



Standards of Practice for Laboratory and Point-of-Care Testing (POCT)

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Introduction

Pharmacists and pharmacy technicians care for patients at all points of the health system and share responsibility for ensuring safe and effective drug therapy. To do this, a pharmacist must collect and consider information to evaluate and respond to patients' health needs, and to determine whether patients have any actual or potential drug therapy problems. Laboratory data is amongst the information that pharmacists may consider when determining the appropriateness of patients' treatment regimens. When an interaction with a patient or consideration of patient-specific information indicates that a pharmacist should review laboratory data, and the data is not available, the pharmacist must order the appropriate test, refer the patient to an appropriate regulated health professional to evaluate the need that a test be ordered, or if appropriate, conduct a point-of-care test (POCT).¹

These standards outline the requirements for pharmacists when ordering laboratory tests or using testing data, and for pharmacists and pharmacy technicians when conducting tests.

Expectations for the use of the standards and guidance

Standards

Standards establish requirements. Standards use the language of "must." A regulated member must comply with each standard.

Failure to comply with a standard may be considered unprofessional conduct.

Guidelines

Guidelines establish the professionally accepted means by which regulated members can achieve compliance with the standards. Guidelines use the language of "should." Guidelines are not recommendations; they establish the expected conduct of regulated members. A regulated member may only depart from a guideline if the regulated member can demonstrate that the regulated member

- achieved compliance with the applicable standard, and
- the member's departure from the guideline
 - did not detract from the safety, effectiveness, or appropriateness of patient care; or
 - did not undermine the integrity of the professions of pharmacists and pharmacy technicians.

¹ Point-of-care test (POCT) means a diagnostic laboratory examination performed by a pharmacist or pharmacy technician within the practice of pharmacy, generally near to, or at the site of the patient/client.

Standards

Ordering laboratory tests

1. When a pharmacist requires laboratory test data to provide professional services to a patient, the pharmacist may
 - (a) order the laboratory test if the requirements of Standard 2 are met, or
 - (b) refer the patient to another regulated health professional.
2. A pharmacist must only order a laboratory test if
 - (a) the test is undertaken for a purpose within the practice of pharmacists;
 - (b) the test is required for the pharmacist to identify or manage a disease state or chronic condition for a patient of the pharmacist;
 - (c) the pharmacist has a professional relationship with the patient;
 - (d) the laboratory test data is not otherwise available (e.g., on the electronic health record);
 - (e) the pharmacist has obtained the informed consent of the patient;²
 - (f) the pharmacist is satisfied that the laboratory test is appropriate after considering clinical suitability, cost effectiveness, and the patient's best interests; and
 - (g) the pharmacist has adequate knowledge of
 - (i) when the testing is appropriate for a patient given their disease state or chronic condition,
 - (ii) which laboratory test to select in the specific situation,
 - (iii) how the results should be interpreted in the context of other patient information, and
 - (iv) what action should be taken based on the results.
3. For the purpose of Standard 2(f), the pharmacist must conduct a patient specific assessment to determine clinical suitability before ordering a laboratory test.
4. A pharmacist must only order those laboratory tests that the pharmacist is personally competent to
 - (a) order and interpret with the context of the patient's disease states or chronic conditions, and
 - (b) use to appropriately identify or manage disease states or chronic conditions.
5. A pharmacist who orders a laboratory test must have a system in place, 24 hours per day, 7 days per week, to ensure the appropriate follow-up of ordered laboratory testing. This must include arrangements to respond to and act upon any critical laboratory results that are reported. In circumstances where the results of a laboratory test are not received within a reasonable period of time, a pharmacist must follow-up with the laboratory or the patient, as appropriate, to determine the status of the test.
6. A pharmacist must obtain informed consent from a patient prior to ordering a test and must communicate directly with the patient³ about any related follow-up plan or communication to other health professionals.

² When a patient is represented by a patient's agent, Standard 1.9 from the [Standards of Practice for Pharmacists and Pharmacy Technicians](#) must be applied with the patient's agent, as appropriate.

³ See footnote 2.

