

Document History:

Title: Point-of-Care Testing (POCT) Policy

Site(s): Shared Health Diagnostic Services

Document #:	100-140-06	Version #:	02
Section:	General	Subsection:	POCT

Approved by: <i>(approval on file)</i>	Dr. A. Kabani	Date:	18-FEB-2025
		Effective Date:	10-APR-2025

Version	Details of Revisions	Author(s)	Date
01	New Document	B. Luhowy	04-FEB-2019
02	Extensive revisions throughout. Added definition of accredited & non-diagnostics/unaccredited facilities. Clarified reporting requirements for provider-performed POCT. Included references to Public Health Act and policies for communicable disease case reporting. Updated POCT organizational chart.	N. Landry	31-DEC-2024

DISCLAIMER: Please be advised that printed versions of any policy, or policies posted on external web pages, may not be the most current version of the policy. Although we make every effort to ensure that all information is accurate and complete, policies are regularly under review and in the process of being amended and we cannot guarantee the accuracy of printed policies or policies on external web pages. At any given time the most current version of any Shared Health Inc. policy will be deemed to apply. Users should verify that any policy is the most current policy before acting on it.

TABLE OF CONTENTS

1.0	PURPOSE	3
2.0	BACKGROUND.....	3
3.0	DEFINITIONS	3
4.0	SCOPE	5
4.1	Accredited Diagnostic Facilities.....	6
4.2	Non-Diagnostic & Unaccredited Settings	6
5.0	APPROVAL OF NEW POCT PROGRAMS WITH SHARED HEALTH OVERSIGHT	6
6.0	POLICY STATEMENTS	6
7.0	ROLES AND RESPONSIBILITIES	9
8.0	REFERENCES	14
	APPENDIX 1: SHARED HEALTH POCT ORGANIZATIONAL CHART	15

1.0 PURPOSE

The purpose of this policy is to outline the service requirements, roles, and responsibilities for Shared Health Diagnostic Services and other stakeholders to support funding, implementation and operation of point-of-care testing (POCT) services.

This is to ensure:

- That POCT services are of high quality and cost-effective, in order to contribute to optimal client care
- A continuum of care for clients when there is no diagnostic staff available to perform testing required for immediate care, or when routine testing turnaround time does not allow for optimal care
- That there is a formal definition of the roles and responsibilities of all POCT stakeholders
- That decisions made with regard to POCT support equitable access to healthcare services
- Any POCT service implemented with the assistance of Shared Health Diagnostic Services conforms to provincial and federal regulations, and in accordance with applicable accreditation requirements.

2.0 BACKGROUND

Point-of-Care Testing (POCT) is defined as testing that is performed near or at the site of a patient with the result leading to possible change in the care of that patient. When used appropriately, POCT provides the advantage of quick results and rapid decision-making. However, if used inappropriately and/or by untrained operators, erroneous results can be produced and acted upon, potentially leading to patient harm and resource wastage.

This document was developed in line with the Western Canadian Accreditation Alliance (WCAA) Standards for Diagnostic Laboratory Accreditation (General; April 2023, version 11), as well as the Accreditation Canada Qmentum Program Standards for Point-of-Care Testing (May 2021; HSO A42004:2018).

3.0 DEFINITIONS

Analyte	Any substance or material for which the presence or concentration of in a specimen is determined by biochemical analysis. It is sometimes referred to as the 'measurand'.
Client	A person from whom a point-of-care test sample is obtained for the purposes of testing and analysis. The use of the term "Client" in this document refers to any of the following: patient, client, resident.
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.
EPT	External Proficiency Testing: 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 an unbiased determination of laboratory performance through inter-laboratory comparisons and other external performance evaluations that may extend throughout all phases of the laboratory testing cycle.

