AH2000 – POINT-OF-CARE TESTING

1.0 PURPOSE

To establish a framework for the governance and oversight of Point-of-Care Testing within Interior Health.

2.0 DEFINITIONS

Point of Care (POC)	Near to or at the site of the patient/client.[1]
Point-of-Care Testing (POCT)	Testing performed outside a central laboratory environment, generally nearer to, or at the site of the patient/client, with the result leading to possible change in the care of the patient.[1,2] POCT ranges between three levels of complexity, from simple procedures such as glucose testing, moderate-complexity procedures (including provider performed microscopy procedures), or high-complexity procedures such as influenza testing. Health Care Professionals delivering POCT usually use test kits, which may include hand-held devices to read blood, saliva, or urine samples.[5] All current IH POCT programs are itemized in Appendix 1. Synonyms: bedside testing, alternative site testing, near patient testing.
Competency	The integration and application of knowledge, skills, attitudes and judgment required to perform safely, ethically and appropriately within an individual's practice or in a designated role or setting.
External Proficiency Testing	An external program in which samples are periodically sent to testing sites for analysis; results are tabulated by the program and a participating site can compare its results with those of other sites that use a similar method[4] (designed as a means of checking the accuracy of instrumentation and as a random check of operator technique).
Diagnostic Accreditation Program (DAP)	The Diagnostic Accreditation Program (DAP) establishes, evaluates and monitors performance standards in diagnostic health care, and administers accreditation programs covering five diagnostic services: diagnostic imaging, laboratory medicine, neurodiagnostics, pulmonary function and polysomnography. The DAP accredits diagnostic services only in the province of British Columbia. The scope of the DAP includes all public and private diagnostic facilities in British Columbia.

3.0 POLICY

Interior Health Laboratory Services, under the direction of the Interior Health Laboratory Medical Director or designate, is responsible for the governance, oversight, operation and quality of all Interior Health Point-of-Care Testing (POCT).[3,5] performed at IH Facility locations

Per the Diagnostic Accreditation Program *the accountability for ensuring that POCT equipment maintenance, Quality Control (QC) and patient examination are appropriately performed and documented rests with the individual(s) who perform each of these functions. That individual is also accountable to their professional college, where applicable, for ensuring that they are competent*[3]

All POCT must be performed using IH approved instrumentation, kits, and reagents.

3.1 Authority and Scope

This policy applies to all Point-of-Care Testing performed by employees of Interior Health and Medical Staff with privileges.

Oversight for Provincial POCT initiatives is provided by the Provincial Health Services Authority; therefore, all such Provincial POCT initiatives are out of scope for this policy.

POCT must be ordered by a physician unless otherwise indicated by guidelines specific to the unit, facility or community practice area. *Note: POCT can be ordered by Pre-Printed Order*

The following are out of scope for this policy:

- Patient self-testing practices and their subsequent results
- Transcutaneous bilirubin testing (no sample obtained)
- HIV testing (Provincial Program)
- Breathalyzer testing (no sample obtained)
- Point-of-Care Testing performed by BC Cancer Agency
- Point-of-Care Testing performed at locations not on this list: IH Facility locations

POCT performed by Interior Health employees outside of their assigned work duties are outside the scope of the policy. These employees act under their own authority and are not to be associated with any Interior Health endorsed activities.

3.2 Approval of POCT Practices

All requests for POCT are reviewed by the Interior Health Laboratory Regional Medical Director or designate in consultation with the Interior Health POCT Advisory Committee and the Interior Health Laboratory Quality Coordinator - POCT prior to approval.[3,5] The evaluation process will include but not be limited to:

- the medical need and appropriateness for the desired application.
- anticipated improvement of patient outcomes (referenced by evidence based medicine).
- an analysis of the service required, the service provided and alternate options.
- method verification prior to implementation
- evaluation and approval of end-user proposals and protocols.
- financial and business analysis.
- client/stakeholder satisfaction

To ensure that funding has been identified to cover the costs of new POCT programs or of significant POCT program expansion; a completed Point-of-Care Testing Program Cost Estimation Form and/or an Interior Health impact assessment must be approved by the requesting program's Vice President and by the Regional Director of Laboratory Services; as well as by the Area Director of Laboratory Operations of the supporting Laboratory.

