds it necessary to change examination procedures?**	**Y**	**P**	**N**		2
Standard: *There should be a policy for notifying the requester when an examination is delayed. Such notification shall be documented for both service interruption and resumption as well as related feedback from clinicians. Clinical personnel do not need to be notified of all delays of examination but should be notified in those situations where the delay could compromise patient care.* ***ISO 15189: 5.8.11***					
4.4 Evaluation Tool and Follow-up **Is there a tool for regularly evaluating client satisfaction, and is the feedback effectively utilized to improve services?**	**Y**	**P**	**N**		2
Standard: *The laboratory should measure the satisfaction of clients, clinicians and patients regarding its services, either on an ongoing basis or through episodic solicitations.* ***ISO 15189: 4.8, 4.15.2 Part (h)***					
SECTION 4: CLIENT MANAGEMENT and CUSTOMER SERVICE Subtotal					**8**

For each item, please circle Yes (Y), Partial (P) or No (N). All elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.

	Y	P	N	Comments	Score
5. EQUIPMENT					
5.1 Adherence to Proper Equipment Protocol **Is equipment installed and placed as specified in the operator's manuals and uniquely labeled or marked?**	**Y**	**P**	**N**		2
Standard: *Equipment should be properly placed as specified in user manual away from the following but not limited to water, direct sunlight, vibrations, in traffic and with more than 75% of the base of the equipment sitting on the bench top to avoid tip-over.* ***ISO 15189: 5.3.3*** *"Each item of equipment shall be uniquely labeled, marked, or otherwise identified."*					
5.2 Equipment and Method Validation/ Verification and Documentation **Are newly introduced equipment and methods validated/verified on-site and are records documenting validation available?**	**Y**	**P**	**N**		2
Standard: *Newly introduced methods or equipment should be validated onsite to ensure that their introduction yields performance equal to or better than the previous method or equipment. Validation may be done versus the method or equipment being replaced or the prevailing "gold standard". An SOP should be in place to guide method of validation.* ***ISO 15189: 5.5.2*** *"The laboratory shall use only validated procedures for confirming that the examination procedures are suitable for the intended use."*					
5.3 Equipment Record Maintenance **Is current equipment inventory data available on all equipment in the laboratory?**	**Y**	**P**	**N**		2
	Tick for each item				
	Yes	**No**	**N/A**		
Name of equipment					
Manufacturer's contact details					
Condition received (new, used, reconditioned)					
Serial number					
Date of purchase					
Date when put "out of service"					
Date of entry into service					
Standard: *Records shall be maintained for each item of equipment used in the performance of examinations. Such equipment list must include major analysers as well as ancillary equipment like centrifuges, water baths, rotators, fridges, pipettes, timers, printers, computers.* ***ISO 15189: 5.3.4***					
5.4 Equipment Maintenance Records **Is relevant equipment service information readily available in the laboratory?**	**Y**	**P**	**N**		2
	Tick for each item				
	Yes	**No**	**N/A**		
Service contract information					
Contact details for service provider					
Decontamination records					
Performance and maintenance records					
Last date of service					

Next date of service					
Current location					

Standard: *Maintenance records must be maintained for each item of equipment used in the performance of examinations. These records shall be maintained and shall be readily available for the lifespan of the equipment or for any time period required by national, regional and local authorities.*

ISO 15189: 5.3.4

5.5 Obsolete Equipment Procedures **Is non-functioning equipment appropriately labeled and removed from the laboratory and storage areas?**	**Y**	**P**	**N**		2

Standard: *The laboratory must have procedures for proper retirement of obsolete equipment and should be removed from the laboratory to free work and storage areas. The equipment shall be properly decontaminated before being removed from the laboratory.*

ISO 15189: 5.3.7

5.6 Adherence to Equipment Calibration Protocol **Is routine calibration of laboratory equipment (including pipettes, centrifuges, balances and thermometers) scheduled, as indicated on the equipment, and verified?**	**Y**	**P**	**N**		2

Standard: *All equipment in the laboratory that requires calibration must be calibrated according to the schedule, which at minimum must meet the manufacturer's recommendations. This should cover major analysers as well as ancillary equipment like pipettes, thermometers, balances, centrifuges, timers, balances.*
ISO 15189: 4.2.5, 5.3.2

5.7 Equipment Preventive Maintenance **Is routine preventive maintenance performed on all equipment and recorded according to SOPs/log sheet?**	**Y**	**P**	**N**		2

Standard: *Preventative maintenance by operators must be done on all equipment used in examinations including centrifuges, autoclaves, microscopes, safety cabinets.*

ISO 15189: 4.2.5, 5.3.2

5.8 Equipment Service Maintenance **Is equipment routinely serviced according to schedule by qualified and competent personnel, and is this information documented in appropriate logs?**	**Y**	**P**	**N**		2

Standard: *All equipment must be serviced at specified intervals by a qualified service engineer either through service contracts or otherwise. Service schedule must at minimum meet manufacturer's requirements.*

ISO 15189: 4.2.5, 5.3.2

5.9 Equipment Parts for Repair **Are parts available to perform minor repairs as per manufacturer's instructions?**	**Y**	**P**	**N**		2

Standard: ISO 15189: 5.3.2 *"Equipment shall be shown (upon installation and in routine use) to be capable of achieving the performance required and shall comply with specifications relevant to the examinations concerned."*

5.10 Equipment Malfunction Response and Documentation **Is equipment malfunction resolved by the effectiveness of the corrective action programme and the associated root cause analysis?**	**Y**	**P**	**N**		2

Standard: *All equipment malfunctions must be investigated and documented on corrective action reports. Where user cannot resolve the problem, a repair order must be initiated.*

