

Ministry of Health

COVID-19 Guidance: Considerations for Antigen Point-of-Care Testing

Version 4.0 March 19, 2021

Key Updates

- Minor update to locations for symptomatic individuals and those with confirmed contact with a COVID-19 case to obtain diagnostic PCR testing (page 3)

This document is intended for individuals or organizations conducting antigen point-of-care testing ('antigen POCT') in Ontario. This guidance provides basic information only. It is not intended to take the place of medical advice, diagnosis, treatment, or legal advice.

Antigen POCT is used for screening purposes only and should NOT be used for diagnosis of COVID-19 infection in symptomatic individuals or individuals with known close contact with a positive COVID-19 case. Testing does not prevent someone from getting COVID-19.

Antigen POCT can be thought of as an additional screening tool.

Antigen POCT does not replace public health measures such as symptom screening, physical distancing, masking and hand hygiene.

Antigen POCT does not replace requirements to protect the health and safety of workers.

Any positive results from antigen POCT must be confirmed with laboratory-based polymerase chain reaction (PCR) testing.

Please see the [COVID-19 Provincial Testing Guidance](#) for more information. Anyone who falls within the current Provincial Testing Guidance should continue to seek diagnostic PCR testing at participating pharmacies, participating licensed community labs, and assessment centres.

In the event of any conflict between this guidance document and any applicable legislation or orders or directives issued by the Minister of Health or the Chief Medical Officer of Health (CMOH), the legislation, order or directive prevails. Please see [Ontario's COVID-19 website](#) for more general information as well as for updates to this document.

Antigen Point-of-Care Testing in Ontario

General Overview

- Organizations must develop a [COVID-19 Workplace Safety Plan](#) to minimize the risk of COVID-19. This includes having written policies and procedures that are in alignment with any sector-specific [guidance](#) issued by the Chief Medical Officer of Health and any other specific measures recommended by public health agencies. See [Resources to Prevent COVID-19 in the Workplace](#) for more information.
- Employers are required to follow the [Occupational Health and Safety Act \(OHSA\)](#).
 - All workplace parties (e.g. employers, supervisors, workers) have statutory responsibilities related to [health and safety](#) in the workplace.
- There are no specific requirements in the [OHSA](#) or its regulations for employers to conduct testing of workers.
- Prior to initiating antigen POCT, organizations should make their [local public health unit](#) (PHU) aware that they will be engaging in antigen POCT.

Eligibility

- Subject to the specimen collection described below, antigen POCT may only be performed using a COVID-19 medical device that has been authorized by the Minister of Health (Canada) for point-of-care use and is available in Ontario.
- Antigen POCT is appropriate for use in asymptomatic individuals only.

- Although some antigen POCT devices have been approved by Health Canada for diagnostic testing of symptomatic individuals, the province is currently only recommending its use for screening of asymptomatic individuals.
- Any individual who is currently symptomatic or has been in a contact with a confirmed case of COVID-19 should be directed to their healthcare provider, to an assessment centre, or a participating licensed community lab to obtain diagnostic PCR testing instead of antigen POCT.
- In general, individuals who have previously been infected with and recovered from COVID-19 should not undergo repeat testing/antigen testing, unless otherwise directed by [local public health](#) or their health care provider as per their symptom and exposure history. Organizations must continue to follow all public health measures and guidelines including screening all individuals.
- In general, antigen POCT should not be conducted in an **outbreak** setting, unless:
 - It is being conducted under the guidance and direction of a local PHU and is not replacing any measures currently in place through PHUs, and;
 - It is being conducted only in addition to, not as a replacement for, diagnostic PCR testing of individuals within the outbreak setting, as outlined in the [provincial testing guidance](#).

Specimen Collection

- Specimen collection must be conducted in accordance with the type of swab included in the test kit and the kit instructions for use.
 - One exception is the use of the Abbott's Panbio™ COVID-19 Ag Rapid Test Device (Nasopharyngeal) where, in addition to the approved nasopharyngeal collection method, MOH is of the opinion that it is appropriate, from a clinical perspective, to conduct specimen collection in a manner that is not currently approved by Health Canada, using the following methods (listed in descending order of preference): combined swabbing of throat and both nares, deep nasal swabbing (both sides), or anterior nasal swabbing (both nares).
 - Another exception is the use of an antigen POCT assay that includes a nasal swab (including Panbio™ COVID-19 Ag Rapid Test Device [Nasal] and BD Veritor™ System for Rapid Detection of SARS-CoV-2) where, in addition to the approved deep nasal collection method, MOH is of the opinion that it is

appropriate, from a clinical perspective, to conduct specimen collection in a manner that is not currently approved by Health Canada, using the following methods (listed in descending order of preference): combined swabbing of throat and both nares, or anterior nasal swabbing (both nares).