Conducting point-of-care tests

7. Before a pharmacist orders or conducts a POCT, or directs a pharmacy technician to conduct a POCT, a pharmacist must consider whether a laboratory test would be more appropriate.
8. A pharmacist must only order, conduct or direct a pharmacy technician to conduct a POCT if
 - (a) the test is undertaken for a purpose within the practice of pharmacists;
 - (b) the test is required for the pharmacist to identify or manage a disease state or chronic condition for a patient;
 - (c) the pharmacist has a professional relationship with the patient;
 - (d) the laboratory test data is not otherwise available (e.g., on the electronic health record);
 - (e) the pharmacist has obtained the informed consent of the patient;⁴
 - (f) the pharmacist is satisfied that the POCT is appropriate after considering clinical suitability, cost effectiveness, and the patient's best interests;
 - (g) the test is low-risk, and is either non-invasive or minimally invasive;
 - (h) the test provides rapid results;
 - (i) the device is intended for single use or certified for multi-patient use; and
 - (j) the pharmacist has adequate knowledge of
 - (i) the specific POCT including the physical and diagnostic characteristics and limitations of the POCT,
 - (ii) when the testing is appropriate for a patient given their disease state or chronic condition,
 - (iii) which POCT to select in the specific situation,
 - (iv) how the results should be interpreted in the context of other patient information, and
 - (v) what action should be taken based on the results.
9. For the purpose of Standard 8(f), the pharmacist must conduct a patient specific assessment to determine clinical suitability before ordering, conducting or directing a pharmacy technician to conduct a POCT.
10. A pharmacy technician must only conduct a POCT on a patient with whom the pharmacy technician has a professional relationship.
11. A pharmacist or pharmacy technician must only conduct a POCT in accordance with their scopes of practice, personal knowledge, skills, and competencies.
12. A pharmacist or pharmacy technician must only use POCTs and related materials (e.g., device, software, reagents, strips, etc.) that are classified and licensed (where required by the Medical Devices Regulations to the *Food and Drugs Act*).
13. A pharmacist or pharmacy technician must only conduct a POCT in accordance with a written standard operating procedure that meets any conditions or requirements of the manufacturer.

⁴ See footnote 2.

14. POCTs must only be conducted in an environment that is clean, safe, private, and appropriate for collecting the sample, conducting the test, storing the device and supplies, and managing hazardous waste disposal.
15. A pharmacist or pharmacy technician must apply routine practices to prevent transmission of infection when conducting tests based on the [Government of Canada – Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Healthcare Settings](#).

Interpreting tests

16. A pharmacist must interpret the results of any laboratory tests the pharmacist orders or POCT the pharmacist orders or conducts. The pharmacist must consider and interpret the data in the context of
 - (a) patient-specific factors,
 - (b) the physical characteristics and limitations of each test, and
 - (c) if the test is intended for diagnostic or screening purposes.
17. A pharmacist who interprets a laboratory test or conducts a POCT must
 - (a) advise the patient if the test is meant for diagnostic or screening purposes,
 - (b) advise the patient of the results, and
 - (c) take appropriate action based on the results of the test.
18. A pharmacist who receives a request for information from a patient about a laboratory test or POCT that the pharmacist did not order must
 - (a) only provide results of the test in accordance with applicable provincial privacy legislation and protocol, and
 - (b) not provide an interpretation of the results of tests unless
 - (i) the pharmacist has the necessary competencies to interpret the test results and take appropriate action within the scope of pharmacy practice, and
 - (ii) the results are pertinent to the service being provided by the pharmacist.

POCT program obligations

19. The licensee must develop, implement and manage a POCT program in accordance with Standard 20 if POCT is conducted within or through a licensed pharmacy.
20. The POCT program must
 - (a) identify each type of POCT that will be available to be conducted, including the specific device to be used for each type of test; and the pharmacists and pharmacy technicians, if any, who can conduct the test;
 - (b) include a clear and comprehensive written standard operating procedure for each POCT performed;
 - (c) ensure that there is an appropriate practice environment and facilities for testing;
 - (d) ensure that pharmacists and pharmacy technicians who conduct tests are trained, competent, and follow standard operating procedures and manufacturer standards;

