

## Emergency Enactment – COVID-19 Rapid Antigen Testing in Pharmacies

Pharmacy involvement in testing is governed by three regulatory frameworks:

Health Canada's [Medical Devices Regulations](#) govern the **sale and import of medical devices in Canada. Pharmacies and pharmacists must adhere to on-label usage**, unless otherwise advised by the SCPP Registrar ([see here](#)).

**AND**

[The Medical Laboratory Licensing Act](#) and its regulations govern **point-of-care testing in Saskatchewan**. In 2021, amendments were made to [The Medical Laboratory Licensing Regulations \(Section 2\(2\)\(d\)\)](#) to exempt point of care COVID-19 specimen collection and testing sites from requiring a laboratory license. **This expanded rapid testing options for non-diagnostic purposes and only on asymptomatic individuals.**

**AND**

[The Pharmacy and Pharmacy Disciplines Act](#) and Saskatchewan College of Pharmacy Professionals (SCPP) Regulatory Bylaws (Part M) govern **pharmacy professionals and pharmacies performing tests.**

### Overview of SCPP Emergency Provisions

In support of federal and provincial “Proof of Vaccination or Negative COVID Test” initiatives, the SCPP Registrar has enacted emergency provisions in the [SCPP regulatory bylaws \(Part M\)](#) for [public access to non-essential business](#), for [work](#), and for [travel](#), under the following conditions:

- **Time-bound:** As per Council, effective Jan. 21, 2022, and until Feb. 28, 2022, and will be tied to the [Public Health Order](#).
- **Purpose:** As per Council decision, COVID-19 Rapid antigen testing **must only** be provided for the following purposes and in accordance with the terms, conditions and standards set by each:
  - **Proof of COVID-19 Vaccination or Negative Test (Public Access to Non-Essential Businesses)** – [Rapid Antigen Testing Services](#) approved by the Ministry of Health and available to the public for access to establishments, businesses and event venues that bring groups of people together, as identified in the Saskatchewan [Public Health Order](#).
  - **Proof of COVID-19 Vaccination or Negative Test (Work)** – Rapid Antigen Testing for employees in workplaces where employers require evidence of vaccination, or a negative COVID-19 test (provided by an independent third party) result before entering the workplace. ([see here](#))

- **Proof of COVID-19 Vaccination or Negative Test (Travel)** – as determined by the entry restrictions put in place by Canada’s federal/provincial governments or international governments, depending on travelers’ final destination. Visit Government of Canada website for information on travel to, from and within Canada (see [here](#)) and the Saskatchewan website (see [here](#)) for additional provincial restrictions.

Note: for information on pharmacists performing *COVID-19 Occupational Health & Safety Testing in Community Pharmacies* (“Test to Protect”) see [here](#).

**All tests performed within or through the pharmacy must follow the SCPP terms, conditions and standards outlined in the [Laboratory Tests and Medical Devices \(Accessing, Ordering, Performing, Using or Interpreting,](#) and [Performing Tests for Drug Therapy Management](#) reference documents (hereafter referred to as the “SCPP laboratory testing documents”).**

- **Pharmacy Prerequisites:** in addition to the prerequisites outlined in the SCPP laboratory testing documents:
  - Testing must only be offered within or through pharmacies which have the human resource and space capacity to provide this service (see question 1);
  - Testing must not impede public access to medically necessary core pharmacy services that are only provided by pharmacists, including dispensing drugs, managing drug therapy and drug shortages (see [SCPP Conflict of Interest policy](#) and [Appendix A – What are Core Pharmacy Services? What is Considered “Medically Necessary?”](#))
  - Written business continuity plan in place to ensure the public has access to core pharmacy services should the pharmacy need to close (See [Emergency Preparedness Tools \(pages 5 & 6\)](#));
  - Must administer publicly-funded COVID-19 vaccine as part of the [COVID-19 Immunization Delivery Plan](#) (see [COVID-19 Immunizers FAQ](#));
  - Pharmacy Manager and Proprietor have signed and submitted the [SCPP declaration](#) attesting that they are aware and will abide by all terms, conditions and standards outlined in this Emergency Enactment;
  - Be in compliance with any other prerequisites as required by the applicable federal/provincial “Proof of Negative” measure that the pharmacy is delivering through its testing service.
- **Patient Requirements:**
  - Asymptomatic patients only
  - Professional relationship with patient not required to perform tests
  - Ages as identified in the applicable federal/provincial “Proof of Negative Test” initiative

- Any other requirements as set by the applicable federal/provincial Proof of Negative initiative
- **Test Devices Approved for Use:**
  - Health Canada-approved COVID-19 **point-of-care rapid antigen tests only** as authorized in [The Medical Laboratory Licensing Regulations \(Section 2\(2\)\(d\)\)](#) and Health Canada's [list of approved COVID-19 "point of care tests"](#) (antibody testing is not permitted);
  - Must be privately procured and meet the specimen collection methods as per section 2(2)(d); and
  - Any other testing device requirements set by the applicable federal/provincial Proof of Negative Test initiative.

