Standards for

Clinical Laboratory Services

Version 2

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Health Policies and Standards Department

Health Regulation Sector (2023)

INTRODUCTION

Health Regulation Sector (HRS) forms an integral part of Dubai Health Authority (DHA) and is mandated by DHA Law No. (14) of 2021 amending some clauses of law No. (6) of 2018 pertaining to the Dubai Health Authority (DHA), to undertake several functions including but not limited to:

- Developing regulation, policy, standards, guidelines to improve quality and patient safety and promote the growth and development of the health sector;
- Licensure and inspection of health facilities as well as healthcare professionals and ensuring compliance to best practice;
- Managing patient complaints and assuring patient and physician rights are upheld;
- Governing the use of narcotics, controlled and semi-controlled medications;
- Strengthening health tourism and assuring ongoing growth; and
- Assuring management of health informatics, e-health and promoting innovation.

The Standards for Clinical Laboratory Services aims to fulfil the following overarching DHA Strategic Priorities (2022-2026):

- Pioneering Human-centered health system to promote trust, safety, quality and care for patients and their families.
- Make Dubai a lighthouse for healthcare governance, integration and regulation.
- Leading global efforts to combat epidemics and infectious diseases and prepare for disasters.
- Pioneering prevention efforts against non-communicable diseases.
- Become a global digital health hub.

- Foster healthcare education, research and innovation.
- Strengthening the economic contribution of the health sector, including health tourism to support Dubai economy.

ACKNOWLEDGMENT

The Health Policy and Standards Department (HPSD) developed this Standard in collaboration with Subject Matter Experts and would like to acknowledge and thank these health professionals for their dedication toward improving quality and safety of healthcare services in the Emirate of Dubai.

Health Regulation Sector

Dubai Health Authority

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EXECUTIVE SUMMARY

The purpose of this document is to assure the provision of the highest levels of safety and quality Clinical Laboratory Services at all times. This Standard has been developed to align with the evolving healthcare needs and international best practice. It includes several aspects required to provide effective, efficient, safe and high-quality Clinical Laboratory Services. This standard includes the registration and licensure of clinical laboratories, health facility and healthcare professional requirements, staffing requirements, management responsibilities, management of clinical laboratory operations, specimen handling and reporting, equipment use and maintenance, patient care and safety requirements, management of health records, quality assurance and blood bank requirements and operations of mobile laboratories, blood bank and transfusion services, cytogenetic testing services, molecular testing services, molecular genetic services, drive through phlebotomy and drive through vaccination. It also addresses pre-assessment, diagnostics, informed consent, infection control, quality control, reporting key performance data and patient rights and responsibilities.

Clinical laboratories are healthcare facilities providing a wide range of laboratory procedures, which aid the physicians in carrying out the diagnosis, treatment and management of patients. Clinical Laboratories could be classified according to test specialization.

Clinical Laboratory Services are supported by a technical team who are trained, competent, experienced and privileged by the Clinical Privileging Committee to perform specified tasks within the confinements of permitted licensure and specialisation.

The key/major updates in the Version 2 of this Standard are as follows:

Addition of the following Standards:

- Standards Seven: Walk-in Laboratory Tests
- Standard Thirteen: Alcohol and Drug Testing Services
- Standard Fourteen: Drive Through Laboratory Services
- Standard Fifteen: Sample Collection Site

Addition of the following Appendix:

- Appendix 3: Permitted walk-in laboratory tests.
- Appendix 4: Validation of tests performed.

DEFINITIONS

Accreditation: in this document shall mean the process of officially evaluating clinical laboratory to maintain satisfactory standards, conducted by international accreditation organizations

Calibration: is the process of checking a measuring instrument to see if it is accurate.

Clinical Audit: is a systematic examination to review and determine whether actual activities and results comply with standards of care.

Clinical Laboratory: is a medical institution, building or place in which procedures for the examination of materials taken from or originating from the human body performed through testing by: chemistry, haematology microbiology, serology, cytology, pathology, immunohematology or other forms of examinations to obtain information for diagnosis, prophylaxis or treatment of humans (forensic pathology laboratories are an exception to this definition).

Confirmatory Test: is used to establish the presence (or absence) of disease as a basis for treatment decisions in symptomatic or screening test positive individuals.

Fine Needle Aspiration (FNA): is a non-surgical procedure by which a sample of tissue can be obtained from virtually any palpable lump for diagnosing of lesions. Typically, FNAs are performed by endocrinologists, cytopathologists, or surgeons and interpreted by experienced clinical cytopathologist. The procedure is fast, convenient, safe and well tolerated by patients. No anaesthesia or hospitalization is required.

Forensic Pathology: is a subspecialty of medicine that deals with the investigation of non-natural and suspicious deaths.

Functional Planning Unit: is a key feature of health facility guidelines and provide detailed information regarding common clinical departments or services in hospitals and other healthcare settings.

Health Care Worker (HCW): shall mean an individual employed by the health facility, whether directly or by contract with another entity, who provides direct or indirect patient care, this includes but not limited, healthcare professionals, medical and nursing students, administrative staff and contract employees who either work at or come to the health facility site.

Healthcare professional: shall mean a natural person who is authorized and licensed by the Dubai Health Authority (DHA) to practice any healthcare professions as per the unified prequalification's requirements for the United Arab Emirates.

Informed Consent: refers to an agreement and permission accompanied by full information on the nature, risks and alternatives of a surgical or interventional procedure. Informed consent for elective surgical procedures under general anaesthesia should be done in two-steps, i.e. consent at the point of pre-op assessment and consent on the day of the procedure. At both points, consent is taken in a written form.

Karyotype: is an individual's collection of chromosomes. The term also refers to a laboratory technique that produces an image of an individual's chromosomes. The karyotype is used to look for abnormal numbers or structures of chromosomes.

Levy Jennings's: is a graphical representation of control data, arranged in chronological order, that shows a mean or target value and one or more sets of acceptable limits.

Licensure: is issuing an official permission to operate a health facility to an individual, government, corporation, partnership, Limited Liability Company (LLC), or other form of business operation that is legally responsible for the facility's operation.

Patient: is any individual who receives medical attention, care or treatment by a DHA licensed healthcare professional in a DHA licensed health facility.

People of Determination: are people with special needs or disabilities, under the National Policy for Empowering People with Special Needs. The UAE law defines a person with special needs as someone suffering from a temporary or permanent, full or partial deficiency or infirmity in his physical, sensory, mental, communication, educational or psychological abilities to an extent that limits his possibility of performing the ordinary requirements as people without special needs.

Safety: means the condition of being protected against physical, psychological, or other types or consequences of failure, error, or harm, which could be considered non-desirable. This can take the form of being protected from the event or exposure to something that causes health losses, such as using a drug, a procedure, or risk in the care environment.

Screening Test: refers to the application of a medical procedure or test to people who as yet have no symptoms of a particular disease, for the purpose of determining their likelihood of having the disease. The screening procedure itself does not diagnoses the illness. Those who have a positive result from the screening test will need further evaluation with subsequent diagnostic tests (confirmatory test) or procedure.

Standard Operating Procedure (SOP): is a document, which contains detailed, written instructions for both operational and analytical procedures. It describes the stepwise process and technique of performing a test or procedure in the laboratory.

Validation: is a process of testing and analysing operations of medical devices to guarantee the output produced consistently fulfils the end user's needs and provide the intended medical benefit in actual-use conditions.

