Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) Checklist

Version 3:2023

For Clinical and Public Health Laboratories

Introduction

Medical laboratories play an essential role in determining clinical decisions and providing clinicians with information that assists in the prevention, diagnosis, treatment, and management of diseases. However, inadequate investment has meant that many medical laboratories in Africa lack the necessary infrastructure, equipment, and resources to provide an effective and quality service. Although the last decade has seen significant strides in the strengthening of laboratory systems in Africa, challenges remain across most countries at all tiers of their systems. Therefore, the strengthening of laboratory systems and services remains a priority. The establishment of a process by which laboratories can establish and monitor management systems towards the achievement of accreditation to international standards remains an invaluable tool for countries to improve the quality of laboratory services in a stepwise and sustainable manner.

In accordance with World Health Organization (WHO) core functions of setting standards and building institutional capacity, WHO Regional Office for Africa (AFRO), in collaboration with the African Society for Laboratory Medicine (ASLM), the United States Centers for Disease Control and Prevention (CDC) and host countries established the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) to strengthen the laboratory management systems of its Member States. SLIPTA is a framework for improving the quality of medical laboratories in developing countries to achieve the requirements of the International Standards Organization (ISO) 15189 standard. 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 samples.

This initiative was spearheaded by several critical resolutions, including WHO 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 2003 Maputo Declaration to strengthen laboratory systems. This quality improvement process towards accreditation further provides a learning opportunity and pathway for continuous quality improvement, a mechanism for identifying resource and training needs, a measure of progress, and a link to the WHO's Laboratory Networks and Services team. Clinical, public health, and reference laboratories participating in the SLIPTA program are supported in the process of establishing or strengthening their management systems to compliance with international standards in a stepwise manner, that recognizes their progress through audits and the awarding of certificates of recognition. This quality improvement process towards accreditation further provides a learning opportunity and pathway for continuous improvement, a mechanism for identifying resource and training needs, better commitment of management and personnel that ensure quality diagnostic service in line with WHO AFRO complete healthcare services.

This checklist was developed as a framework and guide for laboratories on all the necessary elements to set up a functioning laboratory management system that meets international standards. This third edition has been updated through an expert review process to align with the new ISO 15189:2022 standard. This checklist is to be used in parallel with the SLIPTA Implementation Guide, which provides further guidance on requirements and implementation considerations.

Scope

This checklist specifies requirements for quality and compliance aimed to develop and improve laboratory services to established national standards. The elements of this checklist are based on ISO standard 15189:2022 (E) and, to a lesser extent, the Clinical & Laboratory Standards Institute (CLSI) guideline QMS01-A4, Laboratory Management System: A Model for Laboratory Services; Approved Guideline – Fourth Edition.

This document is applicable to medical laboratories in developing their management systems and assessing their compliance.

This document is also applicable to point-of-care testing (POCT).

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

No Stars (0 – 205 pts) *< 55%*	**1 Star** (206 – 240 pts) *55 – 64%*	**2 Stars** (241 – 277 pts) *65 – 74%*	**3 Stars** (278 – 314 pts) *75 – 84%*	**4 Stars** (315 – 352 pts) *85 – 94%*	**5 Stars** (353 – 373 pts) *≥95%*

Purpose

The intended purpose of the SLIPTA Checklist is to evaluate and verify the establishment, implementation and improvement of the quality management systems in medical laboratories. This checklist shall be completed by a trained and certified SLIPTA Auditor and is for recognition purposes based on the SLIPTA star levels. The SLIPTA certificate will not replace accreditation or certification.

Instructions for use

The SLIPTA checklist promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a management system, with the objective of meeting customer expectations and providing laboratory testing services.

When this checklist is used as a soft copy, it can be completed as a form by typing in the grey blocks.

The guidance given as ***"Note"*** in each question describes concepts, examples and methods that can be considered by the organizations when the laboratory is establishing, implementing and maintaining a management systems.

An organization can incorporate guidance from the ***"Note"*** in each question, wholly or in part, into its management system.

Parts of the Audit

This Laboratory audit checklist consists of three parts:

Part I: Laboratory Profile

Part II: Laboratory Audits

Evaluation of Laboratory operating procedures, practices, and tables for reporting performance

Part III: Summary of Audit Findings

Summary of findings of the SLIPTA audit and action planning worksheet

Part I: Laboratory Profile

LABORATORY PROFILE							
Date of this Audit:				**Date of Last Audit:**			
Prior Audit Status as per ASLM official audit	**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: **(Country, City and GPS co-ordinates)**							
Laboratory Telephone:		**Fax:**			**Email:**		
Name of Laboratory Representative:			**Telephone** (**Laboratory Representative**):		Personal:		
					Work:		
Laboratory Level			**Type of Laboratory/Laboratory Affiliation**				
National ☐	Reference ☐	Provincial ☐	Public ☐	Private ☐	Faith-Based ☐		
District ☐	Zonal ☐	Field ☐	Military ☐	Research ☐	Other ☐ Please specify:		

Laboratory Staffing Summary

Profession	***Number of Full Time***	***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 ☐
Data Clerk		Yes ☐ No ☐ Insufficient Data ☐
Phlebotomist		Yes ☐ No ☐ Insufficient Data ☐
Cleaner		Yes ☐ No ☐ Insufficient Data ☐
Is / Are the cleaner(s) dedicated to the laboratory only? Yes ☐ No ☐		*Has the cleaner(s) been trained on safety and waste handling*? Yes ☐ No ☐
Number of Driver/Courier/Messenger		Yes ☐ No ☐ Insufficient Data ☐
Is / Are the driver(s) / courier(s) / messenger(s) dedicated to the laboratory only? Yes ☐ No ☐		*Has / Have driver(s) been trained in biosafety*? Yes ☐ No ☐
Other		Yes ☐ No ☐ Insufficient Data ☐

If the laboratory has information technology (IT) specialists, accountants or non-laboratory-trained management staff, this should be indicated in the description of the organizational structure.

Part II: Laboratory Audits

Laboratory audits are an effective means to:

a. Determine if a laboratory is providing accurate and reliable results;
b. Determine if the laboratory is well-managed and is adhering to good laboratory practices; and
c. Identify areas for improvement.

Auditors must complete this SLIPTA checklist using the methods below to evaluate laboratory operations as per the checklist questions and to document audit findings (including strengths of the laboratory operations).

- **Review laboratory documents** to verify that the laboratory quality manual, policies, standard operating procedures (SOPs) and other manuals (e.g., safety manual and laboratory handbook) are complete, current, periodically reviewed and document controlled.

- **Review laboratory records** such as equipment maintenance records, incident reports, environmental condition logs, personnel files, internal quality control (IQC) records, external quality assessment (EQA) records, etc.

- **Observe laboratory operations** to ensure:
  - Laboratory testing follows written policies and procedures in pre-examination, examination and post-examination processes of laboratory testing;
  - Laboratory procedures are appropriate and current for the testing performed; and
  - Observations and nonconformities identified are adequately investigated and resolved within the defined timeframe.

- **Ask open-ended questions** to clarify documentation reviewed 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 all the laboratory processes (i.e., pre-examination, examination and post-examination).

- **Confirm that each test result or batch of results can be traced** and verified against acceptable IQC results.

- **Confirm EQA / proficiency testing 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.).

- **Interview clinicians** to establish the users' perspective of the laboratory's performance.

Audit Scoring

This SLIPTA Checklist contains 12 main sections with a total of 145 questions and a possible total score of 373 points.

For each question, indicate as relevant, **Yes (Y), Partial (P), No (N) or Not Applicable (NA)**. All elements of the question must be satisfactorily present to indicate **Yes (Y).** Provide comments for each **Partial (P), No (N) or Not Applicable (NA).** In the comment field, the auditor must provide information on what was audited, i.e., make reference to documentation, equipment, personnel, etc.

Each item has been awarded a point value of 2 or 3 based upon relative importance and/or complexity.

- Questions marked **(Y)** will receive the corresponding point value 2 (two) or 3 (three).
  All elements of a question must satisfactorily be present in order to indicate **(Y)** for a given question and thus award the corresponding points.

NOTE: Questions that include 'sub questions' must receive all* (Y) *and/or* (NA) *responses to be marked* (Y) *for the overarching item.

- Items marked **(P)** will receive 1 (one) point for all questions.
- Items marked **(N)** receive 0 (zero) points.

When marking **(P) or (N)**, notes must be written in the comments field to explain why the laboratory did not comply.
Where the checklist question does not apply, indicate as **(NA).** The laboratory shall have documented justification for (**NA)**.

Add the sum of all main questions marked **(NA)** and subtract that sum of **(NAs)** from the total of 373.
Since denominator has changed, the star level will then be determined using % score.

Audit Score Sheet

Section	Audit score obtained	Total possible score
Section 1: Documents and Records		**22**
Section 2: Organisation and Leadership		**26**
Section 3: Personnel Management		**34**
Section 4: Customer Focus		**24**
Section 5: Equipment Management		**44**
Section 6: Assessment		**24**
Section 7: Supplier and Inventory Management		**27**
Section 8: Process Management		**71**
Section 9: Information Management		**24**
Section 10: Nonconforming Events		**13**
Section 11: Continual Improvement		**07**
Section 12: Facilities and Safety		**57**
TOTAL		**373**
Calculated percentage score obtained		**%**

No Stars	1 Star	2 Stars	3 Stars	4 Stars	5 Stars
(0 – 205 pts)	(206 – 240 pts)	(241 – 277 pts)	(278 – 314 pts)	(315 – 352 pts)	(353 – 373 pts)
< 55%	*55 – 64%*	*65 – 74%*	*75 – 84%*	*85 – 94%*	*≥95%*

SECTION 01: DOCUMENT AND RECORDS

For each question, please indicate as relevant, Yes (Y), Partial (P), No (N) or Not Applicable (NA). All elements of the question must be satisfactorily present to indicate Yes (Y). Provide comments for each Partial (P), No (N) or Not Applicable (NA). In the comment field, you may also provide information on what was audited, i.e., make reference to documentation, equipment, personnel, etc.

REQUIREMENTS	Y/P/N/ NA	Comment
1.1 Legal Entity Does the laboratory have documentation stating its legal identity? ***Note: Documentation could be in the form of a National Act, company registration certificate, license number or practice number, official letter from the Ministry of Health or equivalent institution to indicate that it belongs to the government.***		**Score /2**
ISO15189:2022 Clause 5.1		
1.2 Laboratory Management System Policies and Objectives Is there a current document (quality manual or equivalent) that is composed of the management system policies and objectives and has the content being communicated and understood by all personnel? ***Note: A document (however named) must be available that summarizes the laboratory's management system, which includes policies that address all areas of the laboratory service and identifies the goals and objectives of the Laboratory Management System.***		**Score /3**
Does the document include the following elements?		
a. Quality policy statement that includes scope of service, standard of service, measurable objectives of the laboratory management system, and management commitment to compliance to the implementation of the policies;		
b. Documented policies of the laboratory management system that meet the requirements of ISO15189:2022 and the requirements of the accreditation bodies (where relevant);		
c. Description of the laboratory management system and the structure of its documentation; ***(Note: A graphical representation of the hierarchy of the documents and what each level means is required).***		
d. Reference to supporting procedures (e.g., SOPs), including managerial and technical procedures; ***Note: The document number and/or document title is sufficient; a link to the relevant folders may be used for a paperless system.***		
e. Description of the roles and responsibilities of the laboratory director (however named) and other key personnel responsible for ensuring compliance with the established organizational structure (organogram); ***Note: The laboratory management must define its key personnel.***		
f. Record of review and approval of this document (quality manual or equivalent) by authorized personnel;		
g. Records to show that relevant sections of this document were communicated to and understood by the relevant personnel (internal and external persons). ***Note: Internal personnel is any person indicated within the organogram of the organization.***		
ISO15189:2022 Clause 5.5, Clause 8.1.1 and 8.2		
1.3 Document and Information Control System Has the laboratory management established and implemented a document control system to control all documents and information from internal and external sources? ***Note: A document control system ensures that all documents (internal and external) are approved by authorized persons, current, reviewed periodically and revised as required.***		**Score /2**
ISO15189:2022 Clause 8.3		

