



Laboratory Tests and Medical Devices – Accessing, Ordering, Performing, Using, or Interpreting

Understanding Part M of the SCPP Regulatory Bylaws (Laboratory Tests and Medical Devices in the Pharmacy)

There are three overarching regulatory frameworks that impact testing activities in the pharmacy: [The Pharmacy and Pharmacy Disciplines Act](#) which governs pharmacy professionals and pharmacies, [The Medical Laboratory Licensing Act](#) which governs medical laboratories in the province, and Health Canada's authorization of medical testing devices for sale and import in Canada, under the [Food and Drugs Act](#) and [Medical Devices Regulations](#).

When practicing within this authorized area, pharmacists must consider the spirit and intent of all three regulatory frameworks as a whole to ensure that they are following all applicable laws. These laws work together and must not be used to disregard another. For example:

- A Collaborative Practice Agreement as defined in Section 1 of Part K in the SCPP Regulatory Bylaws does not replace requirements under [The Medical Laboratory Licensing Act](#); or
- A change in [The Medical Laboratory Regulations](#) does not alter the authorities of [The Pharmacy and Pharmacy Disciplines Act](#) nor Health Canada's authorization of medical testing devices (e.g. approved indications and intended users).

This document is intended to help you understand when and how these laws work together.

All of Part M practices performed by licensed pharmacists, or provided within or through pharmacies, are subject to *The Pharmacy and Pharmacy Disciplines Act*.

The definitions used in this document are based on the above-mentioned provincial and federal regulatory frameworks. All pharmacies and pharmacy team members must use these definitions when referring to the laboratory-related functions included in Part M of the SCPP Regulatory Bylaws.

All medical testing devices accessed, used, interpreted, performed or sold in a pharmacy must be authorized by Health Canada and used only by the approved user and according to the approved indications. When approving devices, [Health Canada](#) specifies "indications" and "intended users" (e.g. lab staff, health care professionals, general public), which helps to determine the intended settings and other conditions for the various testing applications (i.e. self-testing, point-of-care testing, and laboratory testing).

Health Canada’s regulatory framework for medical device authorization is observed within the SCPP requirements. Pharmacies and pharmacy team members must adhere to on-label usage only. Some activities, involving these devices may also subject pharmacists and pharmacies to the provincial medical laboratory licensing framework (e.g., medical vs. non-medical purposes, who, what, where, when, why and how the test is performed)

For more information on these regulatory frameworks, see the following:

Appendix A – Scope of Practice and Laboratory Activities (*The Pharmacy and Pharmacy Disciplines Act*)

Appendix B – Pharmacies and *The Medical Laboratory Licensing Act/Regulations*

Appendix C – Impact of Collaborative Practice Agreements (CPA) on Laboratory Activities

Appendix D – Pharmacies and Regulation of Medical Testing Devices in Canada

Definitions

“Access” – refers to pharmacists “looking up” test results from medical laboratory tests or patient-administered automated tests as approved by Council criteria and subject to privacy requirements for personal health information in Saskatchewan. Pharmacists are only authorized to access or “look up” medical laboratory test results that are indicated to “assist patients with drug therapy management,” unless otherwise authorized by the Registrar in extraordinary circumstances.

“Collaborative practice environment” – means that a relationship exists between the pharmacist and other regulated health professionals involved in a patient’s care, and that the practitioners can reasonably rely upon the basic competencies of the pharmacist to access, order, perform, use or interpret medical laboratory tests, and to access and use patient-administered automated tests in the best interests of the patient.

“Drug therapy management” – means patient-centered care to optimize safe, effective and appropriate drug therapy, and includes preventing, identifying and resolving drug related problems. Care is provided through collaboration with patients and their health care teams (also referred to as “pharmaceutical care”).

“Interpret” – means understanding and explaining the meaning of reference ranges (intervals), critical values, and detection limits of each technique.

“Medical Laboratory” – [The Medical Laboratory Licensing Act](#), S2(f), defines a “medical laboratory” as a place where a test is performed or where a specimen is taken or collected for the purpose of transporting it to another medical laboratory where it is to be tested, unless it is exempted in [The Medical Laboratory Licensing Regulations](#).

“Medical Laboratory Test” – Also referred to as “Test,” see definition of “Test” below.

“Order” – means issuing a laboratory requisition to an individual or medical laboratory to obtain a specified laboratory test, for the purpose of delivering pharmacy or other health related services.

Note: “ordering” tests is within a pharmacist’s scope of practice, however, is not enabled for pharmacists practising outside of public health institutions (e.g., retail community pharmacies) due to limitations in *The Medical Laboratory Licensing Act* and Regulations and other systems issues.

“Patient-Administered Automated Tests” (PAATs) – refers to any test that is designed for patient self-use outside of a conventional laboratory or health care facility, without the assistance or supervision of a healthcare provider to yield a result (e.g., blood glucose testing, prothrombin time tests, blood pressure monitors, pregnancy tests). These testing devices must be approved by Health Canada for “self-testing” or for personal or home use by the general public, independent of the assistance or supervision of a health care worker. Note: see text box in section 5 below “Demonstration of Testing Devices and Performing Point-of-Care Tests”.

“Perform” – means the series of steps executed to obtain a test result (see definition of “test” below). The steps to performing a test include the collection, handling, transportation, documentation, and storage of specimens, as well as performing the analytical techniques on specimens to obtain the result. May also referred to as “conducting” or “administering” a test, or “testing.”

“Pharmacist” – means licensed pharmacist.

“Point-of-Care Testing” (POCT) – refers to analytical patient testing activities performed outside the physical facilities of a clinical laboratory, using a wide variety of test kits and medical devices (e.g. dipstick urinalysis, occult blood screening through robust hand-held kits to bench-mounted analyzers). POCT is typically performed by operators who are not laboratory-trained personnel, and may not require permanent dedicated space. Often referred to as near-patient testing, bedside testing or rapid tests. (See [CPSS Laboratory Quality Assurance Policy](#) and text box “Performing Tests within Retail Community Pharmacies” in Section 5 below.)

Note: for the purposes of this document, “point-of-care testing” will be used when referring to the use of those devices approved by Health Canada as such, whereas “self-testing devices” will be used synonymously with PAATs.

“Practitioner” – means the physician, dentist, nurse practitioner, optometrist, midwife, podiatrist or pharmacist, or other health professional who may be designated as a practitioner pursuant to [The Drug Schedules Regulations, 1997](#), who has prescribed the drug for the patient.

