MINIMUM SERVICE DELIVERY STANDARDS FOR CLINICAL DIAGNOSTIC LABORATORIES

SINDH HEALTHCARE COMMISSION

Quality Care for All

Introduction:

Primary purpose of a clinical diagnostic laboratory is to provide accurate, reliable and timely results to clinicians. The main objective of producing these Minimal Service Delivery Standards is to provide a common understanding of what is expected from the laboratory to assure provision of consistently high-quality service delivery and to provide a roadmap for improving the quality, safety and reliability of clinical laboratories and collection centers across province of Sindh. In line with global good clinical lab practices (GCLP), these standards cover all key aspects of laboratory management, technical operations, biosafety and quality systems. It is advised that all categories of labs adopt or start to adopt digital systems and processes including for test booking, reporting, Laboratory Information Management System and Laboratory Quality Management System (LQMS). The lab must strive to provide services and diagnostic tests to meet the need of patients and clinicians it serves and must periodically review its scope of services based on population/clinician needs and advances in diagnostic techniques.

Standard Development Process

- ⇓ Stakeholder consultative meeting with representatives of public and private sector laboratories and teaching hospitals
- ⇓ Formation of Working Group
- ⇓ National Health Policy recommendations reviewed and followed as guiding principal for development of draft standards
- ⇓ Review of available standards for clinical laboratories
- ⇓ Final draft reviewed by Working Group
- ⇓ Stakeholder consultation meeting for finalization/dissemination

Scope

These standards are applicable to following categories of laboratory services as registered with Sindh Health Care Commission:

1. **Laboratory Collection Point**: No tests conducted on site; only phlebotomy and non-invasive sample collection, storage, transport and reporting; Reference/parent laboratory must be licensed with SHCC; Applicable standards appended

2. **Health Care Establishment using POC testing for OPD/ER/In-patient**: POC Tests are conducted on-site without requiring a standard laboratory set-up for immediate diagnostic decision-making using testing methods that are simple and accurate as to render the likelihood of erroneous results negligible and pose no unreasonable risk of harm to patient when correctly performed. The POC kits/devices must be registered with DRAP/exemption certificate should be available or certified by a nationally recognized institute such as WHO. Hospitals may use their own lab for validation of POC kits. An area must be designated for this purpose *(minimal pre-analytical, analytical and post analytical standards apply to specified area subject to type of test and pathogen)*

3. **Stat Laboratory**: Free standing laboratory capable of performing abbreviated battery of tests

with generally < 1hour turnaround time (TAT); incudes Lab-on-a-Chip (LOC) and automated devices; service relevant standards apply

4. **Clinical Laboratories of Bio Safety Level 1 and Level 2 and 2+/Clinical** Laboratories of hospitals and Reference Laboratories; all standards apply
5. **Laboratories of Bio Safety Level 3 or 4** which is pre-accredited by national and international bodies

All standards are applicable as per declared scope of services.

Scope of services of all above categories may include any/all of following diagnostic domains which should be clearly stated in the application for licensure:

1. Microbiology including bacteriology, mycology, parasitology
2. Serology
3. Clinical Chemistry/Special chemistry
4. Clinical/Chemical/Histo and /Surgical/anatomical pathology
5. Hematology, transfusion medicine and blood bank (SBTA License required)
6. Immunology
7. Virology
8. Molecular Pathology and Molecular Biology

Biosafety level of lab (BSL) will be determined based on microbe category and type of procedures performed as per the declared scope (*Appendix 2*).

Blood bank associated with laboratories must be registered and have valid license of Sindh Blood Transfusion Authority

Normative References:

Normative references are those documents that contain material that must be understood and used to implement the standard and are an indispensable resource when applying the standards. For implementation of these standards, the following are recommended:

- Good Clinical Laboratory Practices in Pakistan. Pakistan Academy of Sciences 2019, Islamabad, Pakistan https://www.nih.org.pk/wp-content/uploads/2019/04/HANDBOOK-for-Good-Clinical-Lab.pdf
- MSDS and Reference Manual for Clinical Laboratories, Punjab Health Care Commission

Summary:

S.No.	Domain	Standards	Measurable Criteria
1	Responsibilities of management (ROM)	3	15
2	Facility Management and Safety (FMS)	3	15
3	Human Resource Management (HRM)	6	19
4	Management of Equipment and Reagents (MER)	3	15
5	Recording and Reporting System (RRS)	2	13
6	Quality Assurance	5	19
7	Biosafety and Biosecurity (BSBS)	6	24
8	Access, Assessment and Continuity of Care (AAC)	3	8
9	Care of Patients (COP)	3	7
10	Patient Rights and Education (PRE)	3	9
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1. RESPONSIBILITIES OF MANAGEMENT (ROM)

(3 Standards; 15 Measurable Criteria)

ROM-1: The Laboratory is easily identifiable

1.1.1: The laboratory is identifiable with name on a sign board clearly visible from reasonable distance and mentions whether it is a Laboratory or collection center
1.1.2: The laboratory signboard conforms to the prescribed local legal/technical and safety standards
1.1.3: The laboratory is registered/licensed with the SHCC; registration number is displayed on signboard and license is displayed at prominent place inside lab or application receipt is available
1.1.4: Associated collection centers are reflected in the registration certificate/License issued by SHCC where applicable; any change is timely communicated to SHCC for record
1.1.5: Defined process flow and list of SHCC licensed reference laboratories for outsourcing of tests exists preferably with Signed valid MOU, where applicable.

ROM-2: A technically qualified and experienced individual heads the laboratory

1.2.1: The full/part-time (as per workload) technical head of the laboratory is a medical graduate and pathologist with PMDC/PMC recognized qualification commensurate with declared scope of service of the laboratory *(Appendix 1)*
1.2.2: The PMDC/PMC license of technical head is valid or renewal receipt is available and license is displayed at prominent place inside the lab
1.2.3: The technical head is ultimately responsible for all reporting and management of laboratory components

ROM-3: The management has laid down mission statement, key policies and SOPs for all specific processes of the laboratory in collaboration with top management and staff through a documented process

1.3.1: There is a universal mission statement available and displayed for staff and visitors

1.3.2: Those responsible for management establish the laboratory's organogram which is available for review/displayed in the laboratory
1.3.3: Those responsible for management appoint the section heads in the laboratory with relevant qualification *(appendix 1)* as required and a clearly defined process for appointment exists verifiable through documentation
1.3.4: A detailed laboratory policy manual and standard operating procedures (SOPs) is developed, available for review and known to staff
1.3.5: An emergency policy and standard operating procedures (SOPs) is developed, available for review and is readily accessible, available and known to staff
1.3.6: Management has allocated sufficient laboratory budget and resources required to accomplish the mission; the space, staff records, equipment and stock registers and reporting time frame reflect adequate availability as per declared scope of service
1.3.7: Those responsible for management support research activities through approved processes while maintaining patient confidentiality, verifiable through documented affiliation with academic institute

2. Facility Management and Safety (FMS)

(3 Standards; 15 measurable criteria)

FMS-1: The management complies with principles of construction and safety

2.1.1: The building construction and safety verification documents issued by relevant authority are available (updates any amendments to laws and rules)
2.1.2: The management assures that waiting area, sample collection area, sample processing areas are clearly demarcated, adequate and well maintained
2.1.3: The management assures that utilities (water supply, electric supply/backup) are available
2.1.4: The management assures that facility construction and infrastructure meet laboratory specifications such as impervious skid proof floorings, sealed walls with washable paints, impervious/chemical resistant counter tops, adequate lighting and ventilation as required for declared scope of service and biosafety level
2.1.5: The lab provides services in a manner that pose no risk to staff, patients and public
2.1.6: The lab has SOPs for reporting of safety and quality concerns by all staff members without fear of formal/informal disciplinary or punitive action, thus promoting a safety culture

FMS-2: Facility work flow design conforms with the scope of services

2.2.1: The basic design of facility supports scope of services and biosafety level requirements with adequate space allocation and effective clearly marked separation between administrative and technical laboratory areas
2.2.2: Measures are taken to control movement of the technical staff working in various sections of the laboratory; Written SOPs for exit and entry into different technical areas as per biosafety requirement are available and practice is observable

FMS-3: The laboratory has plans for fire and non-fire emergencies within the sections

2.3.1: Plans and provisions for early detection, containment and abatement of fire and non-fire emergencies exist (policy, SOPs, equipment such as smoke detectors, alarms, security, hazard signs)