- (e) establish expectations of pharmacists ordering, receiving, and interpreting tests and pharmacy technicians, if any, conducting tests;
 - (f) ensure that POCT equipment is properly managed, including proper calibration at manufacturer recommended intervals, and ensure that there are adequate and safe supplies for the POCT program;
 - (g) ensure that pharmacists responsible for conducting or directing POCT, consult and collaborate with laboratory POCT experts when required; and
 - (h) include a quality assurance process for POCT.
21. If a pharmacist or pharmacy technician practice in a licensed pharmacy that offers or provides POCT, either within the licensed pharmacy or through the licensed pharmacy, the pharmacist or pharmacy technician must
- (a) satisfy him or herself that the licensee has developed, implemented, and manages a POCT program as required under Standard 20; and
 - (b) adhere to the POCT program.
22. A pharmacist who
- (a) is not practicing in or through a licensed pharmacy, and
 - (b) conducts or directs pharmacy technicians to conduct POCT,
- must ensure that there is a program in place or must implement a program that meets the minimum standards for a POCT program under Standard 20.
23. If there is no POCT program that complies with the requirements of Standards 20
- (a) a pharmacist must not conduct or direct a pharmacy technician to conduct a POCT, and
 - (b) a pharmacy technician must not conduct a POCT.

Documentation

24. A pharmacist or pharmacy technician must record each laboratory test ordered or POCT conducted and the results of the test in the patient record.
25. A pharmacist who has ordered or conducted a laboratory test or POCT must ensure that documentation regarding tests ordered or conducted and the results are communicated as soon as is reasonably possible to other health professionals caring for the patient, as appropriate.
26. A pharmacist who makes a decision based on the interpretation of laboratory or POCT data must
- (a) document the decision and the rationale for it in the patient record;
 - (b) discuss the decision and the rationale with the patient;
 - (c) include any reference to testing data in any communication about the decision with members of the patient's health care team; and
 - (d) in the case of reportable communicable diseases, promptly report the results of positive tests to the medical officer of health.⁵

⁵ The *Public Health Act* requires health care practitioners notify a medical officer of health. Relevant guidelines, documentation and forms can be found [here](#).

27. If the testing data is a result of a POCT, this must be specified in the documentation and in communication of the data to others, including details of the POCT technology and whether the test was a screening test or a diagnostic test.

Specimen collection

28. The licensee, or a pharmacist as described in Standard 31, must develop, implement, and manage a specimen collection program in accordance with Standard 29; if pharmacists or pharmacy technicians are collecting specimens other than for POCT.
29. The specimen collection program must
- (a) ensure that the laboratory to which collected specimens are sent to, is accredited in Canada;
 - (b) ensure that the pharmacist or pharmacy technicians only collect specimens of capillary blood, saliva, or urine;
 - (c) identify each type of specimen collection that will occur, and the pharmacists and pharmacy technicians, if any, who can collect the specimen;
 - (d) include a clear and comprehensive written standard operating procedure for each type of specimen collected, written in accordance with the policies and procedures of the laboratory for which they are collecting the specimen, that describes how the pharmacist or pharmacy technician is to collect, store, and transport specimens;
 - (e) ensure that there is an appropriate practice environment and facilities for collecting the specimen;
 - (f) ensure that pharmacists and pharmacy technicians who collect the specimen are trained, competent, and follow standard operating procedures;
 - (g) ensure that pharmacists understand the etiology and treatment protocols for the disease state or chronic condition for which the specimen is being collected; and
 - (h) outline the nature of the collaborative relationship among the pharmacist, the laboratory and other involved health professionals with respect to
 - (i) responsibilities and protocols for acting on the test results, and
 - (ii) communicating the test results and subsequent actions taken.
30. If a pharmacist or pharmacy technician practice in a licensed pharmacy that collects specimens within the licensed pharmacy or through the licensed pharmacy, the pharmacist or pharmacy technician must
- (a) satisfy him or herself that the licensee has developed, implemented, and manages a specimen collection program as required under Standard 29; and,
 - (b) adhere to the specimen collection program.

31. A pharmacist who is

- (a) not practising in or through a licensed pharmacy, and
- (b) collects or directs pharmacy technicians to collect a specimen,

must ensure that there is a program in place or must implement a program that meets the minimum standards for a specimen collection program under Standard 29.

32. If there is no specimen collection program that complies with the requirements of Standards 29

- (a) a pharmacist must not collect or direct a pharmacy technician to collect a specimen, and
- (b) a pharmacy technician must not collect a specimen.

Conflict of interest

33. A pharmacist must not order a laboratory test, or conduct or direct a pharmacy technician to conduct a POCT, if the motivation for doing so is the financial advantage of the pharmacist or a licensed pharmacy, rather than the best interests of the patient.