Ontario Health

COVID-19 Rapid Antigen Screening Onboarding Guide

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Note: Ontario Health will update this document on a regular basis as new information becomes available and provincial guidance changes.

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Purpose

This document provides planning and implementation guidance for workplaces and congregate settings (e.g., shelters, retirement, and long-term care homes, etc.) and other sectors undertaking on-site screening or at-home self-collection for COVID-19 using rapid antigen tests in Ontario. The Ministry of Health, Public Health Ontario and Ontario Health have contributed to this document.

Provincial Antigen Screening Program

The Provincial Antigen Screening Program (PASP) is a program being led by the Ministry of Health, with support from partner ministries, Public Health Ontario, and Ontario Health. The Provincial Antigen Screening Program (PASP) allows organizations to add an additional safety measure in workplaces, to help reduce the spread of COVID-19. Through the program, rapid antigen screening tests are distributed to enhance existing routine screening measures. Rapid antigen screening tests may allow workplaces to proactively identify cases of COVID-19 that may have otherwise been missed, supporting employee safety and business continuity. Screening for COVID-19 using a rapid antigen test takes about 15 to 20 minutes.

Currently, there are three types of rapid tests available through the PASP - Abbott Panbio™, BD Veritor™, and BTNX Rapid Response™. All of these tests are single use test kits that meet the needs of most organizations. In addition to being used at the workplace, these test kits can also be used for at-home self-screening of asymptomatic individuals. Health Canada has approved the BD Veritor™ test kits available through PASP as a single-use, visually-read device. While Health Canada has approved the use of BD Veritor™ without an analyzer machine for symptomatic use, Ontario has endorsed use of the test without an analyzer for asymptomatic use.

As an analyzer is no longer required to interpret test results, BD Veritor™ may also be used at home to screen. For further details on how to self-screen with BD Veritor without the analyzer, sites are encouraged to view the at-home self-screening resource posted on the Ontario Health Website. Sites with access to an analyzer can still choose to use the analyzer to interpret BD Veritor™ results.

Resources

The documents listed below should be used to support screening implementation using COVID-19 rapid antigen tests. Sites are encouraged to develop internal resources that will help introduce rapid testing to their staff and external partners, as required.

Included in this Document:

Document Name	Description
COVID-19 Rapid Antigen Test Screening Program Frequently Asked Questions (Appendix A)	Provides participating sites with instructions regarding COVID-19 rapid antigen tests, including when to use the test, the testing process, and interpreting test results.
COVID-19 Rapid Antigen Test Information Sheet (Appendix B)	Provides answers to questions about COVID-19 rapid antigen test for individuals being screened.
Primer on Best Practices: COVID-19 Rapid Antigen Tests (Appendix C)	This checklist highlights the suggested approach to quality management for COVID-19 rapid antigen tests.
COVID-19 Rapid Antigen Test Go-Live Readiness Checklist (Appendix D)	Provides a list of essential steps to review prior to initiating testing using COVID-19 rapid antigen tests.
BD Veritor™ Expiry Extension (Appendix E)	Provides updated expiry dates for certain BD Veritor™ kits.

Additional Resources:

Document Name	Description
COVID-19 Guidance: Considerations for Rapid Antigen Screening	Provides guidance on the use of rapid antigen tests. Please see the latest provincial testing guidance under the "Symptoms, Screening, and Testing Resources" section of the Ministry of Health's website.
Ontario Health training modules: • Overview of Provincial Antigen Screening Program • Best Practices for Point-of-Care Testing • Collecting Specimens	Provides planning and implementation guidance for organizations conducting on-site screening for COVID-19 as part of the Provincial Antigen Screening Program. The resources are available on the Ontario Health website at ontariohealth.ca/antigen-test.

