

Guidance for pharmacists and pharmacy technicians

Laboratory and Point of Care Testing (POCT)

Advice to the profession

The following information is provided to support pharmacists and pharmacy technicians in implementing the Standards of Practice for Laboratory and Point of Care Testing (POCT). It is also intended to support pharmacists when ordering laboratory tests, using testing data and to support pharmacists and pharmacy technicians when conducting Point of Care Testing.

Professional relationship with the patient

1. A professional relationship means a relationship formed with the patient for the purpose of optimizing the patient's health or drug therapy.
2. Testing offered to individuals with whom a patient relationship does not exist constitutes the operation of a diagnostic laboratory, which are accredited by the College of Physicians and Surgeons of Alberta. Therefore, pharmacists may only order tests and pharmacists and pharmacy technicians may only conduct a POCT for individuals with whom they have a professional relationship. If a professional relationship does not exist, the pharmacist or pharmacy technician must develop one¹.

The practice of pharmacists and pharmacy technicians

3. A pharmacist may order a test or conduct a POCT only if the test is undertaken within the practice of pharmacists. In their practice, pharmacists promote health and prevent or treat diseases, dysfunctions, and disorders through proper drug therapy and non-drug therapy decisions².
4. A pharmacy technician may conduct a POCT once they are satisfied that the pharmacist has conducted the necessary assessment of the patient and determined whether it is appropriate to perform a POCT. Results of all POCTs conducted by a pharmacy technician must be assessed by a pharmacist or another authorized health care provider designated by the pharmacist.

Limitations of POCT

5. Before ordering or conducting a POCT, pharmacists should consider that
 - a. POCT data is not uploaded to the Electronic Health Record and could result in duplication of tests by other healthcare providers, and
 - b. accuracy of POCT may not be equivalent to testing performed in a laboratory.

¹ Additional information regarding establishing and maintaining a professional relationship is outlined in the Standards of Practice for Pharmacists and Pharmacy Technicians (SPPPT), Standard 2.

² *Health Professions Act*, Schedule 19, Section 3(1).

Identify or manage a disease state or chronic condition

6. Examples of when a pharmacist may order a test or conduct or order a POCT to identify or manage a disease state or chronic condition include but are not limited to
 - a. ensuring that the drug and the dose ordered is appropriate for the individual patient,
 - b. monitoring patients' response to therapy to ensure optimal outcomes,
 - c. monitoring for adverse effects to ensure patient safety, and
 - d. screening of patients with preliminary indicators for untreated health conditions.

Clinical assessment

7. The patient-specific clinical assessment required to order a laboratory test or conduct a POCT and interpret the results may include, but is not limited to
 - a. health history,
 - b. timing of test,
 - c. drug therapy,
 - d. ethnicity,
 - e. disease,
 - f. drug side effects,
 - g. therapeutic effects,
 - h. organ function,
 - i. diet,
 - j. fluid status, and
 - k. test quality.

Avoid conflict of interest

8. Regardless of whether a test is paid for by an individual, the pharmacy, or the health system, the decision to order a laboratory test or conduct a POCT should be made in the context of comprehensive information about the patient, the patient's condition, and the testing technology being used.

Follow-up system

9. To help meet the requirement to respond to and to act upon any reported critical test results 24 hours per day, 7 days per week, pharmacists should consider developing agreements, partnerships, or arrangements, such as on-call groups, with other pharmacists or health professional³ colleagues. After hours emergency contact information should be made available with the pharmacist's regular contact information or should be available via a messaging service at the regular contact number.

³ Pharmacists should only develop agreements, partnerships, or arrangements with healthcare professionals whose scope of practice allows them to interpret and respond to lab results. Pharmacy technicians must not interpret or respond to lab values.

Conducting point of care tests

Informed consent

10. To obtain informed consent, the pharmacist should provide the patient with information that is understandable and sufficient, in order to allow the patient to make an informed decision to accept or to decline the testing service. To support their decision, the pharmacist should provide the opportunity for the patient to ask questions and obtain responses about the test. The information to be provided should include the
 - a. name of the test;
 - b. objective of the test;
 - c. benefits and risks;
 - d. plan for follow-up, if appropriate, including timeline; and
 - e. cost, where applicable.

Testing environment

11. Tests are conducted in an environment that is clean, safe, private, and appropriate for collecting the sample, conducting the test, device and supply storage, and hazardous waste disposal.
 - a. Sample collection and testing should comply with any conditions defined by the manufacturer of the test and the standard operating procedure.
 - b. Tests should be conducted in a location that provides an appropriate level of privacy for the patient.

