



## MINIMUM SERVICE DELIVERY STANDARDS REFERENCE MANUAL





KP HCC-08RM-Ed1



1<sup>st</sup> Edition

# Minimum Service Delivery Standards REFERENCE MANUAL

**Collection Centres of Clinical Laboratories** 

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## Message from Chairman

Aristotle stated, "Quality is not an act, it is a habit." In order to ensure that quality in the health care sector becomes a habit, the government established the Khyber Pakhtunkhwa Health Care Commission (KP HCC) through the Khyber Pakhtunkhwa Health Care Commission Act, 2015. The KP HCC is a statutory



body of the Government of Khyber Pakhtunkhwa to regulate both public and private Health Care Establishments (HCEs) in the province.

Prior to 2015 the private health institutions including hospitals, nursing homes, maternity homes, medical & dental clinics, blood banks, clinical laboratory, x-ray clinics and operation theaters etc. were registered under the Medical and Health Institutions and Regulation of Health Care Services ordinance 2002 (Amendment Act, 2010), which was subsequently repealed through the Act of 2015.

The legal mandate of KP HCC is to regulate the health care services on sound and technical footings in the public and private sectors, make provisions for safe and high quality health care services to the people of Khyber Pakhtunkhwa, and to provide mechanism for banning quackery in all its forms and manifestations.

The Government of Khyber Pakhtunkhwa through the Health Care Commission is committed to improve and maintain the quality of health care. The KP HCC is already registering the various types of Health Care Establishments. The other mechanism to ensure optimum level of safety and quality is the framework of clinical governance. To achieve this end the KP HCC initiated the process of licensing of Health Care Establishments.

The former Board of the KP HCC strived very hard and visited the sister organizations in the other provinces for experience sharing. In order to save energies and resources, the Board adopted the Minimum Service Delivery Standards (MSDS) of the Punjab Healthcare Commission (PHC). I, on behalf of the Board and Khyber Pakhtunkhwa Health Care Commission, am very grateful for support provided by PHC in this regards.

The journey of ensuring quality is not easy and assistance of various stakeholders is required. I would specifically mention the all-out support of the Government of Khyber Pakhtunkhwa and especially the Minister for Health and Secretary to the Government of Khyber Pakhtunkhwa, Health Department. Without their support, initiation of licensing of the HCEs to ensure quality was not possible.

I would take this opportunity to reach out to all the health acre establishments to get themselves registered with KP HCC and implement the Minimum Service delivery Standards in their respective establishments to achieve the required quality of health care and get a license to function. Providing health care without getting license from KP HCC is illegal and may lead to legal consequences, including, but not limited to, closure of the facility.

Dr. Ikram Ghani Chairman, Board of Commissioners

### 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.

The former Board of Khyber Pakhtunkhwa Healthcare Commission took the right decision and 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.

Subsequent to adoption, appropriate amendments were required to adapt the MSDS to the local context and legal provisions of Khyber Pakhtunkhwa. This was a challenging assignment and despite shortage of staff, KP HCC made the required amendments, utilizing its internal resources. I would like to thank the former Board of KP HCC for its wholehearted effort towards improving the quality of healthcare through adoption of 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. Moreover, I am highly grateful to Dr. Shabnum Gul, Director Licensing, KP HCC for her contribution during the process of adaptation of this specific reference manual for collection centres of clinical laboratories.

The MSDS Reference Manual for Clinical Laboratories and Collection Centers comprises 28 standards and its associated compliance requirements. It also provides the survey and scoring methodology, in addition to the guidelines to facilitate implementation and assessment of compliance.

Every journey begins with the first step and I firmly believe that this first step followed by implementation of the MSDS will lead to improved quality of healthcare in Khyber Pakhtunkhwa.

Dr. Nadeem Akhtar Chief Executive Officer INDEX OF STANDARDS

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## **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<sup>1</sup> 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 (Up to 30 beds, 31 to 49 beds, 50 and more beds), Basic Health Units, General Practitioner & Specialist Clinics, Dental Clinics, Clinical Laboratories and Collection Centres, Radiological/Imaging Diagnostic Centers, Homeopathic Clinics, Tibb Clinics etc.

## **1.1 Service Delivery Standards**

Setting service delivery standards and indicators is an established practice for continually improving the provision of quality services in the health sector. Joint Commission International (JCI) in the USA is one such organisation that sets standards to improve the quality of health services. Likewise, the Quality Care Commission in the UK ensures clinical governance with the help of a system of setting standard and facilitating compliance. The Indian Public Health Standards' were introduced in 2005 and since then the Quality Council of India expanded their scope with the launching of 'Standards for the Health and Wellness Industry in 2008. The Australian Council on Healthcare Standards was initiated in 1974 that has facilitated the development of the New Zealand and Singapore Councils. Accreditation Canada (formerly the Canadian Council on Health Services Accreditation) became independent from the Joint Commission for Accreditation of Hospitals (JCAH) in 1953. The Quality Holistic Accreditation (QHA) Trent Accreditation Scheme is based in the UK and Europe and has serviced hospitals in Asia. Internationally accredited hospitals can be found in Pakistan, India, Bangladesh, Kazakhstan, China and Iran.

Standardization of healthcare services by implementing Minimum Service Delivery Standards (MSDS) is however, a newer concept in Pakistan, and Khyber Pakhtunkhwa province has taken the initiative by establishing the Khyber Pakhtunkhwa Health Care Commission.

## **1.2 Reference Manual for Collection Centres**

Collection Centres are Health Care Establishments which are authorized to collect and transport pathology specimens like blood, urine, sputum, tissue etc., to the main clinical laboratory for

<sup>&</sup>lt;sup>1</sup> Khyber Pakhtunkhwa Health Care Commission Act, 2015

conduction of tests. In order to meet its legal obligations towards all recognized systems of healthcare, the Commission has developed the Minimum Service Delivery Standards and Indicators for implementation at clinical laboratories. The standards of collection centres are based on the MSDS of clinical laboratories. This document comprises 28 standards with its associated compliance requirements grouped in 10 universally accepted Functional Areas for such services along with Reference Material and Assessment Scoring Matrix. Keeping in view the ground realities, these standards have been kept **dynamic** and subject to evidence based improvement. All aspects of implementation, assessment and scoring have been included in this single document to better facilitate the implementers at HCEs as well as the surveyors involved in inspections.