Laboratory Director	<p>As per Accreditation Canada: The person responsible for the oversight of the quality of POCT; this person may be:</p> <ul style="list-style-type: none">• 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 <i>or</i>• 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 <i>and</i> has clinical laboratory-specific experience and training. <p>Note: Day-to-day management and supervision of POCT may be assigned to a designate who is a suitably-qualified healthcare professional</p>
MANQAP	<p>Manitoba Quality Assurance Program: establishes standards for diagnostic facilities, to investigate and inspect diagnostic facilities for accreditation, and to monitor compliance with established standards. MANQAP operates under the auspices of the College of Physicians and Surgeons of Manitoba.</p>
Non-Diagnostic Professional	<p>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.</p>
Non-Conformance	<p>An occurrence/event that resulted in, or could have resulted in, an unintended or undesired outcome. Normally, this is an event that is out of compliance with approved policy/procedure.</p> <p>A departure of a quality characteristic from its intended specification requirement (i.e. use of outdated urine dipsticks or expired kit reagents)</p>
POCT	<p>Point of Care Testing: any low- or moderate-complexity testing performed outside the clinical laboratory, at or near where a patient is receiving care. The results are typically used immediately for clinical decision-making. POCT is generally defined by who performs the test rather than where the test is performed, as it may or may not be by laboratory personnel.</p>
POCT Device	<p>Point of Care Testing Device: any instrument or single-use strip or cartridge that measures and/or records a diagnostic or screening 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.</p>
QA	<p>Quality Assurance: the system of standardized procedures designed to maintain a desired level of quality of service, at every stage of the process of delivery. For diagnostic testing, this encompasses all steps from the time the test is ordered, until the result is acted upon by the healthcare provider.</p>
QC	<p>Quality Control: 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.</p>

**Shared Health
Diagnostic Services**

Public provider of screening and diagnostic laboratory testing services within the province of Manitoba.

**Suitably Qualified
Healthcare
Professional
(designate for
Laboratory Director)**

A person that has appropriate professional, scientific and educational qualifications to verify and maintain the day-to-day quality of POCT for a program or site.

4.0 SCOPE

This policy applies to:

- Diagnostic or screening POCT being performed by appropriately-trained healthcare professionals within any program or service being provided under provincial health authorities.
- Appropriately-trained healthcare professionals utilizing Shared Health Diagnostic Services POCT equipment, kits, and related supplies.
- 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.

This policy does not apply to:

- Testing performed by Shared Health Diagnostic Services personnel using Shared Health Diagnostic Services equipment (regardless if the equipment is designated as “POCT” for non-diagnostic staff)
- Patient self-testing and direct-to-consumer testing
- Diagnostic testing generally not involving the collection of patient specimens (e.g. point-of-care ultrasound, transcutaneous bilirubin)
- Virtual care settings where an individual consults over the phone or internet with a healthcare provider (i.e. guided self-testing)
- Third-party, non-diagnostic POCT for the purposes of employment, insurance, or other purposes not related to patient care

Note: This document may be used as a reference or 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 services will be examined by the Provincial POCT Medical Lead on a case-by-case basis.

4.1 Accredited Diagnostic Facilities

Accredited facilities are those operating directly under the auspices of Shared Health and its accreditors or who have obtained accreditation status from another recognized accreditation body. As required by the Government of Manitoba, Shared Health Diagnostic Services (Medical Laboratory and Diagnostic Imaging) are accredited by third-party agencies including the College of American Pathologists and MANQAP (Western Canada Accreditation Alliance).

It is expected that all POCT performed in accredited settings be done in compliance with diagnostic testing quality policies, procedures and systems as well as any applicable accreditation standards.

4.2 Non-Diagnostic & Unaccredited Settings

Non-laboratory healthcare providers considering implementing POCT services in healthcare facilities or in non-healthcare community settings are strongly encouraged to consult and collaborate with the POCT experts of Shared Health Diagnostic Services prior the deployment of such services for their clients.

Healthcare providers choosing to perform POCT in unaccredited settings are advised to adopt the Shared Health POCT policies, and comply with established quality practices used in diagnostic testing to ensure quality results and the provision of a safe and effective, patient-centered service.

