

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

Version 7.0 August 25, 2021

## Key Updates

- Confirmatory testing for a positive antigen POCT can be done by using a rapid molecular test (e.g. IDNow) (throughout)
- Antigen POCT is not recommended for individuals who are fully vaccinated (page 3)
- Information added on self-swabbing, including use of antigen point-of-care test kits (page 4)
- Updated frequency of Antigen POCT (page 5)
- Updates to disposal of hazardous waste (page 6)
- Updated handout for employees (page 9)

This COVID-19 guidance ('guidance document') is intended for individuals or organizations conducting antigen point-of-care testing ('antigen POCT'), also referred to as rapid antigen screening, 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 NOT for diagnostic purposes. Antigen POCT should NOT be used to test for COVID-19 infection in symptomatic individuals or individuals with known close contact with a positive COVID-19 case.**

**Antigen POCT can be used as an additional screening tool.**

**Antigen POCT does not replace public health measures such as vaccination, 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 or molecular POCT (e.g. ID NOW) where the results can be reported into the Ontario Laboratory Information System (OLIS).**

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 [designated testing 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.

### **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 and to [understand and make decisions about antigen screening in your workplace](#).
- 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. However, subsection 63(2) of OHSA requires an employer to obtain a worker's written consent before accessing a worker's health record, including a worker's COVID-19 vaccination status.
- Prior to initiating antigen POCT, all organizations (including those participating in federal testing programs) 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 contact with a confirmed case of COVID-19 should be directed to obtain a diagnostic test instead of antigen POCT.
- Individuals who have previously been diagnosed with and cleared of COVID-19 infection may resume asymptomatic screening testing after 90 days from their COVID-19 infection (based on the date of their positive result).
- **Antigen POCT screening testing is generally not recommended for individuals who are fully vaccinated** (i.e.  $\geq 14$  days after receiving their second dose of a two-dose COVID-19 vaccine series or their first dose of a one-dose COVID-19 vaccine series) as the likelihood of COVID-19 is low for this group which reduces the utility of screening and could result in an increase of false positive results.
- 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 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.

- An 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 swabs (NPS) are the specimen collection type with the highest sensitivity.
  - Swabbing with an NPS is a controlled act 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.
- 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](#)
- Alternate types of specimen collection may be used to support access to testing due to its advantages, including:
  - Reducing the inconvenience or discomfort due to repeated NPS
  - Improving adherence to testing programs
  - Promoting more immediate and robust uptake of this test
- Specimen collection for antigen POCT may be done by health professionals, or other trained individuals (including self-swabbing), in accordance with the manufacturer's label.
- Specimen collection for antigen POCT may also be done with the supervision of a trained individual or 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 voluntary self-swabbing for antigen POCTs in accordance with this guidance document under the following condition:

- Any individual supervising self-swabbing or doing self-swabbing must consult the [self-swabbing training resource](#) developed by Ontario Health in collaboration with Public Health Ontario and ensure they have appropriate knowledge, skills and judgement to perform the test.
- Individuals and organizations are under **no obligation** to conduct antigen POCT using supervised self-swabbing; use of supervised and unsupervised self-swabbing as a means of specimen collection is to be done only on a voluntary basis.

## Frequency of Antigen POCT

- The most appropriate use case for antigen POCT is for frequent, repeated screening of asymptomatic individuals. There is inadequate evidence around the optimal frequency of antigen POCT, however screening may be performed at least one time per week, and up to 2-3 times per week for individuals who are not fully vaccinated.

## 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 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](#) (Program). The Program has been expanded to include any organization within a sector that is currently permitted to be open based on provincial guidelines and that requires workers to be physically present at their applicable workplace, or any organization mandated to test through a provincial directive (e.g. [Directive 6](#)).
  - The Program agreement is with the Government of Ontario and requires a participant of the Program to comply with certain conditions including:
    - ensuring that the COVID-19 antigen POCT kit is used only for the purposes of the Program and in accordance with any applicable laws and policies, including this guidance document,

- submitting data in the form and manner requested by the Government of Ontario,
- complying with the quality assurance requirements that are applicable to the Program, and
- ensuring that there is no fee charged to persons being screened with test kits provided by the Government of Ontario. Such screening must be provided free of charge to the person being tested.

