World Health Organization

REGIONAL OFFICE FOR Africa

Stepwise Laboratory (Quality) Improvement Process Towards Accreditation (SLIPTA) Checklist

For Clinical and Public Health Laboratories

1.0 INTRODUCTION

Laboratory services are an essential component in the diagnosis and treatment of patients infected with the human immunodeficiency virus (HIV), malaria, *Mycobacterium tuberculosis* (TB), sexually transmitted diseases (STDs), and other infectious diseases. Presently, the laboratory infrastructure and test quality for all types of clinical laboratories remain in its nascent stages in most countries in Africa. Consequently, there is an urgent need to strengthen laboratory systems and services. The establishment of a process by which laboratories can achieve accreditation at international standards is an invaluable tool for countries to improve the quality of laboratory services.

In accordance with WHO's core functions of setting standards and building institutional capacity, WHO-AFRO has established the **Stepwise Laboratory (Quality) Improvement Process Towards Accreditation (SLIPTA)** to strengthen laboratory systems of its Member States. The **Stepwise Laboratory (Quality) Improvement Process Towards Accreditation (SLIPTA)** is 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. This initiative was spearheaded by a number of critical resolutions, including Resolution AFR/RC58/R2 on Public Health Laboratory Strengthening, adopted by the Member States during the 58th session of the Regional Committee in September 2008 in Yaoundé, Cameroon, and the Maputo Declaration to strengthen laboratory systems. This quality improvement process towards accreditation further provides a learning opportunity and pathway for continuous improvement, a mechanism for identifying resource and training needs, a measure of progress, and a link to the WHO-AFRO National Health Laboratory Service Networks.

Clinical, public health, and reference laboratories participating in the **Stepwise Laboratory (Quality) Improvement Process Towards Accreditation (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.

2.0 Scope

This checklist specifies requirements for quality and competency aimed to develop and improve laboratory services to raise quality to established national standards. The elements of this checklist are based on ISO standard 15189:2007(E) and, to a lesser extent, CLSI guideline GP26-A4; Quality Management System: A model for Laboratory Services; Approved Guideline – Fourth Edition.

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	1 Star	2 Stars	3 Stars	4 Stars	5 Stars
(0 – 141 pts)	(142 – 166 pts)	(167 – 192 pts)	(193 – 218 pts)	(219 – 243 pts)	(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 work plan.
- Monitor laboratory progress.
- Conduct re-testing where required.
- Continue steps to achieve full accreditation.

3.0 Parts of the Audit

This laboratory audit consists of three parts:

Part I: Profile of Laboratory

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

Part III: Summary of 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 AUDITS

Laboratory audits are an effective means to 1) determine if a laboratory is providing accurate and reliable results; 2) determine if the laboratory is well-managed and is adhering to good laboratory practices; and 3) 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, analyzing, 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 and the 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 Stepwise Laboratory Improvement Process Towards Accreditation Checklist contains 111 main sections (a total of 334 questions) for a total of 258 points. Each item has been awarded a point value of 2, 3, 4 or 5 points—based upon relative importance and/or 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 in order to indicate "yes" for a given item and thus award the corresponding points.**

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

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

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

When marking "partial" or "no", notes should be written in the comments field to explain why the laboratory did not fulfill this item to assist the laboratory with addressing these areas of identified need following the audit.

Audit Score Sheet

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

No Stars	**1 Star**	**2 Stars**	**3 Stars**	**4 Stars**	**5 Stars**
(0 – 141 pts)	(142 – 166 pts)	(167 – 192 pts)	(193 – 218 pts)	(219 – 243 pts)	(244 – 258 pts)
< 55%	*55 – 64%*	*65 – 74%*	*75 – 84%*	*85 – 94%*	*≥95%*

