

PHC Point of Care Testing Policy

PHC Point of Care Overview

At Providence Health Care the Laboratory has the sole responsibility for the provision of diagnostic services related to the analysis of tissue and body fluid for the purpose of diagnosis and treatment. In some situations the best way to provide these services is by Point of Care Testing (POCT). Better patient care, more effective resource utilization and greater patient satisfaction are potential benefits of POCT.

Point of Care Policy

- POCT is defined as analytical testing performed for a patient by a health care professional outside the conventional laboratory setting, typically at or near the patient's bedside.
- POCT programs will be supported by the laboratory when they clearly provide improved patient care and more effective resource utilization.
- St Paul's Hospital Department of Pathology and Laboratory Medicine (laboratory) is responsible and accountable for tests performed at the Point of Care Level at Providence Health Care. POCT is considered laboratory testing and thus must be performed in compliance with best practices and Diagnostic Accreditation Program standards.
- 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.
- POCT will be performed under criteria established by the laboratory physician and clinical area medical director or designate.
- POCT testing will be performed only by health professionals trained on the device and who undergo ongoing competency assessment. Participation in external proficiency testing programs is mandatory.
- With the exception of blood glucose monitors the laboratory does not support the use of patient point of care self testing results for the purpose of diagnosis and treatment while the patients is in an acute care facility in 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 meters at the same time. If difference is greater than 20% the PHC meter should be used.

- For each approved POCT program an interdisciplinary group will be established to assess, implement and monitor an appropriate POCT device

The Point of Care Interdisciplinary group:

Roles	Responsibilities
<p>Clinical Area Program Medical leader & (or)</p> <p>Clinical Area Operations Leader</p>	<ul style="list-style-type: none"> • Requests investigation by laboratory into desired POCT • Identifies need and rationale for POCT: <ul style="list-style-type: none"> ○ Why current testing methodology (lab or poc) of test is not satisfactory. ○ How patient care will be enhanced ○ Potential Cost implications • Identifies the desired features in POCT • Identifies the department making the request, what location and which personnel will be using the POCT device. • Evaluates the effectiveness and the costs of POCT – this requires collaboration from the lab • Ensures adequate funding is available for POCT device, both for capital and operational costs • Obtains administrative approval POCT testing • Works with lab in the assessment/evaluation process • Works with the Laboratory Discipline Medical Pathologist to determine decision limits for POCT testing program • Point of contact for vendors (often joint)
<p>Laboratory medical director or designate – usually discipline medical leader</p>	<ul style="list-style-type: none"> • Oversees and holds overall responsibility for POCT at PHC • Defines the scope of POCT at PHC for his/her discipline • Ensures quality standards are met with POCT • Provides support to laboratory POCT department supervisor and technologist • Reviews requests for new or replacement POCT devices • Provides support and advice to the Clinical Area Program Medical leader requesting POCT. • Assesses need, appropriateness and rationale for POCT • Determines whether current laboratory testing is adequate or could be improved to meet clinical needs, thus negating the need for POCT testing • Determines if existing POCT device should be replaced and what replacement should be. • Oversees the evaluation and implementation of POCT device. • Determines if validation results of POCT device are acceptable • Determines the decision limits for POCT Device
<p>Discipline Technical Leader, technical coordinator and supervisor</p>	<ul style="list-style-type: none"> • Directs Lab POCT Department (TL) • Respond to Clinical Program. Department requesting POCT testing • Works with laboratory and clinical medical, technical and