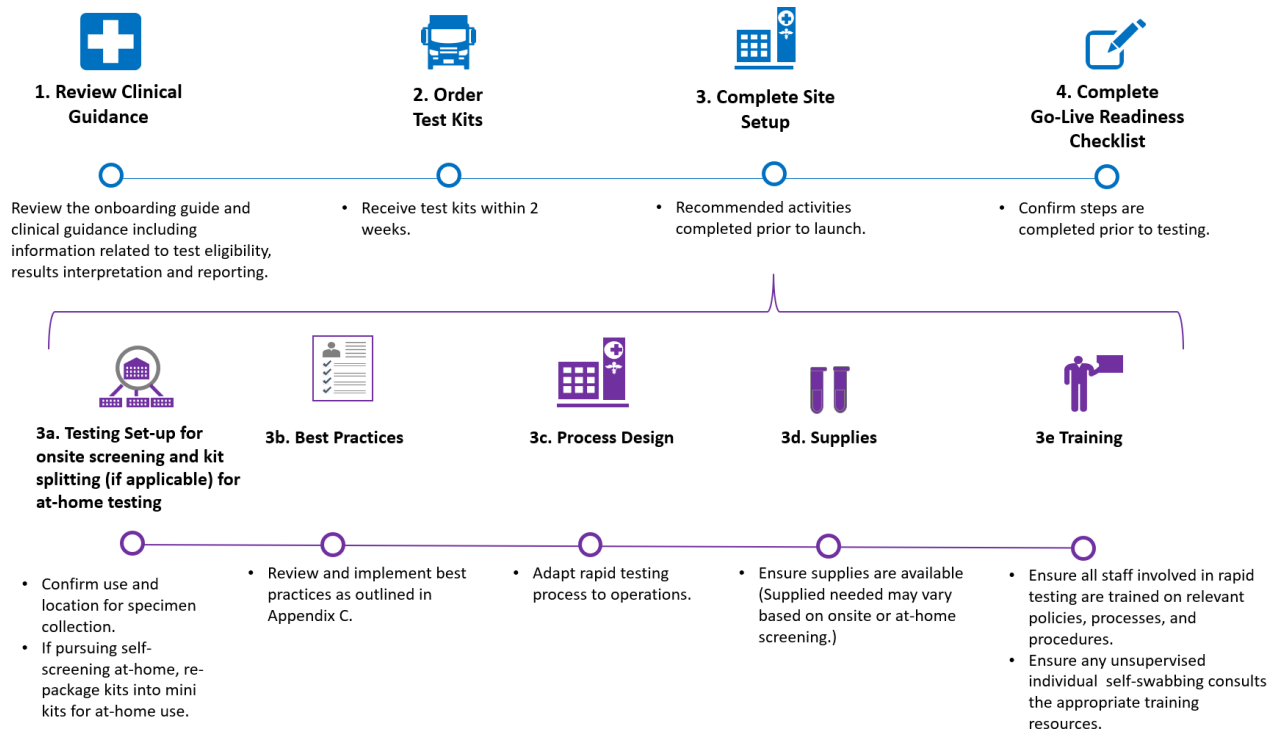
• Self-Collection
• Documenting and reporting results
• COVID-19 rapid antigen test results tracker
• Implementing a rapid antigen screening program
• At-home self-screening Instructions
  • Panbio™
  • BTNX Rapid Response™
  • BD Veritor™	

Onboarding Process Overview

The onboarding process prepares sites to implement a screening program using COVID-19 rapid antigen tests. Figure 1 describes the end-to-end onboarding process for sites.

If you have questions during the onboarding process, please contact covid19testing@ontariohealth.ca.

Figure 1: Onboarding process overview



1. Review Clinical Guidance

The Ministry of Health COVID-19 Guidance: *Considerations for Rapid Antigen Screening* includes information on using rapid antigen tests for asymptomatic individuals. Please see the latest provincial testing guidance under the "Symptoms, Screening, and Testing Resources" section of the Ministry of Health's website. As of August 25, 2021:

- Antigen screening is generally not recommended for fully vaccinated individuals. Individuals are considered fully vaccinated 14 or more 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.
- At-home self-swabbing is permitted. See COVID-19 Guidance: Considerations for Antigen Point-Of-Care Testing Guidance for more information.

2. Order COVID-19 Rapid Antigen Test Kits

Visit the Government of Ontario website to check eligibility and apply for free rapid antigen tests covid-19.ontario.ca/get-free-rapid-tests.

Organizations can order up to a one-month supply to screen unvaccinated employees.

Table 1: Key Technical Specifications for Panbio™

Product Details	Specification
Tests per Inner Case (each)	25 tests
Inner Case Dimensions (in cm)	23 x 12.5 x 9 cm
Tests per Master Case (each)	800 tests
Tests per Pallet (each)	9,600 tests
Temperature Considerations	Tests must be stored and transported between 2° to 30° Celsius. Tests cannot be frozen.

Table 2: Key Technical Specifications for BD Veritor™

Product Details	Specification
Tests per Inner Case (each)	30 tests
Tests per Pallet (each)	2,880 tests
Size of the analyzer (mm)	248 mm x 202 mm x 152 mm
Weight of the analyzer (kg)	0.925 kg
Temperature Considerations	Products must be stored and transported between 2° to 30° Celsius. Products cannot be frozen.

Table 3: Key Technical Specifications for BTNX Rapid Response™

Product Details	Specification
Tests per Inner Case (each)	25 tests
Inner Case Dimensions (in cm)	21 x 13 x 8 cm
Tests per Master Case (each)	650 tests
Tests per Pallet (each)	13,000 tests
Temperature Considerations	Products must be stored and transported between 2° to 30° Celsius. Products cannot be frozen.

3A Complete Site Set-Up – ONSITE TESTING

3A (i): Testing Set-Up

Sites can choose the following modes of testing program delivery:

1. Independently deliver the program (i.e., using existing staff or directly hired new staff).
2. Contract with a service provider of their choosing to deliver the program.

Prior to initiating screening, organizations must contact their local public health unit to make them aware that the organization will be engaging in rapid antigen screening.

3A (ii): Best Practices

Sites conducting COVID-19 rapid antigen screening should ensure that best practices for point-of-care testing are in place. Sites should designate a rapid-testing lead (e.g., an administrator, director of care or other lead) to oversee the rapid testing implementation at your organization. The rapid testing lead must take steps to ensure rapid antigen screening meets the best practices outlined in Appendix C and found in the training module.

