Point-of-Care Testing: Provincial Changes
FAQs
March 2021

Note: This document refers to "point-of-care testing" in order to remain consistent with Health Canada's terminology and classification of test types. Within the provincial (i.e. Ontario) context, it can be considered synonymous with "rapid" testing.

Q1. Who can perform a Health Canada approved COVID-19 point-of-care test (POCT)?

A1. The exemption of Health Canada approved COVID-19 POCTs from the provincial regulations under the Laboratory and Specimen Collection Centre Licensing Act (LSSCLA) increases flexibility for implementation, including expanding who can perform the tests in accordance with the manufacturer's label.

As a result, a broad range of health care and non-health care professionals will be able to deliver point-of-care testing. This includes:

- Providers previously exempted from provincial regulations to provide COVID-19 point of care testing (e.g., physicians, dentists, nurses, pharmacists, paramedics, and community paramedicine practitioners) would still be exempt and permitted to provide COVID-19 point-of-care testing.
- Other regulated and unregulated health care professionals including, but not limited to professionals working in the fields of:
    - Audiology and Speech-Language Pathology; Chiropody and Podiatry; Chiropractic; Dental Hygiene; Dental Technology; Dentistry; Denturism; Dietetics; Homeopathy; Kinesiology; Massage Therapy; Medical Laboratory Technology; Medical Radiation Technology; Medicine; Midwifery; Naturopathy; Nursing; Occupational Therapy; Opticianry; Optometry; Pharmacy; Physiotherapy; Psychology; Psychotherapy; Respiratory Therapy; Traditional Chinese Medicine and Acupuncture.
- Any trained individual who has the knowledge, skills, and judgment to administer the test in accordance with the manufacturer's label.

Q2. Who can collect the specimen (i.e. conduct the swab) for a Health Canada authorized COVID-19 POCT?

A2. Specimen collection for antigen POCTs may be done by health professionals, or other trained individuals, in accordance with the manufacturer's label.

Specimen collection for antigen POCT may also be done by the person being tested ('self-swabbing') if a trained individual is supervising the self-swabbing.

- Any individual supervising self-swabbing must consult the self-swabbing training resource developed by Ontario Health in collaboration with Public Health Ontario and ensure they have the appropriate knowledge, skills, and judgment to provide appropriate self-swabbing oversight, including how to operate the device, personal protective equipment (PPE) requirements, and how to safely dispose of biowaste.
- Initial publicly available training materials (video and instructions) have been posted by Ontario Health for any individual, entity, or organization pursuing supervised self-swabbing.

Q3. Who can supervise self-swabbing?

A3. A trained individual, including, but not limited to, health professionals (regulated or unregulated), can supervise self-swabbing. Any individual who is supervising self-swabbing must consult the self-swabbing training resource and ensure they have the appropriate knowledge, skills, and judgment to provide appropriate self-swabbing oversight, including how to operate the device, PPE requirements, and how to safely dispose of biowaste.

Q4. Who can access self-swabbing?

A4. Anyone undergoing a point-of-care antigen test may choose to conduct a self-swab, if they are supervised by a trained individual (see Q.3). Please note that individuals and organizations are under no obligation to conduct antigen POCT using supervised self-swabbing; use of supervised self-swabbing is voluntary and available as an alternative means of specimen collection.

Q5. Can supervised self-swabbing be used for all point-of-care tests?

A5. Supervised self-swabbing can be used for any Health Canada approved point-of-care antigen test (e.g., Abbott Panbio, BD Veritor, Sofia Quidel, etc.). Supervised self-swabbing cannot be implemented for molecular POCTs (e.g. IDNow, GeneXpert).

Q6. How many people can be doing self-swabbing at once?

A6. The Ministry of Health is not being prescriptive regarding the implementation of supervised self-swabbing for antigen POCTs. It is the responsibility of the sites themselves to determine, based on their own implementation needs and workflow, the most appropriate approach for offering self-swabbing.

Q7. What are the reporting requirements for POCTs?

A7. There are two types of reporting requirements associated with POCTs in the province.

I. *A legislative requirement to report positive results on POCTs to public health, as captured in the Health Protection and Promotion Act (HPPA).*

Under the HPPA, anyone performing a COVID-19 POCT must report the results to the medical officer of health in the local public health unit in which the person *being tested* resides. This includes for positive results from an antigen POCT (such as the Abbott Panbio or BD Veritor).

Where possible, point-of-care molecular test (such as the Abbott IDNow) results are to be entered into the Ontario Laboratories Information System (OLIS). Positive results from POCTs

entered into OLIS are then captured in the Case and Contact Management database and communicated to public health. If data entry into OLIS is not possible, the individual performing the test will report the results directly to the medical officer of health in the relevant local public health unit by other secure mans (e.g. electronic fax).

The Ministry of Health, in collaboration with Ontario Health, is working to close existing gaps in access to OLIS to ensure sites using molecular POCTs are able to enter their data into a secure portal.

2. Programmatic reporting requirements associated with the Provincial Antigen Screening Program

Every site receiving antigen POCTs from the provincial government through the Provincial Antigen Screening Program has a duty to report a minimum aggregate (i.e. deidentified) dataset into the Health Data Collection Service (HDCS) on a weekly basis as a condition of Program participation. The data reported into the HDCS includes: the number of antigen POCTs performed in a given week, the number of individuals tested, the number of positive results (i.e. preliminary positives), and the number of negative results. This aggregate data supports the Ministry of Health in monitoring the implementation of provincially funded POCTs being deployed to priority sectors, including important information related to POCT preliminary positivity rates.

Q8. How have reporting requirements for POCTs changed as a result of the LSCCLA exemption?

A8. The changes to reporting requirements for POCTs as a result of the LSCCLA exemption are minimal. For example, reporting of positive results from POCTs to public health, including preliminary positives identified through antigen POCTs, are not net-new reporting requirements. The only two changes, captured through a regulatory amendment under the Health Protection and Promotion Act (HPPA), are:

- Expanding the definition of who must report positive results to public health, to reflect the exemption of POCTs under the LSCCLA and the expanded list of individuals who can therefore perform the tests. The HPPA now states that <u>any</u> individual performing a POCT, including but not limited to health professionals who already had a duty to report results under the HPPA, must report positive results to the medical officer of health.
- A requirement for any individual conducting a molecular POCT to report results into OLIS wherever possible, to ensure that positive results that are deemed ‘final’ can be captured in the CCM database for the purpose of notifying public health to initiate case and contact management. Where sites or individuals conducting molecular POCTs are not able to enter their results into OLIS, there is a requirement that positive results be reported to the medical officer of health by alternative, secure means (i.e. electronic fax).