	<p>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</p> <ul style="list-style-type: none"> • Ensures devices meet specified performance standards • Assists with cost benefit analysis of POCT testing with Clinical Department as needed. • Supports POCT evaluation, education and implementation plans.
POCT Supervisor (& POCT Technologist)	<ul style="list-style-type: none"> • Responsible for POCT for PHC across all sites • Establishes monitors and enforces all aspects of quality assurance of POCT device. • As directed by the laboratory physicians, designs, evaluates and monitors the QC program for POCT. • Works with Clinical Area to develop an implementation process if POCT device is approved. • With help of laboratory physicians, develops a validation process for potential new/replacement POCT device(s). • Works with clinical area and vendors to train relevant staff • Develops procedures and job guides for POCT device • Determines the informational content, mode and frequency of POCT continuing education • Provides training materials and tools for ongoing competency assessment. • Implements and monitors proficiency testing on POCT devices • Provide ongoing support to end users
POCT Users Representative e.g., Clinical Nurse Leader or Clinical Nurse Educator.	<ul style="list-style-type: none"> • Bring end user concerns to committee, e.g. ease of use of POCT device, workflow. • Work with Lab POCT Supervisor to implement device • Work with POCT Supervisor to develop training schedule for relevant staff. • Complete and meet training and competency requirements before testing patients with POCT device. • Comply with Laboratory quality standards • Work with Lab to achieve ongoing competency
<p>Key topics to be discussed:</p> <ul style="list-style-type: none"> • Who is requesting the POCT Device • Medical Rational for POCT • What are the required features • Locations and Personnel who will be using the POCT device • Cost of POCT • Compliance with quality standards set out by the Laboratory 	

Point of Care Implementation Quality Process

<p>1. POCT Device Exploration</p>	<p>Review POCT device options to determine applicability at PHC.</p>
<p>2. Selection/Validation</p>	<p>Once POCT device(s) have been approved, the laboratory under the direction of Medical Discipline Leader will conduct a validation of the device.</p> <p>Validation Components</p> <ul style="list-style-type: none"> • Accuracy • Precision • Verification of manufactures Reportable Range • Verification of reference intervals. <p>If the evaluation of the device is acceptable then implementation plans will move forward to the next step. If not then the POCT device and request will be reevaluated.</p>
<p>3. Implementation</p>	<p>Point of Care Supervisor along with the Clinical Department Lead and/or End user Representative, will discuss</p> <ul style="list-style-type: none"> • Physical Space required for the device • Where the POCT device will; be located • Number staff require training • Method of training • Procedure and Job Aids • Quality Control • Division of Maintenance duties • Ongoing training of end users • Competency Testing. • Supplies and ordering • Competency Testing
<p>4. Training/Education</p>	<p>Point of Care Supervisor will work with the POC Device Manufacturer and Clinical Department leader to create:</p> <ul style="list-style-type: none"> • Training schedule • Method of training • Number staff requiring training • Super user training – who and how many • Basic end user training <p>Initial training of end users and super user when available will be conducted by the vendor. Alternately vendors may train a few designated staff as super users, the trained super users can then</p>

		further train the end users All Laboratory POC staff will be trained as super users.
5.	Procedures	<p>Written Procedures will be developed by the Point of Care Supervisor for each POCT Device. This will be made available to end users and Point of Care Staff.</p> <p>Procedures will be vetted through the Medical Director.</p> <p>Content of procedures:</p> <ul style="list-style-type: none"> • Purpose of testing • Specimen Requirements e.g. collection, handling • Quality Control Process • Test procedures • Decision Values if required • Reporting and handling of results • Trouble shooting • Maintenance • Material Management
6.	Quality Control	<p>All Point Care devices are subject to Quality Control management that is determined by Medical Lab. This Quality Control managements is structured to meet the standards of both DAP and Accreditation Canada</p> <p>Quality Control Management Includes but is not limited to:</p> <ul style="list-style-type: none"> • frequency with which QC is run • Levels of QC to be run • How QC will be monitored • Measure of Compliance <p>Where possible devices with electronic controls for verification of QC compliance are selected.</p> <p>POC Supervisor and technologist will reviews quality control and inform the CNL/CNE of Clinical Department of any issues.</p>
		<p>Proficiency Testing</p> <p>In addition to Quality Control all Point of Care devices are evaluated by formal proficiency testing or an alternate means of assessment.</p>