A **Color Coding** scheme has been included to facilitate the collection HCE staff responsible to implement and assess implementation status at their own level before formal assessment by the KP HCC. The RED indicators are required to be fully implemented and have been ascribed 100% weightage while in case of YELLOW, partial compliance at least to the extent of 80% is acceptable to qualify for a license from KP HCC and accordingly these indicators have been ascribed 80% weightage. Following scoring scale shall be used for self-assessment by the HCE staff as well as by the KP HCC assessors:

Lowest			Shade	ades of Levels of Implementation Hig					High	est
0	1	2	3	4	5	6	7	8	9	10

The compliance level for collection centres is 100% for all the 28 standards. The HCE staff is advised to have self-assessment to ensure complete implementation, before the KP HCC assessors carry out formal assessment and score the HCE for licensing on the basis of criteria described above.

An implementation Assessment Scoring Matrix is given at the end of each Functional Area for selfassessment practice by the HCE Staff. Summary Scoring Matrix is given at **Annexure A**.

### **1.3 Legitimate Scope of Service**

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

### **1.4 Management & Supervision of Collection**

- 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 Centre

### **1.5 Staffing of the Collection Centre**

#### Minimum:

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

### **1.6 Survey Methodology**

- ✓ The Laboratory Collection Centers are under legal obligation to comply with the relevant standards under the ten Functional Areas of the MSDS for Clinical Laboratories prescribed by the KP HCC for licensing of the labs/collection centers. Every standard has its own compliance requirements
- ✓ A standard will be scored 10/fully met if all the prescribed requirements are complied

# PART 2 STANDARDS AND ASSESSMENT SCORING MATRIX

## 2. Standards and Assessment Scoring Matrix

### 2.1 Responsibilities of Management (ROM)

## Standard 1. ROM-1: The collection center is easily identifiable with the help of a signboard<sup>2</sup>

#### **Compliance Requirements:**

- ✓ Signboard that clearly specifies that it is a collection centre and not a laboratory.
- ✓ The signboard conforms to the prescribed local legal standards.
- ✓ 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.

## Standard 2. ROM-2: A technically qualified and trained staff performs phlebotomy / sample collection at the collection centre<sup>3</sup>

#### **Compliance Requirements:**

- ✓ The person(s) deputed for sample collection / phlebotomist at the collection centre is / are either certified lab technician(s) / lab assistant(s) or trained phlebotomist(s) (see copies).
- Evidence of training in respect of all technicians / lab assistants / phlebotomists on the SOPs prescribed for the assigned duty at the collection centre as per module provided at Annexure B (review).
- ✓ All technicians / lab assistants / phlebotomists have at least three months documented experience of working under supervision of a pathologist / lab technologist (see evidence).
- ✓ The staff deputed at collection centres to collect sample for COVID 19 PCR test are accordingly trained (interview & see evidence).

### Standard 3. ROM-3: Responsibilities of the onsite In-charge/Manager / Front Desk Officer are defined<sup>4</sup>

- ✓ The in-charge / manager / front desk officer / lab technicians / phlebotomists is / are conversant with the legally permissible role assigned to the collection centre (interview and see copies).
- ✓ All staff working at the collection centre wear / display proper identification cards (observe)
- ✓ Documented policies and SOPs prescribed by the parent lab are available at the collection centre and there is evidence to the effect that the SOPs are practiced.
- ✓ Evidence that phlebotomy/ sample collection / other duties assigned to the staff at collection

<sup>&</sup>lt;sup>2</sup> Ind. 4 of MSDS for Clinical Laboratories

<sup>&</sup>lt;sup>3</sup> Ind. 6 of MSDS for Clinical Laboratories

<sup>&</sup>lt;sup>4</sup> Ind. 28-31 of MSDS for Clinical Laboratories

centre are performed according to the protocols prescribed by the parent lab (observe).

- ✓ The staff exhibits a respectful, polite and professional conduct with the patients / clients as per prescribed SOPs and other professional norms (observe).
- ✓ Display of KP HCC Charter of Rights and Responsibilities for Healthcare Establishments and other relevant instructions (observe).
- ✓ Prescribed policies and SOPs to manage emergencies are documented, the staff is trained to implement the SOPs, and there is evidence that these are followed (interview and see copies).

### 2.1 Responsibilities of Management (ROM)

	Standards 1- 3	Max Score	Weightage (Percentage)	Score Obtained
Std 1.	The collection centre is easily identifiable with the help of a signboard	10	100	
Std 2.	A technically qualified and trained staff performs phlebotomy / sample collection at the collection centre	10	100	
Std 3.	Responsibilities of the onsite In- charge/Manager/ Front Desk Officer are defined	10	100	
	Total	30		

### 2.2 Facility Management and Safety (FMS)

## Standard 4. FMS-1: Facility design and space conforms to the scope of services<sup>5</sup>

#### **Compliance Requirements:**

- ✓ Adequate space allocated for:
  - Reception
  - Waiting
  - Phlebotomy/Sampling area
  - Labelling of samples
  - Toilet for patients (for taking urine sample etc.)
  - Temporary storage areas

## Standard 5. FMS-2: The collection centre has SOPs to manage fire and non-fire emergencies<sup>6</sup>

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

<sup>&</sup>lt;sup>5</sup> Ind. 17,18 of MSDS for Clinical Laboratories

<sup>&</sup>lt;sup>6</sup> Ind. 19-24 of MSDS for Clinical Laboratories

### 2.2 Facility Management and Safety (FMS)

	Standards 4- 5	Max Score	Weightage (Percentage)	Score Obtained
Std 4.	Facility design and space conforms to the scope of services	10	100	
Std 5.	The collection centre has SOPs to manage fire and non-fire emergencies	10	100	
	Total	20		