ABBREVIATIONS

ACLS	:	Advanced Cardiac Life Support
AED	:	Automated External Defibrillator
BLS	:	Basic Life Support
CACD	:	Clinical Audit and Control Department
CLS	:	Clinical Laboratory Scientist
CPD	:	Continuing Professional Development
CPR	:	Cardiopulmonary Resuscitation
CSF	:	Cerebrospinal Fluid
DCD	:	Dubai Civil Defence
DHA	:	Dubai Health Authority
DM	:	Dubai Municipality
EQA	:	External Quality Assessment
FANR	:	Federal Authority for Nuclear Regulation
FNA	:	Fine Needle Aspiration
FPU	:	Functional Planning Unit
HRS	:	Health Regulation Sector
IQC	:	Internal Quality Control
LJ	:	Levy Jennings's
LLC	:	Limited Liability Company
MOHAP	:	Ministry of Health and Prevention

PCR	:	Polymerase Chain Reaction
PQR	:	Professional Qualification Requirement
QA	:	Quality Assurance
QAP	:	Quality Assurance Program
SOP	:	Standard Operating Procedures
UAE	:	United Arab Emirates

1. BACKGROUND

Clinical Laboratories services are an essential and critical component at all levels of healthcare provision. They are required to support clinical diagnosis, for rationalizing and monitoring treatment/therapy, screening for epidemiological purposes, surveillance and control of diseases and to provide early warning of disease outbreaks. A Clinical laboratory is a DHA licensed health facility where tests are done on clinical specimens, body fluids such as blood, urine, sputum, stool, Cerebrospinal Fluid (CSF), peritoneal fluid, pericardial fluid, and synovial fluid, as well as other specimens, in order to obtain information about the health of a patient as pertaining to the diagnosis, treatment, and prevention of disease. Clinical Laboratories could provide services in one or more of the specialties listed below:

1. Anatomic Pathology
2. Clinical Biochemistry and Therapeutic Drug Monitoring
3. Hematology and Coagulation
4. Microbiology
5. Immunology
6. Blood bank and Transfusion
7. Histocompatibility (HLA lab)
8. Genetics and molecular biology
9. Forensic pathology

DHA licensed Physicians, Dentists and other healthcare professionals could prescribe Laboratory services to aid in diagnosis, prevention of disease and treatment of patients.

All DHA licenced Clinical Laboratories shall obtain accreditation as per the DHA Clinical Laboratory Accreditation Policy.

2. SCOPE

2.1. Clinical Laboratory services in DHA licensed health facilities.

3. PURPOSE

3.1. To assure provision of the highest levels of safety and quality Clinical Laboratory services in Dubai Health Authority (DHA) licensed health facilities.

4. APPLICABILITY

4.1. DHA licensed healthcare professionals and health facilities providing Clinical Laboratory services.

5. **STANDARD ONE:** REGISTRATION AND LICENSURE PROCEDURES

5.1. All health facilities providing Clinical Laboratory services shall adhere to the United Arab Emirates (UAE) Laws and Dubai regulations.

5.2. Health facilities aiming to provide Clinical Laboratory services shall comply with the DHA licensure and administrative procedures available on the DHA website https://www.dha.gov.ae

5.3. Licensed health facilities opting to add Clinical Laboratory services shall inform Health Regulation Sector (HRS) and apply to HRS to obtain permission to provide the required service.

5.4. The health facility should develop the following policies and procedure; but not limited to:

5.4.1. Patient education and Informed consent

5.4.2. Patient health record

5.4.3. Infection control measures and hazardous waste management

5.4.4. Incident reporting

5.4.5. Patient privacy

5.4.6. Emergency action plan

5.4.7. Patient discharge/transfer.

5.4.8. The laboratory shall have quality assurance policies for all services such as haematology, transfusion medicine, clinical chemistry, coagulation, immunology, microbiology and clinical microscopy etc.

5.5. The health facility shall provide documented evidence of the following:

5.5.1. Equipment maintenance services

5.5.2. Laundry services

5.5.3. Medical waste management as per Dubai Municipality (DM) requirements

5.5.4. Housekeeping services

5.5.5. Calibration of temperature dependent equipment (Refrigerator, freezer, incubator, water bath, room temperature monitoring device etc.)

5.5.6. Calibration of centrifuges, weighing balance, pipette, validation of biological safety cabinet.

5.5.7. Change of HEPA filter annually and fume hood validation.

5.6. The health facility shall develop and maintain easily accessible, detailed Standards Operating Procedures (SOPs) in an easy language, to be referred to as a laboratory benchmark work manual, to cover both analytical and operational procedures according to the scope of services described in the functional program of the Clinical Laboratory, which could include the following, but not limited to:

5.6.1. Professional expertise required to perform the tests

5.6.2. Staff appointment, training, evaluation.

5.6.3. List of tests performed in the clinical laboratory.

5.6.4. Maintenance of laboratory conditions including workspace, lighting, ventilation, temperature regulation, noise control, designated eating and smoking area.

5.6.5. Primary specimen collection.

5.6.6. Cleaning, sterilization and disinfecting procedures.

5.6.7. Equipment care, operation, calibration, validation and maintenance.

5.6.8. Data Management

5.6.9. The methodology for performing the tests

5.6.10. Reference ranges and Turn Around Time (TAT)

5.6.11. Precautions & safety measures including treatment if required and appropriate vaccination of staff

5.6.12. Handling and disposal of waste, including bio-waste

5.6.13. Internal quality control procedures, including procedure for reporting abnormal test results and corrective action procedure for quality control outliers

5.6.14. Internal audit procedures.

5.6.15. Participation in external quality assessment programs.

Note: For Guidelines on developing and managing SOPs, refer to **Appendix 1.**

5.7. The health facility shall maintain charter of patients' rights and responsibilities posted at the entrance of the premise in two languages (Arabic and English).

5.8. The health facility shall ensure it has in place adequate lighting and utilities, including temperature controls, water taps, medical gases, sinks and drains, lighting, electrical outlets and communications.

5.9. Based on the onsite assessment and after meeting the DHA requirements and recommendations, Health Regulation Sector (HRS) will issue a DHA license.

5.10. If a Clinical Laboratory is, a part of a DHA licensed health facility, it is an "Added Specialty".

5.11. The Clinical Laboratory license shall be visibly posted at the reception of the health facility.

5.12. At any time and upon reasonable cause, HRS, Clinical Auditors may conduct random inspections to audit the Clinical Laboratory to determine compliance and take appropriate action if required.

5.13. The onsite inspections may be scheduled or un-announced.

5.14. After every inspection in which non-compliance is identified, the health Inspector shall issue an inspection report stating the identified violation(s).

5.15. The clinical laboratory management shall submit to the HRS, Clinical Audit and Control Department (CACD) a written plan of correction of violations cited within fifteen (15) days after receiving the noncompliance letter stating the identified violations.

6. **STANDARD TWO:** HEALTH FACILITY REQUIREMENTS

6.1. Clinical Laboratory license shall be issued on two main categories:

6.1.1. Medical Laboratory (for standalone health facility)

6.1.2. Diagnostic Centre with two services (Clinical laboratory and diagnostic imaging services).

6.1.3. Add on service to a hospital, outpatient clinics or Day surgical Center.

6.2. All DHA licenced Clinical Laboratories shall obtain accreditation as per the DHA Clinical Laboratory Accreditation Policy.

6.3. The health facility should meet the health facility requirement as per the DHA Health Facility Guidelines (HFG) for Laboratory Unit.

6.4. The health facility should install and operate equipment required for provision of the proposed services in accordance to the manufacturer's specifications and should be validated for it's intended use prior to using it in the service.

6.5. All equipment used in the Clinical Laboratory settings shall be registered with the Ministry of Health and Prevention (MOHAP).

6.6. The health facility shall ensure easy access to the health healthcare services and treatment areas for all patient groups.

6.7. The health facility design shall provide assurance of patients and staff safety.

6.8. The health facility shall have appropriate equipment and trained healthcare professionals to manage critical and emergency cases.

7. **STANDARD THREE:** HEALTHCARE PROFESSIONALS REQUIREMENTS

7.1. All healthcare professionals in the DHA licensed health facility must hold an active DHA professional license and work within their scope of practice.

7.2. Appropriate and adequate number of DHA licensed healthcare professionals shall be present on duty during the working hours of the health facility to meet the functional program.

