POINT OF CARE TESTING POLICY CAPT_ADM_0400

PURPOSE

The purpose of this policy is to ensure that point of care testing performed at BC Cancer Agency, Vancouver Clinic.

- Enhance the quality of patient care
- Is held to the same standard as clinical laboratory testing
- Is administered by a multi-disciplinary committee that reports to the appropriate medical staff and administrative bodies
- Meets hospital and laboratory accreditation standards.

POLICY STATEMENTS

Implementation of a point of care test requires:

- Evaluation and selection of instrumentation and procedures
- Training and certification of non-laboratory personnel
- Establishment of quality control procedures
- Test protocols and records of equipment maintenance and troubleshooting
- Selects examination procedures which have been validated for their intended use.
- Protocols for test requisitioning and result reporting
- Procedures addressing instrument maintenance and supplies.
- Quality Goals for the laboratory examinations include:

    - Accuracy
    - Precision
    - Detection limits
    - Interferences
    - Ease of use

Point of care testing instruments and materials are standardized within the hospital.

Point of care testing on a patient requires a documented prescriber's order.

DEFINITIONS

Point of care testing refers to laboratory testing performed outside the laboratory by non-laboratory personnel. The term includes qualitative and quantitative tests.

COMPONENTS

1. POCT Committee:

A point of care test is implemented only after formal approval by the Point-of-Care Testing Committee. Refer to: CAPT_ADM_0100 BCCA_POCT Committee Terms of Reference

The Committee reviews the medical justification for the test and the evaluations, and considers the impact on standardization of testing in the hospital (standardization within the hospital minimizes training requirements, potential operator error, and number of suppliers, and simplifies maintenance and quality assurance). The Committee will assess operational and cost impacts. The Committee decides whether to approve the test/instrument for implementation. A Memorandum of Understanding is executed between the Clinical Program and the Laboratory, which defines responsibilities and costs assumed by the Clinical Program, prior to implementation.

Proposals for new point of care tests, or changes to existing tests are presented to the Committee who decide whether an evaluation of the proposed test/method is warranted. The Committee requests a laboratory evaluation through the Director, Department of Pathology and Laboratory Medicine. POC1.2.4

- The laboratory conducts a formal evaluation of proposed point of care instruments or methods. The evaluation includes comparison with laboratory instrumentation, analytical range, linearity and precision studies, evaluation of potential for operator error and effect of pre-analytical variables on test results, assessment of technical service requirements.
- If the instrument or method is found unsatisfactory on laboratory evaluation, a report is presented to the point of care testing committee.
- If the laboratory evaluation is satisfactory, non-laboratory personnel participate in a clinical evaluation to assess ease of use, operator acceptability, training, cost and feasibility of implementation in the proposed setting.
- Group identifies opportunities for improvement in POCT activities. POC1.2.6
- Monitoring cost and utilization of testing.
- Point of care testing that has not undergone application to the Committee and received approval is considered unauthorized and the Clinical Program will be informed of this violation and instructed to follow the established application process. The controls and related responsibilities and authorities for dealing with unauthorized POCT are defined. POC2.3.1
    - Flagrant disregard of policies or procedures results in termination of the ability to test. Any unauthorized test must be stopped immediately until proper evaluation process completed.
    - The organization addresses unauthorized POCT by either eliminating unauthorized POCT or by incorporating it into the existing POCT program. Cerner audits are performed monthly to see if any unauthorized tests being done. If discovered, an email will be sent to address the unauthorized test and request to put on hold until decision is made whether or not to incorporate the test. POC2.3.2
    - Records of unauthorized POCT and any subsequent actions taken are maintained. POC2.3.3

2. **Laboratory:** Responsible for:

- The planning and development of

    - Required validation, verification and monitoring of activities specific to POCT. POC1.1.4
    - Records to provide evidence that POCT processes and procedures meet requirements. POC1.1.5

- An appropriate theoretical and practical training program has been developed for personnel performing POCT. POC1.3.1

- The management review of POCT includes quality indicators, internal audits and investigation of nonconformities, corrective action procedures and records of actions to deal with nonconformities. Reviewed at monthly QIC meeting. POC2.2.5

- The laboratory selects examination procedures which have been validated for their intended use. The identity of persons performing activities in examination processes is recorded. The specified requirements (performance specifications) for each examination procedure relate to the intended use of that examination. EXA2.1.2

3. **Equipment:** There are procedures for the selection, and evaluation of POCT equipment.