“Public health care institution” – means a designated facility as defined in [The Facility Designation Regulations](#) pursuant to [The Regional Health Services Act](#) (e.g. hospital) or the Saskatchewan Cancer Agency.

“Specimen Collection” – refers to the process of obtaining specimens from the body (e.g. body fluids, secretions or excreta, including blood, urine, saliva, feces or drainage), for the purpose of administering laboratory or point-of-care test. It is one step in “performing” a test. Specimens may be collected using a variety of methods (e.g. nasal swab, throat swab, saliva sample, blood draw, nasopharyngeal). Receiving, storing and transporting specimens is part of the testing process, regardless of who collects it.

Note: Specimen handling, transportation and delivery for medical purposes, may be subject to the quality assurance requirements of the CPSS LQAP (see [here](#) for example). Transporting biological specimens is also subject to the *Transportation of Dangerous Goods Act, 1992*.

“Test” – (Also referred to as “Medical Laboratory Test unless specified, or the context indicates otherwise.) As per [The Medical Laboratory Licensing Act](#), S2(i) means the **examination or analysis of a specimen taken or collected from a human body to obtain information** for screening, diagnosis, prophylaxis, treatment, **or any other health-related purpose**. This includes tests requiring the collection of a specimen to be analyzed at an accredited medical laboratory by a licensed medical laboratory technologist or through point-of-care testing, to obtain a result to inform a medical intervention.

“Use” – means operating a test to obtain a result. Pharmacists may only use tests in the manner in which they have been approved by Health Canada which is documented on the official package insert (e.g. intended use and indications, storage and stability, specimen collection and storage, test procedure, results interpretation, and other testing instructions such as frequency and test limitations). Unless otherwise authorized by the Registrar in extraordinary circumstances, tests must be for the purpose of assisting with drug therapy management for a patient.

1. PURPOSE

Pharmacist involvement in laboratory testing activities is governed by [The Pharmacy and Pharmacy Disciplines Act](#) and [The Medical Laboratory Licensing Act](#), and impacted by the setting (i.e. public health care institution vs. retail community pharmacy or other private care setting), and impacted by Health Canada’s authorization of medical testing devices under the [Food and Drugs Act](#).

Pharmacists Practicing in Public Health Care Institutions

Due to the significant variations of the patient care environments, Part M of the SCPP's regulatory bylaws, do not apply to pharmacists working in public health care institutions (i.e. Saskatchewan Health Authority (SHA) and the Saskatchewan Cancer Agency (SCA)).

In those settings, the authority of pharmacists to access, order, perform, interpret and use tests is governed by policies of the institution within which those pharmacists are practicing (see Section 3 of Part M of the SCPP Regulatory Bylaws).

However, regardless of the practice setting, all pharmacists must uphold the standards of practice. (See Section 2 Standards of Practice.)

Some of the laboratory practices listed in Part M require the retail community pharmacy to hold a laboratory license with the name of the pharmacists and permitted activities listed on that license. (See [Operate a Medical Laboratory](#) on the Ministry of Health website). When a laboratory license is required, pharmacists and pharmacies involved must **also** follow [The Medical Laboratory Licensing Act](#).

Regardless of whether a laboratory license is required or not, all pharmacists carrying out these authorized activities must also meet the standards of practice and other requirements set by the SCPP.

This is a companion document to [Performing Tests for Drug Therapy Management](#), the [Sale and Distribution of Medical Testing Devices and Other Diagnostic Products](#), and the [Emergency Preparedness Resource Kit for Pharmacists and Pharmacy Technicians](#). All must be taken together as a whole.

2. STANDARDS OF PRACTICE

Private and Public Health Care Settings

In addition to the [NAPRA Model Standards of Practice](#), the following standards apply to all laboratory practices authorized in Part M of the SCPP regulatory bylaws, regardless of setting:

- 2.1. The role of the pharmacist must be consistent with their scope of practice, knowledge, training, and be subject to statutory limitations.
- 2.2. Pharmacists may only access, order, perform, use, interpret tests or provide test results for which they are personally competent, and have maintained their competency.
- 2.3. Pharmacists are expected to recognize and practice within the limits of their competence, and use evidence from credible sources to inform their activities. While training is not required by the SCPP, pharmacists are expected to be sufficiently

knowledgeable about such tests in order to competently discharge services involving these tests. (Source: [SCOPE Special Edition, November 2015, Page 1](#)).

Note: additional training may be required as a condition of the laboratory license, or as a condition when emergency provisions are enacted in extraordinary circumstances.

- 2.4. All laboratory practices must be conducted in such a manner that the privacy of the patient is maintained as per the [SCPP Code of Ethics](#), the provisions of [The Health Information Protection Act](#) (HIPA), and the [Personal Information Protection and Electronic Documents Act](#) (PIPEDA) where applicable.

(Also see [SCPP's Patient Confidentiality and the Release of Confidential Records, Guidelines for Use and Disclosure of Personal Health Information for Secondary Purposes, Privacy Policies and Procedures Template](#), and [OIPC's Guide to HIPA](#).)

Private Health Care Setting (e.g., Retail Community Pharmacy)

The following standards apply to pharmacists working in private health care settings:

- 2.5. The pharmacist must establish or maintain a professional relationship with the patient, when performing all laboratory testing related activities, unless otherwise authorized by the Registrar in extraordinary circumstances.
- 2.6. Pharmacists may access, order, perform, use or interpret medical laboratory tests for the purposes of drug therapy management for disease states or chronic conditions only, unless otherwise authorized by the Registrar in extraordinary circumstances. Examples for normal circumstances include but are not limited to:
 - 2.6.1. Ensuring that the drug and the dose ordered is appropriate for the individual patient,
 - 2.6.2. Monitoring patients' response to therapy to ensure optimal outcomes,
 - 2.6.3. Monitoring for adverse effects to ensure patient safety, and
 - 2.6.4. Screening of patients with preliminary indicators for untreated health conditions that may need referral to their primary practitioner (e.g. using a blood pressure monitor to investigate undiagnosed hypertension based on symptoms presented at the pharmacy e.g. headaches).
- 2.7. All tests, accessed, used, performed or interpreted must be appropriate for the patient after considering clinical suitability including, but not limited to the following Council-criteria (as per Section 1 of Part M):
 - 2.7.1. health history;
 - 2.7.2. timing of test;
 - 2.7.3. drug therapy;
 - 2.7.4. ethnicity;