7.3. The number of DHA licensed healthcare professionals employed and assigned to each service shall be determined by management of the health facility and shall be consistent with type the of services provided.

7.4. All healthcare professionals directly dealing with patient should maintain a valid training/certification of one (1) or more of the following:

7.4.1. Basic Cardiopulmonary Resuscitation (CPR)

7.4.2. Basic Life Support (BLS)

7.4.3. Advanced Cardiac Life Support (ACLS)

7.5. For qualifications, training, experience and Continuing Professional Development (CPD) requirements of healthcare professionals employed by a DHA Clinical Laboratory refer to the Healthcare Professionals Licensing.

7.6. Medical Director/Laboratory Director

7.6.1. The Medical/Laboratory Director in an independent clinical laboratory or laboratory in hospital setup shall be a full time DHA licensed Pathologist (Clinical Pathologist or Anatomic Pathologist) or a licensed holder of a doctoral degree in chemistry, physical, biological, or clinical laboratory science from accredited institution.

7.6.2. In case of a specialized laboratory, a licensed Clinical Laboratory Scientist (CLS) with doctoral degree in the specialized field and appropriate relevant training and experience may serve as the Laboratory Director.

7.6.3. In an Outpatient Care Facility, a full time/part time pathologist may be the designated laboratory director.

7.6.4. To ensure safe and high-quality care is upheld within DHA licensed facilities the Medical Director/laboratory director shall abide by the DHA Policy for Role and Responsibilities of Medical Director.

8. **STANDARD FOUR:** MANAGEMENT RESPONSIBILITIES

8.1. To guarantee the smooth operation and ensure safe and quality services are provided in the Clinical Laboratory, the management lead by the Medical/Laboratory Director has certain responsibilities which include, but not limited to the following:

8.1.1. Comply with all federal and local laws and regulations.

8.1.2. Take necessary measures to distribute new DHA circulars and announcements among all staff.

8.1.3. Ensure policies and procedures are in place for the safe and quality provision of care and appoint responsible staff for developing and reviewing the documents.

8.1.4. Assess the consistent performance of contract and reference laboratory services.

8.1.5. Ensure all healthcare professionals employed have a current DHA license, are privileged as per the Clinical Privileging Policy and work within their scope of practice.

8.1.6. Maintain the recommended immunizations for health professionals working at the clinical laboratory, as per the DHA policy for Health Screening and Immunization of Healthcare Professionals.

a. Personnel reasonably expected to have direct contact with blood and other potentially infectious materials are identified and offered hepatitis B vaccinations free of charge. Personnel that decline the vaccine shall sign a declination form.

8.1.7. Support Continuous Professional Development (CPD) of the staff members by allocation of time for these activities.

8.1.8. Ensure competency assessment of staff that perform patient testing (both waived and non-waived testing).

8.1.9. Designate a qualified person(s) or team for the following:

b. Quality Manager or competent authorized person to ensure quality assurance. For details regarding quality assurance refer to **Appendix 2**.

c. Fire Safety.

8.1.10. Document ongoing assessment activities including corrective action, effectiveness reviews, policy and procedure revisions made to prevent recurrence of a problem and discuss assessment reviews with staff.

8.1.11. Cooperate with HRS inspectors and/or any duly authorized representative when they visit the health facility and/or request for any material.

8.1.12. Avoid giving misleading information and false statements, which may lead to legal action against any employed DHA, licensed healthcare professionals or the health facility.

8.1.13. Settle any violation fines related to employed healthcare professionals or the health facility.

8.1.14. Maintaining malpractice insurance for all licensed healthcare professionals as per article Cabinet Decision no. (40) of 2019 concerning UAE Federal Law concerning Medical Liability.

8.1.15. Use the DHA Infectious Disease Notification Service to report communicable disease required by the Cabinet Decision no. (24) of 2020 concerning Publication and exchange of health information on communicable diseases and

epidemics and misinformation related to human health, and keep a log of it, aligned with DHA Communicable Disease Notification Policy.

8.1.16. Submit to the Health Data and Information Analysis Department in DHA the required statistical data of the health facility.

8.1.17. Obtain prior approval from the Ministry of Health and Prevention (MOHAP) for media and advertisement materials, for further information regarding the media and advertisement materials approval procedures and requirements please visit the MOHAP website.

9. **STANDARD FIVE:** MANAGEMENT OF THE CLINICAL LABORATORY OPERATIONS

9.1. Specimen handling and reporting

9.1.1. Requisition form

a. Should be completed by a licensed physician requesting the tests and sent along with the specimen/patient to the laboratory (in the absence of electronic data transfer).

b. Should contain the patient's identity, age, sex, location, name of physician, last menstrual period, date of specimen collection, source of specimen when appropriate and the investigations requested.

c. The referring physician should be encouraged to mention the provisional or working diagnosis and relevant clinical and treatment history in the space provided.

9.1.2. Receiving specimens from outside the country will require the licensed health facilities/clinical laboratories to obtain approval from MOHAP.

a. Only receive specimens for testing and diagnostic purposes from licensed health facilities/clinical laboratories in the respective country.

b. The testing laboratory shall receive, handle and discard samples with full precautious and infectious control measures.

c. All specimens and infectious substances received must be packaged and shipped in compliance with International Air Transport Association (IATA) and UAE federal regulations.

9.1.3. Specimen collection

a. It is the first phase of interaction between the patient and the laboratory.

b. It can be done at the patient's bedside or in the laboratory phlebotomy room/specimen collection facilities depending on the type of specimen required for the test.

c. Appropriate counselling should be done before specimen collection. Attention should be paid to patient's sensibilities during the entire process. Any error in specimen collection can lead to erroneous results.

d. Trained phlebotomist shall be employed by the clinical laboratory for specimen collection.

e. Physicians, nurses or medical laboratory technologist can collect specimens who are regularly trained, to ensure their competency.

f. The individual collecting the specimen must confirms the patient's identity by checking at least two identifiers before specimen collection and labels the specimen in the presence of the patient.

g. Clinical Laboratory may have a "Primary Specimen Collection Manual", containing information on patient preparation before specimen collection (if any), and exact methodology of specimen collection (type of collection container and amount of specimen to be collected, Phlebotomy order of draw and instructions for fill volume and proper mixing) labelling, handling, transportation and storage of the specimens.

   i. This manual shall be available for reference and should be used for training of staff engaged in specimen collection.

   ii. The laboratory shall provide adequate and appropriate information/instructions to patients wherever necessary.

h. Specimens shall be secured appropriately to prevent leakage, spillage or contamination. They must be transported in biohazard bags and sent to the laboratory along with the completed laboratory requisition form (in the absence of electronic data transfer).

i. A biohazard symbol shall be used on the specimen transportation containers during transportation.

j. Appropriate specimen transportation kit (such as use of dry ice, ice packs, etc.) shall be used wherever required.

k. Clinical laboratories shall have clear criteria for rejection of samples such as haemolysed or lipemic samples.

l. The laboratory shall have procedures to care for patients who experience adverse reactions from phlebotomy such as hematomas, abrasions, nausea, fainting. Vomiting, nerve damage, seizures and injuries.

m. Validation of tests shall be performed as elaborated in **Appendix 4**.

9.1.4. Accession List

a. Record of all the specimens received by the laboratory for analysis shall be prepared by the laboratory at the time of specimen receipt.

b. The accession list must record the patient's identity including name, age, sex, location in the hospital/health facility, name of referring physician, investigations requested, date and time of receipt of specimen and condition of the specimen at receipt.

c. Assigns a unique number to register each specimen received, which can be used to trace the specimen. The test results and remarks if any shall also be entered in the accession list.

d. The accession list may be computer generated and the condition of specimen at receipt may not be recorded unless it has been rejected.

e. Records of specimens referred to other clinical laboratories for testing must be kept at the referring laboratory.

