Minimum Service Delivery Standards (MSDS) for Clinical and Diagnostic Laboratories – IHRA 2025

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1: Service Management

Standard 1: The laboratory ensures clear identification and accessibility.

Indicator 01: The clinical laboratory shall be clearly identifiable through a visible and informative signboard placed at or near the entrance.

Assessment Process:

To comply with this indicator, the laboratory must ensure that the signboard is clearly visible from a reasonable distance. It should be displayed at or near the main entrance of the facility. The signboard must display the following information:

i. The name of the laboratory.
ii. Registration number (issued by the regulatory authority).
iii. Services offered (such as diagnostic tests or sample collection).
iv. Working hours.
v. Contact information (e.g., phone number or email).
vi. Clear mention of whether the facility is a main laboratory and/or a collection center.

Assessment will include physical inspection of the presence, visibility, and content of the signboard during the assessors' approach to the laboratory.

Rating:

If there is a sign board which clearly identifies and complies with the above requirements, then score as **"Met."**

If a signboard is present and visible, but one or more required elements are missing or unclear (e.g., incomplete information, faded text, unclear facility type), then rate as **"Partially Met."**

If there is no sign board to clearly identify the laboratory and does not comply with the above requirements then rate as above, then rate as "**Not Met."**

Indicator 02: The clinical laboratory is easily accessible to all individuals, including persons with disabilities.

Assessment process:

In order to comply with this indicator lab must ensure the following;

- Pathways to and within the lab are wheelchair-accessible, including ramps where necessary and elevators if the lab spans multiple storey.
- Entrances, exits, hallways, and pathways are wide enough for wheelchair users and free from obstructions.
- All staircases are equipped with secure side railings to ensure safe use.

Rating:

If the laboratory complies with the above requirements, then rate as **"Met."**

If the laboratory does not comply with the above requirements, then rate as **"Not Met."**

2: Regulatory Compliance.

Standard 02: The clinical laboratory maintains valid registration, licensing, and documented referral linkages as required by applicable regulatory authorities.

Indicator 3: The laboratory is registered with Islamabad Healthcare Regulatory Authority.

Assessment process:

To comply with this indicator,

- The laboratory must register with IHRA.
- Registration number must be clearly displayed on the sign board, or at a prominent place inside the laboratory.
- Evidence of having applied for registration in case the lab is not yet registered.

The assessor will physically verify valid display of the IHRA registration or evidence of application, as applicable.

Rating:

If the laboratory has a valid IHRA registration certificate, and the registration number is clearly displayed on the signboard or at a prominent place inside the laboratory, then rate as **"Met."**

If the laboratory has applied for IHRA registration (documented evidence available), but the registration is not yet issued or the certificate/number is not properly displayed, then rate as **"Partially Met."**

If the laboratory does not have a valid IHRA registration, has not applied for registration, or there is no display of registration information, then rate as **"Not Met."**

Indicator 4: The laboratory is licensed with Islamabad Healthcare Regulatory Authority.

Assessment Process:

In order to comply with this indicator, the laboratory must have a valid IHRA license, displayed at a prominent place inside the laboratory. If the license has not yet been issued, documented evidence of application for the license must be available.

The assessor will physically verify valid display of the IHRA license or evidence of application, as applicable.

Rating:
If the laboratory has a valid IHRA license, and the license is clearly displayed at a prominent place inside the laboratory, then rate as **"Met."**

If the laboratory has applied for IHRA license (documented evidence available), but the license is not yet issued or is not properly displayed, then rate as **"Partially Met."**

If the laboratory does not have a valid IHRA license, has not applied for license, or there is no display of license information, then rate as **"Not Met."**

Indicator 5: The laboratory's registration or license issued by the Islamabad Healthcare Regulatory Authority includes details of any associated collection centers.

Assessment Process:
To comply with this indicator,

- The laboratory must ensure that all associated collection centers are listed in the Registration Certificate or License issued by the IHRA.
- The License or provisional license number must be linked to the corresponding serial numbers of each collection center (e.g., Clinical Lab Registration #/Collection Center Serial #, such as CL#/CC#).
- If the laboratory is not yet licensed, documented evidence of the application for licensure must be available.

Assessment will include review of documentation to examine the laboratory's Registration Certificate or License to confirm that all associated collection centers are explicitly listed.

Rating:
If the laboratory has a valid IHRA Registration Certificate or License that explicitly lists all associated collection centers, with correct linkage between the license number and the serial numbers of each collection center, then rate as **"Met."**

If the laboratory has applied for an IHRA License (documented evidence available), but the Registration Certificate or License does not yet list all associated collection centers or the linkage information is incomplete, then rate as **"Partially Met."**

If the laboratory does not have a valid IHRA License, has not applied for licensure, or associated collection centers are not listed or linked appropriately, then rate as **"Not Met."**

Indicator 6: A valid and signed Memorandum of Understanding (MoU) exists with another laboratory or organization for the referral of specialized tests.

Assessment Process:
To comply with this indicator, the laboratory must:

- Maintain a current, signed MOU with a qualified external laboratory or organization for the referral of specialized tests (e.g., PCR, genetic testing).
- Ensure the MOU clearly outlines the scope of referred services, responsibilities of each party, and protocols for specimen handling, result reporting, and turnaround times.

The assessor will review documentation, including a valid MoU signed by both parties, clearly defining referral scope and protocols. They will also assess SOPs, tracking logs, and documentation of referred test results within patient reports.

Rating:
If a signed MoU is in place, documentation, SOPs, tracking logs, and referred test results are complete and correct, rate as **"Met."**

If the laboratory does not have a signed MoU, or the MoU lacks clarity in documentation, SOPs, tracking logs, rate as **"Not Met."**

Responsibilities of Management:

Standard 3: The laboratory is led by a technically qualified and experienced professional.

Indicator 7: A registered and experienced pathologist with recognized qualification and requisite experience heads the laboratory.

Assessment Process:
To comply with this indicator, the laboratory must:

- Have a qualified pathologist registered with the relevant medical council (i.e. PM&DC).
- Ensure the pathologist possesses recognized postgraduate qualifications in pathology and requisite years of professional experience (as per regulatory requirement).
- Maintain documentation of the pathologist's valid registration certificate, qualification credentials, and updated CV/resume.
- Demonstrate that the pathologist is actively involved in laboratory oversight, including test validation, quality assurance programs, staff supervision, and reporting of critical values.
  The assessor will review the registration certificate, qualification documents, employment/contract records, duty rosters, and evidence of active participation of the pathologist in laboratory governance and operations.

Rating:

- If a qualified and registered pathologist is formally appointed as laboratory head, with complete documentation and evidence of active oversight, rate as **"Met."**
- If the laboratory is headed by a person without the requisite qualification, registration, or documented evidence of involvement, rate as **"Not Met."**

Standard 4: Responsibilities of Management are defined.

Indicator 8: The laboratory's management develops and documents an approved mission statement.

Assessment process:

To comply with this indicator, the laboratory must have a documented mission statement, developed and approved by the laboratory's top management (laboratory director, technical head and/or administrative leadership). The mission statement must clearly define the laboratory's purpose, scope of services, and commitment to quality. Assessors will conduct a physical inspection of the laboratory premises to confirm the presence and visibility of the mission statement and review supporting documentation to ensure it has been formally approved by the responsible management.

Rating:

If the laboratory has a developed, documented, and visibly displayed mission statement, then rate as **"Met."**

If the laboratory has a documented mission statement, but it is not visibly displayed, then rate as **"Partially Met."**

If the laboratory does not have a documented mission statement, then rate as **"Not Met."**

Indicator 9: The laboratory's management lay down a detailed laboratory policy in line with National Laboratory Policy (NLP)

https://www.nih.org.pk/wp-content/uploads/2018/06/National-Laboratory-Policy.pdf

Assessment Process

To comply with this indicator, the laboratory must have documented policies and standard operating procedures (SOPs) that align with the National Laboratory Policy (NLP) of Pakistan. The document should cover the following key areas;

i. Quality Management Policy.
ii. Biosafety and Biosecurity Policy
iii. Human Resource Policy
iv. Equipment Management Policy
v. Data Management and Information Systems Policy
vi. Specimen Collection and Handling Policy
vii. Waste Management Policy
viii. Emergency Preparedness and Response Policy.
ix. Ethical Conduct and Patient Confidentiality Policy.

Staff must be aware of these policies and demonstrate their implementation in daily operations Assessors will review the documented policies and SOPs for availability

and compliance with the NLP and will interview staff members to verify their awareness and understanding of these documents.

Rating:
If the laboratory has documented policies and SOPs aligned with the National Laboratory Policy (NLP), includes the key points & the staff is aware of them then rate it as **"Met."**

If the laboratory does not have documented policies and SOPs aligned with the NLP, then rate it as **"Not Met."**

Indicator 10: Laboratory's management ensures budget approval and effective procurement of essential resources.

Assessment Process:
To comply with this indicator, the laboratory must maintain a documented and approved budget covering maintenance, management, operating expenses, and capital investments necessary for the laboratory's continuous functioning.
Additionally, the budget must:

- Include the engagement of a laboratory procurement specialist if needed to facilitate specialized purchases.
- Include a secure, targeted allocation for emergency testing during public health emergencies.
- Contain an approved budget line for the procurement of laboratory equipment, consumables, and supplies.
- Maintain a documented supply management system (either electronic or paper-based) to support procurement tracking and inventory management.

Assessors will review budget documents, procurement plans, and supply records to confirm the availability of an approved budget, dedicated funding lines, and an organized procurement aligned with laboratory operations

Rating:
If the laboratory has an approved budget that covers all essential resources, procurement plan is in place, and inventory management is effectively documented, then rate as **"Met."**

If the laboratory lacks an approved budget or sufficient allocation for essential resources or there is no inventory management system in place, then rate as **"Not Met."**

Indicator 11: Laboratory's management establishes the laboratory's organogram.

Assessment Process:
To comply with this indicator laboratory is required to have an organizational chart (organogram) that outlines its structure, showing the titles of all staff members and illustrating their reporting relationships, connections, and supervisory arrangements.
The chart should be displayed, clear and easily understood by all the laboratory staff.

The assessor will physically review the chart and conduct interviews with staff to ensure their awareness.