- 2.7.5. disease;
 - 2.7.6. drug side effects;
 - 2.7.7. therapeutic effects;
 - 2.7.8. organ function;
 - 2.7.9. diet;
 - 2.7.10. fluid status; and
 - 2.7.11. test quality.
- 2.8. All **patient-administered automated tests** accessed, used, performed or interpreted (as per Section 1(d) of Part M) must meet the following Council criteria:
- 2.8.1. Approved by Health Canada for self-use or self-testing by a patient and used only as authorized on the official product label or package insert (i.e. on-label usage only for approved indications, intended users, intended settings and intended conditions for use); and
 - 2.8.2. Sufficient evidence exists from credible sources that the device is reliable and medically relevant for the indication, and accepted as medically relevant by the Roy Romanow Provincial Laboratory or other health authorities where applicable.
- 2.9. These services are provided in a collaborative practice environment. The relationship within that environment means:
- 2.9.1. A relationship between two or more regulated health professionals that is developed to:
 - 2.9.1.1. facilitate communication;
 - 2.9.1.2. determine mutual goals of therapy that are acceptable to the patient;
 - 2.9.1.3. share relevant health information; and
 - 2.9.1.4. establish the expectations of each regulated health professional when working with a mutual patient.
 - 2.9.2. Collaboration with the health system to follow established protocols, to avoid unnecessary duplication of tests and fragmentation of care.

Collaborative Practice and the Code of Ethics

The SCCP [Code of Ethics](#) requires a member to co-operate with other health care practitioners to ensure delivery of the highest level of pharmaceutical services to the public.

3. ACCESSING (LOOKING UP) MEDICAL LABORATORY TEST RESULTS

Unless otherwise authorized by the Registrar in extraordinary circumstances, as per Section 1(a) of Part M of the SCPP regulatory bylaws, pharmacists may only access medical laboratory tests approved by the following Council criteria, and the medical laboratory test must be indicated to assist with the management of drug therapy for a patient.

- 3.1. Pharmacists may only access test results when:
 - 3.1.1. It is in the patient's best interest to do so; and
 - 3.1.2. It is necessary to ensure that a patient's medication therapy is safe, effective and appropriate.
- 3.2. Pharmacists may access the results of tests from the [electronic Health Record \(eHR\) Viewer](#) or other technology as administered by eHealth Saskatchewan (eHS), or from local sources under appropriate arrangements and must abide by all eHS requirements.

Scope of Practice/Roles – Accessing Test Results:

In keeping with *The Health Information Protection Act (HIPA)*, access to patients' personal health information is on a "[need-to-know](#)" basis, as such:

- **Only pharmacists are permitted** to look up laboratory test results to assist with drug therapy management for a patient.
- **Pharmacy technicians** do not need to access test results to perform their role in the pharmacy, as assisting with the management of drug therapy for a patient is a clinical function.
- **Pharmacist interns (students and extended)** are not permitted to access laboratory test results, including while under supervision from a pharmacist. However, pharmacists may demonstrate [how to access](#) laboratory test results (e.g. [eHR Viewer](#) as per [Joint Services/Access Policy](#)) to pharmacist interns (student/extended). Also see section 6 below for when pharmacy interns require laboratory test results to perform an activity within their scope of practice (e.g. medication reviews).
- **Pharmacy assistants** are not permitted to access laboratory test results for any reason (e.g. print them off for the pharmacist).

See Appendix A – Scope of Practice and Laboratory Activities (*The Pharmacy and Pharmacy Disciplines Act*)

4. ORDERING MEDICAL LABORATORY TESTS

- 4.1. When recognized to do so under [The Medical Laboratory Licensing Act](#) and [regulations](#), and after the provincial protocols have been put in place by the [Roy Romanow Provincial Laboratory](#) and/or and other health authorities, pharmacists may only order tests according to any additional terms and conditions set by the SCPP.
- 4.2. The tests ordered by pharmacists must be:
 - 4.2.1. indicated to assist with drug therapy management for the patient; and.
 - 4.2.2. approved by Council (See Appendix F - Council Approved Tests for Pharmacist Ordering).

Ordering Tests within Retail Community Pharmacies or Other Private-Care Settings

Ordering medical laboratory tests falls within the scope of practice of pharmacists only, as per Section 23(3)(d) of [The Pharmacy and Pharmacy Disciplines Act](#). However the [Medical Laboratory Licensing Regulations](#) (Section 10) does not yet authorize laboratory tests to be performed when ordered by a pharmacist outside of a public health care institution. As such:

- Pharmacists in the retail community pharmacy or other private care setting **may not order tests** until amendments to [The Medical Laboratory Licensing Act](#) and/or [regulations](#) are in force recognizing this role of the pharmacist ; and
- **Pharmacists practicing within the SHA or SCA (i.e. public health care institutions)** may order tests in accordance with the policies governing those institutions.

See “Appendix A – Scope of Practice and Laboratory Activities (*The Pharmacy and Pharmacy Disciplines Act*)” and [SCOPE Volume 7 5 Oct 2015.pdf \(saskpharm.ca\)](#).

Also see Appendix C – Impact of Collaborative Practice Agreements (CPA) on Laboratory Activities in Retail Community Pharmacies

5. PERFORMING MEDICAL LABORATORY TESTS WITH MEDICAL DEVICES

Performing Tests within Retail Community Pharmacies

Performing medical laboratory tests falls within the scope of practice of pharmacists only, as per Section 23(3)(d) of [The Pharmacy and Pharmacy Disciplines Act](#). (See definition of “Test” above. This would include testing administered by the pharmacist outside of a medical laboratory setting using point-of-care testing devices or collecting specimens to be sent to a medical laboratory.)

However, [The Medical Laboratory Licensing Regulations](#) do not explicitly recognize pharmacists in Section 9 where it outlines the required qualifications for staff/persons who are employed to perform tests in medical laboratories. Instead, section 9(3) states:

A person employed to perform tests in a Category I or Category IX medical laboratory must have the qualifications specified in the licence.

