Khyber Pakhtunkhwa Health Care Commission

MINIMUM SERVICE DELIVERY STANDARDS

REFERENCE MANUAL

Clinical Laboratories and Collection Centers

KP HCC-08RM-Ed1

Table of Contents

ABBREVIATIONS AND ACRONYMS

LIST OF ABBREVIATIONS AND ACRONYMS	
AL	Alkaline Phosphatase
ALT	Alanine Aminotransferase
APTT	Activated Partial Thromboplastin Time
BT	Bleeding Time
CAP	College of American Pathologists
CBC	Complete Blood Count
CMI	Chemiluminescent Magnetic Microparticle Immunoassay
CQI	Continuous Quality Improvement
DCP	Diploma in Clinical Pathology
EQA	External Quality Assurance
ESR	Erythrocyte Sedimentation Rate
FNAC	Fine Needle Aspiration Cytology
HAI	Healthcare-associated Infections
ICT	Immunochromatographic Test
IHC	Immunohistochemistry
INR	International Normalized Ratio
MD	Doctor of Medicine
MOU	Memorandum of Understanding
MP	Malarial Parasite
NEQAS	National External Quality Assessment Service (UK)
PhD	Doctor of Philosophy
ELISA	Enzyme Linked Immune Sorbent Assay
FCPS	Fellow of the College of Physicians and Surgeons
FRCPath	Fellow of the Royal College of Pathologists
HEC	Higher Education Commission
HMIS	Hospital Management Information System
HR	Human Resource
IQA	Internal Quality Assurance
JCI	Joint Commission International
KP	Khyber Pakhtunkhwa
KPHCC	Khyber Pakhtunkhwa Health Care Commission

LIMS	Laboratory Information Management System
MPhil	Master of Philosophy
MBBS	Bachelor of Medicine and Bachelor of Surgery
MCPS	Member of the College of Physicians and Surgeons
MRCPath	Member of The Royal College of Pathologists
PMC	Pakistan Medical Council
PCR	Polymerase Chain Reaction
PPE	Personal Protective Equipment
PT	Prothrombin Time
QA	Quality Assurance
RAT	Rapid Antigen Test

Foreword

Quality costs but poor-quality costs higher. This is true for all walks of life; however, in the health sector its importance cannot be overemphasized. It ensures safety of patients as well health care providers. Patient safety is not new in the medical field but is relatively newer concept for general public. Regulation of health care services is now a priority at the national and provincial government level. In order to ensure quality of care and safety in health care system of Khyber Pakhtunkhwa, the provincial government established the Khyber Pakhtunkhwa Healthcare Commission (KP HCC) through the promulgation of Khyber Pakhtunkhwa Health Care Commission Act, 2015. KP HCC is a statutory body, constituted to regulate Health Care Establishments (HCEs), both in public and private sectors in the province, to improve quality of health care, and ensure safety of patients and health care providers.

To ensure quality the HCEs are regulated through assessment against set standards. The Punjab Healthcare Commission (PHC) developed the Minimum Service delivery Standards (MSDS) through extensive consultations with the stakeholders. PHC developed MSDS for Category I and II hospitals, providing in-patient care. Moreover, MSDS were also developed for different kinds of Category III HCEs, offering out-patient services, including Basic Health Units in the public sector, and the clinics of general practitioners, dental clinics, clinical laboratories, radiological diagnostic centers, as well as homeopathic clinics and Tibb clinics. This is tremendous achievement on the part of PHC.

The former Board of Khyber Pakhtunkhwa Healthcare Commission, under the Chairmanship of Dr. Ikram Ghani, took a wise decision and instead of reinventing the wheel, the Ex-CEO, Mr. Muhammad Humayun approached the Punjab Healthcare Commission for adoption of their MSDS. Upon concurrence of the PHC, the Board of KP HCC approved adoption of the MSDS of Punjab in its 34th meeting on 6th January 2022. The KP HCC duly acknowledges this gesture of support by the Punjab Healthcare Commission.

The panel of experts, including the prominent pathologists of Khyber Pakhtunkhwa (list is given at annexure C) assisted the KP HCC and customized the standards as well indicators to the local setting and requirements of our province. KP HCC is highly grateful for their dedication and contribution.

Subsequent to adoption of the Minimum Service Delivery Standards of PHC, appropriate amendments were required to adapt the MSDS to the Khyber Pakhtunkhwa local context and legal provisions. This was a challenging assignment and despite shortage of staff, the KP HCC made the required amendments and adapted the MSDSs of all the various kinds of Health Care Establishments to the local setting of the province, utilizing its internal resources. I would like to thank the former Board of KP HCC for their wholehearted effort to swiftly proceed towards improving the quality of healthcare though acquiring and approving the PHC MSDS. My thanks are also due to the whole KP HCC team for working tirelessly and completing the process of adaptation in a very short time. The role of senior management was commendable and Dr. Shabnum Gul contribution needs special menton in the review of this Reference Manual. Moreover, I am highly grateful to Mr. Muhammad Latif Khan, Mr. Adil Waqas, Mr. Malik Waqar Ahmad, Mr. Zeeshan Khan, Mr. Zia Mohyuddin and Mr. Muhammad Farhan Wadud of KP HCC for thoroughly reviewing all the manuals of MSDS, identifying the sections to be changed, and finding appropriate replacements for making the required amendments for adaptation.

The MSDS and Reference Manual for Clinical Laboratories comprise 29 standards and 104 indicators. Every journey begins with the first step and I firmly believe that this first step followed by implementation of these Minimum Service Delivery Standards will lead to improved quality of healthcare in Khyber Pakhtunkhwa.

Dr. Nadeem Akhtar
Chief Executive Officer

1. Introduction

The Government of Khyber Pakhtunkhwa promulgated the Khyber Pakhtunkhwa Health care Commission Act, 2015, to establish the Khyber Pakhtunkhwa Health Care Commission (KP HCC) as a regulatory body with the prime objective to improve the quality of healthcare services and ban quackery in Khyber Pakhtunkhwa in all its forms and manifestations. The KP HCC is legally mandated to regulate all Health Care Establishments (HCEs) in the public and private sectors through registration and licensing. It is the responsibility of the HCEs throughout the province to get registered with KP HCC. Moreover, the KP HCC is ensuring to improve and maintain quality of healthcare through the implementation of Minimum Service Delivery Standards (MSDS). The HCEs are required to follow these standards in order to get license. No Health care Establishment can function legally without being registered and licensed by the Khyber Pakhtunkhwa Care Commission.

The KP HCC has adopted MSDS developed by the Punjab Healthcare Commission (PHC) for the three recognized systems of treatment; Allopathy, Homeopathy, and Tibb. These Minimum Service Delivery Standards include hospitals (Upto 15 beds, 16 to 30 beds, 31 to 49 beds, 50 and more beds), Basic Health Units, General Practitioners/Family Physicians/Specialist Clinics, Dental Clinics, Clinical Laboratories and Collection Points, Radiological/Imaging Diagnostic Centres, Homeopathic Clinics, Tibb Clinics.

The senior Pathologists of the Khyber Pakhtunkhwa provided assistance to the Health Care Commission in the adaptation of the PHC Minimum Service Delivery Standards (MSDS) for laboratories and collection points. List of the experts is attached as annexure C. The Khyber Pakhtunkhwa Health Care Commission appreciates this valuable support and is grateful to all these senior Pathologists.

Setting service delivery standards and specifying indicators for their assessment is an established international practice for improving the quality of delivery of healthcare services across the health sector. The primary objective of developing MSDS is to set a yardstick for healthcare services to become eligible for the grant of a license by the KP HCC.

SECTION – 1 *Minimum Service Delivery Standards for Clinical Laboratories*

2. Laboratory Categories

The following four categories of clinical laboratories are defined.

2.1 Category A Lab: Tertiary Care/ Teaching Hospital Laboratory

A laboratory that is part of or attached to a tertiary care hospital or teaching hospital at both public and private sector.

2.2 Category B Lab: Non-Teaching Hospital Laboratory

A laboratory that is part of or attached to a non-teaching hospital at both public and private sector.

For Example:

1. Laboratories of district headquarter hospital (DHQ) hospitals not attached with medical colleges (public sector)
2. Laboratories of general hospitals or private medical centers with one central lab.

2.3 Category C Lab: Stand Alone Laboratory

A laboratory that stands alone and is not part of or attached to any hospital or healthcare center. In addition, laboratories that are part of or attached to healthcare clinics are included in this category.

For Example:

1. Laboratories in medical centers
2. Laboratories in commercial areas
3. Laboratories attached to clinics

2.4 Category D Lab: Remote Area Laboratory

A laboratory that is allowed to operate in only those districts which are remote. This shall be applicable as long as that district remains in that category. At the moment these districts are,

1. Chitral (Upper and Lower)
2. Dir (Upper and Lower)
3. Kohistan (Upper and Lower)
4. Waziristan (North and South)
5. Shangla
6. Palas
7. Tor Ghar
8. Kurram
9. Orakzai
10. Bajaur
11. Hangu

The status of these districts regarding their categorization would be reviewed after every three years interval or when required.

Important Note:

Pathology laboratory registration and license to practice will be made separate to hospital registration based on the standards and indicators in MSDS for clinical laboratories i.e., registration and licensing of hospital will be separate and registration & licensing of laboratories will be separate or in other words registration & licensing of hospital does not mean registration & licensing of laboratory within hospital automatically.

Laboratories applying for licensing must have the following with application package. Without these documents the application will not be entertained and processed.

1. Academic qualifications of pathologists including MBBS (RMP) with a post graduate degree (MPhil, PhD, FCPS, MRCPath, FRCPath) in any branch of pathology duly recognized by PMC/HEC recognized university (for Category A, B and C labs). Laboratories in remote districts of KP where Category D labs are allowed to work as per the Lab MSDS for a specified time period, an MBBS (RMP) with a post graduate course completion certificate of MPhil, PhD, FCPS, MRCPath, FRCPath in any branch of pathology duly recognized by PMC/HEC recognized university will be accepted.
2. Academic qualifications of laboratory staff and administration staff.
3. List of all staff members in tabulated form with qualifications.
4. CNIC of all staff members.
5. Filled form for licensing of clinical laboratories.

3. Category A Laboratory

29 Standards & 104 Indicators

3.1 Standard 1: Registration and display

Indicators (1 – 5):

Ind 1. The laboratory is identifiable with name on a sign board.

1. Sign board clearly displaying the name of the laboratory or the collection center, as the case may be.
2. Sign board/s placed appropriately for clear visibility.

Ind 2. The laboratory sign board conforms to the prescribed local legal standards.

1. Sign board size should conform to the local legal standards.
2. Sign board fixation should conform to the local legal/technical/safety standards.