9.1.5. Reporting test results

a. Test results approved and signed by the most responsible physician/team and shall be made available to the ordering physician.

b. Results shall be reported clearly, without any errors, specifying measurement procedure where appropriate and units of measurement. Test results shall also contain the following:

   i. Reference intervals as applicable

   ii. Patient details with identification number

   iii. Test details

   iv. Date and time of specimen collection

   v. Result reporting

   vi. Specimen source

   vii. Name

   viii. Address of laboratories that performed the examinations

   ix. Referral laboratory when applicable.

c. For quantitative test, laboratory shall not report any numeric result outside the Analytical Measurement Range of the analyser, unless the sample is processed by dilution, a mixing procedure or concentration.

d. The laboratory shall have a list of antimicrobial agents to be reported for specific organisms isolated from various body sites.

e. The laboratory shall have a policy for identifying and reporting critical results.

f. The laboratory shall ensure that the expected Turn Around Time for each test is well defined in their internal policy.

g. The laboratory shall have a mechanism for correcting erroneous result in a manner that identifies the corrected result as revised and the date and time of correction. Both the original and corrected reports must be maintained and retrievable by the laboratory.

9.1.6. Ethical considerations

a. Referring physicians are strictly prohibited from taking any commission for referring patient to specific Clinical Laboratories.

b. Personnel working in Clinical Laboratories shall be aware of their ethical responsibilities and comply with the DHA Code of Conduct for Healthcare Professionals.

c. Personnel working in Clinical Laboratories shall maintain patient's information confidentiality at all times.

d. Healthcare Professionals working in the clinical laboratory shall not use expired reagents/kits/specimen collection supplies.

i. The clinical laboratory shall validate or verify assay performance of new tests, methods, or instruments prior to patient testing.

ii. Evidence of documented validation must be readily available for any inspection.

9.1.7. Outsourcing Clinical Laboratory Services

a. The outsourced laboratory shall:

I. Be accredited as per the DHA Clinical Laboratory Accreditation Policy.

II. Have a primary sample collection and handling manual, which may be electronic.

III. Have appropriate conditions and facilities for sample transport from the laboratory and a fast turn-around time for the test.

IV. Ensure that reports are received in a timely manner to support the continuity of care.

V. Clinical Laboratory test shall be performed only upon a request from a DHA licensed Physician and sent along with the specimen to the testing Clinical laboratory.

VI. Clinical laboratories shall refrain from promoting or marketing laboratory tests aiming to attract patients directly to visit the laboratory without consulting or referring from the DHA licensed treating Physician.

VII. Clinical laboratories are prohibited from giving direct or indirect recommendations to patients for the use of certain drugs, products or foods, or to follow a specific lifestyle based on laboratory results, these

recommendations should be given only by the treating physician or concerned specialist.

9.1.8. Outsourcing Clinical Laboratory Services outside the UAE

a. It is prohibited to send patient's samples outside UAE, unless the following conditions are met:

I. Unavailability of the requested medical test within the laboratory services in the UAE.

II. Report from a consultant physician in case of rare tumor whose specialization does not exist in the UAE.

III. Sending samples should be through a laboratory or health facility licensed by the DHA.

IV. Clinical laboratories receiving the sample outside the country should be accredited; in accordance with the DHA Clinical Laboratory Accreditation Policy.

V. Notify DHA with the entire laboratory tests sent outside the UAE. Permission shall be obtained once per specific laboratory test.

VI. The notification shall include the following details:

- Data of health facility that requested the investigation test.
- Physician details and specialty.
- Full details of the receiving health facility including the address.
- The purposes of requesting the test outside the country.

- Report all above details to HRS via the following email address: info@dha.gov.ae along with supporting documents.

9.2. Safety

9.2.1. General Safety Considerations

a. Personnel working in clinical laboratories may be exposed to risks from various chemicals, infectious materials, fire hazard, gas leak etc. The environment is also at risk of being contaminated by hazardous materials used and wastes generated. Safety therefore includes protection of both the staff and the environment from hazardous materials. General safety measures include:

I. Documentation of safety Policies and Procedures.

II. All staff shall be aware about the laboratory safety policies and procedures and follow these at all times.

III. Eyewash facility shall be available as "stand-alone" facility or attached to sink or portable. Sealed single use solution bottles may also be used. At locations where, hazardous chemicals are handled by employees, emergency eyewash and shower equipment shall be available no greater than ten (10) seconds travel distance from areas in the laboratory where hazardous chemicals are present with unobstructed pathway. The door must be open in the direction toward the eyewash/ shower station.

IV. Laboratories shall ensure proper preservation and security of specimens.

V. Laboratory personnel shall be thoroughly trained in managing emergencies such as biohazard spillage/large chemical spillage, gas leakage etc. as applicable to the facility.

VI. Periodic checking of all safety equipment and accessories shall be ensured.

VII. Laboratory personnel shall follow safe hygienic practices, which include hand washing, wearing protective clothing, gloves, eye protection etc.

VIII. Mouth pipetting is strictly prohibited. A rubber bulb, automatic pipette or, or other safety device must be used for all pipetting.

IX. For reasons of both safety and security, personal belongings (coats, bags, pocketbooks, etc.) must not be kept in the work areas of the laboratories. Personal belongings must be secured in employees' lockers or staff designated areas.

X. The laboratory shall restrict the access to testing area; for authorized personnel only.

9.2.2. Biohazard Materials

a. An updated list of hazardous materials used in the laboratory shall be maintained. All hazardous materials shall be accounted for on a continuous basis.

b. Biohazard symbol shall be used on all containers containing biohazard materials while being transported to the laboratory or disposed of.

c. Destruction/disposal of hazardous material should be authorized, supervised and handled according to standard procedures.

d. Solid biohazard waste disposal shall be done through contracted DM approved companies.

e. Liquid biohazard waste must be pre-treated and decontaminated using appropriate disinfectants, prior to disposal.

f. All anatomic pathology wastes are placed in a biohazard waste container for incineration.

g. Biohazard spill kits and chemical spill kits must be available in the Laboratory.

h. Accident/incident/injuries record of laboratory personnel should be maintained and reported to the designated authority. The report should include description of the event, factors contributing to the event and information on first aid or other health care provided. This information can

be analysed periodically towards effectively controlling and preventing future events. The laboratory safety officer should check the records.

i. Policies for Tb exposure control if the laboratory is processing the test for mycobacteriology.

j. Establish engineering controls and work practice controls to ensure control and prevention of infection.

k. As part of an institution-wide plan to prepare and respond to a bioterrorism event, the microbiology laboratory must have policies and procedures for the recognition of isolates that may be used as agents of bioterrorism.

9.2.3. Chemical Safety

a. The clinical laboratory shall have policies to ensure the safety of chemicals used in the laboratory that includes information concerning labelling, handling, hazard evaluation, safe storage and safe disposal of chemicals.

b. Chemical Safety Data Sheet (SDS) shall be available and accessible to all staff.

c. Containers of hazardous chemicals shall have precautionary labels indicating type of hazard.

d. The laboratory shall limit the storage of flammable and combustible chemicals as per the amount required and shall store these chemicals inside flammable storage cabinet.

e. The laboratory shall have policy on formalin and xylene safety regarding frequency of monitoring, action limits, and criteria for discontinuation of monitoring and documented records of monitoring shall be available.

9.2.4. Handling Sharps

a. Recapping of needles is strictly prohibited. Contaminated needles or other sharps must not be sheared, bent, recapped, or removed from syringes or other devices unless it can be accomplished using a mechanical device (such as a haemostat) or by using re-sheathing instruments or self-sheathing needles or retractable needles with locking system to prevent recapping of needles by hand. The laboratory shall have procedures to follow after a sharp injury; that includes needlestick injuries.

b. Sharps (i.e., needles, syringes with attached needles, scalpel blades) must be placed in a stable, rigid, puncture-resistant “sharps” container labelled with a biohazard warning label. Slides, coverslips, and capillary tubes may be placed in a rigid, puncture-resistant container or red-bagged biohazard waste container.

c. Sharps containers must not be overfilled. When a sharps container becomes two-thirds full, seal and discard it into a red-bagged biohazard waste container or into a red bag for incineration.