2.3.2: Unobstructed, functional and clearly marked emergency exit points are present
2.3.3: Mock drill plans are available and conducted at least once in a year
2.3.4: Hazards and risks are assessed and timely managed and no hazardous conditions are observable
2.3.5: Staff members are trained for their role in case of such emergencies and training is documented
2.3.6: First aid kits are available in sample collection area
2.3.7: Eye washes and spill kits are available in all key areas

3. Human Resource Management (HRM)

(6 Standards; 19 measurable criteria)

HRM-1: Staff deployment is in accordance with the scope of laboratory work

3.1.1: Job description for every post is identified and documented
3.1.2: Eligibility criteria regarding qualification and experience for each post is available
3.1.3: Recruitments are made according to laid down eligibility criteria

HRM-2: Documented personal record for each staff member exists

3.2.1: Personal files of each full/part-time staff member are maintained containing all relevant documents including educational and professional qualifications, experience, licenses, contract, JD, performance evaluations, competency assessments, trainings, health record and disciplinary actions
3.2.2: All personnel undergo a pre-deployment health check-up, regular screening and color blindness test
3.2.3: SHCC is notified in writing of all technical heads leaving the job with reason and of any professional misconduct in service provision for record purposes
3.2.4: All procurement and technical personnel are free from any internal or external commercial, financial biases or other conflicts of interest that may adversely affect the quality and outcomes of any tests reflecting norms of professional code of ethics

HRM-3: The staff members joining the laboratory are oriented to the laboratory environment, the laboratory sections and their individual jobs and the orientation is documented via handbook/checklist/attendance sheets

3.3.1: A written employee level specific orientation plan including all areas of laboratory exists for newly inducted employees
3.3.2: Each staff member is made aware of laboratory wide policies and procedures as well as section/unit/service/program specific policies and procedures
3.3.3: Each member of staff is made aware of his/her rights and responsibilities
3.3.4: All employees are oriented with regard to patient's rights and responsibilities

HRM-4: An appraisal system for evaluating the performance of employees exist as an integral part of the human resource management process

3.4.1: Well-documented performance appraisal tools exist in the laboratory
3.4.2: All of the employees/consultants/students/voluntary workers are made aware of the performance appraisal tools at the time of induction
3.4.3: The appraisal is used as a tool for further professional development
3.4.4: Performance appraisal is carried out at pre-defined intervals and is documented

HRM-5: In-service staff capacity building record is documented

3.5.1: In-service training plan for staff members is available and execution verifiable through attendance records
3.5.2: All records of in-service training and education are contained in the personal files

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

3.6.1: A system for the verification and validity of documents and certificates of employees with academic institutes, councils and accreditation bodies is present
3.6.2: Verification and validity of credential/documents is done in the laboratory for any newly added qualification/training certificate

4. Management of Equipment and Reagents (MER)

(3 Standards;15 Measurable Criteria)

MER-1: Ensure quality of equipment and reagents through standardized procurement procedures

4.1.1: The procurement procedure of the laboratory is clearly documented
4.1.2: Specification for all the equipment and reagent/kits/consumables to be purchased are documented
4.1.3: Procurement orders are clear, dated and signed
4.1.4: Procured items are regularly entered into stock registers which are up to date
4.1.5: Procured kits and their consumption are compared with tests performed during annual/biannual audit
4.1.6: Reagent-rental agreements, if applicable, are available for review

MER-2: Safe handling and storage of laboratory reagents

4.2.1: Documented policies and standard procedures guide the safe storage and use of reagents as per manufacturer instructions including temperature, light (brown coding) and humidity controls
4.2.2: Documented policy for usage control is present including specifications for restricted or authorized use, hazard information, segregated storage and documented issuance record
4.2.3: An up to date inventory of reagents is maintained
4.2.4: The policies of reagent management include a procedure of alert for near expiry reagents
4.2.5: Labelling of reagents is as per SOPs and includes name, concentration, dates of manufacture

and expiry of chemical/reagent

MER-3: Comprehensive procedures for equipment management and maintenance exist in the laboratory