1.4 Document and Records Are there records detailing all documents of the laboratory management system and indicating their editions and distribution? ***Note: Current authorized editions and their distribution are identified by means of a list (e.g., document register, log, or master index). "Edition" can be regarded as synonymous with "revision or version" number for the documents.***		**Score**	**/2**
ISO15189:2022 Clause 8.3			
1.5 Laboratory Management System Documentation ***Note: The management system documents can be contained in a quality manual; however, if the system is computerized, all files bearing the objectives and policies shall be linked.***		**Score**	**/2**
a. Has the laboratory management established, documented and maintained objectives and policies to fulfil the requirements of ISO 15189:2022 standards?			
b. Are these objectives and policies acknowledged and implemented at all levels of the laboratory?			
ISO15189:2022 Clause 8.2			
1.6 Quality Document Accessibility Are quality documents (paper based and/or electronic copies) easily accessible, available and written in a language commonly understood and communicated to all relevant personnel? ***Note 1: This includes external personnel.*** ***Note 2: All documents must be current and approved by an authorized person. The documents can be in any form or type of medium provided that the documents are readily accessible and protected from unauthorized changes and undue deterioration.***		**Score**	**/2**
ISO15189:2022 Clause 8.2.5			
1.7 Document Control Record Do all quality documents have a record to reflect when it was approved for use, its review and revision history, its version, its location and when it was discontinued?		**Score**	**/2**
ISO15189:2022 Clause 8.3			
1.8 Discontinued Quality Documents Are invalid or discontinued quality documents identified, clearly marked, removed from use and one copy retained for reference purposes? ***Note: Obsolete controlled documents shall be dated and marked as obsolete. At least one copy of an obsolete controlled document is retained for a specified time or in accordance with applicable specified requirements.***		**Score**	**/2**
ISO15189:2022 Clause 8.3.			
1.9 Data Files Are test results, technical and quality records archived for a specified period in accordance with the requirements of Section 9 of this checklist? ***Note: Copies or files of results should be archived. The retention period may vary; however, the reported results shall be retrievable for as long as medically relevant or as required by national, regional, or local authorities.***		**Score**	**/2**
ISO15189:2022 Clause 8.4			
1.10 Archived Patient Results Accessibility Is there an archiving system that allows for easy and timely retrieval of patient results as per the requirements of Section 9 of this checklist? ***Note: Records can be in any form or type of medium, providing they are readily accessible and protected from unauthorized alterations. Archived patient results must be easily, readily and completely retrievable within a timeframe consistent with patient care needs.***		**Score**	**/2**
ISO15189:2022 Clause 8.4			
SECTION 01: DOCUMENT AND RECORDS			**/22**

SECTION 02: ORGANISATION AND LEADERSHIP

For each question, please indicate as relevant, Yes (Y), Partial (P), No (N) or Not Applicable (NA). All elements of the question must be satisfactorily present to indicate Yes (Y). Provide comments for each Partial (P), No (N) or Not Applicable (NA). In the comment field, you may also provide information on what was audited, i.e., make reference to documentation, equipment, personnel, etc.

REQUIREMENTS	Y/P/N/ NA	Comment
2.1 <u>Procedure and/or Process for Organizational Code of Conduct</u> Has the laboratory defined a procedure and/or a process that addresses, but is not limited to, the following?		**Score /3**
a. Adherence to organizational policies and procedures;		
b. Impartiality;		
c. Confidentiality;		
d. Conflicts of interest.		
ISO15189:2022 Clause 4.1		
2.2 <u>Implementation of the Organizational Code of Conduct</u> Has the laboratory implemented the procedure and/or process and does it have records of the following?		**Score /2**
a. Adherence to organizational policies and procedures;		
b. Impartiality;		
c. Confidentiality;		
d. Conflicts of interest.		
ISO15189:2022 Clause 4.1		
2.3 <u>Deputization</u> In the event of the absence of key personnel, has the laboratory implemented a process to ensure the continuity of the laboratory management system?		**Score /2**
ISO15189:2022 Clause 5.2.3		
2.4 <u>Budgetary Projections</u> Are budgetary projections based on personnel needs, scope of test, infrastructure, equipment needs, service and maintenance and quality assurance process and materials (IQC and EQA)?		**Score /2**
ISO15189:2022 Clause 8.2.3		
2.5 <u>Routine Review of Quality and Technical Records</u> Does the laboratory routinely perform a documented review of all quality and technical records? ***Note: There must be documentation that quality records are regularly reviewed and monitored by authorized person(s). This routine review (the laboratory must define their frequency of review, e.g., daily, weekly, monthly) must ensure that recurrent problems have been addressed and new or redesigned activities have been evaluated.***		**Score /3**
a. Follow-up of action items from previous reviews;		
b. Status of corrective actions taken and required risk mitigation actions;		
c. Reports from personnel;		
d. Environmental monitoring logs;		
e. Sample rejection records;		
f. Equipment calibration and maintenance records;		
g. IQC records across all test areas;		
h. Outcomes of PTs and other forms of inter-laboratory comparisons;		
i. Quality indicators;		
j. Customer complaints and feedback;		
k. Results of improvement projects;		

l. Documentation of this routine review and action planning with personnel for resolution and follow-up review.		
ISO15189:2022 Clause 8.1 and 8.4		
2.6 <u>Procedure and/or Process for Management Review</u> Has the laboratory defined a procedure and/or a process that addresses, but is not limited to, the following? ***Note: It is recommended that continued progress management review meetings are held to ensure all actions arising are completed within the defined timeframe.***		**Score /3**
a. Frequency of management reviews;		
b. Review input (agenda as per Clause 8.9.2 of ISO15189:2022);		
c. Key attendees;		
d. Conduct of review activities;		
e. Review output (decisions, actions to be taken, provision of required resources person responsible and due dates);		
f. Communication of decisions and actions to be taken to the relevant persons;		
g. Ensure all actions arising are completed within the defined timeframe.		
ISO15189:2022 Clause 8.9		
2.7 <u>Conduct of Management Reviews</u> Does the laboratory management perform a review and discussion of the laboratory management system at planned intervals?		**Score /2**
ISO15189:2022 Clause 8.9		
2.8 <u>Management Review Inputs</u> Does the management review meeting include the following inputs? ***Note: The minimum list of review inputs should include the requirements of Clause 8.9.2 (a-j) of ISO15189:2022.***		**Score /3**
a. Status of actions from previous management reviews, internal and external changes to the management system, changes in the volume and type of laboratory activities and adequacy of resources;		
b. Fulfilment of objectives and suitability of policies and procedures;		
c. Outcomes of recent evaluations, process monitoring using quality indicators, internal audits, analysis of non-conformities, corrective actions and assessments by external bodies;		
d. Patient, user and personnel feedback and complaints;		
e. Quality assurance of result validity;		
f. Effectiveness of any implemented improvements and actions taken to address risks and opportunities for improvement;		
g. Performance of external providers, including referral laboratories and technical consultants;		
h. Results of participation in interlaboratory comparison programs;		
i. Evaluation of POCT activities;		
j. Other relevant factors, such as monitoring activities and training.		
ISO15189:2022 Clause 8.9		
2.9 <u>Management Review Outputs</u> Does the management review meeting include the following outputs? ***Note: The interval between management reviews should be no greater than 12 months; however, shorter intervals should be adopted when a Laboratory Management System is being established.***		**Score /2**
a. Effectiveness of the management system and its processes;		
b. Improvement of the laboratory activities related to the fulfilment of the requirements of this document;		
c. Provision of required resources;		
d. Improvement of services to patients and users;		

e. Any need for change.		
ISO15189:2022 Clause 8.9		
2.10 <u>Communication of Review Findings</u> Are findings and actions from routine technical and management review meeting communicated to the relevant personnel? ***Note: Findings and actions arising from management reviews shall be recorded and reported to laboratory personnel.***		**Score /2**
ISO15189:2022 Clause 8.9.3		
2.11 <u>Completion and Monitoring of Review Action Items</u> Does laboratory management ensure that actions from routine technical review and management review meetings are completed within defined timeframes and monitored for their effectiveness? ***Note: Laboratory management shall ensure that actions arising from management review and other management meetings are completed within a defined period.***		**Score /2**
ISO15189:2022 Clause 8.9.3		
SECTION 02: ORGANISATION AND LEADERSHIP		**/26**

SECTION 03: PERSONNEL MANAGEMENT

For each question, please indicate as relevant, Yes (Y), Partial (P), No (N) or Not Applicable (NA). All elements of the question must be satisfactorily present to indicate Yes (Y). Provide comments for each Partial (P), No (N) or Not Applicable (NA). **In the comment field you may also provide information on what was audited, i.e., make reference to documentation, equipment, personnel, etc.**		
REQUIREMENTS	**Y/P/N/ NA**	**Comment**
3.1 <u>Procedure and/or Process for Personnel Management</u> Has the laboratory defined a procedure and/or process that addresses, but is not limited to, the following? ***Note: The laboratory must have a documented procedure for personnel management and maintain records for all personnel to indicate compliance with requirements.***		**Score /3**
a. Definition of the structure of the organization (organizational plan) based on the needs of the laboratory activities;		
b. Definition of job profiles and job descriptions for all laboratory positions;		
c. Selection and recruitment of appropriately qualified personnel;		
d. Orientation of newly recruited and appointed personnel;		
e. Establishment and maintenance of personnel records.		
ISO15189:2022 Clause 6.2.1		
3.2 <u>Duty Roster and Daily Routine</u> Does the laboratory have a duty roster that covers normal hours and after hours? ***Note: A duty roster designates specific laboratory personnel to specific workstations. Daily routines should be prioritized, organized and coordinated to achieve optimal service delivery for patients.***		**Score /2**
ISO15189:2022 Clause 6.2.1		
3.3 <u>Organizational Chart and External/Internal Reporting Systems</u> Is an organizational chart available for indicating the relationship between the laboratory and its parent organization? ***Note: 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.***		**Score /2**
ISO15189:2022 Clause 5.4.1		
3.4 <u>Laboratory Management</u> Is the laboratory directed by a person(s) (however named) with specified qualifications, authority, competency and delegated responsibility to perform the following: ***Note: A laboratory director may be a person or persons with responsibility for and authority over a laboratory. The person or persons referred to may be designated collectively as the Laboratory Director. Other settings may not use the term 'Laboratory Director' but in this question, it refers to person/persons that are running the laboratory.***		**Score /3**
a. Provide effective leadership, budgeting and planning;		
b. Communicate with stakeholders;		
c. Ensure adequate competent personnel;		
d. Ensure the implementation of the quality management system;		
e. Select and monitor laboratory supplies;		
f. Select and monitor referral laboratories;		
g. Ensure a safe laboratory environment;		
h. Provide advisory services;		
i. Provide professional development programs for laboratory personnel;		
j. Address complaints, requests, or suggestions from personnel and or laboratory users;		
k. Ensure the implementation and application of risk assessment program;		
l. Design and implement a contingency plan based on the risk assessment program;		

m. Ensure management and operations of POCT activities.		
ISO15189:2022 Clause 5.2.1, 5.2.2 and 5.4.2		
3.5 <u>Compliance with Laboratory Management System</u> Is there a person or persons who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including: ***Note: These roles and responsibilities (quality officer or team) shall be defined, documented, and communicated (e.g., job description, organogram etc.).***		**Score /2**
a. Implementation, maintenance, and improvement of the management system;		
b. Identification of deviations from the management system or from the procedures for performing laboratory activities.		
ISO15189:2022 Clause 5.4.2		
3.6 <u>Procedure and/or Process for Authorization</u> Has the laboratory defined a procedure and/or process that addresses, but is not limited to, the following? ***Note: Authorization may be in the form of a job description, letter of appointment, approved authority matrix, etc.***		**Score /3**
a. List of activities that require authorization;		
b. Defined criteria for authorizing persons for specific laboratory activities;		
c. Documented authorization for the various activities;		
d. Appointed deputies for the key positions where appropriate.		
ISO15189:2022 Clause 6.2.3		
3.7 <u>Authorization</u> Are personnel authorized to perform specific laboratory activities including, but not limited to, the following:		**Score /2**
a. Selection, development, modification, validation, and verification of methods;		
b. Review, release, and reporting of results;		
c. Use of laboratory information systems, particularly accessing patient data and information, entering patient data and examination results, and changing patient data or examination results.		
ISO15189:2022 Clause 6.2.5		
3.8 <u>Procedure and/or Process for Personnel Training</u> Has the laboratory defined a procedure and/or process that addresses, but is not limited to, the following? ***Note: Training includes external and internal trainings.***		**Score /3**
a. Identification of training needs;		
b. Establishment of training program (including initial and refresher training);		
c. Provision of a continuous education program;		
d. Recording of training;		
e. Evaluation of the effectiveness of the training program.		
ISO15189:2022 Clause 6.2		
3.9 <u>Laboratory Personnel Training, Continuing Education and Professional Development</u> Is there a program for training, continuing education and professional development including, but not limited to, the following:		**Score /2**
a. Laboratory management system;		
b. Induction to the organization;		
c. Assigned work processes, procedures, and tasks;		
d. Applicable laboratory information system;		
e. Health and safety, including the prevention or containment of the effects of adverse incidents;		