## 2.3 Human Resource Management (HRM)

## Standard 6. HRM-1: Staff deployment and supervision is in accordance with the scope of work of the collection centre<sup>7</sup>

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

<sup>&</sup>lt;sup>7</sup> Ind. 25,26,27 of MSDS for Clinical Laboratories

### 2.3 Human Resource Management (HRM)

	Standards 6	Max Score	Weightage (Percentage)	Score Obtained
Std 6.	Staff deployment and supervision is in accordance with the scope of work of the collection centre	10	100	
	Total	10		

### 2.4 Management of Equipment and Reagents (MER)

## Standard 07. MER-1: Ensure quality of equipment and consumables through standardized procurement procedures<sup>8</sup>

#### **Compliance Requirements:**

- ✓ A copy of the supply / procurement record is available (review).
- ✓ The collection centre follows the supply / procurement procedure of the parent lab in terms of quality of equipment and consumables (review).
- ✓ 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.
- ✓ Procurement orders are clear, dated, timed and signed in case of procurement by the collection centre or documented evidence of supplies by the parent lab are maintained (review).
- ✓ Documentary evidence / inventory and consumption record for all consumables (purchased by the collection centre or supplied by the lab) (review).

## Standard 08. MER-2: Safe handling and storage of collection centre equipment and consumables<sup>9</sup>

#### **Compliance Requirements:**

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

## Standard 09. MER-3: Standard equipment management and maintenance system is practiced<sup>10</sup>

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

<sup>&</sup>lt;sup>8</sup> Ind. 41-44 of MSDS for Clinical Laboratories

<sup>&</sup>lt;sup>9</sup> Ind. 45-48 of MSDS for Clinical Laboratories

<sup>&</sup>lt;sup>10</sup> Ind. 49-53 of MSDS for Clinical Laboratories

	Standards 7- 9	Max Score	Weightage (Percentage)	Score Obtained
Std 7.	Ensure quality of equipment and consumables through standardized procurement procedures	10	100	
Std 8.	Safe handling and storage of collection centre equipment and consumables	10	100	
Std 9.	Standard equipment management and maintenance system is practiced	10	100	
	Total	30		

## 2.4 Management of Equipment and Reagents (MER)

## 2.5 Recording and Reporting System (RRS)

## Standard 10. RRS-1: The collection centre has a complete, accurate and confidential record for every patient<sup>11</sup>

#### **Compliance Requirements:**

- ✓ Every patient's investigation record has a unique identifier (review & observe).
- ✓ The record provides an up-to-date and chronological account of each patient's record of tests (review & observe).
- ✓ Evidence with time of collection and sending sample for test / analysis to the parent lab is documented (review & observe).
- ✓ Documented evidence of receipt of test results from the parent lab (review).
- ✓ Only authorized person makes entries in the collection centre record is present (review & observe).
- ✓ Every collection centre record entry is dated and timed and the person making entries can be identified (review & observe).
- ✓ The Recording and Reporting system is preferably computerized (interview & review).
- Electronic / Computerized or hard copies of record of every patient is maintained for a minimum of 3 years (review).
- ✓ Confidentiality of patients' record is maintained (interview).

## Standard 11. RRS-2: The collection centre record supports continuity of patient care<sup>12</sup>

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

<sup>&</sup>lt;sup>11</sup> Ind. 54-58 and 118 of MSDS for Clinical Laboratories

<sup>&</sup>lt;sup>12</sup> Ind. 61-62 of MSDS for Clinical Laboratories

### 2.5 Reporting and Recording System (RRS)

	Standards 10- 11	Max Score	Weightage (Percentage)	Score Obtained
Std 10.	The collection centre has a complete, accurate and confidential record for every patient	10	100	
Std 11.	The collection centre record supports continuity of patient care	10	100	
	Total	20		

## 2.6 Quality Assurance (QA)

## Standard 12. QA-1: The collection centre practices the Quality Assurance programme deployed by the parent laboratory<sup>13</sup>

#### **Compliance Requirements:**

- ✓ The collection centre has documented SOPs for QA as prescribed by the parent lab (review).
- ✓ QA SOPs are communicated among the collection centre staff (review & interview).
- ✓ Assigning QA activities to the onsite In-charge of the collection centre is documented (review).
- ✓ Record of QA / QI activities is maintained (review).

# Standard 13. QA-2: The Parent laboratory ensures Quality Assurance through implementation of standardized practices for the collection centre<sup>14</sup>

#### **Compliance Requirements:**

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

## Standard 14. QA-3: Sentinel events are intensively analyzed and corrective actions are taken to prevent recurrence<sup>15</sup>

- ✓ The collection centre has defined sentinel events at a minimum as under (review):
  - Collapsing of a patient during phlebotomy etc.
  - Collection of wrong sample.
  - Issuing wrong report / irrelevant report.
  - Patient violence against staff.
  - Staff violence against patients.
  - Loss of a precious sample.

<sup>&</sup>lt;sup>13</sup> Ind. 63-65 of MSDS for Clinical Laboratories

<sup>&</sup>lt;sup>14</sup> Ind. 68-75 of MSDS for Clinical Laboratories

<sup>&</sup>lt;sup>15</sup> Ind. 108-109 of MSDS for Clinical Laboratories

- Any unexpected fatal incident.
- ✓ The evidence that the parent lab has conducted root cause analysis corrected the factors that contributed to the event (review).