9.2.5. Fire Safety

a. Fire is a potential risk for all healthcare organizations, and is very critical where immobile patients are in locations that are difficult to evacuate. To respond to fire risk the clinical laboratory should:

b. Establish a fire safety plan for early detection, confining, extinguishment, rescue and alerting the DCD.

c. Assess the fire risks to the facility

d. Establish a No Smoking policy

e. Understand and manage risks associated with the facility's location and physical structures

f. Maintain and test fire protection and emergency communication systems

g. Train staff to respond to fire events on the premises.

h. Monitor whether adequate numbers of suitably trained staff are distributed across all shifts to respond appropriately to a fire event.

9.3. Health Records

9.3.1. Laboratory data management includes recording details of the patient, findings of analysis, reporting of results and archiving the data for future reference.

9.3.2. The format of recording and reporting results should be described in the SOPs.

9.3.3. Laboratories sending reports electronically should include electronic signature of the authorized signatory. Laboratories should be able to provide critical information required by a physician on telephone.

9.3.4. Provisions shall be made for securing electronic laboratory reports.

9.3.5. Equipment maintenance reports must be kept for future reference.

9.3.6. Patient Result Records and materials shall be retained aligned to the DHA Guidelines for Managing Health Records.

9.3.7. An internal policy must be available concerning the time keeping of the patient laboratory reports as either hard copy or soft copy according to the clinical laboratory's internal policies. For further information regarding retention of patient result, records and materials refer to DHA Policy for Health Information Assets Management.

10. STANDARD SIX: MOBILE LABORATORIES

10.1. A mobile laboratory is a portable, enclosed structure on a vehicle, designed and equipped with the necessary and appropriate accommodations and environmental conditions for the transportation and use of laboratory equipment to carry out analyses in the field.

10.2. A mobile lab is an add on service to an active facility license and could be a part of a Hospital, Day Surgical Center or a Clinical Laboratory as long it has the following:

10.2.1. The mobile laboratory should be accredited as per the Clinical Laboratory Accreditation Policy.

10.2.2. The mobile laboratory is designed as a regular clinical laboratory, the size depends on the expected volume of testing to be performed, and the number laboratory staff employed.

10.2.3. For facility requirements the mobile laboratory shall align with the DHA Health Facility Guidelines (2019) – Mobile Healthcare Unit.

10.2.4. The mobile laboratory shall have effective and effective storage, testing and documentation solutions.

10.2.5. The scope of services provided by the mobile laboratory should be elaborated and documented and the mobile laboratory should not provide any service that is out of its scope (e.g. a Mobile laboratory licensed to provide phlebotomy services, shall only provide that service).

10.2.6. There should be a dedicated space to park the vehicle to ensure the temperature requirement in the vehicle is maintained, as required.

10.2.7. The mobile clinic shall have the equipment to cater for the registered services.

10.2.8. Approved vendors shall maintain all the equipment and the maintenance performed shall be documented.

10.2.9. Equipment that is very sensitive to movement and fluctuation in temperature shall not be used in a mobile laboratory.

10.2.10. Quality assurance of the mobile laboratory is supervised by the quality assurance team of the health facility it is under.

10.2.11. All healthcare professionals should be employed as per the service provided and should maintain a valid training/certification in basic CPR, or BLS or ACLS.

11. **STANDARD SEVEN:** WALK-IN LABORATORY TESTS

11.1. Licensed Clinical Laboratories may accept walk-in patients for specific laboratory tests that do not require a physician's order. Refer to the list of services permitted elaborated in **Appendix 3**.

11.1.1. Critical laboratory results shall be reported clearly to the patient.

11.1.2. The laboratory should direct the patient to seek further medical advice.

11.1.3. The laboratory shall keep record of the communication with the patient.

12. **STANDARD EIGHT**: BLOOD BANK AND TRANSFUSION SERVICES

12.1. Blood bank and Transfusion Service shall have a medical director who is a licensed physician, qualified by training, experience.

12.1.1. The medical director shall have responsibility and authority for all medical and technical policies, processes and ensures storage of blood and blood components are at appropriate recommended temperatures, with continuous monitoring and recording of temperature-controlled spaces with an alarm system.

12.2. Blood & components storage devices shall have the capacity and design to ensure that the proper temperature is maintained, monitored for storage of blood & component. Storage devices shall have an alarm system.

12.2.1. The alarm shall be set to activate under conditions that will allow proper action to be taken before blood, blood components, reach unacceptable conditions.

12.3. The Laboratory Director of the blood bank and/or transfusion services shall ensure updated policies and procedures are available to guide acceptable practices in the blood bank and/or health facility providing transfusion services, could include (if applicable), but not restricted to the following:

12.3.1. Accuracy of ABO and Rh Reagents

12.3.2. Selecting Blood and Components for Transfusion

12.3.3. Blood Issuance

12.3.4. Quarantine and discard of blood units

12.3.5. Transportation and storage of blood

12.3.6. Reporting, Investigating and Evaluation of suspected Transfusion Reaction.

12.3.7. Transportation and storage of blood

12.3.8. Handling of Life-threatening Situation to expedite testing or abbreviated testing such as in massive transfusion.

12.3.9. All hospitals with blood transfusion services shall have a policy and procedure protocol for managing massive transfusion.

12.4. The transfusion service laboratory shall inspect the blood components upon receival.

12.5. The transfusion service laboratory shall notify the blood donation services when blood components are a suspected primary cause of an adverse reaction.

12.6. Hospital based blood banks are responsible for cross matching the patients' blood with the units intended for transfusion.

12.7. Conducting additional blood test to ensure safety of transfusion.

13. **STANDARD NINE:** CYTOGENETIC TESTING SERVICES

13.1. Genetic testing shall only be requested by a DHA licensed Physician with enough clinical justification, after patient consultation, in a DHA licensed Health facility.

13.2. Genetic testing shall not be sold directly to consumers by any facilities, institutions or organisations that are not DHA licensed Health Facilities and shall not be requested by individuals who are not DHA licensed Physicians.

13.3. A Consultant/Specialist Physician shall be consulted before and after genetic testing.

13.4. Genetic results shall not be communicated to the patients directly. The results shall be directed to the referring/treating Physician.

13.5. Only the referring/treating Physician shall make recommendations or prescribe to the patient any medication or healthcare products, based on the laboratory results.

13.6. All advertisement and marketing materials shall be aligned with the DHA Standards for Medical Advertisement Content on Social Media.

13.7. All Cytogenetics laboratories shall follow the International System for Human Cytogenetic Nomenclature.

13.8. Test results shall not be reported unless control processes are acceptable.

13.9. The Cytogenetic laboratory records and results shall accurately reflect all stages of the process and all results obtained.

13.10. The Cytogenetic laboratory records shall include the following:

13.10.1. Media used

13.10.2. Reactions observed

13.10.3. Number of cells counted

13.10.4. Number of cells karyotyped

13.10.5. Number of chromosomes counted for each metaphase spread

13.10.6. Quality of the banding.

13.11. The resolution should be appropriate for the type of tissue or specimen and the type of study required, based on the clinical information provided to the laboratory.

13.12. An adequate number of karyotypes should be prepared for each patient.

13.13. The Cytogenetic laboratory shall permanently retain slides, negatives, prints, or magnetic media for all abnormal cases.

13.14. The Cytogenetic laboratory report should include the following:

13.14.1. Use of appropriate nomenclature

13.14.2. Summary of the observations

13.14.3. Number of cells counted and analysed

13.14.4. Documentation of any preliminary report, such as a verbal or telephone report

13.14.5. All required clinical information.

13.14.6. For in situ hybridization (ISH) tests that provide independent predictive information, the patient report shall include information on specimen processing, the probe, and the scoring method used.