As such, pharmacists in the retail community pharmacy setting **may not carry out any of the steps to perform testing unless**:

- the individual pharmacist is explicitly authorized to do so under a medical laboratory licence, within the terms and conditions specified in the licence (See [Operate a Medical Laboratory](#) on the Ministry of Health website) AND it is permitted within section 1(c) of Part M of the [SCPP Regulatory Bylaws](#); or
- the pharmacist is performing a test that is permitted under [The Medical Laboratory Licensing Regulations](#) (e.g. see Appendix E - COVID-19 rapid antigen tests) AND it has been enacted by the Registrar under Section 4 of Part M of the SCPP Regulatory Bylaws in extraordinary circumstances.

Pharmacists practicing within the SHA or SCA (i.e. public health care institutions) may perform tests in accordance with the policies governing those institutions.

See “Appendix A – Scope of Practice and Laboratory Activities (*The Pharmacy and Pharmacy Disciplines Act*)”

- 5.1. Unless otherwise authorized by the Registrar in extraordinary circumstances, as per Section 1(c) of Part M of the SCPP Regulatory Bylaws, when governing legislation and provincial protocols are in place by the [Roy Romanow Provincial Laboratory](#) and/or other health authorities, pharmacists may only perform tests, according to:
 - 5.1.1. the medical laboratory license where it is needed; and
 - 5.1.2. standards, terms and conditions set by the SCPP.
- 5.2. The pharmacist responsible for screening, diseases state risk assessment clinics, or any other medical purpose organized by the pharmacy, must ensure that the site where the program/service is being conducted, is licensed under [The Medical Laboratory Licensing Act](#) and participating in the [Laboratory Quality Assurance Program](#), overseen by the College of Physicians and Surgeons of Saskatchewan.
(See [Performing Tests for Drug Therapy Management](#).)

Demonstration of Testing Devices and Performing Point-of-Care Tests

To assist with self-monitoring and disease state management, patients are able to purchase patient-administered automated tests (i.e. devices approved by Health Canada for “self-testing”) for personal use or home use.

Demonstration of Testing Devices (i.e., PAATs)

When a pharmacy is selling a device approved for self-testing, the demonstration must be done without collecting a specimen. Note: “selling” falls outside of the purview of *The Medical Laboratory Licensing Act* and therefore, a laboratory license is not required. (See [Sale and Distribution of Medical Testing Devices and Other Diagnostic Products.](#))

Performing Testing Activities

For the purposes of Part M, tests are being performed when any medical products or devices authorized by Health Canada are **used or administered by pharmacists, or offered within or through pharmacies for any purpose** (i.e. medical or non-medical).

For example:

- The pharmacy or pharmacists are involved in collecting, storing, handling and/or transporting specimens to be analyzed at a medical laboratory; or
- Pharmacists are teaching the patient how to collect a specimen, or “**supervising the collection of a specimen**” that is to be transported to a medical laboratory for analysis or analyzed at a point-of-care site.

(See [Performing Tests for Drug Therapy Management](#) for additional SCPP requirements.)

* See [Appendix D – Pharmacies and Regulation of Medical Testing Devices in Canada for more information on the](#) Health Canada distinction between “self-testing” devices and point-of-care testing devices that rely on “self-collection” or “self-collection under supervision of a health care worker.”

6. USING/INTERPRETING MEDICAL LABORATORY TESTS

Section 1(b) of Part M authorizes pharmacists to use and interpret the results of medical laboratory tests approved by Council if the test is indicated to assist with the management of drug therapy for a patient.

Scope of Practice - Using/Interpreting Test Results:

Although using and interpreting is the sole scope of practice for a pharmacist, as per section 23(3)(d) of [The Pharmacy and Pharmacy Disciplines Act](#), it is important to support training that leads to the acquisition of the qualifications to become a pharmacist.

As such, a pharmacist may access and share the laboratory test results with the pharmacist intern (student/extended), in order for them to use and interpret these results for clinical functions (e.g. patient counselling, medication reviews, assessing appropriateness of drug therapy and identifying appropriate follow up). All information must be shared on a [need-to-know basis](#), and all activities are to be performed under [direct supervision](#) of the pharmacist.

See “Appendix A – Scope of Practice and Laboratory Activities (*The Pharmacy and Pharmacy Disciplines Act*)”

- 6.1. Knowledge that may be required for pharmacists to competently use, interpret or discharge services involving tests, as per Section 2.3, may include:
 - 6.1.1. Interpreting the data in the context of patient-specific factors;
 - 6.1.2. Understanding limitations of the test such as specificity, sensitivity, and precision;
 - 6.1.3. Familiarity with common lab tests to assist with drug therapy management (e.g. electrolytes, kidney function, liver function, endocrine and lipids, and hematology);
 - 6.1.4. Understanding when a test is necessary to monitor a patient’s drug therapy;
 - 6.1.5. Determining if lab values are outside of the expected, normal or reference range;
 - 6.1.6. Understanding drugs that may be contributing to abnormal lab results; or
 - 6.1.7. Recognizing and understanding different units of measure and using lab results appropriately to guide therapeutic choices.
- 6.2. Pharmacists who have a gap in knowledge of the competencies identified in 6.1 for a particular situation, must consider consulting with another pharmacist or health care provider/practitioner and transfer care when they are uncertain of the implications or appropriate follow-up action as per the [SCPP Code of Ethics](#), #1.

(See section 6.1.1. in the [Pharmacy Manager Responsibilities](#) reference document for the role of the pharmacy manager in ensuring that staff are practising within their competency.)

7. FOLLOW-UP

Section 2 of Part M outlines requirements for pharmacists in a private care setting (e.g. retail community pharmacy) who perform any of the laboratory practices or functions authorized in the SCPP Regulatory Bylaws.

As noted in Section 2(b) of Part M, pharmacists who access medical laboratory test results must have a system in place to ensure appropriate follow-up care, and take action if the results of the tests are outside of the expected, normal or reference range. For example, appropriate follow-up may include:

- discussing the results with the patient and/or other members of the patient's health care team;
 - developing and implementing a plan for ongoing monitoring or management;
 - revising drug therapy, if authorized within a [collaborative practice agreement](#) under Level II [Prescribing Authority](#), or recommending changes to drug therapy to another member of the patient's health care team (also see Appendix C - Impact of Collaborative Practice Agreements on Laboratory Activities);
 - recommending or prescribing treatments and devices approved by Health Canada, for on-label use, and indicated for self-testing or self-use, to help the patient monitor their condition and the results of the drug therapy (e.g. blood-glucose monitor, INR monitor, blood pressure monitor). Also see [Sale and Distribution of Medical Testing Devices and Other Diagnostic Products](#);
 - consulting with clinical/medical laboratory staff regarding unexpected or unusual results; and
 - recommending a repeat of the test to a practitioner, who is authorized to do so, when it is believed that it would yield different results. The rationale for the request and the test result must be recorded on the patient's record.
- 7.1. Although every pharmacist is professionally responsible for ensuring that they are competent to identify, use and interpret critical test results, pharmacy managers must develop written policies and procedures to help ensure that appropriate follow-up is taken in a timely manner.