### 2.6 Management of Equipment and Reagents (MER)

	Standards 12- 14	Max Score	Weightage (Percentage)	Score Obtained
Std 12.	The collection centre practices the Quality Assurance programme deployed by the parent laboratory	10	100	
Std 13.	The Parent laboratory ensures Quality Assurance through implementation of standardized practices for the collection centre	10	100	
Std 14.	Sentinel events are intensively analyzed and corrective actions are taken to prevent recurrence	10	100	
	Total	30		

## 2.7 Biosafety and Biosecurity (BSBS)

## Standard 15. BSBS-1: Collection centre follows the biosafety SOPs prescribed by the parent laboratory <sup>16</sup>

#### **Compliance Requirements:**

- ✓ Biosafety SOPs are available at the collection centre (review).
- ✓ Biosafety SOPs are communicated to the staff of the collection centre (review & interview).
- Biosafety requirements for collection of infectious samples like COVID 19 patients as prescribed by the parent lab, (Checklist for the labs and collection centres provided at Annexure E and Annexure F respectively) are available and practiced (observe & review) if applicable.
- ✓ The parent lab has designated the technician for ensuring biosafety activities at the collection centre (review).
- ✓ Quarterly Biosafety monitoring reports regarding the collection centre are generated by the authorized technician / person (review).

## Standard 16. BSBS-2: Biosafety measures for staff are ensured and documented <sup>17</sup>

#### **Compliance Requirements:**

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

#### Standard 17. BSBS-3: Patient biosafety is ensured<sup>18</sup>

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

<sup>&</sup>lt;sup>16</sup> Ind. 79-82 of MSDS for Clinical Laboratories

<sup>&</sup>lt;sup>17</sup> Ind. 83-85 of MSDS for Clinical Laboratories

<sup>&</sup>lt;sup>18</sup> Ind. 86-87 of MSDS for Clinical Laboratories

## Standard 18. BSBS-4: Documented procedure for Bio-risk management<sup>19</sup>

#### **Compliance Requirements:**

- ✓ All incident reports are documented (review).
- ✓ Required disinfectants / spill kits are available in the collection centre (observe).

#### Standard 19. BSBS-5: Biosecurity SOPs are practiced<sup>20</sup>

#### **Compliance Requirements:**

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

#### Standard 20. BSBS-6: Waste management plan is implemented<sup>21</sup>

- ✓ Written SOPs for waste management related to the collection centre are available (review).
- ✓ Waste management SOPs are communicated to the collection centre staff (review & interview).
- ✓ Appropriate consumables, collection and handling systems and equipment for waste management at the collection center including the following are available:
  - Waste segregation in coloured bags / bins as given at Annexure G (observe)
  - Waste storage area (observe)
  - Waste disposal plan (review)
- ✓ Documented arrangement / contract for waste disposal (review).
- ✓ There is a record of waste transport SOPs from the collection centre for final disposal (review).

<sup>&</sup>lt;sup>19</sup> Ind. 98-99 of MSDS for Clinical Laboratories

<sup>&</sup>lt;sup>20</sup> Ind. 90-91 of MSDS for Clinical Laboratories

<sup>&</sup>lt;sup>21</sup> Ind. 92-96 of MSDS for Clinical Laboratories

### 2.7 Biosafety and Biosecurity (BSBS)

	Standards 15- 20	Max Score	Weightage (Percentage)	Score Obtained
Std 15.	Collection centre follows the biosafety SOPs prescribed by the parent laboratory	10	100	
Std 16.	Biosafety measures for staff are ensured and documented	10	100	
Std 17.	Patient biosafety is ensured	10	100	
Std 18.	Documented procedure for Bio-risk management	10	100	
Std 19.	Biosecurity SOPs are practiced	10	100	
Std 20.	Waste management plan is implemented	10	100	
	Total	60		

### 2.8 Access, Assessment, and Continuity of Care (AAC)

#### Standard 21. AAC-1: Collection centre services are easily accessible<sup>22</sup>

#### **Compliance Requirements:**

- ✓ Access into the collection centre is facilitated by providing steps / stairs / ramp(s) / lift(s) as applicable (observe).
- ✓ The following basic facilities are available / maintained in the collection centre (observe):
  - Water supply
  - Power supply with backup
  - Parking place (preferably own)
  - Hand washing facility
- ✓ Clean toilets / washrooms with bolts, preferably separate for males and females, for sample collection (observe).
- Disabled patients are facilitated for reaching the sample collection area by providing wheelchair etc. or alternatively, facilities for collecting sample of the patient in the vehicle are in place (observe).
- ✓ Key points / areas in the collection centre e.g. waiting, sample collection / phlebotomy, storage and washroom etc. are indicated by signage for the guidance of patients (observe).

## Standard 22. AAC-2: Collection centre services are provided as portrayed/claimed<sup>23</sup>

- ✓ The portrayal of services clearly indicate that the facility is a collection centre, as claimed in the application for registration / license submitted to the KP HCC (observe).
- ✓ Services provided at the centre only include collection, labelling, storage and transportation of samples to the parent lab and issuance of reports as per SOPs (observe).
- ✓ The displayed services are available and provided at the collection centre accordingly (observe).
- ✓ Appropriate facilities to perform the services as portrayed, are available (observe).
- ✓ The collection centre does not undertake any test analysis of the samples (observe & interview).
- ✓ The collection centre 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).

<sup>&</sup>lt;sup>22</sup> Ind. 97-102 of MSDS for Clinical Laboratories

<sup>&</sup>lt;sup>23</sup> Ind. 103 of MSDS for Clinical Laboratories

#### Standard 23. AAC-3: A performance assessment system is practiced<sup>24</sup>

- ✓ The Director / Pathologist from the main / parent lab or an authorized representative monitors the performance of the collection centre staff against assigned responsibilities preferably on weekly basis, but at least once every two weeks. Sample KPIs are given at **Annexure H** (review).
- ✓ Periodic Performance Assessment is done by assigned authorized rep of parent lab (review).
- ✓ A copy of the performance monitoring / assessment report, conducted as above, is available at the parent lab (review).

