Laboratory/Clinical
Policy &Procedure

TITLE:	IWK Point of Care Testing	**NUMBER:**	3101
Sponsor:	Director, IWK Health Centre Point of Care Testing Chief of Pathology and Lab Medicine	**Page**:	1 of 10
Approved by:	IWK Health Centre Policy & Practice Committee	**Approval Date:** **Effective Date:**	April 9th, 2019 April 15, 2019
Applies To:	IWK laboratory Staff and Clinical Care Providers using Point of Care Testing		

PREAMBLE

The IWK Health Centre currently utilizes a variety of Point of Care Tests (POCT) including urine dipstick, blood glucose monitoring, pregnancy testing, for example, excluding skin testing for tuberculosis and allergens.

Point of Care Testing (POCT) carries risk to the patient and the health care facility but is managed by a well-designed, fully implemented, quality management system that encompasses:

- Evaluation of new or alternative POCT instruments and systems
- Evaluation and approval of end-user proposals and protocols
- Purchase and installation of equipment
- Maintenance of consumable supplies and reagents
- Training, certification, and competency maintenance of POCT system operators
- Quality Control and Quality Assurance

This document provides policy and guideline for the governance and oversight of Point of Care Testing (POCT) at the IWK Health Centre (IWK) and its associated clinics. The overall policy and guideline is to be augmented by specific analytic/instrument procedures as required**.**

AUTHORITY AND SCOPE

1. The Department of Pathology and Laboratory Medicine (DPLM) Chief is the officer, authorized by the Medical Advisory Committee (MAC), with responsibility for the implementation of this policy and its associated processes.

2. The POCT Director, designated by the DPLM Chief, manages and enforces policies, assigns responsibility to the POCT Coordinator (POCC), and guides the Point of Care Interdisciplinary Committee (POCIC) (*previously called the POCT Management group*).

3. Oversight for Provincial POCT initiatives is provided by the POCT Committee of the Provincial Laboratory Medicine Program; all provincial POCT initiatives are outside the scope of this policy.

4. Patient self-testing practices and their subsequent results are outside the scope of this policy.

5. POCT performed by IWK employees outside of their assigned work duties is outside of the scope of this policy (i.e. using a device on a staff or family member). These employees act under their own authority and are not to be associated with any IWK endorsed activities.

POLICY STATEMENTS

1. The healthcare professional performing the POCT must:
   1.1. Ensure that point-of-care testing equipment maintenance, quality control, and patient testing are appropriately performed and documented.
   1.2. Ensure they are competent. (The current list of Health Care professionals provincially recognized to perform POCT is listed in Appendix A).

2. The IWK Department of Pathology and Laboratory Medicine (DPLM), under the direction of the IWK Laboratory Medical Chief or designate, is responsible for the governance, oversight, operation of quality of all IWK POCT.
   2.1. The IWK Health Centre Board is responsible for confirming that appropriate measures are in place to monitor the accuracy and quality of tests conducted within the IWK and its affiliated clinics.
   2.2. The Medical Advisory Committee(s) (MAC) is responsible for defining the scope of POCT and considers clinical need, financial impacts, and feasibility. The MAC assigns overall responsibility for POCT to the DPLM and its Medical Chief.
   2.3. The POCT Director is appointed by the DPLM Chief and oversees the IWK POCT Coordinator, the POCIC, and liaises (directly or via designate) with Provincial POCT counterparts.

3. All POCT within IWK must be performed in accordance with Accreditation Canada Standards, ISO 15189 and ISO 22870, and current best practice; under the direction/jurisdiction of the laboratory.

4. All personnel performing POCT must complete training and demonstrate competency for each specific POC test.

5. Current comprehensive procedures must be available for staff performing POCT. Procedures and processes are documented, current, accurate, and controlled.

6. POCT is subject to the requirements of the Laboratory Quality Management System, including, but not limited to, the items outlined in the guidelines below under “Quality and Quality Assurance”.

7. POCT results must be recorded in/on the patient’s medical record manually or electronically at the time of test performance.
    7.1. Records must include the descriptors specific to POCT and must be readily distinguishable from test results performed in the laboratory.
        7.1.1. Specify testing is Point of Care (POC) i.e. POC glucose
        7.1.2. Unit of measure
        7.1.3. Collectors initials/signature
        7.1.4. Date, time and testers initials/signature
    7.2. Critical Values for POC test results are defined in the standard operating procedure.
    7.3. All critical values must be notified by the individual performing POCT to the responsible physician and documentation of action included in the patient health record.

