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Document History:

Title:	Point-of-Care-Testing (POCT) Policy	Site(s):	Shared Health - Diagnostic Services
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Section:	**General**	**Subsection:**	**POCT**

Approved by:	Dr. A. Kabani 	**Date:**	04-FEB-2019
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Details of Recent Revision

Initial Issue

1.0 PURPOSE

1.1 To outline the service requirements, roles and responsibilities for Shared Health – Diagnostic Services and other stakeholders to support to the funding, implementation and operation of a Point of Care Testing (POCT) service.

1.2 To ensure that a POCT service is high quality and cost effective, in order to contribute to optimal client care.

1.3 To ensure a continuum of care for clients when there is no diagnostic staff available to perform testing required for immediate care or when routine diagnostic testing turnaround time does not allow for optimal client care.

1.4 To ensure there is a formal written agreement in place to clearly define roles and responsibilities around POCT being provided by non-diagnostic healthcare professionals.

1.5 To ensure that decisions made with regard to POCT support health equity.

1.6 To ensure any POCT service implemented conforms to provincial and federal regulations and applicable accreditation standards and requirements.

2.0 DEFINITIONS

2.1 **Point of Care Testing (POCT):** any low complexity testing that does not require specimen manipulation that is performed by non-diagnostic healthcare professionals where the result of the test is used for clinical decision making. POCT is generally defined by ***who*** performs the test rather than ***where*** the test is performed.

2.2 **Point of Care Testing Device:** an instrument that measures and/or records a test result; the device may be located at or close to the patient's bedside or may be at a more remote location to which the specimen is sent for evaluation.

2.3 **Shared Health - Diagnostic Services:** public provider of screening and diagnostic laboratory testing services within the province of Manitoba.

2.4 **Laboratory Director (as per Accreditation Canada):** The person responsible for the oversight of the quality of POCT. This person may be:

- A physician specialist registered to practice in the province of Manitoba by the College of Physicians and Surgeons of Manitoba (CPSM) with lab-specific experience and training *or*
- A person who holds a PhD in a biomedical field such as (but not limited to) biochemistry, chemistry, biology, microbiology, molecular biology, hematology or pathology *and* has clinical laboratory-specific experience and training.

Note: Day-to-day management and supervision of POCT may be assigned to a designate who is a suitably qualified healthcare professional

2.5 **Suitably Qualified Healthcare Professional (as it applies to being a designate for the Laboratory Director):** a person that has appropriate professional, scientific and educational qualifications to verify and maintain the day-to-day quality of POCT

2.6 **Non-diagnostic Professional:** a professional recognized as qualified by the appropriate professional association and pursuant to the professional legislation in force, following appropriate training, to perform the duties of collecting clinical samples and determining the result of POCT as well as counseling the client if necessary.

2.7 **Clinical Medical Laboratory:** a laboratory where tests are usually performed on clinical specimens obtained from humans in order to obtain information about the health of a patient as pertaining to the diagnosis, treatment and prevention of disease.

2.8 **Quality Control (QC):** set of procedures designed to monitor the test method and the results to assure that the test system meets specified levels of performance prior to the release of patient results.

2.9 **Proficiency Testing (PT):** the testing of unknown samples sent by a third party which are graded and analyzed to determine how accurately a laboratory is performing the testing; it is a tool the laboratory can use to verify the accuracy and reliability of its testing. Determination of laboratory performance through inter-laboratory comparisons and other external performance evaluations that may extend throughout all phases of the laboratory testing cycle.

2.10 **Analyte:** any substance or material for which the presence or concentration of in a specimen is determined by analysis

2.11 **Non-conformance (NC);** an occurrence/event that resulted in or could have resulted in an unintended or undesired outcome. Normally an event that is out of compliance with approved policy/procedure.

A departure of a quality characteristic from its intended specification requirement (ie. use of outdated urine dipsticks)

2.12 **Client:** a person from whom a point-of-care test sample is obtained for the purposes of POCT and analysis. The use of the term "Client" in this document refers to: patient, client, resident

2.13 **OCMO:** the Office of the Chief Medical Officer (Shared Health Diagnostic Services)

3.0 SCOPE

3.1 This policy applies to:

- Testing that would typically be carried out on client specimens (i.e. urine & blood) in the controlled and regulated environment of a clinical medical laboratory
- POCT being performed by appropriately trained healthcare professionals within any program or service being provided under provincial health authority in a designated health facility. Appropriately trained healthcare Professionals utilizing Shared Health - Diagnostic Services POCT equipment