3.3 POCT Practice Standards

All POCT within Interior Health will be performed in accordance with Accreditation Canada Standards, Diagnostic Accreditation Program Standards and current best practice.

All personnel performing POCT must complete training and demonstrate competency for each specific Point-of-Care Test.[3,5]

Personnel are required to demonstrate competency on an annual basis.[4,5]

Current comprehensive procedures must be available for staff performing POCT. Procedures and processes are documented, current, accurate, and controlled.[3,5]

Quality Assurance processes must be in place as mandated by the Diagnostic Accreditation Program and/or as determined by the Interior Health Laboratory Medical Director. This includes performance of formal External Proficiency Testing programs or of alternative proficiency testing procedures for all testing by the POCT Operators.[3]

Unacceptable proficiency testing or alternate assessment results are investigated and corrective action is implemented where indicated.[3]

POCT results and any action taken as a result of POCT are recorded with the patient's medical record manually or electronically and will, when possible, be included in the Laboratory Information System. Records are in a standardized format that provides necessary information for clinical decision making.[3,5]

The accountability for ensuring that POCT equipment maintenance, QC and patient examination are appropriately performed and documented rests with the individual(s) who perform each of these functions. That individual is also accountable to their professional college, where applicable, for ensuring that they are competent.[3]

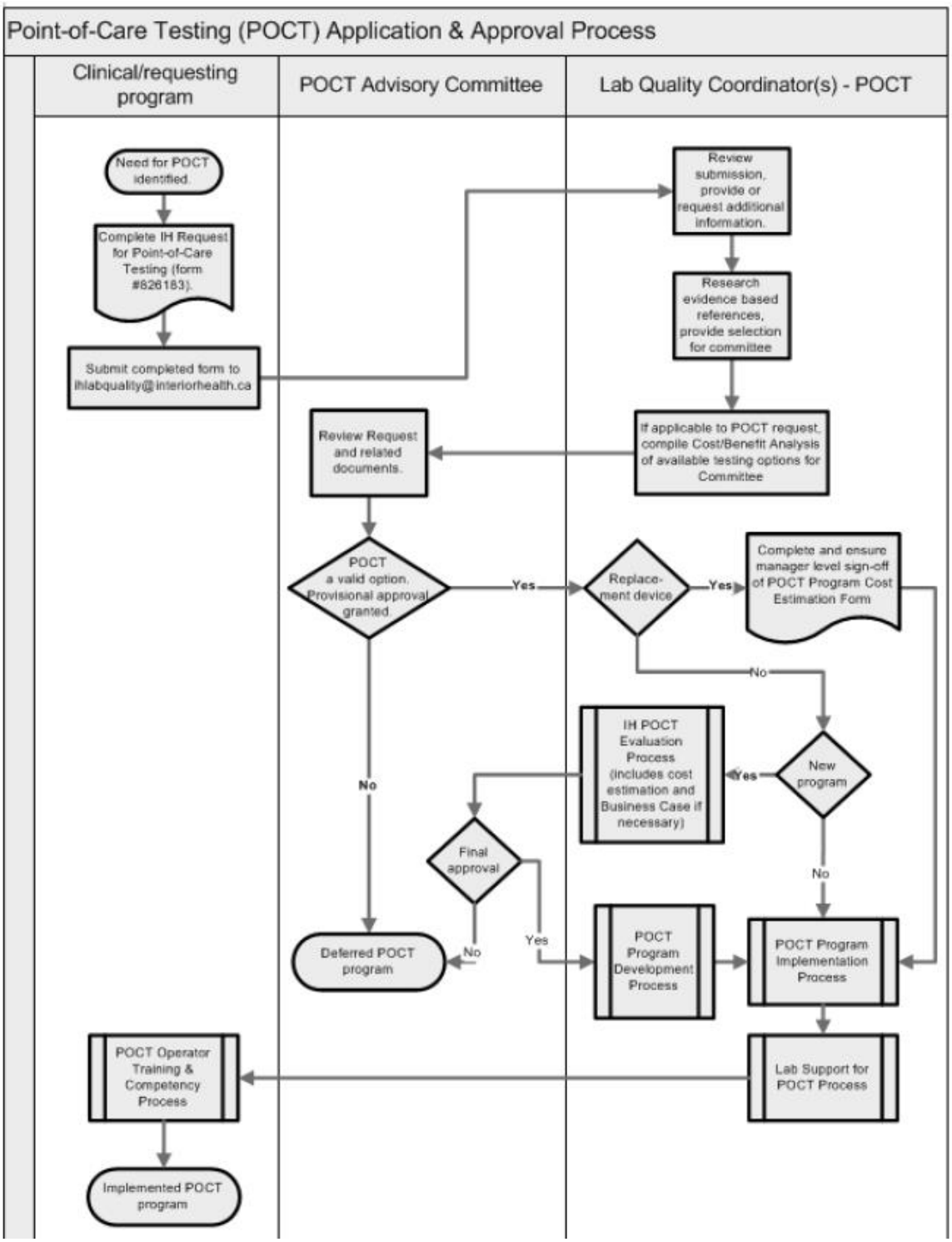
If the POCT is not done at the bedside the sample must be labelled in accordance with CS 0035 Laboratory Sample Labelling Job Aid.