<sup>&</sup>lt;sup>24</sup> Ind. 104 of MSDS for Clinical Laboratories

	Standards 21- 23	Max Score	Weightage (Percentage)	Score Obtained
Std 21.	Collection centre services are easily accessible	10	100	
Std 22.	Collection centre services are provided as portrayed/claimed	10	100	
Std 23.	A performance assessment system is practiced	10	100	
	Total	30		

### 2.8 Access, Assessment, and Continuity of Care (AAC)

## 2.9 Care of Patients (COP)

## Standard 24. COP-1: Protocols for management of patients in emergency are followed<sup>25</sup>

#### **Compliance Requirements:**

- ✓ Protocols for providing first aid to patient(s) in case of emergency situations that may arise in the collection centre, including inter-alia the following are documented (review):
  - The patient or an attendant may suffer syncope/cardiac arrest/asthmatic attack / respiratory distress etc. while present at the collection centre for providing sample
  - Unusual bleeding of patient on phlebotomy
- Arrangement for basic life support measures including; availability of blood pressure apparatus, stethoscope, bandages to stop bleeding, splints for supporting fractures and medicines to control generalized pain, and preferably oxygen cylinder with regulator and giving mask, sublingual nitroglycerine tablets for such emergencies (review & observe)
- ✓ The collection centre staff are trained for first aid and BLS in above cases (review & interview).
- ✓ Relevant contact numbers for emergency evacuation/referral are available in the collection centre (observe).

### **Standard 25. COP-2: The collection centre policies and procedures support domiciliary services to the patients (if applicable / claimed)**<sup>26</sup>

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

<sup>&</sup>lt;sup>25</sup> Ind. 106-107 of MSDS for Clinical Laboratories

<sup>&</sup>lt;sup>26</sup> Ind. 110-111 of MSDS for Clinical Laboratories

### 2.9 Care of Patients (COP)

	Standards 24- 25	Max Score	Weightage (Percentage)	Score Obtained
Std 24.	Protocols for management of patients in emergency are followed	10	100	
Std 25.	The collection centre policies and procedures support domiciliary services to the patients (if applicable / claimed)	10	100	
	Total	20		

## **2.10** Patient Rights and Education (PRE)

## Standard 26. PRE-1: A system for obtaining consent is in place when it is required<sup>27</sup>

#### **Compliance Requirements:**

- ✓ List of situations where specific informed consent is required (review).
- ✓ The policy describes who can give consent when the patient is incapable of independent decisionmaking (review).
- ✓ Evidence that informed consent is taken when needed (review, interview & observe).

## Standard 27. PRE-2: Patients and families have a right to information on expected costs<sup>28</sup>

#### **Compliance Requirements:**

- ✓ The tariff list is available to patients and the patients are upfront informed about cost of the test/analysis (review & observe).
- ✓ Patients / families are informed about the additional reports that are generated / included in the report with the same sample and cost if applicable (interview).

## Standard 28. PRE-3: Patients and families have a right to complain and there is a mechanism to address the grievances<sup>29</sup>

- ✓ Patients' complaints are accepted by the collection centre and properly registered and forwarded to the parent lab as relevant (review).
- Relevant information for the clients, as given at Annexure I, is displayed at the collection centre (observe).
- ✓ The contact number of the complaint cell / relevant person in the parent lab is displayed (observe).
- $\checkmark$  The parent lab has an easy feedback mechanism (interview & review).
- ✓ Complaint register / box for receiving grievances of patients / clients is maintained at the collection centre and handled by the relevant person of the parent lab (review).
- ✓ Proper actions and remedial measures are taken by the collection centre/parent lab in response to patients' complaints (review).

<sup>&</sup>lt;sup>27</sup> Ind. 112-113 of MSDS for Clinical Laboratories

<sup>&</sup>lt;sup>28</sup> Ind. 114-115 of MSDS for Clinical Laboratories

<sup>&</sup>lt;sup>29</sup> Ind. 116-117 of MSDS for Clinical Laboratories

# Assessment Scoring Matrix

### 2.10 Patient Rights and Education (PRE)

	Standards 26- 28	Max Score	Weightage (Percentage)	Score Obtained
Std 26.	A system for obtaining consent is in place when it is required	10	100	
Std 27.	Patients and families have a right to information on expected costs	10	100	
Std 28.	Patients and families have a right to complain and there is a mechanism to address the grievances	10	100	
	Total	30		

PART 3 ANNEXURES

## 3. Annexures

# ANNEXURE A: Summary Assessment Scoring Matrix

	Functional Area	Max Score	Weightage (percentage)	Score Obtained
2.1	Responsibilities of Management (ROM)	30	100	
2.2	Facility Management and Safety (FMS)	20	100	
2.3	Human Resource Management (HRM)	10	100	
2.4	Management of Equipment and Reagents (MER)	30	100	
2.5	Recording and Reporting System (RRS)	20	100	
2.6	Quality Assurance (QA)	30	100	
2.7	Bio Safety and Security (BSS)	60	100	
2.8	Access, Assessment, and Continuity of Care (AAC)	30	100	
2.9	Care of Patients (COP)	20	100	
2.10	2.10 Patient Rights and Education (PRE)		100	
	Total	280	-	

### **ANNEXURE B: Front Desk Officer Training Module**

Subject:	Department:	Human Resource Development	Effective On:		
Front Desk Officer	Pages:	01	Revision Date:		
Training Module	Scope of Policy:	This Policy covers the relevant aspects of the Training of a Front Desk Officers appointed at the Collection Centres.			

### **Description of Policy:**

The objective of developing and maintaining this Training Module is to train the Front Desk Officer(s) for appointment at the Lab Collection Centres to fulfil the requirement of providing quality services.

### Procedure:

The candidates/staff selected for appointment as Front Desk Officer(s) at the Lab Collection Centres are provided classroom training as well as demonstrations and hands-on practice covering the following areas/topics:

- 1. HRD Orientation: Introduction to HRD Policies
- 2. Presentation on Self Grooming
- 3. Waste Management: Orientation to Waste Management in Diagnostic Labs and Collection Centres
- 4. Blue Card Membership Program Training
- 5. Interpersonal Communication Skills
- 6. Introduction to the policies of Audit and SOPs related to Audit
- 7. Introduction to Sample Management: Theory and Practice
- 8. Phlebotomy: A Comprehensive Combination of Theory and Practice
- 9. Customer Services and Personality Grooming
- 10. Quality Improvement Introduction and SOPs

### **ANNEXURE C: Selection Criteria for Front Desk Officer**

### 1. Scope of Policy

This policy covers the selection criteria of all Front Desk Officers to be appointed in collection centres.

