Purpose:

To ensure that point-of-care (decentralized) laboratory testing is high quality and cost-effective, in order to contribute to optimal patient care within Vancouver Coastal Health Authority and Providence Health Care.

Definitions:

Point of Care (POC): Near or at location where care is delivered to patient

Point of Care Testing (POCT): Analytic testing performed outside a central laboratory environment, typically at or near the patient's bedside.

Low Complex Testing: Non-critical tests which have been approved by Health Canada for home use, employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible, or pose no reasonable risk of harm to the patient if performed incorrectly.

Moderately Complex Testing: Tests which require minimal scientific and technical knowledge and training to perform accurately, operational steps are either automatically executed or easily controlled, and minimal interpretation and judgment are required.

Highly Complex Testing: Tests which require specialized scientific and technical knowledge, training and experience to perform accurately, operational steps require close monitoring or control, and extensive independent interpretation and judgment are required.

External Proficiency Testing (EPT): An external quality control program designed to check instrument and operator performance

---

Point of Care Overview

The provision of diagnostic services related to the analysis of tissue and body fluid for the purpose of diagnosis and treatment falls within the responsibility of the clinical diagnostic Laboratory. In some situations, better patient care, more effective resource utilization and greater patient satisfaction may be potential benefits of POCT. In such situations, the Laboratory will closely engage with the clinical service to oversee and support all aspects of selection, implementation, training, competency assessment and testing, as outlined in this document.

Point of Care Policy

- Vancouver General Hospital's Department of Pathology and Laboratory Medicine (laboratory) is responsible and accountable for tests performed at the Point of Care Level within Vancouver Coastal Health.

- St. Paul's Hospital's Department of Pathology and Laboratory Medicine (laboratory) is responsible and accountable for tests performed at the Point of Care level within Providence Health Care.
- POCT performed by VCH and PHC employees and Medical Staff with privileges, is considered laboratory testing and thus must be performed in compliance with best practices and Diagnostic Accreditation Program standards, and is within scope of this policy.
    - Patient self-testing practices and their subsequent results are out of scope for this policy.
    - POCT performed by VCH and PHC employees outside of their assigned work duties are out of scope for this policy.
    - The following are approved to perform POCT: Registered Nurse (RN), RN Certified Practice (RNc), Licensed Practical Nurse (LPN), Registered Psychiatric Nurses (RPN), Nurse Practitioners (NP), Medical Laboratory Technologists (MLT), Respiratory Therapists, Perfusion Therapists, Physicians, Physician assistants and Allied Healthcare Professionals.
- POCT will be performed only by health professionals trained on the device and who undergo ongoing competency assessment. Participation in external proficiency testing program or alternate assessment is mandatory.
- Vendors who market laboratory test kits, reagents, and instruments will be referred to the laboratory. The laboratory will engage with HSSBC as appropriate.
- Discipline medical leaders and senior technical staff will work with colleagues in clinical areas to assess the need for POCT and what type of POC testing device best suits that need.
- The Point-of-Care Testing Committee establishes standards for Point-of-Care Testing, monitors all Point-of-Care Testing sites for compliance & proficiency as required, reviews for approval all requests to establish Point-of-Care Testing, arranges for evaluation of all POC test devices/kits by central laboratory and approves all such devices/kits before they are put into service. All sites performing Point-of-Care testing must be authorized to do so by the POCT Committee for each test performed.
- For each approved POCT program, an interdisciplinary group will be established to assess, implement and monitor an appropriate POCT device. Written approval is required prior to implementation of a POCT system within Vancouver Coastal Health and Providence Health Care.
- The laboratory ensures that current, written policies and procedures for testing are available at the test site and in the laboratory. These outline roles and responsibilities, proper use of device, sample collection, pre-analytical variables, training of operators, quality control procedures, results handling, reference ranges, documentation of testing, and ongoing competency assessment and continuing education of users.

- The apparent simplicity of POCT can be deceptive to the user. It is expected that accuracy and reproducibility of the POCT result is comparable to that in a hospital laboratory.
- With the exception of blood glucose meters, the laboratory does not support the use of patient point of care self testing results for the purpose of diagnosis and treatment while the patient is in a care facility within VCH and PHC.