4.3.1: A detailed inventory of each equipment is maintained and available for review
4.3.2: Regular periodic maintenance, calibration, breakdown and repairs record of all the equipment is available in the log book
4.3.3: Documented relevant log sheet is displayed on each equipment
4.3.4: Emergency contact number/s is/are displayed on all equipment

5. Recording and Reporting System (RRS)

(2 Standards; 13 Measurable Criteria)

RRS-1: The laboratory has a complete and accurate laboratory record for every patient

5..1.1: The laboratory has an established process for test registration that assures accuracy of patient identification and includes all relevant details for subsequent clinical correlation and surveillance reporting
5.1.2: Each test record has a unique identifier for every patient and record provides an up to date chronological data of patient's investigations
5.1.3: Only authorized person makes entries in the laboratory record
5.1.4: There is a mechanism for internal data validation and results shall be reviewed and validated by authorized person before release
5.1.5: Every laboratory record entry is dated, timed and the data entry person can be identified
5.1.6: Digital/computerized/EMR system record of every patient is maintained for minimum 3 years; manual record maybe retained for 6 months – 1year except for histopathology and bone marrow for up to 5 years/lifetime)

RRS-2: A comprehensive reporting system exists in the laboratory

5.2.1: A computerized reporting system is available
5.2.2: Minimum reporting time for every test is documented and conveyed to patient
5.2.3: Reports are accessible to individual patients through a specific code
5.2.4: Critical results are timely reported to patient/ordering physician
5.2.5: Repeat results indicate addendum/modification clearly
5.2.6: Digital/manual records are protected from malware, unauthorized access and damage
5.2.7: Disease data of notifiable communicable diseases and non-communicable disease registries is regularly and timely shared as directed by the health authorities

6. Quality Assurance (QA)

(5 Standards; 19 Measurable Criteria)

QA-1: The laboratory has a comprehensive and documented internal and external quality assurance (QA) program (IQA and EQA)

6.1.1: The laboratory has quality assurance (QA) SOPs for both Internal (IQA) and External (EQA) assessment; preferably Lab Quality Management System is present and utilized
6.1.2: There is a designated focal person responsible for quality assurance activities in the laboratories with documented assignment
6.1.3: Quality Assurance SOPs are communicated and coordinated among the staff

QA-2: Internal quality assurance (IQA) is ensured in the collection area through standardized laboratory practices and procedures manual

6.2.1: Policies and procedures guide the safe collection of specimens to avoid contamination; SOPs are available in procedure manual with evidence of implementation
6.2.2: Policies and procedures guide the identification and proper labeling of specimens; SOPs are available with evidence of implementation
6.2.3: Policies and procedures guide the safe and correct handling of specimens; SOPs are available with evidence of implementation
6.2.4: Policies and procedures guide the safe internal and external transportation of specimens; SOPs are available with evidence of implementation

QA-3: Internal quality assurance (IQA) is ensured in the test processing area through standardized laboratory practices and procedures manual

6.3.1: Policies and procedures guide the safe processing of specimens; SOPs are available with evidence of implementation
6.3.2: Controls and control charts for internal quality assurance (IQA) are available and utilized
6.3.3: Policies and procedures guide the identification and handling of process non-conformance
6.3.4: Process cycle records are maintained including date, start and end time of process, sample identity, total samples in each process and signature of person carrying out the process
6.3.5: Policies and procedures guide the safe disposal of specimens; SOPs are available with evidence of implementation

QA-4: Continuous laboratory improvement is documented

6.4.1: Gaps are identified through IQA and EQA reports and used as tools for improvement evident through relevant reports and documents
6.4.2: Incidents of non-conformance are investigated and corrective actions are implemented and documented
6.4.3: Documented preventive actions are taken to minimize recurrence of errors
6.4.4: There is a system to monitor and measure the performance of all processes of the laboratory through comprehensive internal audit, preferably bi annually

QA-5: External Quality Assurance (EQA) compliance procedure and tools are available

in the laboratory

6.5.1: Yearly external quality assurance (EQA) of the laboratory is ensured through external assessment by the nationally/internationally recognized bodies and valid certifications are available
6.5.2: Record of external quality assurance (EQA) reports are maintained
6.5.3: The laboratory utilizes Proficiency Testing at least once a year

7. Biosafety and Biosecurity (BSBS)

(6 Standards; 24 Measurable Criteria)