(Note: Adapted from [Canadian Alliance of Medical Laboratory Professionals Regulators National Standards of Practice for Medical Laboratory Technologists, adopted by the Saskatchewan Society of Medical Laboratory Technologists](#) (SSMLT). The SSMLT is the regulatory body for the Medical Laboratory Technologists in Saskatchewan.)

Scope of Practice/Roles – Follow Up:

- **Pharmacists interns (students/extended)** are not permitted to access laboratory test results from the eHR viewer, however, they may monitor responses and outcomes of drug therapy, and develop care plans, based the laboratory test results shared by the pharmacists, providing it is performed under [direct supervision](#) of the pharmacist.
- **Pharmacy technicians and pharmacy technician interns (students/extended)** may receive information from patients regarding their responses to drug therapy and document that information in the patient profile. However, all therapeutic issues and questions must be referred to the pharmacist.
- **Pharmacy assistants** are not permitted to follow up on any of the activities outlined in Part M of the SCPP regulatory bylaws, however, they may document information received from patients and refer therapeutic issues or questions to the pharmacist.

See “Appendix A – Scope of Practice and Laboratory Activities (*The Pharmacy and Pharmacy Disciplines Act*)”

8. PROVIDING TEST RESULTS TO PATIENTS

As noted in Part M of the SCPP Regulatory bylaws, when a pharmacist **accesses test results** they may only provide test results to patients with whom a professional relationship exists (Section 2(a) of Part M) and it must be for the purpose of assisting with the management of drug therapy (Sections 1(a) and (b) of Part M).

In addition, when a pharmacist **receives a request** from a patient regarding a test, they are allowed to provide the patient **with the test results** if deemed appropriate in the pharmacist’s professional opinion (Section 2(d)(i) of Part M). However, the pharmacist is not **permitted to provide an interpretation** of the test results unless it pertains to the pharmacy service being provided by the pharmacist (Section 2(d)(ii) of Part M).

- 8.1. When exercising their professional judgement to provide a test result at the request of a patient, pharmacists may give consideration to:
 - 8.1.1. An interpretation that is beyond their scope of practice (e.g. not diagnosing);
 - 8.1.2. Their knowledge of the tests, its limitations, and its applicability to drug therapy management or the pharmacy service being provided;
 - 8.1.3. The immediate health consequences if the results are not provided to the patient, and the pharmacist’s ethical duty to uphold the health and safety of the public (e.g. life-threatening vs. patient has reasonable time to consult a practitioner);
 - 8.1.4. The system they have put in place to ensure appropriate follow-up care;

- 8.1.5. Steps the pharmacist will take to maintain the collaborative practice environment with the patient's health care providers to prevent fragmented care; and
 - 8.1.6. Steps the pharmacist will take to maintain continuity of care with the provincial health system and, where applicable, to ensure that provincial or public health direction is being followed.
- 8.2. Pharmacists who provide test results at the request of a patient when exercising their professional judgement are encouraged to document the reason for their decision and the follow-up action taken. (See Section 9 below, Documentation, Record Keeping and Communication)
 - 8.3. If permitted to provide test results in extraordinary circumstances under Section 4 of Part M, it must be done within the terms and conditions specified by the Registrar in accordance with Council policy. (Also see [Emergency Preparedness Resource Kit for Pharmacists and Pharmacy Technicians](#))

Protecting Patient Privacy in the Pharmacy

The [SCPP Code of Ethics](#), [HIPA](#) and [PIPEDA](#) require that pharmacists who provide test results must protect patient privacy and confidentiality. This includes being aware of the surroundings in which test results are being provided, as personal health information may be unintentionally shared with unauthorized persons nearby. For example:

- when communicating in person, use a separate counselling room that provides visual and sound barriers to protect patient privacy;
- when communicating remotely via telephone, virtual call, mail, fax or any other means, ensure the information cannot be overheard or accessed by others.

(See [Pharmacy Renovation Guidelines](#) for further guidelines on proposed patient care/patient counseling area).

Scope of Practice/Roles – Providing Test Results

- Providing test results to patients is a clinical function to be performed by the **pharmacist**, as outlined in Section 2 of Part M of the SCPP regulatory bylaws.
- **Pharmacist interns (students/extended)** may not provide test results to patients. However, in support of training, they may monitor responses and outcomes of drug therapy and advise patients by providing drug information respecting a drug therapy selection, under [direct supervision](#) of the pharmacist.

For example, when counselling patients or providing medication assessments, pharmacist interns (students/extended), may provide test results **relative to reference ranges** (e.g. test result is in “normal range”) while explaining why certain drugs are used. However, if needed, **specific** laboratory values must be given to the patient by the pharmacist. This permits the pharmacist intern to perform a portion of this authorized practice while remaining in accordance with the bylaws.

- **Pharmacy technicians and pharmacy technician interns (students/extended)** are not permitted to provide test results to patients. This is a clinical function reserved for the pharmacist.
- **Pharmacy assistants** are not permitted to provide test results to patients. However, in extraordinary circumstances may be permitted to provide test results to others as specified by the Registrar (e.g. pharmacy staff).

Note: Given that the nature of extraordinary circumstances may vary, this permission is timebound and specific when enacted, and must be carried out as per the terms and conditions communicated by the Registrar and/or provincial authority. (See [Emergency Preparedness Resource Kit for Pharmacists and Pharmacy Technicians](#)).

See “Appendix A – Scope of Practice and Laboratory Activities (*The Pharmacy and Pharmacy Disciplines Act*)”

9. DOCUMENTATION, RECORD KEEPING AND COMMUNICATION

Information flow is critical to quality patient care. It ensures that healthcare decisions are based on the most accurate and up-to-date information, and maintains the collaborative practice environment. Proper documentation ensures the information is available, and may move between the pharmacist and the patient, primary care provider, pharmacy team and other health providers as needed.