ISO 15189: 5.3.7, 4.9

5.11 Equipment Repair Monitoring and Documentation **Are repair orders monitored to determine**	**Y**	**P**	**N**		2

if the service is completed? Does the laboratory verify and document that it is in proper working order before being put back into service?					
Standard: All equipment should receive thorough documented checks to ensure proper functioning before being returned to service following any absence from the laboratory. ***ISO 15189: 5.3.10***					
5.12 <u>Equipment Failure Contingency Plan</u> Are there back-up procedures for equipment failure (including SOPs for handling specimens during these times, identification of a back-up lab for testing, and referral procedures)?	**Y**	**P**	**N**		2
Standard: *Contingency plans must be in place, in the event of equipment failure, for the completion of testing. In the event of a testing disruption, planning may include the use of a back-up instrument, the use of a different testing method, the referral of samples to another laboratory, or the freezing of samples until testing is re-established.* ***ISO 15189: 5.3.1*** *"The laboratory shall be furnished with all items of equipment required for the provision of services (including primary sample collection, and sample preparation and processing, examination and storage). In those cases where the laboratory needs to use equipment outside its permanent control, laboratory management shall ensure that the requirements of this international standard are met."*					
5.13 <u>Manufacturer's Operator Manual</u> Are the equipment manufacturer's operator manuals readily available to testing staff, and where possible, available in the language understood by staff?	**Y**	**P**	**N**		2
Standard: *Operator manuals must be readily available for reference by testing staff.* ***ISO 15189: 5.3.5***					
5.14 <u>Communication on Effectiveness of Quality Management System</u> Are equipment specifications and maintenance needs routinely communicated to upper management?	**Y**	**P**	**N**		2
Standard: *Laboratory management should ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the quality management system.* ***ISO 15189: 4.1.6***					
5.15 <u>Laboratory Testing Services</u> Has the laboratory provided uninterrupted testing services, with no disruptions due to equipment failure in the last year (or since the last audit)?	**Y**	**P**	**N**		2
SECTION 5: EQUIPMENT Subtotal					**30**

For each item, please circle Yes (Y), Partial (P) or No (N). All elements of the item must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.

	Y	P	N	Comments	Score
6. INTERNAL AUDIT					
6.1 Internal Audits **Are internal audits conducted at intervals as defined in the quality manual and do these audits address areas important to patient care?**	**Y**	**P**	**N**		5
	Tick for each item				
	Yes	**No**			
Are audits being carried out by persons who are not involved in laboratory activities in the section being audited?					
Are the personnel conducting the internal audits trained and competent in auditing?					
Is cause analysis performed for nonconformities/noted deficiencies?					
Are internal audit findings documented and presented to the laboratory management and relevant staff for review?					
6.2 Audit Recommendations, Action Plan and Follow-up **Are recommendations for corrective/preventive actions made based on audit findings; is an action plan developed with clear timelines and documented follow-up?**	**Y**	**P**	**N**		5
Standard: *Internal audits should be conducted at least annually. Investigation of individual problems may not reveal trends or patterns. Errors and incident reports should be reviewed periodically to determine whether systemic problems are responsible for errors and/or incidents. Laboratory management shall monitor the results of any corrective action taken in order to ensure that they have been effective in overcoming the identified problems.* ***ISO 15189: 4.2.4, 4.10.3, 4.14***					
SECTION 6: INTERNAL AUDIT Subtotal					**10**

For each item, please circle Yes (Y), Partial (P) or No (N). All elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.

	Y	P	N	Comments	Score
7. PURCHASING AND INVENTORY					
7.1 Inventory and Budgeting System **Is there a system for accurately forecasting needs for supplies and reagents?**	**Y**	**P**	**N**		2
Standard: *The laboratory must have a systematic way of determining its supply and testing needs through inventory control and budgeting systems that take into consideration past patterns, present trends and future plans.* ***ISO 15189: 4.6.4*** *"The laboratory shall evaluate suppliers of critical reagents, supplies and services that affect the quality of examinations and shall maintain records of these evaluations and list those approved."* ***ISO 15189: 5.1.4 (i) "****Provide effective and efficient administration of the medical laboratory service, including budget planning and control with responsible financial management."*					
7.2 Service Supplier Performance Review **Are supply and reagent specifications periodically reviewed; are approved suppliers identified?**	**Y**	**P**	**N**		2
Standard: *All suppliers of services used by the laboratory must be reviewed for their performance. Those that perform well must be identified and listed as approved suppliers. Results of these reviews must be documented.* ***ISO 15189: 4.6.4***					
7.3 Manufacturer/Supplier List **Is an up-to-date list of approved manufacturers/suppliers available, and does the list include complete contact information?**	**Y**	**P**	**N**		2
Standard: *Each laboratory should keep a comprehensive and up-to-date list of approved manufacturers/suppliers that includes full contact details to expedite ordering, tracking and follow-up.* ***ISO 15189: 4.6.4***					
7.4 Budgetary Projections **Are budgetary projections based on personnel, test, facility and equipment needs as well as quality assurance procedures and materials?**	**Y**	**P**	**N**		2
Standard: ISO 15189: 5.1.4 (i) *"Provide effective and efficient administration of the medical laboratory service, including budget planning and control with responsible financial management."*					
7.5 Management Review of Supply Requests **Does management review the finalized supply requests?**	**Y**	**P**	**N**		2
7.6 Order Tracking, Inspection and Documentation **Are all orders tracked until delivery; are orders inspected, receipted and labeled with date of receipt when checked in?**	**Y**	**P**	**N**		2
Standard: *All incoming orders should be inspected for condition and completeness, receipted and documented appropriately; the date received in the laboratory and the expiry date for the product should be clearly indicated.* ***ISO 15189: 4.6.1 and 4.6.3***					