Rating:
If the laboratory has a clear and updated organizational chart which is displayed, and the staff is aware of it, then rate as **"Met."**

If the laboratory has an organizational chart, but is not displayed and/or understood by the staff, then rate as **"Partially Met."**

If the laboratory lacks an organizational chart, then rate as **"Not Met."**

Indicator 12: Laboratory's management appoints the Quality Control Manager.

Assessment Process:
To comply with this indicator, the Laboratory Head/Manager must appoint a Quality Control Manager who reports regularly to the laboratory head (at least twice a month, or more frequently if needed). The Quality Control Manager is responsible for overseeing and maintaining the day-to-day operations of the quality management system, ensuring the implementation of quality procedures and processes across all aspects of the laboratory's services. The assessor will review documentation to confirm the appointment of a Quality Control Manager. They will also interview the Quality Control Manager to ensure they are knowledgeable about the quality control processes and their responsibilities.

Rating:
If the laboratory management has appointed a Quality Control Manager who is knowledgeable about their responsibilities, rate as **"Met."**

If the laboratory management has not appointed a Quality Control Manager, then rate as **"Not Met."**

Indicator 13: Laboratory's management appoint the section head/s.

Assessment Process:
In order to comply with this indicator, the laboratory director/manager appoints the section head/s, ensuring effective operation and management of specific laboratory areas, contributing to the overall success of the laboratory. The assessors will review documented process for appointing section heads.

Rating:
If the laboratory director/manager has appointed section head(s), and there is a documented process in place that outlines how these appointments are made, then rate as **"Met."**

If the laboratory director/manager has appointed section head(s), but the documented process for appointing them is incomplete, then rate as **"Partially Met."**

If the laboratory director/manager has not appointed section head(s), or there is no documented process for the appointment of section heads, then rate as **"Not Met."**

Indicator 14: Laboratory's management support research activities.

Assessment Process:
To comply with this indicator, the laboratory management must formally approve all research activities. The laboratory director, in consultation with other relevant team members, is responsible for the approval process.
The assessors will review the documented process for research approval, including the approval of research reports by management. In cases where the laboratory does not conduct independent research, assessors will verify records of sharing disease-related data with relevant authorities or research organizations, ensuring patient confidentiality is maintained.

Rating:
If documented evidence of research approval and/or shared disease-related data is available, rate as **"Met."**

If there is no documented evidence of research approval or shared disease-related data, rate as **"Not Met."**

Facility Management and Safety:

Standard 5: The laboratory's management ensures its facility design, infrastructure, and safety systems support efficient and safe workflow while complying with local laws and regulations for construction and operation.

Indicator 15: The laboratory management ensures that the facility's construction is in line with applicable laws & regulations, i.e. Capital Development Authority (CDA) and/or any other relevant body.

Assessment process:
To comply with this indicator, laboratory management must ensure that all construction activities are conducted in full adherence to local laws and regulations i.e. Capital Development Authority (CDA) or any other body. The assessors will review all documentation related to CDA NOC and construction approvals to verify that the laboratory has obtained the necessary permits and approvals before construction commenced. Any identified gaps in compliance will require evidence of corrective actions being taken by laboratory management.

Rating:
If there is documented evidence that the laboratory has received all necessary CDA approvals and that construction complies with CDA regulations, then rate as **"Met."**

If there is no documented evidence that the laboratory has received all necessary CDA approvals**,** then rate as **"Not Met."**

Indicator 16: Laboratory's management establishes the laboratory's workflow.

Assessment Process:

To comply with this indicator, the laboratory management is responsible for defining the workflow. Workflow design must promote safety, efficiency, and error minimization, and should be based on discussions with end-users to align the facility's layout with operational needs. The organizational structure must support smooth and effective sample handling.

Assessors will review documented workflow diagrams or written descriptions and physically inspect the laboratory layout and processes to ensure that the workflow is implemented effectively, supporting safety and operational efficiency.

Rating:

If the laboratory has a documented, end-user-informed workflow that is properly implemented, then rate as **"Met."**

If the laboratory has a workflow document, but it is incomplete, not fully aligned with practices, or lacks end-user input, then rate as, **"Partially Met."**

If no documented or functional workflow exists, then rate as, **"Not Met."**

Indicator 17: The design and facilities of the laboratory are aligned with its scope of services, while adhering to regulatory requirements and international standards.

Assessment Process:

To comply with this indicator, the laboratory's infrastructure must meet the essential requirements necessary for safe and effective service delivery.

- Reception and waiting areas must be available for patients, with clear directional signage guiding them to various sections/departments within the laboratory.
- Space allocation and effective separation exists between administration and technical laboratory areas.
- It is crucial to include vital safety features, such as biosafety requisites, fire protection and detection systems, and emergency showers and eye wash stations.
- Separate designated rooms/areas for specimen collection, including private spaces for special needs (e.g., semen collection) and accessible facilities for disabled persons.
- Toilets and washrooms must be available for patients, including separate facilities for males and females, and accessible toilets for disabled individuals.
- Staff must have dedicated toilets and washrooms equipped with appropriate eye wash and body wash stations.
- Waste disposal facilities compliant with biomedical waste management standards.
- Environmental control systems (ventilation, temperature, humidity).
- Uninterrupted power supply and availability of laboratory-grade water for testing purposes.
- Dedicated spaces for administrative activities, staff training, and meetings.

- Storage areas for specimens, slides, reagents, consumables, and archives, including provision for cold storage if required.
- Restricted access control for examination and data storage areas.
- Clear marking and warning signage for hazardous areas (handling of carcinogens, radioisotopes, biohazards, lasers).
- Communication facilities with referral centers and arrangements for safe specimen transport.

Rating:
If the laboratory's design fully supports its services, meets the above requirements then rate as **"Met."**

If the laboratory's some infrastructure improvements are needed, to support the scope of services, then rate as, **"Partially Met."**

If the laboratory's design does not support its services, then rate as, **"Not Met."**

Standard 06: All persons are protected from potential hazards in the laboratory.

Indicator 18: Access to the laboratory must be restricted to authorized personnel only.

Assessment Process:
In order to comply with this indicator access to areas where records are maintained, samples are analyzed, or hazardous chemicals and materials are stored must be limited to authorized personnel, typically laboratory and maintenance staff. Access control can be enforced through door signage and appropriate locking mechanisms, preferably RFID. The assessor will physically inspect these areas to verify compliance with access restrictions.

Rating:
If access to restricted areas is controlled through visible door signage and secure locking mechanisms (e.g., RFID) then rate as **"Met."**

If no signage, locks, or RFID is in place, then rate as, **"Not Met."**

Indicator 19: Safety rules must be established in order to reduce risks to staff and patients

Assessment Process:
In order to comply with this indicator, it is important for all laboratory staff to recognize the potential dangers & comply with the requirements below in order to reduce risk to a minimum;

i. SOPs must be prepared to ensure safe handling of laboratory equipment.
ii. SOPs must be developed to ensure the safe handling of all samples and procedures such as phlebotomy, sample transport, subsampling, analytical

procedures, storage and disposal of samples. They should be available at all work stations and provided to
appropriate staff.

iii. SOPs for safe handling of all referred samples must be available and provided to appropriate staff.

iv. SOPs must be available in the event of a spillage/leakage of biological, chemical or radiochemical materials or patient samples, including when containers are broken in a centrifuge.

v. The employing authority, through the laboratory head, is responsible for ensuring adequate protection of laboratory personnel to avoid occupational hazards. This includes the following:

- Use of vaccines, for example, against hepatitis B virus (HBV) infection.
- Use of post-exposure prophylaxis (PEP) against HIV infection & protocol for Hepatitis B & C, must be followed in case of needle-stick injury.
- Exclusion of highly susceptible individuals (e.g. pregnant women or immunocompromised individuals) from highly hazardous laboratory work.
- Provision of personal protective equipment (PPE).

To assess compliance, the surveyor will review SOP documentation for safe equipment and sample handling, verify staff vaccination records, and interview staff to ensure awareness of safety protocols.

Rating:

If SOPs for safe handling of equipment & samples are documented and accessible. Staff are vaccinated, aware of safety protocols, then rate as **"Met."**

If SOPs for safe handling of equipment & samples are not documented, then rate as **"Not Met."**

Standard 7: The laboratory has plans for fire and non-fire emergencies within the sections

Indicator 20: Emergency exit routes are clearly marked for fire and non-fire situations, and regular mock drills are conducted to ensure preparedness.

Assessment Process:

To comply with this indicator, clearly marked and illuminated emergency exit signs must be displayed at all times for both fire and non-fire emergencies. Mock drills must be conducted at least once a year and clearly documented to ensure staff preparedness. The surveyor will verify the presence of exit signage, physically inspect emergency exits, and assess staff awareness through interviews. Documented evidence of conducted drills and staff attendance will also be reviewed.

Rating:

If emergency exit points are clearly marked and illuminated, mock drills are regularly conducted with documentation, and staff is aware of evacuation procedures, rate as **"Met."**

If emergency exits are marked and illuminated but drills are not regularly documented and/or staff is not well aware of the evacuation procedures, rate as **"Partially Met."**

If emergency exits are not clearly marked and/or mock drills are not conducted or not documented, then rate as **"Not Met."**

Standard 8. HRM:

Staff deployment is in accordance with the scope of laboratory work

Indicator 21: Job descriptions for all posts are identified and documented.

Assessment Process:
To comply with this indicator, the laboratory must maintain a documented job description (JD) for every post. Each JD should clearly outline the tasks, functions, and responsibilities specific to that position. The JD must be signed by both the employer and the respective employee. During the assessment, the assessor will review personnel files to confirm the availability and completeness of signed JDs for all staff members.

Rating:
If all posts have documented JDs signed by both employer and employee, rate as, **"Met."**

If JDs are not developed or not signed, rate as, **"Not Met."**

Indicator 22: Documented eligibility criteria regarding qualification and experience are available for each job.