Ind 3. The laboratory is licensed/registered with the KPHCC.

1. KPHCC Registration/License number is clearly displayed on the sign board or separately.
2. Registration Certificate/License with the KPHCC displayed at a prominent place inside the laboratory.
3. A copy of PMC/HEC/institutional affiliation of the technical head placed at a prominent place inside the laboratory.

Ind 4. Associated collection centers are reflected in the Registration /License Certificate issued by the KPHCC

1. Registration Certificate/License of the laboratory is linked with serial numbers of the collection center/s e.g. (CL#/CC#).
2. Evidence of having applied for licensure in case it is not licensed.

Ind 5. Signed and valid MOU, showing linkage with any other laboratory or organization for referral of specialized tests, exists

1. Written and valid MOU signed with the referral laboratory which fulfills the above requirements.

3.2 Standard 2: Scope of Services

Indicators (6 – 7):

The scope of services of a clinical laboratory is dependent upon expertise of the technical head supervising that laboratory.

Ind 6. Routine clinical laboratory services shall be supervised by a technical head with MBBS (RMP) and a post graduate degree (MPhil, PhD, FCPS, MRCPath, FRCPath) in any sub-specialty of pathology duly recognized by PMC/HEC recognized university. These include:

1. Routine Hematology (CBC, ESR, Reticulocyte count, MP, BT, CT, PT, APTT, INR).
2. Routine Chemical Pathology (Blood Glucose, Electrolytes, Urea, Creatinine, Bilirubin, ALT, ALP, Cholesterol, Urinalysis, Fecal Analysis).
3. Routine Microbiology (RAT).

Ind 7. Advanced clinical laboratory services shall be supervised by a technical head with MBBS (RMP) and a post graduate degree in any sub-specialty of pathology (MPhil, PhD, FCPS, MRCPath, FRCPath), duly recognized by PMC/HEC recognized University, such as:

1. Advanced Hematology (Peripheral smear, Bone Marrow Examination, Coagulation Studies, Blood Banks)
2. Electrophoresis, ELISA, Flow Cytometry, Genotyping, Immunology, Molecular Biology. Molecular Pathology.
3. Advanced Chemical Pathology (Fluid RE, CMIA, Clinical Endocrinology, ELISA)
4. Advanced Microbiology (Culture and Sensitivity, ELISA, PCR).
5. Histopathology (Biopsies, FNAC, Frozen Sections, Special staining, IHC, FISH, CISH).

3.3 Standard 3: Technical Head

Indicators (8 – 10):

A technical head is the supervisor of the laboratory who is specialized in the field of pathology and without whom, the laboratory cannot be registered.

Ind 8. Head of the Department

1. The Head of department shall be MBBS (RMP) with a post graduate degree (MPhil, PhD, FCPS, MRCPath, FRCPath etc) in any branch of pathology duly recognized by PMC/HEC recognized university (for Category A, B and C labs)

2. Laboratories in remote districts of KP where Category D labs are allowed to work for a specified time period, however the head of department shall be MBBS (RMP) with a post graduate course completion certificate of MPhil, PhD, FCPS, MRCPath, FRCPath in any branch of pathology duly recognized by PMC/HEC recognized university

Ind 9. Section Head

For sub sections of the clinical laboratory such as Microbiology, Histopathology, Chemical Pathology, Hematology, etc., the Technical Head shall be MBBS (RMP) with a post graduate degree (MPhil, PhD, FCPS, MRCPath, FRCPath) in the relevant branch of pathology duly recognized by PMC/HEC recognized university. Section head will only be applicable for category A laboratories.

Ind 10. Number of laboratories per Technical Head

One technical head can supervise not more than two laboratories provided that the distance between these two laboratories is justified.

3.4 Standard 4: Responsibilities of Management

Indicators (11 – 17):

The management shall make sure the following responsibilities are met with:

Ind 11. Laboratory's mission statement is properly laid down

1. Documented mission statement that fulfills the above requirements.
2. Mission statement is displayed for the staff and patients to view.

Ind 12. Detailed laboratory policy and standard operating procedures (SOPs) are laid down.

1. Written laboratory policy and SOPs are available.
2. Evidence of involvement of senior leadership, including those involved in the laboratory's management, in the process of developing policy and SOPs.
3. Staff is aware of the laboratory policy and SOPs.

Ind 13. SOPs of Emergency laboratory policy are laid down.

1. Written laboratory emergency policy and SOPs covering the above requirements are available.
2. The emergency policy and SOPs are available to the staff or patients for consultation.

Ind 14. Sufficient laboratory budget and resources are allocated.

1. Adequate laboratory spaces are allocated for the required activities.
2. The staff, equipment and consumables remain available to support the scope of laboratory services as evidenced from the stock register and incumbency record/duty roster.
3. There is no evidence of delay in reporting the test results on account of non-availability of equipment, kits/reagents or the concerned staff.

Ind 15. Laboratory's organogram is established.

1. The organogram is approved and documented.
2. The organogram is displayed for patients and the staff.

Ind 16. Section heads are appointed.

1. Section heads for each section of the laboratory are appointed.
2. Evidence of adopting due process for appointing section heads exist.

Ind 17. Research activities are supported and collaborations are established.

1. Compilation of disease related data/research and its sharing with relevant authorities/research organizations while ensuring patient confidentiality is supported and recorded.
2. Support is provided to universities and other organizations who intend to collaborate for research purposes.

3.5 Standard 5: Facility Management Regulations

Indicators (18 – 20):

Ind 18. The management is aware of and complies with the relevant laws, bylaws, rules and regulations, and facility inspection requirements.

Ind 19. The management updates the amended requirements.

Ind 20. The management ensures implementation of these requirements.

1. Evidence that the relevant laws, regulations and rules are properly implemented, for example:
   A. Implementation of waste management is in such a way that all key requirements are clearly observable.
   B. Compliance of the building and fire safety requirements, etc.

3.6 Standard 6: Facility Design

Indicators (21 – 24):

Ind 21. The management is aware of the specific space requirement for the lab.

Copies of current/updated design of space are available.

Ind 22. Laboratory staff is aware of the space design and knows how those relate to their functioning. Facility design conforms to the scope of services.

1. The Laboratory includes designated spaces and sections for:
   A. Reception/Reporting
   B. Phlebotomy
   C. Patient/Staff Washroom
   D. Patient Waiting Area
   E. Separate Working Stations
   F. Offices
   G. Inventory Store

Ind 23. Safe environment for patients and the staff

Effective separation between administrative and technical laboratory areas exists.

Ind 24. Measures are taken to restrict movement of the technical staff working in different sections of the laboratory:

1. Staff wears the identity badges during duty.
2. Written SOPs for the staff regarding exiting the workplace for any interaction with patient/ client are available. The SOPs are displayed at the exit/ entry point of each section.

3.7 Standard 7: Facility Safety for fire and non-fire Emergencies

Indicators (25 – 31):

Ind 25. The laboratory has plans for fire and non-fire emergencies within the sections.

1. Plans and provisions for early detection of fire and non-fire emergencies exist.
   A. The plan addresses the requirement of early detection of fire and non-fire emergencies.

B. Resources are allocated to detect the above emergency situations at an early stage as laid out in the plan, e.g.:
   i. Smoke detector/s.
   ii. Monitoring through CCTV cameras.
   iii. Trained staff physically deployed to ensure the required outcome.
C. The staff is aware of the plan.

Ind 27. Provisions for prevention of fire and non-fire emergencies exist.

1. An environment which has a lesser chances of occurrence of fire and non-fire emergencies is ensured:
   A. There is no loose electric wiring to cause short circuiting.
   B. No loose plugs and sockets which can spark.
   C. No power cord/s that is/are worn out to cause electrocution.
   D. Ramps, if they exist, are non-slippery.
   E. Stairs have supporting rails etc.
   F. Building meets the local construction standards.

Ind 28. Provisions for containment of fire emergencies exist.

1. Water source
2. Sand buckets
3. Shovel
4. Fire extinguisher/s
5. Fire blankets

Ind 29. Safe entry/ exit points in case of fire and non-fire emergencies exist.

1. Emergency exit points with 24/7 illuminated sign board/s are displayed as required.
2. The emergency exits are not obstructed at any time.
3. Staff is aware of the emergency exits.

Ind 30. Mock drills are held at least once in a year.

1. Record of mock drills/attendance.
2. Record confirms that all staff was subjected to the mock drill.
3. Record of corrective actions taken after mock drills.

Ind 31. Staff members are trained for their role in case of such emergencies.

Record that confirms participation of at least the key staff from each shift.

3.8 Standard 8: Human Resource is in accordance with scope of work

Indicators (32 – 34):

The standards under human resource (HR) are intended to ensure that the clinical laboratory determines the qualifications and competencies for staff positions that match the organization's mission and workload. The laboratory management must provide the right number of qualified staff to meet the routine workload and emergency requirements.

Ind 32. Job description for every post is identified and documented

1. Documented individual job descriptions.
2. Job descriptions are signed by the employer and the concerned employee.

Ind 33. An eligibility criterion of qualification and experience for each job is available.

Ind 34. Recruitments are made according to the laid down eligibility criteria.

3.9 Standard 9: Human Resource Orientation

Indicators (35 – 39):

Ind 35. The staff members joining the laboratory are oriented to the laboratory environment, the laboratory sections and their individual jobs.

Ind 36. An appropriate orientation plan exists for the newly inducted employees.

1. Written orientation plan covering the following:
   A. General laboratory working
   B. Safety
   C. Biosafety
   D. Quality assurance
   E. SOPs
   F. Specific techniques/tasks assigned to the individual employees

Ind 37. Each staff member is made aware of laboratory wide policies and procedures as well as section/unit/service/program specific policies and procedures

1. Written record of level specific orientation sessions conducted for all staff covering:
   A. Laboratory wide policy and procedures (general SOPs).
   B. Section/Unit/Service/Program specific policies and procedures.

Ind 38. Each staff member is made aware of his/her rights and responsibilities.

Written job contract having clear description of employee rights and responsibilities.

Ind 39. All employees are educated about patients' rights and responsibilities.

Written record of orientation sessions conducted for all staff regarding patients' rights and responsibilities.

3.10 Standard 10: Human Resource Personal Record

Indicator (40):

Ind 40. Documented personal record for each staff member exists.

1. Personal files of all employees having the following information are maintained:
   A. Employee's contract showing date of employment
   B. Copies of qualifications like degrees/diplomas/transcripts
   C. Laboratory personnel's licenses (registration where required)
   D. Training and experience
   E. Records of continuing education
   F. Job description
   G. Disciplinary background
   H. Evaluation reports
   I. Health status, etc.