f. Laboratory ethics, impartiality and confidentiality of patient information;		
g. Supervision of persons undergoing training,		
h. Continuous education (advancement in laboratory practice, clinical diagnostics, surveillance, etc.);		
i. Review of effectiveness of the training program.		
ISO15189:2022 Clause 6.2		
3.10 <u>Procedure and/or Process for Competency Assessment</u> Has the laboratory defined a procedure and/or a process that addresses, but is not limited to, the following? ***Note: Competency could be assessed using a combination of some or all the following methods: direct observation, monitoring and recording of examination results, review of work records, problem solving skills, blinded samples, review of accumulative IQC and EQA. Competency assessment for professional judgment should be designed as specific and fit for purpose.***		**Score /3**
a. Defining the methods of performing competency assessment;		
b. Defining the competency requirements, criteria and frequency for each laboratory activity or function (managerial or technical tasks);		
c. Assessment of ongoing competency;		
d. Providing feedback (verbal, written, etc.) to persons assessed;		
e. Scheduling retraining based on assessment outcomes;		
f. Retention of records of competency assessments and outcomes.		
ISO15189 :2022 Clause 6.2.2		
3.11 <u>Implementation of Procedure and/or Process of Personnel Competency</u> Does the laboratory assess the competency of its personnel according to its defined criteria for all relevant activities including the following: ***Note: Newly hired laboratory personnel must be assessed for competency before performing duties independently. Personnel assigned to a new section should be assessed before fully assuming new duties independently. When deficiencies are noted, retraining and reassessment must be planned and documented. If the employee's competency assessment consistently 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.***		**Score /2**
a. Records that indicate which skills were assessed, how those skills were measured, and who performed the assessment;		
b. Competency assessments performed according to defined criteria for new hires and existing personnel;		
c. Retraining and re-assessment where needed.		
ISO15189:2022 Clause 6.2.2		
3.12 <u>Procedure and/or Process for Review of Personnel Performance</u> Has the laboratory defined a procedure and/or process that addresses, but is not limited to, the following?		**Score /2**
a. Planning and performing personnel performance appraisals;		
b. Establishing frequency of monitoring and reviewing of personnel performance outcome;		
c. Keeping records of personnel performance.		
ISO15189:2022 Clause 6.2.2 and 8.1.3 b)		
3.13 <u>Personnel Meetings</u> Are personnel meetings held regularly and do they address the following meeting items? ***Note: The laboratory should hold regular personnel meetings to ensure communication within the laboratory. Meetings should have recorded progress notes to facilitate the review of progress over time.***		**Score /2**
a. Follow-up of action items from previous personnel meetings;		

b. Systemic and/or recurrent problems and issues addressed, including actions to prevent recurrence;		
c. Complaints;		
d. Communication on reviewed/revised/redundant SOPs and changes to the laboratory management system;		
e. Review of results from prior to corrective actions;		
f. Discussion and evaluation of improvement topics/projects;		
g. Feedback given by personnel that have attended hospital meetings, clinical rounds, external meetings, training, conferences, workshops, etc.;		
h. Provide advisory and/or interpretation of laboratory results and updates on laboratory attendance at meetings with clinicians (use of laboratory services);		
i. Recording, monitoring and follow-up of meeting actions;		
j. Importance of meeting, needs and requirements of users and management system (ISO15189:2022).		
ISO15189:2022 Clause 5.3.2		
3.14 <u>Personnel Records</u> Are records of personnel maintained (hardcopy or electronic copy) and do they include the following? ***Note: Personnel files must be maintained for all current personnel. Wherever (offsite or onsite) and however the records are kept, the records must be easily accessible. In some laboratories, not all personnel records may be kept in a single file in one place, e.g., training and competency records may be kept in the laboratory, whereas medical and health information may be kept with the administration department.***		**Score /3**
a. Educational and professional qualifications;		
b. Determination of the competency requirements specified in Section 3 of this checklist;		
c. Job descriptions in relation to the designated position;		
d. Training and re-training;		
e. Authorization of personnel;		
f. Monitoring of competency of personnel.		
ISO15189:2022 Clause 6.2.5		
Section 03: PERSONNEL MANAGEMENT.		**/34**

SECTION 04: CUSTOMER FOCUS

For each question, please indicate as relevant, Yes (Y), Partial (P), No (N) or Not Applicable (NA). All elements of the question must be satisfactorily present to indicate Yes (Y)". Provide comments for each Partial (P), No (N) or Not Applicable (NA). **In the comment field you may also provide information on what was audited i.e., make reference to documentation, equipment, personnel, etc.**

REQUIREMENTS	Y/P/N/ NA	Comment
4.1 <u>Procedure and/or Process for Advisory Services</u> Has the laboratory defined a procedure and/or process that addresses, but is not limited to, the following?		**Score /3**
a. Advice on the choice of examinations;		
b. Communication of advisory services to its users;		
c. Advice on clinical indications and limitations of examination procedures;		
d. Advise on the frequency of examinations;		
e. Provision of individual clinical advice;		
f. Advice on interpretation of results;		
g. Promotion of the effective utilization of laboratory services;		
h. Consultation on scientific and logistic matters;		
i. Advice on required sample types and volumes for testing. ***Note: This information may be available in the Laboratory Handbook or website, etc.***		
ISO15189:2022 Clause 5.3.3		
4.2 <u>Advice and Instruction by Qualified Personnel</u> Do laboratory personnel with appropriate professional qualifications provide patients and users with advice and/or training regarding required types of samples, choice of examinations, repeat frequency, and interpretation of results? ***Note: Authorized (trained and competent) personnel should provide advice on sample type, examination choice, frequency, and result interpretation.***		**Score /2**
ISO15189:2022 Clause 5.3.3		
4.3 <u>Procedure and/or Process for Handling of Complaints and Feedback</u> Has the laboratory defined a procedure and/or process that addresses, but is not limited, the following?		**Score /3**
a. Receipt and acknowledgment of complaints;		
b. Investigation and action taken from complaints and feedback (where relevant);		
c. Tracking and recording of complaints and feedback (where relevant);		
d. Defining timeframes for closure and feedback to the complainant;		
e. Monitoring the effectiveness of corrective actions taken on complaints and feedback to complainant.		
ISO15189:2022 Clause 7.7		
4.4 <u>Receipt and Resolution of Complaints</u> Does the laboratory implement a process for the receipt and resolution of complaints? (Are there records of the original complaint and tracking and feedback?) ***Note: Feedback includes acknowledgment of receipt and resolution of complaint.***		**Score /2**
ISO15189:2022 Clause 7.7		
4.5 <u>Requirements Regarding Patients</u> Has the laboratory established and implemented a process for treatment of patients' well-being, samples, or remains, with due care and respect? ***Note: Code of Ethics may be defined to satisfy the above requirements.***		**Score /2**
ISO15189:2022 Clause 4.3 e)		

4.6 <u>Procedure and/or Process for Service Agreements (including POCT)</u> Has the laboratory defined a procedure and/or process that addresses, but is not limited to, the following?		**Score**	**/3**
a. Establishment of service agreements (requirements are specified);			
b. Review and approval of service agreements (capability and adequate resources);			
c. Management of walk-in patients (where applicable);			
d. Communication of changes of the service agreement that affect examination results;			
e. Communication to the requester of any work that has been referred;			
f. Defining specified responsibilities and authorities for POCT activities in the service agreements.			
ISO15189:2022 Clause 6.7			
4.7 <u>Implementation of the Procedure and/or Process for Service Agreements (including POCT)</u> Has the laboratory implemented a procedure and/or process and have records including but not limited to the following?		**Score**	**/3**
a. Establishment of service agreements (requirements are specified);			
b. Review and approval of service agreements (capability and adequate resources);			
c. Management of walk-in patients, (where applicable);			
d. Communication of changes of the service agreement that affect examination results;			
e. Communication to the requester of any work that has been referred;			
f. Definitions of specified responsibilities and authorities for POCT activities in the service agreements.			
ISO15189:2022 Clause 6.7			
4.8 <u>Laboratory Information for Patients and Users</u> Is laboratory information available for patients and laboratory users in the language understood by the community? ***Note 1: Laboratory information may be in the form of Laboratory Handbook, brochure, videos, website, etc.*** ***Note 2: The laboratory should provide its clients with a handbook that outlines the laboratory hours of operation, available tests, sample collection instructions, packaging, and shipping directions, and expected turnaround times.***		**Score**	**/2**
ISO15189:2022 Clause 7.2			
4.9 <u>Communication Policy on Delays in Service</u> Is timely-documented notification provided to patients and users when the laboratory experiences delays or interruptions in testing (due to equipment failure, stock outs, personnel levels, etc.) or finds it necessary to change examination procedures and when testing resumes? ***Note 1: There must be a policy for notifying patients or users when the laboratory experiences delays or interruptions in testing*** ***Note 2: There must be records of communication. Communication may be in the form of telephonic messages, memos, emails, etc. There must be records of communication when an examination is delayed to the requester and or clinical personnel.***		**Score**	**/2**
ISO15189:2022 Clause 7.4.1.1 b)			
4.10 <u>Utilization of Customer Feedback</u> Are there opportunities for laboratory patients, users and personnel to provide information to aid the laboratory in improving its management system, laboratory activities, and services to users? ***Note 1: The laboratory should measure the satisfaction of patients, users, and personnel regarding its services on an ongoing basis.*** ***Note 2: There must be records of feedback including actions taken.***		**Score**	**/2**
ISO15189:2022 Clause 8.6.2			

SECTION 04: CUSTOMER FOCUS /24

SECTION 05: EQUIPMENT MANAGEMENT

For each question, please indicate as relevant, Yes (Y), Partial (P), No (N) or Not Applicable (NA). All elements of the question must be satisfactorily present to indicate Yes (Y). Provide comments for each Partial (P), No (N) or Not Applicable (NA). In the comment field you may also provide information on what was audited, i.e., make reference to documentation, equipment, personnel, etc.

REQUIREMENTS	Y/P/N/ NA	Comment
5.1 <u>Procedure and/or Process for Management of Laboratory Equipment</u> Has the laboratory defined a procedure and/or process that addresses, but is not limited to, the following?		**Score /3**
a. Determining the need and specification of equipment;		
b. Selection of equipment;		
c. Procurement of equipment;		
d. Acceptance and installation;		
e. Creation and maintenance of equipment records (including the equipment service schedule);		
f. Unique labelling of equipment (serial number, asset number, date of calibration, etc.);		
g. Defining the equipment maintenance and service frequency;		
h. Management of defective equipment (including decontamination);		
i. Training and authorization of personnel to operate equipment use;		
j. Management of obsolete equipment;		
k. Management of safe handling, transportation, storage and use to avoid deterioration and contamination;		
l. Tracking and verification of completion of repairs and services.		
ISO15189:2022 Clause 6.4		
5.2 <u>Access to Required Equipment</u> Does the laboratory have access to the required equipment for the performance of laboratory activities?		**Score /2**
ISO15189:2022 Clause 6.4		
5.3 <u>Adherence to Proper Equipment Protocol</u> Is equipment installed and placed as specified in the operator's manuals and uniquely labelled or marked? ***Note: Equipment should be properly placed as specified in the user manual away from potential hazards including but not limited to the following: water, direct sunlight, vibrations, traffic.***		**Score /2**
ISO15189:2022 Clause 6.4		
5.4 <u>Training, Competency and Authorization of Equipment Users</u> Is all equipment operated by trained, competent and authorized personnel? ***Note: Records of training, competency and authorization shall be available.***		**Score /2**
ISO15189:2022 Clause 6.4.4 b)		
5.5 <u>Procedure and/or Process for Validation and Verification of Equipment</u> Has the laboratory defined a procedure and/or process that addresses, but is not limited to, the following? ***Note: Refer to CLSI documents for guidance, e.g., QMS23-ed2.***		**Score /2**
a. Defining the validation or verification protocol (including the authorization for the intended use);		
b. Performing equipment verification or validation;		
c. Defining verification or validation report.		
ISO15189:2022 Clause 6.4		