Assessment Process:
To comply with this indicator, the laboratory must have documented eligibility criteria specifying required qualifications and relevant experience for each post. The eligibility criteria shall be developed as per the criteria outlined in the PM&DC Ordinance 1962 (as amended from time to time), a medical graduate with qualifications registered by PM&DC is eligible to manage a laboratory in accordance with its category.
The summarized guidelines are as follows:

- Higher-level specialization such as FCPS/FRC(Pathology), PhD, or an equivalent qualification in pathology is required to head laboratories offering a broad range of diagnostic services.
- Mid-level specialization such as an MPhil in pathology is required for heading a Category-B laboratory.
- A diploma or equivalent qualification in clinical pathology is the minimum requirement for managing a Category-C laboratory.
- A qualified technologist must be designated to lead each specific laboratory section.

Rating:

If documented eligibility criteria for all posts are available and align with regulatory standards, rate as **"Met."**

If no eligibility criteria exist, rate as **"Not Met."**

Indicator 23: Recruitment is conducted according to established eligibility criteria.

Assessment Process:
To comply with this indicator, the laboratory must ensure that all staff are recruited based on documented eligibility criteria. Each employee's personal file must contain verified copies of qualifications and experience. The assessor will randomly select and review 5–10 personnel files (or all, if fewer than five employees) to ensure qualifications and experience meet the criteria for each role.

Rating:
If all reviewed employee files include valid documents that meet the eligibility criteria, rate as **"Met."**

If any reviewed file fails to meet the documented eligibility requirements, or records are missing, rate as **"Not Met."**

Standard 9. HRM-2: The staff members joining the laboratory are oriented to the laboratory environment, the laboratory sections and their individual jobs

Indicator 24: The laboratory shall maintain an appropriate orientation plan for newly inducted employees.

Assessment Process:
To comply with this indicator, the laboratory must maintain a written orientation plan and checklist covering key areas essential for newly inducted staff. The checklist should include the following components:

- General laboratory operations
- Safety and biosafety
- Quality assurance
- Ethics and confidentiality
- Working hours and staff conduct
- Relevant standard operating procedures (SOPs)
- Specific tasks or techniques assigned to the individual

The content of the orientation plan must be documented to ensure that standardized and consistent information is delivered to all new staff.

Rating:
If a written orientation plan and checklist is available covering all of the above areas, then score as **"Met."**

If the plan and checklist are available but cover at least 80% of the required areas, then score as **"Partially Met."**

If no orientation plan exists, or it covers less than 80% of the required areas, then score as **"Not Met."**

Indicator 25: Staff are made aware of laboratory-wide and section-specific procedures

Assessment Process:
To comply with this indicator, the laboratory must ensure that all staff receive orientation on both general laboratory procedures and those specific to their assigned section, unit, service, or programme. Documentation of these orientation sessions must be maintained. The assessor will verify compliance by reviewing orientation records and interviewing staff to assess their knowledge of the relevant procedures.

Rating:
If staff are aware of both general and section-specific procedures and orientation records are maintained, then score as **"Met."**

If orientation is not conducted or staff is unaware of procedures, then score as **"Not Met."**

Indicator 26: Each staff member is made aware of their rights and responsibilities

Assessment Process:
To comply with this indicator, the laboratory must provide each employee, at the time of induction, with a written job contract that clearly outlines their rights and responsibilities in accordance with applicable labor laws and institutional policies. The job contract must be duly signed by both the employer and the employee. The assessor will review personnel records to verify the presence of signed contracts and conduct staff interviews to confirm awareness of their rights and responsibilities.

Rating:
If each staff member has a duly signed written job contract outlining rights and responsibilities, and interviews confirm staff awareness, rate as **"Met."**

If any staff member does not have a signed job contract, or the staff is unaware of their rights and responsibilities, rate as, **"Not Met."**

Indicator 27: All employees are educated about patients' rights and responsibilities

Assessment Process:
To comply with this indicator, all staff must be educated about patients' rights and responsibilities as part of their general orientation. The assessor will verify this through documentation of orientation sessions and by interviewing staff to assess awareness.

Rating:
If documented evidence exists and staff are aware of patients' rights and responsibilities, then score as **"Met."**

If fewer than 80% of staff have been educated, then score as **"Partially Met."**

If there is no evidence that this education has been imparted, then score as **"Not Met."**

Standard 10. HRM-3: An appraisal system for evaluating the performance of employees exists as an integral part of the human resource management process

Indicator 28: Well-documented performance appraisal tools exist in the laboratory

Assessment process:

To comply with this indicator, the laboratory must maintain comprehensive, documented performance appraisal tools that assess actual performance targets. These tools should include evaluation of key areas such as:

- Technical competency
- Work efficiency
- Adherence to institutional policies and protocols
- Observance of safety and biosafety procedures
- Communication and interpersonal skills
- Responsiveness to clients/patients
- Punctuality and attendance
- Professional conduct and teamwork

The assessor will review the appraisal tools to verify that they are in place, formally structured, and designed to evaluate performance-based outcomes aligned with the laboratory's goals.

Rating:

If documented performance appraisal tools covering the above aspects are available, rate as, **"Met"**

If no such performance appraisal tools are available, rate as, **"Not Met."**

Indicator 29: All employees/consultants/students/voluntary workers are made aware of the performance appraisal tools at the time of induction

Assessment Process:

To comply with this indicator, the laboratory must ensure that all staff; including employees, consultants, students, and voluntary workers; are oriented on the performance appraisal system at the time of induction. This information should be part of the orientation program, and documented records (e.g., signed contract) confirming that the employee understood how they would be evaluated. must be maintained as evidence.

The assessor will review orientation records and conduct interviews with the staff to confirm their awareness of the performance appraisal system.

Rating:

If there is documented evidence of staff being oriented on appraisal tools and staff is aware of it, rate as, **"Met."**

If there is no documentation or staff is unaware of the appraisal system, rate as, **"Not Met."**

Indicator 30: Performance appraisals are used as a tool for employee development

Assessment Process:
To comply with this indicator, the laboratory must ensure that performance appraisal reports are maintained and used to identify gaps in individual performance. These identified gaps should lead to documented corrective actions, such as task-specific training or other relevant professional development interventions. The assessor will review appraisal records to verify that performance gaps and appropriate follow-up corrective actions have been documented and implemented.

Rating:

If there is documented evidence of gap identification, recommended actions for improvement, and follow-up actions taken, rate as, **"Met."**

If gap identification and recommendations are documented, but there is no evidence of follow-up actions, rate as, **"Partially Met."**

If the appraisal tool does not provide gap identification, rate as, **"Not Met."**

Indicator 31: Performance appraisals are conducted at predefined intervals and are documented

Assessment Process:
To comply with this indicator, the laboratory must have a well-documented schedule for employee appraisals, typically within the first 3–4 months for new staff and annually for others. The assessor will review a few employee files to confirm that appraisals were carried out as scheduled and documented accordingly.

Rating:
If a defined appraisal schedule exists and all reviewed employee files contain timely appraisals, rate as, **"Met."**

If the schedule exists but only about 80% of reviewed files contain timely appraisals, rate as, **"Partially Met."**

If no schedule exists or fewer than 80% of employees received timely appraisals, rate as, **"Not Met."**

Standard 11: Documented personal record for each staff member exists

Indicator 32: Personal files are maintained for all full-time and part-time employees

Assessment Process:
To comply with this indicator, the laboratory must maintain a personal file for each employee, whether full-time or part-time. These files should contain comprehensive documentation, including;

- Employment contracts.
- Qualifications (degrees/diplomas/transcripts).
- Laboratory personnel licenses (where required).
- Training and experience records.
- Continuing education records.
- Job descriptions.
- Date of employment.
- Disciplinary records.
- Performance evaluation reports.
- Health status information.

The assessor will randomly select 5–10 employee files to verify the presence of the required documentation.

Rating:
If all reviewed files contain the required documentation, rate as, **"Met."**

If any of the reviewed files lack the required documentation, rate as, **"Not Met."**

Standard 12: In-service staff capacity building record is documented

Indicator 33: The laboratory has a documented in-service training plan for all employees.

Assessment Process:
To comply with this indicator, the laboratory must maintain a documented in-service training plan that outlines structured training and capacity-building activities for all staff members. The plan should include defined training topics, schedules, targeted staff members, and relevant policies. The assessor will review the training plan and verify its implementation through staff training records.

Rating:
If the in-service training plan exists and all staff have received the planned training, rate as, **"Met."**

If the training plan exists and up to 80% of staff have received the planned training, rate as, "**Partially Met."**

If there is no training plan or less than 80% of staff have received the planned training, rate as, **"Not Met."**

Standard 13. HRM-6: There is a process for collecting, verifying and evaluating the credentials (education, registration, training and experience) of laboratory professionals, including doctors, technologists and others

Indicator 34: A system for verification of employee credentials and certificates exists in the laboratory.

Assessment Process:

To comply with this indicator, the laboratory must have a documented and implemented process for verifying:

- Initial credentials and certificates of all employees (e.g., educational qualifications, professional licenses, training certificates) at the time of hiring.
- Any newly added qualifications or training certificates submitted after initial hiring.

Verification must be conducted with the primary source – such as the university, the training organization or the professional councils., and supporting documentation should be retained in the employee's personnel file. The assessor will review the documented verification procedure. Check selected personnel files to confirm that both initial and newly added credentials/certificates have been appropriately verified and documented.

Rating:
If a comprehensive, documented process exists and verification records are available for both initial and newly added credentials/certificates, rate as, **"Met."**

If there is no documented process, or if verification records for initial or newly added credentials are missing, rate as, **"Not Met."**

Management of Equipment and Reagents

Standard 14: Ensure quality of equipment and reagents through standardized procurement procedures.
Indicator 35: The procurement procedure of the laboratory is laid down.

To comply with this indicator, the laboratory must have a procurement procedure manual that outlines the following sequence of steps.

i. **Need Assessment**: Procurement planning must begin with a thorough assessment of laboratory needs, based on the specific services provided at each level. This should include detailed specifications for all equipment, reagents, kits, and consumables intended for purchase.
ii. **Planning by Technical Groups**: National, provincial, and institutional technical groups should develop procurement plans aligned with identified needs.
iii. **Selection**: Equipment and reagents must be selected in compliance with the Drug Regulatory Authority of Pakistan Act 2012 and Medical Devices Rules 2017(as amended from time to time) framed under the Act.
iv. **Budgeting**: Procurement must align with available budgets, including costs for training and annual maintenance to ensure equipment sustainability.
v. **Documentation and Authorization:** Procurement orders must be clearly documented, properly dated, and signed by authorized personnel to ensure traceability and accountability.