3.11 Standard 11: Quality of equipment and reagents ensured

Indicators (41 – 44):

Laboratory result errors due to faulty equipment, poor quality chemicals/reagent/kits are one of the most common healthcare issues, which require due care and attention for their prevention. Such errors are among the most frequently reported adverse events.
Standards under the management of equipment and reagents help laboratories to sustain and improve the quality of lab results by creating a system for selecting, ordering, procuring, storing, preparing, labeling, dispensing, and monitoring proper use of equipment and chemicals/reagents/kits.

Ind 41. The procurement procedure of the laboratory is laid down.

Documented procurement SOPs to comply with the rules/regulations.

Ind 42. Specifications for all the equipment and reagents/kits/consumables to be purchased are documented.

Ind 43. Procurement orders are clear, dated and signed.

Clear, dated and signed procurement orders are ensured.

Ind 44. Procured items are regularly entered into stock registers.

Stock registers are maintained.

3.12 Standard 12: Safe handling and storage of laboratory reagents

Indicators (45 – 48):

Ind 45. Policies and procedures for safe storage and use of reagents are documented.

1. Written SOPs which guide safe storage and use of reagents. Issuance and usage are done as per SOPs.

Ind 46. Inventory of reagents is maintained

Inventory of stored reagents is updated.

Ind 47. The policies of reagent management include a procedure of alert for near expiry reagents.

Availability of written SOPs for creating an alert about any item which has an expiry date of one month.

Ind 48. Labeling of reagents is as per SOPs

The labels must bear the following:

1. Full name of the chemical/reagent
2. Concentration (strength)
3. Date of manufacturing/issuing (as applicable)
4. Date of expiry

3.13 Standard 13: Equipment management and maintenance

Indicators (49 – 53):

Ind 49. Log books of all equipment are available

Ind 50. Regular periodic maintenance and calibration record of all the equipment is documented in the log books

The log books contain record of any breakdowns, repairs and maintenance.

Ind 51. A Log sheet is displayed on each equipment

A log sheet, containing record of last repair/maintenance as well as due date of next calibration, is displayed on the equipment.

Ind 52. Emergency contact number/s is/are displayed on all equipment

Emergency contact number of the technician or the firm for emergency management of equipment breakdown is displayed on the equipment.

Ind 53. Equipment inventory is maintained

Availability of equipment inventory showing:

1. Date of purchase
2. Its source (manufacturer/importer/distributor/vendor)
3. Date of commissioning (date of first operation)
4. Date/s of calibration

3.14 Standard 14: Recording system for every patient
Indicators (54 – 57):

Correct and timely generation of lab reports contributes significantly to the facilitation of physicians towards precise diagnosis and patient care. The clinical staff must be facilitated for generation of timely and accurate information from the labs to ensure a coordinated and integrated care. In addition, it is important to protect the privacy of data collected and to limit an unauthorized access to the patients' information.

Ind 54. Electronic record of every patient is maintained.

Computerized laboratory record of all tests conducted is available.

Ind 55. Every laboratory record has a unique identifier.

Use of unique identifier numbers for each patient is ensured.

Ind 56. History of each patient's record of tests is present.

Patient’s record is chronological and up to date.

Ind 57. Only authorized person shall make entries in the laboratory record.

Written authorization of the relevant staff for data entry is ensured and he can be identified from his ID.

3.15 Standard 15: Reporting system in the lab
Indicators (58 – 60):

Ind 58. A computerized reporting system is available.

Ind 59. Signatures of the authenticating official exist.

Digital/manual signatures/names of the authenticating pathologist are ensured.

Ind 60. Critical results and notifiable diseases are reported.

1. Critical results are reported to the concerned consultant/client immediately.
2. All notifiable disease reports are submitted to concerned authorities.

3.16 Standard 16: Quality Assurance
Indicators (61 – 63):

The processes of quality assurance (QA) and continuous quality improvement (CQI) are employed to ensure precision in the functioning of the lab systems to deliver authentic and reliable tests results. QA includes the internal quality assurance (IQA) and external quality assurance (EQA).

Ind 61. The laboratory has documented QA SOPs

Written SOPs on laboratory QA covering both IQA and EQA components.

Ind 62. Designated focal person responsible for QA in the laboratory.

Designation of a focal person with clear responsibilities regarding QA in the laboratory is ensured.

Ind 63. QA SOPs are communicated and coordinated among the staff

1. Written SOPs on laboratory QA covering both IQA and EQA components.
2. Documentary evidence of staff orientation on SOPs.
3. Staff orientation is ensured through an interview.

3.17 Standard 17: External Quality Assurance
Indicators (64 – 65):

Ind 64. EQA of the laboratory is ensured through external assessment.

Ind 65. Record of EQA reports is maintained.

3.18 Standard 18: Internal Quality Assurance
Indicators (66 – 72):

Ind 66. Policies and procedures guide the safe collection of specimens.

1. SOPs for safe collection of specimens are available.
2. Evidence of implementation of the above SOPs.

Ind 67. Policies and procedures guide the identification and proper labeling of specimens.

1. SOPs for patient identification and labeling of specimens are available.
2. Evidence of implementation of the above SOPs.

Ind 68. Policies and procedures guide the safe handling of specimens.

1. SOPs for safe handling of specimens are available.
2. Evidence of implementation of the above SOPs.

Ind 69. Policies and procedures guide the safe handling of specimens.

1. SOPs for safe internal and external transportation of specimens are available.
2. Evidence of implementation of the above SOPs.

Ind 70. Policies and procedures guide the safe processing of specimens

1. SOPs for safe processing of specimens are available.
2. Evidence of implementation of the above SOPs.

Ind 71. Policies and procedures guide the safe disposal of specimens

1. SOPs for safe disposal of specimens are available.
2. Evidence of implementation of the above SOPs.

Ind 72. Availability of controls for IQA is ensured

1. Controls are available for IQA.
2. Controls are used for IQA as per technical instructions.

3.19 Standard 19: Biosafety program

Indicators (73 – 76):

Prevention of healthcare associated infections (HAI) is one of the major safety initiatives a clinical laboratory is required to undertake. A large number of infected specimens of human origin are brought to the laboratory for testing and reporting. Therefore, the laboratory staff can come in contact with any of such samples accidentally resulting in serious consequences. Necessary measures adopted for reducing the risk of unintentional exposure to pathogens and toxins or their accidental release, thereby reducing the risk of infections/disease, is referred to as Biosafety.

Ind 73. Availability of laboratory Biosafety SOPs.

Documented laboratory Biosafety SOPs are available.

Ind 74. Biosafety SOPs are communicated to the laboratory employees.

1. Record confirms that copies of written Biosafety SOPs are provided to the laboratory employees.
2. Record confirms that the staff was trained to implement these SOPs.

Ind 75. The laboratory has a designated qualified technician for ensuring Biosafety activities.

Evidence of designation of a qualified technician for ensuring Biosafety activities.

Ind 76. Regular Biosafety monitoring reports are generated in the laboratory.

1. Record of monthly Biosafety monitoring reports prepared by the designated technician is available.
2. The above reports are submitted to the laboratory head on a regular basis.

3.20 Standard 20: Staff biosafety ensured

Indicators (77 – 79):

Ind 77. The laboratory has appropriate consumables, equipment and facilities to ensure Biosafety.

Availability of required PPE is ensured.

Ind 78. All staff involved in the handling and disposal of laboratory waste receives regular vaccination.

Record of vaccination of staff at risk of Hepatitis B and other exposures is available.

Ind 79. Annual medical check-up of all staff is documented.

Record of annual medical checkup of all staff involved in handling of bio hazardous laboratory material is available.

3.21 Standard 21: Staff biosafety ensured

Indicators (80 – 81):

Ind 80. Properly ventilated waiting areas for patients are available.

Effective ventilation either naturally or by means of exhaust fan/s.

Ind 81. Patients are not allowed inside the laboratory working area.

Evidence of controlled entry into the laboratory working area.

3.22 Standard 22: Documented Biorisk Management (Ind 80 – Ind 81)

Ind 80. All incident reports are documented.

Record of reporting the incidents which breached laboratory Biosafety is available along with action/s taken on such an event.

Ind 81. Required disinfectants/spill kits are available in the laboratory.

1. Availability of required disinfectants/spill kits in the laboratory is ensured.
2. Record of regular use of the above is available.

3.23 Standard 23: Biosecurity

Indicators (82 – 83):

Patient samples are subject to security risks as misuse of the stored samples can be a potential source of biohazard at the national and international level. Due protection and security of such sources of biohazards is a mandatory responsibility of every laboratory. Measures adopted for reducing the risk of unauthorized access, loss, theft, misuse, diversion or intentional release of such samples for any such acts is referred to as Biosecurity.

Ind 82. Only authorized persons are permitted to enter the sample storage area.

1. Only authorized persons are permitted to go to the sample storage area.

2. The above authorized personnel are identifiable through an ID.

Ind 83. Any transportation of samples is properly recorded

Record of samples transported to other labs, if any, is available.

3.24 Standard 24: Waste Management Plan

Indicators (84 – 89):

Ind 84. Laboratory waste management SOPs are available

Ind 85. Written laboratory waste management SOPs are available.

Ind 86. Waste management SOPs are communicated to the laboratory employees.

1. Copies of the lab waste management SOPs are provided to the laboratory employees.
2. Laboratory employees are conversant with the lab waste management SOPs.

Ind 87. The laboratory has appropriate consumables, collection and handling systems and equipment for waste management.

Ind 88. Contracts with waste disposal service organizations are available

Written contract with waste disposal services is available if the lab does not dispose off the hazardous waste through an onsite mechanism.

Ind 89. Waste transported from collection centers for final disposal is recorded.

3.25 Standard 25: Accessible laboratory services

Indicators (90 – 94):

Temporal access alone is a major factor which plays a pivotal role in the utilization of services provided by a clinical laboratory. If one cannot easily reach the laboratory location, there is a great likelihood that it will either be dropped or diverted to anyone facility which may not be of a similar standard.

Ind 90. The laboratory's location is easily accessible.

1. Laboratory's location is easily accessible through an easy map.
2. Laboratory can be accessed round the clock.

Ind 91. Basic facilities are available in the laboratory.

The following should be available at the least:

1. Clean water supply.
2. Power supply with backup.

Ind 92. There are clean toilets/washrooms with bolts

1. Cleanliness is ensured.
2. Privacy is ensured.

Ind 93. Disabled patients are facilitated for phlebotomy.

Disabled persons can easily reach the phlebotomist or they can come to them.

Ind 94. Directional arrows pointing towards various important areas for patients are displayed in the laboratory.