		<p>Alternate means of assessment include but are not limited to:</p> <ul style="list-style-type: none"> • Blind QC • Patient Comparisons between POC device and Lab Equivalent <p>All devices will at minimum be tested twice a year with either proficiency testing or alternate as per DAP guidelines.</p>
7.	<p>POCT Patient Results</p>	<p>When Point Care Testing Device is Used on a patient the following guidelines must be applied:</p> <p>Patient must be identified with a minimum of two identifiers.</p> <p>POCT results are clearly linked to the patient at all times</p> <p>POCT Results must be clearly and legibly recorded As POCT test results in the patients permanent medical charts and include the following</p> <ul style="list-style-type: none"> ○ Requestor ○ Date and time of the test ○ Individual performing the test ○ POCT device and Test Results (must include appropriate units) ○ Any action that was taken as a result of POCT result ○ Any instrument print out dated must include patient information, QC information and be dated. <p>Where applicable the laboratory medical leader along in consultation with clinical area medical leader will determine reference intervals and critical limits.</p> <p>Instructions regarding the handling of critical values must be strictly adhered to.</p> <p>Any results that are not consistent with patient diagnosis should be repeated and reconfirmed by laboratory testing</p>
8.	<p>Future Training and Continuing Education</p>	<p>Logistic of Future training of POCT device will be discussed by the Point of Care Supervisor and the Clinical Department Leader. A process will be developed which outlines how new users will be trained and by whom and what documentation is needed.</p>



Request for Point of Care of Testing

Point of Care testing is defined as testing performed outside a central lab environment, near or at the patient bed side/site. The Laboratory at St Paul's Hospital is responsible for the governance, oversight, operation and quality of all Point of Care Testing at PHC. Any request for POCT testing must be evaluated and approved by the appropriated Laboratory Discipline Medical Pathologist.

Please fill out this form to as much as possible and scan/email to phclabpoc@providencehealth.bc.ca or fax Attention Point of Care at 604-806-8815

Section A: GENERAL INFORMATION

Date	Clinical Area Requesting POCT		
Clinical Area Medical Lead		Email/contact	
Clinical Area Operations Leader or Designate		Email/contact	
End User Representative:			

Section B: POCT REQUESTS

Test					
Current method of test delivery Laboratory <input type="checkbox"/> Point of Care <input type="checkbox"/> move on to Section C					
Current average lab turn around time from collection to result					
Current Test volume per month	Current Test volume per day				
Brief explanation how current lab method is not satisfying testing needs <table border="1" style="width: 100%; height: 40px; border-collapse: collapse;"> <tr><td> </td></tr> <tr><td> </td></tr> <tr><td> </td></tr> <tr><td> </td></tr> </table>					
Purpose of Test Screen <input type="checkbox"/> Monitor <input type="checkbox"/> Diagnose <input type="checkbox"/> Rule in/Rule out disease <input type="checkbox"/>					
Preferred Test Kit or POCT method					

Must Haves of POCT method

1	
2	
3	
4	

Section C: COST BENEFIT ANALYSIS (Laboratory can assist with this analysis)

POCT is generally more expensive than laboratory testing when cost is evaluated on test alone however there are many cost savings when an entire episode of care is examined and at times the cost of testing is justified measured against enhanced patient care.

E.g. POC INR can provide result at bed side that can eliminate the need of unnecessary blood products faster than the traditional lab INR. Thereby reducing cost and patient's exposure to unnecessary blood product(s).

Laboratory Cost Per Test

Equipment	
Labour	
Consumables	
Total	

Comments

Point of Care Cost Per Test

Equipment	
Training	
Consumables	
Total	

Comments

Potential savings with implementation POCT.

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E.g. POC INR can provide result at bed side that can eliminate the need of unnecessary blood products faster than the traditional lab INR.

How will POCT Enhance Patient Care

Have funds been approved for POCT request :

Section D: STAFF/LOCATION

Location of testing

Personnel using POCT

Number of staff requiring training

Shift work

Section E: LABORATORY APPROVAL

POCT Request Approved

Approved

Yes

No

If Yes Comment

If No Comment

Final Outcome

Section F Request for additional or Replacement POCT Equipment

POCT Device/Replacement Needed:

Cost To Replace

Revision/Review History:

Date	Revision Type	By	Summary of Changes
April 02 2014	New	Gurjit Bubra	New file for QMS upload

Hard Copy Distribution Log:

Location(s)	Archived Obsolete version, replaced with Current version by:	Date
POC	NA	June25 2014