7.7 Inventory Control System **Is an inventory control system in place?**	**Y**	**P**	**N**		2
Criteria and procedures	**Tick for each item**				
	Yes	**No**			
Acceptance and rejection of consumables					
Recording of lot number, date of receipt, receiver and date placed into service					
Storage of consumables					
Standard: *The laboratory should have an inventory control system for supplies that monitors receipt, storage and use of consumables.* ***ISO 15189: 4.6.1, 4.6.3***					
7.8 Laboratory Inventory System **Are inventory records complete and accurate, with minimum and maximum stock levels denoted?**	**Y**	**P**	**N**		2
Standard: *The laboratory inventory system should reliably inform staff of the minimum amount of stock to be kept in order to avoid interruption of service due to stock-outs and the maximum amount to be kept by the laboratory to prevent expiry of reagents.* ***ISO 15189: 4.6.3***					
7.9 Usage Rate Tracking of Consumables **Is consumption rate monitored?**	**Y**	**P**	**N**		2
Standard: *The inventory control system must allow the laboratory to track the rate of usage of consumables.* ***ISO 15189: 4.6.3***					
7.10 Inventory Control System and Stock Counts **Are stock counts routinely performed?**	**Y**	**P**	**N**		2
Standard: *The laboratory must routinely perform stock counts as part of its inventory control system.* ***ISO 15189: 4.6.3***					
7.11 Storage Area **Are storage areas set up and monitored appropriately?**	**Y**	**P**	**N**		2
	Tick for each item				
	Yes	**No**	**N/A**		
Is the storage area well-organized and free of clutter?					
Are there designated places labeled for all inventory items?					
Are hazardous chemicals stored appropriately?					
Is adequate cold storage available?					
Are storage areas monitored as per prescribed storage conditions?					
Is the ambient temperature monitored routinely?					
Is storage in direct sunlight avoided?					
Is the storage area adequately ventilated?					
Is the storage area clean and free of dust and pests?					
Are storage areas access-controlled?					
Standard: CAP Laboratory General Checklist, 2010 ***GEN 61300, 61400,61500,61600,61900,62000 and 62100***					
7.12 Inventory Organization and Wastage Minimization **Is First-Expiry-First-Out (FEFO) practised?**	**Y**	**P**	**N**		2

USAID Standard: *To minimize wastage from product expiry, inventory should be organized in line with the First-Expiry-First-Out (FEFO) principle. Place products that will expire first in front of products with a later expiry date and issue stock accordingly to ensure products in use are not past their expiry date. Remember that the order in which products are received is not necessarily the order in which they will expire.* ***USAID Deliver Project, Logistics Handbook, Task Order 1***					
7.13 <u>Disposal of Expired Products</u> Are expired products labeled and disposed of properly?	**Y**	**P**	**N**		2
Standard: *Expired products should be disposed of properly. If safe disposal is not available at the laboratory, the manufacturer/supplier should take back the expired stock at the time of their next delivery.*					
7.14 <u>Product Expiration</u> Are all reagents/test kits in use (and in stock) currently within the manufacturer-assigned expiration dates or within stability?	**Y**	**P**	**N**		2
CAP Standard: *All reagents and test kits in use, as well as those in stock, should be within the manufacturer-assigned expiry dates. Expired stock should not be entered into use and should be documented before disposal.* ***Chemistry and Toxicology Checklist, CHM 12660, 2010***					
7.15 <u>Laboratory Testing Services</u> Has the laboratory provided uninterrupted testing services, with no disruptions due to stock-outs in the last year or since last audit?	**Y**	**P**	**N**		2
Standard: *Testing services should not be subject to interruption due to stock-outs. Laboratories should pursue all options for borrowing stock from another laboratory or referring samples to another testing facility while the stock-out is being addressed.*					
SECTION 7: PURCHASING and INVENTORY Subtotal					**30**

For each item, please circle Yes (Y), Partial (P) or No (N). All elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.

	Y	P	N	Comments	Score
8. PROCESS CONTROL AND INTERNAL AND EXTERNAL QUALITY ASSESSMENT					
8.1 Are guidelines for patient identification, specimen collection (including client safety), labeling and transport readily available to persons responsible for primary sample collection?	**Y**	**P**	**N**		2
Standard: ISO 15189: 5.4.2 *"Specific instructions for the proper collection and handling of primary samples should be documented and implemented by laboratory management and made available to those responsible for primary sample collection."*					
8.2 Are adequate sample receiving procedures in place?	**Y**	**P**	**N**		3
	Tick for each item				
	Yes	**No**	**N/A**		
Are specimens labeled with patient ID, test, date, time of collection, date of collection and authorized requester?					
Are all test requests accompanied by an acceptable and approved test requisition form?					
If not a 24-hour lab, is there a documented method for handling specimens received after hours?					
Are all samples that are either received or referred to a higher level laboratory accompanied by a sample delivery checklist or transmittal sheet?					
Are received specimens evaluated according to acceptance/rejection criteria?					
Are specimens logged appropriately upon receipt in the laboratory (including date, time and name of receiving officer)?					
When samples are split, can the portions be traced back to the primary sample?					
Is a two-identifier system in use, and is each sample assigned a unique identifying number?					
Are procedures in place to process "urgent" specimens and verbal requests?					
Are specimens delivered to the correct workstations in a timely manner?					
Standard* : *ISO 15189: 5.4.1, 5.4.5, 5.4.7, 5.4.8, 5.4.10, 5.4.11, 5.4.13					
8.3 Are specimens stored appropriately prior to testing?	**Y**	**P**	**N**		2
Are specimens disposed of in a safe manner?					
Standard: *Specimens should be stored under the appropriate conditions to maintain the stability of the specimen. Specimens no longer required should be disposed of in a safe manner, according to biosafety regulations.* ***ISO 15189: 5.2.9, 5.7.3*** *"Relevant storage space and conditions shall be provided to ensure the continuing integrity of samples, slides, histology blocks, retained micro-organisms, documents, files, manuals, equipment, reagents, laboratory supplies, records and results."*					
8.4 Are specimens packaged appropriately according to local and or international regulations and transported to referral laboratories within acceptable timeframes?	**Y**	**P**	**N**		2