BSBS-1: The laboratory has a comprehensive and coordinated biosafety program

7.1.1: There is a policy for ongoing bio risk assessment and mitigation
7.1.2: Laboratory biosafety manual and SOPs are available which cover bio-safe practices in pre-analytical, analytical and post analytical processes and promotion of safety culture through regular staff trainings and refreshers
7.1.3: Biosafety SOPs are communicated to the laboratory staff as evident from record
7.1.4: The laboratory has a designated qualified technician for ensuring biosafety activities
7.1.5: Regular monthly biosafety monitoring reports are generated in the laboratory and available for review
7.1.6: Pathogen and Material Safety datasheets are available as relevant and utilized for worker safety

BSBS-2: Continuous staff biosafety measures are ensured and documented

7.2.1: The laboratory has appropriate consumables, equipment and facilities for biosafety, evident through inventory/stock registers
7.2.2: All staff involved in the handling and disposal of biohazard material and waste shall receive regular vaccination evident from records
7.2.3: Annual medical check-up of all staff dealing with biohazard materials and waste is documented

BSBS-3: Patient and visitor biosafety is ensured and documented

7.3.1: Waiting areas for patient and visitors are properly ventilated via fans/exhaust and air from laboratory working area is directed away from waiting area
7.3.2: Patients and visitors are not allowed inside the laboratory working area with evidence of controlled entry and signs are clearly marked

BSBS-4: There is documented procedure of bio-risk management

7.4.1: All incidents of laboratory biosafety breach are reported and documented
7.4.2: Required disinfectants/spill kits are available in the laboratory with clearly marked location and SOP for use

7.4.3: An annual antibiogram report is generated for national antimicrobial resistance database

BSBS-5: Measures to ensure biosecurity in the laboratory are practiced

7.5.1: Only authorized persons are permitted to enter the sample storage area and staff is identifiable through uniform/identity cards
7.5.2: Complete record of any transportation of samples is maintained
7.5.3: The waiting areas and non-containment areas for routine operations are well ventilated utilizing cross and artificial ventilation methods so as to assure flow and dilution of air and prevent stagnation. (A unidirectional, non-circulated airflow of 10 air exchanges per hour is recommended for routine operations where HVAC system is in place)
7.5.4: Hand and eyewash stations are available within 50 feet of all workstations

BSBS-6: The laboratory has well designed, comprehensive and coordinated waste management plan

7.6.1: Written laboratory waste management SOPs are available
7.6.2: Waste management SOPs are communicated to the laboratory staff with adequate training
7.6.3: The laboratory has appropriate consumables, collection and handling systems and equipment for waste management including PPE, color coded bins, sharps bins, bags, trolleys and secure storage area
7.6.4: Terminal waste disposal mechanism is available either on site or via contracts with waste disposal service organization
7.6.5: Waste is disinfected/steam autoclaved before final disposal and laboratory waste water drainage system assures treatment to render effluent biologically harmless before discharge
7.6.6: Record of date, time, type and weight of waste for final disposal is recorded and record is available for review

8. Access, Assessment and Continuity of Care (AAC)

(3 Standards; 8 Measurable Criteria)

AAC-1 Laboratory services are easily accessible

8.1.1: The location of sample collection area of laboratory is easily accessible
8.1.2: Basic facilities of clean water, light, ventilation parking backup power are accessible in the laboratory
8.1.3: There are clean toilets/washrooms with bolts, preferably separate for males and females are clearly marked
8.1.4: Toilets for disabled patients are available with wheelchair accessibility and support bars or alternate sample collection methods are offered
8.1.5: Disabled patients are facilitated for phlebotomy and other sample collection
8.1.6: Directional arrows pointing towards various important areas for patients are displayed in the laboratory

AAC-2: Laboratory services are provided as portrayed/claimed

8.2.1: List of laboratory services being provided are displayed/available

ACC-3: The laboratory record supports continuity of patient care

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

9. Care of Patients (COP)

(3 Standards; 7 Measurable Criteria)

COP-1: Emergency handling of patients is guided by protocols

9.1.1: SOPs for providing first aid/emergency care to the patients are documented
9.1.2: First aid kit is available and staff is conversant on its use
9.1.3: Relevant contact numbers for emergency services and referral are available and displayed at a prominent location in the laboratory

