Standards for Point of Care Testing (POCT) Services

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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 the year (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
- Assuring management of health informatics, e-health and promoting innovation.

The Standards for Point of Care Testing 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.

- 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 document in collaboration with Subject Matter Experts. HRS 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 Point of Care Testing (POCT) services at all times. The standards have been developed to align with the evolving healthcare needs and international best practice. The standards include several aspects required to provide effective, efficient, safe and high-quality POCT Services. The standards include general requirements, health facility requirements, equipment selection and implementation healthcare professional requirements and quality control and patient safety.

The key updates in this document, which was previously a Guideline and is now a Standard, are set out below:

1. POCT services may be carried out in the following DHA licensed health facilities:
    a. Hospitals
    b. Day surgical centers
    c. Outpatient care facilities
    d. Home healthcare facilities.
    e. Convalescence house
2. The basic POCT list has been modified as per stakeholder input and current international best practice.
3. The equipment used shall be registered by the Ministry of Health and Prevention (MOHAP) in the United Arab Emirates (UAE) and approved by at least one of the following international authorities or equivalent:
    a. Food and Drug Administration (FDA)

b. Health Canada

c. Conformité Européenne (CE)

d. Australian Register of Therapeutic Goods (ARTG)

e. Ministry of Food and Drug Safety (MFDS) Korea

f. Taiwan Food and Drug Administration (TFDA)

g. Japans Ministry of International Trade and Industry (MITI).

h. Medicines and Healthcare Products Regulatory Agency (MHRA).

4. Reporting of critical results generated by POCT should follow hospital or healthcare facility's protocol.
5. Addition of Standard 4: Governance of POCT Services
6. Competency of POCT equipment must be evaluated annually.
7. The Appendix 1 from the previous document for POCT is deleted.

DEFINITIONS

Healthcare Professionals: are healthcare personnel working in healthcare facilities and required to be licensed as per the applicable laws in United Arab Emirates.

Licensure: is the issuance of a license to operate a health facility to an individual, government, corporation, partnership, Limited Liability Company, or other form of business operation that is legally responsible for the facility's operation.

Lot is a batch of reagents produced by the manufacturer under uniform conditions, and passing as a unit through the same series of processes

Outpatient Care: shall means any health care delivered on an outpatient basis. Outpatient care facilities includes, but not limited to, Polyclinic, Specialty clinic, General clinic, Dental clinic, or any other health facility where health care services are provided to individuals on an outpatient basis.

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

POCT coordinator: is a qualified DHA licensed medical/paramedical staff (physician, nurse, or lab technician) who has been adequately trained in the use of POCT devices and will be responsible to perform duties related to quality, training, assessment, review of reports etc. associated with the POCT program.

Point of Care Testing (POCT): is any analytical testing performed at sites outside the traditional laboratory environment, usually at or near where care is delivered to individuals.

Trained non-Laboratory healthcare worker: is a DHA licensed healthcare professional either a registered nurse or a medical doctor (consultant/specialist/GP) or an emergency medical technician who has been specifically trained in the use and interpretation of the POCT technology/results and has be evaluated for competency on a regular basis.

ABBREVIATIONS

AN	:	Assistant Nurse
ARTG	:	Australian Register of Therapeutic Goods
CE	:	Conformité Européene
DHA	:	Dubai Health Authority
EMT	:	Emergency Medical Technician
EQC	:	External Quality Control
FABP	:	Fatty Acid Binding Protein
FDA	:	Food and Drug Administration
GP	:	General Practitioner
HPSD	:	Health Policies and Standards Department
HRS	:	Health Regulation Sector
ICU	:	Intensive Care Unit
ID	:	Identification
INR	:	International Normalized Ratio
IQC	:	Internal Quality Control
LIS	:	Laboratory Information System
MFDS	:	Ministry of Food and Drug Safety
MITI	:	Ministry of International Trade and Industry
MOHAP	:	Ministry of Health and Prevention
NICU	:	Neonatal Intensive Care Unit

OR	:	Operating Room
POCT	:	Point of Care Testing
PT	:	Prothrombin Time
RN	:	Registered Nurse
RSV	:	Respiratory Syncytial Virus
SME	:	Subject Matter Experts
SOP	:	Standard Operating Procedure
TFDA	:	Taiwan Food and Drug Administration
UAE	:	United Arab Emirates