Standard: *All samples should be transported to the laboratory in such a manner as to prevent contamination of workers, patients or the environment.* ***ISO Safety Standard 15190: Clause 26***					
8.5 Are referred specimens tracked properly using a logbook or tracking form?	**Y**	**P**	**N**		2
Standard: ISO 15189: 4.5.3 *"The laboratory shall maintain a register of all referral laboratories that it uses. A register shall be kept of all samples that have been referred to another laboratory" The referral log must be reviewed routinely for outstanding results and turnaround times.*					
8.6 Is a complete procedure manual available at the workstation or in the work area?	**Y**	**P**	**N**		3
Standard: ISO 15189: 5.5.3 *"All procedures shall be documented and be available at the workstation for relevant staff. Documented procedures and necessary instructions shall be available in a language commonly understood by the staff in the laboratory."*					
8.7 Is there a reagent logbook for lot number and dates of opening that reflects verification of new lots?	**Y**	**P**	**N**		2
Standard: "*Purchased equipment and consumable supplies that affect the quality of the service shall not be used until they have been verified as complying with standard specifications or requirements defined for the procedures concerned. This may be accomplished by examining quality control samples and verifying that results are acceptable."* ***ISO 15189: 4.6.2***					
8.8 Is each new lot number, new shipment of reagents, or consumable verified before use?	**Y**	**P**	**N**		2
Standard: ISO 15189: 4.6.2 *"Purchased equipment and consumable supplies that affect the quality of the service shall not be used until they have been verified as complying with standard specifications or requirements defined for the procedures concerned. This may be accomplished by examining quality control samples and verifying that results are acceptable."*					
8.9 Is internal quality control performed, documented and verified before releasing patient results?	**Y**	**P**	**N**		3
Standard: ISO 15189: 4.2.2, 5.6.1 *"The laboratory shall design internal quality control systems that verify the attainment of the intended quality of results. It is important that the control system provide staff members with clear and easily understood information on which to base technical and medical decisions."*					
8.10 Are QC results monitored and reviewed (biases, shifts, trends and Levy-Jennings charts)? Is documentation of corrective action done in a timely manner when quality control results exceed the acceptable range?	**Y**	**P**	**N**		3
Standard: ISO 15189: 5.6.1 *"The laboratory shall design internal quality control systems that verify the attainment of the intended quality of results." As part of the laboratory internal quality control systems L-J charts should be used to monitor quantitative tests on a daily basis and reviewed routinely.*					
8.11 Are environmental conditions checked and reviewed accurately?	**Y**	**P**	**N**		2
	Tick for each item				
Are the following environmental conditions checked daily?	**Yes**	**No**	**N/A**		
Room temperature					
Freezer					
Refrigerator					
Incubator					
Water bath					
Standard: **ISO 15189: 5.2.5** ***"****The laboratory shall monitor, control and record environmental conditions, as required by relevant specifications or where they may influence the quality of the results."*					
8.12 Have acceptable ranges been defined for	**Y**	**P**	**N**		2

all temperature-dependent equipment with procedures and documentation of action taken in response to out-of-range temperatures?					
Standard: SMILE, Johns Hopkins University, Baltimore, MD, Pro 71-07, May 20, 2010 "*Acceptable ranges or criteria must be defined, with documentation of action taken in response to out of range temperatures."*					
8.13 Does the laboratory participate in external proficiency testing (PT) or exercise an alternative performance assessment system when appropriate?					3
Are the following criteria met?	**Tick for each item**				
	Yes	**No**	**N/A**		
Are blinded characterized samples routinely distributed for testing to determine accuracy?					
Do PT samples come from providers who are accredited or approved?					
Are PT specimens handled and tested the same way as patient specimens?					
Is cause analysis performed for unacceptable PT results?					
Is corrective action documented for unacceptable PT results?					
Standard: *The laboratory should handle, analyse, review and report results for proficiency testing in a manner similar to regular patient testing. Investigation and correction of problems identified by unacceptable proficiency testing should be documented. Acceptable results showing bias or trends suggest that a problem should also be investigated.* ***ISO 15189: 4.2.2, 5.6.4, 5.6.5, 5.6.7***					
8.14 Are test requests checked with test results, thereby assuring the accuracy and completion of all tests?	**Y**	**P**	**N**		2
Standard: *A standard procedure should be followed for cross-checking all results. In instances where there is a laboratory information system daily printing of pending reports, a list should be done routinely to cross-check the completion of all tests within the defined turnaround times.* ***ISO 15189: 5.7.1 "****Authorized personnel shall systematically review the results of examinations, evaluate them in conformity with the clinical information available regarding the patient and authorize the release the results."*					
SECTION 8: PROCESS CONTROL and INTERNAL and EXTERNAL QUALITY ASSESSMENT Subtotal					**33**

For each item, please circle Yes (Y), Partial (P) or No (N). All elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.

	Y	P	N	Comments	Score
9. INFORMATION MANAGEMENT					
9.1 Test Result Reporting System **Are test results legible, technically verified by an authorized person and confirmed against patient identity?**	**Y**	**P**	**N**		2
Standard: *Results must be written in ink and written clearly with no mistakes in transcription. Cancellation must follow Good Lab Practices. The persons performing the test must indicate verification of the results. There must be a signature or identification of the person authorizing the release of the report.* ***ISO 15189: 5.8.3***					
9.2 Testing Personnel **Are testing personnel identified on the requisition and record?**	**Y**	**P**	**N**		2
Standard: *The person who performed the procedure must be identified on the report for purposes of audit trail.* ***ISO 15189: 5.4.7 "****All primary samples received shall be recorded in an accession book, worksheet, computer or other comparable system. The date and time of receipt of samples, as well as the identity of the receiving officer, shall be recorded."*					
9.3 Test Result Records **Are test results recorded in a logbook or electronic record in a timely manner?**	**Y**	**P**	**N**		2
Standard: *In line with maintaining agreed turnaround times, the laboratory should perform and record test results in a timely manner, and confidentiality of reported and stored result reports should be maintained.*					
9.4 Analytic System/Method Tracing **When more than one instrument is in use for the same test, are test results traceable to the equipment used for testing?**	**Y**	**P**	**N**		2
Standard: *It is important that the laboratory has the ability to trace specimen results to a specific analytical system or method. Proficiency testing specimens would also fall under specimen results.*					
9.5 Result Cross-check System **Is there a system of reviewing for transcription errors?**	**Y**	**P**	**N**		2
Standard: *The laboratory must have a system for cross-checking of results before release to requesters in order to identify and correct errors.* ***ISO 15189: 5.8.3 "****Results shall be legible, without mistakes in transcription and reported to persons authorized to receive and use medical information."*					
9.6 Archived Data Labeling and Storage **Are archived results (paper or data-storage methods) properly labeled and stored in a secure location accessible only to authorized personnel?**	**Y**	**P**	**N**		**2**
Standard: *All patient data, paper, tapes, disks should be properly labeled and stored securely in places accessible only to authorized personnel.* ***ISO 15189: 5.8.3 Annex B 6.4.***					
9.7 Information and Data Back-up System **Are there documented procedures to prevent the loss of test result data in the event of hardware/software failure, fire or theft?**	**Y**	**P**	**N**		**2**
Standard: *The laboratory should have a procedure to protect essential data in the event of equipment failure and/or an unexpected destructive event. These procedures could include flood and fire safe storage of data, periodic backing up and storing of information, and off-site storage of back-up data.* ***ISO 15189: 5.8.3 Annex B 3.3.***					

