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Performance of Point-of-Care Testing in Unaccredited Settings

A Guideline for Non-laboratorians

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Introduction

This guideline is for **non-laboratory** healthcare providers that operate outside of the auspices of Alberta Health Services, who use or rely on point-of-care laboratory testing (POCT) for their patients. This includes the use of POCT in clinical practice/office settings, occupational medicine clinics, pharmacies, private long-term care facilities etc.

The purpose of this guideline is to outline the key components that should be considered to ensure the provision of safe and reliable POCT results.

POCT is also known as "Near-patient testing" or "Point-of-Collection testing".
CPSA accredits and endorses the use of POCT when it is under the auspices of an accredited laboratory. When healthcare providers use unaccredited POCT, they must understand its limitations and risks and ensure that it is performed within the scope of the manufacturer's intended use.

As POCT results can be used to make important decisions about a patient, it is vital that the equipment works properly to yield the correct results and that the operators are trained and competent. This requires that a quality testing framework is established and administered by supervisors and followed by the operators.

If POCT is performed outside of established policies, processes and procedures, this may lead to inconsistent and unreliable results which can be of high risk to patients being tested. Risks include the possibility of reporting erroneous results, which could lead to incorrect or inappropriate decisions being made in relation to the health, management, or care needs of patients.

However, testing from which more critical decisions are made should be subject to higher quality standards and should be performed in an accredited laboratory facility. Examples include, but are not limited to:

- Drug testing
- Coagulation testing (e.g. D-Dimer and INR)
- Cardiac marker identification/quantitation
- Virus detection (e.g. Influenza)
- Bacteria detection (e.g. Streptococcus)

A healthcare provider must never use unaccredited POCT on anyone who is not their own patient. Laboratory testing offered to anyone other than one's own patient constitutes the operation of a diagnostic laboratory, which invokes CPSA requirements for the accreditation of a diagnostic laboratory.

Training and experience are required to achieve accurate and reliable results from POCT. That expertise starts at the choice of appropriate test procedure/kit and extends through sample collection, management of equipment and supplies, performance of the test, interpretation of the results and reporting/documentation of results in each patient's context.

Although the use of unaccredited POCT for screening purposes may seem to lessen the risk for patients, errors will still adversely affect detection of disease or management of those patients. Some POCT is not diagnostic (e.g. drugs of abuse screening) and clinical decisions should not be made based on these screening results. It is recommended that samples be sent to the laboratory for confirmatory testing to ensure appropriate clinical decision making.

Non-laboratory healthcare providers considering implementing POCT are strongly encouraged to collaborate and consult with laboratory POCT experts for support in developing a quality testing framework.

Healthcare providers choosing to perform unaccredited POCT are advised to comply with the following guidelines:

POCT testing can be divided into three phases which include the pre-testing, testing and post-testing phases.

This document will outline the activities within each phase which need to be considered in order to ensure the quality of test results.

Pre-Testing Phase

This phase includes all activities performed before the test can be implemented and/or performed.

1. Planning and development of the POCT service

Before selecting the tests and instrumentation for each POCT, ask:

- What is the purpose of the test and the outcomes expected by providing the test?
- What are the performance characteristics of the test that include accuracy, precision and reliability?
- What are the quality control procedures?
- How simple is the device to use?
- Is the device/kit approved for use by Health Canada where applicable?
- Who will be performing the test?
- Is there a suitable testing environment that ensures safety and confidentiality of patients as well as adequate space for operators?
- What training is required and how will operators be trained?
- How will results be recorded / reported?
- What are the reference ranges? Do they differ from the typical laboratory values?
- What are the reagent storage requirements?
- What are the maintenance requirements?
- What is the sample type and preparation requirements? (i.e., centrifugation)

Based on consideration of these factors, the POCT instrumentation that is most appropriate for a given testing scenario should be considered "fit-for-purpose". In some cases, the purpose for testing can require a highly complex piece of equipment that is very precise and accurate and in other cases, a simple screening "rule out" test, which is easier to use, less expensive and more portable may be more appropriate. This is considered "fit for purpose". Lack of understanding of the testing requirements can

result in selection of instrumentation that is not fit-for-purpose and can impact patient safety.

2. Ensuring readiness for use of POCT instruments and devices

Prior to use of Equipment / Reagents / Kits, the following processes must occur:

- equipment / kit validation/verification to ensure they are performing as intended
- inspection and validation of incoming materials and new lot numbers
- calibration of equipment (instrument/ reagent system) if required by the manufacturer
- Verification of reference ranges for the population being tested (e.g. pediatric vs. adult)

Validation: is the process of establishing the performance characteristics and limitations of the POCT equipment.

- Where equipment and tests have been sourced from a commercial manufacturer or supplier, it can be expected that the validation has been performed by the manufacturer and it does not need to be repeated.
- If the manufacturer has not validated the equipment, then the validation needs to be performed prior to use. It is recommended to contact the Laboratory POC experts for further guidance on this process.

Verification: is the process of demonstrating that the instrument or device meets the expected performance claims documented by the manufacturer but under the operator's own conditions.

- It is recommended to use a statistically significant number of samples to determine accuracy and precision (the generally recommended number is 20 samples).