COP-2: Sentinel events are intensively analyzed

9.2.1: The laboratory has defined sentinel events and written definition is available
9.2.2: Sentinel events are intensively analyzed when they occur and corrective action is taken and documented

COP-3: The laboratory policies and procedures support home-based services to the patients (if applicable)

9.3.1: The laboratory is equipped with means of communication and transport services for home-based patient sample collection
9.3.2: The laboratory has appropriate means of collection and transportation of home-based samples including secure carry case, PPE, appropriate sample collection equipment and storage containers

10. Patient Rights and Education (PRE)

(3 Standards; 9 Measurable Criteria)

PRE-1: A system exists for obtaining consent when it is required

10.1.1: The laboratory has listed those situations where specific informed consent is required; form is available and there is evidence of correct utilization
10.1.2: The policy describes who can give consent when a patient is incapable of independent decision-making

PRE-2: Patients and families have a right to information on expected cost

10.2.1: The tariff list is available to patients and laboratory bears the cost of sample recollection when required

10.2.2: The lab offers and informs patients of cost-effective bundles and implements cost ceilings when defined by regulatory authority

PRE-3: Patient rights for appeals, complaints and confidentiality are assured

10.3.1: The laboratory has a documented policy and procedure for the registering and resolution of complaints or other feedback received from clinicians, patients or other parties

10.3.2: The laboratory provides contact details of management/ complaint system to public 10.3.3: Complaints are systematically investigated and corrective and remedial measures are taken and documented

10.3.4: Confidentiality of patient record is maintained

10.3.5: Disease data sharing is restricted to relevant authorities and there is strict policy on release of data directly or indirectly to unauthorized persons or media

Appendix 1
Laboratory Personnel Specifications

Position	Qualifications	Scope
Head of Laboratory	MBBS and preferably Fellowship/M-Phil-PhD level postgraduation in pathology/subject specialization recognized by PMDC	Can perform complex non & semi-automated procedures and advanced level inferences and interpretations; final verifyer and signatory *
Section Head	MBBS and Membership/fellowship/MSc/MPhil or PhD level postgraduation in related field recognized by PMDC or any other relevant professional council	Can perform complex non & semi-automated procedures and advanced level inferences and interpretations
Senior Medical Lab Technologist	MBBS/BSc 4 yr(MLT/MT/CLS/BMS) and MSc /Phd in related subject recognized by PMC/HEC	Can perform complex non & semi- automated procedures with automated interpretations
Medical Lab Technologist	MBBS/BSc 4 yr(MLT,CLS,MT) and 2 year Diploma recognized by PMDC/AHC	Can perform semi-automated/automated procedures with automated interpretations
Lab Technologist/Collection Center In charge	Matric/ FSc with 2 year Diploma in Lab Tech (SMF)	Can collect samples and perform automated /LIC and simple auto interpreted tests
Phlebotomist/In charge collection center	Matric; Phlebotomy or Lab technician 1 year certificate course (SMF or internal training)	Obtains blood samples, manages samples and performs administrative work
Quality Officer	Suitable for JD	
Stock Officer	Suitable for JD	
Bio-risk Officer	Suitable for JD	
Equipment Officer	Suitable for JD	
Administrator/Receptionist	Suitable for JD	

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

Appendix 2

Standards Applicable to Collection Centers	
ROM	**1**
FMS	**1,2,3**
HRM	**1,2,3,4,5,6**
QA	**2, 4**
BSBS	**1,2,3,4,5,6**
AAC	**1,2,3**
COP	**1,2,3**
PRE	**1,2,3**

Appendix 3

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

Appendix 4
POC/Kit Based screening/ RDTs
(Incudes NAAT, Antigen and Anti body-based tests, Lateral Flow Test, LAMP test)

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

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

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

POC/RDT tests can be utilized when

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

Recommended tests for PHC Centers/Out-patient Setting:

Some common tests are listed below <u>including but not limited to</u>:

- Pregnancy test
- Urine dipstick
- RDT for Malaria
- RDT for Dengue
- RDT for HIV
- RD for Hepatitis B
- RDT for Hepatitis C
- CBC using Automated Blood Analyzer
- Blood Grouping (manual)
- RDT for SARs CoV
- Hemoglobin
- Fecal Occult Blood
- Trop T

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