For each item, please circle either 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
1.0 DOCUMENTS & 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, and has the manual content been communicated to and 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 program, includes policies that address all areas of the laboratory service, and identifies the goals and objectives of the quality program. 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 (QSE).* ***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 ,d 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 within a timely manner. If documents and records are maintained in electronic form they should be backed up on CD 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 & 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 ***Standard 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 . ***Standard: 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, inquiries, verbal discussions and requests for additional examinations, meetings, and meeting minutes ***Standard: 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 ***Standard: ISO 15189: 4.5.1***					
Purchasing and Inventory Control Defines the processes for 1) requesting, ordering and receipt of supplies, 2) the 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 ***Standard: ISO 15189: 4.6***					
Advisory Services Defines the required qualifications and responsibility for providing advice on: 1) choice of examinations, 2) the 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 ***Standard: 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 ***Standard: 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 ***Standard: 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 ***Standard: 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 ***Standard: 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 ***Standard: 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 nonconformances raised within the agreed timeframe and effectiveness of corrective actions implemented ***Standard: 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 ***Standard: 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 ***Standard: ISO 15189: 5.1***				
Personnel Training Defines staff appraisals, staff orientation, initial training, refresher training, continuous education program, recommended and required trainings, and record-keeping of training ***Standard: 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 ***Standard: ISO 15189: 5.1.11***				
Authorization Defines the level of authorization for all tasks, roles and deputies for all staff ***Standard: 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 ***Standard: 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 ***Standard: ISO 15189: 5.3***				
Calibration of Equipment Defines frequency, the 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 from 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 backup 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 reissuance 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 <u>Policy and SOPs Accessibility</u> 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 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.* ***ISO 15189: 5.5.3, 4.3.2 Part C***					
1.6 <u>Policies and SOPs Communication</u> 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, programs, procedures and instructions shall 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 <u>Document Control Log</u> 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 Part (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 <u>Discontinued Policies and SOPs</u> 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 Part (e) and (f) – see above***					
1.9 <u>Data Files</u> Are test results and technical and quality records archived in accordance with national/international guidelines?	**Y**	**P**	**N**		2
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 requirements.* ***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 & RECORDS Subtotal					**25**

For each item, please circle either 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
2.0 MANAGEMENT REVIEWS					
2.1 <u>Workplan and Budget</u> **Does management develop and implement a workplan and develop 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 work plan 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 Part (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?	**Yes**	**No**			
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 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					
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 program 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 Interlaboratory 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 program 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 either 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
3.0 ORGANIZATION & PERSONNEL					
3.1 <u>Workload, Schedule and Coverage</u> **Do work schedules show task assignments & coordination of work for adequate lab 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 shall be enough staff resources adequate to cover the work as required and tasks should be prioritized, organized, and coordinated based upon 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 <u>Duty Roster And Daily Routine</u> **Are daily routine work tasks established, assigned (duty roster and workstation assignments/tasks), monitored and supervised by qualified professional staff, and which indicates 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 <u>Organizational Chart and External/Internal Reporting Systems</u> **Are lines of authority and responsibility clearly defined for all lab 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 Part (e & j)					
3.4 <u>Quality Management System Oversight</u> **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 <u>Personnel Filing System</u> **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 & 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 their 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 trainings 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 (HR) 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 lab 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: *"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. "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***					
SECTION 3: ORGANIZATION & PERSONNEL Subtotal					**20**

For each item, please circle either 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
4.0 CLIENT MANAGEMENT & 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 shall 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. This does not mean that the clinical personnel are to be notified of all delays of examination, but only 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 received effectively utilized to improve services?**	**Y**	**P**	**N**		2
Standard: *The laboratory should measure the satisfaction of client 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 & CUSTOMER SERVICE Subtotal					**8**