  Patients who wish to use their own blood glucose meter may do so with a Physician's Order. Accuracy testing of the patient owned meter must be performed by comparing a simultaneous capillary sample on both patient-owned and VCH or PHC-owned meters at the same time. If difference is greater than 15%, the VCH or PHC meter should be used.
- Approved POCT areas retain fiscal responsibility for ordering POCT supplies, maintaining their supply inventory and ensuring lot numbers and expiration dates of POCT materials and reagents are within current date and ensure environmental conditions will be conducive with the recommendations of the device manufacturer.

IMPLEMENTATION / PROCEDURES

A. Interdisciplinary Point-of-Care Testing Committee

1. The Point-of-Care Testing Committee is chaired by the Laboratory Regional Medical Director and may include the following people or their designees:
   - Medical Nursing
   - Clinical Area Medical Leader
   - Emergency Medicine
   - Purchasing
   - Risk Management
   - Biomedical Engineering
   - IMITS
   - Chemistry and Hematology Technical Practice Leads
   - Discipline Medical leads – Chemistry, Hematology
   - Others as necessary are invited to participate on an ad hoc basis
2. The committee meets at least semiannually with conclusions, recommendations, complaint management, and actions documented in the minutes.
3. The Committee:
   a. Reviews for approval all requests for Point of Care testing, taking into consideration the following issues:
      i. Medical need for immediate turnaround time
      ii. Anticipated improvement of patient outcomes (referenced by evidence-based medicine)
      iii. Procedure complexity
      iv. Appropriate Health Canada certification for requested testing

v. Ongoing testing proficiency
vi. Financial and business analysis

b. Assigns Point of Care testing oversight to the appropriate lab staff by establishing site specific project teams, working groups or subcommittees as needed
c. Reviews reports of performance for all areas performing laboratory testing and
   i. recommends and implements corrective actions as necessary
   ii. executes or request the performance of periodic audits (of practices, of results reporting, of the handling of critical results)
   iii. recommends and implements modifications/improvements as required.

B. Guidelines

1. Requests for POCT require a completed request form – see POC Request Form.
2. The Laboratory evaluates and recommends items to the Point of Care Testing Committee before purchase is approved.

   Technical evaluation includes:
   - comparison with laboratory instrumentation
   - analytical range
   - linearity and precision studies
   - evaluation of potential for operator error
   - effect of pre-analytical variables on test results
   - assessment of technical service requirements
   - verification of manufacturer's reportable range
   - verification of reference intervals
3. The Point of Care Testing Committee assigns oversight of the testing to the appropriate clinical laboratory staff. The department performing the testing ensures that testing complies with all pertinent accrediting agencies and provincial and federal standards, and payment of the applicable fees, if a separate license is required.
4. Point of care testing instruments and materials are standardized within the hospital. Standardization within the region minimizes training requirements, potential operator error, number of suppliers, and simplifies maintenance and quality assurance.
5. Test procedures are written by the laboratory in standard format that is clear to the user and meets all regulatory requirements. Procedures are controlled documents, and are reviewed at least annually and as required by change of law or practice.
   The following elements are defined in each test-specific SOP:
   a. The tests and the extent to which the test results are used in an individual's care (definitive or used only as a screen)
   b. Specimen requirements [collection, handling]

c. The individuals responsible for test performance
d. The individuals responsible for direction / supervision of the testing activity
e. Orientation and specific training, and competency testing of those individuals performing the tests
f. Location of written policies and procedures regarding performance of the test. These policies and procedures describe specimen collection and preservation, instrument calibration, quality control and remedial action, equipment performance evaluation and test performance
g. Quality control checks
h. Quality control and test record maintenance
i. Trouble shooting and maintenance / disinfection
j. Material management
k. Reference intervals, and panic (critical values)
l. Defined processes for confirmatory laboratory testing if applicable
m. Results handling, and documentation [reporting]

6. Preventative maintenance is performed and documented in accordance with manufacturer's instructions and regulatory standards.
7. Laboratory personnel provide continuing review of all documentation, provide feedback to the appropriate responsible authority in that testing area, and present reports of performance to the Point of Care Testing Committee.
8. Units, clinics or sites may not borrow POCT kits, supplies, or devices for testing unless the site is already approved by the POCT Committee to perform the test(s) involved.
9. Disregard for these standards will be recognized as contrary to the best interest of patient care and result in termination of the testing opportunity at the direction of Vancouver Coastal Health or Providence Health Care Laboratory Regional Medical Director.