### 2. Description of Policy

The objective of prescribing the selection criteria for appointment of Front Desk Officer with suitable education and experience is to ensure that the incumbent fulfills the basic requirements for provide quality services and to maintain standards at the collection centre as envisaged by the lab.

### 3. Procedure

Following is the criteria to hire a Front Desk Officer:

### i. Education

The minimum education for selecting the FDO is Matriculation, preferably Intermediate or graduate.

### ii. Experience

The candidate for FDO must have minimum 1-year experience with graduation and 2 years' experience in case of Intermediate.

### 4. Staff Review/Acknowledgment Signature Sheet

Name	Signature	Date

Notes:

# ANNEXURE D: Job Description and Key Performance Indicators

	JOB DETAILS		
Job Title:	Front Desk Officer		
Reports to: Center In-charge/Lab Director/Official designated by the Lab			
Department:	Customer Relations/Operations of the pare		
	JOB PURPOSE		
Responsible to:         1. Look after the front desk and         2. Maintain front desk and rela         3. Provide services and treat the         Qualifications Required:         1. Matric, preferably Intermed         Regional Manager	ne patient nicely iate or graduate <b>POSITION DIMENSIONS</b>	Desk Officer	
KEY AC	COUNTABILITIES	KEY RESPONSIBILITY AREAS	
1. To take blood sample as per	DESCRIPTION		
<ul> <li>Greeting with profession</li> <li>Verify from patient all Registration Lab Bill.</li> <li>Read the request form be Ensure proper posture of with arm support.</li> <li>Explain the procedure to Prepare all the material</li> <li>Put on gloves and mask.</li> <li>Apply tourniquet.</li> <li>Palpate and examine the Wipe the selected area a</li> <li>Tight the needle and rel</li> <li>Insert the needle.</li> <li>Release tourniquet whe firm pressure for 30-60 when bleeding stops.</li> <li>Ask the patient about ar</li> </ul>	hal attitude in a good manner. the particulars to be mentioned on the before phlebotomy. of the patient posture in a relaxed position the patient. according to the lab bill. e arm/clear vein. and properly clear vein with alcohol swab,	Phlebotomy	
<ol> <li>To deliver reports to the conguidance of Collection Centration protocols of the parent lab a</li> <li>To keep close coordination departments of the parent</li> </ol>	oncerned patients in accordance with the ntre In-charge/Lab Manager and preset	Customer Handling	

-			
3.	To keep updated information regarding any ch	ange/alteration in	
	predefined procedures or protocols or test report	rts and to provide	
	accurate information regarding such changes to the	e asking patients or	
	their companions, either on the phone or in person.		
4.	To attend phone calls and to provide appropriate gu	idance/information	
	to the patients/clients on the phone.		
5.	To keep and maintain an updated record of patient		
	information, in order to provide on-spot informati	on to the querying	
	patients.		
6.	To guide visiting patients and their companions to th	e concerned official	
	or department in the parent/respective lab.		
7.	To receive and deal with the visiting patients and the	eir companions in a	
	respectable manner.		
1.	Accurate Data Entry:		
	• To maintain proper record of all cash discourt	-	
	patients during specific shift timings and reconc		
	with the Accounts Office of the parent/respectiv		
	<ul> <li>To maintain proper record of all payments bei provide shift timing and paying dispersionality</li> </ul>	•	Operational
	specific shift timings and periodic reconciliation		Efficiency
	the Accounts Office of the parent/respective lak		
	To provide immediate information regarding any charge. Collection. Control (Job. Manager, and Control (Job. Manager).	• •	
	charge Collection Centre/Lab Manager and regarding any suitable/possible solution of the p		
1			
т.	Sample preservation as per SOPs as follows:	romants of the test	
	<ul> <li>Transfers blood from syringe to vial as per requi and its SOPs.</li> </ul>	rements of the test	Samala
	<ul> <li>To label the samples with the Patient's Name,</li> </ul>	Casa na Data with	Sample Management
	month, Time Fasting/Random/2 HRS, A.M/P.M e		wanagement
	of the patient.	itel, in the presence	
1.	Ensures general or non-infectious waste is placed in	white plastic bags	
2.	Ensures all infectious waste is collected in yellow ba		
3.	Ensures sharps are collected in rigid, puncture-p		
	sharps container. Cuts all the sharps before		Waste Management
	containers.	5	
4.	Ensures waste is arranged in colour-coded plastic ba	ags or containers.	
1.	Is active and energetic.		
2.	Has a customer-oriented approach.		
3.	Has strong interpersonal communication skills. Ho	lds self and others	Competencies
	accountable.		
4.	Avoids a 9 to 6 thinking approach.		
	APPROVALS		
Не	ad of the Department/Collection Center In-charge	Head	of HRD
١,	hereby,	Team Member's	s Signature & Date
	lv understand and feel myself responsible for my Job		<b>J</b>
	scription as mentioned above and will put my best		
	orts & knowledge to achieve entire satisfaction of Seniors in this regard.		