For each item, please circle either 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
5.0 EQUIPMENT					
5.1 <u>Adherence to Proper Equipment Protocol</u> Is equipment installed and placed as specified in the operator's manuals and uniquely labeled or marked?	**Y**	**P**	**N**		2
Standard: *Equipments 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 <u>Equipment and Method Validation/ Verification and Documentation</u> 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 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 <u>Equipment Record Maintenance</u> 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 analyzers as well as ancillary equipment like centrifuges, water baths, rotators, fridges, pipettes, timers, printers, computers.* ***ISO 15189: 5.3.4***					
5.4 <u>Equipment Maintenance Records</u> 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 regulations.* ***ISO 15189: 5.3.4***					
5.5 Obsolete Equipment Procedures **Is non-functioning equipment appropriately labeled and removed from the laboratory & 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 lab* ***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 require calibration must be calibrated according to the schedule, which at minimum must meet the manufacturer's recommendations. This shall cover major analyzers as well as ancillary equipments 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 equipments must be serviced at specified intervals by a qualified service engineer either through service contracts or otherwise. Service schedule must at minimum meet manufactures 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: *"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."* ***ISO 15189: 5.3.2***					
5.10 Equipment Malfunction - Response and Documentation **Is equipment malfunction resolved by the effectiveness of the corrective action program 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 if the service is completed? Does the laboratory verify and document that it is in proper working order before being put it back into service?**	**Y**	**P**	**N**		2
Standard: All equipment should receive thorough documented checks to ensure proper functioning before being returned into service, following its 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 reestablished.* ***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 shall 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 either 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
6.0 INTERNAL AUDIT					
6.1 <u>Internal Audits</u> **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 lab 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 <u>Audit Recommendations and Action Plan & Follow up</u> **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 either 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
7.0 PURCHASING & INVENTORY					
7.1 <u>Inventory and Budgeting System</u> 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 <u>Service Supplier Performance Review</u> Are supply & reagent specifications periodically reviewed and 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 <u>Manufacturer/Supplier List</u> Is an up-to-date list of approved manufacturers/suppliers available and includes their 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 <u>Budgetary Projections</u> Are budgetary projections based on personnel, test, facility and equipment needs, and 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 <u>Management Review of Supply Requests</u> Does management review the finalized supply requests?	**Y**	**P**	**N**		2
7.6 <u>Order Tracking, Inspection, and Documentation</u> Are all orders tracked until delivery and inspected, receipted, and labeled with date of receipt when the orders are checked in?	**Y**	**P**	**N**		2
Standard: *All incoming orders should be inspected for condition and completeness, receipted and documented appropriately and 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 <u>Inventory Control System</u> Is an inventory control system in place?	**Y**	**P**	**N**		2
Criteria and procedures for	**Tick for each item** **Yes**	**No**			
Acceptance and rejection of consumables					
Recording of lot number, date of receipt, received by and date placed into service					
Storage of consumables					
Standard: *There laboratory shall 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 <u>Laboratory Inventory System</u> Are inventory records complete and accurate, with minimum and maximum stock levels denoted?	**Y**	**P**	**N**		2
Standard: *The Laboratory inventory system shall reliably inform the Laboratory of how much at minimum must be kept in the laboratory to avoid interruption of service due to stock outs and how much at maximum must be kept by the lab to prevent expiry of reagents* ***ISO 15189: 4.6.3***					
7.9 <u>Usage Rate Tracking of Consumables</u> Is the consumption rate monitored?	**Y**	**P**	**N**		2
Standard: *The inventory control system must allow the Laboratory to track rate of usage of consumables* ***ISO 15189: 4.6.3***					
7.10 <u>Inventory Control System – Stock Counts</u> 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 <u>Storage Area</u> 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?					
CAP Standard: Laboratory General Checklist, 2010 ***GEN 61300, 61400,61500,61600,61900,62000 and 62100***					
7.12 <u>Inventory Organization and Wastage Minimization</u> Is First-Expiration-First-Out (FEFO) practiced?	**Y**	**P**	**N**		2
USAIDStandard: *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, the Logistics Handbook, Task Order 1, 2007***					

7.13 <u>Disposal of Expired Products</u> **Are expired products labeled and disposed 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 reagent 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 & INVENTORY Subtotal					**30**

For each item, please circle either 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
8.0 PROCESS CONTROL and INTERNAL & EXTERNAL QUALITY AUDIT					
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: *"Specific instructions for the proper collection and handling of primary samples shall be documented and implemented by laboratory management and made available to those responsible for primary sample collection."* ***ISO 15189: 5.4.2***					
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, and 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 of 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: *"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." 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***					
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 shall 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: "*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* ***ISO 15189: 4.5.3***					
8.6 Is complete procedure manual available at the workstation or in the work area?	**Y**	**P**	**N**		3
Standard: "*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."* ***ISO 15189: 5.5.3***					
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 consumables verified before use?	**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***					
8.9 Is internal quality control performed, documented, and verified before releasing patient results?	**Y**	**P**	**N**		3
Standard: *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* ***ISO 15189: 4.2.2, 5.6.1***					
8.10 Are QC results monitored and reviewed (biases, shifts, trends, and Levy-Jennings charts)? Is there documentation of corrective action when quality control results exceed the acceptable range in a timely manner?	**Y**	**P**	**N**		3
Standard: *"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 shall be used to monitor quantitative tests on a daily basis and reviewed routinely.* ***ISO 15189: 5.6.1***					
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					
Freezers					
Refrigerator					
Incubators					
Water Bath					
Standard: "*The laboratory shall monitor, control and record environmental conditions, as required by relevant specifications or where they may influence the quality of the results."* **ISO 15189: 5.2.5**					
8.12 Have acceptable ranges been defined for all temperature- dependent equipment with procedures and documentation of action taken in response to out of range temperatures?	**Y**	**P**	**N**		2
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?	**Y**	**P**	N		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, analyze, review, and report results for proficiency testing in manner similar to regular patient testing. Investigation and correction of problems identified by unacceptable proficiency testing should be documented. Acceptable results that show bias or trends suggest 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: "*Authorized personnel shall systematically review he results of examinations, evaluate them in conformity with the clinical information available regarding the patient and authorized the release the results." A standard procedure should be followed for crosschecking all results. In instances where there is a LIS (laboratory information system) daily printing of the pending reports list should be done routinely to cross-check the completion of all tests within the defined turnaround times.* ***ISO 15189: 5.7.1***					
SECTION 8: PROCESS CONTROL and INTERNAL & EXTERNAL QUALITY AUDIT Subtotal					**33**