   Any nonconformities identified during the ongoing audit processes are immediately brought to the attention of the testing area Patient Care Manager, and a repeat audit will take place. Repeat nonconformities are immediately brought to the attention of the POC committee for resolution. An investigation should take place to identify the causes of nonconformity, and remedial actions are undertaken and documented.
10. Unauthorized POCT when discovered are documented and brought to the immediate attention of the POCT Committee for the drafting of an immediate action plan to include a discovery discussion with the appropriate testing area personnel, and begin the formal approval and implementation process or the discontinuation of the POCT at the direction of Vancouver Coastal Health or Providence Health Care Laboratory Regional Medical Director.

C. Approval of a Point Of Care System

For consideration of any point of care test or device, a written request (see POC Request Form) must be submitted to the Laboratory POCT Committee which meets minimally semiannually.

Written approval by the following is required prior to implementation of a point of care test or device within Vancouver Coastal Health or Providence Health Care prior to submission to the POCT Committee:

- Clinical Area Medical Lead
- Clinical Area Operations Leader
- Laboratory Medical Director

The Regional Medical Lab Director and the POCT Committee will review the request and compare it to relevant literature and other available technology taking into consideration the cost analysis. Additional review by other clinical specialists may be sought. The decision in writing is made to the requesting site or department.

If the POCT system is new, VCH or PHC Lab Services will take the initiative on the selection and evaluation of the POCT system in collaboration with the clinical area and a system process is developed.

D. Defined Roles and Responsibilities

The outlined roles and responsibilities listed below act as guidelines. If roles and responsibilities are further defined in the POC test-specific SOP, those should be adhered to.

Laboratory Medical Director or designate (discipline medical leader)

- Will provide clinical perspective and consideration when establishing and approving point of care policies and procedures.
- Oversees and holds overall responsibility for POCT within VCH or PHC.
- Ensures quality standards are met with POCT
- Provides support to laboratory POCT supervisors and technologists.
- Is involved in the approval or non approval of the POC device
- Determines the decision limits for POC device
- Review trends in patient safety issues related to POCT, ensuring appropriate reporting mechanisms are in place
- Will appoint the multidisciplinary POCT management group.

Clinical Area Medical Lead (MD or RN)

- Will provide administrative perspective on the rational for POCT requirement
- Identifies the location and which personnel who will use the POC device.
- Evaluates the effectiveness and costs of POCT
- Ensures adequate funding is available for POCT purchase and operations

- Works with Lab Medical Director to determine decision limits for POC device

Interdisciplinary POCT Committee will:

- oversee the quality of POC devices and assess the performance of the system
- ensure internal quality controls and external proficiency testing programs meet Diagnostic Accreditation Program (DAP) standards
- with help of laboratory physicians, develops a validation process for potential new / replacement POCT device(s)
- monitor compliance of associated policies and procedures and report non-compliances to Laboratory Director
- oversee the training program in conjunction with the Regional Technologist, Site Supervisor, Technical Coordinator
- ensure there is a system for documentation of POCT training and recertification
- respond to Clinical Program Department requesting POCT testing
- work with laboratory and clinical medical, technical and nursing personnel to determine if current laboratory testing is adequate or could be improved to meet clinical department needs, negating the need for POCT testing
- ensure devices meet specified performance standards
- assist with cost benefit analysis of POCT testing with Clinical Department as needed
- support POCT evaluation, education and implementation plans.
- Review trends in patient safety issues related to POCT, ensuring appropriate reporting mechanisms are in place