In addition to POCT kits being provided free of charge by the province, Health Canada approved POCTs may also be available for direct purchase in Ontario.

## Conducting the Test

- For detailed information on specimen collection, see [specimen collection section](#) above.
- Health professionals conducting the POCT 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 not a diagnostic result and individuals who have tested positive should follow-up with a laboratory-based PCR test or a molecular POCT to confirm the diagnosis. If individuals receive a negative molecular POCT following a positive antigen POCT they will need to get a laboratory-based molecular test.
- 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.

## Disposal of Hazardous Waste

- Waste generated from on-site workplace rapid antigen screening programs is

considered a hazardous waste under the Environmental Protection Act. Waste from these tests is exempt from collection, storage and transportation requirements as long as the waste is disposed in Ontario. This waste must still be disposed of at a waste facility approved to handle biomedical waste. Anyone collecting, storing or transporting these kits should follow Ontario's guidance on the [Safe Handling and Management of Rapid Antigen COVID-19 Testing Waste.](#)

- For waste generated from at-home rapid antigen screening the regulatory requirements for managing the hazardous waste under the Environmental Protection Act do not apply. Instead, persons undertaking at-home rapid antigen tests should consult their local municipality's by-laws on the proper disposal of this waste to ensure it can be disposed of with the household trash.

## Organizational Responsibilities

- Organizations providing antigen POCT for screening are responsible for:
  - Retaining existing public health measures such as vaccination, symptom screening, appropriate distancing, using personal protective equipment, hand-hygiene activities. Antigen POCT is not a replacement for any of these measures.
  - Ensuring compliance with any applicable legislation related to the collection of personal health information, including PHIPA and OHSA.
  - Ensuring that any individuals performing the antigen POCT at-home (i.e. unsupervised self-swabbing) receive a copy of this guidance document and comply with its conditions and instructions before operating the testing device.
  - Cooperating with their local PHU in the event of a potential workplace exposure of COVID-19 or an outbreak investigation.
  - Having a systematic procedure in place to inform each tested individual of the result of their antigen POCT, a process in place for steps to take when there is a positive antigen POCT result, recommendation for and information about accessing confirmatory laboratory-based or molecular POCT, and return to work requirements.

- Having [plans in place](#) to respond should any individuals be exposed to or diagnosed with COVID-19 through a PCR test.
- Giving written notice to the persons listed below within 4 days of being advised that one of your workers has tested positive for COVID-19 on a diagnostic molecular test due to exposure at the workplace, or that a claim has been filed with the Workplace Safety and Insurance Board (WSIB):
  - 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)
- Reporting 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.



# Handout for Employees: What to do if you have a positive COVID-19 rapid antigen test

A positive rapid antigen result means that you may be infected with COVID-19. However, antigen tests may occasionally produce false positive results, and you will need a regular laboratory test or a rapid molecular test in order to confirm your result.

Here are key steps to follow if you get a positive rapid antigen result:

## 1. Confirm the result

- Get tested as soon as possible (ideally within 48 hours) with a regular laboratory test or a rapid molecular test. Go to [covid-19.ontario.ca](https://covid-19.ontario.ca) to find a designated testing centre near you.

## 2. Self-isolate

- Go home immediately and [self-isolate](#) at home until you receive your confirmatory test result.
  - This means that you should only leave your home for critical reasons (like a medical emergency) and avoid contact with other people (including your household members).
- If your confirmatory test is positive, you will need to continue self-isolating, and your local public health unit will be in contact with you.
- If the confirmatory test is a rapid molecular test and this is negative, you will still need to undergo a confirmatory laboratory-based test to clarify if you have COVID-19 infection. Continue to [self-isolate](#) while waiting for the laboratory result.

## 3. Safely return to work

- If you receive a negative result from a confirmatory laboratory-based test at a designated testing centre you may be able to [return to work](#) before 10 days at the direction of your public health unit.

If you do not get a confirmatory test, you should remain self-isolated until 10 days have passed since your positive antigen test result. If you do not get a confirmatory test you should inform everyone you were in close contact with in the 48 hours before your antigen positive result that they should self-isolate and get tested unless they are fully vaccinated or previously positive and asymptomatic.