3.4 Compliance

POCT standard operating procedures must be followed.[5] All efforts shall be made by stakeholders to maintain effective communication and to resolve identified issues.

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 Interior Health Laboratory Regional Medical Director.

4.0 PROCESS



5.0 RELATED DOCUMENTS

Request for Point-of-Care Testing, Form #826183
Applying for Point-of-Care Testing (POCT) Procedure
POCT Evaluation Process
POCT Program Development Process
POCT Program Implementation Process
Lab Support for POCT Process
POCT Operator Training and Competency Process

6.0 REFERENCES

1. CLSI. *Selection Criteria For Point-of-Care Testing Devices; Approved Guideline.* CLSI document POCT09-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2010.
2. ISO. *Point-of-Care Testing (POCT) – Requirements for quality and competence.* ISO 22870. Geneva, Switzerland: International Organization for Standardization; 2006.
3. DAP. *Diagnostic Accreditation Standards, Point of Care Testing 2019.*
4. CLSI. Point-of-Care In Vitro Diagnostic (IVD) Testing: Approved Guideline – Second Edition. CLSI document POCT4-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2006.
5. Accreditation Canada. *Qmentum Program Standards, Point-of-Care Testing*; 2010

7.0 Appendix 1: IH Point-of-Care Testing Menu

Common POCT Tests *May not be available at all sites.* *IH POCT Application & Approval Process must be followed.*	**Approved Device/Test Kit/Method**
Activated Clotting Time	Medtronic ACT+ Hemochron Response Hemochron Signature Elite
Blood Gas/critical care panel	GEM 4000 (where supported by Cardiopulmonary) i-STAT
Hemoglobin	HemoCue or i-STAT
Hemoglobin A1c	Siemens DCA systems
Hemostasis Assessment	TEG® Thromboelastograph
INR	i-STAT

Common POCT Tests *May not be available at all sites.* *IH POCT Application & Approval Process must be followed.*	**Approved Device/Test Kit/Method**
Pregnancy Testing	N.C.S. hCG One Step or Clinitest hCG with Clinitek Status
Troponin	i-STAT
Urinalysis	Siemens Multistix 10SG manually or using or Clinitek Status
Whole Blood Glucose*	Nova Stat Strip Glucometer*
Urine Drug Screen	Sure-Step Multi-Drug One Step Screen Test Card (Urine) Sure-Step Multi-Drug One Step Screen Key Cup Sure-Step Multi-Drug One Step Screen Fentanyl Stick BTNX 8.12.3 Multi Drug Cup (Urine)
CBC	poCHi-100

*IH-wide program, pre-approved for all IH sites and Practice Areas.