Chief Technologist [or Site Team Lead] or Technical Coordinator (or POCT designate) will:

- review quality control results monthly and communicate with the testing area manager when non-compliance or quality assurance issues are noted
- monitor compliance of associated policies and procedures and promptly report non-compliances to the POCT Committee
- monitor and enforce with support from the POCT committee all aspects of quality assurance of POCT device
- will manage the external proficiency testing program for the POC device
- with help of laboratory physicians and POCT Committee, develops a validation process for potential new / replacement POCT device(s)
- work with clinical area and vendors to train relevant staff
- assist in procedures and job guides for POCT device
- assist in the informational content, mode and frequency of POCT continuing education and competency assessment
- provide ongoing support to end users

Regional Technologist or Technical Practice Lead will:

- Assist in developing systems to assess and monitor the performance of POC Testing
- Provide continuing education information and assist in competency assessment materials
- Review and update POC documents annually and update as necessary

POCT Area Nursing Manager, Clinical Nurse Educators/Leaders or designate will:

- Review POC needs annually and be aware of location of electronic document
- Train new employees and retain completed training and competency documentation
- Monitor and ensure compliance of associated policies and procedures
- Review and discuss non-compliances with POC operators
- Ensure maintenance and quality control are performed as directed
- Troubleshoot problems as outlined in procedure documents
- Notify laboratory when unable to resolve issues
- Review trends in patient safety issues related to POCT, ensuring appropriate reporting mechanisms are in place

POCT Operator will:

- perform a point of care test only when a written or electronic request is received from a primary care provider
- perform POCT only after verifying a quality control check has been done according to the test procedure
- verify at minimum two patient identifiers prior to performing the test
- only use their operator ID when performing any testing and never share their ID code
- be knowledgeable about how and when the test can be provided, including limitations and possible outcomes of the test and that failure to correctly identify patients may result in a range of adverse events such as medication or treatment errors
- properly label specimens and/or report form to maintain traceability between patient and sample
- maintain specimen integrity by collecting and handling specimens as directed in the test procedure and recognize unacceptable specimens
- record and report results as directed according to the test procedure, including identification of critical values
- will perform and document quality control and cleaning and maintenance of POC device
- be aware of location in testing area of testing procedure, quality control records, and maintenance records
- bring end user concerns to the laboratory e.g. ease of use of POCT device, workflow.
- work with Laboratory staff to implement device
- complete and meet training and competency requirements before testing patients with POCT device
- will lose their certification if not compliant with POCT policies and procedures
- comply with Laboratory quality standards
- perform external proficient testing when required
- be accountable for test results with respect to POCT policies and procedures

E. Quality Control (QC)

The Laboratory POCT staff monitors test systems (equipment and reagents) and testing techniques. A Quality Control procedure is established with data collected in the routine course of the performance of laboratory testing by those personnel producing the results in the patient care setting.

Quality Assurance processes must be in place as mandated by the Diagnostic Accreditation Program (DAP). Internal and external proficiency testing is established when appropriate, with results monitored by the Laboratory. Sub-optimal performance on proficiency testing that has not been rectified is brought to the immediate attention of the Point-of Care Testing Committee, which determines corrective action.

- Quality control testing is conducted in the same manner as patient sample testing by all POC operators
- If the POC device has a quality control failure lock out, it is recommended that this functionality is employed.
- Where possible, devices with electronic controls for verification of QC compliance are selected.
- Frequency of quality control is specified in SOP for each point of care system
- Quality control is documented regularly on quality control charts and signed and dated by the individual performing the QC.
- Quality control is reviewed monthly by the lab
    - for non-interfaced devices, QC charts are sent to the lab monthly by the POCT area
    - for interfaced devices, QC is uploaded automatically into a QC database
- All quality control records and corrective actions for outliers are retained for a period of two years.
- A quality assurance (QA) report is issued to the testing area manager when non-compliance or quality assurance issues are noted.
    - Unresolved QA issues are reported to the POCT Committee
    - The Laboratory on the advice of the Laboratory Medical Director has the authority to withdraw POC devices or discontinue POCT examination in the event of serious POCT proficiency testing or alternate assessment problems are identified and remain unresolved.
- All users of POCT systems will participate in an external proficiency program. All devices will be tested at minimum twice a year.