- Equipment is operated by trained and authorized personnel at all times. ERS.4.2.3
    - **Glucose Meter**
        - Learning Hub Course & in person competency. Required to gain access to meter.
    - **Pregnancy Test**
        - Learning Hub Course & in person competency
    - **Urine Dipsticks**
        - Learning Hub Course

- Responsibility for the control of POCT inventory is defined and access to POCT equipment is controlled. POC3.2.1

- Locations and performance records for each piece of POCT equipment are maintained. POC3.2.2

    - Paper records are stored in the office of the POCT coordinator
    - Electronic documents are stored at:
        - H:\Lab_Medicine\POCT - Point of Care
        - OMNI https://phsa.omni-assistant.net/lab/MasterSearchResults.aspx
        - BC Cancer Website: http://www.bccancer.bc.ca/health-professionals/clinical-resources/laboratory-services/point-of-care-testing

- Removing an instrument from use when policies and procedures are not followed.

4. **Maintenance:** There are procedures for maintenance of POCT equipment. POC1.1.7

- POCT equipment records include the serial number or other identifier and the manufacturer or supplier. POC3.3.1

- POCT equipment records include the date received, maintenance records and removal from service dates. POC3.3.2

- POCT equipment is maintained according to the manufacturer's recommendations. The maintenance and repair of POCT equipment is documented. POC3.3.3

- Resource and service personnel are defined and communicated to POCT users. End users contact the laboratory directly for support. POC3.3.4

- POCT equipment that is entering into service after repair is verified, as appropriate.

  *Note: Glucose meters are not repaired at BCC. Meters are sent back to vendor and replaced with new meters. New meters need to be validated before entering service. Meters are not calibrated. POC3.3.5

5. **Inventory Control:** Procedures for inventory control:

- The laboratory has established an inventory control system for reagents and consumables. ERS2.2.4

- POCT reagents are labeled with content, expiry date and storage requirements. POC3.2.3

- Lot numbers and expiration dates of materials and reagents used for POCT are recorded. POC3.2.4

- Periodic monitoring of reagent integrity, instrument performance and comparability with routine laboratory methods.

- The laboratory stores received reagents and consumables according to manufacturer's specifications. ERS2.2.6

- The temperature is monitored where reagents are stored at room temperature.
  Guidance: Temperature monitoring need not be performed in situations where an assessment has determined there is a low risk of the ambient temperature falling outside the manufacturer's suggested storage temperature range ERS2.2.11

- There are procedures for temperature monitoring of equipment and corrective activity. ERS3.3
  Refer to: CAPT_ORD_0300 Monitoring Temperatures of POCT Consumables

6. **Operator Competency:**

- 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. POC1.1.7

  - Laboratory - Maintains equipment, certifies user, quality control, documentation, and audits.
  - Nursing/Technologists - Glucose meter and urine dipsticks part of training. Competency via Learning Hub & In person training. Patient examination. Proficiency testing.

- A training manager; POCT Quality Manager, Nurse Educators, PET Technologists, with theoretical knowledge and experience has been appointed to manage POCT training and competency assessment. POC1.3.2

- Point of care testing is performed only by trained and certified individuals and according to written policies and procedures. POC1.3.5

- Hospital POCT devices should be used for all POCT patient testing in the institution performed by certified operators. Specific policies and procedures regarding training,

certification and recertification of operators are developed jointly by laboratory and operators.

- Training, certification and recertification are performed by laboratory personnel or delegated to appropriately trained and certified non-laboratory personnel. Training includes all aspects of testing included in the procedure manual. QC is performed in the same manner as patient samples and rotated among all operators who perform the examination.

- Operators are responsible for appropriate sample collection, quality control and reagent checks, test performance, reporting, follow-up of unusual results, documentation, basic maintenance (if applicable), and performance of proficiency testing. POCT operator performance is monitored for compliance with procedures. POC1.3.6

- An updated list of certified operators and trainers is maintained in the laboratory and at the testing site via Aegis software.

