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# Standards for Point of Care Testing (POCT) Services

Version 1

Issue date: 22/03/2022

Effective date: 22/05/2022

Health Policies and Standards Department  
Health Regulation Sector (2022)

## INTRODUCTION

Health Regulation Sector (HRS) forms an integral part of Dubai Health Authority (DHA) and is mandated by DHA Law No. (6) of 2018 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.

## 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 includes 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 shall 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).
4. Reporting of critical results generated by POCT should follow hospital or healthcare facility's protocol.
  5. Competency of POCT equipment must be evaluated annually.
  6. The Appendix 1 from the previous document for POCT is deleted.
  7. The standard shall align with the following:
    - [DHA Health Facility Guidelines Laboratory Unit 220](#)
    - [Clinical Laboratory Regulation](#)
    - [DHA Clinical Privileging Policy](#)
    - [DHA Guidelines for Managing Health Records](#)
    - [DHA Guidelines for Patient Consent](#)
    - [DHA Continuing Professional Development Guideline](#)
    - [DHA Outpatient care facility Regulation \(2012\)](#)
    - [DHA Guidelines for Medical Advertisement Content on Social Media](#)
    - [Unified Professional Qualification Requirement](#)
    - Any DHA COVID-19 related policies, standards or guidelines that may be relevant.

## 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.

**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 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 been evaluated for competency on a regular basis.

## ABBREVIATIONS

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

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<b>PT</b>	:	Prothrombin Time
<b>RN</b>	:	Registered Nurse
<b>RSV</b>	:	Respiratory Syncytial Virus
<b>SME</b>	:	Subject Matter Experts
<b>SOP</b>	:	Standard Operating Procedure
<b>TFDA</b>	:	Taiwan Food and Drug Administration
<b>UAE</b>	:	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](http://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 shall be carried out only in health facilities licensed by DHA and health facilities that provide home healthcare services 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](http://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

6.2. 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 does not need to be solely dedicated to performing POCT. For example, a consultation or nurse's room may be suitable.

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

- 6.4.1. Blood glucose glucometer
- 6.4.2. HbA1c measurement
- 6.4.3. Urine pregnancy tests
- 6.4.4. Haemoglobin and Haematocrit (by finger prick)
- 6.4.5. Urine dip stick for urine analysis

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- 6.4.6. Cardiac Troponin (FDA and/CE marked analysers) for myocardial infarction detection, Myoglobin and Fatty Acid Binding Protein (FABP)
- 6.4.7. Full Blood count/Complete Blood count
- 6.4.8. D-dimer test
- 6.4.9. Bilirubinometer
- 6.4.10. Blood gas analyser with electrolytes
- 6.4.11. Prothrombin Time (PT) and International Normalized Ratio (INR) for coagulation study
- 6.4.12. Rapid test kits for infectious disease limited to:
- a. Influenza virus- nasal swabs
  - b. Rapid Strep A- nasal swabs
  - c. Respiratory Syncytial Virus (RSV)- nasal swabs
  - 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. FDA approved-Rapid PCR test

- 6.5. Results from the POCT shall be used only as a guide and a confirmation of the test shall 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](http://www.dha.gov.ae).

## 7. STANDARD THREE: EQUIPMENT SELECTION AND IMPLEMENTATION

- 7.1. Health facilities providing POCT shall ensure the following:

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

7.1.2. Equipment is safe

7.1.3. Quality control standards are being adequately maintained

7.1.4. Healthcare professionals using POCT services are trained

7.1.5. Competency is evaluated annually

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

- 7.2. The Laboratory Director shall be responsible for the selection and approval of POCT device.

- 7.3. The POCT coordinator and the laboratory staff, 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.

7.4. 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:

7.4.1. Food and Drug Administration (FDA)

7.4.2. Health Canada

7.4.3. Conformité Européenne (CE)

7.4.4. Australian Register of Therapeutic Goods (ARTG)

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

7.4.6. Taiwan Food and Drug Administration (TFDA)

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

7.5. The SOPs shall include:

7.5.1. Principle of normal operation techniques

7.5.2. Health and safety requirements

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

7.5.4. Hazard warning and safety information

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

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

7.5.7. Basic troubleshooting if an instrument malfunction is recognised

7.5.8. Preparation of reagents and other materials

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- 7.5.9. Calibration
  - 7.5.10. Quality control procedures
  - 7.5.11. Sample analysis procedures
  - 7.5.12. Reporting of results, including abnormal results
  - 7.5.13. Documentation/transmission of results
  - 7.5.14. Criteria for referral of samples
  - 7.5.15. Criteria for Critical Values and/or unusual values and reporting
  - 7.5.16. Limitations of the procedure
  - 7.5.17. Reference values
  - 7.5.18. Specimen storage, stability and transfer to a clinical laboratory
  - 7.5.19. Safe disposal of reagents and biological material
  - 7.5.20. Safe handling of all specimens and spillages
  - 7.5.21. Sample collection
  - 7.5.22. Clinical utility and limitations
  - 7.5.23. Reagent storage
  - 7.5.24. Technical limitations of the device
  - 7.5.25. Response to results that fall outside of predefined limits
  - 7.5.26. Infection control practices/policy with special reference to hand held devices
  - 7.5.27. Correct documentation and maintenance of results.