9.8 <u>Test Result Report</u> Is the laboratory result report(s) in a standard form determined to be acceptable by customers?	**Y**	**P**	**N**		2
Indicate for each item	**Tick for each item**				
	Yes	**No**			
Is the laboratory issuing the report clearly identified?					
Does the report contain the patient's name and address and the destination (hospital) for the report?					
Is the name of the person requesting the test indicated on the report?					
Is the type of sample received and the test requested included in the report?					
Are the date and time of specimen collection, receipt of specimen and release of report indicated?					
Does the report indicate biological reference ranges for each test?					
Is the result reported in SI units where applicable?					
Is there space for interpretation of results, when applicable, and for indication of when specimens are received and unsuitable for the procedure requested for testing?					
Does the result contain the name of the person authorizing release of the report and the signature of the person accepting responsibility for its content?					
9.9 <u>Test Result</u> Are test results validated, interpreted and released by appropriately authorized personnel?	**Y**	**P**	**N**		2
SECTION 9: INFORMATION MANAGEMENT Subtotal					18

For each item, please circle Yes (Y), Partial (P) or No (N). All elements of the item must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.

	Y	P	N	Comments	Score
10. CORRECTIVE ACTION					
10.1 Do all laboratory-documented occurrence reports indicate the root cause of the problem(s) and corrective and preventive actions taken to prevent recurrence?	**Y**	**P**	**N**		5
Standard: *There must be at least a description of what happened and what was done to prevent recurrence.* ***ISO 15189: 4.8*** *"Laboratory shall have a policy and procedures for the resolution of complaints or other feedback received from clinicians, patients or other parties. Records of complaints and of investigations and corrective actions taken by the laboratory shall be maintained."*					
10.2 Is non-conforming work reviewed and submitted for troubleshooting and cause analysis?	**Y**	**P**	**N**		2
Standard: ISO 15189: 4.10.1; 5.6.7 *"Procedures for corrective action shall include an investigative process to determine the underlying cause or causes of the problem. These shall, where appropriate, lead to preventive actions. Corrective action shall be appropriate to the magnitude of the problem and commensurate with possible risks. The laboratory shall document, record and, as appropriate, expeditiously act upon results from these comparisons. Problems or deficiencies identified shall be acted upon and records of actions retained."*					
10.3 Is corrective action performed on all non-conforming aspects of the quality management system documented?	**Y**	**P**	**N**		3
Indicate for each item	**Tick for each item**				
	Yes	**No**			
Are results withheld, if indicated by the level of control violated? ***ISO 4.9.1 part d***					
Have these been recalled and corrected, if results *have been released?* ***ISO 4.9.1 part f***					
Is this approved by an authorized person, when testing resumes? ***ISO 4.9.1 part g***					
Standard: ISO 15189:4.9.1 ***"****Laboratory management shall have a policy and procedure to be implemented when it detects that any aspect of its examinations does not conform with its own procedures or the agreed upon requirements of its quality management system or the requesting clinicians."*					
10.4 Are discordant results tracked and appropriate corrective action taken?	**Y**	**P**	**N**		2
Standard: ISO 15189: 4.10.1 *"Procedures for corrective action shall include an investigative process to determine the underlying cause or causes of the problem."*					
SECTION 10: CORRECTIVE ACTION Subtotal					**12**

For each item, please circle Yes (Y), Partial (P) or No (N). All elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.

	Y	P	N	Comments	Score
11. OCCURRENCE MANAGEMENT AND PROCESS IMPROVEMENT					
11.1 **Are graphical tools (charts and graphs) used to communicate quality findings and identify trends?**	**Y**	**P**	**N**		2
Standard: *Use of graphical displays of quality data communicates more effectively than tables of numbers. Examples of graphical tools commonly used for this purpose include Pareto charts, cause-and-effect diagrams, frequency histograms, trend graphs, and flow charts.* ***ISO 15189: 4.11.2 , Note 1*** *"Apart from the review of the operational procedures, preventive action might involve analysis of data, including trend-and risk-analyses and external quality assurance."*					
11.2 **Are quality indicators (TAT, rejected specimens, stock-outs, etc) selected, tracked and reviewed regularly to monitor laboratory performance and identify potential quality improvement activities?**	**Y**	**P**	**N**		5
11.3 Are the outcomes of internal and external audits, PT, customer feedback and all other information derived from the tracking of quality indicators used to improve lab performance?	**Y**	**P**	**N**		**3**
11.4 Is the outcome of the action taken checked and monitored to determine the effectiveness of improved quality of lab performance?	**Y**	**P**	**N**		**2**
Standard: *Key indicators of quality must be monitored regularly and evaluated for opportunities to improve testing services. Indicators should be drawn from pre-analytic, analytic and post-analytic phases and reflect activities critical to patient outcomes, those that correspond to a large proportion of the laboratory's patients, or areas that have been problematic in the past. These indicators should be compared against a benchmark from an acknowledged guideline.* ***ISO 15189: 4.12.4, 5.8.11*** *"Laboratory management shall implement quality indicators for systematically monitoring and evaluating the laboratory… These indicators should be compared against a benchmark from an acknowledged guideline. Laboratory management, in consultation with the requesters, shall establish turnaround times for each of its examinations. A turnaround time shall reflect clinical needs."*					
SECTION 11: OCCURRENCE MANAGEMENT and PROCESS IMPROVEMENT Subtotal					**12**

For each item, please circle Yes (Y), Partial (P), or No (N). All elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.