1. BACKGROUND

Point of Care Testing (POCT) involves performing a diagnostic test close to the site of patient care outside of a clinical laboratory setting to produce a rapid and reliable result, aiding in identifying or managing chronic diseases and acute infections. The key driver is the concept that clinical decision making may be delayed when samples are sent to the clinical laboratory. POCT provides a rapid result near the patient and which can be acted upon immediately. However, instruments used are often operated by staff not trained in laboratory medicine and hence are prone to errors in the analytical phase (as opposed to laboratory testing where the analytical phase has the least errors). When POCTs are incorrectly performed or inappropriately utilized, they can generate misleading results that require additional follow-up at increased cost and risk to the patient, hence POCTs need to be audited and controlled by relevant authorities for safe practice.

DHA reserves the right to amend this document without prior notice. The latest version of which will be published on the DHA website www.dha.gov.ae.

2. SCOPE

2.1. Management of POCT services provided by DHA licensed Healthcare Professionals in DHA licensed Health Facilities.

3. PURPOSE

3.1. To establish the minimum requirements for POCT services in the Emirate of Dubai.

3.2. To ensure the provision of the highest level of safety and quality care for patients at all times.

4. APPLICABILITY

4.1. All DHA licensed Health Facilities and Healthcare Professionals providing POCT services.

5. STANDARD ONE: GENERAL REQUIREMENTS

5.1. POCT services may be carried out in health facilities including home healthcare services, licensed by DHA and by DHA licensed healthcare professionals.

5.2. Licensed health facilities shall list the POCTs offered and have them visibly placed for patient access and have a documented quality control program.

5.3. Licensed health facilities shall maintain POCT equipment as recommended by the manufacturer and ensure all equipment are calibrated as per recommended protocols and have the records available.

5.4. All maintenance records shall be documented.

5.5. POCT services carried out shall be recorded and maintained in the patient Health Records.

5.6. Licensed health facilities shall have trained POCT coordinators, licensed, and trained non-laboratory healthcare professional to oversee and carry out the POCT services.

5.7. Special permission shall be obtained from HRS to carry out any health camps where POCT services are conducted.

Note: For further information regarding the laboratory design and equipment, requirements see the DHA Clinical Laboratory Regulation available in the Health Regulation section of DHA website www.dha.gov.ae.

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

6.1. POCT services shall be carried out in the following DHA licensed health facilities:

6.1.1. Hospitals

6.1.2. Day surgical centers

6.1.3. Outpatient care facilities

6.1.4. Home healthcare facilities.

6.1.5. Convalescence house

6.1.6. Renal Dialysis

6.2. POCTs could be conducted in areas that have adequate space for instruments, consumables, documentation, waste disposal and does not compromise patient safety and privacy.

6.3. The area where POCT is conducted must be in a clean adequate environment, away from staff area and waste management rooms.

6.4. The area where POCT is conducted does not need to be solely dedicated to performing POCT. For example, a consultation or nurse's room may be suitable.

6.5. POCT equipment and supplies shall be kept in an appropriate temperature as per manufacturers guidelines.

6.5.1. These temperatures will be monitored to confirm suitability of POCT use.

6.6. The basic POCT list includes the following, but not limited to:

6.6.1. Blood glucose glucometer

6.6.2. HbA1c measurement

6.6.3. Urine pregnancy tests

6.6.4. Haemoglobin and Haematocrit (by finger prick)

6.6.5. Urine dip stick for urine analysis

6.6.6. Cardiac Troponin (FDA and/CE marked analysers) for myocardial infarction detection, Myoglobin and Fatty Acid Binding Protein (FABP)

6.6.7. Full Blood count/Complete Blood count

6.6.8. D-dimer test

6.6.9. Bilirubinometer

6.6.10. Blood gas analyser with electrolytes

6.6.11. Prothrombin Time (PT) and International Normalized Ratio (INR) for coagulation study

6.6.12. Molecular POCT testing (NEAR Technology) CLIA Waived (FDA approved)

6.6.13. COVID-19

6.6.14. Flu A/B

6.6.15. Streptococcal A

6.6.16. RSV

6.6.17. Rapid test kits for infectious disease limited to:

a. Influenza virus- nasal swabs

b. Rapid Strep A- throat swabs

c. Respiratory Syncytial Virus (RSV)- nasal swabs/nasal wash

d. Adeno virus- nasal swab

e. Rota Virus- in stool

f. Adenovirus- in stool

g. Malarial antigen- in blood

h. Dengue Rapid Detection Test

i. Giardia- in stool

j. Cryptosporidium- in stool.