### ANNEXURE E: COVID-19 PCR Laboratories Assessment List (Collection Centre)

Laboratory Name:		_Surveyor(s) Name: (1) (2) (2)
KP HCC Reg #:		_Address:
Inspection Date:	District:	Focal Person Name:
Designation:	Contact:	Email ID:

Standard No.	Standard	Indicators	Priority E=Essential P= Preferable	Indicator Y/N	Standard Y/N	Comments (Findings & Recommendations for compliance)
		E. Sample Collection				
		Sample collection procedures are documented	E			
	Cura sina su	Sample collection procedures available to relevant staff	E			
E.1	Specimen Collection	Standard specimen request form available	E			
	Conection	Specimens are recorded manually/ computerized	E			
		Specimens labelled with unique identifier number	E			
E.2	Specimen Handling	Are specimens adequately stored	E			
	Specimens	Laboratory has appropriate packaging material for referral	F			
E.3	Referral/	of specimens	Ľ			
	Transport	Sample collection team is trained	E			

### **ANNEXURE F: COVID-19 PCR Laboratories Assessment List**

Laboratory Name:		_Surveyor(s) Name: (1) (2) (2)
KP HCC Reg #:		Address:
Inspection Date:	District:	_ Focal Person Name:
Designation:	Contact:	_Email ID:

Standard No.	Standard	Indicators	Priority E=Essential P= Preferable	Indicator Y/N	Standard Y/N	Comments (Findings & Recommendations for compliance)
		A. Physical Requirements				
		Access to an autoclave for decontamination of waste	E			
		Access to the laboratory is restricted when work is being conducted	E			
		Appropriate PPE is worn, including lab coats and gloves, eye protection and face shields	E			
	The laboratory satisfies	Walls, ceilings and floors should be smooth, easy to clean, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be slip-resistant	E			
A.1	requirements of a BSL 2 facility.	Bench tops should be impervious to water and resistant to disinfectants, acids, alkalis, organic solvents and moderate heat	E			
		Space and facilities should be provided for the safe handling and storage of solvents, radioactive materials, and compressed and liquefied gases	E			
		Biohazard warning symbol and sign must be displayed on the doors of the rooms where microorganisms are handled.	E			

		Biological safety cabinet (mention make, model and manufacturer name in remarks column. Attach pictures showing make, model and manufacturer name) for containing any work that generates aerosols	E		
		Facilities for storing outer garments and personal items should be provided outside the laboratory working areas	E		
		Safety systems should cover fire, electrical emergencies, emergency shower	E		
		A stand-by generator is desirable for the support of essential equipment, such as incubators, biological safety cabinets, freezers, etc.	E		
		Hand washing sink	E		
		Eye washing station	E		
		Doors that close and lock automatically	Р		
		Open-toed footwear must not be worn in laboratories	Р		
		First-aid areas or rooms suitably equipped and readily accessible should be available	Ρ		
		Physical separation of these areas is required for completely manual assays	E		
A.2	Separate areas are designated for reagent prep, sample extraction and amplification.	Semi-automated assays can use two areas: one for reagent preparation (performed in UV dead box)/specimen processing (performed in BSC) and one for amplification/ detection.	E		
		Each area should be large enough for comfortable placement of equipment, staff movement and provide adequate workspace	Р		
A.3		List of dedicated equipment in each area is available (attach list of equipment with make, model and	E		

	All work areas have	manufacturer name. Attach pictures of equipment		
	dedicated instruments	showing make, model and manufacturer name)		
	and consumables.	Equipment is labelled according to area	E	
	Instruments and	Maintenance records	E	
	equipment are well	Schedule for daily calibration and maintenance	r	
A.4	maintained and in good	checks must be available	E	
	working condition.	Plan available if equipment breaks down.	Р	
	Temperature and	Daily record of room temp and humidity	E	
A.5	humidity of the work	Room temp should be between 21-25C	E	
	areas is controlled	Room humidity should be between 30-60%	Р	
		B. Biosafety		
	Risk assessment has	Risk assessment form is available	Р	
B.1	been performed	Risk assessment has been approved by the lab or	Р	
	been performed	institutional Biosafety Officer/Committee	F	
	Appropriate biosafety	Biosafety manual available	E	
B.2	guidelines available and	Lab biosafety officer/coordinator conducts training	Р	
	followed	and review of safety practices	1	
	Staff trained for special	SOP providing additional guide for precautions when	E	
B.3	precautions working	working with COVI-19 samples		
210	with COVID-19	Use of N95 masks, disposable gowns, goggles	E	
		and hair nets recommended	_	
		Biological Safety Cabinet (BSC) is available in the	E	
		sample prep area		
		Waste is sealed properly double bagged before	E	
	Control measures are in	leaving the lab.		
B.4	place to minimize	Area can be sealed and decontaminated.	E	
	contamination in all	Waste is autoclaved before leaving the lab.	E	
	areas.	A pipetting aid must always be used for pipetting	_	
		procedures. Mouth pipetting must be strictly forbidden.	E	
		Negative pressure	Р	

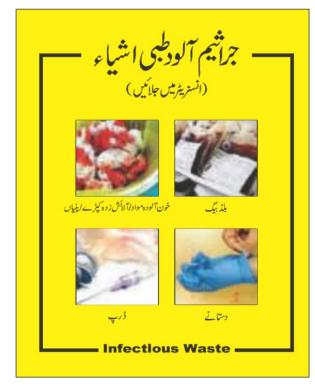
		Room air extracted by HEPA filtration	Р	
B.5	Biological Safety Cabinet (BSC) is available in the	Area is restricted for staff involved in COVID-19 testing only	E	
	sample prep area	Maintenance and service record	E	
	The lab area is separated from any	Area is restricted for staff involved in COVID-19 testing only.	E	
B.6	other activities in the same building	Housekeeping staff is trained and using PPEs will clean the lab at a time when no testing is being performed.	E	
B.7	Safety and well-being of staff monitored during work hours.	There is a means of viewing occupants from outside such as an observation window or alternative	E	
	Spillage and emergency	SOP for spill management	E	
B.8	procedures, including exposures management in place.	Training/drill sessions completed	E	
	Work area and	Work surfaces are impervious to water; easy to clean and resistant to acids, alkalis, solvents and Disinfectants	E	
B.9	equipment are cleaned and decontaminated regularly	Cleaning is performed using and cleaning and disinfection agents (70% alcohol, 1% hypochlorite) labelled with preparation date and expiry date	E	
		Cleaning frequency is recorded on a daily basis	Р	
B.10	Hand washing within the laboratory wherever possible	Hands disinfection available	E	
	Health surveillance and monitoring of staff	Temp of staff working in the lab is recorded daily	E	
B.11		Staff must be assessed for symptoms on a daily basis	E	
0.11		Staff duty rota should change every 5 days, no one	Р	
		should work for more than 5 consecutive days.		