- 9.1. Pharmacists who perform activities related to medical laboratory tests must ensure that:
 - 9.1.1. Records are clear, accurate and legible;
 - 9.1.2. Information is documented on the patient’s pharmacy profile in a timely manner (i.e., as they are performing the task or as soon as possible afterwards);

- 9.1.3. They personally document their activities and the information necessary to support the rationale and quality of these activities;
- 9.1.4. They document their decisions/actions, supporting patient information, and their interpretation of this information, including:
 - 9.1.4.1. Accessing of patient's laboratory test results to identify problems in the patient's medication therapy;
 - 9.1.4.2. Assessment of laboratory test results in the context of other patient information, to identify problems in their medication therapy;
 - 9.1.4.3. Review results of patient administered automated test, when shared by patient, to identify problems in the patient's medication therapy;
 - 9.1.4.4. Actions to rectify medication therapy problems identified via laboratory test results or PAATs; and
 - 9.1.4.5. Recommendations for repeated testing to a practitioner.
- 9.1.5. The patient's practitioner is informed of any relevant information, including rationale and actions taken in response to any test result;
- 9.1.6. All documentation is kept in a retrievable format and retained as outlined in the [SCPP Record Keeping Requirements](#).

10. RELATED RESOURCES

- 10.1. [Performing Tests for Drug Therapy Management](#)
- 10.2. [Sale and Distribution of Medical Testing Devices and Other Diagnostic Products](#)
- 10.3. [Supervision of Pharmacy Interns](#)
- 10.4. [SCPP's Patient Confidentiality and the Release of Confidential Records](#)
- 10.5. [Guidelines for Use and Disclosure of Personal Health Information for Secondary Purposes](#)
- 10.6. [Privacy Policies and Procedures Template](#)
- 10.7. [OIPC's Guide to HIPA](#)

11. AUTHORITY

- 11.1. [The Pharmacy and Pharmacy Disciplines Act](#) (SK)
- 11.2. [The Medical Laboratory Licensing Act](#) (SK)
- 11.3. [The Medical Laboratory Licensing Regulations](#) (SK)
- 11.4. [Food and Drugs Act](#) (Federal)
- 11.5. [Medical Devices Regulations](#) (Federal)

Appendix A – Scope of Practice and Laboratory Activities (*The Pharmacy and Pharmacy Disciplines Act*)

The Pharmacy and Pharmacy Disciplines Act and Scope of Practice

Section 23 (3) of [The Pharmacy and Pharmacy Disciplines Act](#) (the Act) explicitly authorizes pharmacists to undertake expanded roles with patient-administered and medical laboratory tests (i.e. pharmacist-administered tests using medical devices). However, the scope of practice for pharmacy technicians and interns practising under supervision, defined in Sections 23(1) and (2), does not include any laboratory testing activities and therefore their role is very limited*.

(3) A licensed pharmacist who meets the qualifications set out in this Act and the bylaws, may, subject to the terms, conditions and restrictions on that licensed pharmacist's license, perform all or any of the following practices:.....

(c) access and use patient-administered automated tests designated in the bylaws and interpret the results of those tests;

(d) access, order, perform, use or interpret medical laboratory tests in accordance with the regulatory bylaws made pursuant to this Act and the regulations made pursuant to [The Medical Laboratory Licensing Act, 1994](#).

The roles of pharmacy team members outside of public health institutions (e.g. retail community pharmacies) may be summarized as follows:

Role of Pharmacists

Only pharmacists are permitted to carry out the medical laboratory testing activities listed in Section 23(3) of the Act and Part M of the SCPP regulatory bylaws, when enabled to do so within both regulatory frameworks. Section 23(3) does not permit the SCPP to authorize any delegation of the functions related to medical laboratory practices by a pharmacist.**

Therefore no surrogacy, nor delegation of responsibilities and accountability, is permitted with respect to medical laboratory testing activities. (See [SCOPE Volume 7 5 Oct 2015.pdf \(saskpharm.ca\)](#)).

Role of Pharmacy Technicians

Pharmacy technicians are not authorized to carry out the medical laboratory testing activities outlined in Part M. However, may support the sale and distribution of patient-administered automated testing devices. (See [Sale and Distribution of Medical Testing Devices and Other Diagnostic Products](#)).

Role of Pharmacist Interns (Student and Extended)

Pharmacist interns (student and extended) are not authorized to carry out the medical laboratory testing activities outlined in Part M. However, in support of training to acquire the qualifications to become a pharmacist, pharmacist interns may carry out portions of the authorized practices as outlined in this policy.

Role of Pharmacy Assistants

Unless otherwise authorized by the Registrar in extraordinary circumstances, pharmacy assistants are not permitted to carry out any of medical laboratory activities. However, when acting within a pharmacy setting, their actions must be conducted in accordance with the terms and conditions of the Registrar and the provincial authority that authorized these activities. (Also see [Sale and Distribution of Medical Testing Devices and Other Diagnostic Products](#)).

*This interpretation of the *Act* is consistent with the principle of implied exclusion: Which means that the explicit expression of one thing in a statute suggests the exclusion of another. By specifically conferring the authority to practice testing-related activities only on pharmacists, the Legislature has excluded that practice from the pharmacy technicians and interns practising under supervision altogether.

****Delegation of Functions** - Section 14(2)(u) of the Act empowers the SCPP to make regulatory bylaws that govern the delegation of functions by a pharmacist or pharmacy technician. This means that only the SCPP is authorized to delegate functions when it is permitted in the Act. Pharmacists and pharmacy technicians **are not permitted** to delegate unless authorized by the SCPP. And when delegation is permitted, it must be done in accordance with the SCPP's policies, standards and bylaws. However, **Section 23(3) does not permit the delegation of medical laboratory practices.**

Appendix B - Pharmacies and The Medical Laboratory Licensing Act/Regulations

Pharmacies and *The Medical Laboratory Licensing Act*

In Saskatchewan, the examination or analysis of a specimen taken or collected from a human body for the purposes of screening or assessment of risk for any health-related purpose is considered to be a “test” within the meaning of [The Medical Laboratory Licensing Act](#). **This also includes the acts of receiving, storing and handling specimens collected by the patient, or any other person, for purposes referenced in [The Medical Laboratory Licensing Act](#).**

Any site where such tests, including the above activities are performed must be licensed through the Ministry of Health, in accordance with [The Medical Laboratory Licensing Act](#) and [The Medical Laboratory Licensing Regulations](#), and meet personnel, instrumentation and testing proficiency criteria.