8. POCT Standard Operating Procedures (SOP) must be followed. Refer to individual POCT for details of SOP (i.e. IWK Health Centre Policy # 3103 - POCT Stat Strip Lactate Meter). Systemic failure to comply with defined policies, processes, and procedures will result in removal of the Point-of-Care testing at the direction of the DPLM Medical Chief or designate.

9. All requests for implementation of POCT methods must be reviewed by the IWK POCT Coordinator/Director, in consultation with the Point of Care Interdisciplinary Committee (POCIC) prior to approval.

PROTOCOL

1. **POCT Request and Approval**
   1.1. Requests for POCT for a specific care area/department must be submitted to the POCIC for review. The application and approval process is outlined in Appendix B.
   1.2. The POCT requests will include, but not be limited to:
      1.2.1. the medical need and appropriateness for the desired application
      1.2.2. anticipated improvement of patient outcomes (referenced by evidence-based medicine)
      1.2.3. an analysis of the service required, the service provided, and alternative option
      1.2.4. method verification prior to implementation
      1.2.5. evaluation and approval of end-user proposals and protocols
      1.2.6. financial and business analysis
      1.2.7. client/stakeholder satisfaction input
   1.3. To ensure that funding has been identified to cover the costs of new or expanded POCT programs, cost estimation must be approved by the requesting program's Chief of Service/Management and Laboratory Operations Director prior to final approval by the POCIC.

2. Competency and Training

2.1. The POCT Director appoints the POC coordinator(s), a Medical Laboratory Technologist(s) (MLT), to design, implement, evaluate and maintain a POCT program to confirm that all personnel who perform POCT have the required training and proficiency.

2.2. A practical training program is provided to all POCT operators. Responsibility for overseeing training of operators on a specific POCT instrument/system is assigned to the POCC(s) and/or other certified MLT(s) designated as technical specialist.

2.3. Records of trainers, trained operators, and date of completion of training, certification, and re-certification are maintained by POCC. Re-training intervals will be established where necessary.

2.4. The content of the training program and the knowledge/skill level assessment process are documented for each individual POCT in the associated Standard Operating Procedure (SOP). The knowledge/skill requirements include, but are not limited to:
   2.4.1. The ability to appropriately use the device
   2.4.2. Understanding its clinical utility and limitations
   2.4.3. Quality control and quality assurance processes
   2.4.4. Understanding technical limitations of the device
   2.4.5. How to respond to results that fall outside of predefined limits
   2.4.6. Sample procurement

2.4.7. Infection control practices, and
2.4.8. Correct documentation of results.

2.5. Only designated health care professionals, who have completed the training and demonstrated competency are authorized to perform the specific POC test.

3. Purchasing and Inventory

3.1. The lot numbers and expiration dates of materials and reagents used for POC testing, as outlined in specific POCT SOPs will be documented and maintained by the POCC.

3.2. The clinical programs are responsible for maintaining sufficient supplies of materials and reagents, at the appropriately controlled storage conditions used for POC testing. Whenever possible, supplies will be managed through the IWK stores system.

4. Equipment

4.1. The evaluation and selection of POC testing equipment and systems will be conducted by the IWK laboratory in collaboration with the clinical teams.

4.2. The technical, analytical and clinical utility for each POC test will be assessed prior to its introduction.

4.3. An inventory for all POC equipment is recorded by the POCC.

4.4. The record will be maintained by the IWK Laboratory and will include the following:
4.4.1. A serial number or unique identifier
4.4.2. Name of manufacturer
4.4.3. Date received and service history including dates out of service.

4.5. Reagents, quality control supplies and equipment performance will be verified and results validated prior to implementation for clinical use.

4.6. Access to POC equipment will be controlled by the use of unique operator identification numbers.

4.7. When equipment does not have electronic capability, documentation will be maintained to identify individuals performing the test. An example of this would be the StatStrip Xpress Meter. Refer to the details of the StatStrip Xpress Glucose Meter Point of Care Testing detailed in IWK Health Centre Policy # 3101.1.
4.7.1. Documentation of quality control for the Xpress Meter is documented on the “Quality Control Log for the Nova StatStrip Xpress Glucose Meter”
4.7.2. Documentation sent to POCC on a monthly basis for record keeping

4.8. Maintenance and repair of equipment for POCT will be documented and monitored by the laboratory POCT team and kept on file with the POCC office.

4.9. Remove expired, damaged, or defective equipment and/or supplies from clinical use and contact POCC office.

4.10. The laboratory will manage a process for the comparability of results between devices or methods measuring the same analytes.

5. Testing Process

5.1. POC tests are performed only on the written request of the recognized Health Professional granted test ordering privileges.