	Waste management processes in place.	Waste is autoclaved before sending to central waste disposal Waste is segregated in proper containers Chemical waste containers tagged, labelled, dated and kept closed Chemical waste containers appropriately handled and stored Liquid waste from extraction process is	E E E E		
		decontaminated in 1% hypochlorite	_		
	The individual in all sures	C. Competency of Staff			
C.1	The individual in charge of the molecular section of the lab has the requisite appropriate technical qualifications and experience	1) At least bachelor degree in Molecular Biology or equivalent subject under supervision of pathologist	E		
		D. Test Performance			
D.1	Detailed Standard Operating Procedure (SOP) available for COVI- 19 testing.	Following details are required: Kit being used with details of established performance specifications from validation study (IVDs kits with following Regulatory status are mandatory: a) EU regulatory status such as CE marked, b) FDA approved/ notified, c) Asia Regulatory Status. Attach list of kits/ reagents with make, model, manufacturer name and regulatory status. Attach pictures of kits/ reagents showing make, model, manufacturer name and regulatory status)	E		
		Sample collection, handling and transport	E		
		Sample acceptance/rejection criteria	E		
		Sample processing steps - maximum samples per run	E		
		Quality Controls	E		
		Result interpretation	E		

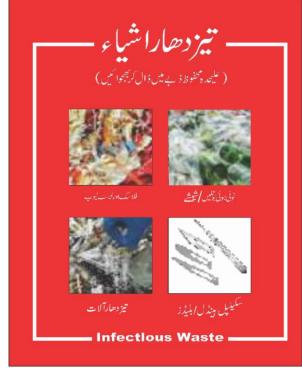
		Reporting criteria	E	
D.2	Quality controls are used in each run	Record of internal quality control available	E	
D.3	Samples and reagents are stored properly in temperature controlled	Kits/reagents are stored separately at 2-8C	E	
		Samples/Nasopharyngeal in VTM - stored separately <5 days 2-8C and >5 days-70C	E	
	storage facilities.	Extracted RNA - stored -70C	E	
	Sample are tracked and	Samples labelled with bar code	E	
D.4	identifiable through all phases of testing - there is system to positively identify all patient specimens and aliquots through all phases of the analysis, including specimen receipt, nucleic acid extraction, nucleic acid quantification, amplification, and storage	Bar code readers scan and enter data into a computer system	E	
D.5	Data from each run must be maintained for review and QA purposes.	Hard copy of results of each run/batch must be maintained	E	
		QC data of each run must be collated and reviewed weekly	Р	
D.6	Reporting of results	Molecular Biologist should review the results	E	
		QCs for each run must be acceptable before results verified	E	
		Immediate notification of results on online portal	E	
		Clinical correlation with results required		

# ANNEXURE G: Segregation of Waste (both Clinical & Municipal) for Disposal

1. Yellow Colour

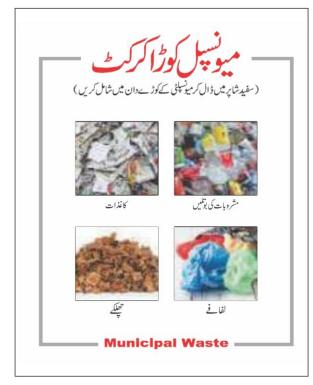


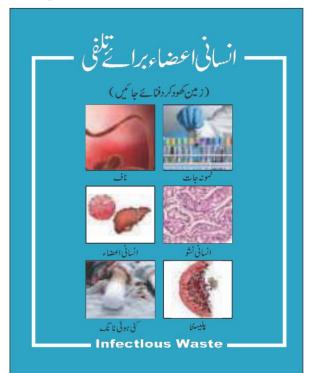
2. Red Colour



3. White Colour

4. Light Blue





### **ANNEXURE H: KPIs of Front Desk Officer**

#### KRA - 1: Phlebotomy

#### Allocated Weightage:20%

Unacceptable	No SOPs are followed
Improvement Needed	Some SOPs are followed
Average	SOPs are followed as per Job Descriptions
Above Average	SOPS are follows and has strict self-assessment on it
Exceed Expectations	100% SOPs are followed and provide proper guidance to other fellows

#### **KRA - 2: Customer Handling**

Allocated Weightage: 25%

Unacceptable	50% customers are satisfied
Improvement Needed	60% customers are satisfied
Average	80% customers are satisfied
Above Average	90% customers are satisfied
Exceed Expectations	100% customers are satisfied

#### **KRA - 3: Operational Efficiency**

Allocated Weightage: 15%

Unacceptable	50% operational efficiency
Improvement Needed	60% operational efficiency
Average	80% operational efficiency
Above Average	90% operational efficiency
Exceed Expectations	100% operational efficiency

#### KRA - 4: Sample Management

Allocated Weightage: 10%

	00
Unacceptable	Less than 85
Improvement Needed	90% accuracy of Sample Management
Average	95% accuracy of Sample Management
Above Average	100% accuracy of Sample Management
Exceed Expectations	100% accuracy of Sample Management along with training to others

#### KRA - 5: Waste Management

Allocated Weightage: 10%

Unacceptable	Less than 85
Improvement Needed	90% accuracy of Waste Management
Average	95% accuracy of Waste Management
Above Average	100% accuracy of Waste Management
Exceed Expectations	100% accuracy of Waste Management along with training to others

#### **KRA - 6: Competencies**

Allocated Weightage: 20%

Unacceptable	Zero competency has been met
Improvement Needed	Two competencies have been met
Average	Three competencies have been met
Above Average	Four competencies have been met
Exceed Expectations	All competencies have been met

### **ANNEXURE I: Information for Clients**





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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