Assessors will review the updated laboratory procurement procedure manual and confirm that the defined procurement steps are being followed in practice.

Rating:
If the laboratory has a documented procurement procedure manual outlining all required steps. The procedure is actively implemented, procurement orders are properly documented and records of procured items are maintained, rate as **"Met."**

If the laboratory lacks a documented procurement procedure manual and/or there is no evidence of consistent implementation and records of procured items are inadequately maintained, rate as **"Not Met."**

Indicator 36: Procured laboratory items are consistently documented in a stock register.

Assessment Process
To comply with this indicator, all procured items, including equipment, reagents, kits, and consumables, are consistently recorded in stock registers to ensure traceability, proper stock management, and prevention of shortages or misuse. The stock register should be updated regularly and include the following details for each item:

i. Name and signature of the person receiving the materials
ii. Date of receipt
iii. Expiration date
iv. Quantity of the material received
v. Minimum stock that should be on hand
vi. Current stock balance.

Assessors will review stock registers to verify that entries are up-to-date, appropriately maintained.

Rating:
If all procured items are documented with complete, regularly updated entries, then rate as, **"Met."**

If procured items are documented in a stock register, but the entries are incomplete or not up-to-date then rate as, **"Partially Met."**

If no procured items are not documented in a stock register, then rate as **"Not Met."**

Indicator 37: An accurate and up-to-date inventory of laboratory supplies is maintained.

Assessment Process:
To comply with this indicator,

i. An inventory recording template must be developed, reviewed, and approved by the laboratory supervisor.
ii. A designated staff member should be assigned responsibility for inventory control.
iii. Weekly physical counts must be conducted to verify stock levels and confirm system accuracy.
iv. The laboratory must maintain a documented inventory for all reagents and supplies.

Assessors will verify compliance through interviews with responsible staff and review of inventory documentation.

Rating:
If the laboratory maintains a documented inventory and a designated staff member is managing inventory, then rate as **"Met."**

If the laboratory does not maintain a documented inventory and lacks a responsible person for inventory control, then rate as **"Not Met"**

Standard 15: Safe handling and storage of laboratory reagents.

Indicator 38: Documented policies and procedures guide the safe storage and use of reagents.

Assessment process:
To comply with this indicator,

- Policies and standard operating procedures (SOPs) must be formally documented providing clear guidelines for the safe storage, distribution, and usage of all reagents.
- Documented SOPs for the segregation of reagents prior to storage must be developed in accordance with national and international guidelines.
- Storage areas should be kept well-ventilated and protected from direct sunlight.
- Controlled conditions for temperature, light, humidity, should be maintained in accordance with the manufacturer's instructions.
- Shelf life and stability data for all reagents and kits should be kept documented as per the manufacturer's specifications.
- Any reagent or chemical close to expiry date must be informed to laboratory manager.

In order to check compliance, the assessor will review documented SOPs, and conduct a physical inspection to assess cleanliness and verify temperature-controlled storage conditions.

Rating:
If policies and SOPs are documented with clear guidance on reagent storage and use; storage areas are clean, ventilated, and meet manufacturer-specified conditions, rate as **"Met."**

If documented policies and SOPs on reagent storage and use are absent and/or storage areas are disorganized or lack proper environmental controls, rate as **"Not Met."**

Indicator 39: Labeling of reagents is as per SOPs.

Assessment process:
Proper labeling of all chemicals, reagents, kits, and containers is essential to ensure safety and accurate testing. Labels must not be removed or defaced. Each label should clearly display the following information;

- Full name of chemical/reagent
- Concentration/strength

- Batch/lot number
- Date of receipt/opening
- Expiry date
- Opened by (initial/signature)
- Storage conditions (if applicable)
- Hazard/safety label (if applicable)

Rating:
If all issued reagent bottles are appropriately labeled, then score as **"Met."**

If any issued reagent bottle is not completely labeled, then score as **"Not Met."**

Standard 16: The laboratory has established comprehensive procedures for equipment management and maintenance

Indicator 40: Log books of all equipment are available

Assessment process
To comply with this indicator, laboratories must maintain a dedicated equipment logbook for each equipment, documenting all relevant operational and maintenance elements. This includes a schedule of preventive maintenance, calibration records, function checks, and any repairs or servicing performed by the manufacturer. In case of any malfunction, the nature of the problem, dates of removal and return (if sent for repair), the cause of malfunction, corrective actions taken, and any changes made to maintenance protocols as a result must be clearly documented in the logbook.
Assessors will review equipment logbooks to verify that entries are up-to-date, complete, and reflective of actual maintenance practices.

Rating:
If the laboratory maintains complete and up-to-date logbooks for each equipment, including records of any malfunctions and corresponding actions taken, rate as **"Met."**

If the laboratory does not maintain equipment logbooks or the logbooks lack essential entries such as maintenance, calibration, or malfunction records, rate as **"Not Met."**

Indicator 41: Calibration records for the all lab equipment is documented.

Assessment Process:
To comply with this indicator, laboratories must maintain documented calibration records for all relevant equipment. The manufacturer's guidelines must be followed during equipment calibration.
Calibration records must include:

- The date of calibration
- Calibration results
- Reference standards used
- Next due date for calibration
- Signature of the personnel who performed the calibration

Assessors will review documented calibration records to determine whether calibration practices are aligned with documented procedures and manufacturer recommendations.

Rating:
If the calibration records for all relevant equipment is maintained, complete and up-to-date, then rate as **"Met."**

If calibration records are not maintained, then rate as **"Not Met."**

Indicator 42: A documented and relevant log sheet is visibly placed on each equipment.

Assessment Process:
To comply with this indicator, log sheets of equipment requiring maintenance based on usage hours, must be maintained to monitor running time and ensure timely servicing. Log sheets should be visibly placed on each relevant equipment and updated after every use. These records must be preserved and systematically linked with corresponding equipment logbooks, in line with the laboratory's workload and internal policies. Assessors will physically inspect equipment to verify the presence, completeness, and accuracy of displayed log sheets.

Rating:
If all equipment has a displayed and updated log sheet, then rate as **"Met."**

If up to 80% of the equipment have a displayed and updated log sheet, then rate as **"Partially Met."**

If fewer than 80% of the equipment have a displayed and updated log sheet, then rate as **"Not Met.**

Indicator 43: Equipment inventory of each equipment is maintained.

Assessment Process:
To comply with this indicator, the equipment inventory log should have a record of:

- Instrument type, make, model and serial number.
- Purchasing date of equipment and status (new, used or reconditioned).
- Manufacturer's emergency contact number for breakdown management
- Calibration date(s)
- Documentation of spare part and maintenance contract.
- Warranty period.
- Inventory number indicating the year of acquisition.

Rating:
If the laboratory maintains a complete and up-to-date inventory log with all required details for each equipment, rate as **"Met."**

If the inventory log is not maintained for each equipment, rate as **"Not Met."**

Standard 17: The Laboratory has a complete accurate laboratory record for every patient.

Indicator 44: The laboratory has an established policy for maintaining electronic records of every patient

Assessment Process:
To comply with this indicator, laboratories must develop and implement written policies and procedures for the maintenance of electronic records of patients. The policy must address the following elements;

i. Confidentiality and access control.
ii. Record retention period.
iii. Data retrieval.
iv. Disaster recovery and backup.

Assessors will review the laboratory's documented policy and confirm implementation through staff interviews and supporting documentation.

Rating:
If the laboratory has a documented policy and the staff is well aware of it, then rate as **"Met."**

If the laboratory does not have a documented policy, then rate as **"Not Met."**

Indicator 45: Every patient must be assigned a unique identification number.

Assessment Process:
A unique patient identifier is an essential element for handling information in a laboratory. This is important as any duplication of a unique identification code can lead to major errors. To comply with this indicator, the laboratory must assign unique identifier to each patient, which can be auto-generated patient registration or record number, CNIC number or mobile number.
To assess compliance with this indicator, patient records should be reviewed to confirm that each patient is consistently assigned a unique identifier across all laboratory documents, including request forms, reports, and logs.

Rating:
If the laboratory has assigned unique identification number to each patient, rate as **"Met."**

If the laboratory does not assign unique identifier to each patient, rate as **"Not Met."**

Indicator 46: The record provides an up-to-date and chronological account of each patient's record of tests.

Assessment Process

To comply with this indicator, the laboratory must maintain each patient's record of tests in chronological order. To assess compliance, a random review of 15–20 patient records will be conducted to verify that complete test results are documented and that all records are maintained in chronological order.

Rating

If the laboratory record shows chronological order of each patient's tests done in the laboratory, then score as **"Met."**

If the laboratory record does not show chronological order of each patient's tests done in the laboratory, then score as **"Not Met."**

Indicator 47: Only authorized personnel shall make entries in laboratory records, and results shall be reviewed by authorized person before they are released.

Assessment Process:

Only authorized personnel can make entries into patients' laboratory records. Results shall be reviewed and authorized prior to release.
Assessors will review documented evidence listing the authorized personnel permitted to make entries into laboratory records and reviewing the records.

Rating:

If laboratory record entries and results are reviewed by authorized personnel, rate as **"Met."**

If there is any entry made by an unauthorized person, then rate as **"Not Met."**

Indicator 48: Each entry of patient results is dated, timed, and identifies the person making the entry.

Assessment Process:

To comply with this indicator, the test results must be reported on forms approved by laboratory management under the quality system and must include:

- Patient identification
- Date and time of specimen collection
- Test performed
- Reference or normal range
- Laboratory interpretation, where applicable.
- Name or initial of person performing the test
- Authorized signature of person reviewing the report and releasing the results

To assess compliance, a random review of patient records will be conducted to verify that test reports are complete and include all the required elements listed above.

Rating:

If all test reports are complete and include above mentioned elements, then rate as **"Met."**

If the test reports do not comply with the above mentioned elements, then rate as **"Not Met."**

Standard 18: A comprehensive reporting system exists in the laboratory

Indicator 49: A computerized laboratory information system is available.