As a condition of the medical laboratory license, the licensee must participate in the [Laboratory Quality Assurance Program \(LQAP\)](#) administered by the College of Physicians and Surgeons of Saskatchewan.

The LQAP is responsible for establishing the requirements and standards of medical laboratories in Saskatchewan and to ensure their compliance with [The Medical Laboratory Licensing Act](#) and regulations. The College of Physicians and Surgeons of Saskatchewan (CPSS) is contracted by the Province of Saskatchewan’s Ministry of Health to operate the LQAP Program.

Laboratory testing performed in non-licensed settings is not approved and may be in contravention of [The Medical Laboratory Licensing Act](#). (See the CPSS’ [Laboratory Quality Assurance Policy](#) which outlines requirements in Saskatchewan)..

Transporting of biological specimens is subject to the [Transportation of Dangerous Goods Act, 1992](#).

Note: Specimens taken and testing performed for non-medical purposes (e.g. travel, occupational requirements, recreation) are not subject to [The Medical Laboratory Licensing Act](#). **However, all specimens taken and testing performed by licensed pharmacists, or within or through pharmacies, for any purpose (medical or non-medical) are subject to [The Pharmacy and Pharmacy Disciplines Act](#), and SCPP terms, conditions and standards.**

Appendix C - Impact of Collaborative Practice Agreements on Laboratory Activities

Impact of Collaborative Practice Agreements (CPA) on Laboratory Activities in Retail Community Pharmacies

A [Collaborative Practice Agreement](#) is a written agreement between a pharmacist(s) and practitioner(s) to allow pharmacists to perform level two prescribing (see [Prescriptive Authority - Pharmacists](#)).

- Pharmacists who “access” medical laboratory tests may use the results to take appropriate follow up action if permitted within the CPA (e.g. revising drug therapy authorized by the CPA) as per Section 2(c)(iii) of part M; however,
- It **does not** permit any delegation of responsibilities and accountability with respect to medical laboratory testing activities. For example, it does not authorize a pharmacist to order a laboratory test under a physician’s name or to perform a laboratory test.

A CPA created under the authority of [The Pharmacy and Pharmacy Disciplines Act](#) does not apply to “medical laboratory practices”, which are governed by [The Medical Laboratory Licensing Act](#). Pharmacists practicing within a retail community pharmacy or other private-care setting may only “order” or “perform” tests when explicitly authorized under a medical laboratory license. (See [Operate a Medical Laboratory](#) on the Ministry of Health website)

Appendix D – Pharmacies and Regulation of Medical Testing Devices in Canada

Regulation of Medical Testing Devices in Canada

Under the authority of [Food and Drugs Act](#), and [Medical Devices Regulations](#), Health Canada regulates the sale and import of medical devices, including commercial testing devices. **Only testing devices authorized by Health Canada may be imported or sold in Canada.**

Health Canada takes a [risk-based approach](#) to regulating and classifying these devices proportional to the public health risk from the use of the device, ranging from Class I (lowest-risk) to Class IV (highest-risk). Following are the classification levels of some common devices that would be found in the pharmacy:

- Class I – thermometers, masks, face shields, non-prescription compression hosiary
- Class II – infrared thermometers, gloves, syringes, pregnancy tests
- Class III – blood glucose monitors, prothrombin time tests
- Class IV – COVID testing devices .

Medical devices intended to be used outside the body for the examination of specimens are referred to as *in vitro* diagnostic devices (IVDD).

Health Canada has categorized these testing applications into 3 types, including:

- **Laboratory-based Tests** – when samples are collected and sent to a laboratory for analysis by a trained laboratory technician;
- **Point-of-care tests** – are used by an approved operator (often a health care professional) when sample collection and testing in a near-patient environment like a medical office or at the bedside. The patient waits for the results. i
- **Self-testing devices (also referred to as “patient-administered automated tests” by the SCPP)**– are those that can be purchased and used by the general public. Enables individuals to test at home without supervision of a healthcare professional.

When Health Canada authorizes medical testing devices for commercial sale and import, manufacturers must ensure that performance claims are supported by studies carried out: for the intended users, intended setting and intended conditions for use. This information can be found on the product label or package insert.

Note: Medical testing devices approved by Health Canada for “self-testing” should not be confused with point-of-care testing devices approved for “self-collection” or “self-collection under supervision of a health care worker.” These are different. “Self-testing” refers to a completely independent self-administered testing, from sample collection to reading results. Whereas “self-collection” refers to the testing process where the specimen collection is being performed by the person being tested, and the sample processing/analysis is done by a point-of-care testing site or a professional in a laboratory. . (Source: [Priority strategies to optimize self-testing in Canada - Canada.ca](#))

Application in the Pharmacy

While Health Canada regulates the device, it **does not** regulate who can collect a sample from a patient. This is the responsibility of the provinces.

In Saskatchewan, when a pharmacist, or other health care professional in the pharmacy, are collecting specimens for medical/health-related purposes (e.g. screening, diagnosis, prophylaxis, treatment), these activities typically fall under [The Medical Laboratory Licensing Act](#), regardless of whether the device has been approved for “self-testing” or “point of care testing.”

Examples of other criteria used to determine when an activity requires a laboratory license, may depend on: who is involved, what they are doing, where it is occurring or how the specimen is being collected.

Also note that laboratory related activities involving pharmacy professionals and pharmacies are also regulated by [The Pharmacy and Pharmacy Disciplines Act](#). **To understand the interaction of all these regulatory frameworks for each authorized activity in Part M of the SCPP’s regulatory bylaws, check the relevant sections of SCPP’s reference documents.**

Sources:

- [Health Canada “List of Authorized Testing Devices for COVID-19 Testing,](#)
- [Health Canada - Priorities Strategies to Optimize Self-Testing in Canada.](#)
- [Health Canada - Testing Devices for COVID-19: Overview](#)
- [Health Canada - Testing devices for COVID-19: Point-of-care and self-testing devices](#)
- [Health Canada Guidance Document: Guidance for the Risk-based Classification System for In Vitro Diagnostic Devices \(IVDDs\) - Canada.ca](#)
- [Health Canada Guidance Document on Labelling IVDDs](#)

Appendix E- COVID-19 Rapid Antigen Tests and Pharmacies

Appendix E- COVID-19 Rapid Antigen Tests and Pharmacies

In 2021, amendments were made to Section 2(2)(d) of [The Medical Laboratory Licensing Regulations](#), to permit COVID-19 rapid antigen testing for asymptomatic individuals to be performed outside of a licensed laboratory. It states:

2(2) For the purposes of subclause 2(f)(iv) of the Act and in these regulations, the following types of facilities are not medical laboratories

(d) premises in which point-of-care antigen testing for COVID-19 and collecting specimens for that purpose have met the following conditions:

(i) the collection of specimens is limited to the following:

(A) anterior nasal swab;

(B) nasal mid-turbinate swab;

(C) combined throat and nasal or anterior nares;

(D) saliva sampling;

(E) throat swab;

(ii) the point-of-care antigen testing or specimen collection is performed only on a non-diagnostic basis with respect to asymptomatic individuals.