13.15. All errors that are identified in the final report shall be thoroughly investigated, and the results of such investigations shall be recorded.

13.16. Samples shall be identified in all phases of analysis, including the following:

13.16.1. Specimen collection and accessioning

13.16.2. Cultures

13.16.3. Cell preparations

13.16.4. Photography or other image reproduction technique

13.16.5. Photographic printing and storage

13.17. The Cytogenetic laboratory shall notify Physicians wishing to order a cytogenetic test that an informed consent is required and shall make available to the practitioner test-specific information for patient use in decision-making and the informed consent process shall be aligned with the DHA Guidelines for Patient Consent.

13.18. Quality control data shall be reviewed and assessed once a month by the laboratory director or designee.

14. STANDARD TEN: MOLECULAR TESTING SERVICES

14.1. The laboratory shall develop and maintain written policies and procedures for molecular testing as follows:

14.1.1. Appropriateness of testing (Note: For genetic testing, additional information might be required to select appropriate tests and to ensure accurate test interpretation and reporting of results).

14.1.2. Prevention of nucleic acid contamination (including in work areas, equipment, personal protective equipment, and reagents) during specimen preparation and testing and monitoring the presence of false positive results (e.g., due to nucleic acid contamination).

14.1.3. Documentation of all nucleic acid reagents, including probes and primers, used in a particular test.

14.1.4. Quality and quantity of nucleic acid needed for a particular test.

14.1.5. Investigation and corrective action taken for internal controls that fail to amplify.

14.1.6. Competition between target and internal controls (for example, false negatives or presence of a target signal is strong, with a negative internal control signal).

14.1.7. Investigation of discrepant results between different methods.

14.1.8. Reuse of patient specimens for quality control purposes.

14.2. Validation studies shall include representatives from each specimen type expected those that are to be tested in the assay and specimens representing the scope of reportable results.

14.3. Molecular testing reports shall include specific testing information including the following information:

14.3.1. Testing methodology

14.3.2. Limitations of the method

14.3.3. Interpretation of findings

14.3.4. Recommendations for additional testing.

15. STANDARD ELEVEN: MOLECULAR GENETIC SERVICES

15.1. Molecular Genetic testing shall only be carried out against a DHA licensed Physician's order.

15.2. The DHA licensed health facility shall refrain from requesting or performing paternity or genealogical tests; except in the following cases:

15.2.1. Obtain prior official written approval from DHA.

15.2.2. Upon a request from the competent judicial authorities in UAE and the concerned health authorities.

15.3. All tests carried out should be FDA approved or equivalent.

15.4. The laboratory shall develop and maintain policies and procedures that address recommending referral for genetic counselling.

15.5. The laboratory shall have policies for molecular genetic testing that includes purification or isolation of nucleic acids, measuring the quantity and quality of nucleic acid, running of quality control, Nucleic Acid Amplification and interpretation of result.

15.6. Molecular genetic testing reports shall include the following information:

15.6.1. List of mutant genes for alleles tested.

15.6.2. Any recommendations for referral to a genetic counsellor.

15.6.3. Detection rate of the test.

15.6.4. Use of standard nomenclature for genes and mutations.

15.6.5. Clinical implications of mutations detected.

15.7. The laboratory should consider three categories of test performance in the evaluation process:

15.7.1. Analytic validity

15.7.2. Clinical validity

15.7.3. Clinical utility.

16. STANDARD TWELVE: CYTOPATHOLOGY SERVICES

16.1. The laboratory shall have procedures to prevent cross contamination of specimens between gynaecologic and non-gynaecologic specimens and non-gynaecologic cases

that have high potential for cross-contamination from other nongynecological specimens during processing and staining.

16.2. Each individual evaluating cytology preparations by manual microscopic technique shall examine no more than hundred (100) slides (gynaecologic and non-gynaecological or both) in a day.

16.3. For the laboratory that perform immunochemical tests that provide predictive information that are independent of diagnosis or other cytopathologic findings, the patient report must include information on specimen fixation, specimen processing, antibody clone used and the scoring method used.

16.4. The laboratory shall have a policy for correlation of the results of specialized studies (e.g., molecular studies, immunocytochemistry) with the cytologic diagnosis for non-gynaecologic cytopathology cases.

16.5. The laboratory shall have a policy on communication of significant and unexpected cytopathology findings and notification of significant amendments to patient reports. The laboratory shall have documented records of the same.

16.6. Ensure cytopathology findings are corelated with clinical information and with histologic diagnosis, when available.

16.7. All cytopathologic reports shall be authorized by a DHA licensed pathologist.

16.8. The cytopathology reports shall include a concise descriptive diagnosis in a standard descriptive terminology that includes a general categorization and descriptive diagnosis.

16.9. The laboratory shall promptly notify the responsible clinician(s) when there are changes in the reports that significantly affect patient care.

16.10. Cytology slides and blocks are properly stored in a temperature controlled, pest-free, organized manner to prevent contamination from blood or other fluids or tissue and be readily accessible for retrieval.

17. STANDARD THIRTEEN: HISTOPATHOLOGY SERVICES

17.1. All macroscopic tissue gross examinations are performed by a DHA licensed pathologist or by qualified competent laboratory DHA licensed healthcare professional under the supervision of a qualified pathologist.

17.2. The laboratory shall have a policy that includes the proper dissection, description and histologic sampling of various specimen types and to prevent cross-contamination of specimens during grossing.

17.3. All histopathology results shall be reviewed and authorized by a DHA licenced pathologist.

17.4. The laboratory shall have a policy regarding the communication of significant and unexpected surgical pathology findings and notification of significant amendments to patient reports. The laboratory shall have documented records of the same.

17.5. The laboratory shall promptly notify the responsible clinician(s) when there are changes to reports such as that significantly affect patient care.

17.6. The laboratory shall correlate the results of specialized studies with the morphologic diagnosis.

17.7. Slides and blocks shall be stored properly in a temperature-controlled, pest-free, organized manner to prevent contamination from blood or other fluids or tissues and be readily accessible for retrieval.

17.8. The laboratory shall have a policy to prevent cross-contamination during the various phases of tissue handling such as processing, embedding, microtomy, staining and slide preparation.

17.9. Previous cytologic and/or histologic material from the patient is reviewed with current material being examined when appropriate.

17.10. When frozen section and final diagnosis results are discrepant, there is a review of findings, and the discrepancy is resolved and shall record this in the final report.

18. STANDARD FOURTEEN: ALCOHOL AND DRUG TESTING SERVICES

18.1. Clinical Laboratories should apply for alcohol, drug and substance abuse testing through Sheryan (under amend facility license request). The application should include:

18.1.1. Name and contact details of the accountable person or the laboratory manager who will be responsible for this service.

18.1.2. Name of the alcohol and drug tests that will be carried in service.

18.1.3. Change in facility design layout (if required).

18.2. Alcohol and Drug Testing Laboratories should acquire the following accreditations within 2 years of application:

18.2.1. College of American Pathologists (CAP)

18.2.2. ISO accreditations ISO/IEC 17025

18.3. Each lab should have procedure manual copies of all procedures and dates on which they are in effect should be maintained as part of the manual, which includes but not limited to:

18.3.1. Criteria of the collection site.

18.3.2. Chain of custody form.

18.3.3. Confidentiality of the Individual.

18.3.4. The principles of each test, preparation of reagents, standards and controls, calibration procedures, sensitivity of the method used for testing and cut-off values.

18.3.5. Mechanism of reporting results.

18.3.6. Criteria for unacceptable specimens and results.

18.3.7. Corrective actions to be taken when the test system is outside of acceptable limits.

18.3.8. Sampling method on direct observation.

18.3.9. Procedure of splitting sample and procedure of transportation of the samples.

18.3.10. Drug Screening Records (where, custodian, how long it is kept)

18.4. Each laboratory should have the capability to perform the screening and confirmatory tests at the same laboratory site.