4.0 OUT OF SCOPE

4.1 This policy does not apply to:

- Patient self-testing
- Testing performed by Shared Health - Diagnostic Services personnel being performed on Shared Health - Diagnostic Services equipment (regardless if the equipment is designated as "POCT" for non-diagnostic staff)
- Diagnostic testing generally not involving the collection of patient specimens

Note: This document may be used as a reference / guidance document and Shared Health - Diagnostic Services may work with any individual areas or programs to assist with establishment of POCT programs upon request. All requests for POCT will be examined by OCMO on an individual basis

5.0 POLICY

5.1 A Laboratory Director (or suitably qualified health care professional) will oversee, manage and supervise the POCT program.

5.2 Roles and responsibilities shall be clearly defined by formal written agreement ("Service Agreement") between Shared Health – Diagnostic Services and the RHA/Clinical Program within

which POCT is being delivered. This includes:

- Healthcare professionals delivering POCT services
- RHA/Clinical Program
- Laboratory service Provider (Shared Health – Diagnostic Services)

5.3 Any screening or diagnostic testing, including testing that is performed outside of an accredited Clinical Medical Laboratory by non-diagnostic personnel shall conform to and maintain provincial and federal regulations and applicable accreditation standards and requirements.

5.4 Healthcare professionals performing POCT shall be trained and deemed competent prior to performing and reporting any tests. This includes:

- On-going training and development
- Documentation of all training and competency assessment performed
- On-going performance evaluations/competencies of non-diagnostic healthcare professionals delivering POCT; the performance evaluations are retained
    - Nature and frequency of these evaluations shall be determined and approved by the POCT Laboratory Director
    - When there is evidence that a competency requirement is not met, the personnel will not perform POCT until there is documentation that remedial action has been taken and the personnel is deemed competent to perform that procedure

5.5 For each POCT performed there shall be a written or electronic request (order) from an authorized healthcare prescriber; any verbal requests shall be followed up with a written or electronic request.

- Individual POCT programs shall follow direction of Shared Health - Diagnostic Services with regard to requirements for requisitions
- Local organizations may have approved policies / protocols / standard orders that authorize specific testing to be performed without an additional order from an authorized healthcare prescriber (ie. glucose monitoring, urine dips)
    - Such policies / protocols / standard orders must have an authorized prescriber approval on file (ie. Physician / Nurse Practitioner)

5.6 The POCT service shall have a quality improvement process which is monitored and reviewed for its effectiveness and improved accordingly. This will be developed in collaboration with the Shared Health - Diagnostic Services and will include, but not be limited to, tracking of metrics related to:

- Quality Control
- Proficiency Testing
- Non-conformances
- Critical Incidents and/or Occurrences
- Complaints
- Other as required

5.7 Tracking of quality metrics will be performed by the party responsible for direct oversight or authority or responsibility for the particular POCT program. This responsibility shall be outlined in the applicable service agreement.

5.8 There shall be a POCT quality manual (developed in collaboration with Shared Health – Diagnostic Services) that includes all aspects of test performance including pre-analytic, analytic and post analytic phases of testing.

5.9 Quality control shall be performed and data shall be gathered and documented as defined for each POCT device or product

5.10 Proficiency testing (PT) shall be performed for each analyte measured by POCT. Frequency will

be determined by the individual PT service provider.

5.11 There shall be communication with the Healthcare Providers to ensure there is clear understanding of the values that will be reported utilizing POCT devices as compared to laboratory produced results.

- For instance, units of measure may be different between a POCT device and a laboratory analyzer.

5.12 All POCT results shall become part of the patient medical / health record.

5.13 All POCT results shall be clearly distinguishable from results generated by the central laboratory or its satellites.

5.14 When applicable, instrument printouts should be placed into the patient record; these printouts should be dated and labeled with patient Identification information.

- Thermal printer printouts fade over time therefore photocopies are acceptable if a digital scan cannot be incorporated into an electronic medical record.

5.15 Standardized Operating Procedures (SOPs), approved by the Laboratory Director / designate shall be available for each POCT performed.

- Shared Health - Diagnostic Services shall assist with provision of standardized documents such as operating instructions, forms, logs, etc.
- These documents shall be easily accessible to the non-diagnostic healthcare professionals delivering POCT (electronic or hard copy)
- Manufacturer's instructions for routine cleaning/disinfection shall be reviewed for each POCT device and incorporated into operating instructions.