  If a program is not available, alternate means of assessment is established by the laboratory medical director or medical discipline lead. Alternate assessment may include but is not limited to:

- Blind QC
- Patient comparisons between POC device and Laboratory equipment.

F. Training and Competency

A POCT training program is established under the general direction and authority of the POCT Medical Director. This program is managed by POCT Coordinators, Site Supervisors or Chief Technologists with the support of the POCT Committee, for each point of care system.

The training program incorporates when available manufacturer recommendations and ensures that testing personnel meet regulatory requirements and provides regularly scheduled review of training and techniques. Personnel who perform the testing are identified individually, and only those individuals whose training and competence have been established and documented are authorized to use a point of care system.

Certification

All appropriate staff are trained at time of orientation. Vendor training may be included.

Initial orientation and training consists of acquisition of theoretical knowledge concerning the test as demonstrated by a successful passing score or better on the post-test, and practical demonstration of technique to a qualified trainer or educator.

POCT competency documentation is retained by the testing area in the POCT binder and retained for minimally two years. It is then available for the ongoing audits made by the POCT Committee or designate.

Where applicable, the POCT user is given a unique Operator ID to access and operate the POCT device.

Recertification

Staff is assessed for competency on an annual basis.

Recertification is required for a POCT user after not using the POC device for a period of 1 year.

Recertification requirements are specific to the POCT system and will consist of one or more of the following:

- attaining a passing grade on a written exam
- practical demonstration of technique to an authorized evaluator
- electronic documentation of successful quality control or test performance

Retraining

Retraining for POCT users is required for any of the following reasons:

- User shows inadequate test performance or
- User is non-compliant with policies or procedures or
- User is unable to attain recertification

The user is not to use that POCT system until retraining is complete and they are deemed competent to use the system. All training activities are documented.

G. Documentation and Results Reporting

POCT examinations are ordered by physicians with privileges by written request, or where available, with electronic order entry.

Results, including repeated analyses to verify the first reading are recorded on the patient chart or on a report form, where patient is identified with a minimum of two identifiers.

Results are documented clearly and legibly along with

- Requesting physician
- date and time of sample collection
- date and time of test result
- name or initial of person performing the test

Thermal print outs cannot be attached to the patient's chart. If thermal printouts are to be attached, they must be photocopied.

Any actions taken as a result of POCT is noted in the patient's medical record.

Results that are charted on paper or uploaded electronically to the Electronic Medical Record (EMR) will be distinguished as "POCT", and are traceable to the POC device used to generate the result.

- Manual POC result entry by clinical staff into EMR requires a verification step. Manual entry or scanning in of POC device serial number is performed.
- Manual POC result entry by laboratory staff into the Laboratory Information System (LIS) requires a verification step and is accomplished in the following manner:

  Lab use: LIS Sunquest text codes:

  POCT [Testing done by nursing. See patient report.]

  POCTR [Testing performed on Point of Care analyzer by caregiver]

  example of data entry:

  xx.x-POCTR-;March 14 13:15h / CJC

  Testing performed on Point of Care analyzer by caregiver. (date/initials):

  March 14 13:15h / CJC

Patient self-testing results are not charted.

All equipment maintenance records are documented on appropriate records forms and retained at the testing site and signed by the operator.

H. Point-of-Care Testing Menu

The test menu of VCH & PHC POCT is found in Appendix 1and defines the testing methods and conditions under which they will be performed at the patient's bedside or in the Ambulatory practice setting in accordance with provincial law and regulations.