5.6 Equipment Verification and Documentation Is all equipment verified onsite upon installation after maintenance and repair before use? ***Note: Newly introduced equipment must be verified onsite to ensure that its introduction yields performance equal to or better than the previous equipment. Manufacturers' validation information may be used. Back-up equipment must also be included in verification procedures.***		**Score /3**
a. Are specific verification protocols in place for each item of equipment?		
b. Has validation information been obtained from the manufacturer as part of the verification?		
c. Have performance characteristics been appropriately selected and evaluated as per intended use?		
d. Were the verification studies appropriate and adequate?		
e. Was the analysis of data appropriate for the selected performance characteristics?		
f. Have the verification results and reports been reviewed and approved by an authorized person?		
ISO15189:2022 Clause 6.4.3		
5.7 Equipment Records Is current equipment inventory data available for all equipment in the laboratory?		**Score /3**
a. Manufacturer and supplier details, and sufficient information to uniquely identify each item of equipment, including software and firmware;		
b. Dates of receipt, acceptance testing and entry into service;		
c. Evidence of verification or validation that equipment conforms with specified acceptability criteria;		
d. Current location of equipment;		
e. Condition when received (e.g., new, used, or reconditioned);		
f. Manufacturer's instructions;		
g. Program for preventive maintenance;		
h. Maintenance activities performed by the laboratory or approved external service provider;		
i. Damage to, malfunction, modification, or repair of the equipment;		
j. Equipment performance records, such as reports or certificates of calibrations or verifications, or both, including dates, times, and results;		
k. Date of last service;		
l. Date of next service.		
ISO15189:2022 Clause 6.4.7		
5.8 Defective Equipment Waiting for Repair Is defective equipment waiting for repair not used and clearly labelled? ***Note 1 Labels should include the date of malfunction and 'not in use' and signature of approval.*** ***Note 2: All equipment malfunctions must be investigated and documented as per the non-conforming procedure. If the user cannot resolve the problem, a repair order must be initiated.***		**Score /2**
ISO15189:2022 Clause 6.4.5		
5.9 Obsolete Equipment Is obsolete equipment appropriately labelled and removed from the laboratory or path of workflow?		**Score /2**
ISO15189:2022 Clause 6.4.5		
5.10 Procedure and/or Process for Calibration of Equipment Has the laboratory defined a procedure and/or process that addresses, but is not limited to, the following?		**Score /3**
a. Frequency of calibration;		

b. Handling of in-house calibrations (pipettes, thermometers, timers, etc.);		
c. Management of calibrations performed by external service providers;		
d. Recording of metrological traceability;		
e. Handling of failed calibrations;		
f. Retention of calibration records (use of stickers and calibration certificates).		
ISO15189:2022 Clause 6.5		
5.11 <u>Equipment Calibration and Metrological Traceability</u> ***Note: Documentation of calibration traceability to a higher order reference material or reference procedure may be provided by an examination system manufacturer. Such documentation is acceptable if the manufacturer's examination system and calibration procedures are used without modification.***		**Score /3**
a. Is routine calibration of laboratory measuring equipment (including pipettes, centrifuges, balances, and thermometers) scheduled, at minimum following manufacturer's recommendations?		
b. When routine calibration of laboratory measuring equipment (including pipettes, centrifuges, balances, and thermometers) is performed offsite (externally), are there records of verification before use?		
c. Is information on metrological traceability (e.g., use of reference materials and equipment like certified thermometers, tachometer) available? ***Note: Calibration certificates, calibration reports, etc. may be used as records of metrological traceability information.***		
d. Is there evidence of review of calibrations records (e.g., calibration certificates, calibration reports, etc.) by the laboratory before acceptance back into use?		
e. Where it is not possible to provide traceability using an accredited calibration laboratory, are certified reference materials, examination and calibration by another procedure, use of mutual consent standards or methods used for in house calibrations?		
ISO15189:2022 Clause 6.5.3, c)		
5.12 <u>Equipment Preventive Maintenance</u> Is routine user preventive maintenance performed on all equipment and recorded according to manufacturer's minimum requirements? ***Note: Preventative maintenance by operators must be done on all equipment used in examinations including centrifuges, autoclaves, microscopes, and safety cabinets.***		**Score /2**
ISO15189:2022 Clause 6.4.5		
5.13 <u>Equipment Service Maintenance</u> Is equipment routinely serviced according to a schedule as per the minimum manufacturer's recommendations by approved internal or external service providers and is this information documented in appropriate logs? ***Note: All equipment must be serviced at specified intervals by a qualified service engineer either through service contracts or otherwise. Service schedules must at minimum meet manufacturer's requirements***		**Score /2**
ISO15189:2022 Clause 6.4.5		
5.14 <u>Equipment Adverse Incident Reporting.</u>		**Score /2**
a. Are there records of investigation, identification and implementation of corrective actions taken and follow-up?		
b. Is there documentation of reports made to manufacturers or suppliers and appropriate authorities of adverse incidents and accidents where applicable?		
ISO15189:2022 Clause 6.4.6		
5.15 <u>Manufacturer's Operator Manual</u>		**Score /2**

Are the manufacturer's operator manuals readily available to testing personnel and available in the language understood by personnel?		
ISO15189:2022 Clause 6.4.4		
5.16 <u>Use of Equipment</u>		**Score /2**
Are there precautions (e.g., password protection) in place to prevent unintended adjustments of automated equipment, where applicable?		
ISO15189:2022 Clause 6.4.4		
SECTION 05: EQUIPMENT MANAGEMENT		**/44**

SECTION 06: ASSESSMENTS

For each question, please indicate as relevant, Yes (Y), Partial (P), No (N) or Not Applicable (NA). All elements of the question must be satisfactorily present to indicate Yes (Y). Provide comments for each Partial (P), No (N) or Not Applicable (NA). In the comment field you may also provide information on what was audited, i.e., make reference to documentation, equipment, personnel, etc.

REQUIREMENTS	Y/P/N/ NA	Comment
6.1 <u>Procedure and/or Process for Internal Audits</u> Has the laboratory defined a procedure and/or process that addresses, but is not limited to, the following? ***Note 1: Inputs into planning, scheduling and conduct of internal audits may include:*** ***i. Priority given to risk posed to patients resulting from laboratory activities;*** ***ii. Identified risks;*** ***iii. Outcomes of both external evaluations and previous internal audits;.*** ***iv. Occurrence of nonconformities, incidents, and complaints;*** ***v. Changes affecting the laboratory activities.*** ***Note 2: The cycle for internal auditing should normally be completed in one year. It is not necessary that internal audits cover each year, in depth, all elements of the Laboratory Management System.***		**Score /3**
a. Inputs into planning, scheduling, and conduct of internal audits;		
b. Scheduling of internal audits;		
c. Frequency of internal audits;		
d. Scope of internal audits;		
e. Criteria for internal audits;		
f. Selection of internal auditors;		
g. Recording of audit findings;		
h. Addressing identified nonconformities;		
i. Implementation of corrective actions;		
j. Monitoring of the effectiveness of corrective actions.		
ISO15189:2022 Clause 8.8.3		
6.2 <u>Internal Audits</u> Are internal audits conducted at intervals as defined in the internal audit program and do these audits address all areas of the laboratory management systems? ***Note: The cycle for internal auditing should normally be completed in one year and at planned intervals.***		**Score /3**
Is there an audit program that ensures all activities of the laboratory are audited? ***Note: Internal auditing shall cover all activities in the Laboratory Management System, including pre-examination, examination, and post-examination***		
a. Are audits being carried out with minimal conflict of interest where possible, carried out by persons who are not involved in activities in the section being audited?		
b. Are the personnel conducting the internal audits trained, qualified, and authorized to conduct internal audits?		
c. Are internal audit findings documented and presented to laboratory management and relevant personnel for review?		
ISO15189:2022 8.8.3		
6.3 <u>Audit Recommendations and Action Plan and Follow-up</u>		**Score /3**
a. Are internal audits reports generated, disseminated, and communicated to laboratory management and relevant personnel for review?		
b. Is an action plan developed with clear timelines, assigned personnel and documented follow-up within the timeframe defined by laboratory management?		

c. Are recommendations for improvement actions made based on audit findings? ***Note: For actions that are not implemented as per the due dates there should be a motivation and an approval of extension.***		
ISO15189:2022 8.8.3		
6.4 <u>Procedure and/or Process for Risk Management</u> Has the laboratory defined a procedure and/or process that addresses, but is not limited to, the following? ***Note: Risk must be managed at the pre-examination processes, examination processes and post-examination processes. The laboratory shall evaluate the impact of work processes and potential failures on examination results as they affect patient safety and shall modify processes to reduce or eliminate the identified risks and document decisions and actions taken. Risk management must take into consideration patient care and laboratory activities.***		**Score /3**
a. Methods used to identify risks and opportunities;		
b. Areas for identifying risks and opportunities associated with its examinations and activities;		
c. Development of action plans to address both risks and opportunities for improvement;		
d. Evaluation of the effectiveness of implemented actions and modification where required;		
e. Recording and communication of decisions made, and actions taken on risks and opportunities.		
ISO15189:2022 Clause 5.6 and 8.5 ***ISO22367:2020 and ISO35001:2019 and ISO31000:2018***		
6.5 <u>Risk Management</u> Has laboratory management developed and implemented a risk management program that identifies risks and opportunities for improvement in all laboratory processes including but not limited to:		**Score /3**
a. Impartiality;		
b. Confidentiality;		
c. Structural and governance requirements;		
d. Personnel;		
e. Facilities and environmental activities;		
f. Equipment;		
g. Reagents and consumables;		
h. Service agreements;		
i. Externally provided products and services		
j. Pre-examination processes;		
k. Examination processes (including POCT) ;		
l. Post-examination processes;		
m. Nonconforming work;		
n. Control of data and information management;		
o. Complaints;		
p. Management system documentation;		
q. Control of management system documents;		
r. Control of records;		
s. Nonconformities and corrective actions;		
t. Evaluations;		
u. Management review.		
ISO15189:2022 5.6 and ISO 22367:2022		
6.6 <u>Risk Management Assessment</u> Does the laboratory use evaluation tools to identify risks and opportunities for improvements? ***Note: Tools such as brainstorming, SWOT analysis, 5 WHYs***		**Score /2**

a. Internal audits;		
b. Customer complaints/feedback;		
c. Nonconforming event management;		
d. Management review;		
e. Quality indicators		
ISO15189:2022 5.6		
6.7 <u>Risk and Opportunities Action Plan</u>		**Score /3**
a. Is an action plan for identified risks and opportunities for improvement developed and implemented with clear timelines and responsibilities?		
b. Does laboratory management evaluate the effectiveness of the risk and/or opportunities for improvement action plan?		
c. Are actions modified when actions are identified as being ineffective?		
ISO15189:2022 5.6		
6.8 <u>Quality Indicators</u> Are quality indicators selected to cover pre-examination, examination, and post-examination processes (e.g., turnaround times, rejected samples, stock-outs, etc.), defined, measured, and monitored? ***Note 1: The identification of the quality indicators should include establishing the objectives, methodology, interpretation, limits, action plan and duration of monitoring.*** ***Note 2: The laboratory should select quality indicators in line with meeting its objectives from pre-analytic, analytic, and post-analytic phases critical to patient outcomes.***		**Score /2**
ISO15189:2022 8.8.3 and 5.5 d)		
6.9 <u>Monitoring of Quality Indicators</u> Are the outcome of the review of quality indicators used to improve laboratory processes? ***Note: The laboratory should review the quality indicators at defined intervals.***		**Score /2**
***ISO15189:2022 Clause 8.8.2 and 5.6,* ISO22367:2022**		
SECTION 06: ASSESSMENTS		**/24**

SECTION 07: SUPPLIER AND INVENTORY MANAGEMENT

For each question, please indicate as relevant, Yes (Y), Partial (P), No (N) or Not Applicable (NA). All elements of the question must be satisfactorily present to indicate Yes (Y). Provide comments for each Partial (P), No (N) or Not Applicable (NA). In the comment field you may also provide information on what was audited i.e., make reference to documentation, equipment, personnel, etc.

REQUIREMENTS	Y/P/N/ NA	Comment
7.1 <u>Procedure and/or Process for Externally Provided Products and Services</u> Has the laboratory defined a procedure and/or process that addresses, but is not limited to, the following?		**Score /3**
a. Selection of required products and services;		
b. Establishment of selection criteria;		
c. Establishment of acceptance criteria;		
d. Selection, approval of suppliers and technical consultants;		
e. Maintenance of approved suppliers list;		
f. Defining the requirements of its purchase supplies and services (purchase documentation);		
g. Reviewing and monitoring of the performance of its approved suppliers;		
h. Frequency of reviewing and monitoring the performance.		
ISO15189:2022 Clause 6.8		
7.2 <u>Procedure and/or Process for Purchasing and Inventory Control of Equipment, Reagents, and Consumables</u> Has the laboratory defined a procedure and/or process that addresses, but is not limited to, the following?		**Score /3**
a. Requisition, ordering and receipt of purchased items;		
b. Establishment of acceptance and rejection criteria for purchased items;		
c. Acceptance testing;		
d. Storage of purchased items;		
e. Management of inventory;		
f. Monitoring and handling of expired items;		
g. Responding to manufacturers recall or other notices.		
ISO15189 :2022 Clause 6.8.3		
7.3 <u>Inventory and Budgeting System</u> ***(Including the requirements for POCT)*** Is there a process for accurately forecasting needs for services, supplies and reagents? ***Note 1: External services include referral laboratories and consultants.*** ***Note 2: 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.***		**Score /2**
ISO15189:2022 Clause 6.6.1		
7.4 <u>Purchasing Specifications</u> Does the laboratory provide specifications for their services, supplies and consumables that are required when placing a requisition? ***Note: Specification could be in the form of catalogue number, item number, manufacturer name, etc.***		**Score /2**
ISO15189:2022 Clause 6.6.1		
7.5 <u>Service Supplier Performance Review</u> Does laboratory management monitor the performance of external suppliers (including referral laboratories, technical consultants, and EQA providers) to ensure that they continually meet the stated criteria of the approved suppliers? ***Note: All suppliers of services used by the laboratory must be reviewed and monitored for their performance.***		**Score /2**