**Disclaimer:**

Although reference is being made to specific sections for further clarity, the terms, conditions and standards in the following SCPP documents must be taken together as a whole when referring to authorized practices under Part M of the SCPP Regulatory Bylaws: [Laboratory Tests and Medical Devices \(Accessing, Ordering, Performing, Using or Interpreting\)](#), the [Sale and Distribution of Medical Testing Devices and Other Diagnostic Products](#), and [Performing Tests for Drug Therapy Management](#). It is strongly recommended that pharmacists familiarize themselves with these requirements before participating in any testing activities to ensure that they are practicing within the scope and standards of practice required to maintain public safety, as well meeting statutory obligations with respect to their license and malpractice insurance.

**Q1. SCPP Requirements and Guidance for Pharmacies that Perform COVID-19 Rapid Antigen Testing Service**

Testing **must only** be offered within or through pharmacies which have:

- Met the requirements for pharmacy managers, personnel and point-of-care testing program/services, Standard Operating Procedures and Quality Assurance Process as outlined in [Performing Tests for Drug Therapy Management](#).

To provide COVID-19 rapid antigen testing services under this Emergency Enactment, the Standard Operating Procedures must include robust infection prevention control measures suitable for COVID-19, including:

- Appropriate Personal Protective Equipment (e.g., appropriate masks, goggles) available for staff
- Alcohol-based hand rubs must be accessible, including at entrances/exits, testing and waiting areas;

- Testing area must be fully cleaned and disinfected between every patient; and
- Regular testing/screening protocols for staff as part of Occupational Health and Safety;

Also see SCPP requirements in the [Infection Control Standards and Guidelines](#), the [Respiratory Hygiene and Cough Etiquette Standards and Guidelines](#); and the [Hand Hygiene Guidelines](#).

- An environment that is clean, safe, private, and appropriate for conducting the test, storing the device and supplies, and managing hazardous waste disposal, including:
  - Physical layout and design of the space minimizes exposure of employees and patients to biohazards introduced from the testing service (e.g. use of physical barriers, with considerations for additional air filtration, using space segregated from the rest of the pharmacy)
- Management of patient flow through the pharmacy to prevent crowding and exposure for staff and patients (e.g., separate waiting and testing areas, separate entrances, dedicated times of service for testing patients, informing patients to wait in car until notified, and not to come to appointment early, screening questions before coming to appointment). (See Question 3 below for advanced screening processes that are required to perform COVID rapid testing services enabled under this Emergency Enactment.)
- Must ensure the public is aware that pharmacy is offering COVID testing services (e.g., visible signage on entry doors, phone messages and website) as not all members of the public will want to be in a testing facility for health reasons.
- Workflow minimizes the number of patient-personnel interactions and movement of both to other areas of the pharmacy (i.e., one person should not be moving from testing to immunizing and then trying to also cover duties in the dispensary).
  - Dedicated staff who are not performing other activities (e.g., running back and forth dispensing, immunizing and testing);

*Government Proof of Negative Test Requirement:*

- Check the following for additional eligibility criteria, application processes and other requirements to provide COVID-19 rapid antigen testing services for [public access to non-essential business](#)(also see [here](#)), for [work](#), and for [travel](#).

## Q2. Who may perform COVID-19 rapid antigen testing?

### *SCPP Requirements:*

- **Only pharmacists** are authorized to perform these tests and must do so in accordance with the SCPP terms, conditions and Standards of Practice in the [Laboratory Tests and Medical Devices - Accessing, Ordering, Performing, Using or Interpreting](#) and the [Performing Tests for Drug Therapy Management](#).
- **Pharmacy technicians, pharmacy students and extended interns, and pharmacy assistants are not authorized** to perform tests under *The Pharmacy and Pharmacy Disciplines Act*.
- See question 8, if planning to hire another licensed health care professional from a non-pharmacy discipline.
- The Pharmacy Manager must be satisfied that all health care professionals performing the tests within or through the pharmacy are competent and that it is safe and appropriate for the employee to do so. This includes understanding the manufacturer's operating instructions for the device (e.g. set up, specimen collection and storage, test procedure, limitations of the test, set up).

### *Government Proof of Negative Test Requirement:*

- Check the following for additional eligibility and training requirements when providing COVID-19 rapid antigen testing services for [public access to non-essential business](#), for [work](#), and for [travel](#).

## Q3. Who may be tested in the pharmacy?

### *SCPP Requirements:*

- Advanced [Screening](#) processes must be in place to ensure patients are **asymptomatic** and wherever possible testing should be a pre-booked appointment to avoid walk in cases that may not meet screening criteria and may disrupt patient care and safety.
- Pharmacist performing the test must verify the identity of the patient, in accordance with the federal/provincial Proof of Negative initiative. Note: SCPP's [Patient Identification Verification](#) policy allows for pharmacist discretion **when dispensing** in the absence of ID, the Government Proof of Negative Test initiative identification requirements may be different.