3.26 Standard 26: Care of Patients

Indicators (95 – 96):

The process of patient care includes planning of emergency care, providing emergency care, evaluating patient's response to care and planning follow-up in case of referral. This section demands availability of written SOPs and staff knowledge for management of such untoward events.
In case of an emergency developed during phlebotomy or in cases where a patient or relative suffers a medical emergency while in the premises of the laboratory, immediate required care should be provided.

Ind 95. Protocols for providing first aid/emergency care to the patients are documented

1. SOPs to manage emergency conditions as mentioned above are available.
2. Staff is conversant and trained with the SOPs.

Ind 96. Relevant contact numbers for emergency evacuation/referral are available in the laboratory

List of contact numbers of the following for use in emergency is displayed:

1. Nearest referral hospitals/clinics
2. Rescue 1122
3. Other ambulance services
4. Police Station
5. Fire Brigade
6. NGOs/CBOs etc. operating in the area

3.27 Standard 27: Patient Rights on consent

Indicators (97 – 98):

The Laboratory shall define patient and family rights and responsibilities as per guidelines/charters provided by the KPHCC. The staff is aware of these and is trained to protect patients' rights. Patients are informed of their rights and educated about their responsibilities at the time of accessing services. They are informed about the process, the possible outcomes and are involved in decision making. The costs are explained in a clear manner to the patient and/or family and the test/investigation rates are displayed. Patients are educated about the mechanisms available for addressing grievances.

Ind 97. The laboratory has listed those situations where specific informed consent is required

A list of situations requiring informed consent is available.

Ind 98. The policy describes who can give consent when a patient is incapable of independent decision-making.

Written directions about the person who can give consent when a patient is incapable of independent decision- making for providing informed consent are available.

3.28 Standard 28: Right to information on costs of tests offered

Indicators (99 – 100):

Ind 99. Patients and families have a right to information on expected costs and the rate list of tests should be available for review by patients.

Patients/clients are informed about the rates of the required tests before they can decide on the testing.

Ind 100. Patients/families are informed about additional reports which are generated/ included in the report with the same sample and cost.

1. Clients are informed about additional reports possible in a cost effective package.
2. The above information is provided by a doctor or a qualified and authorized lab technician.

3.29 Standard 29: Patient's rights for appeals, complaints & confidentiality Indicators (101 – 103):

Ind 101. Patient's complaints are accepted by the laboratory and properly registered.

1. A complaint register/record is maintained.
2. A complaint box is affixed in the patient waiting area.

Ind 102. Proper actions and remedial measures are taken in response to patients' complaints

Record of actions taken on the complaint is available.

Ind 103. Confidentiality of patient record is maintained.

Only the authorized personnel have access to patient related information.

4. Category B Laboratory

29 Standards & 104 Indicators

All 29 standards and 104 indicators as described in previous section (section 3 for category A lab) apply to category B labs.

5. Category C Laboratory

29 Standards & 104 Indicators

All 29 standards and 104 indicators as described in previous section (section 3 for category A lab) apply to category C.

6. Category D Laboratory

29 Standards & 104 Indicators

All 29 standards and 104 indicators as described in previous section (section 3 for category A lab) apply to category D.
However, standard 2 and 3 differ as follows,

6.1 Scope of Services

1. Routine Hematology (CBC, ESR, Reticulocyte count, MP, BT, CT, PT, APTT, INR).
2. Routine Chemical Pathology (RBS, Electrolytes, Urea, Creatinine, Bilirubin, ALT, ALP, Cholesterol, Urinalysis, Fecal Analysis).
3. Routine Microbiology (RAT).

6.2 Technical Head

1. MBBS (RMP) with a post graduate qualification in any branch of pathology duly recognized by PMC/HEC recognized university.
2. If qualified person mentioned above is not available then MBBS (RMP) with a course completion certificate of postgraduate qualification in pathology for a remote area laboratory only should be considered.
3. One technical head can supervise two clinical laboratories provided that distance between the two laboratories is justified.

Important Note:

1. Cabin laboratories are small labs that are functioning in private medical centers or attached closely to a private clinic. These laboratories do not fall under any standards and will be sealed and closed for pathology testing with immediate effect.
2. This document is subject to amendment from time to time through the committee notified by KPHCC dated 16Feb2022 #HCC/HO/L&R/118.

SECTION – 2 *Minimum Service Delivery Standards for Collection Points*

LEGITIMATE SCOPE OF SERVICE

- ✓ Laboratory collection centers collects samples and transports to the main referral /parent laboratory for test /analysis
- ✓ Collection centers are responsible to comply with the standard protocols for collection, labelling, storage and transportation of samples
- ✓ Collection centers may also deliver the tests reports to patients/ care providers on behalf of the designated laboratory and maintain record

MANAGEMENT AND SUPERVISON OF COLLECIOTN CENTERS

- ✓ Overall /off-site supervision by the Pathologist/Director/Technical staff of the Main/Parent Laboratory through prescribed/documented reporting system and periodic visits
- ✓ On-site supervision by the Laboratory technologist/Phlebotomist /Front Desk Officer In-charge/supervisor at the Collection Center

STAFFING OF THE COLLECTION CENTER

Minimum:

- ✓ One (x1) Phlebotomist/ Technician and /or Front Desk Officer
- ✓ Cleaner (Full time/ Part time)

Survey Methodology

The laboratory Collection Centers are under legal obligation to comply with the relevant standards under the MSDS for Clinical Laboratories prescribed by the KPHCC for licensing of the labs / collection centers.

Every standard has its own compliance requirements.

7.1. Standard 01: The collection center is easily identified with the help of a signboard

Compliance Requirements:

1. Signboard that clearly specifies that it is a collection center not a laboratory.
2. The signboard conforms to the prescribed local legal standards.
3. Registration No. / License Number of the main / parent lab is displayed on the signboard (CL#/CC#) as evidence of authorization / affiliation with the parent lab / HCE.

7.2. Standard 02: A technically qualified and trained staff performs phlebotomy / sample collection of the collection center

Compliance Requirements:

1. The person(s) deputed for sample collection / phlebotomist at the collection center is / are either certified lab technician(s) / lab assistant(s) or trained phlebotomist(s) (see copies).
2. Evidence of training in respect of all technician's / lab assistants / phlebotomists.
3. All technicians' / lab assistants / phlebotomists have at least three months documented experience of working under supervision of a pathologist / lab technologist (see evidence).
4. The staff deputed at collection centres to collect sample for COVID-19 PCR test are accordingly trained (interview & see evidence).

7.3. Standard 03: Responsibilities of the onsite in-charge/ Manager / Front Desk Officer are defined

Compliance Requirements:

1. The in-charge / manager / front desk officer / lab technicians / phlebotomists is / are conversant with the legally permissible role assigned to the collection center (interview and see copies).
2. All staff working in the collection center wear / display proper identification cards (observe).
3. Documented policies and SOP's prescribed by the parent lab are available at the collection center and there is evidence to the effect that the SOP's are practiced.
4. Evidence that phlebotomy/sample collection / other duties assigned to the staff at collection center are performed according to the protocols prescribed by the parent lab (observe).
5. The staff exhibits a respectful, polite and professional conduct with the patients / clients as per prescribed SOP's and other professional norms (observe).
6. Display of KPHCC Charter of Rights and Responsibilities for Healthcare Establishments and other relevant instructions (observe).
7. Prescribed policies and SOP's to manage emergencies are documented, the staff is trained to implement the SOP's and there is evidence that these are followed (interview and see copies).

7.4. Standard 04: Facility design and space conforms to the scope of services

Compliance Requirements:

Adequate space allocated for:

1. Reception
2. Waiting
3. Phlebotomy/ Sampling area
4. Labelling of samples
5. Toilets for patients (for taking urine samples).
6. Temporary storage areas

7.5. Standard 05: The collection center has SOPs to manage fire and non-fire emergencies

Compliance Requirements:

1. SOPs to manage fire and non-fire emergencies, defining what is to be done and by whom (see copies).
2. Electronic smoke detectors are affixed and/ or staff is trained for early detection of fire and non-fire emergencies (observe and interview).
3. Provisions for abatement of fire and non-fire emergencies (observe).
4. Provisions/ equipment for firefighting at least fire extinguishers are available (observe).
5. Safe exit points in case of fire and non-fire emergencies are marked (observe).

7.6. Standard 06: Staff deployment and supervision is in accordance with the scope of work of the collection center

Compliance Requirements:

1. Eligibility criteria regarding qualification and experience of the staff for the relevant job(s) is / are available (review).
2. Staff is appointed (by the patient lab or the collection center as applicable (in accordance with the laid down eligibility criteria (review).
3. Job description for every staff is defined and documented as per sample (observe).
4. The staff joining the collection center is/ are oriented to the collection center environment and their individual jobs as well as to the parent lab (interview).
5. Staff is aware of his / her rights and responsibilities (interview).
6. Staff is educated with regard to patient's rights and responsibilities (interview)
7. Personal files are maintained in respect of a full time/ part time staff at the parent lab and a copy of the file is kept at the collection center or vice versa (review)

7.7. Standard 07: Ensure quality of equipment and consumables through standardized procurement procedures.

Compliance Requirements:

1. A copy of the supply/ procurement record is available (review).
2. The collection center follows the supply/ procurement procedure of the parent lab in terms of quality of the equipment and consumables (review).
3. Specifications for all the equipment relevant to the permissible services, e.g. refrigerator, centrifuge, UPS, etc., and consumables, e.g. sample collection tube/ vials, urine/ stool containers and single-use/ AD syringes, syringe cutters etc., to be purchased locally are available in documented form.
4. Procurement orders are clear, dated, timed and signed in case of procurement by the collection center or documented evidence of supplies by the parent lab are maintained (review).
5. Documentary evidence/ inventory and consumption record for all consumables (purchased by the collection center or supplied by the lab) (review).

7.8. Standard 08: Safe handling and storage of collection center equipment and consumables

Compliance Requirements:

1. SOPs for the safe storage and use of sample collection containers and other consumables are available and practiced (review & observe).
2. Labelling of sample containers is as per SOP, including:
   A. Name of tube/ container (the purpose for which it is used) is evidenced (observe)
   B. Expiry date of the consumables as applicable is observed

7.9. Standard 09: Standard equipment management and maintenance system is practiced

Compliance Requirements:

A. Up-to-date logbooks of all equipment relevant to the services permissible at the collection center, e.g. refrigerator, centrifuge, UPS, etc., are maintained and relevant log sheet is displayed on each equipment (observe).
B. Break down/ preventive maintenance record as applicable, is documented and available (observe).
C. Contact number(s) for equipment maintenance are available (observe).