Assessment Process:
To comply with this indicator, the clinical laboratory must have a computerized Laboratory Information System (LIS) in place to manage the flow of data related to individual patient. The system must be used for the following minimum functions:

- Patient registration
- Sample collection entry (e.g., blood, urine, etc.)
- Test reporting (computer-generated reports)
- All reports must bear digital or manual signatures, or clearly mention the name of the authenticating pathologist or authorized person
- Tracking of patient history (access to past reports or test data)

The assessor will review **10–20 patient reports** generated in the last **12 months** to verify that they are **computerized/system-generated** and comply with the **minimum functional requirements**

Rating:
If the laboratory has a computerized LIS in place with all required minimum functions, rate as **"Met."**

If the laboratory does not have a computerized LIS in place, rate as, **"Not Met."**

Indicator 50: Procedure for result reporting shall be clearly defined.

Assessment Process:
To comply with this indicator, the laboratory must have a documented procedure for result reporting. This procedure must ensure that results are legible and free from transcription errors, and that reports clearly indicate if a sample was unacceptable for testing. Responsibilities and procedures for the release of examination results, including by whom and to whom results are reported, must be clearly defined. The assessor will verify the presence of a procedure manual that outlines the entire process for result reporting, ensuring it includes all specified elements.
Rating:
If the laboratory has a procedure manual for reporting of results, rate as, "Met."

If the laboratory has not procedure manual in place, rate as, "Not Met."

Indicator 51: Critical results are reported to the treating physician.

Assessment Process:
To comply with this indicator, an SOP must be developed and implemented to inform lab results which are as per established critical values immediately, to the treating

physician or other authorized person and documented by the concerned lab technician in the lab record,. Documentation should include the date and time of notification, the responsible person, the individual notified, the results conveyed, verification of accurate communication, and any difficulties encountered during the process. To assess compliance, the assessor will check records of critical results submitted to the relevant persons/authorities and verify that proper documentation of reporting has been maintained.

Rating:
If records of critical results are submitted to the relevant persons/authorities and proper documentation of reporting is maintained, rate as, **"Met."**

Indicator 52: Timely reporting of notifiable diseases to concerned authority

Assessment Process:
To comply with this indicator, the laboratory must have documented standard operating procedures (SOPs) for timely reporting of the notifiable diseases to the relevant persons or authorities, as applicable. The assessor will review the documented SOPs and check the submission of reports of notifiable diseases to relevant persons/authorities to ensure compliance.

Rating:
If the laboratory has documented standard operating procedures (SOPs) for timely reporting of the notifiable diseases to the relevant persons or authorities, rate as, **"Met."**

If no documented (SOPs) are in place for timely reporting of the notifiable diseases to the relevant persons or authorities, rate as, **"Not Met."**

Standard 19: The laboratory record supports continuity of patient care.

Indicator 53: Minimum reporting time for every test is documented.

Assessment Process:
To comply with this indicator, the minimum reporting time for each test must be documented and clearly mentioned on the receipt provided to patients/clients, ensuring they are informed about when their reports will be available. The assessor will verify the documented minimum reporting times for all tests and review records from the past week to confirm that actual reporting time aligns with the specified minimum reporting times.

Rating:
If computerized reports are electronically or otherwise accessible after the minimum reporting time, then score as "**Met."**

If there is no access to reports electronically or otherwise after the minimum reporting time, then score as "**Not Met."**

Indicator 54: Reports are accessible to individual patients through a specific code.

Assessment Process:
To comply with this indicator, the laboratory must ensure that patients can access their test records electronically using a specific code provided on the receipt, if such access is requested. The assessor will review receipt copies to verify the presence of the code.

Rating:
If computerized reports are electronically accessible through the given code number, then score as "**Met.**"

If no access to reports through codes electronically is available, then score as "**Not Met.**"

Standard 20: The laboratory has a comprehensive and documented quality assurance (QA) program.

Indicator 55: The laboratory has a documented Quality Manual

Assessment Process:
To comply with this indicator, the laboratory must maintain a comprehensive Quality Manual that is documented and reflects current practices. The manual must include an index and an amendment page, which should be updated whenever changes are made. The Quality Manual should be organized into major sections, covering at a minimum:

- Main functions and responsibilities of the laboratory
- Personnel files including employment policies, job descriptions, staff education, and continuing professional development (CPD)
- Inventory of instruments and records of repair and preventive maintenance
- Written procedures for calibration and functioning of instruments, reagents, and analytical systems
- Written safety policies and instructions
- Sampling and transport procedures
- Management of samples and biological material
- Quality assurance systems including Internal Quality Control (IQC) and participation in External Quality Assessment Schemes (EQAS)
- Policies and procedures for document management
- Policies and procedures on customer service and continuous improvement

Assessors will review the documented Quality Manual to ensure it covers all major required sections and will verify that it is regularly updated.

Rating:
If a comprehensive Quality Manual is available, updated, covers all required sections, rate as, **"Met."**

If a Quality Manual exists but is missing key sections or is not updated, rate as, **"Partially Met."**

If no Quality Manual is available, rate as, **"Not Met."**

Indicator 56: The laboratory staff implements the policies and procedures outlined in the Quality Manual.

Assessment Process:

To comply with this indicator, staff must be aware of the policies and procedures documented in the Quality Manual and demonstrate their implementation in daily operations. Roles and responsibilities for quality assurance activities must be clearly assigned and documented. Assessors will interview selected staff members to evaluate staff awareness of relevant policies and procedures & to ensure that the quality assurance activities are implemented effectively, supporting safety and operational efficiency.

Rating:

If the staff is aware of the relevant policies and procedures, rate as, **"Met"**

If the staff is unaware of the policies and procedures, rate as, **"Not Met."**

Standard 21: External quality assurance (EQA) compliance procedure and tools are available in the laboratory.

Indicator 57: External Quality Assurance (EQA) of the laboratory is ensured through assessment by nationally or internationally recognized bodies.

Assessment Process:

To comply with this indicator, the laboratory must participate in an External Quality Assurance (EQA) program conducted by a recognized institute/body. Evidence of such participation must be available in the form of an EQA certificate issued within the last one year. To assess compliance assessors will review documentation to verify the availability and validity of an EQA certificate issued during the last 12 months.

Rating:

If the laboratory provides a valid EQA certificate from any recognized institute/body issued within the last one year, rate as, **"Met."**

If no valid EQA certificate is available from the past one year, rate as, **"Not Met."**

Indicator 58: Records of external quality assurance (EQA) reports are maintained.

Assessment Process:

To comply with this indicator, the laboratory must maintain a record of EQA reports received from a recognized institute/body.
To assess compliance assessor will review documented records of EQA reports.

Rating:

Fully Met: Records of EQA reports received from a recognized institute/body are maintained, are available for review, and cover the required/relevant testing activities of the laboratory.
Not Met: EQA reports are not maintained, are not available for review, or the laboratory does not have evidence of participation in an appropriate external quality assurance program.

Standard 22: Internal quality assurance (IQA) is ensured through standardized laboratory practices.

Indicator 59: Policies and procedures guide the safe collection of specimens.

Assessment Process:

To comply with this indicator, the laboratory must have policies and procedures manual with documented SOPs to ensure safe, accurate and clinically appropriate sample collection and pre-examination storage. The SOPs are as follow:

a. Verification of the identity & preparation of the patient from whom primary sample is collected (e.g. instructions to caregivers, sample collectors and patients);

b. Instructions to patients including their fasting state and collection of timed samples;

c. Type of sample container to be used for various laboratory tests, volume of sample required; any special/necessary additives including anticoagulants;

d. Recording of the identity of the person collecting the primary sample and the collection date, and, when relevant, recording of the collection time;

e. Requirements for separating or dividing the primary sample when necessary;

f. Stabilization and proper storage conditions before collected samples are delivered to the laboratory;

g. Labelling of primary samples in a manner that provides an unequivocal link with the patients from whom they are collected;

h. Safe disposal of materials used in the collection process.

i. Provision of clinical information relevant to, or affecting sample collection, examination performance or result interpretation (e.g. history of administration of drugs);

j. The laboratory's criteria for acceptance and rejection of samples specific to the examinations requested.

To verify compliance assessors will review the laboratory policy and procedure manual to verify that it covers the SOPs for safe sample collection, with sufficient details to ensure that the integrity of the sample is not compromised. They will also conduct staff interviews to confirm proper implementation of these SOPs.

Rating:

If the SOPs for safe collection of specimens are available and being implemented, then score as fully met.

If the SOPs for safe collection of specimens are not being implemented, then score as not met.

Indicator 60: Policies and procedures guide the identification and proper labeling of specimens.

Assessment Process:
To comply with this indicator, the laboratory must have a policy and procedure manual with documented SOPs for identification and labelling of specimens. Each sample should be clearly labelled with:

a. The patient's full name
b. A unique identification number—a number assigned by the laboratory;
c. The test that has been requested;
d. The time and date of collection;
e. The initials of the person collecting the sample.

To verify compliance, assessors will review the laboratory's policy and procedure manual to confirm the presence of SOPs on specimen identification and labeling. Additionally, they will verify implementation by reviewing recent specimen records and observing the identification and labeling process to ensure patient safety practices are followed.

Rating:
If the SOPs for specimen identification are available and being implemented, then score as fully met.

If the SOPs for sample identification and proper labeling are not being implemented, then score as not met.

Indicator 61: Policies and procedures guide the safe handling of specimens.

Assessment Process:
To comply with this indicator, the laboratory must have developed and implemented SOPs addressing the safe handling of patient samples, biological materials, chemicals, and referred specimens. These SOPs must include, at a minimum:

- Safe handling of incompatible chemicals and measures to minimize environmental release.
- Handling of patient samples and use of appropriate personal protective equipment (PPE)
- Special handling requirements for samples (e.g., refrigeration, light protection, urgent delivery)
- Safe handling and transport of referred samples

Assessors will verify the availability of these SOPs at relevant workstations, confirm that they are accessible to staff, and assess staff awareness and implementation through interviews and observation.

Rating:
Required SOPs for the safe handling of specimens are available, accessible to relevant staff, and are being implemented in practice, then score as met.

Required SOPs are not available, are not accessible to relevant staff, or the prescribed safe specimen-handling procedures are not being implemented, then score as not met.

Indicator 62: Policies and procedures guide the safe transportation of specimens.