- A point of care test is performed only by a certified operator, following written policies and procedures. An individual is eligible to become a certified operator only if the POCT test falls within the scope of practice of that individual's profession.

Recommending retraining for operators who show inadequate test performance.

Non-compliant operators are forbidden to perform testing until competency is reassessed.

- Operators must complete hands on training with educators and complete online course in learning hub before being allowed to proceed testing. POC1.3.5
- Non-compliance includes failing proficiency testing, incomplete training, failing to maintain competency ex: glucometer not meeting yearly compliance of 1 set of QC (1x Level 1 & 1x Level 3), 3 patient samples, and yearly refresher quiz or failure to perform POC quality control. If competency not completed, operator will be locked out and must be recertified. POC1.3.7

7. Quality:

- The overall laboratory QMS includes POCT, or a QMS has been implemented for POCT that meets the requirements of the DAP QMS accreditation standards.

- Testing is not performed if a sample is unacceptable or pre-analytical instrument or quality control checks fail.

- Designing appropriate internal quality control procedures and training operators in their use.

- Regularly reviewing operators' testing, quality control and maintenance records.

- Designing appropriate external quality control programs, e.g., testing blind controls, and arranging simultaneous sampling for analysis in the laboratory or other procedures.

- Monitoring external quality control results – proficiency testing.

- Monitoring other quality assurance parameters such as sample quality, pre-analytical variables result turnaround time.

- Verifying that all operators known to be certified participate in quality control activities. Timely reporting of test and quality control performance issues to operators by a mutually determined mechanism.

- Checking reagents, instrument and/or operator performance as needed to follow-up questionable test results, quality control failures, or other signs of suboptimal test performance.

The laboratory undertakes the following Quality Assurance activities for point of care testing:

- A POCT quality manager (or otherwise titled*)

  *BCC Site Supervisor responsibility at BCC-VCC

  - With specific training and experience has been appointed. POC2.1.3
  - Is responsible to the laboratory director for the quality of all POCT. POC2.1.4
  - Is responsible for the design, implementation and operation of QC that ensures POCT conforms to the quality standards of the laboratory. POC2.1.5
  - All QC results for POCT are reviewed at a defined frequency (every month)

8. Document Control:

- Current written policies and procedures for testing are available at the test site and in the laboratory. These include tests available, test ordering, instrument maintenance, reagents, quality control, sample collection and acceptability, pre-analytical variables, testing, reporting, reference ranges, follow-up of unusual results (critical values), and documentation of testing, results and quality control.
- Policies and procedures are reviewed at least annually by designated laboratory and non-laboratory personnel and review is documented.

9. Reporting Results:

- The relationship between values obtained in the laboratory and POCT are established and made available upon request. BCC does not have a chemistry lab, so test results are provided by Vancouver General Hospital. Members can compare POCT with Lab results via Cerner. Staff can also use comparability studies to compare POCT with analyzers from Vancouver General. POC2.1.6

  For glucose value that is ≥ 4.7mmol/L, the test will pass if %bias are within +/-15%

  For glucose value from VGH are <4.7mmol/L, the test will pass if the absolute bias is within +/-0.7mmol/L.

- Point of care testing on a patient requires a documented provider's order specifying the test(s) to be done, and the frequency of repeat testing (if applicable).
- The operator documents valid patient results in the hospital record, including date and time of test, and operator identification. All patient testing, as well as quality control and equipment maintenance, are also documented on appropriate records kept at the testing site and signed by the operator.
- Where technically feasible, results are transmitted to the laboratory or otherwise entered into the laboratory information system and/or hospital information system for inclusion in the patient hospital record. POCT results are recorded as a POCT result and incorporated into the patient's permanent medical record. POC6.1.3
- Every examination requested is recorded. POC6.1.2

- POCT results are clear and legible. Thermal printouts are not used to record results. POC6.1.4
- POCT results identify the user requesting, and the personnel performing POCT. POC6.1.5
- POCT results identify the date and time of examination, captured via Cerner. POC6.1.6
- Any action taken as a result of POCT is noted in the patient's medical record. POC6.2.4
- Periodic monitoring of patient results, records, result reporting mechanisms and follow-up of critical results.