حكومة دبي
GOVERNMENT OF DUBAI

هيئة الصحة بدبي
DUBAI HEALTH AUTHORITY

Point of Care Testing Guidelines

Health Regulation Department

Dubai Health Authority

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Table of Contents

Acknowledgement

Dubai Health Authority (DHA) is pleased to present the Point of Care Testing (POCT) Guidelines, which represents a milestone towards fulfilling the DHA strategic objective to improve quality standards in health facilities.

This document emphasis on the service criteria with a focus on quality of services and safety of patients and healthcare professionals based on international standards of best practices in this domain, while taking into consideration the local and federal laws.

The Health Regulation Department (HRD) has developed this document in collaboration with subject matter experts. The contribution of these subject matter experts is invaluable and HRD would like to gratefully acknowledge these healthcare professionals and thank them for their dedication to quality in health and their commitment in undertaking such a complex task.

The Health Regulation Department
Dubai Health Authority

I. Scope

This document applies to any health facility and healthcare professionals subject to licensure under the Dubai Health Authority (DHA) establishment law providing point of care testing services, which include governmental and semi-governmental, private and health facilities operating in free zone areas.

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

II. Purpose

DHA is the sole responsible entity for regulating, licensing and monitoring all health facilities and healthcare professionals in the Emirate of Dubai. The development of this document aims to establish the minimum requirements and framework for point of care testing facilities to ensure the provision of the highest level of safety and quality care for patients and healthcare professionals at all times.

III. Definitions

Healthcare professional shall mean healthcare personal working in healthcare facilities and required to be licensed as per the applicable laws in United Arab Emirates.

Licensure shall mean issuing 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.

Point of care testing (POCT) coordinator shall mean a qualified DHA licensed healthcare professional who has been adequately trained in the use of POCT equipment 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) shall be defined as analytical testing performed at sites outside the clinical laboratory environment, usually at or near where care is delivered to individuals.

Trained non-laboratory healthcare professionals shall mean a licensed healthcare professional, either a registered nurse or a physician (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.

IV. Acronyms

DHA	:	Dubai Health Authority
EMT	:	Emergency Medical Technician
HRD	:	Health Regulation Department
IQC	:	Internal Quality Control
POCT	:	Point of care testing

1. Introduction

1.1. Point of care testing (POCT) is defined as analytical testing performed at sites outside the clinical laboratory environment, usually at or near where care is delivered to individuals (patient self-testing is not covered).

1.2. The results from the POCT shall be used only as a guide, and the confirmation of the test should be conducted by a certified and accredited clinical laboratory.

1.3. POCT shall be carried out in the following sites:

- 1.3.1. Hospitals
- 1.3.2. Day surgical centers
- 1.3.3. Outpatient facilities
- 1.3.4. At homes where home healthcare services are provided

1.4. Health facilities shall list the POCT offered and maintain a documented Internal Quality Control (IQC) program for each test performed and on each piece of testing equipment as recommended by the manufacturer.

1.5. Situations in which POCT may be appropriate include:

- 1.5.1. Clinical management in an acute or life threatening situation
- 1.5.2. Change in therapeutic management
- 1.5.3. Reduction of total attendance time for the patient

1.6. POCT conducted shall be limited to:

- 1.6.1. Full blood count/ Haemoglobin concentration
- 1.6.2. Coagulation test
- 1.6.3. Blood gas analysis
- 1.6.4. d-dimer test
- 1.6.5. Bilirubin test
- 1.6.6. Blood sugar
- 1.6.7. Cardiac enzymes
- 1.6.8. Electrolytes
- 1.6.9. Rapid test kits for infective screenings shall include:
  - 1.6.9.1. Influenza virus- nasal swabs
  - 1.6.9.2. Rapid Strep A- nasal swabs

1.6.9.3. Respiratory Syncytial Virus -nasal swabs

1.6.9.4. Adeno virus- nasal swab

1.6.9.5. Rota Virus- in stool

1.6.9.6. Adenovirus- in stool

1.6.9.7. Malarial antigen- in blood

1.6.9.8. Giardia -in stool

1.6.9.9. Cryptosporidium- in stool

1.6.10. Urine analysis

1.6.11. Urine pregnancy test

1.6.12. Troponin, Myoglobin, and Fatty Acid Binding Protein

1.7. In outpatient facilities and home healthcare only the following POCTs can be conducted:

1.7.1. Blood sugar glucometer

1.7.2. Urine pregnancy tests

1.7.3. Hemoglobin and Hematocrit (by finger prick)

1.7.4. Urine dip stick

1.7.5. Troponin, Myoglobin, and Fatty Acid Binding Protein (FABP)

For further information regarding clinical laboratory service requirements see the DHA Clinical Laboratory Regulation, which is available in the Health Regulation section of DHA website www.dha.gov.ae.

