Ontario

Ministry of Health

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

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Key Updates

- Positive results issued from antigen POCT assays are no longer required to be reported to the local public health unit.

This 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 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 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.

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 and to understand and make decisions about antigen screening in your workplace.
- Employers are required to follow the Occupational Health and Safety Act (O HSA).
    - 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, 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 a contact with a confirmed case of COVID-19 should be directed to their healthcare provider, to an assessment centre, or community site to obtain diagnostic PCR testing 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).
- 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, or 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 properly 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, PPE requirements, and how to safely dispose of biomedical waste (Hazardous Waste Class 312).
- 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 (as determined by the province) antigen POCT should be performed 2-3 times per week.
- For low prevalence areas (as determined by the province), 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 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 (PASP) . The PASP has been expanded to include any organization within a sector that is currently permitted to be open under the "Reopening Ontario (A Flexible Response to COVID-19) Act" and that requires employees to be physically present.
  - 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
- ensure that there is no fee charged to persons being screened with test kits provided by the province or an agent of the province. Such screening must be provided free of charge to the person being tested.

In addition to POCT test 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

- 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 not a diagnostic result and individuals who have tested positive are required to follow-up with confirmatory laboratory-based PCR testing and self-isolate until the confirmatory test results are known. .
- 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 providing antigen POCT screening 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.

- 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.
- Properly storing and disposing of the test waste with registered haulers (approved to carry biomedical waste) to ensure ongoing protection of human health and the environment. Note: sites using antigen point-of-care test kits are exempt from requirements associated with manifesting and registration of biohazardous waste under the Environmental Protection Act (EPA).

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.
- 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.