If contracting with a service provider to deliver the program, the rapid testing lead will be a consistent primary liaison to the service provider and the service provider should take steps to ensure rapid antigen screening meets the best practices as outlined in Appendix C. The Antigen Testing Services Directory provides a list of service providers who can do rapid testing for the Provincial Antigen Screening Program

3A (iii): Process Design

The *Implementing a COVID-19 Rapid Antigen Screening Clinic* webinars provide suggestions on how to plan, set-up and operate an **on-site rapid antigen screening clinic**. Sites will need to develop new or adapt their existing processes to integrate rapid testing based on their setting.

3A (iv): Supplies for Organizations Performing On-Site Rapid Antigen Screening

Table 4 lists the general supplies and equipment required to perform COVID-19 rapid antigen testing onsite. General supplies are to be obtained by sites on their own.

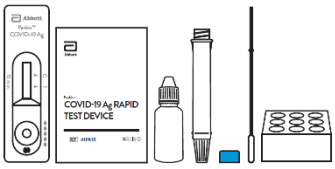
Table 5 lists the equipment found in each of the different rapid antigen test kits.

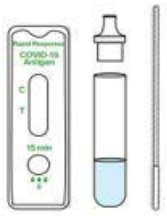
Table 4: Supplies and equipment for COVID-19 rapid antigen testing

#	Supplies/Equipment	Description and Use
1	Personal Protective Equipment (PPE) for clinic staff	Gloves, gowns, medical masks and face shields will be needed for all individuals running the rapid screening clinic, including throughout the testing process.
2	Hand Sanitizer	Used by rapid-testing clinic staff throughout the testing process as well as individual undergoing rapid antigen test.
3	Disinfectant	Used by rapid-testing clinic staff throughout the testing process to clean the test space between each test.
4	Plexiglass Shield (recommended)	Recommended to be used by rapid testing clinic staff while performing swabbing.
5	Biohazard Waste Containers	Required to safely dispose of the swabs, test kits, and PPE after use as per the Environmental Protection Act[1].
6	Masking Tape	Can be used by rapid-testing clinic staff to record the time when testing the specimen.
7	Timer	Used by rapid-testing clinic staff to monitor the testing time to result.

[1] Refer to the Ministry of the Environment and Climate Change for Safe handling and management of rapid antigen COVID-19 testing waste.

Table 5: Equipment for Panbio™, BD Veritor™, and BTNX Rapid Response™ COVID-19 rapid antigen tests

#	Supplies/Equipment	Description and Use
1	Panbio™ COVID-19 Ag Rapid Test Kit 	Each testing kit includes: • 25 test devices packaged in individual foil pouches • 9 ml bottle of buffer • 25 extraction tubes • 25 extraction tube caps • 1 positive control swab (for quality control testing) • 1 negative control swab (for quality control testing) • 25 sterilized swabs for sample collection • 1 tube rack • 1 quick reference guide • 1 set of instructions for use
2	BD Veritor™ Analyzer (No longer required; now optional) 	May be used to interpret the result of the BD Veritor™ test. Ontario has endorsed the off-label use of BD Veritor™ as a self-read device. In addition, Health Canada approved the use of the BD Veritor™ rapid antigen test as a visually-read device (see COVID-19 testing device applications authorized by Health Canada), without the use of an analyzer machine. The use of BD Veritor™ as a visually-read device will be particularly helpful for enabling at-home screening. **Sites can still choose to use the analyzer machines, and sites that already have analyzer machines can continue to request BD Veritor™ to use with their existing devices when placing orders.**

3	BD Veritor™ SARS-CoV-2 Antigen Test 	Each testing kit includes: • 30 single use reaction tubes, each pre-filled with 325 µL extraction reagent and having an integral dispensing tip • 30 test devices • 1 positive control swab • 1 negative control swab • 30 sterilized swabs for sample collection • 1 quick reference card • 1 set of instructions for use • 1 nasal sampling instructions Disposable tube rack
4	**BTNX Rapid Response™** 	Each testing kit includes: • 25 individually packed test devices • 2 bottles of extraction buffer • 25 individual aliquots of extraction buffer • 25 single use extraction tubes • 25 single use nozzles with filter • 25 sterilized swabs for sample collection • 1 tube stand • 1 set of instructions for use There is also a 5-pack version of this testing kit, which includes • 5 individually packed test devices • 5 individual aliquots of extraction buffer • 5 single use extraction tubes • 5 single use nozzles with filter • 5 sterilized swabs for sample collection • 1 tube stand • 1 set of instructions for use

3A (v): Training

Ontario Health has developed training resources, in addition to this onboarding guide, for rapid antigen screening. These training resources are available on the Ontario Health website at ontariohealth.ca/antigen-test and include topics such as:

- **Overview of the Provincial Antigen Screening Program**: Outlines requirements of the program, clinical guidance on antigen screening and testimonials from workplaces.
- **How to implement a rapid antigen screening clinic if offering on-site antigen screening** - Covers staffing, materials and space required, how to collect and test samples, and how to interpret and communicate results.
- **How to collect specimens for rapid antigen screening -** Teaches health professionals, or other individuals that have little or no experience with specimen collection, how to conduct swabbing for rapid testing.
- **How to collect a self- swab:** Teaches participants how to swab their own nose for sites choosing to use supervised self-collection on site.
- **Following best practices for quality rapid antigen screening implementation**: Provides more detail on how to run the quality control testing, the frequency of quality control testing and reviews biosafety considerations.
- **How to document and report rapid antigen screening results**: Provides guidance on how to collect, store and report data for COVID-19 rapid antigen screening.

