POINT OF CARE TESTING POLICY

PURPOSE

The purpose of this policy is to ensure that point of care testing performed at Children's & Women's Health Centre of British Columbia.

- enhances 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

A point of care test is implemented only after formal approval by the Point-of-Care Testing Hospital Committee.

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.

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
- protocols for test requisitioning and result reporting
- procedures addressing instrument maintenance and supplies.

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.

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

Flagrant disregard of policies or procedures results in termination of the ability to test.

Hospital POCT devices should be used for all POCT patient testing in the institution performed by certified operators. However, patient self-testing using the patient's POCT meter (e.g. glucose) may be permitted and is decided by the Clinical Program.

DEFINITIONS

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

PROCEDURES

1. 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.

2. 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.

3. If the instrument or method are found unsatisfactory on laboratory evaluation, a report is presented to the point of care testing committee.

4. 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.

5. 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.

6. Specific policies and procedures regarding training, certification and recertification of operators are developed jointly by laboratory and operators.

7. 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.

8. An updated list of certified operators and trainers is maintained in the laboratory and at the testing site.

9. 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.

10. Policies and procedures are reviewed at least annually by designated laboratory and non-laboratory personnel and review is documented.

11. 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).

12. 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.

13. 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.

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

15. 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.

16. 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.

17. The laboratory undertakes the following quality assurance activities for point of care testing:

- 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, arranging
- simultaneous sampling for analysis in the laboratory or other procedures.
  Monitoring external quality control results.
- 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.
- Recommending retraining for operators who show inadequate test performance.
- Periodic monitoring of reagent integrity, instrument performance and comparability with routine laboratory methods.
- Periodic monitoring of patient results, records, result reporting mechanisms and followup of critical results.
- Monitoring other quality assurance parameters such as sample quality, pre-analytical variables result turnaround time.
- Monitoring cost and utilization of testing.
- Removing an instrument from use when policies and procedures are not followed

REVISION & APPROVAL LOG

Version	Revision Type	Description of Change	Revision Date	Technical Approval	Medical Approval
1.0	New Document	New Document for LabQMS	Nov 2, 2018	Calvin Lee	Dr. McFadden
1.1	Minor	Added revision log.	Nov 4, 2018	Calvin Lee	

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