5.0 APPROVAL OF NEW POCT PROGRAMS WITH SHARED HEALTH OVERSIGHT

Any requests for implementation of a new POCT program with oversight by Shared Health Diagnostic Services, or changes to existing POCT programs with laboratory supervision, are reviewed by Diagnostic Services on an individual basis.

The evaluation process will include, but is not limited to:

- The medical need and appropriateness for the testing requested
- The anticipated improvement of patient outcomes
- An analysis of current services provided and alternate options to POCT
- Method verification prior to implementation, if needed
- Cost-benefit analysis

All such requests are received using the Point-of-Care Testing Request Form (F100-140-06), and the proposed site or program must obtain approval from Provincial POCT Lead.

6.0 POLICY STATEMENTS

- 6.1 A Laboratory Director (or suitably qualified health care professional) is responsible for the quality of POCT at a given site or program. This individual shall oversee, manage and supervise the POCT service, and they or their delegate shall be available to answer inquiries related to quality, performance and effectiveness.
- 6.2 Any screening or diagnostic testing, including testing that is performed outside of an accredited Clinical Medical Laboratory by non-diagnostic personnel shall conform (and maintain conformance to) provincial and federal regulations and applicable accreditation standards and requirements.
- 6.3 POCT shall only be performed using Health Canada approved devices or kits.

- 6.4 Healthcare professionals performing POCT shall be trained and deemed competent prior to performing and reporting any tests. This includes:
- Documentation of all training and competency assessment performed
 - On-going training and development
 - 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

- 6.5 a) There shall be a POCT Quality Manual that includes all aspects of test performance including pre-analytic, analytic and post analytic phases of testing for testing performed within accredited diagnostic facilities.
- b) For POCT performed at non-diagnostic and/or unaccredited sites, a site- or program-specific POCT Quality Manual (developed in collaboration with Shared Health Diagnostic Services) should be created to support and ensure safe and high-quality point-of-care services. Consult the *POCT Quality Manual Checklist* (F100-140-06) for requirements.
- 6.6 All POCT results shall become part of the patient medical / health record. If entry into the laboratory information system (LIS) and provincial electronic patient record (eChart) is not possible, then results must be retained in the local patient record at the testing site for a minimum of 2 years.
- 6.7 All POCT results shall be clearly distinguishable from results generated by the central laboratory or its satellites, and easily separated from other clinical notes and documents (i.e. they cannot be entered into the record as part of a progress note).
- 6.8 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 or standard orders that authorize specific testing to be performed without an additional order from an authorized healthcare prescriber (i.e. glucose monitoring, urine dipsticks). **Such policies and standard orders may be pre-printed, but there must be an authorized prescriber approval on file.** Consult the following Shared Health Policy for more information: [Authorization to Order Diagnostic Tests 10-50-04](#)

- 6.9 If the Authorized healthcare prescriber is the one performing the POCT (“provider-performed testing”) as part the care for their patient, there must be documentation of patient consent, and of the test result in the patient record which is clearly distinguishable from other charting notes. The result must be accompanied by the following information:
1. The test performed
 2. The date/time of specimen collection
 3. The test result and any interpretive notes

