

Status Update – COVID-19 Rapid Antigen Tests in Pharmacies

Federal and provincial regulations around COVID-19 testing have seen many changes over the past year and SCPP would like to provide guidance to members of the following provisions that are in force based on our information as of **Mar. 27, 2024**.

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 practising 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.

Practice Area	Tests Authorized	Description	Authorization
Selling COVID-19 Self- Tests (NB "selling" and "distributing" are not the same and have different terms and conditions.)	Health Canada approved COVID-19 " self-testing " devices . See <u>here</u> for Health Canada's list of approved COVID-19 Self-Testing Devices.	Must be approved for "self-testing", by Health Canada. Intended user is the general public to perform testing for personal use independent of a health care worker. Note: devices approved for "self- collection" or "self- collection under supervision of a health care worker" are point-of care testing devices (POCT). For more information on the difference between "POCT" and "self- tests" (also known	 SCPP For more information on SCPP terms, conditions and standards see: <u>Laboratory Tests and</u> <u>Medical Devices –</u> <u>Accessing, Ordering,</u> <u>Performing, Using, or</u> <u>Interpreting (Appendix</u> <u>D)</u> <u>Sale and Distribution</u> <u>of Medical Testing</u> <u>Devices and Other</u> <u>Diagnostic Products.</u> Medical testing devices approved for self-testing may be sold in the pharmacy. (See <u>section 2</u> for SCPP standards).

Practice Area	Tests Authorized	Description	Authorization
		as "patient- administered tests") see <u>here</u> .	Note: Pharmacies are not permitted to sell to the general public:
			Point-of-care tests;
			 Any rapid antigen tests distributed through federal/provincial publicly funded programs; or
			Serological (antibody) testing devices.
Distributing	Rapid Antigen Self	Self-screening to	SCPP
Self-Tests and Point-of-Care Tests to Priority Individuals as part of the Other Diseases (Paxlovid) prescribing s.19 of Part K. (Federal/Provincial Publicly Funded)	Tests or POCT supplied provincially or federally.	support priority populations and prescribing Paxlovid under Other Diseases Identified by Minister of Health.	 All distribution from, or through a pharmacy, must comply with the terms, conditions, and standards of the SCPP, see: <u>Laboratory Tests and</u> <u>Medical Devices –</u> <u>Accessing, Ordering,</u> <u>Performing, Using, or</u> <u>Interpreting; and</u> <u>Sale and Distribution</u> of Medical Testing <u>Devices and Other</u> <u>Diagnostic Products.</u> Note: as per s.2.13, any POCT distributed by a pharmacy must be done in accordance with the terms and conditions set for the federal/provincial publicly funded programs).
			Federal/Provincial Governments
			Federal

Practice Area	Tests Authorized	Description	Authorization
			Interim enforcement order in effect until <u>Dec. 31,</u> <u>2024</u>) which permits off- label distribution and use of RATS for provincial initiatives (see <u>here</u> for details).
			See <u>here</u> for full list of Medical Device Compliance Program bulletins.
			Provincial
			See <u>here</u> for Provincial/ Territorial Resources and <u>here</u> for more information on Saskatchewan rapid test screening program.
Distributing	Rapid Antigen	Occupational	SCPP
Point-of-Care Tests to Businesses for Occupational Health & Safety (also known as "Test to Protect"	POCT supplied through federal/provincial workplace screening programs	health and safety purposes only. Workplace screening to help businesses detect early cases of COVID-19, for people who are asymptomatic.	Same as above (Distributing POCT to Priority Individuals for Paxlovid)" Federal/Provincial Governments
and the federal	Point of Care Tests no longer available for this initiative.		Federal
SME program) (Federal/Provincial Publicly Funded)			Same as above (Distributing POCT to Priority Individuals for Paxlovid
Workplace screening initiative			Provincial
is no longer underway.			Same as above (Distributing POCT to Priority Individuals for Paxlovid)