5.16 All POCT shall be performed in compliance with diagnostic testing quality policies, procedures and systems as well as any applicable accreditation standards, regardless of where the testing is performed.

5.17 There shall be a process for detecting and reporting Non-conformances (NC), investigating them and taking appropriate corrective and preventive action.

5.18 Documentation shall be retained as required to meet accreditation and standard requirements and applicable retention policy requirements.

5.19 Single use devices shall not be re-used. This includes single use consumables such as lancets and test strips

5.20 Any requests for changes to existing POCT programs or requests for implementation of a new POCT program/test must include a completed "Point-of-Care Testing Request Form". All such requests must receive approval from OCMO before proceeding.

6.0 ROLES & RESPONSIBILITIES

6.1 Individual Clinical program leadership shall have direct oversight or authority or responsibility with regard to the POCT being performed unless otherwise specified by a signed service agreement.

6.2 Shared Health - Diagnostic Services will act as a Lead with regard to POCT within the province; Shared Health – Diagnostic Services will have no direct oversight or authority or responsibility with regard to the POCT being performed outside of the laboratory setting unless otherwise specified by a formal signed service agreement. For example, if Shared Health – Diagnostic Services is engaged in a purely consultant role, there will be no formal signed agreement.

6.3 Shared Health facilities and equipment / test kits / supplies shall not be utilized by non-Shared Health personnel for purposes of diagnostic testing without a formal signed service agreement that clearly outlines roles and responsibilities of all parties involved. In addition, Shared Health personnel shall not utilize non-Shared Health equipment / test kits / supplies for purposes of performing diagnostic testing without a formal signed service agreement in place.

6.4 Shared Health – Diagnostic Services will work collaboratively to review and endorse all products utilized in POCT.

- Consideration shall be given to standardization of POCT being offered and equipment/test kits being utilized and operating procedures being used

6.5 Laboratory Director (Note: this must be a named individual – it cannot be a generic person/role):

- Is responsible for the medical, technical and scientific oversight of testing in the POCT program
- Is responsible for the day-to-day management and supervision of POCT
  - This function may be delegated to a suitably qualified Healthcare professional
- Is available to discuss issues with the day-to-day operations manager, coordinator, or person responsible for POCT when necessary
- Will make statistical and clinical decisions about POCT
- Works with an interdisciplinary professional committee to define the scope of services and oversee the delivery of POCT
- Ensures non-diagnostic healthcare professionals performing POCT are trained appropriately
- Reviews and evaluates the effectiveness of operating procedures, and training activities
- Reviews adverse event reports related to POCT activities

Note: if the organization does not have a laboratory director, it must utilize the Shared Health Laboratory to make statistical and clinical decisions about POCT.

6.6 Healthcare Professionals delivering POCT will, be responsible to:

- Follow all applicable policy and/or procedures and manufacturer's instructions
- Comply with all requirements set forth for POCT
- Safely and effectively carry out the POCT
- Accurately and securely document and report POCT results (both routine and urgent values)
- Complete a training program and maintain competency for each POCT Analyte being tested
- Protect the client's privacy and confidentiality and adhere to all applicable policy and/or procedures as it relates to the Personal Health Information Act (PHIA)
- Ensure test supplies and samples are safeguarded against loss, damage, expiry or contamination and are stored under appropriate conditions as per manufacturer's instructions
  - Ensure there is documentation of appropriate storage
- Inform ordering practitioner when POCT is not completed due to inappropriate specimens or technical issues
- Maintain equipment maintenance records as required
- Perform Proficiency Testing as required
- Perform Quality Control Testing as required
- Report adverse events related to POCT activities

6.7 Service Provider will:

- Define who is responsible for POCT within the particular program
- Determine appropriateness of any proposed POCT program in consultation with Shared Health - Diagnostic Services
- Secure the required funding for all the costs associated with the POCT program (ie. devices, consumables, education, training, etc)