ISO15189:2022 Clause 6.8.3 a) and c)		
7.6 <u>Inventory Control</u> Does the laboratory maintain records for each reagent and consumable that contributes to the performance of examinations? These records shall include but not be limited to the following:		**Score /3**
a. Identity of the reagent or consumable;		
b. Batch code or lot number;		
c. Manufacturer or supplier name and contact information;		
d. Received date, expiration date, date of entry into service and date material was taken out of service, where applicable;		
e. Manufacturer's instruction/package insert;		
f. Records of inspection of reagents and consumables when received (e.g., acceptable or damaged); ***Note: All incoming orders must be inspected for condition and completeness of the original requests, receipted, and documented appropriately, date received in the Laboratory and expiry date for the product should be clearly indicated.***		
g. Reference to the person or persons undertaking the preparation of reagents, resuspension or combined in-house, as well as the dates of preparation and stability. ***Note: The above the information(a-g) may be captured on the actual item but is also required to be captured on the inventory log.***		
ISO15189:2022 Clause 6.6.7		
7.7 <u>Management Review of Supply Requests</u> Does laboratory management review and approve the laboratory's requirements for all externally provided products and services? ***Note: Since laboratories have different purchasing approval systems, there should be a system in place that the laboratory reviews final approval of their original request.***		**Score /2**
ISO15189:2022 Clause 6.8.3		
7.8 <u>Laboratory Inventory System</u> ***Note: The laboratory inventory system should reliably inform personnel of the minimum amount of stock to be kept to avoid interruptions of service due to stock-outs and the maximum amount to be kept by the laboratory to prevent expiry of reagents.***		**Score /2**
a. Are inventory records complete and accurate with minimum and maximum stock levels denoted and monitored?		
b. Is the consumption rate of all reagents and consumables monitored?		
c. Are inventory/stock counts routinely performed?		
ISO15189:2022 Clause 6.6.4		
7.9 <u>Storage Area</u> Are storage areas set up and monitored appropriately? ***Note: Storage of supplies and consumables must be as per the manufacturer's specifications.***		**Score /2**
a. Is the storage area well-organized and free of clutter to prevent damage and deterioration?		
b. Are there designated places for all inventory items for easy access (separation of inspected and uninspected items)?		
c. Is adequate cold storage available?		
d. Is the humidity of the room monitored routinely, when appropriate?		
e. Is the temperature of the room monitored routinely?		
f. Is storage in direct sunlight avoided? Is direct sunlight avoided in storage areas?		
g. Is the storage area adequately ventilated?		
h. Is the storage area clean and free of dust and pests?		
i. Are storage areas access-controlled?		

ISO15189:2022 Clause 6.6.2		
7.10 <u>Inventory Organization and Wastage Minimization</u> Is First-Expiration-First-Out (FEFO) practiced? ***Note: To minimize wastage from product expiration, inventory should be organized in line with the FEFO principle. Place products that will expire first in front of products with a later expiration date and issue stock accordingly to ensure products in use are not past their expiration date. Remember that the order in which products are received is not necessarily the order in which they will expire.***		**Score /2**
ISO15189:2022 Clause 6.6.4 and **QMS 01, WHO 2013**		
7.11 <u>Product Expiration</u> Are all reagents/test kits in use (and in stock) currently within the manufacturer-assigned expiration or within stability? ***Note 1: All reagents and test kits in use, as well as those in stock, should be within the manufacturer-assigned expiry dates.*** ***Note 2: Expired controls and calibrators must not be used.***		**Score /2**
ISO15189:2022 Clause 6.6.5		
7.12 <u>Disposal of Expired Products</u> Are expired products labelled and disposed of properly? ***Note: Expired products should be disposed of properly and records maintained. 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.***		**Score /2**
ISO15189:2022 6.6.7		
SECTION 07: SUPPLIER AND INVENTORY MANAGEMENT /27		

SECTION 08: PROCESS MANGEMENT

For each question, please indicate as relevant, Yes (Y), Partial (P), No (N) or Not Applicable (NA). All elements of the question must be satisfactorily present to indicate Yes (Y). Provide comments for each Partial (P), No (N) or Not Applicable (NA). In the comment field you may also provide information on what was audited i.e., make reference to documentation, equipment, personnel, etc.

REQUIREMENTS	Y/P/N/ NA	Comment
8.1 <u>Procedure and/or Process for Continuity and Emergency Preparedness Planning (Contingency Plan)</u> Has the laboratory defined a procedure and/or process that addresses, but is not limited to, the following activities and measures to address and mitigate the consequences of any event that leads to interruptions of services including but not limited to: ***Notes: Contingency plans should be periodically tested. Where the laboratory uses another laboratory as a backup, the performance of the back-up laboratory shall be regularly reviewed including contingency plans in the event of failure of the back-up laboratory.***		**Score /3**
a. Personnel;		
b. Equipment breakdown;		
c. Power outages;		
d. Stock outs of reagents and consumables;		
e. Fire, natural disasters, e.g., severe weather or floods, bomb threats or civil disturbances		
ISO15189:2022 Clause 7.8, CLSI GP36-A		
8.2 <u>Implementation of Continuity and Emergency Preparedness Planning</u>		**Score /3**
a. Has laboratory management developed and implemented a continuity and emergency preparedness plan covering all laboratory operations (including inputs from risk assessments, internal audits, management reviews, safety audits, etc. ***Note: Reference CLSI GP36-A [35]***		
b. Is the continuity and emergency preparedness plan periodically tested for its continued effectiveness and are actions taken to address any identified gaps?		
c. Are there records of monitoring the effectiveness of the continuity and emergency preparedness plan?		
d. Has the continuity and emergency preparedness plan been communicated and training provided to all relevant laboratory personnel?		
ISO15189:2022 Clause 7.8		
8.3 <u>Procedure and/or Process for Pre-examination Processes</u> Has the laboratory defined a procedure and/or process that addresses, but is not limited to, the following? ***Note: The laboratory must have documented procedures and information for pre-examination activities to ensure the validity of the results of examinations***		**Score /3**
a. Location(s) of the laboratory, operating hours, and contact information;		
b. Procedures for requesting and collection of patient samples;		
c. Instructions for collection activities (including sample, volume, and transportation requirements);		
d. Instructions for pre-collection activities;		
e. Preparation and storage prior to dispatch to the laboratory;		
f. Scope of laboratory activities and time for expected laboratory results;		
g. Time limits and special handling of patient samples;		
h. Patient sample acceptance and rejection criteria;		
i. Factors known to significantly impact the performance of examinations or interpretation of results;		

j. Availability of advisory services;		
k. Requirements for patient consent;		
l. Ensuring patient confidentiality;		
m. Complaints procedure.		
ISO15189:2022 Clause 7.2		
8.4 <u>Instructions for Collection Activities</u> Are records available to show implementation of the following:		**Score /3**
a. Verification of the identity of the patient from whom a primary sample is collected;		
b. Verification and, when relevant, recording that the patient meets pre-examination requirements (e.g., fasting status, medication status [time of last dose, cessation], sample collection at predetermined time or time interval);		
c. Collection of primary samples, with descriptions of the primary sample containers and any necessary additives, as well as the order of sample collection, where relevant;		
d. Labelling of primary samples in a manner that provides an unequivocal link with the patient from whom they are collected;		
e. Recording of the identity of the person collecting the primary sample and the collection date, and, when relevant, recording of the collection time;		
f. Requirements for separating or dividing the primary sample, when necessary;		
g. Stabilization and proper storage conditions before collected samples are delivered to the laboratory;		
h. Safe disposal of materials used in the sample collection process.		
ISO15189:2022 Clause 7.2.4.4		
8.5 <u>Test Request</u> Does the laboratory adequately collect information needed for examination performance? ***Note 1: Each request accepted by the laboratory for examination(s) shall be considered an agreement. The request may be paper-based or electronic-based;*** ***Note 2: The review of service agreements occurs on sample reception. All portions of the primary sample must be unequivocally traceable to the original primary sample.***		**Score /3**
a. Are all test requests accompanied by an acceptable and approved test requisition (e.g., a transmittal sheet/checklist/manifest/request form where applicable)?		
b. Does the request include patient identifiers, including gender, date of birth, location of patient and unique identifier?		
c. Name, initials, and signature (where applicable) of authorized requester;		
d. Type of sample and examination requested;		
e. Clinically relevant information;		
f. Date of sample collection (may include time where appropriate);		
g. Date and time of sample receipt (pre-analytical);		
h. Informed consent when required.		
ISO15189:2022 Clause 4.3 and 7.2.4.4		
8.6 <u>Primary Sample Receipt Procedure</u> Does the laboratory implement the sample receipt procedures and are there records of implementation of the following:		**Score /3**
a. Unique patient identifier;		
b. Are received samples evaluated according to acceptance and rejection criteria?		

c. Are samples logged appropriately upon receipt in the laboratory (including date of receipt, time of receipt, and name of receiving personnel)?		
d. Are procedures in place to process 'urgent' samples?		
e. Are procedures in place to process oral requests?		
f. When samples are split, can the portions be traced back to the primary sample?		
g. Are samples delivered to the correct workstations as per the laboratory processes?		
ISO15189:2022 Clause 7.3.2		
8.7 <u>Pre-examination Handling, Processing and Storage</u> Prior to testing, are samples handled, processed, and stored according to specific sample type stability and testing requirements? ***Note: Samples should be stored under the appropriate conditions to maintain the stability of the sample according to international best practice and or testing guidelines.***		**Score /2**
ISO15189:2022 Clause 7.2.7		
8.8 <u>Sample Transportation</u> ***Note: All samples shall be transported to the laboratory in a manner that is safe to patients, users, personnel (including transporters), community and the environment. The laboratory must ensure that the samples were received within a temperature and time interval specified for sample collection.***		**Score /2**
a. Are samples either received at the laboratory or referred to another site, packaged according to national guidelines/regulations?		
b. When specimens are transported across borders (i.e., internationally) is the packaging and transportation in full compliance with international (e.g., IATA) regulations?		
c. Are samples transported within acceptable timeframe and temperature intervals?		
d. Are specimens packaged according to national regulations when either received at the laboratory or referred to another site?		
ISO15189:2022 Clause 7.2.5		
8.9 <u>Procedure and/or Process for Referral Laboratories and Technical Consultants</u> Has the laboratory defined a procedure and/or process that addresses, but is not limited to, the following?		**Score /3**
a. Defining criteria for referral laboratories and technical consultants;		
b. Selection and approval of referral laboratories;		
c. Technical consultants who provide advice and interpretation;		
d. Evaluation and monitoring of the performance of referral laboratories and technical consultants;		
e. Maintenance of a list of approved referral laboratories and technical consultants;		
f. Maintenance of records of referred samples;		
g. Tracking of referred samples and their results;		
h. Reporting of results from referral laboratories;		
i. Management of critical results received from referral laboratories;		
j. Packaging and transportation of referred samples;		
k. Record of communication of results from referral laboratories and technical consultants.		
ISO15189:2022 Clause 6.8.2		
8.10 <u>Referral Laboratories and Technical Consultants</u> ***Note: The laboratory must have systems in place to ensure that the referral laboratories are competent to perform the services required. Evaluations may be in the form of checking their accreditation status, using a questionnaire, performing audits, use of blinded samples, etc.***		**Score /2**

a. Does the laboratory select referral laboratories and technical consultants based on specific criteria?		
b. Are there documented reviews and evaluations of referral laboratories and technical consultants as defined by the laboratory?		
c. Is there a register of referral laboratories and technical consultants?		
d. Are referred samples tracked properly using a logbook, tracking form or electronically?		
e. Does the laboratory ensure that the results obtained by the referral laboratory are tracked to ensure timely delivery to the user?		
ISO15189:2022 Clause 6.8.2		
8.11 <u>Procedure and/or Process for Documentation of Examination Procedures</u> Has the laboratory defined a procedure and/or process that addresses, but is not limited to, the following? ***Note: Working instructions, job aids, flow process diagrams or similar systems that summarize key information are acceptable for use as a quick reference at the workbench, provided that a fully documented examination procedure (e.g., SOP) is available for reference. Information from product instructions for use can be incorporated into examination procedures by reference in the SOP.***		**Score /2**
a. Defining the format, language, and appropriate location of examination procedures;		
b. Selection and approval of referral laboratories.		
ISO15189:2022 Clause 7.3.6		
8.12 <u>Location of Examination Procedures</u> Are examination information and instructions available in appropriate locations? ***Note: Examination information and instructions may include SOPs, package inserts, user manuals, job aids, etc.***		**Score /2**
ISO15189:2022 Clause 7.3.6		
8.13 <u>Reagents and Consumables Acceptance Testing</u> Is verification performed and documented before use for each new preparation, new lot, and new shipment of reagents and consumables? ***Note: Verification can be in-house or based on the Certificate of Analysis of the reagent.***		**Score /2**
ISO15189:2022 Clause 6.6.3		
8.14 <u>Procedure and/or Process for Internal Quality Control (IQC)</u> Has the laboratory defined a procedure and/or process that addresses, but is not limited to, the following? ***Note: The laboratory should choose concentrations of control materials, wherever possible, especially at or near clinical decision values, which ensure the validity of decisions made. Use of independent third-party control materials should be considered, either instead of, or in addition to, any control materials supplied by the reagent or instrument manufacturer.***		**Score /3**
a. Definition of IQC criteria (acceptance and rejection);		
b. Frequency of processing IQC;		
c. Definition of acceptable ranges (package inserts or in house);		
d. Use of alternate quality control methods when appropriate quality controls are not available (in-house produced IQC materials, EQA materials, etc.);		
e. Recording, evaluating, and monitoring ongoing IQC performance;		
f. Troubleshooting unacceptable IQC performance.		
ISO15189:2022 Clause 7.3.7		
8.15 <u>Quality Control</u>		**Score /3**
a. Is internal quality control performed and verified to be within acceptable limits before testing and release of results?		