References

1. College of American Pathologists POCT Policy. www.cap.org/apps/docs/committees/pointofcare/poct_policy.pdf
2. Clinical and Laboratory Standard Institute. POCT04-A2 Point of Care In Vitro Diagnostic (IVD) Testing; Approved Guideline – Second Edition. 2006
3. Clinical and Laboratory Standard Institute. POCT08-A Quality Practices in Non-Instrumented Point-of-Care Testing: An Instructional Manual and Resources for Health Care Workers; Approved Guideline. Dec 2010
4. Clinical and Laboratory Standard Institute. POCT09-A Selection Criteria for Point of Care Testing Devices; Approved Guideline. April 2010
5. Clinical and Laboratory Standard Institute. POCT07-A Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline. October 2010
6. Diagnostic Accreditation Program of BC. Accreditation Standards 2015 Laboratory Medicine. Point of Care Testing Standards POC 1.0 – 6.0, ORG 4.8

Appendix 1: Current list of Approved POCT within VCH/PHC

PHC: up to date listing of Approved POCT can be found on the PHC intranet

POC tests	**Approved device/test/kit**	**Sites -** Not available at all nursing units or clinics
Whole blood glucose	Roche Accu-Chek Inform II glucose meter	VCH PHC
	Roche Accu-Chek Performa glucose meter	SPH VCH Community only
	Nova Express glucose meter	VCH Community only
Urinalysis	Siemens Multistix 10SG ▪ visual read or using Siemens Clinitek Status	VCH PHC
Blood Gases	Radiometer ABL 90	VCH SPH
Blood Gases, ionized calcium, NA, K, Chloride, Urea, Creatinine, Troponin I, HCG,	Abbott iSTAT analyzer	VCH
Oximetry	AVOXimeter 1000E whole blood oximeter	VCH SPH
Pregnancy test	NCS One step pregnancy test device	VCH PHC
Occult blood	Hemoccult	MSJ
Hemoglobin A1C	Siemens DCA Vantage	VCH SPH
Fetal Scalp Lactate	Nova Biomedical StatStrip Lactate meter	VCH SPH
Cotinine	Instant-view Cotinine test	SPH
Amphetamine, benzodiazepines, cocaine, Hydromorphone, methadone metabolite, Methamphetamine, morphine, and oxycodone	Innovacon SureStep Urine Multi Drug test panel Innovacon Urine Drug Screen for Methamphetamine BTNX Rapid Response Hydromorphone single drug test strip	SPH
Hemoglobin	HemoCue	VCH
CBC + 3 part diff	Sysmex PocHi	VCH
INR	CoaguChek XS, XS PRO	VCH
	CoaguChek XS	SPH
D-Dimer	Roche cobas h232 POC System	VCH
Global Hemostasis	ROTEM	SPH

Activated Clotting Time	Medtronic ACT II / ACT II Plus	VCH
	Medtronic ACT Plus	SPH

Revision / Review History:

Version	Revision / Review Date:	By:	Summary of Changes
1.00	Dec 7, 2015	Jim Yakimec with review by Adelina Lim	New document
1.00	Mar 14, 2017	Jim Yakimec	Peer review
2.00	29 Sept, 2017	Jim Yakimec Karen Ng Dr M Trotter Dr K Dallas Dr A Mattman Dr A Fung Dr M Hudoba Sheri Young Elsie Chan POC Committee	PHC-VCH committee review, incorporated recommended changes.
2.01	Jan 24, 2018	Karen Ng	Updated % difference of glucose results using a patient owned meter compared to a VCH/PHC meter must be within 15%. This aligns with ISO standard for glucometer accuracy is +/- 15%
2.02	23 Aug, 2018	Jim Yakimec	Added DDIM – Roche cobas h232 (VCH). Added manual POC result entry requires a verification step.
2.03	1 Nov, 2018	Karen Ng	Removed EPOC and ABL80 Devices (VCH) that have been decommissioned.
2.04	26 Feb, 2019	Jim Yakimec	Alternate assessment established by medical director
2.05	15 July, 2020	Jim Yakimec Sheri Young	Training considers manufacturer recommendations. Recertification after extended absence ORG4.6.2. Added UDS: methamphetamine, hydromorphone Added Nova express glucose meter. Added VCH for fetal scalp lactate Added SPH for Coaguchek XS Updated Cotinine test kit (SPH) Removed BNP (VCH)