	Y	P	N	Comments	Score
12. FACILITIES AND SAFETY					
12.1 **Is the size of the laboratory adequate and the overall layout of the laboratory organized so that workstations are positioned for optimal workflow?**	**Y**	**P**	**N**		2
Standard: *The laboratory floor plan should be configured to promote high quality work, personnel safety and efficient operations.* ***ISO 15189: 5.2.2***					
12.2 Are the patient care and testing areas of the laboratory distinctly separate from one another?	**Y**	**P**	**N**		2
Standard: *Client service areas (i.e. waiting room, phlebotomy room) should be distinctly separate from the testing areas of the laboratory. Client access should not compromise "clean" areas of the laboratory. For biosafety reasons, microbiology and TB testing should be segregated in a separate room(s) from the general laboratory testing.* ***ISO 15189: 5.2.6*** *"There shall be effective separation between adjacent laboratory sections in which there are incompatible activities. Measures shall be taken to prevent cross-contamination."*					
12.3 Is each individual workstation maintained free of clutter and set up for efficient operation?	**Y**	**P**	**N**		2
Are the following criteria met?	**Tick for each item**				
	Yes	**No**	**N/A**		
Does the equipment placement/layout facilitate optimum workflow?					
Are all needed supplies present and easily accessible?					
Are the chairs/stools at the workstations appropriate for bench height and the testing operations being performed? ***ISO 15190: 6.3.5***					
Is reference material readily available (critical values and required action, population reference ranges, frequently called numbers)?					
CAP Standard: *Age-and sex-specific reference intervals (normal values) must be verified or established by laboratory. If a formal reference intervals study is not possible or practical, then the laboratory should carefully evaluate the use of published data for its own reference ranges and retain documentation of this evaluation.* ***General Checklist, GEN.42162, 2010***					
12.4 Is the physical work environment appropriate for testing?	**Y**	**P**	**N**		2
Is the workplace:	**Tick for each item**				
	Yes	**No**	**N/A**		
Free of clutter? ***ISO 15190: 13.0***					
Adequately ventilated? ***ISO 15190: 6.3.3***					
Free of excess humidity? ***ISO 15190: 6.3.3***					
Adequately lit? ***ISO 15190: 6.3.1***					

Climate-controlled for optimum equipment function? ***ISO 15190: 6.3.2***					
Are filters checked, cleaned and/or replaced at regular intervals, where air-conditioning is installed?					
Are wires and cables properly located and protected from traffic?					
Is there a functioning back-up power supply (generator)?					
Is critical equipment supported by uninterrupted power source (UPS) systems?					
Is equipment placed appropriately (away from water hazards, out of traffic areas)?					
Is a contingency plan in place for continued testing in the event of prolonged electricity disruption?					
Are appropriate provisions made for adequate water supply, including deionized or distilled water, if needed?					
Is clerical work completed outside the testing area?					
Is major safety signage posted and enforced, including NO EATING, SMOKING, DRINKING?					
Standard: *The laboratory space should be sufficient to ensure the quality of work, safety of personnel and the ability of staff to carry out quality control procedures and documentation. The laboratory should be clean and well organized, free of clutter, well ventilated, adequately lit and within acceptable temperature ranges.* ***ISO 15189: 5.2.5 and 5.2.10 and CAP GEN.66100, General Checklist, 2010*** *"Emergency power supply should be adequate for refrigerators, freezers, incubators, etc to ensure preservation of patient specimens. Depending on the type of testing performed in the laboratory, emergency power may also be required for the preservation of reagents, the operation of laboratory instruments, and the functioning of the data processing system."*					
12.5 Is the laboratory properly secured from unauthorized access with appropriate signage?	**Y**	**P**	**N**		2
Standard: *The access of unauthorized persons to the laboratory should be strictly limited to avoid the unnecessary contact of individuals with contaminated areas, reagents or equipment. Unnecessary traffic should not disturb workflow or distract staff members.* ***ISO 15189: 5.2.7***					
12.6 Is laboratory-dedicated cold and room temperature storage free of staff food items, and are patient samples stored separately from reagents and blood products in the laboratory refrigerators and freezers?	**Y**	**P**	**N**		2
Standard: *Staff food items should be stored in separate locations dedicated to that purpose, not in laboratory storage areas, particularly cold storage. Laboratory reagents and blood products should be stored separately when refrigerated or frozen.* ***ISO 15190: 11.1***					
12.7 Is the work area clean and free of leakage and spills, and are disinfection procedures conducted and documented?	**Y**	**P**	**N**		2
Standard: *The work area should be regularly inspected for cleanliness and leakage. An appropriate disinfectant should be used. At a minimum, all bench tops and working surfaces should be disinfected at the beginning and end of every shift. All spills should be contained immediately and the work surfaces disinfected.* ***ISO 15189: 5.2.10; ISO 15190:13***					
12.8 Is a certified and appropriate biosafety cabinet (or an acceptable alternative processing procedure) in use for all specimens or organisms considered to	**Y**	**P**	**N**	If required by testing activities.	2

be highly contagious by airborne routes? (Biosafety cabinet should be recertified according to national protocol.)					

Standard: *A biosafety cabinet should be used to prevent aerosol exposure to contagious specimens or organisms. For proper functioning and full protection, biosafety cabinets* require periodic maintenance and should be serviced accordingly.