2. Professional Requirement

2.1. POCT can be performed by the following licensed and trained and competent healthcare professionals:

2.1.1. Registered Nurse

2.1.2. Cardiac Perfusionist

2.1.3. Emergency Medical Technician (EMT)[1]

2.1.4. Physician and Dentist

[1]As per the current applicable regulations in the Emirate of Dubai, Dubai Corporation for Ambulance Services (DCAS) licenses EMT / EMT Paramedics are considered as licensed healthcare professionals.

2.1.5. Clinical pathologist

2.1.6. Medical laboratory healthcare professionals

2.2. Any health facility providing POCT shall nominate a trained, qualified and experience POCT coordinator who will be responsible for all aspects of the POCT including quality and training.

2.3. If the clinical laboratory services are provided within the health facility, the licensed clinical pathologist in charge shall hold the ultimate responsibility to ensure the quality of POCT performed and the competency of the healthcare professionals to conduct the POCT.

2.4. The medical in charge shall be the ultimate responsible individual, in health facilities not attached to a clinical laboratory but permitted to carry out POCT services.

2.5. Healthcare professionals shall not carry out POCT in which they have not trained or competent.

2.6. All healthcare professionals carrying out POCT shall be vaccinated for Hepatitis B.

3. POCT Equipment

3.1. Health facilities providing POCT shall ensure that:

3.1.1. Equipment selection and use, matches the permitted list of POCT mentioned above.

3.1.2. Appropriate installation, operation and regular calibration of the POCT equipment shall be in accordance with manufacturer specifications.

3.1.3. The equipment used shall be safe, adequately maintained and results shall be comparable with equipment in associated clinical laboratory.

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

3.1.4.1. Food and Drug Administration (FDA)

3.1.4.2. Health Canada

3.1.4.3. Conformité Européenne (CE)

3.1.4.4. Australian Register of Therapeutic Goods (ARTG)

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

3.1.4.6. Taiwan Food and Drug Administration (TFDA)

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

3.1.5. Provision of written standard operating procedures (SOP), which could include:

3.1.5.1. Sample collection and safe handling of all specimens

3.1.5.2. Preparation, storing and safe disposal of reagents

3.1.5.3. Disposal of biological materials

3.1.5.4. Actions to be taken for results outside of predefined limits

3.1.5.5. Action to be taken in the event of a fault in the instrument

3.1.5.6. Specimen storage, stability and transportation

3.1.5.7. Training of staff

3.1.5.8. Calibration of equipment

3.1.5.9. Recording and reporting of results

3.1.5.10. Criteria for referral of samples

3.1.5.11. Infection control practices

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

3.1.7. Appropriate backup arrangements for equipment, reagents and supplies shall be consistently available.

4. Documentation and Transmission of Results

4.1. All POCT investigations should have a request form that should include the name of requesting physician/ dentist and full patient identity details (full name, medical record number, date of birth, date, and time).

4.2. Maintain a documentation of patient details, healthcare professional identification, POCT tests conducted and test results.

4.3. The POCT results shall be stored in the patient's health record.

4.4. All results from POCT should be retained for at least 2 years.

5. Quality Control

5.1. An IQC system shall be established and demonstrate quality control checks on every test performed and on each piece of testing equipment as recommended by the manufacturer. These checks should be recorded and accessible for review.

5.2. The health facility shall undertake regular audits to ensure an effective IQC system.

5.3. All results shall be recorded and maintained with the patient demographics, operator identification and results.

5.4. New equipment shall not be introduced until they are evaluated and a valid training program is conducted.

5.5. All waste generated, because of POCT shall be handled as biohazard waste and disposed according to DHA requirements.

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