7.10. Standard 10: The collection center has a complete, accurate and confidential record for every patient

Compliance Requirements:

1. Every patient's investigation record has a unique identifier (review and observe).

2. The record provides an up-to-date and chronological account of each patient's record of tests (review and observe).
3. Evidence with time of collection and sending samples for test/analysis to the parent lab is documented (review and observe).
4. Documented evidence of receipt of test results from the parent lab (review).
5. Only authorized person makes entries in the collection center record is present (review and observe).
6. Every collection center record entry is dated and timed and the person making entries can be identified (interview and review).
7. Electronic/ computerized or hard copies of record of every patient is maintained for a minimum of 3 years (review).
8. Confidentiality of patients' record is maintained (interview).

7.11. Standard 11: The collection center record supports continuity of patient care

Compliance Requirements:

1. Minimum reporting for every test is defined/documented (review).
2. Evidence that the reporting time is compiled/test reports are issued as per defined time line (review).
3. Reports are issued to the advising/treating doctor/the individual patient/authorized person (as per ethical practices) only (review and observe).
4. In case of electronic reporting, test reports are preferably accessible to treating doctor/ individual patients through a specific QR code (review).
5. List of the test/ analysis conducted by the parent lab is displayed (review).
6. Particulars of the referral lab contracted by the parent lab for conducting specialized tests are maintained.
7. Collection center staff is aware of the system at the parent lab for reporting/ communicating critical result immediately to the advising health care practitioner/patient (interview).

7.12. Standard 12: The collection center practices the Quality Assurance programme deployed by the parent laboratory

Compliance Requirements:

1. The collection center has documented SOPs for QA as prescribed by the parent lab (review).
2. QA SOPs are communicated among the collection center staff (review & interview).
3. Assigning QA activities to the onsite In-charge of the collection center is documented (review).

7.13. Standard 13: The Parent laboratory ensures Quality Assurance through implementation of standardized practices for the collection center

Compliance Requirements:

1. SOPs for safe collection of specimens are practiced (observe).
2. SOPs for proper labelling of specimens are available and practiced (review & observe).
3. Identification of specimens is done as per prescribed SOPs (review & observe).
4. SOPs for safe handling of specimens are followed (observe).
5. SOPs for safe transportation of specimens are available and followed (review & interview)
6. SOPs for receipt and release of reports are practiced (review, interview & observe)
7. Corrective actions taken upon identification of gaps are documented (review)
8. Measures are taken to minimize recurrence of errors (review).
9. Policies and procedures guide the safe collection and disposal of clinical waste (review).

7.14. Standard 14: Sentinel events are intensively analyzed and corrective actions are taken to prevent recurrence

Compliance Requirements:

1. The collection center has defined sentinel events at a minimum as under (review):
   A. Collapsing of a patient during phlebotomy etc.
   B. Collection of wrong sample.
   C. Issuing wrong report/ irrelevant report.
   D. Patient violence against staff
   E. Staff violence against patients.
   F. Loss of a precious sample.
   G. Any unexpected fatassl incident
2. The evidence that the parent lab has conducted root cause analysis corrected the factors. The evidence that the parent lab has conducted root cause analysis corrected the factors

7.15. Standard 15: Collection center follows the biosafety SOPs prescribed by the parent Laboratory

Compliance Requirements:

1. Biosafety SOPs are available at the collection center (review).
2. Biosafety SOPs are communicated to the staff of the collection center (review & interview).
3. Biosafety requirements for collection of infectious samples like COVID 19 patients as prescribed by the parent lab are available and practiced (observe & review) if applicable.
4. The parent lab has designated the technician for ensuring biosafety activities at the collection center (review).
5. Quarterly Biosafety monitoring reports regarding the collection center are generated by the authorized technician/ person (review).

7.16. Standard 16: Biosafety measures for staff are ensured and documented

Compliance Requirements:

1. The collection center has appropriate consumables, equipment and facilities to ensure biosafety of the staff (observe)
2. All staff involved in the handling and disposal of clinical waste at the collection center shall receive Hep B vaccination (review).
3. Periodic screening/ medical check-up of all staff is ensured and the record is maintained (review)

7.17. Standard 17: Patient biosafety is ensured

Compliance Requirements:

1. Patients' waiting and sample collection area is properly ventilated (observe).
2. Patients are not allowed access to the technical working /sample storage area of the collection center (observe).

7.18. Standard 18: Documented procedure for Bio-risk management

Compliance Requirements:

1. All incident reports are documented (review).
2. Required disinfectants/ spill kits are available in the collection center (observe).

7.19. Standard 19: Biosecurity SOPs are practiced

Compliance Requirements:

1. Only authorized persons have access to the sample storage area of the collection center (observe).
2. Transportation of samples is as per documented SOPs and is properly recorded (review)

7.20. Standard 20: Waste management plan is implemented

Compliance Requirements:

1. Written SOPs for waste management related to the collection center are available (review)
2. Waste management SOPs are communicated to the collection center staff (review & interview)
3. Appropriate consumables, collection and handling systems and equipment for waste management at the collection center including the following are available
   A. Waste segregation in colored bags/bins (observe)
   B. Waste storage area (observe)
   C. Waste disposal plan (review)
4. Documented arrangement/ contract for waste disposal (review)
5. There is a record of waste transport SOPs from the collection center for final disposal (review).

7.21. Standard 21: Collection center services are easily accessible

Compliance Requirements:

1. Access into the collection centre is facilitated by providing steps / stairs / ramp(s) / lifts) as applicable (observe).
2. The following basic facilities are available /maintained in the collection centre (observe):
   A. Water supply
   B. Power supply with backup
   C. Hand washing facility
3. Clean toilets / washrooms with bolts
4. Key points / areas in the collection center e.g. waiting, sample collection / phlebotomy, storage and washroom etc are indicated by signage for the guidance of patients (observe).

7.22. Standard 22: Collection center services are provided as portrayed/claimed

Compliance Requirements:

1. The portrayal of services dearly indicate that the facility is a collection centre, as claimed in the application for registration/license submitted to the KPHCC (observe).
2. Services provided at the center only include collection, labelling, storage and transportation of samples to the parent lab and issuance of reports as per SOPs (observe).
3. The displayed services are available and provided at the collection center accordingly (observe)
4. Appropriate facilities to perform the services as portrayed, are available (observe)
5. The collection center does not undertake any test analysis of the samples (observe & interview)
6. The collection center does not attempt taking samples that mandate presence of a qualified medic, e.g. fine needle aspiration, ascetic or pleural tap, lumbar puncture, etc. (observe & interview).

7.23. Standard 23: A performance assessment system is practiced as

Compliance Requirements:

1. The Director /Pathologist from the main / parent lab or an authorized representative monitors the performance of the collection center staff against assigned responsibilities preferably on weekly basis, but at least once every two weeks (review).
2. Periodic Performance Assessment is done by assigned authorized rep of parent lab (review)
3. A copy of the performance monitoring/ assessment report, conducted as above, is available at the parent lab (review)

7.24. Standard 24: Protocol for management of patients in emergency are followed

Compliance requirements:

1. Protocols for providing first aid to the patients in case of emergency center including inter-alia the following are documented (review)
   A. the patient or an attendant may suffer syncope /cardiac arrest/ asthmatic attack /RDS during sample collection
   B. unusual bleeding of the patients on phlebotomy
2. ii. Arrangement for the basic life support measures including (BP, stethoscope, bandages etc)
3. Relevant contact numbers for emergency, evacuations/ referrals are available in the collection center (observe)

7.25. Standard 25: the collection center policies and procedures support domiciliary services to the patient (If applicable/claimed)

Compliance requirements:

1. The collection center has appropriate means of home-based sample collection and transportation to the parent lab (observe)
2. The response time for home-based sample collection call is documented and followed (review and interview)

7.26. Standard 26: A system for obtaining consent is in place when it is required

Compliance requirements

1. List of situations when specific informed consent is required
2. The policy describes who can give consent when the patient is incapable of independent decision making
3. Evidence that informed consent is taken when needed (review, interview and observe)

7.27. Standard 27: Patient and families have a right to information on expected costs

Compliance requirements

1. The tariff list is available to patients and the patients are upfront informed about the cost of tests/ analysis (review and observe).
2. Patients and families are informed about the additional reports that are generate4d/ include in the report with the same sample and cost if applicable (review)

7.28. Standard 28: Patient and families have a right to complain and there is a mechanism to address the grievances

Compliance requirements

1. Patients complaints are accepted by the collection center and properly registered and forwarded to the parent lab as relevant
2. Relevant information for the client, as depicted in annexure Viii is displayed at the collection center (observe)
3. Contact number of the complaint cell/ relevant person in the parent lab is displayed
4. The parent lab has an easy feedback mechanism (interview/review)
5. Complaints register/box for receiving grievances /client is maintained at the collection center and handled by the relevant person of the parent lab
6. Proper actions and remedial measures are taken by the collection centers / parent lab in response to patient's complaints (review).

SECTION – 3 Checklist for MSDS of Clinical Laboratories and Collection Points for Licensing

Annexure – A: Checklist for MSDS of Clinical Laboratories for Licensing

Laboratories applying for licensing must have the following with application package. Without these documents the application will not be entertained and processed.

1. Academic qualifications of pathologists including MBBS (RMP) with a post graduate degree (MPhil, PhD, FCPS, MRCPath, FRCPath) in any branch of pathology duly recognized by PMC/HEC recognized university (for Category A, B and C labs). Laboratories in remote districts of KP where Category D labs are allowed to work as per the Lab MSDS for a specified time period, an MBBS (RMP) with a post graduate course completion certificate of MPhil, PhD, FCPS, MRCPath, FRCPath in any branch of pathology duly recognized by PMC/HEC recognized university will be accepted.
2. The name of the owner and qualified pathologist must be provided.
3. Academic qualifications of laboratory staff and administration staff.
4. List of all staff members in tabulated form with qualifications.
5. CNIC of all staff members.
6. Filled form for licensing of clinical laboratories.

TORs for Scoring of Checklist:

1. There are 29 standards and 104 indicators for MSDS of clinical laboratories.

2. Each table is specified for a standard and relevant indicator.

3. Standards will be mandatory without which license will be not be granted.

4. Scoring criteria:

There are three grades for scoring

- **A. FULLY MET:** When standard is completely achieved for a specific indicator. It is scored as 10 marks.
- **B. PARTIALLY MET:** When standard is partially achieved for a specific indicator. It is scored as 5 marks.
- **C. NOT MET:** When standard is not achieved for a specific indicator. It is scored as zero mark.
- **D. NOT APPLICABLE:** When standard or indicator might not be applicable. Thus, the score will be accordingly adjusted.