k. COVID-19 Antigen (Nasal/Nasopharyngeal)

l. H pylori - Stool

m. Faecal Occult Blood – Stool

n. Norovirus – Stool

6.6.18. Molecular (PCR/NAT) genetic test for the following:

a. HBC/HCV PCR (for virus detection)

b. HIV PCR (for virus detection)

6.7. Results from the POCT shall be used as a guide and/or confirmation based on disease management guidelines where test can be performed in an accredited DHA licensed Clinical Laboratory (if required).

Note: For further information regarding clinical laboratory service requirements see the DHA Standards for Clinical Laboratory, which is available in the HRS page of the DHA website www.dha.gov.ae.

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

7.1. POCT can be performed by licensed Pathologist or Laboratory Technician and also by licensed and trained non-laboratory healthcare professionals listed below:

7.1.1. Physician

7.1.2. Registered Nurse (RN) or Assistant Nurse (AN)

7.1.3. Emergency Medical Technician - Advanced (Paramedic) EMT-P

7.1.4. Cardiac Perfusionist.

7.2. A POCT coordinator shall take responsibility for all aspects of the POCT service, including quality and training.

7.3. The laboratory director shall have the ultimate responsibility to select the POCT devices for the health facility.

7.3.1. The POCT coordinator shall ensure the quality of POCTs performed and the competency of the healthcare workers to conduct the POCT services.

7.4. All healthcare professionals who undertake POCT shall be been trained (by the vendors and healthcare professionals from accredited Clinical Laboratories), supervised and certificated as competent to perform these tests. Evidence of the training shall be documented and maintained by the health facility.

7.5. POCT coordinator roles and responsibilities are to:

7.5.1. Ensure compliance with DHA regulatory requirements.

7.5.2. Identify trained healthcare professionals to perform POCT.

7.5.3. List the POCT services to be provided.

7.5.4. Evaluate, verify and validate the POCT equipment and technologies.

7.5.5. Maintain policies and procedures and update these as necessary.

7.5.6. Establish and monitor a quality assurance program that encompasses the following:

a. Compliance

b. Action taken for non-compliance

c. Quality control

d. Proficiency testing

e. Safety

f. Documentation of test results.

7.5.7. Be responsible for the quality, availability and storage of reagents.

7.5.8. Coordinate training and competency programs for all POCT operators.

7.5.9. Provide support whenever required by the healthcare professionals performing POCT services.

7.5.10. Provide feedback to the POCT providing healthcare professionals as well as the laboratory director regarding POCTs.

7.5.11. Serve as a liaison for the Clinical laboratory by interacting with other health facilities.

7.6. Healthcare professionals, who use POCT devices shall be authorized, trained and have obtained a valid certificate of competence for that specific device issued by the POCT coordinator.

7.7. Manufacturers may be involved in staff training following the commissioning of new equipment and may also provide subsequent refresher courses. Training will include the following:

7.7.1. Patient preparation and sample collection techniques

7.7.2. Contra-indications and limitations of the method – familiarization with policy and procedures to ensure good practice

7.7.3. Interpretation of results

7.7.4. Maintenance of equipment and corresponding log – recording of patient results

7.7.5. Internal quality control and log

7.7.6. External quality assessment

7.7.7. Waste disposal and health and safety aspects

7.7.8. Responsibility for ensuring continuing competence in performing analyses

7.7.9. Arranging for further training sessions as deemed appropriate

7.8. Healthcare Professionals shall not carry out POCT procedures in which they have not been trained and competency evaluated.

7.9. Training could include the following but not limited to:

7.9.1. The basic principles of the analytical method, its limitations and the clinical relevance of the results produced. The latter shall include knowledge of results that must be made known to the clinician immediately and be familiar with error codes, intermediate values (grey value results), which are indicative of an error or failure in the procedure or of a possible interfering substance.

7.9.2. The correct procedure for preparation of the patient and the potential for production of an erroneous result that may arise from incorrect preparation of the patient or incorrect sample type.

7.9.3. The correct procedure for preparation of the reagents, devices and/or equipment before performance of the test.

7.9.4. The correct procedural way of performing the test.

7.9.5. Documenting and reporting of critical results generated by POCT shall follow hospital or healthcare facility's protocol.