Assessment Process:

To comply with this indicator, the laboratory must maintain documented SOPs for the transportation of specimens, covering procedures that ensure sample integrity, personnel safety, and timely delivery. These SOPs must include guidance on:

- Training of personnel responsible for specimen transport.
- Specific temperature requirements (e.g., room temperature, refrigerated 2–8ºC, or frozen)
- Sample preservation methods, if applicable.
- Photosensitivity precautions.
- Maintenance of sample integrity and stability during transit.
- Special packaging protocols for shipments, where required.
- Defined timelines for sample delivery.
- Safety of the personnel handling the sample.

Assessors will review the laboratory's policy and procedure manual to verify that these SOPs are documented and implemented. Staff involved in sample transportation may be interviewed to assess awareness and adherence to the procedures.

Rating:

- **Fully Met:** Required SOPs for the safe transportation of specimens are available and implemented, and evidence demonstrates that specimens are transported safely while maintaining their integrity and required conditions.
- **Not Met:** Required SOPs are not available or are not being implemented, or specimen transportation practices do not adequately ensure specimen integrity, personnel safety, or timely delivery.

Indicator 63: Policies and procedures guide the safe disposal of specimens.

Assessment Process:

To comply with this indicator, the laboratory must have documented Standard Operating Procedures (SOPs) for the safe disposal of specimens and general laboratory waste, as part of its policy and procedure manual. These SOPs must align with the Hospital Waste Management Rules, 2018, as amended from time to time, based on the EPA Act.

Assessors will review the laboratory's policy and procedure manual to verify that SOPs for waste disposal are in place & align with regulatory requirements.

Rating:

- **Fully Met:** Required SOPs for the safe disposal of specimens and laboratory waste are available, comply with applicable regulatory requirements, and are being implemented in practice.

- **Not Met:** Required SOPs are not available, do not comply with applicable regulatory requirements, or safe specimen and laboratory waste disposal procedures are not being implemented.

Indicator 64: Availability and use of controls for Internal Quality Assurance (IQA) is ensured.

Assessment Process:

To comply with this indicator, the laboratory must ensure that appropriate control materials are available and routinely used as part of its Internal Quality Assurance (IQA) procedures. These controls must be incorporated into testing processes to validate the performance of test kits, procedures, and equipment.

The assessor will verify the availability of controls for relevant laboratory tests and review documented evidence confirming their use in accordance with manufacturer or technical instructions.

Rating:

If there is availability of controls that are used properly in tests, then score as, "Met."

If there are no controls being used in tests, then score as "Not Met."

Indicator 65: Process cycle records for each equipment are maintained.

Assessment Process:

To comply with this indicator, the laboratory must maintain complete and accurate process cycle records for all relevant equipment. These records must include the following

i. Date of the process.
ii. Start and end times of process.
iii. Sample identification.
iv. Total number of samples processed.
v. Signature of the authorized personnel operating the equipment.

Assessors will review a sample of process cycle records to ensure they are properly maintained and meet the specified documentation requirements.

Rating:

If process cycle records are available and contain all required information, rate as "Met."

If no process cycle records are available, rate as "Not Met."

Standard 23: Continuous laboratory improvement is documented.

Indicator 66: Quality assurance (QA) reports are reviewed to identify gaps and used for improvement.

Assessment Process:

To comply with this indicator, the laboratory must regularly review Internal Quality Assurance (IQA) and External Quality Assurance (EQA) reports to identify gaps in procedures and processes. Identified gaps should be documented and utilized for continuous quality improvement within the laboratory.

Note: If QA reports are satisfactory and no gaps are identified, mark this indicator as **Not Applicable**.

Rating:

If gaps are identified in QA reports and documented evidence shows these have been used for improvement, rate as, **"Met"**

If gaps are identified but there is no evidence of corrective or improvement measures taken, rate as, **"Not Met"**

Indicator 67: Corrective Actions Are Implemented Upon Identification of Gaps

Assessment Process:

To comply with this indicator, the laboratory must demonstrate that corrective actions are taken in response to gaps identified through Internal Quality Assessment (IQA) and External Quality Assessment (EQA) reports. These corrective actions should be clearly documented and implemented in a timely manner to address the deficiencies.

Rating:

If corrective actions are clearly suggested in QA reports and documented evidence confirms they have been implemented.

If corrective actions are not suggested or there is no evidence of their implementation.

Indicator 68: Measures Are Taken to Minimize Recurrence of Errors

Assessment Process:

To comply with this indicator, the laboratory must implement and document measures aimed at preventing the recurrence of previously identified errors. These may include updates to standard operating procedures, staff retraining, or process modifications based on root cause analysis.

Rating:

If there is clear documentation of measures taken to minimize recurrence of errors.

If no documented preventive measures have been taken following error identification.

Standard 24: The laboratory has a comprehensive and coordinated biosafety program

Indicator 69: Availability of laboratory biosafety SOPs covering all essential activities necessary for infection control and safety.

Assessment process:

To comply with this indicator, the laboratory must maintain documented biosafety SOPs that are readily available and up to date. These SOPs should comprehensively address the following areas: safe handling of specimens, isolation procedures, proper sample storage, hand hygiene practices, disposal of specimens and hazardous waste, chemical and radiation safety, correct use of personal protective equipment (PPE), and emergency response protocols. The assessor will review the SOPs to verify that they are up to date and include all the required elements.

Rating:

If written SOPs covering all required elements are available and up to date, then score as **"Met."**

If there are no written SOPs, then score as, **"Not Met."**

Indicator 70: The laboratory shall ensure the availability of required disinfectants and spill kits.

Assessment Process:

To comply with this indicator, the laboratory must maintain stock and usage records for standard disinfectants and spill kits. To comply with this indicator, the laboratory must maintain stock and usage records for standard disinfectants and spill kits. The assessor will review stock registers to confirm availability and review records to ensure regular use of the same.

Rating:

If disinfectants and spill kits are available in the laboratory and there is documented evidence of their regular use, then score as **"Met."**

If disinfectants and spill kits are not available, then score as **"Not Met."**

Indicator 71. Biosafety SOPs are communicated to the laboratory employees

Assessment Process:

To comply with this indicator, the laboratory must maintain training records of relevant staff to ensure they are aware of the biosafety SOPs and that these procedures are correctly followed in daily operations. The assessor will review the training records and interview staff to verify their awareness of the biosafety SOPs and confirm that the procedures are being implemented.

Rating:

If training records are maintained, the staff are aware of and implement these SOPs, then rate as **"Met."**

If the training record are not maintained, or the staff is not aware of the SOPs, rate as, **"Not Met."**

Indicator 72: The laboratory has appointed a qualified biosafety officer for ensuring biosafety activities.

Assessment process:

To comply with this indicator a biosafety officer with sufficient training and experience should be appointed to provide guidance to relevant staff on biological

safety issues and to ensure that biosafety SOPs are being properly followed. To assess compliance, the assessor will review documentation to confirm the appointment of biosafety officer and will interview the officer to verify their awareness of biosafety processes and job responsibilities.

Rating:

If the laboratory management has appointed a biosafety officer, who is aware about the biosafety processes and their job responsibilities, rate as **"Met."**

If the laboratory management has not appointed a Biosafety Officer, then rate as **"Not Met."**

Indicator 73: Regular biosafety monitoring reports are generated in the laboratory

Assessment Process:

To comply with this indicator, the designated biosafety officer must generate monthly biosafety monitoring reports. These reports should be documented and regularly submitted to the laboratory head. The assessor will review the available reports to verify their preparation and submission on a monthly basis.

Rating:

If monthly biosafety monitoring reports are available and regularly submitted to the laboratory head, then score as **"Met."**
If there are no biosafety monitoring reports available, then score as **"Not Met."**

Standard 25 Continuous staff biosafety measures are ensured and documented

Indicator 74: The laboratory has appropriate consumables, equipment and facilities to ensure biosafety

Assessment Process:

To comply with this indicator, the safety officer shall be responsible for ensuring the availability and adequacy of equipment and supplies necessary for maintaining biosafety. This includes personal protective equipment (PPE), appropriate storage and cabinets for flammable and toxic chemicals, eye washers, emergency showers, waste disposal supplies and equipment, & first aid equipment. The assessor will verify the presence of these items through physical inspection and review stock registers to confirm the availability of all required items.

Rating:

If all required biosafety equipment and supplies are present, functional, and properly recorded in stock registers, then score as **"Met."**

If the required equipment and supplies are not available or not recorded, then score as **"Not Met."**

Indicator 75: All staff involved in the handling and disposal of laboratory waste shall receive regular vaccination provided by HCE.

Assessment Process:

To comply with this indicator, the laboratory must maintain vaccination records for all staff at risk of exposure to biohazardous materials. This includes ensuring that complete doses of recommended vaccines, such as hepatitis B, have been administered. The assessor will review vaccination records to confirm that all at-risk staff have received appropriate and complete doses of vaccinations.

Rating:

If there is documented evidence that all at-risk staff have received appropriate vaccinations with complete doses, then score as **"Met."**

If vaccination records are absent or staff have not received the full course of required vaccinations, then score as **"Not Met."**

Indicator 76: Documented evidence of annual medical check-ups for all staff involved in handling biohazardous materials.

Assessment Process:

To comply with this indicator, the laboratory must maintain records of annual medical check-ups for all staff who handle biohazardous materials. The assessor will review these records to verify that the annual check-ups of the relevant staff are conducted regularly on annual basis.

Rating:

If there is documented evidence that all staff involved in handling biohazardous materials have undergone annual medical check-ups, then score as **"Met."**

If there is no documented evidence of annual medical check-ups for the relevant staff, then score as **"Not Met."**

Indicator 77: HCPs shall periodically assess staff for communicable diseases and maintain the record in the staff file, including Hepatitis B, C, HIV, TB, and recommended immunizations (Hep B, Influenza, etc.).

Assessment Process:

The assessment team shall verify that the HCP has established procedures for periodic health screening of staff for communicable diseases and for maintaining recommended immunizations. On-site review of staff files will be conducted to confirm documentation of assessments, test results, and immunization status.

The team shall assess whether screenings and immunizations are performed according to national guidelines and schedules, and whether follow-up actions are taken for any identified health concerns. Staff interviews may be conducted to confirm awareness and participation in health monitoring programs.