5. For marking of individual standard, the following formula is used

- **A.** Marks in standard = Total score of indicators in a specific standard x weightage of standard

6. The grading of lab will determine by percentage ;

- **B.** Grading of lab = Obtain Marks in Standards x 100/ Max Marks in Standards

7. Interpretation of Grading of Lab

Grade of Lab	Average standards %	Inspection Recommendation	Licensing
A	>80	Next inspection may be carried out after 05 years	Regular
B	60 to 80	Next inspection may be carried out within 6 months	Conditional
C	<60	No further inspection till re-application for license	Suspension of License
KPHCC conduct of business regulations 2016 shall apply.			

Standards	Area of Concern	Max Score	Total score of indicators of standard	Weightage factor (out of 104)	Max Marks in Standards	Obtain Marks in Standards	%age with Grade
Standard 1	Registration and display	100		3	300		
Standard 2	Scope of services	80		7	560		
Standard 3	Technical head	40		5	200		
Standard 4	Responsibilities of management	160		2	320		
Standard 5	Facility management regulations	40		2	80		
Standard 6	Facility design	60		2	120		
Standard 7	Facility safety for fire and non-fire emergencies	170		3	510		
Standard 8	Human resource is in accordance with scope of work	40		2	80		
Standard 9	Human resource orientation	40		2	80		
Standard 10	Human resource personal record	20		3	60		
Standard 11	Quality of equipment and reagents ensured	40		6	240		
Standard 12	Safe handling and storage of laboratory reagents	40		3	120		
Standard 13	Equipment management and maintenance	50		6	300		
Standard 14	Recording system for every patient	40		3	120		
Standard 15	Reporting system in the lab	50		3	150		
Standard 16	Quality Assurance	50		6	300		
Standard 17	External Quality Assurance	20		3	60		
Standard 18	Internal Quality Assurance	140		6	840		
Standard 19	Biosafety program	60		6	360		
Standard 20	Staff biosafety ensured	30		4	120		
Standard 21	Patient biosafety ensured	20		3	60		
Standard 22	Documented bio-risk management	30		3	90		

Standard 23	Biosecurity	30		3	90		
Standard 24	Waste Management Plan	70		3	210		
Standard 25	Accessible laboratory services	70		3	210		
Standard 26	Care of Patients	40		3	120		
Standard 27	Patient Rights on consent	20		3	60		
Standard 28	Right to information on costs of tests offered	40		3	120		
Standard 29	Patient's rights for appeals, complaints and confidentiality	40		3	120		
	Total	**1630**		**104**	**6000**		

Standards	**Area of Concern**	**Fully Met** (10 marks)	**Partially Met** (05 marks)	**Not Met** (zero marks) /Not Applicable	**Total Score of indicators in standard**
Standard 1	**Registration and display**				
Ind 1	**The laboratory is identifiable with name on a sign board.**				
	Sign board clearly displaying the name of the laboratory or the collection center, as the case may be.				
	Sign board/s placed appropriately for clear visibility.				
Ind 2	**The laboratory sign board conforms to the prescribed local legal standards.**				
	Sign board size should conform to the local legal standards.				
	Sign board fixation should conform to the local legal/technical/safety standards.				
Ind 3	**The laboratory is licensed/registered with the KPHCC.**				
	KPHCC Registration/License number is clearly displayed on the sign board or separately.				
	Registration Certificate/License with the KPHCC displayed at a prominent place inside the laboratory.				
	A copy of PMC/HEC/institutional affiliation of the technical head placed at a prominent place inside the laboratory.				
Ind 4	**Associated collection centers are reflected in the Registration /License Certificate issued by the KPHCC**				
	Registration Certificate/License of the laboratory is linked with serial				

	numbers of the collection center/s e.g. (CL#/CC#).				
	Evidence of having applied for licensure in case it is not licensed.				
Ind 5	**Signed and valid MOU, showing linkage with any other laboratory or organization for referral of specialized tests, exists**				
	Written and valid MOU signed with the referral laboratory which fulfills the above requirements.				

Standards	Area of Concern	Fully Met (10 marks)	Partially Met (05 marks)	Not Met (zero marks) /Not Applicable	Total Score of indicators in standard
Standard 2	**Scope of services**				
Ind 6	**Routine clinical laboratory services shall be supervised by a technical head with MBBS (RMP) and a post graduate degree (MPhil, PhD, FCPS, MRCPath, FRCPath) in any sub-specialty of pathology duly recognized by PMC/HEC recognized university. These include:**				
	Routine Hematology (CBC, ESR, Reticulocyte count, MP, BT, CT, PT, APTT, INR).				
	Routine Chemical Pathology (Blood Glucose, Electrolytes, Urea, Creatinine, Bilirubin, ALT, ALP, Cholesterol, Urinalysis, Fecal Analysis).				
	Routine Microbiology (RAT).				
Ind 7	**Advanced clinical laboratory services shall be supervised by a technical head with MBBS (RMP) and a post graduate degree in any sub-specialty of pathology (MPhil, PhD, FCPS, MRCPath, FRCPath), duly recognized by PMC/HEC recognized University, such as:**				
	Advanced Hematology (Peripheral smear, Bone Marrow Examination, Coagulation Studies, Blood Banks)				
	Electrophoresis, ELISA, Flow Cytometry, Genotyping, Immunology, Molecular Biology. Molecular Pathology.				
	Advanced Chemical Pathology (Fluid RE, CMIA, Clinical Endocrinology, ELISA)				
	Advanced Microbiology (Culture and Sensitivity, ELISA, PCR).				
	Histopathology (Biopsies, FNAC, Frozen Sections, Special staining, IHC, FISH, CISH).				

Standards	Area of Concern	Fully Met (10 marks)	Partially Met (05 marks)	Not Met (zero marks) /Not Applicable	Total Score of indicators in standard
Standard 3	**Technical head**				
Ind 8	**Head of the Department**				
	The Head of department shall be MBBS (RMP) with a post graduate degree (MPhil, PhD, FCPS, MRCPath, FRCPath) in any branch of pathology duly recognized by PMC/HEC recognized university (for Category A, B and C labs)				
	Laboratories in remote districts of KP where Category D labs are allowed to work for a specified time period, however the head of department shall be MBBS (RMP) with a post graduate course completion certificate of MPhil, PhD, FCPS, MRCPath, FRCPath etc in any branch of pathology duly recognized by PMC/HEC recognized university				
Ind 9	**Section Head**				
	For sub sections of the clinical laboratory such as Microbiology, Histopathology, Chemical Pathology, Hematology, etc., the Technical Head shall be MBBS (RMP) with a post graduate degree (MPhil, PhD, FCPS, MRCPath, FRCPath) in the relevant branch of pathology duly recognized by PMC/HEC recognized university. Section head will only be applicable for category A laboratories.				
Ind 10	**Number of laboratories per Technical Head**				
	One technical head can supervise not more than two laboratories provided that the distance between these two laboratories is justified.				

Standards	Area of Concern	Fully Met (10 marks)	Partially Met (05 marks)	Not Met (zero marks) /Not Applicable	Total Score of indicators in standard

Standard 4	**Responsibilities of management**				
Ind 11	**Laboratory's mission statement is properly laid down**				
	Documented mission statement that fulfills the above requirements.				
	Mission statement is displayed for the staff and patients to view.				
Ind 12	**Detailed laboratory policy and standard operating procedures (SOPs) are laid down.**				
	Written laboratory policy and SOPs are available.				
	Evidence of involvement of senior leadership, including those involved in the laboratory's management, in the process of developing policy and SOPs.				
	Staff is aware of the laboratory policy and SOPs.				
Ind 13	**SOPs of Emergency laboratory policy are laid down.**				
	Written laboratory emergency policy and SOPs covering the above requirements are available.				
	The emergency policy and SOPs are available to the staff or patients for consultation.				
Ind 14	**Sufficient laboratory budget and resources are allocated.**				
	Adequate laboratory spaces are allocated for the required activities.				
	The staff, equipment and consumables remain available to support the scope of laboratory services as evidenced from the stock register and incumbency record/duty roster.				
	There is no evidence of delay in reporting the test results on account of non-availability of equipment, kits/reagents or the concerned staff.				
Ind 15	**Laboratory's organogram is established.**				
	The organogram is approved and documented.				
	The organogram is displayed for patients and the staff.				
Ind 16	**Section heads are appointed.**				
	Section heads for each section of the laboratory are appointed.				

	Evidence of adopting due process for appointing section heads exist.				
Ind 17	Research activities are supported and collaborations are established.				
	Compilation of disease related data/research and its sharing with relevant authorities/research organizations while ensuring patient confidentiality is supported and recorded.				
	Support is provided to universities and other organizations who intend to collaborate for research purposes.				

Standards	Area of Concern	Fully Met (10 marks)	Partially Met (05 marks)	Not Met (zero marks) /Not Applicable	Total Score of indicators in standard
Standard 5	**Facility management regulations**				
Ind 18	**The management is aware of the specific space requirement for the lab**				
	Copies of current/updated design of space.				
	Laboratory staff is aware of the space design and knows how those relate to their functioning.				
Ind 19	**The management regularly updates any amendments in the prevailing relevant laws and rules**				
	Evidence that a process to keep the relevant laws, regulations and rules properly updated is adopted.				
Ind 20	**The management ensures implementation of these requirements.**				
	Evidence that the relevant laws, regulations and rules are properly implemented, for example: Implementation of waste management is in such a way that all key requirements are clearly observable. Compliance of the building and fire safety requirements, etc.				

Standards	Area of Concern	Fully Met (10 marks)	Partially Met (05 marks)	Not Met (zero marks) /Not Applicable	Total Score of indicators in standard
Standard 6	**Facility design**				

Ind 21	**The management is aware of the specific space requirement for the lab.**				
	Copies of current/updated design of space are available.				
Ind 22	**Laboratory staff is aware of the space design and knows how those relate to their functioning.**				
	Facility design conforms to the scope of services.				
	The Laboratory includes designated spaces and sections for: Reception/Reporting Phlebotomy Patient/Staff Washroom Patient Waiting Area Separate Working Stations Offices Inventory Store				
Ind 23	**Safe environment for patients and the staff**				
	Effective separation between administrative and technical laboratory areas exists.				
Ind 24	**Measures are taken to restrict movement of the technical staff working in different sections of the laboratory:**				
	Staff wears the identity badges during duty.				
	Written SOPs for the staff regarding exiting the workplace for any interaction with patient/ client are available. The SOPs are displayed at the exit/ entry point of each section.				