- Nasopharyngeal swab (NPS) is the specimen collection type with the highest sensitivity.
 - NPS are controlled acts that require a specialized workforce and may limit the number of settings that are able to adopt the test.
 - NPS may be uncomfortable, particularly where frequent testing is proposed.
- Alternate types of specimen collection may have the advantage of:
 - Reducing the inconvenience or discomfort due to repeated nasopharyngeal swabs
 - Improving adherence to testing programs
 - Promoting more immediate and robust uptake of this test
- Deep and lower nasal collection methods may be less sensitive than nasopharyngeal specimens for the detection of COVID-19.
 - For more details on the effect of specimen collection on sensitivity, please see PHO Evidence Brief on [The Use of Alternate Specimen Collection Methods for COVID-19 PCR Testing](#)
- Specimen collection for POCT antigen tests may be done by health professionals, or other trained individuals, in accordance with the manufacturer's label.
- Specimen collection for POCT antigen tests may also be done by the person being tested ('self-swabbing'). Self-swabbing for POCT antigen tests is not currently approved by Health Canada, but the MOH is of the opinion that it is appropriate, from a clinical perspective, to do self-collection for antigen POCTs under the following specific circumstances:
 - If a trained individual, including a health care professional (regulated or unregulated) 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, PPE requirements, and how to safely dispose of waste.
- Individuals and organizations are under **no obligation** to conduct antigen POCT using supervised self-swabbing; use of supervised self-swabbing as a means of

specimen collection is to be done only on a voluntary basis.

Frequency of Antigen POCT:

- For individuals in high prevalence areas (Yellow/Orange/Red/Grey) antigen POCT should be performed 2-3 times per week.
- For low prevalence areas (Green), antigen POCT should be performed 1-2 times per week.

Accessing a Point-of-Care Test

- All persons conducting COVID-19 POCT using a device that was approved by Health Canada for point-of-care use, including an antigen POCT device, are now exempt from the [Laboratory and Specimen Collection Centre Licensing Act](#) (LSCCLA).
- Access to antigen POCT devices continues to be available to those enrolled by program agreement as a participant in the Provincial Antigen Screening Program or a person acting on behalf of the participant.
 - The Program agreement is with the Province of Ontario or an agent of the Province and participation in the Program is subject to the conditions that the participant will,
 - ensure that the COVID-19 antigen POCT test kit is used only for the purposes of the Program,
 - submit data in the form and manner requested by the Province of Ontario,
 - comply with the quality assurance requirements that are applicable to the Program, and
 - meet any other requirements set out in the Program agreement.
- In addition to POCTs being deployed and publicly-funded by the province, Health Canada approved POCTs may also be available for direct purchase in Ontario.

Conducting the Test

- Health professionals are responsible for satisfying all applicable legislative and regulatory requirements, including those under the [Health Protection and Promotion Act](#) (HPPA), [Personal Health Information Protection Act](#) (PHIPA), [Health Care Consent Act](#) (HCCA), and [Regulated Health Professions Act](#) (RHPA).
- A positive result on an antigen POCT is considered a preliminary positive. Individuals who receive a positive result through antigen POCT must:
 - Seek an immediate laboratory PCR test (i.e. within 24 hours) to act as a confirmatory test as per [Provincial Testing Guidance](#).
 - Immediately self-isolate until the result of the confirmatory lab-based PCR test is known.
- All preliminary positive results from antigen POCT must also be reported to the local PHU, in accordance with the HPPA.
- Individuals who receive a negative result from antigen POCT should be reminded to continue to practice strict infection prevention and control measures (e.g. masking, hand hygiene, physical distancing).
- Appropriate biosafety precautions, in accordance with the manufacturer's label, must be taken for all antigen POCT to ensure the safety of the individual being tested as well as the individual conducting or supervising the specimen collection and performing the test.

Organizational Responsibilities

- Organizations that conduct antigen POCT are responsible for:
 - Retaining existing public health measures such as symptom screening, appropriate distancing, using personal protective equipment and hand-hygiene activities. Antigen POCT is not a replacement for any of these measures.
 - Following all public health guidance for managing an individual with a preliminary positive result, including: reporting of preliminary positives to the local public health unit as required by the [Health Protection and Promotion Act](#), requiring that the individual receive a laboratory PCR test within 24 hours, and that the individual who received a preliminary positive result immediately self-isolate until the result of the confirmatory lab-based PCR test is known.

- Ensuring compliance with any applicable legislation related to the collection of personal health information, including PHIPA
- Cooperating with their local PHU in the event of a potential workplace exposure of COVID-19 or an outbreak investigation.

Reporting Requirements

- Organizations should have a systematic procedure in place to provide follow-up on results.
- Organizations should have [plans in place](#) to respond should any individuals be exposed to or diagnosed with COVID-19.
- All preliminary (presumptive) positive COVID-19 tests performed using an antigen POCT device must be reported to the local PHU in accordance with the [HPPA](#) by the person conducting the test or the individual supervising the self-swabbing.
- If you are advised that one of your workers has tested positive for COVID-19 due to exposure at the workplace, or that a claim has been filed with the Workplace Safety and Insurance Board (WSIB), you must give notice in writing within four days to:
 - The Ministry of Labour, Training and Skills Development
 - The workplace's joint health and safety committee or health and safety representative
 - The worker's trade union (if applicable)
- Additionally, you must report any occupationally acquired illnesses to the WSIB within three days of receiving notification of the illness.
- You do not need to determine where a case was acquired. If it's reported to you as an occupational illness, you must report the case.