Rating:

- **Met:** Periodic assessments for communicable diseases and recommended immunizations are conducted for all staff, and documented in staff files as per national guidelines.
- **Not Met:** Assessments or immunizations are not conducted, incomplete, or not documented, posing a risk to staff and patient health.

Standard 26: There is a documented procedure of bio risk management:

Indicator 78: All incident reports are documented

Assessment Process:
To comply with this indicator, the laboratory must maintain a record of all incident reports and ensure they are submitted to the designated authority. Each report should include a description of the event, contributing factors, and action(s) taken in response. The assessor will review the incident report records and verify that they have been appropriately reported to the designated authority.

Rating:
If incident reports are documented with all required details and reported to the designated authority, then score as **"Met."**

If incident reports are not documented, then score as **"Not Met."**

Standard 27. The laboratory has a well-designed, comprehensive and coordinated waste management plan.

Indicator 79: Written laboratory waste management SOPs are available

Assessment Process:
To comply with this indicator, the laboratory shall develop and implement waste management SOPs including proper collection, handling, segregation, labelling, and disposal of waste.

Rating:
If laboratory waste management SOPs are available, then rate as **"Met."**

If the laboratory waste management SOPs are not available, then rate as **"Not Met."**

Indicator 80: Waste management SOPs are communicated to the laboratory employees

Assessment Process:
To comply with this indicator, the laboratory must ensure that staff are trained on the waste management SOPs and implement them in daily operations. Copies of the SOPs should be provided to all relevant staff, and training records shall be maintained. The assessor will review these records and interview staff to verify their awareness and understanding of the waste management SOPs.

Rating:
If training records are maintained and staff are aware of and implement the waste management SOPs, then score as **"Met."**

If training records are not maintained or staff are not aware of the SOPs, then score as **"Not Met."**

Standard 28: Measures to ensure biosecurity in the laboratory are practiced

Indicator 81: Access to the sample storage area shall be restricted to authorized personnel only.

Assessment Process:

To comply with this indicator, the laboratory must ensure that only authorized staff have access to the sample storage area. Authorized individuals should be clearly identifiable by their ID cards. The assessor will verify this by reviewing documentation of access permissions and observing whether only authorized personnel with proper identification are allowed entry.

Rating:

If access to the sample storage area is restricted to authorized personnel identifiable through ID cards, then score as **"Met."**

If unrestricted access is observed or no evidence of access control is available, then score as **"Not Met."**

Indicator 82: All sample transportation activities shall be properly recorded.

Assessment Process:

To comply with this indicator, the laboratory must maintain a log/record of any sample transported to other laboratories. This record should include necessary details such as date, the receiving laboratory, and nature of the samples. The assessor will review the sample transportation records to verify compliance.

Rating:

If a transportation log/record is available and maintained, then score as **"Met."**

If no record/log for sample transportation is available, then score as **"Not Met."**

Standard 29: Continuous staff biosafety measures are ensured and documented

Indicator 83: The laboratory shall have appropriate consumables, collection and handling systems, and equipment for effective waste management.

Assessment Process:

To comply with this indicator, the laboratory management shall ensure the availability of sufficient and appropriate consumables, collection and handling systems, and equipment for waste management. This includes:

- Color-coded waste collection bins
- Color-coded bags for waste segregation
- Color-coded waste trolleys
- Designated storage area for hazardous waste

- An effective waste disposal mechanism

The assessor will physically inspect various areas of the laboratory to verify the availability of the above requirements.

Rating:
If all the above resources are available and adequate, then rate as **"Met."**

If any of the required items or systems are missing, then rate as **"Not Met."**

Indicator 84: Contracts with waste disposal service organizations are available

Assessment Process:
To comply with this indicator, the laboratory must have a written contract/MoU with a certified waste disposal agency/company for the final disposal of hazardous waste, unless the laboratory has the infrastructure and facility to dispose of the waste onsite. The assessor will review documentation to verify the existence of a current contract, or physically inspect the facility to verify the presence of a functioning onsite waste disposal mechanism.

Rating:
If a valid contract with a waste disposal service is available, or there is evidence of proper onsite disposal by the laboratory, then score as **"Met."**

If there is no such contract or onsite disposal arrangement, then score as **"Not Met."**

Indicator 85: Waste transported from collection centers for final disposal shall be properly documented.

Assessment Process:
To comply with this indicator, the laboratory must maintain a detailed record of hazardous waste transported from collection centers to the final disposal site. This record should include the date, time, and weight of each consignment. The assessor will review the transportation records to verify compliance.

Rating:
If a complete record of waste transportation from collection centers is available, then score as **"Met."**

If no record of waste transportation is maintained, then score as **"Not Met."**

Access to Care:

Standard 30: Laboratory services are provided as portrayed/claimed.

Indicator 86: The laboratory shall prepare a brochure listing the diagnostic services provided, as per the scope of services

Assessment Process:
To comply with this indicator, the laboratory shall have a brochure that clearly outlines the scope of diagnostic services offered, including the types of tests performed across departments such as biochemistry, microbiology, histopathology,

and hematology. This brochure must be made accessible to patients and visitors. The assessor will verify compliance by reviewing the brochure to confirm that the list of services is clearly mentioned and available.

Rating:

If the laboratory has a brochure listing the diagnostic services provided, as per the scope of services, rate as, "Met"

If no brochure is available, rate as, "Not Met."

Standard 31: A comprehensive audit system for laboratory performance assessment exists in the laboratory

Indicator 87: The laboratory shall have a system to monitor and measure its performance biannually.

Assessment Process:

To comply with this indicator, the laboratory must maintain documentation, such as minutes of senior management meetings, demonstrating that the laboratory's performance is reviewed at least twice a year using objective measures and indicators. The assessor will review these documents to verify compliance.

Rating:

If there is documented evidence of biannual monitoring and measurement of laboratory performance, then score as **"Met."**

If there is no such documentation available, then score as **"Not Met."**

Indicator 88: Procured kits and their consumption are compared with tests performed during laboratory performance audit

Assessment Process:

To comply with this indicator, the laboratory must maintain proper documentation of all diagnostic kits procured and conduct regular audits comparing the number of tests that should be performed based on kit capacity with the actual number of tests conducted. During the assessment, the assessor will review stock registers, procurement records, and test logs to verify that the kits received and consumed are in alignment with the stated capacity of diagnostic tests performed. The assessor will also check whether any identified discrepancies have been followed up with appropriate documented corrective actions.

Rating:

If the laboratory maintains documentation of kits procured and the number of tests conducted is comparable with the expected capacity, rate as **"Met."**

If there is a disparity between the kits procured and the number of tests conducted, and no supporting documentation is available, rate as **"Not Met."**

Standard 32: A system exists for obtaining consent when it is required

Indicator 89: The laboratory has listed situations where informed consent is required

Assessment Process:

To comply with this indicator, the laboratory must have a written policy or documented list identifying situations where informed consent is required from patients. During the assessment, the assessor will review the policy or documented list of situations requiring consent and examine laboratory records of patients for whom informed consent is applicable according to the laboratory's policy.

Rating:

If all relevant records document informed consent in accordance with the laboratory's policy, rate as "Met."
If any relevant record lacks the required informed consent documentation, rate as "Not Met."

Indicator 90: The policy describes who can give consent when a patient is incapable of independent decision-making

Assessment Process:

To comply with this indicator, the laboratory must have a written policy that clearly defines who is authorized to provide informed consent on behalf of a patient who is incapable of making decisions independently. The assessor will review this policy to verify that it includes specific guidance on who may provide consent in such situations.

Rating:

If there is a policy describing who, other than the patient, may give informed consent when the patient is incapable of decision-making, rate as "Met."

If there is no such policy available, rate as "Not Met."

Standard 33: Patients and families have a right to information on expected costs for the services provided.

Indicator 91: The Laboratory develops a pamphlet, lists the services provided, their costs, the kinds of samples/specimen needed, and the estimated time needed to report for testing and it is readily available.

Assessment Process:

In order to comply with this indicator, a pamphlet (outlining the services offered by the laboratory) must be available to patients, either in print or digitally, outlining the services offered by the laboratory. This pamphlet should include a comprehensive list of tests and services, the types of specimens required for each, the prices for the tests, and the approximate reporting time for results. The information should be clear, accurate, and easy to understand to help patients make informed decisions. The hospital must regularly update the pamphlet to reflect any changes in services, pricing, or procedures, and ensure that it is easily accessible to patients either in the hospital or through online platforms. Review of pamphlets shall be conducted to assess whether the pamphlet clearly outlines all the required information.

Rating:

Fully Met: A current pamphlet, available in print or digital form, clearly provides the laboratory's services, applicable test costs, required specimen/sample types, and estimated reporting times, and is readily accessible to patients.

Not Met: The required pamphlet is not available, or it does not contain the required information, is not readily accessible to patients, or the information provided is not current or accurate.

Indicator 92: The Laboratory display detailed information at main entrance, including provision of services and its price respectively.

Assessment Process:

In order to comply with this indicator, the laboratory shall ensure that prices of all healthcare services including commonly undertaken procedures as well as other procedures and consultation by any of its personnel shall be made accessible to the public at large, by displaying the same at the main entrance and such other places as notified by the Authority.

Rating:

Fully Met: Detailed information regarding laboratory services and their applicable prices is clearly displayed at the main entrance and/or other locations notified by the Authority and is readily accessible to patients and the public.

Not Met: Required information regarding laboratory services and prices is not displayed at the main entrance or designated locations, or the displayed information is incomplete, unclear, inaccessible, or not current.

Indicator 93: Patients/families are informed about additional reports generated from the same sample at no extra cost

Assessment Process:

To comply with this indicator, the laboratory must have a defined process to inform patients or their families about additional test reports that may be generated using the same sample without incurring additional charges. This information should be provided as part of a cost-effective package and must be communicated by a knowledgeable and authorized individual, such as a qualified laboratory technician or a doctor/pathologist. During the assessment, the assessor will review how this information is conveyed, verify the presence of a documented process, and confirm that communication is carried out by appropriately trained personnel.

Rating:

If there is a process in place to inform patients or their families about additional reports included at no extra cost, and the information is provided by a qualified and authorized person, rate as "Met."

If there is no process in place rate as Not Met.