ISO 15190: 16

12.9 Is a laboratory safety manual available, accessible and up-to-date?	**Y**	**P**	**N**		3
	Tick for each item				
Does the safety manual include guidelines on the following topics?	**Yes**	**No**	**N/A**		
Blood and body fluid precautions					
Hazardous waste disposal					
Hazardous chemicals/materials					
MSDS sheets					
Personal protective equipment					
Vaccination					
Post-exposure prophylaxis					
Fire safety					
Electrical safety					

Standard: A *safety manual should be readily available in work areas as required reading for all employees. The manual should be specific to the laboratory's needs; it should be reviewed and updated at least annually by laboratory management.*

ISO 15190: 7.4

12.10 Is sufficient waste disposal available and is waste separated into infectious and non-infectious waste, with infectious waste autoclaved?	**Y**	**P**	**N**		2

Standard: *Waste should be separated according to biohazard risk, with infectious and non-infectious waste disposed of in separate containers. Infectious waste should be discarded into containers that do not leak and are clearly marked with a biohazard symbol. Sharp instruments and needles should be discarded in puncture resistant containers. Both infectious waste and sharps containers should be autoclaved before being discarded to decontaminate potentially infectious material. To prevent injury from exposed waste, infectious waste should be incinerated, burnt in a pit or buried.*

ISO 15190:22

12.11 Are hazardous chemicals/materials properly handled?	**Y**	**P**	**N**		2
	Tick for each item				
	Yes	**No**	**N/A**		
Are hazardous chemicals properly labeled?					
Are hazardous chemicals properly stored?					
Are hazardous chemicals properly utilized?					
Are hazardous chemicals properly disposed of?					

Standard: *All hazardous chemicals must be labeled with the chemical's name and with hazard markings clearly indicated. Flammable chemicals must be stored out of sunlight and below their flashpoint, preferably in a still cabinet in a well-ventilated area. Flammable and corrosive agents should be separated from one another. Distinct care should always be taken to handle hazardous chemicals safety in the workplace.*

ISO 15190: 17.1 and 17.3

12.12 Are sharp instruments handled and disposed of properly in separate containers that are appropriately utilized?	**Y**	**P**	**N**		2

Standard: *All syringes, needles, lancets or other bloodletting devices capable of transmitting infection must be used only once and discarded in puncture resistant containers that are not overfilled. Sharps containers should be clearly marked to warn handlers of the potential hazard and should be located in areas where sharps are commonly used.*

ISO 15189: 5.2.10; CAP GEN.773100, General Checklist, 2010

12.13 Is fire safety included as part of the	**Y**	**P**	**N**		2

laboratory's overall safety programme?					
	Tick for each item				
	Yes	**No**	**N/A**		
Are all electrical cords, plugs and receptacles used appropriately and in good repair?					
Is an appropriate fire extinguisher available, properly placed, in working condition and routinely inspected?					
Is an operational fire warning system in place in the laboratory, and are there periodic fire drills?					

Standard: *Electrical cords and plugs, power-strips and receptacles should be maintained in good condition and utilized appropriately. Overcrowding should be avoided and cords should be kept out of walkway areas. An approved fire extinguisher should be easily accessible within the laboratory and be routinely inspected and documented for readiness. Fire extinguishers should be kept in their assigned place and not hidden or blocked; the pin and seal should be intact, nozzles should be free of blockage, pressure gauges should show adequate pressure, and there should be no visible signs of damage. A fire alarm should be installed in the laboratory and tested regularly for readiness; all staff should participate in periodic fire drills.*

ISO 15190: 19.7 and 9.3

12.14 Are safety inspections or audits conducted regularly and documented?	**Y**	**P**	**N**		2

Standard: *Safety inspections or audits, using a safety checklist, should be conducted periodically to ensure that the laboratory is a safe work environment; audits should identify areas for redress and correction.*

ISO 15190 7.3.1 and 7.3.2

12.15 Is standard safety equipment available and in use in the laboratory?	**Y**	**P**	**N**		2
	Tick for each item				
	Yes	**No**	**N/A**		
Biosafety cabinet(s) ***ISO 15190: 16***					
Covers on centrifuge(s)					
Hand-washing station ***ISO 15190: 12.7***					
Eyewash station/bottle(s) and showers where applicable ***ISO 15190: 12.10***					
Spill kit(s)					
First aid kit(s) ***ISO 15190: 12.9***					

Standard: *It is the responsibility of laboratory management to ensure that the laboratory is equipped with standard safety equipment. The list above is a partial list of necessary items. Biosafety cabinets should be in place and in use and all centrifuges should have covers. Hand-washing stations should be designated and equipped and eyewash stations (or an acceptable alternative method of eye cleansing) should be available and operable. Spill kits and first aid kits should be kept in a designated place and checked regularly for readiness.*

ISO 15190: 5.1

12.16 Is personal protective equipment (PPE) easily accessible at the workstation and utilized appropriately and consistently?	**Y**	**P**	**N**		2

Standard: *Management is responsible for providing appropriate personal protective equipment (gloves, lab coats, eye protection, etc) in useable condition. Laboratory staff must utilize PPE at all times while in the laboratory. Protective clothing should not be worn outside the laboratory. Gloves should be replaced immediately when torn or contaminated and not washed for reuse.*

ISO 15190: 12

12.17 Are laboratory personnel offered	**Y**	**P**	**N**		2

appropriate vaccination//preventive measures?					
Standard: *Laboratory staff should be offered appropriate vaccinations—particularly Hepatitis B. Staff may decline to receive the vaccination, but they must then sign a declination form to be held in the staff member's personnel file.* ***ISO 15190: 11.3***					
12.18 Are post-exposure prophylaxis policies and procedures posted and implemented after possible and known exposures?	**Y**	**P**	**N**		2
Standard: *The laboratory must have a procedure for follow-up of possible and known percutaneous, mucus membrane or abraded skin exposure to HIV, HBV or HCV. The procedure should include clinical and serological evaluation and appropriate prophylaxis.* ***ISO 15190: 9***					
12.19 Are occupational injuries, medical screening or illnesses documented in the safety occurrence log?	**Y**	**P**	**N**		2
Standard: *All occupational injuries or illnesses should be thoroughly investigated and documented in the safety log or occurrence log, depending on the laboratory. Corrective actions taken by the laboratory in response to an accident or injury must also be documented.* ***ISO 15190: 9***					
12.20 Are drivers/couriers and cleaners working with the laboratory trained in biosafety practices relevant to their job tasks?	**Y**	**P**	**N**		2
Standard: *All occupational injuries or illnesses should be thoroughly investigated and documented in the safety log or occurrence log, depending on the laboratory. Corrective actions taken by the laboratory in response to an accident or injury must also be documented.* ***ISO 15190: 10***					
12.21 Is a trained safety officer designated to implement and monitor the safety programme in the laboratory, including the training of other staff?	**Y**	**P**	**N**		2
Standard: *A safety officer should be designated to work with the laboratory manager to implement the safety programme, monitor the ongoing safety conditions and needs of the laboratory, coordinate safety training, and serve as a resource for other staff. This officer should receive safety training.* ***ISO 15190: 7,10***					
SECTION 12: FACILITIES and SAFETY Subtotal					**43**