18.4.1. If confirmatory test is not done in the same clinical laboratory, then there should be a contract in place with the outsourced laboratory that clearly includes the name of laboratory and their accreditation on each tested drug/substance.

18.5. The testing procedure of each laboratory shall be capable of detecting drugs, drugs metabolites, adulterants, and substituted specimens.

18.6. The specimen should be treated as evidence and all aspects of the procedure shall be documented and available for possible court testimony.

18.7. Drug testing laboratory should use chain of custody procedure to maintain control and accountability of specimens from receipt through completion of testing, reporting of results, during storage, and continuing until final disposition of specimens.

18.7.1. The date and purpose should be documented on a laboratory chain of custody form each time a specimen is handled or transferred, and every individual in the chain should be identified.

18.8. The availability of MOHAP approved Evidential Breath analyser is mandatory to conduct alcohol testing.

18.8.1. The analyser should have a distinguishing level for alcohol from acetone at the 0.02% alcohol concentration.

18.9. The laboratory shall have the capability of conducting blood alcohol concentration, or urine alcohol level, these tests can be used as an extra evidential method in cases of positive breath analyser test.

18.10. An additional approval from General Civil Aviation Authority is required to conduct Alcohol and Drug Testing for all aviation industries.

19. STANDARD FIFTEEN: DRIVE THROUGH LABORATORY SERVICES

19.1. Requests for drive through add-on service is applicable for the following:

19.1.1. Hospital

19.1.2. Medical laboratory or

19.1.3. Outpatient clinics with existing laboratory services.

19.2. The drive through laboratory services shall be provided in an area within the premise of a DHA licensed Health facility.

19.3. No Objection Certificate (NOC) from landlord or concerned authorities is required.

19.4. Drive-through laboratory services may include but not limited to the following:

19.4.1. Phlebotomy

19.4.2. Swab collection

19.4.3. Specimen receiving.

19.5. The drive through laboratory services shall be provided only by DHA licensed healthcare professionals (Registered Nurses or Phlebotomists)

19.6. Testing shall be initiated only upon physician's order and the result should be sent back to the treating physician. A copy of the results could be shared with the patient.

19.6.1. For walk-in patients refer to information mentioned above.

19.7. All staff shall maintain a current Basic Life Support (BLS) certification.

19.8. The drive through laboratory facility shall maintain accessibly available life support items and an Automated External Defibrillator (AED) for immediate and safe provision of care, if required. Mock drill should be conducted accordingly.

19.9. The drive through laboratory facility shall maintain an Emergency Readiness Policy and Procedure to address any unforeseen emergencies.

19.10. Tests that requires special phlebotomy procedure such as blood culture tests and which requires a sterile technique, shall not be performed at these facilities.

19.11. These facilities shall have a tunnel for entrance of the vehicle, where appropriate temperature is maintained, a registration area, and a dedicated storage area with maximum temperatures of 24 degrees centigrade.

19.12. Curtains with 60% visibility could be positioned to divide the lane into 2 compartments at entry, in the middle and at the exit.

19.13. There shall be availability of an adjustable table to be inserted through the door of the car, in order for the patient to rest the arm.

19.14. Ensure provision of a blood collection chair for patients from who blood cannot be collected while sitting in the car.

19.15. Ensure availability of shaded parking spaces dedicated as resting areas after the blood collection.

19.16. These facilities are not entitled to provide telemedicine consultation. Telemedicine Consultation should be provided only by licensed telehealth providers permitted for tele-consultation services and as aligned with the DHA Standards for Telehealth Services.

19.17. Patients privacy should be ensured, especially for female patients.

19.18. Infants and children below the age of seven (7) years shall not tested at a drive through laboratory services.

20. STANDARD SIXTEEN: SAMPLE COLLECTION SITE

20.1. Sample collection site shall require a separate DHA license as a Medical laboratory.

20.2. Only the following DHA licensed facilities can apply for off-site sample collections site license:

20.2.1. Hospital(s).

20.2.2. Medical laboratories/Diagnostic centre(s).

20.3. The name of the sample collection site should be linked to the main facility as "Main Facility name - Collection Site".

20.4. The collection site shall be divided into minimum sections of waiting, collection, receiving, storage and medical waste.

20.5. Patient privacy shall be maintained at all times.

20.6. There shall be a minimum of two full-time healthcare professionals in the collection site who may be a DHA licensed physician, registered nurse or phlebotomists.

20.7. The collection site shall obtain accreditation within two (2) years from the date of obtaining the license and upon renewal.

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APPENDICES

APPENDIX 1: GUIDELINES ON STANDARD OPERATING PROCEDURES (SOPS)

1. Clinical Laboratories must develop detailed SOPs that cover both analytical and operational procedures according to the scope of services described in their functional program and provided by the health facility.
2. SOP is a document, which contains detailed, written instructions for both operational and analytical procedures. It describes the stepwise process and technique of performing a test or procedure in the laboratory.
3. SOPs should be simple and written in an easy language to understand.
4. It is important for Analytical SOP documents to be readily available in the working area and to be referred to as laboratory bench work manual.
5. SOPs may contain information on who can perform the test, how to carry out the test including pre-analytical, analytical and post-analytical stages of test/procedure, laboratory conditions required for the test/procedure, routine care and maintenance of equipment, precautions and safety instructions, troubleshooting measures, waste disposal and linkage with reference laboratories.
6. The procedure described in the SOPs must be followed exactly by all staff members to ensure high quality results.
7. SOPs are controlled documents and can be changed only with approval of the clinical laboratory quality manager and/or Laboratory Director.

8. SOPs help to ensure uniformity, consistency and control over the processes carried out. They ensure that the procedures are done in exactly the same way each time irrespective of the operator.
9. The Laboratory Director shall ensure that the SOPs are current, titled along with version number, dated and signed.
10. The header of SOP may display the following information on all pages:
    - 10.1. Title of SOP and Document number
    - 10.2. Version number with dates of revision
    - 10.3. Issue number and date of issue of the document
    - 10.4. Page number/Number of pages
11. The Text of Analytic SOP May Contain Information On:
    - 11.1. Name of test
    - 11.2. Scope of test
    - 11.3. Principle of the test
    - 11.4. Equipment and materials required
    - 11.5. Detailed test procedure including type, quantity and condition of specimen required, sample processing and preparation. Alternative procedure for test in case of breakdown of equipment should also be stated.
    - 11.6. Documentation of results including calculations
    - 11.7. Limit of detection (Analytical sensitivity)
    - 11.8. Analytical Measurement Range (AMR)

11.9. Reference range

11.10. Clinical significance, Inference and limitation of the test

11.11. Critical alert values (shall be reported immediately to the referring physician)

11.12. References of test procedure

11.13. Precautions & Safety

11.14. Quality Control procedures

11.15. Specimen preservation and storage before analysis and after analysis

11.16. Data management.

APPENDIX 2: GUIDELINES ON QUALITY ASSURANCE

1. All laboratories must have a Quality Assurance Program (QAP) in place to provide Quality Assurance (QA), and to improve their standards when necessary to ensure continuous quality improvement.
2. QA is the total process whereby the quality of laboratory reports can be guaranteed. Incorrect Laboratory results may be due to:
    2.1. Pre-analytical stage: errors occurring during specimen collection
    2.2. Analytical stage: errors occurring during testing
    2.3. Post-analytical stage: errors occurring during reporting or interpreting test results.
3. Quality Manager, designee or competent authorized person should review the quality control data and maintain record of evaluation. The two important tools toward maintaining laboratory quality are:
    3.1. Internal Quality Control (IQC)- for detection and minimization of immediate errors
    3.2. External Quality Assessment (EQA)- for monitoring long-term precision and accuracy of results.
    3.3. The laboratory should treat IQC/EQA samples and patients' specimens alike and use same procedures for analysis
4. Practice of IQC includes the following:
    4.1. Recognition of errors, which arise within the laboratory during analytical stage (testing).
    4.2. Taking steps to minimize errors.