b. Is corrective action taken and documented when quality control results fall outside the acceptable range and reviews identify non-conformities in a timely manner?		
c. Does the laboratory evaluate the results from patient samples that were examined after the last successful quality control result in the event of a quality control failure?		
ISO15189:2022 Clause 7.3.7.2		
8.16 <u>Monitoring of Quality Control Performance</u>		**Score /3**
a. Are quality control results monitored and reviewed to assess the performance of the method and/or identify errors over time for quantitative tests? ***Note: Monitoring of quality controls can include biases, trends, and Levy-Jennings charts.***		
b. Is appropriate action taken and documented when there is an error or rule violation with the quality control results? ***Note: The laboratory must document and implement a system it would use to evaluate patient results since the last successful quality control. The evaluation could be done by re-examining selected samples of various batches or re-examining samples as per the stability of the quality control.***		
ISO15189:2022 Clause 7.3.7.2		
8.17 <u>Comparability of Examination Results</u> Does the laboratory compare results to ensure there is no clinically significant variation when the same test for a patient sample is performed with different methods or equipment, including POCT? ***Note: The laboratory should document and implement a system to ensure there is comparability of results. This could be done using EQA performance, using blinded samples, and parallel testing.***		**Score /2**
a. Does the laboratory record the results of comparability performed and its acceptability?		
b. Does the laboratory periodically review the comparability of results?		
c. Does the laboratory evaluate and act upon the impact of any differences on biological reference intervals and clinical decision limits?		
d. Does the laboratory inform users of any clinically significant differences in comparability of results?		
ISO15189:2022 Clause 7.3.7.4		
8.18 <u>Monitoring and Recording Environmental Conditions.</u> Are the following environmental conditions monitored and recorded daily? ***Note: The laboratory shall monitor, control, and record environmental conditions, as required by relevant specifications or where it may influence the quality of the sample, results, and/or the safety of patients, visitors, laboratory users, and personnel.***		**Score /2**
a. Room temperatures, including storage areas and all areas involved with testing, e.g., server rooms;		
b. Freezers;		
c. Refrigerators;		
d. Incubators;		
e. Water baths.		
ISO15189:2022 Clause 6.3		
8.19 <u>Reviewing of Environmental Conditions</u>		**Score /2**
a. Have acceptable ranges been defined for all environmental conditions?		
b. Is there evidence of documentation for action taken in response to unacceptable conditions?		
ISO15189:2022 Clause 6.3		
8.20 <u>Procedure and/or Process for External Quality Assessment (EQA)</u>		**Score /3**

Has the laboratory defined a procedure and/or process that addresses, but is not limited to, the following? **Note:** ***EQA should cover the pre-examination process, examination process and post-examination process. Where an EQA program is not available, the laboratory can use alternative methods with clearly defined acceptable results, e.g., exchange of samples with other laboratories, testing certified materials, EQA samples previously tested. All procedures or equipment used as backup must also be included in the EQA program.***		
a. All examinations, including POCT, must be enrolled in EQA or alternative methods, in the event EQA is not available;		
b. Defining EQA processing criteria (treating EQA as routine);		
c. Frequency of processing as per the EQA schedule;		
d. Defining acceptable performance criteria;		
e. Use of alternate approaches when the EQA program is not available (e.g., reference materials, blind testing, etc.);		
f. Recording, evaluating, and monitoring ongoing EQA performance;		
g. Troubleshooting unacceptable EQA performance.		
ISO15189:2022 Clause 7.3.7		
8.21 <u>Participation in External Quality Assessment (EQA)</u> Does the laboratory participate in EQA or external alternative assessment procedures (APP) for all tests? ***NOTE1: Acceptable alternatives include:*** • ***Participation in sample exchanges with other laboratories;*** • ***Interlaboratory comparisons of results of examinations of identical IQC materials, which evaluates individual laboratory IQC results against pooled results from participants using the same IQC material, analysis of a different lot number of the manufacturer's end-user calibrator or the manufacturer's trueness control material;*** • ***Analysis of microbiological organisms using split / blind testing of the same sample by at least two persons, or on at least two analysers, or by at least two methods;*** • ***Analysis of reference materials considered to be commutable with patient samples;*** • ***Analysis of patient samples from clinical correlation studies;*** • ***Analysis of materials from cell and tissue repositories.***		**Score /3**
a. Do EQA or AAP materials come from providers who are approved suppliers? ***Note: Suppliers may be approved by the laboratory, relevant Ministry, or authorized persons.***		
b. Are EQA or AAP materials handled and tested the same way as routine patient specimens?		
c. Is the EQA or AAP performance of the laboratory reviewed and discussed with relevant personnel?		
d. Is root cause analysis performed for unacceptable EQA or AAP performance?		
e. Is corrective action documented for unacceptable EQA or AAP performance? ***Note: The laboratory should handle, analyse, review and report results for EQA or AAP in a manner like routine patient testing. Investigation and correction of problems identified by unacceptable EQA or AAP should be documented. Acceptable results showing bias or trends suggest that a problem should also be investigated.***		
ISO15189:2022 Clause 7.3.7		

8.22 <u>Procedure and/or Process for Verification and Validation of Examinations Methods</u> Has the laboratory defined a procedure and/or process that addresses, but is not limited to, the following? ***Note 1: Validations should be done on a) non-standard methods, b) laboratory designed or developed methods, c) standard methods used outside their intended scope, d) validated methods subsequently modified.*** ***Note 2: 'Verification' is performed on methods that are being used without any modifications and is a process of evaluating of whether the procedure meets the performance characteristics stated by the manufacturer, i.e., the manufacturer's validation claims. The performance characteristics are obtained from the manufacturer (validation reports) or from package inserts. Comparison of different methods used for same tests is ongoing verification. The frequency and characteristics to be checked in ongoing verification must be clearly defined.*** ***Note 3: All procedures or equipment used as backup must also be validated/verified as relevant.***		**Score**	**/3**
a. Defining the validation or verification protocol (including the authorization for the intended use);			
b. Performing method validation or verification;			
c. Defining validation or verification report.			
ISO15189:2022 Clause 7.3.2 and 7.3.3			
8.23 <u>Records of Verification of Examination Methods</u> ***Note 1: Newly introduced methods must be verified onsite to ensure that their introduction yields performance equal to or better than the manufacturer's claims/specifications.*** ***Note 2: 'Verification' is performed on methods that are being used without any modifications and is a process of evaluating of whether the procedure meets the performance characteristics stated by the manufacturer, i.e., the manufacturer's validation claims. The performance characteristics are obtained from the manufacturer (validation reports) or from package inserts. Comparison of different methods used for same tests is ongoing verification.***		**Score**	**/3**
a. Has the laboratory developed, reviewed, and approved the verification plan (protocol) for each testing method in use prior to verification?			
b. Has the laboratory defined a verification report?			
c. Has the verification report been reviewed by an authorised person?			
d. Has the laboratory generated, reviewed, and approved the verification report for each testing method in use?			
e. Are verification records available (including raw data, calculations, etc.)?			
ISO15189:2022 Clause 7.3.2			
8.24 <u>Records of Validation of Examination Methods</u> ***Note: Validations should be done on a) non-standard methods, b) laboratory-designed or -developed methods, c) standard methods used outside their intended scope, d) validated methods subsequently modified.***		**Score**	**/3**
a. Has the laboratory developed, reviewed, and approved the validation plan (protocol) for each testing method in use prior to validation?			
b. Has the laboratory generated, reviewed, and approved the validation report for each testing method in use?			
c. Are validation records available (including raw data, calculations, etc.)?			
ISO15189:2022 Clause 7.3.3			
8.25 <u>Procedure and/or Process for Measurement Uncertainty (MU)</u> Has the laboratory defined a procedure and/or process that addresses, but is not limited to, the following? ***Note: MU is used to indicate the confidence we have that the reported figure is correct. MU may be calculated using the calculated CV of at least 30 sets of internal precision quality control data: CV% x 2 = MU.***		**Score**	**/2**

a. Determining MU (analytical error) on measured quantity values (quantitative tests);		
b. Defining performance requirements for MU.		
ISO15189:2022 Clause 7.3.4 ***ISO/TS 20914*:2019**		
8.26 <u>Measurement Uncertainty of Measured Quantitative Tests</u> Does the laboratory have documented estimates of MU for each semi-quantitative and quantitative test in use? ***Note: MU should be calculated at different clinical decision limits. Cumulative IQC (minimum 6 months data) may be used to calculate MU.***		**Score /3**
a. Has the laboratory calculated MU for each quantitative test in use? ***Note: If quantitative values are used to decide a qualitative result, then MU must be performed.***		
b. Has the laboratory defined the performance requirements (factors that affect MU) for the MU of each measurement examination and does the laboratory regularly review estimates of MU?		
c. Does the laboratory make its calculated MU available to its users upon request?		
d. Does the laboratory document reasons for exclusion from MU estimation for examination procedures where evaluation of MU is not possible or relevant?		
ISO15189:2022 Clause 7.3.4		
8.27 <u>Procedure and/or Process for Biological Reference Intervals or Clinical Decision Limits</u> Has the laboratory defined a procedure and/or process that addresses, but is not limited to, the following? ***Note: The laboratory shall define the biological reference intervals or clinical decision values, document the basis for the reference intervals or decision values and communicate this information to users.***		**Score /3**
a. Defining biological reference intervals or clinical decision limits;		
b. Biological reference intervals for examinations that identify presence or absence of a characteristic;		
c. Source of reference intervals or clinical decision limits;		
d. Communication of changes of biological reference intervals or clinical decision limits to users.		
ISO15189:2022 Clause 7.3.5		
SECTION 08: PROCESS CONTROL		**/71**

SECTION 09: INFORMATION MANAGEMENT

For each question, please indicate as relevant, Yes (Y), Partial (P), No (N) or Not Applicable (NA). All elements of the question must be satisfactorily present to indicate Yes (Y). Provide comments for each Partial (P), No (N) or Not Applicable (NA). In the comment field you may also provide information on what was audited i.e., make reference to documentation, equipment, personnel, etc.

REQUIREMENTS	Y/P/N/ NA	Comment
9.1 <u>Procedure and/or Process for Reporting and Release of Results</u> Has the laboratory defined a procedure and/or process that addresses, but is not limited to, the following?		**Score /3**
a. Defining report format;		
b. Medium (electronic or paper based);		
c. Reviewing of patient results;		
d. Communication of alert, urgent and critical patient results;		
e. Release of results and reports by authorized persons;		
f. Amendments of results and reports;		
g. Issue of amended reports;		
h. Reporting of results performed by a referral laboratory;		
i. Identification of the referral laboratory;		
j. Retention and maintenance of patient results.		
ISO15189:2022 Clause 7.4.1		
9.2 <u>Test Result Reporting System</u> Are test results legible, technically verified, and confirmed against patient identity? **Note:** ***Paper-based reports must be written in ink and have documentation of review and verification. Evidence of documentation of verification must be available.***		**Score /2**
ISO15189:2022 7.4.1		
9.3 <u>Testing Personnel</u> Is the person authorizing the release of the result identified on the result report or other records (paper- or electronic-based)?		**Score /2**
ISO15189:2022 Clause 7.4.1.2		
9.4 <u>Requirements for Reports</u> Does the laboratory report contain at least the following:		**Score /3**
a. Clear, unambiguous identification of the examinations performed (including POCT reports);		
b. Identification of the laboratory issuing the report;		
c. Identification of all examinations performed by a referral laboratory or part of a research or development program;		
d. Patient identification, location, date of primary sample collection (and time, relevant to patient care), date of issue on every page of the report;		
e. Name of the requester (user);		
f. Identification of examination method used, where relevant, and including, where possible and necessary, harmonized (electronic) identification of the measurand and measurement principle;		
g. Type of primary sample and any specific information necessary to describe the sample; ***Note: (e.g., source, site of sample, macroscopic description, etc.)***		
h. Provisional reports;		
i. Reporting of result in SI units, when applicable;		
j. Biological reference intervals, clinical decision limits, likelihood ratios;		
k. Presence of space for interpretation or comments of results, when applicable;		
l. Indication of critical results;		