7.9.6. The correct quality control procedures, recording of such data and its interpretation, all of which must be completed and validated before release of the patient result.

7.9.7. The correct procedure for disposal of consumables, reagents and used analytical devices and any decontamination procedure required.

7.9.8. Safe handling of needles, sharps, and correct procedure if a needle stick injury occurs in accordance with the Infection Control Protocol.

7.10. A register of all trained staff should be kept and updated as required.

8. **STANDARD FOUR:** GOVERNANCE OF POCT SERVICES

8.1. A governance structure shall be implemented, ensuring multidisciplinary involvement.

8.2. Health facilities providing POCT services in an acute care setting shall ensure the following:

8.2.1. The laboratory director or designate shall appoint a multidisciplinary POCT management group with representation from:

a. The laboratory

b. The administration

c. Clinical programmes including medical and nursing to advise on the provision of POCT.

8.2.2. There shall be a middleware solution in place in the acute care setting for regular review by a designated POCT Coordinator. This will collect information such as:

a. Devices types and location

b. Liquid & electronic quality control/proficiency testing data

c. Material lot(s) and expiry dates

d. Operator management (access, expiry dates etc)

e. Results review and validation

f. Reports

8.3. Healthcare facilities providing POCT services in Ambulatory/Primary Care Clinic services shall be overseen by the laboratory with dedicated POCT services and POCT staff.

8.3.1. A clinic POCT group shall be created with the following members:

a. Leadership: Clinic manager, responsible for overseeing overall POCT services, ensuring services meet the required standards and comply with local regulations

b. Medical Director or lead clinician to support development and implementation of clinic specific policies.

c. Quality manager shall be a nurse with quality responsibility within the clinic assigned tasks associated with POCT Quality Management System, process improvements and compliance with local regulations.

8.4. The management group for acute care or ambulatory settings shall ensure that responsibilities and authorities are defined and communicated within the organization.

8.4.1. Responsibilities will include but not limited to the following:

a. Method and analyser selection

b. Method validation & setup

c. Selection of personnel to perform testing.

d. Personnel training

e. Ongoing competency assessment

f. Daily Quality Control (QC) review

g. Review of monthly QC data and other quality data

h. Review of reports from POCT Coordinator

i. Collation and review of Key Performance Indicators

j. Collation and review of performance improvement projects. Decisions based on review of personal information data

k. Connectivity & LIS systems

l. Review of results (data entry/critical result reporting etc)

m. Accreditation (mandatory/voluntary) & local regulations

n. Overall Quality of the service

o. Key Performance Indicators covering the 3 phases of testing (pre examination, examination and post examination)

8.5. The laboratory director or designated person will report periodically to a governing group of the organisation on behalf of the POCT committee.

8.5.1. This shall include consideration of the following:

a. Clinical need for POCT

b. Financial implications of POCT

c. Overall quality of the service

d. Technical feasibility

e. The ability of the organization to fulfil the need.

9. **STANDARD FIVE:** EQUIPMENT SELECTION AND IMPLEMENTATION

9.1. Health facilities providing POCT shall ensure the following:

9.1.1. Equipment selection and use align with the list of permitted POCTs

9.1.2. Equipment is safe

9.1.3. Quality control standards are being adequately maintained

9.1.4. Healthcare professionals using POCT services are trained

9.1.5. Results are comparable with those from instruments in the supporting laboratory.

9.2. The laboratory director shall be responsible for the selection and approval for POCT device(s).

9.3. The POCT coordinator, in conjunction with the manufacturer of the device, shall take responsibility for the initial installation, setting up and calibration of equipment and provide written standard operating procedures (SOP) for the use of instrument.

