Performance of Point-of-Care Testing in Unaccredited Settings:

A Guideline for Non-Laboratorians

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Introduction:

This guideline was prepared for non-laboratory healthcare providers, 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.

POCT is also known as “Near-patient testing” or “Point-of-Collection testing”

The College 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.

POCT performed outside of established policies, processes, procedures and instructions for use 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.

The small number of tests traditionally performed in physician offices/clinics on their own patients are not generally of concern, for example, urinalysis dipstick screening and glucose meters.

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 his or her own patient. Laboratory testing offered to others than one’s own patient constitutes the operation of a diagnostic laboratory, which invokes College 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.

Non-laboratory healthcare providers considering implementing POCT are strongly encouraged to collaborate and consult with laboratory POCT experts. They have a wealth of POCT knowledge in all disciplines and facets of testing.

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

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

- What is the purpose of the test?
- What is the accuracy, precision and reliability of the test?
- 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?
- How much training is required and how will they 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?

2. Prior to Use of Equipment / Reagents / Kits, the following need to 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)

3. Procedures should be written which address the following:

- principle of operation
- purpose of the test
- specimen collection, identification and handling
- preparation of reagents and other materials
- quality control procedures
- stepwise instructions for use
- reporting and documentation of results
- special alerts to out-of-control and “critical result” values
- limitations of the procedure
- establishment of acceptable target or reference ranges for QC materials
- remedial action when out-of-control
- reference interval ("normal values")
- reagent, test unit(s), and material storage
- action if test system is inoperable
- adverse event protocols related to all phases of testing
- criteria for referral of specimens to an accredited laboratory

4. Training and on-going competency assessment of personnel should be performed and documented

- All POCT operators are to successfully complete a comprehensive training program that describes the key aspects of the testing process to ensure operators can produce accurate and reliable results
- Operators should be assessed for competence prior to being allowed to collect or test samples and on an on-going basis at defined intervals (training does not equate to competency)
- Training and competency assessment programs should be updated when significant changes occur to the testing service

5. Safety issues to be considered include:

- personal protective equipment (e.g. gloves, gowns/coats)
- evaluation and follow-up of workers after accidental exposure to blood and body fluids
- a safety training program for employees who routinely work with blood or other infectious materials
- special waste disposal considerations
- cleaning requirements for contaminated surfaces and supplies
- management of patient adverse events/reactions (e.g. fainting)

6. Specimen Collection and preparation are as important as the analysis because if done improperly, could invalidate the remainder of the process.

Issues to consider include:

- 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)

7. Quality Control

- Control materials should be 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)

8. Post-testing considerations

- Safe disposal of samples and collection devices
- Cleaning of the testing environment
- Review, interpretation, and reporting of results

9. 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), and a mechanism established to ensure this is done. 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.

10. 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.

11. 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.

12. 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 reagent)
- 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; and operator errors.

13. POCT Challenges

- Healthcare providers performing POCT should be aware of the following challenges:
    - lack of test ordering/requesting documentation; lack of medical directives that outline defined procedures for ordering POCT
    - result documentation inconsistencies/errors due to lack of connectivity to electronic health record; can result in an increase in duplicate testing
    - issues with consistent training and recertification of POCT operators
    - quality assurance
    - accuracy of testing / procedure limitations (e.g. false positive/false negative results)
    - accountability for testing
    - result follow-up and patient counselling
    - confusion for clinicians with result interpretation if results are not distinguished as POCT results
    - cost of POCT

14. Business Practices

- Business/financial interests are not to direct the performance of POCT.

References:

1. AHS. *Point-of-Care Testing (POCT). Document* # PS-90. Alberta Health Services; December 29, 2016.
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5. CSA. *Point-of-care testing (POCT) - Requirements for quality and competence.* CAN/CSA Z22870-07:2006(E); Mississauga, ON: CSA; 2007.