m. Identification of the person(s) reviewing and authorizing the release of the report;		
n. Date and time of the report;		
o. Page number to total number of pages (e.g., 'Page 1 of 5');		
p. Clear identification of revisions, including reference to the date and patient identity on the original report, and user notification of the revision, when issuing revised reports;		
q. Presence on revised record of time and date of change and name of the person responsible for the change; ***Note: When the reporting system cannot capture amendments, changes or alterations, a record of such shall be kept.***		
r. Presence of original report entry in the record. ***Note: Applicable to paper- and electronic-based systems.***		
ISO15189:2022 Clause 7.4.1.6		
9.5 <u>Analytic System / Method Tracing</u> Are test results traceable to the equipment used for testing when more than one instrument is in use for the same test? ***Note: There must be traceability of sample results, including proficiency testing results, to a specific analytical system or method.***		**Score /2**
ISO15189:2022 Clause 7.3.7.4, 7.4.1.3 and 7.4.1.4		
9.6 <u>Procedure and/or Process for Laboratory Information System (LIS) (computerised or non-computerised)</u> Has the laboratory defined a procedure and/or process that addresses, but is not limited to, the following? ***Note: 'Information systems' includes the management of data and information contained in both computer and non-computerized systems. Some of the requirements may be more applicable to computer systems than to non-computerized systems. Computerized systems can include those integral to the functioning of laboratory equipment and stand-alone systems using generic software, such as word processing, spreadsheet and database applications that generate, collate, report and archive patient information and reports.***		**Score /3**
a. Verification of the LIS on installation and after every upgrade;		
b. Definition of authorities and responsibilities for management and use of the LIS;		
c. Patient confidentiality;		
d. Maintenance and troubleshooting of the LIS;		
e. Back-up and storage of non-computerized system;		
f. Ongoing checks of calculations used to generate results;		
g. Data transfers checks (interface between testing systems and LIS) for protection and security of the system against external and internal access and tampering;		
h. Automated selection, review, release and reporting of results.		
ISO15189:2022 Clause 7.6.3		
9.7 <u>Archived Data Laboratory and Storage</u> Are archived results (paper or data-storage media) properly labelled and stored in a secure location accessible only to authorized personnel? ***Note: All patient data, paper, and external storage devices must be retained as per the laboratory's retention policy and should be stored in a safe and access-controlled environment.***		**Score /2**
ISO15189:2022 Clause 8.4.3		

9.8 <u>Authorities and Responsibilities for Information Management</u> Has the laboratory designated authorities and responsibilities for the management and use of the LIS, both paper- and electronic-based, including access, maintenance and modifications that may affect patient care? ***Note 1: 'Information systems' includes the management of data and information contained in both computer and non-computerized systems. Some of the requirements may be more applicable to computer systems than to non-computerized systems. Computerized systems can include those integral to the functioning of laboratory equipment and standalone systems using generic software, such as word processing, spreadsheet and database applications that generate, collate, report and archive patient information and reports."*** ***Note 2: Authorities and responsibilities may be defined in the authority matrix, job description, etc.***		**Score /2**
Is the following in place and implemented?		
a. Controlled access to patient data and information;		
b. Controlled access to enter patient data and examination results;		
c. Controlled access to modifying patient data or examination results;		
d. Controlled access to the release of examination results and reports.		
ISO15189:2022 Clause 7.6.2		
9.9 <u>Verification of Electronic Laboratory Information System</u> ***Note: The laboratory must perform verification of the system after upgrades and to ensure previously stored patient results have not been affected.***		**Score /2**
a. Has the system been validated and or verified before implementation and version upgrades?		
b. Are ongoing system checks available for correct transmission, calculation and storage of results and records?		
c. Are there records to check the functioning of the interface of the LIS to other systems (e.g., analyser's, hospital information system)?		
ISO15189:2022 Clause 7.6.3		
9.10 Records of Maintenance of the Laboratory Information System ***Note 1: If the LIS is maintained offsite, records of maintenance must be readily available. The laboratory should include the LIS as part of their internal audit.***		**Score /3**
a. Records of regular service by authorized and trained personnel;		
b. Records of system failures with documented appropriate root cause analysis, corrective actions and verification;		
c. Records that the system is operated in an environment recommended by the supplier for optimal functioning;		
d. Evidence that the laboratory has implemented a process to ensure the protection and security of the LIS ***Note 1: If the LIS is maintained offsite, records of maintenance must be readily available. The laboratory should include the LIS as part of their internal audit.***		
ISO15189:2022 Clause 7.6.3		
SECTION 09: INFORMATION MANAGEMENT.		**/24**

SECTION 10: NONCONFORMING EVENT MANAGEMENT

For each question, please indicate as relevant, Yes (Y), Partial (P), No (N) or Not Applicable (NA). All elements of the question must be satisfactorily present to indicate Yes (Y). Provide comments for each Partial (P), No (N) or Not Applicable (NA). In the comment field you may also provide information on what was audited i.e., make reference to documentation, equipment, personnel, etc.

REQUIREMENTS	Y/P/N/ NA	Comment
10.1 <u>Procedure and/or Process for Handling of Nonconforming work, Nonconformities and Corrective Action</u> Has the laboratory defined a procedure and/or process that addresses, but is not limited to, the following?		**Score /3**
a. Identification of nonconforming work and nonconformities in any aspect of the laboratory management system;		
b. Documentation of nonconforming work and nonconformities;		
c. Determination of level of risk and evaluation of the impact;		
d. Performing root cause analysis;		
e. Determination of the need for corrective action (how and where);		
f. Assignment of roles and responsibilities for recalling, resolving and resumption of the nonconforming work and nonconformities;		
g. Determining time frame for resolving nonconforming work and nonconformities;		
h. Implementation of corrective action (including halting examinations and recalling of released results, where applicable);		
i. Monitoring, reviewing and evaluating the effectiveness of the corrective action taken;		
j. Retention of records of nonconforming work and nonconformities.		
ISO15189:2022 Clause 7.5 and 8.7		
10.2 <u>Identification and Management of Nonconforming Work and Nonconformities</u> ***Note: Nonconformities should be identified and managed in any aspect of the laboratory management system, including pre-examination, examination, or post-examination processes. Nonconforming examinations or activities occur in many different areas and can be identified in many ways, including clinician complaints, internal quality control indications, instrument calibrations, checking of consumable materials, inter-laboratory comparisons, personnel comments, reporting and certificate checking, laboratory management reviews, and internal and external audits.***		**Score /3**
Are nonconforming work and nonconformities documented as required below:		
a. Investigation and determination of the root cause (root cause analysis), and conduct of risk assessment (to determine the level of risk and the need for action); ***Note: Root cause analysis is a process of identifying and removing the underlying factor of the nonconformance.***		
b. Actions (immediate and corrective) taken to control and/or correct the nonconformity or non-conforming work; ***Note 1: Are examinations halted and results withheld or recalled where the nonconformity compromises patient results?*** ***Note 2: Informing the requester where nonconforming work/nonconformity influences the management of the patient.***		
c. Follow up and review of actions to assess effectiveness. ***Note: Implemented corrective action does not imply effectiveness; therefore, the laboratory must monitor to ensure that the nonconformity has not recurred.***		
ISO15189:2022 7.5 and 8.7		
10.3 <u>Records of Identification and Management of Nonconforming Work and Nonconformities</u> Are there records of communication to the requester where nonconforming work or a nonconformity influences the management of the patient?		**Score /2**
ISO15189:2022 Clause 7.5		

10.4 <u>Resumption of Testing</u> Is authorization for the resumption of testing documented (where testing has been halted)?		**Score** **/2**
ISO15189:2022 Clause 7.5		
10.5 <u>Corrective Action</u> Is corrective action performed and documented for nonconforming work or nonconformities?		**Score** **/3**
ISO15189:2022 Clause 8.7		
SECTION 10: NONCONFORMING EVENT MANAGEMENT		**/13**

SECTION 11: CONTINUAL IMPROVEMENT

For each question, please indicate as relevant, Yes (Y), Partial (P), No (N) or Not Applicable (NA). All elements of the question must be satisfactorily present to indicate Yes (Y). Provide comments for each Partial (P), No (N) or Not Applicable (NA). In the comment field you may also provide information on what was audited i.e., make reference to documentation, equipment, personnel, etc.

REQUIREMENTS	Y/P/N/ NA	Comment
11.1 <u>Procedure and/or Process for Continual Improvement</u> Has the laboratory defined a procedure and/or process that addresses, but is not limited to, the following? ***Note: Improvement activities must be identified within the pre-examination, examination, and post-examination processes. Laboratory management shall ensure that the laboratory participates in continual improvement activities that encompass relevant areas and outcomes of patient care and results records.***		**Score /3**
a. Identification of improvement activities within the laboratory management system;		
b. Development and documentation of improvement plans;		
c. Communication of improvement plans and related goals to relevant personnel;		
d. Implementation of action plans;		
e. Recording of improvement plans;		
f. Evaluation of effectiveness of actions taken.		
ISO15189:2022 Clause 8.6.1 and 8.5		
11.2 <u>Implementation of Continual Improvement of Management System</u> Does the laboratory identify and undertake continual quality improvement activities? ***Note: The laboratory should use its management review activities to continually improve its laboratory management system by comparing its actual performance to its intentions stated in the quality policy and objectives.***		**Score /2**
ISO15189:2022 Clause 8.6		
11.3 <u>Communication of Continual Improvement Activities</u> Are the outcomes of continual improvement activities communicated to laboratory management, personnel, and users? ***Note 1: The communication can be done using graphical tools (such as charts, graphs, tables) and in personnel and management meetings.*** ***Note 2: Examples of graphical tools commonly used for this purpose include LJ charts, Pareto charts, cause-and-effect diagrams, frequency histograms, trend graphs, and flow charts.***		**Score /2**
ISO15189:2022 Clause 8.6		

SECTION 11: CONTINUAL IMPROVEMENT /07

SECTION 12: FACILITIES AND SAFETY

For each question, please indicate as relevant, Yes (Y), Partial (P), No (N) or Not Applicable (NA). All elements of the question must be satisfactorily present to indicate Yes (Y). Provide comments for each Partial (P), No (N) or Not Applicable (NA). In the comment field you may also provide information on what was audited i.e., make reference to documentation, equipment, personnel, etc.

REQUIREMENTS	Y/P/N/ NA	Comment
12.1 <u>Procedure and/or Process for Laboratory Safety</u> Has the laboratory defined a procedure and/or process that addresses, but is not limited to, the following? ***Note 1: The safety procedures and or processes can be in the form of a safety manual.*** ***Note 2: Laboratory management must implement a safe laboratory environment in compliance with good laboratory practice and applicable requirements.***		**Score /3**
a. Ensure all safety measures are implemented at the laboratory as applicable to national and/or international guidelines and regulations.		
ISO15190:2020 Clause 12.10		
12.2 <u>Facilities and Environmental Conditions (including POCT)</u> Has the laboratory defined a procedure and/or process that addresses, but is not limited to, the following? ***Note. Evaluating and determining the sufficiency and adequacy of space may be done during internal audits, risk assessments or at management review meetings. However, it must be documented that it was evaluated and found to be adequate.***		**Score /3**
a. Define how to evaluate and determine the sufficiency and adequacy of the space allocated for the performance of the scope of work;		
b. Ensure storage and disposal facilities meet applicable requirements;		
c. Ensure personnel have space for personal activities (supply of drinking water, storage space for personal and protective equipment and clothing);		
d. Monitor, control and record any specific environmental and facility requirements;		
e. Sample collection facilities, taking into consideration patient privacy, comfort, and needs (e.g., disabled access, toilet facility) of patients and accommodation of accompanying persons (e.g., guardian or interpreter) during collection;		
f. Implementation, recording, monitoring, and reviewing of facility controls (access, safety, etc.).		
ISO15189:2022 Clause 6.3		
12.3 <u>Adequacy of Size and Layout of Laboratory</u> Is there documented evidence that the laboratory has evaluated the adequacy of the size and layout of the laboratory and organized the space so that workstations are positioned to reduce risk, ensure optimal workflow, and prioritize occupational health? ***Note: Documentation could be in the form of a floor plan, results from internal audits, risk assessment. Chairs/stools at the workstations should be appropriate for bench height and for the testing operations being performed.***		**Score /2**
ISO15190:2020 Clause 4.2 and 12		
12.4 <u>Patient Care Areas</u> Are patient care and testing areas of the laboratory distinctly separate from one another? ***Note: Patient care areas (i.e., waiting room, phlebotomy room) should be distinctly separate from the testing areas of the laboratory. For biosafety reasons, microbiology tuberculosis, and molecular testing should be segregated in a separate room(s) from the general laboratory testing.***		**Score /2**
ISO15189:2022 Clause 6.3.1		
12.5 <u>Housekeeping</u> Are housekeeping activities performed to ensure the efficient operations of the laboratory and the safety of the personnel, users, and patients?		**Score /2**
a. Are there records of housekeeping duties performed daily (at the minimum)?		