Standard 34: Patient Rights for Appeals, Complaints, and Confidentiality

Indicator 94: Patient complaints are accepted by the laboratory and properly registered

Assessment Process:

To comply with this indicator, the laboratory must maintain a complaint register or record and ensure that a complaint box is affixed in the patient waiting area. During the assessment, the assessor will verify the presence of the complaint box and review the complaint register to determine whether patient complaints are being properly recorded and maintained.

Rating:

If a complaint box is affixed in the patient waiting area and the complaint register is properly maintained, rate as **"Met."**
If the complaint box is not present and/or the complaint register is not maintained, rate as **"Not Met."**

Indicator 95: Proper actions and remedial measures are taken in response to patient complaints

Assessment Process:

To comply with this indicator, the laboratory must document the actions and remedial measures taken in response to patient complaints. The assessor will review complaint records to verify whether appropriate actions have been taken and documented in response to each complaint received.

Rating:

If actions in response to patient complaints are appropriate and properly documented, rate as **"Met."**
If there is no record of action taken in response to patient complaints, rate as **"Not Met."**

Indicator 96: Confidentiality of patient is maintained.

Assessment Process:

To comply with this indicator, the laboratory must ensure that patient records—whether electronic or paper-based—are protected through secure systems along with regular Staff training on data privacy and confidentiality practices. During the assessment, the assessor will review the laboratory's record management system, and review documented evidence of staff training on confidentiality protocols.

Rating:

If patient records are protected through secure systems and documented evidence of regular staff training on data privacy and confidentiality is available, rate as **"Met."**

If secure systems are not in place or if there is no documented staff training on confidentiality, rate as **"Not Met."**

Standard 35: Emergency handling of patients is guided by protocols

Indicator 97: Protocols for providing first aid and emergency care to patients are documented

Assessment Process:

To comply with this indicator, the laboratory must have documented standard operating procedures (SOPs) for managing emergency situations, such as a sudden drop in blood pressure, collapse, or any adverse event occurring during specimen collection or while the patient is present in the laboratory. The assessor will review these policies and SOPs and interview staff to confirm their awareness and understanding of the emergency protocols and their roles in such situations.

Rating:

If SOPs for emergency care are available, and staff members are aware of the procedures, rate as "Met."

If SOPs are not available, first aid arrangements are lacking, or staff are not aware of the protocols, rate as "Not Met."

Indicator 98: Relevant contact numbers for emergency evacuation and referral are available in the laboratory

Assessment Process:

To comply with this indicator, the laboratory must maintain and clearly display a list of emergency contact numbers for immediate use during emergency situations. This list should include contact details for nearby referral hospitals or clinics, ambulance services (e.g., Rescue 1122), the nearest police station, and the fire brigade. During the assessment, the assessor will verify the presence and visibility of this emergency contact list within the laboratory premises and assess whether staff is aware of these contacts and how to effectively use in emergencies.

Rating:

If emergency contact numbers are available, clearly displayed in the laboratory, and staff are aware of them, rate as "Met."
If emergency contact numbers are available and known to staff but not displayed, rate as "Partially Met."
If emergency contact numbers are neither available nor known to staff, rate as "Not Met."

Standard 36: Sentinel events are intensively analyzed

Indicator 99: The laboratory has defined sentinel events

Assessment Process:

To comply with this indicator, the laboratory must have a clearly written definition of sentinel events. At a minimum, the definition should include:

(i) All unexpected deaths
(ii) Any anaphylactic reaction or patient collapse during specimen collection
(iii) Incorrect reporting with potential life risk

(iv) Patient violence against staff
(v) Staff violence against patients
(vi) Loss of a critical or irreplaceable sample.

The assessor will review the written documentation to verify that the definition is present and that a list of possible sentinel events has been developed and is available. The assessor will also check whether the system in place allows for root cause analysis and identification of contributing factors in such events.

Rating:
If the laboratory has a documented definition of sentinel events and a comprehensive list of possible events is available, rate as **"Met."**

If no definition or list exists, or if the list is incomplete or insufficient, rate as **"Not Met."**

Indicator 100: Sentinel events are intensively analyzed when they occur

Assessment Process:
To comply with this indicator, the laboratory must document any sentinel events and ensure each is thoroughly analyzed. The assessor will review records from the past 12 months to confirm whether any sentinel events were reported and, if so, whether appropriate corrective actions—such as changes in policies, procedures, or staff training—were taken. If no events were reported, the assessor will evaluate whether a reliable reporting system exists to identify and respond to such events when they occur.

Rating:
If a sentinel event occurred and was intensively analyzed with documented corrective action, or if no event occurred but the reporting and analysis system is evidently functional, rate as "Met."

If a sentinel event occurred but was not analyzed properly or the analysis was superficial (e.g., limited to assigning blame), rate as "Not Met."

Standard 37: The laboratory policies and procedures support domiciliary services to the patients (where applicable/ claimed)

Indicator 101: The laboratory is equipped with communication and transport services for home-based patient sample collection

Assessment Process:
To comply with this indicator, if the laboratory offers home-based sample collection services, it must have functional means of communication and suitable transport arrangements to support these services. During the assessment, the assessor will verify the availability of communication tools and transportation methods (such as motorbikes, etc) used by phlebotomists. The assessor will also review documented records of home-based sample collection services provided over the past year.

Rating:

If functional communication and transport arrangements are in place and records of home-based services are available, rate as “Met.”

If communication and transport arrangements exist but records are not available for review, rate as “Partially Met.”

If neither communication/transport arrangements nor service records exist, rate as “Not Met.”

Indicator 102: The laboratory has appropriate means for the collection and transportation of home-based samples.

Assessment Process:

To comply with this indicator, the laboratory must have proper equipment for safe collection and transport of samples taken from home-based patients, if such services are claimed. The assessor will verify the availability of sample transport boxes that include all essential phlebotomy items such as tourniquets, alcohol swabs, disposable syringes with appropriate gauge needles, and containers for various samples (blood, urine, sputum, etc.). The box must be suitable for secure transport of specimens back to the laboratory.

Rating:

If sample transport boxes equipped with all required phlebotomy items are available and ready for use, rate as “Met.”

If such boxes are not available, or lack essential items, rate as “Not Met.”

If the laboratory does not offer home-based services, mark as “Not Applicable.”

Appendix 1
Laboratory Personnel Specifications

Position	Qualifications	Scope
Head of Laboratory	MBBS and preferably Fellowship/M-Phil-PhD level postgraduation in pathology/subject specialization recognized by PMDC	Can perform complex non & semi-automated procedures and advanced level inferences and interpretations; final verifier and signatory *
Section Head	MBBS and Membership/fellowship/MSc/MPhil or PhD level postgraduation in related field recognized by PMDC or any other relevant professional council	Can perform complex non & semi-automated procedures and advanced level inferences and interpretations
Senior Medical Lab Technologist	MBBS/BSc 4 yr(MLT/MT/CLS/BMS) and MSc /Phd in related subject recognized by PMC/HEC	Can perform complex non & semi- automated procedures with automated interpretations
Medical Lab Technologist	MBBS/BSc 4 yr (MLT,CLS,MT) and 2 year Diploma recognized by PMDC/AHC	Can perform semi-automated/automated procedures with automated interpretations
Lab Technologist/Collection Center In charge	Matric/ FSc with 2 year Diploma in Lab Tech (SMF)	Can collect samples and perform automated /LIC and simple auto interpreted tests

Phlebotomist/In charge collection center	Matric; Phlebotomy or Lab technician 1 year certificate course (SMF or internal training)	Obtains blood samples, manages samples and performs administrative work
Quality Officer	Suitable for JD	
Stock Officer	Suitable for JD	
Bio-risk Officer	Suitable for JD	
Equipment Officer	Suitable for JD	
Administrator/Receptionist	Suitable for JD	

*1 person may head 3-5 labs to be determined by the IHRA on case to case basis subject to driving distance/time and specialty of practice

Appendix 2

Pathogen Based Bio-risk Assessment and Biosafety Containment Level					
Agent Category	**Human Risk**	**Virulence/Pathogenicity**	**Mode of transmission**	**Infectious Dose**	**Containment requirement**
Category 1	Very low individual or community risk	Low virulence; low severity	Not easily transmissible	Very high	**BSL 1** No BSC; Open Benchtop
Category 2	Moderate individual and low community risk	Moderate virulence; moderate severity	Not generally airborne	High	**BSL 2/ 2+** BSC 2a; access control; PPE; higher containment for specific pathogens +;
Category 3	High individual and moderate community risk	High virulence; high severity	Airborne	Moderate	**BSL 3** High containment
Category 4	High individual and high community risk	Unknown or high	Unknown, airborne/aerosol	Unknown/low	**BSL 4** Highest containment

Appendix 3
POC/Kit Based screening/ RDTs
(Incudes NAAT, Antigen and Anti body-based tests, Lateral Flow Test, LAMP test)

The WHO defines a rapid test as an assay that is "designed for use where a preliminary screening test result is required and is especially useful in resource-limited countries". These tests are characterized as being:

- High-quality, easy-to-use tests for use in a resource-poor setting
- Quick and easy to perform and requiring little or no additional equipment
- Designed for use with a single or limited number of samples, making them more economical in low-throughput laboratories
- Possible to store at room temperature for an extended period
- Able to give same-day results, thus providing timely treatment interventions.

"ASSURED" is an acronym to summarize the criteria for an ideal RDT-Affordable, Sensitive, Specific, User-friendly, Rapid, and Robust. Utilization of new and emerging technology and kits is encouraged to improve effectiveness, efficiency and quality of patient care. Kits should fulfill the above recommended criteria and must be validated by a recognized authority.

POC/RDT tests can be utilized when

- Specimen required is Non-invasive or minimally invasive such as urine, feces, saliva, throat/nasal swab, expectorated sputum, capillary blood. For invasive venipuncture trained Lab technician/phlebotomist is available
- Test is fully automated and generates its printed result not requiring any human sample processing or interpretation
- The test is not used for commercial lab purposes (no report issued) and is utilized for quick diagnosis of patient availing OPD service/emergency services
- Test result is noted in patient records along with time of specimen collection and details of kit and entered in referral form when applicable
- Test cost to patient is either free (public sector/NGO) or minimal (not > 5%) of market cost of the individual kit
- An area is designated to store material and carry out the test. Used kits/ remaining specimens are disposed off as infectious waste

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