3B. Complete Home Set-Up –SELF-SCREENING AT HOME

3B (i): Testing Set-Up

Sites can choose to permit individuals to conduct self-swabbing at home.

Prior to initiating screening, organizations must contact their local public health unit to make them aware that the organization will be engaging in rapid antigen screening.

3B (ii): Best Practices -Self Swabbing

Specimen collection for rapid antigen screening tests may be done voluntarily by the person being tested ('self-swabbing'). Any individual doing self-swabbing must consult the self-swabbing training resource developed by Ontario Health in collaboration with Public Health and ensure they have appropriate knowledge skills and judgement to perform the test including how to operate the device.

Unsupervised self-swabbing enables employees to complete the antigen screening test at home before they travel to the workplace,

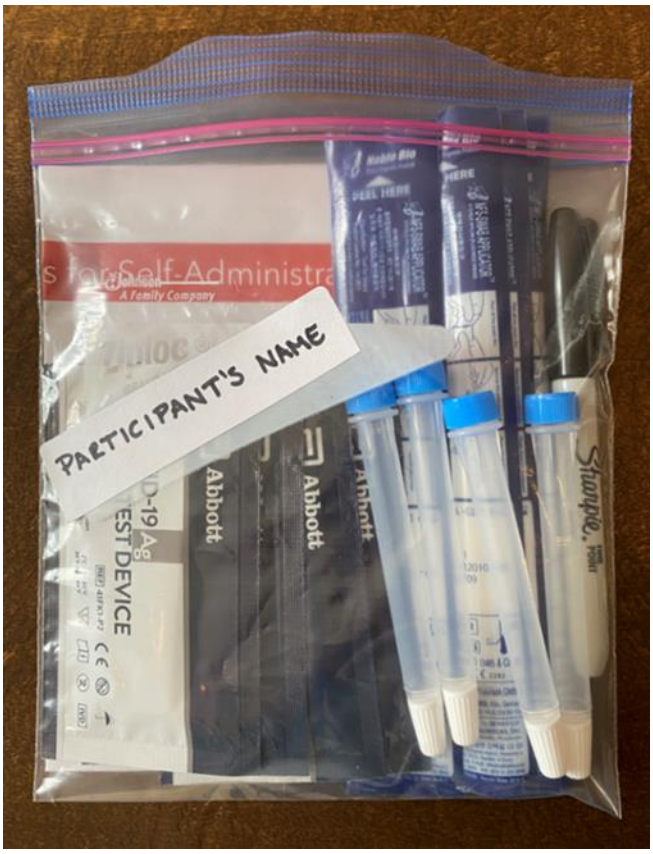
3B (iii): Repackaging Rapid Antigen Test Kits for At-Home Self-Screening

Organizations should not be sending a full box of tests home (with the exception of the BTNX 5-pack) with individuals who are self-screening at home to avoid test wastage. Instructions on how to create mini-kits for each test type are provided below. Mini screen kits should contain all the supplies needed for up to four weeks' worth of screening for each participant.

If the box of tests comes with a control swab, the organization should conduct the positive and negative control swabs on each new lot or shipment tests for quality assurance purposes. Control swabs should not be included in the mini-kit.

Panbio™ Tests:

Organizations should split a kit of 25 tests into mini screen kits for at-home screening.



In order to make the mini-screen kits, do the following:

1. Collect all the supplies needed for the chosen frequency of screening, including packaged swabs, tubes, blue caps, test cartridges, and any written documentation about the at-home screening process (see attached image).
2. Pre-fill all tubes with the buffer solution to the fill line (approximately ten drops).
    - If you use too little or too much liquid, you may get an incorrect test result.
    - Do not touch the liquid itself, the bottle dispenser tip, or the test tube opening with your hands.
    - Use only the liquid provided in the kit. Do not replace the liquid with any other liquids (e.g., tap water) otherwise the results may not be correct.
    - Note that the buffer solution will last in the tubes until the expiration date of the test.
3. Ensure the caps on both ends of the tube are securely fastened.
4. Put supplies into a Ziploc® bag or another container and label with the participant's name (if desired) and expiry date of supplies used in the kit.

<u>BD Veritor Kits:</u>
Organizations should split a kit of 30 tests into mini screen kits for at-home screening.