### *Government Proof of Negative Test Requirement:*

- Check the following for additional requirements when providing COVID-19 rapid antigen testing services for [public access to non-essential business](#), for [work](#), and for [travel](#).

#### **Q4. Who may give the test result?**

##### *SCPP Requirement:*

- Under [The Pharmacy and Pharmacy Disciplines Act \(s. 23\(3\)\(d\)\)](#), only pharmacists are authorized to perform tests under terms, conditions and standards set by the SCPP.
- The pharmacist who performed the COVID-19 test must provide the test result to the patient, in accordance with the following:
  - [Performing Tests for Drug Therapy Management \(sections 9.19 and 9.20\)](#);
  - [Laboratory Tests and Medical Devices - Accessing, Ordering, Performing, Using or Interpreting \(section 6\)](#)
- Providing test results may not be delegated to anyone else, including pharmacy technicians, pharmacy student or extended interns, and pharmacy assistants.

Note: Pharmacists are only permitted to provide test results to those individuals who have received a COVID rapid antigen test through the pharmacy. Emergency provisions to provide [COVID-19 test results](#) from the eHR viewer are not enacted at this time.

##### *Government Proof of Negative Test Requirement:*

- Check the following for additional communication, training and eligibility requirements when providing COVID-19 rapid antigen testing services for public access to non-essential business, for work, and for travel.

#### **Q5. What happens when someone tests positive?**

##### *SCPP Requirements:*

- The pharmacist performing the test must ensure appropriate follow up occurs, as per:
  - [Current provincial testing and self-isolation policies for COVID-19 \(see here\)](#).
  - [Laboratory Tests and Medical Devices - Accessing, Ordering, Performing, Using or Interpreting \(sections 2 & 7\)](#);
  - [Performing Tests for Drug Therapy Management \(section 9\)](#).

##### *Government Proof of Negative Test Requirement:*

- Check the following for additional self-isolation, communication, follow up and reporting requirements when providing COVID-19 rapid antigen testing services for public access to non-essential business, for work, and for travel.

## Q6. What documentation and reporting is required?

### *SCPP Requirements:*

- **Pharmacists must personally document the details of all tests they performed** (see: [Laboratory Tests and Medical Devices - Accessing, Ordering, Performing, Using or Interpreting \(section 9\)](#), and [Performing Tests for Drug Therapy Management \(section 9\)](#)).

### *Government Proof of Negative Test Requirement:*

- Check the following for additional documentation and reporting requirements when providing COVID-19 rapid antigen testing services for [public access to non-essential business](#), for [work](#), and for [travel](#).

## Q7. What insurance do I need?

### *SCPP Requirements*

- Pharmacists – malpractice insurance when practising within conditions set by the SCPP
- Proprietors – maintain coverage at level prudent for community pharmacies as required to implement the federal or provincial Proof of Negative Test service.

### **Disclaimers**

The Saskatchewan College of Pharmacy Professionals (SCPP) is not an insurance provider and therefore recommends that pharmacists and proprietors confirm coverage requirements under their malpractice and/or business insurance in light of the additional risks of exposing patients and staff to COVID-19 as a result of the testing service, or the potential impacts of false positive/negative results from the COVID-19 rapid antigen test.

The SCPP is not responsible for any and all liabilities, loss, costs, damages and expenses (including legal, expert and consultant fees), causes of action, actions, claims, demands, lawsuits or other proceedings, by whomever made, sustained, incurred, brought or prosecuted, in any way arising out of or in connection with enacting these emergency exemptions under [Section 4 of Part M of the SCPP Regulatory Bylaws](#), including the provision of the testing services.



**Q8. Are pharmacies permitted to hire another licensed health care professional to perform testing in the pharmacy?**

*SCPP Requirements:*

- Other licensed health care professionals, from non-pharmacy disciplines, are permitted to perform tests within or through the pharmacy, so long as it is:
  - within their scope of practice,
  - they are recognized as competent to do so,
  - they are practising within the standards required by their regulatory body, and
  - they are practising within the SCPP standards as required for services provided within or through pharmacy (see [Performing Tests for Drug Therapy Management \(section 5\)](#)).
- **Pharmacy managers and professionally licensed non-pharmacy discipline COVID-19 rapid testers are responsible to work with the regulatory body for that licensed professional to ensure that they are practising within their licensure requirements.**

*Government Proof of Negative Test Requirement:*

- Check the following for additional eligibility and training requirements when providing COVID-19 rapid antigen testing services for [public access to non-essential business](#), for [work](#), and for [travel](#).

**Q9. Where can I find more information?**

- Monitor the SCPP [COVID-19 web page](#), the [Status Update – COVID-19 Rapid Antigen Tests in Pharmacies](#) and any other updates as they become available. SCPP will only respond to questions about COVID testing that are regulatory in nature.
- Also monitor communication from the [Ministry of Health](#) and [Public Health Orders](#).to stay up-to-date on provincial developments. For all other questions on providing Rapid Antigen Testing Services for provincial requirements email [CRU@health.gov.sk.ca](mailto:CRU@health.gov.sk.ca).