5.2. A Care Directive specific to the clinical area is an acceptable written request. POC tests are performed only for those patient groups selected for each application.

5.3. Operators will collect samples according to individual procedures.

5.4. Operators will perform tests according to POCT standard operating procedures.

5.5. Operators will perform quality control tests according to the specific procedures, at the frequency defined. All POC patient test results must be traceable to a control result. The laboratory will monitor quality control results and retain records in accordance with CSA Standards (Standard # Z22870) as per the retention schedule. *Refer to IWK Health Centre Policy #115 - Retention of Records.*

5.6. Operators will be required to perform testing for external quality assessment programs, as available. The laboratory will review results.

5.7. POCT results must correlate with test results provided by IWK laboratory or recognized differences are accepted and managed appropriately.

6. Quality Control and Quality Assurance

6.1. The POCT quality program is designed, implemented, and operated by the POCC in collaboration with the POC Director and MLTs as required.

6.2. The program is integrated with the IWK laboratory quality program activities to ensure POC testing conforms to the quality standards of licensed laboratories. The program monitors the whole process from pre-analytical to post-analytical activities and supports quality improvement of the testing process.

6.3. Procedures, processes, forms, and records for each POCT program are subject to the IWK document control policies and procedures.

6.4. Manufacturer's recommendations regarding quality control of a specific instrument system are accepted as minimal practice. Increased frequency of quality control testing may be required. Instrument-generated (e.g. internal or electronic quality control) quality control is acceptable only if regulatory authorities have accepted it as valid.

6.5. Accuracy and, where appropriate, linearity of the instrument response is verified by the quality control program.

6.6. Corrective action taken for out-of-control results is specified in the standard operating procedures.

6.7. The quality assurance program will include periodic review of the impact of POCT on patient outcomes, monitors test ordering patterns, carries out audits to verify record keeping, and review critical value reports.

6.8. Those patient care areas that permit patient self-testing using POCT instruments/systems not owned and operated by the IWK do so under their own clinical policies and are outside of the scope of this policy. Results entering the IWK medical record are to be only from laboratory-supported devices.

REFERENCES

Legislative Acts/References

Accreditation Canada (2018). Qmentum Program Standards, Point of care testing.

Clinical & Laboratory Standards Institute (2010). Selection Criteria for Point of Care Testing Devices; approved guideline. POCT09-A. Retrieved on March 2nd, 2019 from https://clsi.org/media/1499/poct09a_sample.pdf

Clinical & Laboratory Standards Institute (2016).Essential Tools for Implementation and Management of a Point of Care Testing Program (3rd Ed.).POCT04. Retrieved on March 2nd, 2019 from https://clsi.org/media/1503/poct04ed3_sample.pdf

International Organization for Standardization (ISO) (2016). Point of Care Testing (POCT) – Requirements for quality and competence, ISO 22870. Retrieved on March 2nd, 2019 from https://www.iso.org/obp/ui/#iso:std:iso:22870:ed-2:v1:en

RELATED DOCUMENTS

Policies

IWK Health Centre Policy #3101.1 - Blood Glucose Testing Using the Nova StaStrip and the StaStrip Xpress Glucose Meter Point of Care Testing

IWK Health Centre Policy # 3103 - Point of Care Testing (POCT) StatStrip Lactate Meter

IWK Health Centre Policy # 115 - Retention of Records

Nova Scotia Health Authority (NSHA) Policy #DT-POC-001 - Point of Care Testing

Request for Point of Care Testing Form – email point.of.care@iwk.nshealth.ca

Appendices

Appendix A – Definitions

Appendix B- POCT Application and Approval Process

APPENDIX A

DEFINITIONS

Point-of-Care: Near to or at the site of the patient/client.

Point-of-Care Testing (POCT): Testing performed outside a central laboratory environment, by authorized health care personnel, generally nearer to, or at the site of the patient/client, with the result leading to possible change in the care of the patient.

Point of Care Interdisciplinary Committee (POCIC): Previously called the POCT Management group. Includes individuals from laboratory, nursing and other services as required. It operates according to its Terms of Reference to define the scope of POCT, establish competency requirements, approve a training program and monitor the delivery of quality POCT.

Laboratory: The facilities of the IWK, operated at the IWK and accredited by Accreditation Canada and its associated regulations.

Quality Control: The set of procedures designed to monitor the test method and the results to assure test system performance by detecting gradual or sudden changes in performance.