Standards	**Area of Concern**	**Fully Met** (10 marks)	**Partially Met** (05 marks)	**Not Met** (zero marks) /Not Applicable	**Total Score of indicators in standard**
Standard 7	**Facility safety for fire and non-fire emergencies**				
Ind 25	**The laboratory has plans for fire and non-fire emergencies within the sections.**				
	Plans and provisions for early detection of fire and non-fire emergencies exist.				
	The plan addresses the requirement of early detection of fire and non-fire emergencies.				
	Resources are allocated to detect the above emergency situations at an early stage as laid out in the plan, e.g.: Smoke detector/s.				

	Monitoring through CCTV cameras. Trained staff physically deployed to ensure the required outcome.				
	The staff is aware of the plan.				
Ind 26	**Provisions for prevention of fire and non-fire emergencies exist.**				
	An environment which has a lesser chances of occurrence of fire and non-fire emergencies is ensured: There is no loose electric wiring to cause short circuiting. No loose plugs and sockets which can spark. No power cord/s that is/are worn out to cause electrocution. Ramps, if they exist, are non-slippery. Stairs have supporting rails etc. Building meets the local construction standards.				
Ind 27	**Provisions for containment of fire emergencies exist.**				
	Water source				
	Sand buckets				
	Shovel				
	Fire extinguisher/s				
	Fire blankets				
Ind 28	**Safe entry/ exit points in case of fire and non-fire emergencies exist.**				
	Emergency exit points with 24/7 illuminated sign board/s are displayed as required.				
	The emergency exits are not obstructed at any time.				
	Staff is aware of the emergency exits.				
Ind 29	**Mock drills are held at least once in a year.**				
	Record of mock drills/attendance.				
	Record confirms that all staff was subjected to the mock drill.				
	Record of corrective actions taken after mock drills.				
Ind 30	**Staff members are trained for their role in case of such emergencies.**				
	Record that confirms participation of at least the key staff from each shift.				

Standards	Area of Concern	Fully Met (10 marks)	Partially Met (05 marks)	Not Met (zero marks) /Not Applicable	Total Score of indicators in standard
Standard 8	**Human resource is in accordance with scope of work**				
Ind 31	**Job description for every post is identified and documented**				
	Documented individual job descriptions.				
	Job descriptions are signed by the employer and the concerned employee.				
Ind 32	**An eligibility criterion of qualification and experience for each job is available.**				
	Documentary evidence of qualified staff is available				
Ind 33	**Recruitments are made according to the laid down eligibility criteria.**				
	All appointments are according to eligibility criteria				

Standards	Area of Concern	Fully Met (10 marks)	Partially Met (05 marks)	Not Met (zero marks) /Not Applicable	Total Score of indicators in standard
Standard 9	**Human resource orientation**				
Ind 34	**An appropriate orientation plan exists for the newly inducted employees.**				
	Written orientation plan covering the following: General laboratory working Safety Biosafety Quality assurance SOPs Specific techniques/tasks assigned to the individual employees				
Ind 35	**Each staff member is made aware of laboratory wide policies and procedures as well as section/unit/service/program specific policies and procedures**				
	Written record of level specific orientation sessions conducted for all staff covering: Laboratory wide policy and procedures (general SOPs). Section/Unit/Service/Program specific policies and procedures.				
Ind 36	**Each staff member is made aware of his/her rights and responsibilities.**				
	Written job contract having clear description of employee rights and responsibilities.				
Ind 37	**All employees are educated about patients' rights and responsibilities.**				

	Written record of orientation sessions conducted for all staff regarding patients' rights and responsibilities.				

Standards	Area of Concern	Fully Met (10 marks)	Partially Met (05 marks)	Not Met (zero marks) /Not Applicable	Total Score of indicators in standard
Standard 10	**Human resource personal record**				
Ind 38	**Personal files are maintained in respect of all full time/part time employees**				
	Personal files of all employees having the following information are maintained: Employee's contract showing date of employment Copies of qualifications like degrees/diplomas/transcripts Laboratory personnel's licenses (registration where required) Training and experience Records of continuing education Job description Disciplinary background Evaluation reports Health status, etc.				
Ind 39	**In-service training plan for staff members is available**				
	Documented plan showing listing of staff including all categories for in-service trainings/capacity building.				

Standards	Area of Concern	Fully Met (10 marks)	Partially Met (05 marks)	Not Met (zero marks) /Not Applicable	Total Score of indicators in standard
Standard 11	**Quality of equipment and reagents ensured**				
Ind 40	**The procurement procedure of the laboratory is laid down.**				
	Documented procurement SOPs to comply with the rules/regulations.				
Ind 41	**Specifications for all the equipment and reagents/kits/consumables to be purchased are documented.**				
	Documented procurement SOPs to comply with the rules/regulations				
Ind 42	**Procurement orders are clear, dated and signed.**				
	Clear, dated and signed procurement orders are ensured.				
Ind 43	**Procured items are regularly entered into stock registers.**				

	Stock registers are maintained.				

Standards	Area of Concern	Fully Met (10 marks)	Partially Met (05 marks)	Not Met (zero marks) /Not Applicable	Total Score of indicators in standard
Standard 12	**Safe handling and storage of laboratory reagents**				
Ind 44	**Policies and procedures for safe storage and use of reagents are documented.**				
	Written SOPs which guide safe storage and use of reagents. Issuance and usage are done as per SOPs.				
Ind 45	**Inventory of reagents is maintained**				
	Inventory of stored reagents is updated.				
Ind 46	**The policies of reagent management include a procedure of alert for near expiry reagents.**				
	Availability of written SOPs for creating an alert about any item which has an expiry date of one month.				
Ind 47	**Labeling of reagents is as per SOPs**				
	The labels must bear the following: Full name of the chemical/reagent Concentration (strength) Date of manufacturing/issuing (as applicable) Date of expiry				

Standards	Area of Concern	Fully Met (10 marks)	Partially Met (05 marks)	Not Met (zero marks) /Not Applicable	Total Score of indicators in standard
Standard 13	**Equipment management and maintenance**				
Ind 48	**Log books of all equipment are available**				
	Availability of updated log books				
Ind 49	**Regular periodic maintenance and calibration record of all the equipment is documented in the log books**				
	The log books contain record of any breakdowns, repairs and maintenance.				
Ind 50	**A Log sheet is displayed on each equipment**				
	A log sheet, containing record of last repair/maintenance as well as due date of next calibration, is displayed on the equipment.				
Ind 51	**Emergency contact number/s is/are displayed on all equipment**				

	Emergency contact number of the technician or the firm for emergency management of equipment breakdown is displayed on the equipment.				
Ind 52	**Equipment inventory is maintained**				
	Availability of equipment inventory showing: Date of purchase It source (manufacturer / importer / distributor / vendor) Date of commissioning (date of first operation) Date/s of calibration				

Standards	Area of Concern	Fully Met (10 marks)	Partially Met (05 marks)	Not Met (zero marks) /Not Applicable	Total Score of indicators in standard
Standard 14	**Recording system for every patient**				
Ind 53	**Electronic record of every patient is maintained.**				
	Computerized laboratory record of all tests conducted is available.				
Ind 54	**Every laboratory record has a unique identifier.**				
	Use of unique identifier numbers for each patient is ensured.				
Ind 55	**History of each patient's record of tests is present.**				
	Patient's record is chronological and up to date.				
Ind 56	**Only authorized person shall make entries in the laboratory record.**				
	Written authorization of the relevant staff for data entry is ensured and he can be identified from his ID.				

Standards	Area of Concern	Fully Met (10 marks)	Partially Met (05 marks)	Not Met (zero marks) /Not Applicable	Total Score of indicators in standard
Standard 15	**Reporting system in the lab**				
Ind 57	**A computerized reporting system is available.**				
	Availability of a computerized reporting system.				
	All reports to bear digital/manual signatures/name of the authenticating pathologist.				
Ind 58	**Critical results and notifiable diseases are reported.**				
	Critical results are reported to the concerned consultant/client immediately.				

	All notifiable disease reports are submitted to concerned authorities.				
Ind 59	**Minimum reporting time for every test is documented**				
	The minimum reporting time for every test is documented and displayed for the information of patients/clients.				

Standards	Area of Concern	Fully Met (10 marks)	Partially Met (05 marks)	Not Met (zero marks) /Not Applicable	Total Score of indicators in standard
Standard 16	**Quality Assurance**				
Ind 60	**The laboratory has documented QA SOPs**				
	Written SOPs on laboratory QA covering both IQA and EQA components.				
Ind 61	**Designated focal person responsible for QA in the laboratory.**				
	Designation of a focal person with clear responsibilities regarding QA in the laboratory is ensured.				
Ind 62	**QA SOPs are communicated and coordinated among the staff**				
	Written SOPs on laboratory QA covering both IQA and EQA components.				
	Documentary evidence of staff orientation on SOPs.				
	Staff orientation is ensured through an interview.				

Standards	Area of Concern	Fully Met (10 marks)	Partially Met (05 marks)	Not Met (zero marks) /Not Applicable	Total Score of indicators in standard
Standard 17	**External Quality Assurance**				
Ind 63	**EQA of the laboratory is ensured through external assessment.**				
	EQA registration during last one year is available				
Ind 64	**Record of EQA reports is maintained.**				
	EQA report during last one year is available				

Standards	Area of Concern	Fully Met (10 marks)	Partially Met (05 marks)	Not Met (zero marks) /Not Applicable	Total Score of indicators in standard
Standard 18	**Internal Quality Assurance**				
Ind 65	**Policies and procedures guide the safe collection of specimens.**				
	SOPs for safe collection of specimens are available.				

	Evidence of implementation of the above SOPs.				
Ind 66	**Policies and procedures guide the identification and proper labeling of specimens.**				
	SOPs for patient identification and labeling of specimens are available.				
	Evidence of implementation of the above SOPs.				
Ind 67	**Policies and procedures guide the safe handling of specimens.**				
	SOPs for safe handling of specimens are available.				
	Evidence of implementation of the above SOPs.				
Ind 68	**Policies and procedures guide the safe transportation of specimens.**				
	SOPs for safe internal and external transportation of specimens are available.				
	Evidence of implementation of the above SOPs.				
Ind 69	**Policies and procedures guide the safe processing of specimens**				
	SOPs for safe processing of specimens are available.				
	Evidence of implementation of the above SOPs.				
Ind 70	**Policies and procedures guide the safe disposal of specimens**				
	SOPs for safe disposal of specimens are available.				
	Evidence of implementation of the above SOPs.				
Ind 71	**Availability of controls for IQA is ensured**				
	Controls are available for IQA.				
	Controls are used for IQA as per technical instructions.				