For each item, please circle either 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
9.0 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, 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 signature or identification of 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 shall perform and record test results in a timely manner and confidentiality of reported and stored result reports shall 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 for 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 media) 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 Backup 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 backup 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 its 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, address, and the hospital/destination of 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 for 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?					2
SECTION 9: INFORMATION MANAGEMENT Subtotal					**18**

For each item, please circle either 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
10.0 CORRECTIVE ACTION					
10.1 Are all laboratory-documented occurrence reports indicating the root cause of the problem(s) and corrective & preventive actions taken to prevent recurrence?	**Y**	**P**	**N**	There must be at least a description of what happened and what was done to prevent it from happening again.	5
Standard: *"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."* ***ISO 15189: 4.8***					
10.2 Is non-conforming work reviewed and submitted for troubleshooting and cause analysis?	**Y**	**P**	**N**		2
Standard: *"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."* ***ISO 15189: 4.10.1; 5.6.7***					
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: *"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."* ***ISO 15189:4.9***					
10.4 Are discordant results tracked and appropriate corrective action taken?	**Y**	**P**	**N**		2
Standard: *"Procedures for corrective action shall include an investigative process to determine the underlying cause or causes of the problem."* ***ISO 15189: 4.10.1***					
SECTION 10: CORRECTIVE ACTION Subtotal					**12**

For each item, please circle either 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
11.0 OCCURRENCE / INCIDENT MANAGEMENT & PROCESS IMPROVEMENT					
11.1 Are graphical tools (charts and graphs) used to communicate quality findings and identify trends?	**Y**	**P**	**N**		2
Standard: *"Apart from the review of the operational procedures, preventive action might involve analysis of data, including trend-and risk-analyses and external quality assurance. "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***					
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: "*Laboratory management shall implement quality indicators for systematically monitoring and evaluating the laboratory's contributing These indicators should be compared against a benchmark from an acknowledged guideline." " Laboratory management, in consultation with the requesters, shall establishes turnaround times for each of its examinations. A turnaround time shall reflect clinical needs." 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***					
SECTION 11: OCCURRENCE/INCIDENT MGT, & PROCESS IMPROVEMENT Subtotal					**12**

For each item, please circle either 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
12.0 FACILITIES & SAFETY					
12.1 Is the size of the laboratory adequate and the layout of the laboratory, as a whole, 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: **"***There shall be effective separation between adjacent laboratory sections in which there are incompatible activities. Measures shall be taken to prevent cross-contamination." 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***					
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 water (DI) 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 that the quality of work, the 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. "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."* ***ISO 15189: 5.2.5 and 5.2.10 and CAP GEN.66100, General Checklist, 2010***

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 also disturbs workflow and can 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 & 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 be highly contagious by airborne routes? (Biosafety cabinet should be recertified according to national protocol).	**Y**	**P**	**N**	If required by testing activities.	2

Standard: *A Biosafety cabinet should be used for 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 shall be readily available in work areas as required reading for all employees. The manual shall be specific for the laboratory's needs. The Safety Manual shall 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?					
Standard: *All hazardous chemicals must be labeled with the chemical's name 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 'sharps' handled and disposed of properly in 'sharps' 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 laboratory's overall safety program?	**Y**	**P**	**N**		2
	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? ***ISO 15190: 19.7***					
Is an operational fire warning system in place in laboratory with periodic fire drills?					

ISO 15190: 9.3					
Standard: *Electrical chords and plugs, power-strips, and receptacles should be maintained in good condition and utilized appropriately. Overcrowding should be avoided and chords 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, not be 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 and all staff should participate in periodic fire drills.*					
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 the laboratory is a safe work environment and 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 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 to provide appropriate personal protective equipment—gloves, lab coats, eye protection, etc. — in useable condition. Laboratory staff must utilize personal protective equipment in the laboratory at all times. 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 appropriate vaccination//preventive measures?	**Y**	**P**	**N**		2
Standard: *Laboratory staff should be offered appropriate vaccinations--particularly Hepatitis B. Staff may decline to receive the vaccination, but should 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	**Y**	**P**	**N**		2

	Biosafety practices relevant to their job tasks?					
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 program 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 program, 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 & 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	w/ 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 & % 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 (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 practiced 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 AFRO 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% (at least 142 pts):	Score	**Y**	**N**

No Stars (0 – 141 pts) *< 55%*	**1 Star** (142 – 166 pts) *55 – 64%*	**2 Stars** (167 – 192 pts) *65 – 74%*	**3 Stars** (193 – 218 pts) *75 – 84%*	**4 Stars** (219 – 243 pts) *85 – 94%*	**5 Stars** (244 – 258 pts) *≥95%*

Lead Auditor Signature
Date

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