- In consultation with Shared Health - Diagnostic Services shall ensure appropriate policy/procedure are available
- Define who can order tests and communicate results; explore and establish the scope of healthcare provider responsibilities as it relates to POCT
- Define by policy how to report routine results and how to escalate communication of urgent/critical results
- Determine how patient POCT results are entered into the patient medical record
- In partnership with Shared Health - Diagnostic Services, establish process for uploading results to eChart Manitoba
- Work with Shared Health - Diagnostic Services to provide training and on-going competency assessment
- Maintain records of training and on-going competency assessment as per retention requirements
- Maintain a list of clients who have testing performed via POCT devices in the event there is a recall on the device or consumables and they would need to be contacted
- Ensure regular calibration and maintenance of equipment
- Establish infection/prevention control practices in relation to POCT equipment
- Ensure accreditation standards are being met with regard to any POCT program in place
- Ensure communication with the Primary Care Providers regarding test values that will be reported via POCT versus laboratory generated results
- Determine how communication of results to client will occur
- Ensure participation in appropriate QC and PT Programs

6.8 **Shared Health - Diagnostic Services** will:

- Act as a consultant with no direct oversight or authority or responsibility with regard to POCT being performed outside of Shared Health - Diagnostic Services diagnostics unless agreed to by formal signed service agreement
- Provide support to POCT services/programs as agreed to by service agreement. This may include, but not be limited to:
    - Establishing appropriateness of proposed POCT program
    - Investigating if there are issues with current laboratory service that need to be resolved
    - Equipment/device/test selection
    - Initial training and on-going competency requirements
    - Provision of Standard Operating Procedures (SOP)
    - QC and PT programs
    - Technical support from subject matter experts
- Assist with preparation of formal written agreement between Shared Health - Diagnostic Services and the RHA/site
    - Participate in periodic review and revision of agreements
- Provide direction on appropriate process to move results into eChart Manitoba
- Establish how to differentiate POCT results from laboratory generated results in electronic reporting systems

6.9 A Provincial POCT committee will be convened to deal with POCT issues as they arise. Membership of the committee will determined on a case by case basis and should consist of representation all pertinent stakeholders

7.0 REFERENCES

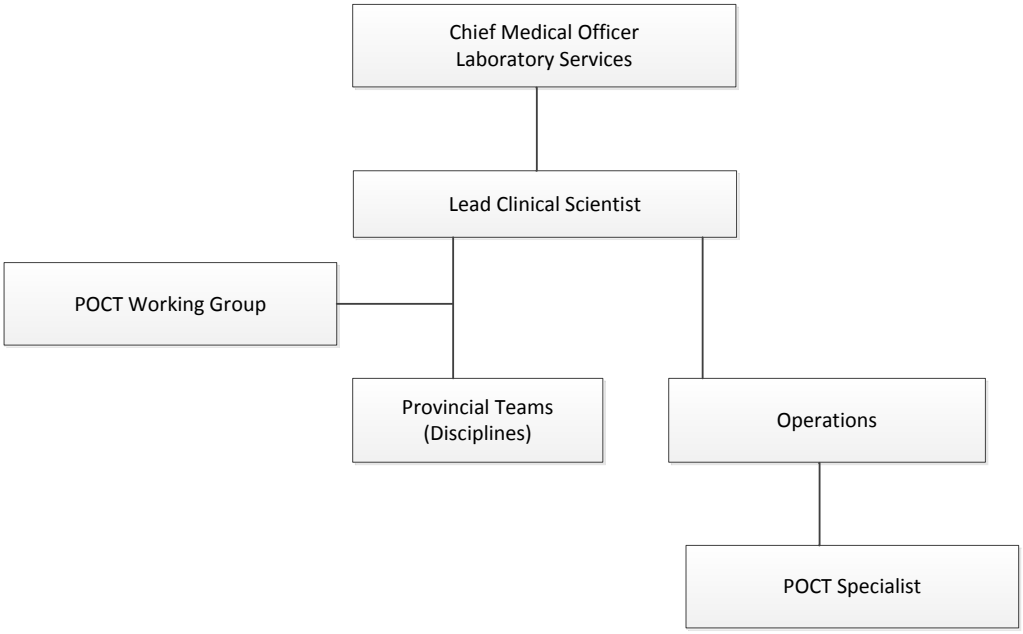
7.1 Point-of-Care Testing Standards, December 21, 2015 Ver. 10, Accreditation Canada Qmentum

7.2 Point-of-Care-Testing Checklist, CAP Accreditation Program, 07.28.2015

7.3 Point-of-Care testing (POCT) – Requirements for Quality and Competence, ISO 22870:2006(E)

Appendix A:

Point of Care Testing (POCT) Organizational Structure*



*Based on Accreditation Canada Qmentum POCT Standards 21 December 2015, version 10, College of American Pathology & Shared Health Quality Manual (SOP# 10-51-01)