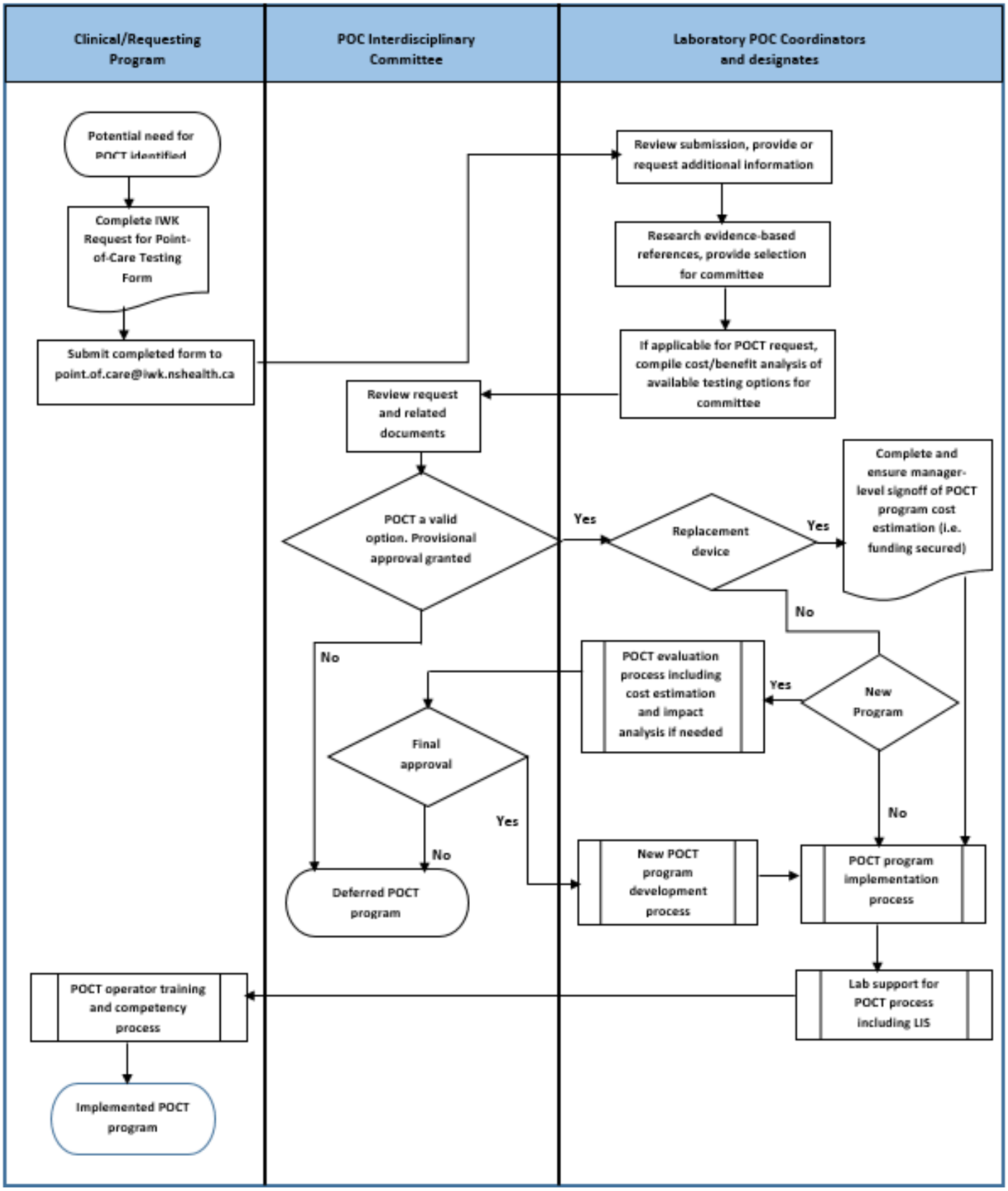
Quality Management System: A comprehensive set of policies, procedures, processes and practices used to monitor the entire testing process, take corrective actions, and ensure reliable test results

POCT Director: A clinical/medical laboratory professional who has the authority and responsibility to oversee the POCT program.

Healthcare Professional Delivering Point of Care Testing: 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. This healthcare professional may be a physician, medical technologist, registered nurse, licensed practical nurse, dietician, pharmacist, or pharmacist technician provided they are members of their required professional health associations and have received appropriate training.

Appendix B

POCT Application and Approval Process



District Health Authority/IWK Policies Being Replaced

(Please List)

Version History

(To Be Completed by the Policy Office)

Major Revisions (e.g. Standard 4 year review)	Minor Revisions (e.g. spelling correction, wording changes, etc.)