- 6.10 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 and detection limits may be different between a POCT device and a laboratory analyzer.
- 6.11 If the POCT is not done immediately at the bedside, the specimen must be labelled in accordance with *Shared Health Specimen Acceptance Policy 10-50-03*.
- 6.12 Single-use devices shall not be re-used, and must be disposed of appropriately. This includes single-use consumables such as lancets, cartridges, and test strips.
- 6.13 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 and are therefore not acceptable for long-term storage of patient results. Photocopies of thermal print reports are acceptable if a digital scan cannot be incorporated into an electronic medical record.
- 6.14 Current Standardized Operating Procedures (SOPs), approved by the Laboratory Director / designate shall be available for each POCT performed. These may be individual documents, or compiled into a site-specific POCT Quality Manual (see F100-140-06 for requirements).
- Shared Health - Diagnostic Services shall assist with provision of standardized documents such as operating instructions, forms, logs, etc.
 - These documents must be easily accessible to the non-diagnostic healthcare professionals delivering POCT (electronic or hard copy)
 - Manufacturers' instructions for routine cleaning/disinfection shall be reviewed for each POCT device and incorporated into operating instructions.
- 6.15 Quality control shall be performed and data shall be gathered and documented as defined for each POCT device or product
- 6.16 External Proficiency Testing (EPT) shall be performed for each analyte measured by POCT at regular intervals. If EPT is not available for an analyte, then alternative proficiency testing procedures may be undertaken, under the guidance of Shared Health Diagnostic services.
- 6.17 Unacceptable EPT results are to be investigated and corrective actions implemented where indicated.
- Consult Shared Health Document 270-10-01 *Proficiency Testing for Point-of-Care Testing (POCT) Programs* for more information.
- 6.18 There shall be a process for detecting, investigating, and reporting Non-conformances (NC), critical incidents, and near misses, and taking appropriate corrective and preventive action.
- 6.19 The POCT service shall have a quality improvement process which is monitored and reviewed for its technical and clinical effectiveness and improved accordingly. This will be developed in collaboration with Shared Health Diagnostic Services and will include, but is not be limited to, tracking of metrics related to:

- Quality Control
- Proficiency Testing (if available)
- Process Non-conformances and Corrective Actions
- Critical Incidents and/or Occurrences
- Complaints
- Accreditation requirements
- Other key performance indicators & metrics, as required

- 6.20** Tracking of quality metrics will be performed by the party responsible for direct oversight or authority or responsibility for the particular POCT program. If applicable, this responsibility shall be outlined in a service agreement with Shared Health.
- 6.21** All documentation shall be retained as required to meet accreditation and standard requirements and applicable document retention policy requirements.
- 6.22** Failure to comply with the above-defined policies, processes, and quality assurance procedures will result in removal of POCT at the direction of the Provincial Medical Specialty Lead for Laboratory Services.

7.0 ROLES AND RESPONSIBILITIES

- 7.1** Individual clinical program and/or site leadership shall have direct oversight or authority and responsibility with regard to the POCT being performed unless otherwise specified by a signed service agreement with Shared Health.
- 7.2** Shared Health Diagnostic Services will act as a Lead with regard to POCT within the public health services provided in the province of Manitoba, but will have no direct oversight, authority, or responsibility with regard to the POCT being performed outside of the clinical 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.
- 7.3** Shared Health facilities, equipment, test kits, and related 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, and related supplies for purposes of performing diagnostic testing without a formal signed service agreement in place.

- 7.4** Shared Health Diagnostic Services will work collaboratively to review and endorse all products utilized in POCT. Consideration shall be given to the standardization of POCT being offered, including SOPs and equipment and test kits being used.
- 7.5** **The POCT Laboratory Director (see 3.0 Definitions):**
- **Must be a named health care professional – it cannot be a generic person/role or organization**
 - 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 health 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 regarding the appropriateness of the 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

7.6 Healthcare Professionals, including non-regulated workers delegated duties under professional supervision, delivering POCT are 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), and follow relevant provincial policies regarding the reporting of results which are of importance to public health, as defined by *The Public Health Act*.
- Complete a training program and maintain competency for each analyte/panel tested; this includes being re-certified on an annual basis at minimum.
- 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
 - In addition, they must ensure there is documentation of appropriate storage
- Inform the 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

7.7 The POCT Service Provider will:

- Define who is assigned responsibilities related to POCT within the particular program. Responsibilities that must be assigned include:
 - Inventory of equipment, consumables, personal protective equipment
 - Monitoring expiry dates on all consumables