9.4. The equipment used shall be registered by the Ministry of Health and Prevention (MOHAP) in the United Arab Emirates (UAE) and approved by at least one of the following international authorities or equivalent:

9.4.1. Food and Drug Administration (FDA)

9.4.2. Health Canada

9.4.3. Conformité Européenne (CE)

9.4.4. Australian Register of Therapeutic Goods (ARTG)

9.4.5. Ministry of Food and Drug Safety (MFDS) Korea

9.4.6. Taiwan Food and Drug Administration (TFDA)

9.4.7. Japans Ministry of International Trade and Industry (MITI)

9.5. The SOPs shall include:

9.5.1. Principle of normal operation techniques

9.5.2. Health and safety requirements

9.5.3. Specimens required, patient sample and request form identification criteria and specimen handling

9.5.4. Hazard warning and safety information

9.5.5. Contra-indications and limitations of the instrument and technique

9.5.6. Perform of routine operations such as maintenance and routine internal and external decontamination

9.5.7. Basic troubleshooting if an instrument malfunction is recognised

9.5.8. Preparation of reagents and other materials

9.5.9. Calibration

9.5.10. Quality control procedures

9.5.11. Sample analysis procedures

9.5.12. Reporting of results, including abnormal results

9.5.13. Documentation/transmission of results

9.5.14. Criteria for referral of samples

9.5.15. Criteria for Critical Values and/or unusual values and reporting

9.5.16. Limitations of the procedure

9.5.17. Reference values

9.5.18. Specimen storage, stability and transfer to a clinical laboratory

9.5.19. Safe disposal of reagents and biological material

9.5.20. Safe handling of all specimens and spillages

9.5.21. Sample collection

9.5.22. Clinical utility and limitations

9.5.23. Reagent storage

9.5.24. Technical limitations of the device

9.5.25. Response to results that fall outside of predefined limits

9.5.26. Infection control practices/policy with special reference to hand held devices

9.5.27. Correct documentation and maintenance of results.

9.6. All POCT equipment shall have a preventive maintenance schedule and a service contract, together with a logbook documenting operational details, faults, repairs or other corrective action.

9.7. There shall be appropriate backup arrangements for equipment.

10. **STANDARD SIX:** QUALITY CONTROL AND PATIENT SAFETY

10.1. The health facility shall appoint a POCT coordinator with defined responsibility for ensuring that the POCT quality management system is implemented and maintained.

10.2. The POCT coordinator shall monitor the performance of healthcare professionals providing POCT services.

10.3. Periodicity of review of internal quality control by the POCT coordinator and pathologist/laboratory director shall be defined.

10.4. The management of the health facility providing POCT services shall ensure the following:

10.4.1. Documented quality control checks on POCT equipment as recommended by the manufacturer.

10.4.2. Lot verification is included in quality management program of POCT.

a. A full audit trail shall be in place for each patient test of all lot numbers that have been used. This will allow full identification of all patients affected by any product recalls that may occur.

10.4.3. Reagents and supplies are consistently available.

10.4.4. Healthcare professionals providing POCT services have a sound understanding of the principles of Quality Assurance such as Internal Quality Control (IQC) and audit.

a. Records of materials and reagents purchased for POCT will be recorded which allows an audit trail to any test performed.

b. Records of batch numbers of test kits used, opening dates and expiry dates must be kept for all reagents

10.4.5. Undertake regular quarterly audits to ensure that the quality system is being implemented.

a. This shall include the 3 phases of testing: Pre examination, examination and post examination.

b. Unusual laboratory results shall be investigated and followed up on.

c. Errors relating to patient testing shall be tracked and monitored.

d. Repeated errors related to specific Healthcare staff will result in the removal of testing privileges.

10.4.6. Undertake regular External Quality Control (EQC) to ensure that the quality system is being implemented.

10.4.7. All results are recorded and maintained in the health records of the patients in alignment with the DHA Policy for Health Information Assets Management.

10.4.8. New devices are not introduced until they are evaluated and a valid training program is conducted.

10.4.9. All waste generated, because of POCT is handled as biohazard waste and disposed of according to DHA requirements.

10.4.10. Handheld or portable testing devices must be disinfected after each patient use.

10.5. Reporting of results

10.5.1. POCT test results shall be available in patient health records in a timely manner.

10.5.2. POCT Critical values shall be defined in the policy and need to be followed by the healthcare professionals who performs POCT services.

10.5.3. Critical Result report need to be communicated to clinician and documented.

10.5.4. Any unusual result, which does not match the clinical picture, shall be referred to laboratory for testing.

10.5.5. For reporting of results in the acute care setting:

a. Connectivity solutions shall be in place to ensure effective control of the POCT program.

b. Interfacing with the medical record is desirable.

c. In the event of no interfacing, regular audits will take place to ensure the correct documentation of patient results is occurring.

10.5.6. The record shall distinguish between POCT results and those from the central laboratory.

10.5.7. The identity of the physician performing the test shall be documented.

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