Choice of POCT

12. Pharmacists make informed choices among tests based on an understanding and evaluation of test characteristics. These characteristics should include
 - a. intended purpose of the test (disease state management, screening, or diagnosis);
 - b. type of test (quantitative or qualitative);
 - c. sample that is required and the related testing considerations (environment, regulatory, and other considerations, e.g. if sample is blood, urine, or saliva);
 - d. test performance characteristics (sensitivity, specificity, accuracy, repeatability, reproducibility, measurement/reference range, and interferences);
 - e. patient population (e.g., pediatric population vs adults, as predictive value varies in different populations);
 - f. test system (simplicity, length of time to obtain result, level of technical support provided by manufacturer, special training required, and patient information required);
 - g. sample collection protocols and equipment, sample stability;
 - h. method to discard samples and other testing material;
 - i. cost to patients (i.e., when to refer to central lab for testing);
 - j. cost to the health system ('cost stewardship'); and
 - k. ability of the POCT assay data to be standardized against central laboratory data.

Routine practices⁴

13. Routine practices to prevent transmission of infection when conducting POCT, include but are not limited to
 - a. hand hygiene,
 - b. use of personal protective equipment,
 - c. specimen handling consistent with standard precautions,
 - d. routine cleaning and decontamination procedures,
 - e. safe disposal of sharps/biohazardous waste, and
 - f. follow-up in the event of accidental exposure to blood or body fluids.

Interpreting results and ensuring appropriate action

14. Appropriate action following a pharmacists' interpretation of laboratory testing or POCT may include
 - a. confirmatory testing if necessary;
 - b. patient follow-up including engagement, advising patient of all the results of the test, and subsequent activities;
 - c. collaboration and coordination of care with other healthcare professionals when appropriate;
 - d. implementation of therapy, change in drug dosage, or discontinuation of therapy, where appropriate; and
 - e. result reporting and sharing of data with public health agencies and/or other healthcare professionals when appropriate.

POCT program obligations

15. A POCT program should consider
 - a. the purpose of the test;
 - b. the accuracy, precision and reliability of the test;
 - c. the quality control procedures for the test;
 - d. the degree of difficulty in using the test device;
 - e. the training required to conduct the test;
 - f. whether the level of staffing enables and supports safe and effective testing without compromising the quality of other pharmacy services; and
 - g. agreements that are required with testing device and material suppliers regarding education, support, and adverse event reporting.

⁴ Based on the Government of Canada document [Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Healthcare Settings](#)

16. Standard operating procedures for a POCT program are clear, comprehensive and should address the

- a. purpose of the test;
- b. specimen collection, identification, and handling;
- c. preparation of reagents and other materials;
- d. calibration of equipment (instrument/reagent) as required by the manufacturer;
- e. quality control procedures including ensuring reagents, materials, and equipment are stable and not expired;
- f. stepwise instructions for use;
- g. training requirements and procedures;
- h. personal protective equipment (PPE);
- i. special alerts to out-of-control and "critical result" values;
- j. disposal of waste;
- k. cleaning of contaminated surfaces and equipment;
- l. limitations of the test and procedure;
- m. establishment of acceptable target or reference ranges for QC materials;
- n. remedial action for out-of-control readings;
- o. reference interval ("normal values") for populations being treated;
- p. reagent, test unit, and material storage;
- q. validation/verification of device/equipment;
- r. action required if test system is inoperable;
- s. adverse event protocols related to all phases of testing;
- t. reporting and documentation of results; and,
- u. criteria for referral of specimens to an accredited laboratory.

17. Quality assurance process established for a POCT program should include

- a. monitoring and evaluation of testing process for compliance with the standard operating procedures and opportunities for improvement,
- b. regular quality control testing of equipment and consumables,
- c. regular maintenance of equipment,
- d. proficiency testing for test and for personnel performing the test,
- e. a system for documentation and regular review of errors and incidents, and
- f. a system for regular review of quality control records and documents.

Additional resources

- Nova Scotia College of Pharmacists, [Standards of Practice: Testing](#), September 2015
- Government of Canada, [Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Healthcare Settings](#)
- College of Physicians & Surgeons of Alberta, [Performance of Point-of-Care Testing in Unaccredited Settings: A Guideline for Non-laboratorians](#), December 2021