- Validation of shipments of test kits & reagents (e.g. performing QC)
 - Temperature monitoring of equipment and consumables, as required
 - Review of temperature and quality control logs
 - Tracking of staff training and competencies, including annual assessments
 - Enrollment in external proficiency testing (EPT), receiving EPT sample shipments, and submitting results for evaluation to the EPT provider
-
- 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 (i.e. staff, devices, consumables, education, training, proficiency testing, quality management, etc)
 - In consultation with Shared Health Diagnostic Services, shall ensure appropriate policies and procedures are available
 - Define who can order tests and communicate results; 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
 - Adhere to all regulations set forth by the *The Public Health Act* and the Public Health branch of Manitoba Health regarding case reporting for contact tracing and surveillance of communicable diseases, as required.
 - Determine how patient POCT results are entered into the patient medical record. This may—in partnership with Shared Health Diagnostic Services—include establishing a 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 (where applicable)
 - Establish infection/prevention control practices in relation to POCT equipment, procedures and waste
 - 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 external proficiency testing programs

7.8 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 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 kit selection & validation for clinical use
 - 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, whenever possible
- Establish how to differentiate POCT results from laboratory generated results in physical/paper and electronic reporting systems

7.9 The Provincial POCT Committee will:

- Report to the Provincial Medical Specialty Lead, Laboratory Services
- May include membership from all pertinent stakeholders, including:
 - **Laboratory:**
 - POCT Medical Lead
 - Executive Director of Laboratory Operations
 - Discipline Medical Directors, *ad hoc*
 - Discipline Technical Directors, *ad hoc*
 - Regional Diagnostic Services Directors, *ad hoc*
 - Regional POCT Specialists
 - **Diagnostic Imaging:**
 - Medical Directors, *ad hoc*
 - **Shared Health Quality**

- **Laboratory Information System and Digital Shared Services representatives, *ad hoc***

- **Clinical area designates**, as appropriate

- Other stakeholders and community partners, as appropriate

- Convene on a quarterly basis to deal with POCT issues as they arise
- Monitor adverse incidents involving POCT devices
- Identify opportunities for improvement and makes suitable recommendations
- Define the scope of POCT and make amendments to the POCT Policy as required
- Select and evaluate instruments, testing procedures, and training and competency requirements, as needed
- Inform the development of best practices and standard operating procedures
- Generate an annual report of POCT activities within Shared Health and with community partners

8.0 REFERENCES

1. AC. *Standards. Point-of-Care Testing*. Ver. 14. Ottawa ON: Accreditation Canada; 2021. HSO A42004:2018.
2. CAP. Laboratory Accreditation Program. *Point-of-Care Testing Checklist*. Northfield, IL: College of American Pathologists; 10.24.2022.
3. Nichols JH, Alter D, Chen Y, et al. 2020. AACC Guidance Document on Management of Point-of-Care Testing. *J Appl Lab Med*. doi: 10.1093/jalm/jfaa059
4. CLSI. *Essential Tools for Implementation and Management of a Point-of-Care Testing Program; Approved Guideline - Third Edition*. CLSI document **POCT04**. Wayne, PA: Clinical and Laboratory Standards Institute; 2016.
5. CLSI. *Selection Criteria for Point-of-Care Testing Devices; Approved Guideline*. CLSI document **POCT09-A**. Wayne, PA: Clinical and Laboratory Standards Institute; 2010 (R2017).
5. Western Canada Accreditation Alliance. April 2023. *Standards for Diagnostic Laboratory Accreditation: General. G.11.0 POINT OF CARE TESTING (POCT)*. Version 11.
6. GOC - Health Canada. Health Products and Food Branch. *Guidance for the Risk Based Classification System of In Vitro Diagnostic Devices*. Ottawa ON; 2016.
7. Government of Manitoba – Manitoba Health, Seniors and Active Living. *The Personal Health Information Act* C.C.S.M c. P33.5. Winnipeg, MB; 2022. <http://web2.gov.mb.ca/laws/statutes/ccsm/pdf.php?cap=p33.5>
8. Government of Manitoba – Manitoba Health, Seniors and Active Living. *The Public Health Act*. C.C.S.M. c. P210. Winnipeg, MB; 2023. <https://web2.gov.mb.ca/laws/statutes/ccsm/p210.php?lang=en>

APPENDIX 1: SHARED HEALTH POCT ORGANIZATIONAL CHART