In order to make mini-screen kits, do the following:

1. Collect all the supplies needed for the chosen frequency of screening, including:
    - 10 packaged swabs
    - 1 sealed back of 10 pre-filled reaction tubes
    - 10 test devices
    - Any written documentation about the at-home screening process
2. Put supplies into a Ziploc® bag or another container and label with the participant's name (if desired) and expiry date of supplies used in the kit.

BTNX Rapid Response™:
Organizations can repackage a box of 25 tests into mini screen kits for at-home screening.

In order to make mini-screen kits, do the following:

1. Collect all the supplies needed for the chosen frequency of screening, including packaged swabs, extraction tubes, test devices, nozzles with filter, pre-filled aliquots and any written documentation about the at-home screening process. **Mini kits must only be made using the pre-filled aliquots**. Do not create mini kits by pre-filling extraction tubes with buffer solution.
2. Put supplies into a Ziploc® bag or another container and label with the participant's name (if desired) and expiry date of supplies used in the kit.

3B (iv): Supplies for Individuals Performing At Home Self Screening

Table 6 lists the general supplies required to perform COVID-19 rapid antigen tests. A site should notify participants of supplies they will require in order to perform self-screening at home.

Table 6: Examples of supplies needed for At Home Self-Screening

#	Supplies	Description and Use
1	Prepared Test Mini Kit	Mini kits should contain all the supplies needed for up to four weeks' worth of screening for each participant.
2	Hand Sanitizer or Soap and Water	Used by throughout the testing process to clean hands.

3	Disinfectant (suggested)	Used throughout the testing process to clean the test space before and after the test.
5	Trash Can	to dispose of the swabs and test kits after use.
7	Timer	Used to monitor the testing time to result.

3B (v): Self-Swabbing Training

Any individual performing unsupervised-self swabbing must consult Ontario Health's self-swabbing training resource.

In addition to this onboarding guide, for rapid antigen screening. Training resources are available on the Ontario Health website at ontariohealth.ca/antigen-test

4. Complete the Go-live Readiness Checklist

The COVID-19 Rapid Antigen Test Go-live Readiness Checklist (Appendix D) provides a list of essential steps to review prior to initiating testing using COVID-19 Rapid Antigen Tests.

5. Issues Management

Please send any issues to covid19testing@ontariohealth.ca with a description of your issue.

6. Acknowledgement

This onboarding guide was adapted by Ontario Health from the *COVID-19 Rapid Testing ID NOW™ Onboarding Package for New Sites*, which was developed by the ID NOW™ Rapid Testing Resources Committee.

Thank you to Abbott, BD, and BTNX for permission to use illustrations.

Appendix A: COVID-19 Provincial Antigen Screening Program Frequently Asked Questions

What is a COVID-19 rapid antigen test?

- It is an antigen test that can be used for point-of-care testing (POCT) to screen for COVID-19. Antigen POCT can be used as an additional screening tool. It does not replace public health measures such as vaccination, symptom screening, physical distancing, masking and hand hygiene. It does not replace requirements to protect the health and safety of workers.
- Antigen POCT should NOT be used to test for COVID-19 infection in symptomatic individuals, individuals with known contact with a COVID-19 case or in outbreaks. The way this test is used may evolve as more information about test performance becomes available.

When should you perform a COVID-19 rapid antigen test?

- See the Ontario Ministry of Health's COVID-19 Guidance: Considerations for Rapid Antigen Screening for details regarding the recommended use of COVID-19 Rapid Antigen Tests as a screening tool.
- 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 without a close contact to a confirmed COVID-19 case** .
- Symptomatic individuals, or individuals who have had close contact with a confirmed case of COVID-19 should be directed to a designated testing site to obtain a diagnostic molecular test instead of antigen POCT.
- In general, COVID-19 rapid antigen tests **should not be conducted in an outbreak setting**, unless it is being conducted under the guidance and direction of a local Public Health Unit and it is being conducted only in addition to, not as replacement for, diagnostic testing of individuals within the outbreak setting as outlined in the provincial testing guidance.
- Individuals who have **previously been diagnosed with and cleared of COVID-19** infection may resume asymptomatic antigen screening after 90 days form their COVID-19 infection (based on the date of their confirmed PCR positive result).
- Antigen screening is generally **not** recommended for individuals who are **fully vaccinated** as the likelihood of COVID-19 is low for this group which reduces the utility of screening and may result in an increase of false positive results. Individuals are considered fully vaccinated 14 or more 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.

Who can perform a COVID-19 rapid antigen test?

- Specimen collection for rapid antigen tests may be done by health professionals, or other trained individuals (including self-swabbing), in accordance with the manufacturer's label.
- Specimen collection for rapid antigen screening may also be done with the supervision of a trained individual or done by the person being tested (self-swabbing)

- Self-swabbing for rapid 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 rapid antigen tests 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 resources developed by Ontario Health in collaboration with Public Health Ontario and ensure they have the appropriate knowledge, skills and judgement to perform the test

- Beyond self-swabbing, the remaining testing process may also be done by the person being tested ("self-testing") under the following conditions:
    - Any individual doing self-testing must consult the self-testing training resources (video and written instructions) developed by Ontario Health in collaboration with Public Health Ontario.
- Nasopharyngeal specimen collection is a controlled act and can only be conducted by a regulated health professional.