- 7.6. 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.
- 7.7. There shall be appropriate backup arrangements for equipment.

#### **8. STANDARD FOUR: HEALTHCARE PROFESSIONAL REQUIREMENTS**

- 8.1. POCT can be performed by licensed Pathologist or Laboratory Technician and also by licensed and trained non-laboratory healthcare professionals listed below:
  - 8.1.1. Physician
  - 8.1.2. Registered Nurse (RN) or Assistant Nurse (AN)
  - 8.1.3. Emergency Medical Technician - Advanced (Paramedic) EMT-P
  - 8.1.4. Cardiac Perfusionist.
- 8.2. A POCT coordinator shall take responsibility for all aspects of the POCT service, including quality and training.
- 8.3. The laboratory director shall have the ultimate responsibility to select the POCT devices for the health facility, ensure the quality of POCTs performed and the competency of the healthcare workers to conduct the POCT services.
- 8.4. 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.
- 8.5. POCT coordinator roles and responsibilities are to:



- 8.5.1. Ensure compliance with DHA regulatory requirements.
- 8.5.2. Identify trained healthcare professionals to perform POCT.
- 8.5.3. List the POCT services to be provided.
- 8.5.4. Evaluate, verify and validate the POCT equipment and technologies.
- 8.5.5. Maintain policies and procedures and update these as necessary.
- 8.5.6. 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.
- 8.5.7. Be responsible for the quality, availability and storage of reagents.
- 8.5.8. Coordinate training and competency programs for all POCT operators.
- 8.5.9. Provide support whenever required by the healthcare professionals performing POCT services.
- 8.5.10. Provide feedback to the POCT providing healthcare professionals as well as the laboratory director regarding POCTs.
- 8.5.11. Serve as a liaison for the Clinical laboratory by interacting with other health facilities.

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- 8.5.12. Monitor and document the competence of the POCT staff to perform the tests annually.
- 8.6. 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.
- 8.7. Healthcare Professionals shall not carry out POCT procedures in which they have not been trained and competency evaluated.
- 8.8. Training could include the following but not limited to:
- 8.8.1. 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.
- 8.8.2. 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.
- 8.8.3. The correct procedure for preparation of the reagents, devices and/or equipment before performance of the test.
- 8.8.4. The correct procedural way of performing the test.
- 8.8.5. Documenting and reporting of critical results generated by POCT shall follow hospital or healthcare facility's protocol.

- 8.8.6. 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.
- 8.8.7. The correct procedure for disposal of consumables, reagents and used analytical devices and any decontamination procedure required.
- 8.8.8. Safe handling of needles, sharps, and correct procedure if a needle stick injury occurs in accordance with the Infection Control Protocol.

## 9. STANDARD FIVE: QUALITY CONTROL AND PATIENT SAFETY

- 9.1. Clinical Laboratory management shall appoint a POCT coordinator with defined responsibility for ensuring that the POCT quality management system is implemented and maintained.
- 9.2. The POCT coordinator shall monitor the performance of healthcare professionals providing POCT services.
- 9.3. Periodicity of review of internal quality control by the POCT coordinator and pathologist/laboratory director shall be defined.
- 9.4. The management of the health facility providing POCT services shall ensure the following:
  - 9.4.1. Documented quality control checks on POCT equipment as recommended by the manufacturer.
  - 9.4.2. Lot verification is included in quality management program of POCT.
  - 9.4.3. Reagents and supplies are consistently available.

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- 9.4.4. POCT equipment generate results that are comparable to those of a clinical laboratory.
- 9.4.5. Healthcare professionals providing POCT services have a sound understanding of the principles of Quality Assurance such as Internal Quality Control (IQC) and audit. All POCT operators carry out IQC checks on the devices as advised. These checks shall be recorded and accessible for review.
- 9.4.6. Undertake regular quarterly audits to ensure that the quality system is being implemented.
- 9.4.7. All results are recorded and maintained in the health records of the patients in alignment with the [DHA Guidelines for Managing Health Records](#).
- 9.4.8. New devices are not introduced until they are evaluated and a valid training program is conducted.
- 9.4.9. All waste generated, because of POCT is handled as biohazard waste and disposed of according to DHA requirements.
- 9.4.10. Handheld or portable testing devices must be disinfected after each patient use.
- 9.5. Reporting of results
- 9.5.1. POCT test results shall be available in patient health records.
- 9.5.2. POCT Critical values shall be defined in the policy and need to be followed by the healthcare professionals who performs POCT services.
- 9.5.3. Critical Result report need to be communicated to clinician and documented.

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

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