While this exemption increases access to COVID-19 rapid antigen testing, it does not:

- Change the “indications for use” or the “intended user” approved by Health Canada for COVID-19 or other medical testing devices (e.g. self-testing by general public vs. point-of-care testing by health care professional vs laboratory testing by laboratory staff) (also see “List of [Authorized Testing Devices for COVID-19 Testing](#),” and “[Testing Devices for COVID-19 Overview](#)”);
- Permit pharmacies to carry out other laboratory activities for medical purposes without a laboratory license (e.g. involvement in specimen collection where samples are subsequently transported to a laboratory for processing for medical purposes, perform testing using devices authorized by Health Canada for “point-of-care testing”; Note: tests that use serology-based technologies (i.e. detect antibodies) are not considered medically relevant.in Saskatchewan. or
- Remove requirements under [The Pharmacy and Pharmacy Disciplines Act](#) and Part M of the SCPP Regulatory Bylaws (e.g. indicated to assist with drug therapy management; on-label use as approved by Health Canada and by Council).

In extraordinary circumstances, federal and provincial regulators may expand the “indications-for-use” or “intended-users,” remove restrictions or expand involvement of pharmacies.

However, pharmacies and pharmacy team members are not permitted to carry out additional laboratory-related activities unless explicitly permitted to do so by the Registrar or other appropriate regulator and only within the terms and conditions communicated. When in doubt, confirm with the SCPP.

See [Emergency Preparedness Resource Kit for Pharmacists and Pharmacy Technicians.](#))

Appendix F - Council Approved Tests for Pharmacist Ordering

Pharmacist **ordering** is not enabled for those working in the retail community pharmacy or other private care setting.

When governing legislation (e.g. [The Medical Laboratory Licensing Regulations](#)), and **provincial protocols**, developed by the [Roy Romanow Provincial Laboratory](#) and/or Saskatchewan Health Authority, **are in place**, pharmacists may only order the following tests upon direction from the SCPP as approved by Council:

√ = Able to order	X = Not able to order
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Laboratory Test	Retail Community Pharmacies or Other Private-Care Settings	Public Health Care Institutions
Albumin	√	√
Bilirubin (Total and Direct)	√	√
Blood glucose (fasting and random)	√	√
B-Type Natriuretic Peptide (BNP) (including NT-pro BNP)	X	X
Creatine Kinase (CK) ⁱ	√	√
C-Reactive Protein (hsCRP)	X	X
Complete Blood Count	√	√
Electrolytes ⁱⁱ	√	√
eGFR	√	√
HbA1C (glycolated hemoglobin)	√	√
Immune serology: Hep A, Hep B, rabies, rubella, varicella, yellow fever	X	X
International Normalized Ratio	√ ⁱⁱⁱ	√
Iron Indices ^{iv} Iron, ferritin, TIBC, transferrin, Tsat	√	√
Lipid panel/profile	√	√
Liver enzymes (ALT, AST, ALP, GGT).	√	√
Partial Thromboplastin Time (aPTT)	X	√
Protein (Total)	√	√
Serum drug levels:		
<i>Cardiac</i> : Digoxin	√	√
<i>Cardiac</i> : Amiodarone	X	X
<i>Antiepileptics</i> : carbamazepine, ethosuximide	X	X
<i>Antiepileptics</i> : valproic acid, phenytoin	√	√
<i>Antiepileptics</i> : Phenobarbital with primidone (<i>must be ordered together</i>)	√	√

Laboratory Test	Retail Community Pharmacies or Other Private-Care Settings	Public Health Care Institutions
<i>Antiepileptics: Lamotrigine</i>	X	√
<i>Bronchodilators: Theophylline</i>	X	X
<i>Psychiatric drugs: antidepressants</i>	X	X
<i>Psychiatric drugs: Lithium</i>	√	√
<i>Aminoglycosides: amikacin, gentamycin, tobramycin^v</i>	X	√
Vancomycin ^{vi}	X	√
<i>Immunosuppressants: cyclosporine, tacrolimus, sirolimus</i>	X	√
Serum Creatinine	√	√
Thyroid function: TSH (only)	√	√
T3	X	X
T4	X	X
Urea	√	√
Urine ACR	√	√
Urinalysis: Basic	√	√
Urine drug screen	X	X
Urine C & S	X	X
Vitamin B12	√	√
Vitamin D – (25-OH Vitamin D only)	X	√
Vitamin D (1,25 dihydroxyvitamin D)	X	X
Pharyngitis Throat Swab ^{vii}	√	√

Note: As per special edition of [SCOPE](#), November 2015 this list pertains to "ordering" only, and does not address tests that may be "accessed" or "performed" by community pharmacists.

ⁱ This is an important test for adverse effects of statin therapy. Ordering staff should be reminded that elevated levels can be seen after heart attacks due to damage to the heart muscle.

ⁱⁱ Low Mg can be a potential cause of refractory hypokalemia. Pharmacists should be aware of the difference between calcium and ionized calcium, and the role of albumin in interpreting calcium results. Due to the potential cardiac sequelae of critically high/low values (up to and including heart attack and sudden death), these should, at least in the short-term, **be restricted to pharmacists who are able to provide after-hours coverage to address emergent results.**

ⁱⁱⁱ Plan in place to handle critical value

^{iv} Ordering pharmacists should be aware of the potential harms of iron over-supplementation in the setting of wrongly-diagnosed iron deficiency (e.g. thalassaemias).

^v Contact for critical results in required

^{vi} Contact for critical results is required

^{vii} MUST only use SHA approved throat swabs, MUST have a lab license authorizing the performing of this test and pharmacists MUST have completed the lab training modules as well as the physical assessment course by USask. CPE.