How does a COVID-19 rapid antigen test compare to regular laboratory-based PCR tests?

- Compared to the regular laboratory-based PCR test, COVID-19 rapid antigen tests have a higher risk of providing either a false negative or a false positive result.
- Interpretation of results in different populations varies based on specimen type collected and pre-test probability of COVID-19 in the patient being tested.

How often should someone be screened for COVID-19 using a COVID-19 rapid antigen test?

- Antigen screening may be performed at minimum one time per week, and up to two to three times per week for individuals who are not fully vaccinated.
- Some ministries may require certain sectors to perform screening at a defined frequency.

When will individuals get their rapid antigen test results?

- Rapid antigen tests often provide results within 15 minutes.
- For testing done at the workplace, if the COVID-19 rapid antigen test is positive, the individual should be notified according to the site's procedures, usually within about two hours.
- Although less ideal than communicating all results, some sites follow a "no news is good news approach" where individuals are not directly told if their result is negative.

What are the safety precautions that need to be taken while administering COVID-19 rapid antigen tests?

- Please refer to Appendix C: Primer on Best Practices for COVID-19 Rapid Antigen Tests.

How should specimens be disposed of?

- Guidance on how waste from rapid testing kits should be handled in the workplace has been developed by the Ministry of Environment, Conservation and Parks, and can be found here: 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. Persons undertaking at-home 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.

Do individuals who test positive on the rapid antigen test need to be confirmed with lab-based PCR testing?

- Yes, a positive result on a rapid antigen test means that a person MAY be infected with COVID-19; it is considered a preliminary positive result. A person who receives a positive rapid antigen result requires a confirmatory laboratory-based PCR test or rapid molecular test as soon as possible (ideally within 48 hours) to confirm the result.
- The individual must follow local public health guidance and self-isolate immediately until they receive a confirmatory test result:
    - If the **confirmatory test is negative AND received from a laboratory-based PCR test**, the person may be able to return to work before ten days at the direction of their public health unit.
    - If the **confirmatory test is a rapid molecular test AND the result is negative**, **the person will still need to undergo a confirmatory laboratory-based test** to confirm the COVID-19 infection.
        - If the **individual does not get a confirmatory test**, they should remain self-isolated until ten days have passed since their positive antigen test result, and also inform everyone they were in close contact with in the 48 hours before the antigen positive result to self-isolate and get tested unless they're fully vaccinated or previously positive and asymptomatic.
    - If the **confirmatory test is positive**, the person will need to continue self-isolating, and the local public health unit will be in contact with further instructions.

Which results are considered final if results from rapid antigen testing and laboratory-based PCR testing differ?

- Antigen test results are never considered final.
- A negative result is considered final if coming from a regular laboratory-based PCR test
- A positive result is considered final if coming from either a regular laboratory-based PCR test or a molecular point-of-care test.

For more guidance on the interpretation of testing results and when a parallel or subsequent repeat test is required, see Appendix 9: Management of Individuals with Point-of-Care Testing Results.

If an individual previously tested positive for COVID-19, should they be tested with rapid antigen screening?

- Individuals who have previously been diagnosed with and cleared of COVID-19 infection should resume asymptomatic screening after 90 days from their COVID-19 infection (based on the date of their confirmed positive PCR result).

Does a preliminary positive result on the rapid antigen test mean the site is in outbreak?

- No, a preliminary positive result does not mean the site is in outbreak.
- Local public health units will remain the authoritative body on the declaration of a COVID-19 outbreak.

Appendix B: What You Need to Know About Rapid Testing for COVID-19

This information sheet includes questions commonly asked by individuals being tested with COVID-19 rapid antigen tests.

What is a COVID-19 rapid test?

- A rapid antigen test is a test for COVID-19 that gives results faster than a molecular (e.g. PCR) test (between 15 minutes and 2 hours).
- The test shows if you have a protein of the COVID-19 virus.
- Compared to a molecular PCR COVID-19 test, rapid antigen tests have a higher risk of false positive results (a result that shows a person is infected with COVID-19 when they are not) and false negative results (a result that shows a person is not infected with COVID-19 when they are).
- For this reason, antigen screening should be done at regular intervals.

Who can get a COVID-19 rapid antigen test?

- You may be eligible for rapid antigen screening if the following conditions are applicable:
    - You have **no symptoms**
    - You are unvaccinated*
    - You haven't been in contact with someone who has COVID-19
    - You have passed regular COVID-19 screening
    - There are no suspected or confirmed outbreaks of COVID-19 at your facility

*Note: Provincial guidance recommends not conducting antigen screening for fully-vaccinated individuals as the likelihood of COVID-19 is low for this group which could result in an increase of false positive results. In practice, this means that regardless of vaccination status, an individual may still choose to participate in rapid antigen screening and does not need to disclose their vaccination status to participate or not participate in sectors where screening is voluntary.