Standards	**Area of Concern**	**Fully Met** (10 marks)	**Partially Met** (05 marks)	**Not Met** (zero marks) /Not Applicable	**Total Score of indicators in standard**
Standard 19	**Biosafety program**				
Ind 72	**Availability of laboratory Biosafety SOPs.**				
	Documented laboratory Biosafety SOPs are available.				
Ind 73	**Biosafety SOPs are communicated to the laboratory employees.**				
	Record confirms that copies of written Biosafety SOPs are provided to the laboratory employees.				
	Record confirms that the staff was trained to implement these SOPs.				

Ind 74	**The laboratory has a designated qualified technician for ensuring Biosafety activities.**				
	Evidence of designation of a qualified technician for ensuring Biosafety activities.				
Ind 75	**Regular Biosafety monitoring reports are generated in the laboratory.**				
	Record of monthly Biosafety monitoring reports prepared by the designated technician is available.				
	The above reports are submitted to the laboratory head on a regular basis.				

Standards	Area of Concern	Fully Met (10 marks)	Partially Met (05 marks)	Not Met (zero marks) /Not Applicable	Total Score of indicators in standard
Standard 20	**Staff biosafety ensured**				
Ind 76	**The laboratory has appropriate consumables, equipment and facilities to ensure Biosafety.**				
	Availability of required PPE is ensured.				
Ind 77	**All staff involved in the handling and disposal of laboratory waste receives regular vaccination.**				
	Record of vaccination of staff at risk of Hepatitis B and other exposures is available.				
Ind 78	**Annual medical check-up of all staff is documented.**				
	Record of annual medical checkup of all staff involved in handling of bio hazardous laboratory material is available.				

Standards	Area of Concern	Fully Met (10 marks)	Partially Met (05 marks)	Not Met (zero marks) /Not Applicable	Total Score of indicators in standard
Standard 21	**Patient biosafety ensured**				
Ind 79	**Properly ventilated waiting areas for patients are available.**				
	Effective ventilation either naturally or by means of exhaust fan/s.				
Ind 80	**Patients are not allowed inside the laboratory working area.**				
	Evidence of controlled entry into the laboratory working area.				

Standards	Area of Concern	Fully Met (10 marks)	Partially Met (05 marks)	Not Met (zero marks) /Not Applicable	Total Score of indicators in standard
Standard 22	**Documented bio-risk management**				
Ind 81	**All incident reports are documented.**				
	Record of reporting the incidents which breached laboratory Biosafety is available along with action/s taken on such an event.				
Ind 82	**Required disinfectants/spill kits are available in the laboratory.**				
	Availability of required disinfectants/spill kits in the laboratory is ensured.				
	Record of regular use of the above is available.				

Standards	Area of Concern	Fully Met (10 marks)	Partially Met (05 marks)	Not Met (zero marks) /Not Applicable	Total Score of indicators in standard
Standard 23	**Biosecurity**				
Ind 83	**Only authorized persons are permitted to enter the sample storage area.**				
	Only authorized persons are permitted to go to the sample storage area.				
	The above authorized personnel are identifiable through an ID.				
Ind 84	**Any transportation of samples is properly recorded**				
	Record of samples transported to other labs, if any, is available.				

Standards	Area of Concern	Fully Met (10 marks)	Partially Met (05 marks)	Not Met (zero marks) /Not Applicable	Total Score of indicators in standard
Standard 24	**Waste Management Plan**				
Ind 85	**Laboratory waste management SOPs**				
	Written laboratory waste management SOPs are available				
Ind 86	**Waste management SOPs are communicated to the laboratory employees.**				
	Copies of the lab waste management SOPs are provided to the laboratory employees.				
	Laboratory employees are conversant with the lab waste management SOPs.				
Ind 87	**The laboratory has appropriate consumables, collection and handling systems and equipment for waste management.**				

	Color coded bags and bins are available				
	Waste disposal mechanism is available				
Ind 88	**Contracts with waste disposal service organizations are available**				
	Written contract with waste disposal services is available if the lab does not dispose off the hazardous waste through an onsite mechanism.				
Ind 89	**Waste transported from collection centers for final disposal is recorded.**				
	Record in terms of weight, time and date, of risk waste for offsite final disposal.				

Standards	Area of Concern	Fully Met (10 marks)	Partially Met (05 marks)	Not Met (zero marks) /Not Applicable	Total Score of indicators in standard
Standard 25	**Accessible laboratory services**				
Ind 90	**The laboratory's location is easily accessible.**				
	Laboratory's location is easily accessible through an easy map.				
	Laboratory can be accessed round the clock.				
Ind 91	**Basic facilities are available in the laboratory.**				
	The following should be available at the least: Clean water supply. Power supply with backup.				
Ind 92	**There are clean toilets/washrooms with bolts**				
	Cleanliness is ensured.				
	Privacy is ensured.				
Ind 93	**Disabled patients are facilitated for phlebotomy.**				
	Disabled persons can easily reach the phlebotomist or they can come to them.				
Ind 94	**Directional arrows pointing towards various important areas for patients are displayed in the laboratory.**				
	Directional arrows pointing towards at least the following: Sample collection area Report collection area Toilets				

Standards	Area of Concern	Fully Met (10 marks)	Partially Met (05 marks)	Not Met (zero marks) /Not Applicable	Total Score of indicators in standard
Standard 26	**Care of Patients**				
Ind 95	**Protocols for providing first aid/emergency care to the patients are documented**				
	SOPs to manage emergency conditions as mentioned above are available.				
	Staff is conversant and trained with the SOPs.				
Ind 96	**Relevant contact numbers for emergency evacuation/referral are available in the laboratory**				
	List of contact numbers of the following for use in emergency is displayed: Nearest referral hospitals/clinics Rescue 1122 Other ambulance services Police Station Fire Brigade NGOs/CBOs etc. operating in the area				
Ind 97	**The laboratory has defined sentinel events**				
	Laboratory has defined sentinel events and a written definition is available. List of possible sentinel events is; all unexpected deaths, any anaphylactic reaction/collapsing of a patient during obtaining of sample (blood sample), wrong reporting carrying a potential life risk, patient violence against staff, staff violence against patients. loss of a precious sample. Look to see if the system analyses the root cause and associated factors that contributed to the event.				

Standards	Area of Concern	Fully Met (10 marks)	Partially Met (05 marks)	Not Met (zero marks) /Not Applicable	Total Score of indicators in standard
Standard 27	**Patient Rights on consent**				
Ind 98	**The laboratory has listed those situations where specific informed consent is required**				
	A list of situations requiring informed consent is available.				
Ind 99	**The policy describes who can give consent when a patient is incapable of independent decision-making.**				
	Written directions about the person who can give consent when a patient is incapable of independent decision- making for providing informed consent are available.				

Standards	Area of Concern	Fully Met (10 marks)	Partially Met (05 marks)	Not Met (zero marks) /Not Applicable	Total Score of indicators in standard
Standard 28	**Right to information on costs of tests offered**				
Ind 100	**Patients and families have a right to information on expected costs and**				
	The rate list of tests should be available for review by patients.				
	Patients/clients are informed about the rates of the required tests before they can decide on the testing.				
Ind 101	**Patients/families are informed about additional reports which are generated/ included in the report with the same sample and cost.**				
	Clients are informed about additional reports possible in a cost effective package.				
	The above information is provided by a doctor or a qualified and authorized lab technician.				

Standards	Area of Concern	Fully Met (10 marks)	Partially Met (05 marks)	Not Met (zero marks) /Not Applicable	Total Score of indicators in standard
Standard 29	**Patient's rights for appeals, complaints and confidentiality**				
Ind 102	**Patient's complaints are accepted by the laboratory and properly registered.**				
	A complaint register/record is maintained.				
	A complaint box is affixed in the patient waiting area.				

Ind 103	**Proper actions and remedial measures are taken in response to patients' complaints**				
	Record of actions taken on the complaint is available.				
Ind 104	**Confidentiality of patient record is maintained.**				
	Only the authorized personnel have access to patient related information.				

Annexure – B: Checklist for collection center Licensing

TORs for Scoring of Checklist:

1. There are 28 standards for collection center.
2. **Scoring Criteria:** There are three grades for scoring
   - **A. FULLY MET:** When standard is completely achieved for a specific indicator. It is scored as 10 marks.
   - **B. PARTIALLY MET:** When standard is partially achieved for a specific indicator. It is scored as 5 marks.
   - **C. NOT MET:** When standard is not achieved for a specific indicator. It is scored as zero mark.
   - **D. NOT APPLICABLE:** When standard or indicator might not be applicable. Thus, the score will be accordingly adjusted.
3. For marking of individual standard, the following formula is used
   - **A.** Marks in standard = Total score of indicators in a specific standard x weightage of standard
4. The grading of lab will determine by percentage ;
   - **B.** Grading of lab = Obtain Marks in Standards x 100/ Max Marks in Standards

Interpretation of Grading of Collection Centre

Grade of Lab	Average standards %	Inspection Recommendation	Licensing
A	>80	Next inspection may be carried out after 05 years	Regular
B	60 to 80	Next inspection may be carried out within 6 months	Conditional
C	<60	No further inspection till re-application for license	Suspension of License
KPHCC conduct of business regulations 2016 shall apply.			

Standards	Max Score	Total score of Compliance Requirement	Weightage factor (out of 100)	Max Marks in Standards	Obtain Marks in Standards	Percentage with Grade
Standard 1	30		3	90		
Standard 2	40		7	280		
Standard 3	70		5	350		
Standard 4	60		2	120		
Standard 5	50		2	100		
Standard 6	70		2	140		
Standard 7	50		3	150		
Standard 8	20		2	40		
Standard 9	30		2	60		
Standard 10	80		3	240		
Standard 11	70		6	420		
Standard 12	30		3	90		
Standard 13	90		6	540		
Standard 14	20		3	60		
Standard 15	50		3	150		
Standard 16	30		6	180		
Standard 17	20		3	60		
Standard 18	20		5	100		
Standard 19	20		6	120		
Standard 20	50		4	200		
Standard 21	40		3	120		
Standard 22	60		3	180		
Standard 23	30		3	90		
Standard 24	30		3	90		
Standard 25	20		3	60		
Standard 26	30		3	90		
Standard 27	20		3	60		
Standard 28	60		3	180		
	1190		**100**	**4360**		

Annexure-C: List of Contributors

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The Khyber Pakhtunkhwa Health Care Commission (KP HCC) has the legal mandate (Khyber Pakhtunkhwa Health Care Commission Act, 2015) to regulate the health care services in both public and private sectors in the province. The objective is to improve and maintain quality of healthcare, and ensure safety of patients and healthcare providers. The Health Care Establishments (HCEs) are assessed against set standards for this purpose. It is mandatory for the HCEs, including primary, secondary and tertiary levels to acquire license from the KP HCC through the implementation of the Minimum Service delivery Standards.

Khyber Pakhtunkhwa Health Care Commission

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