ETHICAL PRINCIPLES IN LABORATORY MEDICINE

"Laboratories shall uphold the principle that the welfare and interest of the patient are paramount and patients should be treated fairly and without discrimination." (ISO 15189 Annex C.2.1)

"Every medical laboratory shall provide its services to all users in a manner that respects their health rights and without discrimination." (ISO 15189 Annex C 2.2)

"Every medical laboratory shall ensure that patient consent is obtained for all procedures carried out on the patient. In emergency situations, if consent is not possible under these circumstances, necessary procedures may be carried out, provided they are in the best interest of the patient." (ISO 15189 Annex C 4.1)

"Medical laboratories should have in place policy guidelines that address conflicts of interest, undue internal or external pressure, and confidentiality that could influence the credibility of the work conducted and information generated by the laboratory." (ISO 15189 Clause 4.1.4 and 4.1.5 b, c, d and 5.1.13)

"Personnel employed within medical laboratories shall not compromise their organization by engaging in activities that could adversely affect quality of work, competence, impartiality, judgment or operational integrity." (ISO 15189 Clause 4.1.5 b, d).

Criteria 1	Are internal quality control procedures routinely conducted for all test methods?	FREQUENCY		
		Daily	Weekly	With Every Run
1.1	**Monitoring of control values**			
	Quantitative tests			
	Semi-quantitative tests			
	Qualitative tests			
1.2	**Monitoring with internal standards**			
	Quantitative tests			
	Semi-quantitative tests			
	Qualitative tests			
1.3	**Monitoring quality of each new batch of kits**			
	Quantitative tests			
	Semi-quantitative tests			
	Qualitative tests			
1.4	**Documentation of internal controls and kits validation**			
	Quantitative tests			
	Semi-quantitative tests			
	Qualitative tests			
COMMENTS and RECOMMENDATIONS				

Criteria 2	Has the laboratory achieved acceptable PT results of at least 80% on the two most recent PT challenges?	Date of panel receipt	Were results reported within 15 days?		Results and % correct
	HIV Serology				**%**
2.1	Most recent HIV panel		**Y**	**N**	
2.2	Second most recent HIV panel		**Y**	**N**	
	HIV DNA PCR				**%**
2.3	Most recent HIV DNA PCR panel		**Y**	**N**	
2.4	Second most recent HIV panel		**Y**	**N**	
	HIV Viral Load				**%**
2.5	Most recent HIV DNA PCR panel		**Y**	**N**	
2.6	Second most recent HIV panel		**Y**	**N**	
	CD4 Count				**%**
2.7	Most recent CD4 panel		**Y**	**N**	
2.8	Second most recent CD4 panel		**Y**	**N**	
	Chemistry				**%**
2.9	Most recent chemistry panel		**Y**	**N**	
2.10	Second most recent chemistry panel		**Y**	**N**	
	Hematology				
2.11	Most recent hematology panel		**Y**	**N**	
2.12	Second most recent hematology panel		**Y**	**N**	
	Malaria				**%**
2.13	Most recent malaria panel		**Y**	**N**	
2.14	Second most recent malaria panel		**Y**	**N**	
	Mycobacterium tuberculosis				**%**
2.15	Most recent TB smear panel		**Y**	**N**	
2.16	Second most recent TB smear panel		**Y**	**N**	
2.17	Most recent TB culture panel		**Y**	**N**	
2.18	Second most recent TB culture panel		**Y**	**N**	
2.19	Most recent drug susceptibility panel		**Y**	**N**	
2.20	Second most recent drug susceptibility panel		**Y**	**N**	
	Other disease of public health significance (please specify)				**%**
2.21	Most recent PT panel		**Y**	**N**	
2.22	Second most recent PT panel		**Y**	**N**	
	Other disease of public health significance (please specify)				**%**
2.23	Most recent PT panel		**Y**	**N**	
2.24	Second most recent PT panel		**Y**	**N**	

PART III: SUMMARY OF AUDIT FINDINGS

SUMMARY

Noted Commendations

Noted Challenges

RECOMMENDATIONS

ACTION PLAN (if applicable)

Follow-up Actions	Responsible Person	Timeline	Signature

Criteria for SLIPTA (5-star certification and accreditation of international standards)

1. **Test results are reported by the laboratory on at least 80% of specimens within the turnaround time specified (and documented) by the laboratory in consultation with its clients.** *Turnaround time to be interpreted as time from receipt of specimen in laboratory until results reported.* **DATA NOT COLLECTED ON THIS ELEMENT**

2. **Internal quality control (IQC) procedures are practised for all testing methods used by the laboratory.** Ordinarily, each test kit has a set of positive and negative controls that are to be included in each test run. These controls included with the test kit are considered internal controls, while any other controls included in the run are referred to as external controls. QC data sheets and summaries of corrective action are retained for documentation and discussion with auditor.

3. **The scores on the two most recent WHO Regional Office approved proficiency tests are 80% or better.** Proficiency test (PT) results must be reported within 15 days of panel receipt. Laboratories that receive less than 80% on two consecutive PT challenges will lose their certification until such time that they are able to successfully demonstrate achievement of 80% or greater on two consecutive PT challenges. Unacceptable PT results must be addressed and corrective action taken.

   NOTE: A laboratory that has failed to demonstrate achievement of 80% or greater on the two most recent PT challenges will not be awarded any stars, regardless of the checklist score they received upon audit.

Score on annual on-site inspection is at least 55% (143 points):					Score	**Y**	**N**
No Stars (0–42 pts) *<55%*	**1 Star** (143–165 pts) *55–64%*	**2 Stars** (166–191 pts) *65–74%*	**3 Stars** (192–217 pts) *75–84%*	**4 Stars** (218–243 pts) *85–94%*	**5 Stars** (244–258 pts) *≥95%*		

Lead auditor signature_____

Date_____