4.3. Equipment & method calibration, method validation.

4.4. For quantitative tests, laboratories should perform IQC every day by using 2 levels of QC (high and low) on tests run daily or every time the tests are run in case of infrequently run tests.

4.5. IQC checks should be employed for qualitative tests wherever applicable.

4.6. IQC for Quantitative Tests: using Levy Jennings's (LJ) chart or any similar chart may be used to plot daily QC values and Westgard rules or any similar may be used to interpret daily QC values.

5. The level of QC per day for Quantitative Tests:

5.1. The following guidelines will be useful to the laboratories in the practice of IQC using either one level or two-level QC materials:

5.1.1. When one level QC is used: Reject test run if following errors occur:

a. Value is outside 3 SD (13s)

b. 2 consecutive values are outside 2 SD on the same side, but within 3 SD (2_{2s})

c. 4 consecutive value are outside 1SD on the same side, but within 2SD (41s)

5.1.2. When two level QC are used: Reject test run if following errors occur:

a. Either QC value is outside 3 SD (13s)

b. Both QC values are outside 2 SD on the same side, but within 3SD (22s)

c. Difference between the two-level QC values is >4 SD i.e. one level QC is >2 SD and other level QC is < 2 SD (R4s)

d. 10 consecutive values of the same level QC are above or below the mean, but within 2 SD (10x)

e. 5 consecutive values of one level QC and 5 consecutive values of the other level QC are above or below the mean, but within 2 SD (10x).

5.2. Laboratories need to establish guidelines for responding to out of control situations Tests.

5.3. Tests for which control material is not available or when running of control is not viable due to low volume of tests, the laboratory should apply alternate quality control techniques such as:

5.3.1. Testing of previously tested patient specimens in duplicate.

5.3.2. Split sample testing with another method or with another laboratory

5.3.3. Testing of patient specimens in duplicate by same individual or by different individual.

5.4. IQC for Qualitative non-waived tests should include tests with positive and negative controls on the day of patient testing. For waived testing, the laboratory should follow manufacturer's instructions for quality control and records acceptability prior to reporting patient results.

5.4.1. Wherever applicable, appropriate controls should be used when a new kit/lot number is used. Built-in test controls should be monitored as well.

5.4.2. For staining procedures, gram stains require both Gram positive and Gram-negative control organisms to be used once per week.

5.4.3. IQC should also be run whenever a new lot of the stain procedure kit is used and/or any of the four components of the stain procedure kit is replaced with a new lot.

6. Practice of External Quality Assurance (Proficiency Testing)

6.1. The laboratory shall have written policy for External Quality Assurance program.

6.2. The laboratory must participate in external quality assurance program for each analyte tested in the laboratory.

6.3. The test for which, external quality assurance program is not covered by the provider; the laboratory must establish alternative performance assessment such as split sample analysis with another laboratory, using reference material or clinical validation by chart review.

6.4. The laboratory shall evaluate the performance of external quality assurance program/alternative performance assessment and must perform investigation, root cause analysis, corrective and preventive action for each failure.

APPENDIX 3: PERMITTED WALK IN LABORATORY TESTS

Category	Permitted walk in laboratory tests	Physician order is required
Anatomic Pathology		All tests under this category requires Prescription
Clinical Biochemistry	General Clinical Biochemistry Testing Does not require Prescription	Special Clinical Biochemistry testing such as body fluids samples other than blood, especial enzymes and iso enzymes
Therapeutic Drug Monitoring		All tests under this category requires Prescription
Drug Abuse Monitoring		All tests under this category requires Prescription
Haematology	General haematology testing Does not require Prescription	Special haematology testing such as Malaria film, Bone marrow smear and biopsy
Coagulation	General Coagulation testing Does not require Prescription	Special Coagulation testing such as Factor testing, protein C, Protein S and Lupus Anticoagulant
Microbiology	General Microbiology and culture Do not require Prescription	Special Microbiology testing such as blood cultures, tissue sample cultures, CSF cultures and cultures which requires special sample to be collected
Immunology and endocrinology	General immunology and endocrinology Do not require Prescription	Special immunology and endocrinology testing such as hormonal suppression and challenging tests.

Infectious disease	Infectious disease screening on condition that laboratory must comply with patients consent and notification of positive cases for authorities	
Blood bank and Transfusion	Only blood grouping for screening purposes and not for blood transfusion	All other tests under this category requires Prescription
Histocompatibility (HLA lab)		All tests under this category requires Prescription
Molecular biology	All screening molecular biology testing such as Respiratory, GIT, STDs panels, and HPV screening	All other tests under this category requires prescription
Genetics		All tests under this category requires Prescription
Forensic pathology		All tests under this category requires prescription

APPENDIX 4: VALIDATION OF TESTS PERFORMED

1. Validation/verification is the process by which a laboratory determines that a test performs according to the specifications set forth by the manufacturer when used as directed.
2. The laboratory shall have a policy for validation.
3. Laboratories are required to perform validation or verification of each test, method, or instrument system before use in patient testing, regardless of when it was first introduced by the laboratory, including instruments of the same make and model.
4. Laboratories should include Pipette Carryover Studies in the validation.
    a. Run known high patient samples, followed by known low samples to see if the results of the low-level material are affected.
    b. If carryover is detected, the laboratory must determine the analyte concentration above which subsequent samples may be affected, and define this value in the procedure.
    c. If results that exceed the defined level are detected, then the appropriate course of action must be defined.

    Note: Evaluation for carryover is not required for automatic pipettes that use disposable tips.

2. For qualitative test, the laboratory validates or verifies the test performance for Accuracy, Precision, Sensitivity and Specificity, as applicable and clinically relevant
3. For quantitative test that are not modified or not a lab developed test, the laboratory verifies the test performance for:

3.1. Analytical accuracy

3.2. Analytical precision

3.3. Reportable range (Analytical Measurement Range)

3.4. Reference range verification

4. Analytical Accuracy: Accuracy is verified by comparing results to a reference method or an established comparative method or comparing the results of an accredited laboratory.
5. For verifying accuracy, the laboratory shall use previous patient sample or reference materials. The use of routine quality control materials or calibrators is not appropriate. For quantitative tests, a minimum of 20 samples with various analyte concentrations covering the entire span of Analytical Measurement Range must be used. For qualitative tests, a minimum of 20 samples, including positive, negative, and low-positive samples should be used.
6. Precision: Precision is validated by repeat measurement of samples at varying concentrations or activities within-run and between-run over a period of time. The laboratory can use Quality control samples for this purpose. For qualitative tests, a minimum of 20 runs consist of negative and positive samples must be used, as applicable. For quantitative test, a minimum of 20 runs consist of high and low values must be used.
7. Reportable range (Analytical Measurement Range): is the range of test result values over which the laboratory has established accuracy of the instrument or test system measurement response. This can be achieved through a linearity check using reference material or 3rd party linearity material or unaltered patient sample of high concentration.

8. Reference Range Verification: The laboratory verifies the reference range of the test for the patient population being tested. Samples from a minimum of 20 healthy representative individuals can be used to verify reference range. If a formal reference interval study is not possible or practical, then the laboratory should carefully evaluate the use of published data.
9. For modified test or laboratory developed test or the test that are not validated by the manufacturer; the laboratory shall validate the full range of performance specifications that includes;
    9.1. Accuracy
    9.2. Precision
    9.3. Reportable Range
    9.4. Analytical Sensitivity (Lower limit of Detection)
    9.5. Analytical Specificity (Interference or cross reactivity).
10. The laboratory director shall approve the validation or verification study prior to patient testing.