On site testing: What will happen during my appointment?

- During on-site testing, a trained individual will swab inside of your nose to take a sample for the rapid test. You may also be asked to swab yourself. At-home self-swabbing is also permitted. See Considerations for Antigen Point-Of-Care Testing guidance.

How will I get my COVID-19 rapid test results?

- **How to get my results at work**
  - If you are being screened at your workplace, a staff member at your appointment will let you know what to expect if your test result is negative or invalid.

  If the COVID-19 rapid antigen test result is **positive**, you will be notified according to the procedures at your workplace, usually within about two hours.

- **How to get my results at home**
  - If you are self-screening at home, you must read the results 15 minutes after putting the liquid in the cartridge.
  - If the COVID-19 rapid antigen test result is **positive**, you must notify your workplace according to their procedures.

- **What further testing do I require if the result is positive?**
  - You will need to have a second swab taken within 48 hours with a regular laboratory-based PCR test or a rapid molecular test. This may occur at a designated testing site. The result from this test will confirm if you truly tested positive for COVID-19.
    - If the molecular COVID-19 test is positive, you will get a call from your local public health unit to let you know. You can also find your molecular COVID-19 test results at http://covid-19.ontario.ca/.
    - If your second test is a rapid molecular test and is negative, you will need to have another laboratory-based molecular COVID-19 test ("PCR test") to confirm your result one last time. Continue to self-isolate while waiting for the laboratory PCR test result.

- **What further testing do I require if the result is negative?**
  - If the COVID-19 rapid antigen test result is **negative**, your chance of being infected with COVID-19 is unlikely, but a false negative is possible depending on the timing and quality of your test sample, as well as the prevalence of COVID-19 in your community. You could become infected with COVID-19 in the future. Continue to follow public health guidance on physical distancing, wearing a mask, and washing your hands to avoid getting COVID-19. If you start to experience symptoms of COVID-19, even if you have recently had a rapid antigen test, you should have a laboratory-based PCR test done at a designated testing site.

What if my COVID-19 rapid antigen test result is different from my regular COVID-19 test result?

- The results of the regular laboratory-based PCR test is the final test result.

- If the result of a (rapid) molecular point of care test is negative, following a positive result of a rapid antigen test, you will need to obtain a laboratory-based PCR test to confirm your result one last time. Continue to self-isolate while waiting for the result of the laboratory PCR test result.

Do I need medical care?

- If you start to feel sick, contact your health care provider or Telehealth Ontario (1-866-797-0000).
- As always, if you have a medical emergency, call 911 immediately.

Do you need more information?

- If you have any questions or need more information about your test results, contact your local public health unit: https://www.phdapps.health.gov.on.ca/PHULocator/

Appendix C: Primer on Best Practices for On-Site Screening for COVID-19 Rapid Antigen Tests

This primer highlights key best practices for COVID-19 Rapid Antigen Tests being performed on-site.

Quality Oversight, Personnel, and Training and Competency

- ☐ Identify a rapid testing lead, who will be accountable for the quality of the rapid-testing program at your site.
- ☐ Identify health professionals, or other trained individuals who will collect specimens, perform testing, and communicate test results to individuals being tested.
- ☐ Train and confirm the competency of all staff involved in the entire testing process: pre-testing (e.g., specimen collection, labelling), testing, and post-testing (e.g., result recording/notification) and re-train if not involved in testing clinics in the last three months.

Facilities

- ☐ Ensure your rapid testing area is safe. Examples include having a closed-off room (if possible), allowing for physical distancing, access to eye-wash devices, hand-hygiene products, splash guards, and avoiding absorbent floors (e.g., carpets), walls, tables, furniture, fans, and stand-alone air conditioners in the rapid-testing area.
- ☐ Keep the test kit materials, specimens not yet tested, discarded waste, and the test processing area separate from one another.

Equipment and Supplies

- ☐ When receiving new kits, inspect and depending on how you ordered your antigen kits, notify Ontario Health, your partner ministry or your local chamber of commerce if kits are damaged or defective.
- ☐ Track kit lot numbers and expiry dates, being sure to use tests before they expire. Make sure to clearly communicate any shelf-life extensions with the end user to avoid any confusion.

Specimen Collection, Testing, and Results Interpretation/Recording/Notification

- ☐ Before collecting a sample, confirm the individual's identification by checking at least two unique identifiers.
- ☐ Handle only one specimen at a time when setting up a test.
- ☐ Track the individual's two unique identifiers on the test and confirm that they match those of the individual.
- ☐ Follow the product insert and/or provincial authorities when performing and interpreting the test.
- ☐ Record test results on paper, or electronically, with the name of the individual tested (with two unique identifiers), test result, test used, and date and time tested.
- ☐ Ensure the following can be traced back to the testing result if necessary: who performed the test, who was notified of the test result, the kit lot number, and quality control results.
- ☐ Communicate test results to the person being tested.

Document Management

☐ Ensure there are rapid testing program procedures at your site and that the most recent version is used.