3. Process and procedure development

Procedures should be written which address the following elements:

- principle of operation
- purpose of the test
- specimen collection and specimen handling
- patient consent, identification and preparation
- preparation of reagents and other material requirements
- quality control procedures
- calibration procedures (if required)
- stepwise instructions for use of the instrument or device
- reporting and documentation of results
- how to handle out-of-control and "critical result" values
- limitations of the procedure including interfering substances
- establishment of acceptable target or reference ranges for QC materials
- reference interval ("normal values")
- reagent, test unit(s), and material storage
- preventative maintenance of the instrument or device
- troubleshooting of the instrument or device
- adverse event protocols related to all phases of testing
- criteria for referral of specimens to an accredited laboratory

4. Training and competency assessment program development

A training and competency program must be developed to ensure the quality of results and should include the following elements:

- All POCT operators must successfully complete a comprehensive training program which includes an understanding of the purpose and limitations of the test and awareness of procedures and processes relating to all aspects of operating the device.
- Operators should be assessed for competence after initial training and on an on-going basis at defined intervals depending on the level of test complexity or degree of difficulty (training does not equate to competency)
- Re-training and competency re-assessment should occur if there are non-conformances or adverse events relating to patient testing
- Training and competency assessment programs should be updated when significant changes occur to the testing service

Testing Phase

It is important to note that POC equipment should only be used according to the intended use and exactly as specified by the manufacturer. If POCT is performed outside of established instruction, this could lead to inconsistent and unreliable results and pose a risk to patients.

When performing patient testing on the POCT device, the following activities must be incorporated into the testing phase to ensure accurate and reliable results for patients:

5. Quality Control Program

All POCT equipment/devices require regular quality control testing to be performed at defined intervals to ensure that the equipment is working properly and the results are accurate and reliable.

The following elements should be included in the quality control program:

- Control materials should be performed and used to monitor the integrity of the test system by comparing the analyzer's results with an expected value.
- Quality control and/or calibration must be performed as specified by the manufacturer.
- Quality control failures must be documented and investigated
- Significant failure event/trends that indicate an continued problem with a particular kit/equipment have defined protocols for notification to manufacturers and regulatory bodies (e.g. Health Canada)

6. Specimen Collection and Preparation Protocols

- Collection of the appropriate specimen must be in accordance with the manufacturer's instructions
- Volume, handling, and storage of samples must conform to requirements specified by the manufacturer of the test reagent and instrument.
- Patient/Client Preparation considerations/requirements (e.g. fasting, lack of interfering drugs) should be documented.
- A protocol should be developed to ensure that each specimen is associated with and appropriately labelled with the patient/client name and patient/client identification number (ID#).

- Collection of sample at the appropriate time (e.g. toxicology or therapeutic drug monitoring (TDM) tests)
- Test should be performed in the presence of the patient
- Patient samples should be processed one at time
- Where timing is critical to the test result, timers should be available for the operators to use.

7. Interpretation of Results

Pre-analytic, biologic, and analytic errors and variations should be taken into account for correct interpretation of a test result.

Examples of pre-analytic errors include:
- incorrect collection site preparation (e.g., wrong disinfecting agent)
- incorrect specimen handling and preparation
- incorrect specimen and wrong patient/client identification
- incorrect specimen collection procedure
- inappropriate specimen collected (e.g., venous vs. capillary)
- inappropriate pretest requirements (e.g., fasting requirements)
- inappropriate time of sample collection

Examples of biologic variation include:
- gender
- age
- patient/client diet (fasting/non-fasting)
- interference by medication
- disease
- genetics

Examples of analytic errors and variations include:
- instrument variation/device errors
- specimens inappropriately sampled
- inappropriate reference interval for specific test method
- operator errors.

Post-testing phase

All test results must be reported to a person who has been authorized to receive the results which can include the health practitioner who requested the test, the patient who has been tested or someone else that has been clearly identified as appropriate to receive the result.

It is also important to consider that some types of POC testing that is performed has significant medical risk and social impact for patients when receiving results (such as HIV or other infectious diseases). In these cases, Physicians should be consulted to provide advice.

The following activities should be incorporated into the post testing phase:

8. Result Reporting/Record Keeping

- For reporting patient results, the following questions should be considered:
  - Are control results acceptable? (If not, then patient results must not be reported.)
  - Have the procedures for specimen preparation, reagent preparation, and instrument maintenance outlined in the written procedure and operators manual been followed?
- POCT results must be recorded in a permanent record (which may be the patient's chart or directly into an electronic medical record), and the record/patient report must clearly state that this is a POCT result.
- The length of time that records are retained must be in compliance with established best practice guidelines.

9. Result Follow-up

- There must be arrangements/processes in place to respond to and act upon any critical POCT laboratory results.
- A healthcare provider who makes a decision based on the interpretation of POCT data must:
  - document the decision and the rationale in the patient record.
  - discuss the decision and the rationale for the decision with the patient as appropriate.
  - include reference to the POCT data in any communication about the decision with other members of the patient's health care team.
  - be cautioned that clinical decisions should not be based on the results of screening POCT (e.g. toxicology). Screening tests are not diagnostic.

10. Evaluation of Proficiency

- An external program for evaluating the accuracy of the POCT system (equipment, reagents, and operators) is highly recommended. External proficiency testing survey programs provide "blinded" specimens containing the analyte(s) being tested. Participants receive performance evaluation against the user's peers for a given test analyte for a given test method/system.

Health and Safety Considerations for POCT

The health and safety of both patient and staff is an essential component of the POCT program and applies to all areas of the workplace and in the provision of service. It is important for the POCT provider to consult with the equipment manufacturer, local healthcare providers and local and provincial authorities for the current and legislative requirement for health and safety.

The following elements should be included in the health and safety program:

- Use of personal protective equipment when dealing with patients and testing of samples(e.g. gloves, gowns/coats)
- evaluation and follow-up of workers after accidental exposure to blood and body fluids
- implementation of a safety training program for employees who routinely work with blood or other infectious materials

- biological / medical waste disposal considerations that is subject to local, regional and national regulations.
- proper training in the use and disposal of sharps.
- cleaning requirements for contaminated surfaces, supplies and equipment
- management of patient adverse events/reactions (e.g. fainting)
- hazard assessment for the identification and mitigation of possible hazards that could be encountered when using the POCT device.

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