b. Are all necessary housekeeping supplies present and easily accessible?		
c. Are all equipment and work surfaces (that are used for processing contaminated materials) cleaned and disinfected with appropriate agents both before and at the end of each working shift and whenever spills or other contamination has occurred?		
ISO15190:2020 Clause 18		
12.6 <u>Physical Work Environment</u> Is the physical work environment appropriate for testing?		**Score /3**
a. Free of clutter? ***ISO 15190: 2020 Clause 18 j***		
b. Adequately ventilated? ***ISO 15190: 2020 Clause 9.2***		
c. Climate-controlled for optimum equipment function? ***ISO 15189:2022 Clause: 6.3.1***		
d. Are filters checked, cleaned and/or replaced at regular intervals, where air-conditioning is installed?		
e. Are wires and cables properly installed and protected from hazardous factors and from traffic?		
f. Is there a functioning back-up power supply (generator) and are there records of maintenance?		
g. Is critical equipment supported by uninterrupted power source systems?		
h. Is all equipment placed appropriately (away from water hazards, out of traffic areas)?		
i. Are appropriate provisions made for adequate water supply, including deionized water or distilled water, if needed?		
j. Is clerical work performed in a designated clean area?		
k. Is safety signage posted and enforced, including "**NO EATING, SMOKING, OR DRINKING"**?		
ISO15190:2020 Clause 4.2		
12.7 <u>Laboratory Access</u> Is the laboratory properly secured from unauthorized access with appropriate systems and signage? ***Note: Access control should take into consideration safety, confidentiality and quality and safeguard medical information and patient samples.***		**Score /2**
ISO15190:2020 Clause 4.3.3 and ISO15189:2022 Clause 6.3.1		
12.8 <u>Laboratory Storage Areas</u> Is there adequate storage space under the appropriate conditions and properly labelled for the following? ***Note: There should be effective separation to prevent contamination.***		**Score /3**
a. Samples;		
b. Equipment;		
c. Reagents and consumables;		
d. Documents and records;		
e. Patient samples and materials used in examination processes (stored separately);		
f. Hazardous materials and biological waste appropriate to the classification in context of any statutory or regulatory requirements;		
g. Personnel items, food, and drinks.		
ISO15189:2022 Clause 6.3		
12.9 <u>Laboratory Facilities</u> ***Note: The work area should be cleaned regularly. 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 decontaminated, as appropriate, and the work surfaces disinfected.***		**Score /2**

a. Are laboratory facilities maintained in a functional and reliable condition (e.g., housekeeping and maintenance, etc.)?		
b. Does the laboratory have adequate safety facilities and devices, where applicable, and regularly verify their proper functioning (eye wash stations, emergency showers, fire alarms, etc.)?		
c. Is the work area clean and free of leakage and spills, and are disinfection and decontamination procedures conducted and documented, where appropriate?		
ISO15189:2022 Clause 6.3 and ISO 15190: 2020 clause 4.2		
12.10 <u>Safety Cabinet (biosafety cabinet, laboratory hood, etc.)</u> Where a biosafety cabinet is present and required to perform work, are the following conditions met, where appropriate? ***Note: A biosafety cabinet should be used to prevent aerosol exposure to contagious samples or organisms. For proper functioning and full protection, biosafety cabinets require periodic maintenance and should be serviced accordingly. Biosafety cabinets should be recertified according to national protocols or manufacturer requirements.***		**Score /3**
a. Selection, location, design, and type of biological safety cabinet utilized appropriate to the level of risk containment required for safe working;		
b. Used in such a manner as to avoid compromising the cabinet's function (e.g., jarring or mishandling delicate HEPA filters);		
c. Vented appropriate to the microbiological risk and consistent with safety requirements; frequently monitored to ensure that they function as designed;		
d. Tested/certified upon installation, when moved or repaired and annually; records shall be kept of the inspection and any functionality testing result;		
e. Proof of inspection indicated by a certification label displayed on the cabinet.		
ISO15190:2020 Clause 7.7.		
12.11 <u>Safety Program</u> Does the laboratory have a safety program that includes, but is not limited to, the following elements?		**Score /3**
a. Safety and health policy;		
b. Written work procedures that include safe work practices;		
c. Education and training of laboratory-associated personnel;		
d. Supervision of personnel;		
e. Regular inspections;		
f. Hazardous materials and substances;		
g. Health surveillance and prophylaxis;		
h. First aid services and equipment;		
i. Investigation of accidents and illnesses;		
j. Records and statistics;		
k. Requirement for follow-up to ensure that all required actions arising from the audit are completed;		
l. Fire safety;		
m. Oversight of good housekeeping practices.		
ISO 15190:2020 Clause 5.7 and Clause 18		
12.12 <u>Laboratory Safety Manual</u> Is a laboratory safety manual available, accessible, and up to date?		**Score /3**
Does the safety manual include guidelines on the following topics?		
a. Safety policy;		
b. Blood and body fluid precautions;		
c. Biosafety and biosecurity hazards, where appropriate;		

d. Risk assessment and mitigation;		
e. Biological hazards;		
f. Hazardous waste disposal;		
g. Chemical safety;		
h. Radiation;		
i. Vaccination;		
j. Post-exposure prophylaxis		
k. Fire prevention;		
l. Electrical safety.		
ISO15190:2020 Clause 5.6		
12.13 <u>Waste Disposal</u> ***Note 1: 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 prevent injury from exposed waste; infectious waste should be incinerated, burnt in a pit, or buried.*** **Note 2:** ***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 available in areas where sharps are commonly used.***		**Score /2**
a. Is sufficient waste disposal available and adequate?		
b. Is waste separated into infectious and non-infectious waste, with infectious waste autoclaved/incinerated?		
c. Are 'sharps' handled and disposed of properly in 'sharps' containers that are appropriately utilized?		
d. Are adequate records of hazardous waste disposal retained in an accessible file by the laboratory?		
ISO15190:2020 Clause 17.		
12.14 <u>Hazardous Chemicals</u> Are hazardous chemicals/materials properly handled**?** ***Note: Chemicals present a broad range of physical (e.g., flammable, corrosive) and biological (e.g., toxic, radioactive, carcinogenic) hazards.***		**Score /3**
a. Are hazardous chemicals properly classified and labelled?		
b. Are chemicals segregated and stored by reactivity class and flammability?		
c. Are hazardous chemicals properly utilized according to safety data sheets (SDS)? ***Note: The SDS may be available in a computerized format as long personnel are trained on how to access them, the computers are kept in working order and the employer can provide a hard copy of the SDS on request.***		
d. Are hazardous chemicals properly disposed of according to national and/or international guidelines or SDS?		
e. Is there documented information and records of communication with laboratory personnel regarding the potential routes of entry for toxic chemicals and how best to perform the necessary precautions to prevent exposure?		
• Are oxidizing materials used with appropriate precautions?		
• Are corrosive materials used with appropriate precautions?		

• Are suitable chemical spill measures provided, including neutralizing agents, spill containment, and absorbents appropriate for the chemicals used. ***Note: All hazardous chemicals must be labelled with the chemical's name and with hazard markings. Flammable chemicals must be stored out of sunlight and below their flashpoint, preferably in a steel cabinet in a well-ventilated area. Flammable and corrosive agents should be separated from one another. Distinct care should always be taken when handling hazardous chemicals.***		
ISO15190:2020 Clause 8.		
12.15 <u>Fire Safety</u>		**Score /2**
a. Are all electrical cords, plugs, and receptacles used appropriately, installed, and in good condition? ***Note: Overloading should be avoided, and cords should be kept out of traffic areas***		
b. Is an appropriate fire extinguisher available, properly placed, in working condition, and routinely inspected? ***Note 1: An approved fire extinguisher should be easily accessible within the laboratory and be routinely inspected and documented for readiness.*** ***Note 2: Fire extinguishers should be kept in their assigned place and not hidden or blocked, the pin and seal should be intact, nozzles should be free of blockage, pressure gauges should show adequate pressure, and there should be no visible signs of damage.***		
c. Are there automatic smoke-detection, heat-detection, and alarm systems adequately placed within the laboratory? ***Note: A fire alarm should be installed in the laboratory and tested regularly for readiness.***		
d. Is there a training program in fire safety including fire drills and use of fire extinguishers, which is given to all laboratory workers and personnel who share the building? ***Note: All personnel should participate in periodic fire drills. Fire safety training should be performed during orientation and annually at a minimum.***		
ISO15190:2020 Clause 11		
12.16 <u>Safety Audits</u> Are safety inspections or audits conducted regularly and documented? ***Note: Work sites shall be surveyed/inspected at least annually.***		**Score /2**
a. Is there a safety audit plan or schedule that ensures all activities of the laboratory are checked for safety compliance?		
b. Are safety inspections or safety audits being carried out by authorized personnel?		
c. Are the personnel conducting the internal audits trained in safety?		
d. Is root cause analysis and corrective action taken for safety inspection findings?		
e. Are safety inspection findings documented and presented to the laboratory management and relevant personnel for review?		
ISO15190:2020 Clause 5.7		
12.17 <u>Safety Equipment</u> Is standard safety equipment available and properly used within the laboratory? ***Note: Management is responsible for providing appropriate personal protective equipment (gloves, lab coats, eye protection, etc.) in useable condition. Laboratory personnel must always utilize personal protective equipment while in the laboratory. Protective clothing should not be worn outside designated working areas.***		**Score /3**
a. Safety cabinet(s) (including biosafety cabinets, laboratory hoods, etc.); ***ISO 15190:2020 Clause 7.7***		
b. Covers, safety caps, safety buckets on centrifuge(s);		

c. Hand-washing station; ***ISO 15190: 2020 Clause 4.2***		
d. Eyewash station/bottle(s) and emergency showers where applicable; ***ISO 15190: 2020 Clause 10.3***		
e. Spill kit(s); ***ISO 15190: 2020 Clause* 10.5**		
f. First aid kit(s). ***ISO 15190: 2020 Clause 10.2***		
ISO15190:2020 Clause 15.		
12.18 <u>Personnel Protective Equipment</u> Is personal protective equipment easily accessible at the workstation and utilized appropriately and consistently?		**Score /2**
ISO15190:2020 Clause 15		
12.19 <u>Personnel Vaccinations</u> Are post-exposure prophylaxis policies and procedures readily available to laboratory personnel and implemented after possible and known exposures? ***Note 1: The laboratory must have a procedure for follow-up of possible and known percutaneous, mucus membrane or abraded skin exposure to HIV, hepatitis B virus, hepatitis C virus, tuberculosis bacteria, and other applicable pathogens. The procedure should include clinical and serological evaluation and appropriate prophylaxis.*** ***Note 2: Laboratory personnel should be offered appropriate vaccinations—particularly for hepatitis B virus. Personnel may decline to receive the vaccination. In that situation, personnel must sign a declination form which must be filed in their respective personnel file***		**Score /2**
***ISO15190:2020* Annex I**		
12.20 <u>Post-Exposure Prophylaxis</u> Are adverse incidents, accidents, or injuries (from equipment, reagents, consumables, occupational injuries, medical screening, or illnesses, etc.) fully investigated, documented, and subsequent steps taken to reduce the possibility of recurrence? ***Note: The laboratory must have a procedure for follow-up of possible and known percutaneous, mucus membrane or abraded skin exposure to HIV, hepatitis B virus, or hepatitis C virus. The procedure should include clinical and serological evaluation and appropriate prophylaxis.***		**Score /2**
ISO15190:2020 Clause 7.1.2		
12.21 <u>Management of Adverse Incidents or Injury</u> Are adverse incidents or injuries from equipment, reagents, occupational injuries, medical screening, or illnesses, documented and investigated? ***Note: 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.***		**Score /2**
ISO15189:2022 Clause 5.3.1.6, 5.3.2.6, ISO15190:2020 Clause 19.1		
12.22 <u>Safety Training</u> Are all personnel (including drivers / couriers, phlebotomists and cleaners) performing laboratory activities trained in safety practices relevant to their job tasks (including general safety, biosafety, and biosecurity, where appropriate)? ***Note: All personnel must be trained in prevention or control of the effects of adverse incidents.***		**Score /2**
ISO15189:2022 Clause 6.2		
12.23 <u>Laboratory Safety Officer</u> Is a trained safety officer designated to implement and monitor the safety program in the laboratory? ***Note: A safety officer should be appointed to implement and monitor the safety program, coordinate safety training, and handle all safety issues. This officer should receive safety training.***		**Score /2**
ISO15190:2020 Clause 5.5		

12.24 <u>Biosecurity</u> Are biosecurity policies, processes, and procedures implemented by the laboratory, where appropriate?		**Score** **/2**
ISO15190:2020 Clause 7		

SECTION 12: FACILITIES AND SAFETY /57

Summary of the Audit

Noted Commendations

Noted Limitations

Recommendations

References

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[5] ISO 15198:2004, *Clinical laboratory medicine — In vitro diagnostic medical devices — Validation of user quality control procedures by the manufacturer*

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[23] ISO 20166-2:2018, *Molecular in vitro diagnostic examinations — Specifications for pre- examinations processes for formalin-fixed and paraffin-embedded (FFPE) tissue — Part 2: Isolated proteins*

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[28] ISO 20184-3:2021, *Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for frozen tissue — Part 3: Isolated DNA*

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