Quality Assurance

☐ Perform quality control checks regularly, including when a new person is trained to perform testing, when a new shipment is received, when there is a change in lot number, when recommended by the manufacturer and (where relevant), provincial authorities.
☐ Investigate failed quality control checks and stop new specimen testing until the cause of the failure has been corrected.

Infection Prevention, Occupational Health, and Safety

☐ Do not eat, drink, smoke, vape, handle contact lenses, or apply cosmetics in the rapid-testing area.
☐ Use infection prevention and safety precautions recommended by the manufacturer or provincial authorities.
☐ Clean and disinfect the rapid-testing area regularly and as soon as any spills occur.

Ethical Conduct

☐ Treat all heath information as confidential following the *Personal Health Information Protection Act* (PHIPA).

Appendix D: COVID-19 Rapid Antigen Test Go-live Readiness Checklist for On-site Screening

#	Requirement	Completed
1	Reviewed the Ministry of Health's COVID-19 Guidance: Considerations for Rapid Antigen Screening.	
2	Reviewed the *COVID-19 Rapid Antigen Testing Onboarding Guide*	
3	COVID-19 Rapid Antigen Testing implementation procedures have been reviewed and are understood by the staff conducting rapid antigen screening.	
4	Staff identified and trained to operate rapid testing clinic: • Registration, preparation of kits, labelling; • Swabbing; and • Testing specimens and documenting results.	
5	Confidentiality agreements signed by staff operating the rapid-test clinic.	
6	Ordered and received COVID-19 rapid antigen test kits.	
7	Additional materials required for testing are available: • PPE for clinic staff (mask, gown, face shield); • Plexiglass shield; • Hazardous waste containers; • Masking tape; • Box of gloves; • Timer; • Disinfectant (clean spills, wipe down equipment pre/post clinic); and • Hand sanitizer.	
8	Dedicated space for testing identified.	
9	Process for documenting results established.	

Appendix E: BD Veritor™ Expiry Extensions

Further testing was conducted on BD Veritor™ kits to support a shelf-life of 12 months. There are some lots of BD Veritor™ test kits that will have the original expiry, which can now be extended. For these lots, the product Unique Device Identifier (UDI) barcode on the kit box will display the original expiry date until you receive kits with the updated labeling. **Please ONLY refer to the lot number provided on the kit box and not on the contents of the box, as they may contain different lot numbers that will not correspond with the list below.** The expiration date has been extended on the following kits.

Lot	Original Expiry	New Expiry	Lot	Original Expiry	New Expiry
0340740	5/20/2021	11/20/2021	1029376	7/6/2021	01/06/2022
0343900	5/20/2021	11/20/2021	1032077	7/6/2021	01/06/2022
0346215	5/22/2021	11/22/2021	1035279	7/6/2021	01/06/2022
0349155	5/26/2021	11/26/2021	1027050	7/7/2021	01/07/2022
0357565	5/31/2021	11/31/2021	1033798	7/7/2021	01/07/2022
0358634	6/2/2021	12/02/2021	1035122	7/7/2021	01/07/2022
0356935	6/4/2021	12/04/2021	1028825	7/9/2021	01/09/2022
0364277	6/7/2021	12/07/2021	1031666	7/9/2021	01/09/2022
0365333	6/9/2021	12/09/2021	1036924	7/10/2021	01/10/2022
0361837	6/10/2021	12/10/2021	1046484	7/10/2021	01/10/2022
1002327	6/11/2021	12/11/2021	1038934	7/12/2021	01/12/2022
1003502	6/14/2021	12/14/2021	1038689	7/13/2021	01/13/2022
1007570	6/16/2021	12/16/2021	1041056	7/15/2021	01/15/2022
1013906	6/22/2021	12/22/2021	1042874	7/15/2021	01/15/2022
1017995	6/22/2021	12/22/2021	1040092	7/16/2021	01/16/2022
1014710	6/24/2021	12/24/2021	1045248	7/16/2021	01/16/2022
1022146	6/24/2021	12/24/2021	1044778	7/19/2021	01/19/2022
1016642	6/25/2021	12/25/2021	1047008	7/19/2021	01/19/2022
1020841	6/25/2021	12/25/2021	1050036	7/19/2021	01/19/2022
1019883	6/29/2021	12/29/2021	1050033	7/19/2021	01/19/2022
1018218	6/30/2021	12/30/2021	1047060	7/20/2021	01/20/2022

1026113	6/30/2021	12/30/2021	1050617	7/20/2021	01/20/2022
1021217	7/1/2021	01/02/2022	1047054	7/21/2021	01/21/2022
1022997	7/2/2021	01/02/2022	1047064	7/21/2021	01/21/2022
1024065	7/4/2021	01/04/2022	1050591	7/21/2021	01/21/2022

Appendix F: Panbio™ Expiry Extensions

The Panbio COVID-19 Ag Rapid Test Device (Nasal) has received authorization from Health Canada to have its shelf-life extended to 24 months (Authorization reference number 324506, Amendment Reference Number: 335165).