

# COVID-19 Antigen Rapid Testing

**Onboarding Guide** 

Version 4 – September 24, 2021

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Note:

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

As of March 5, 2021, changes to Ministry of Health guidance allow for trained individuals to perform point-of-care antigen screening, in accordance with the product manufacturer's label. Supervised self-swabbing for point-of-care antigen screening is now also permitted. Please see the Ministry of Health guidance document for more information.

As of August 25, 2021, changes to Ministry of Health guidance include information about self-screening kits as well as updated clinical guidance for asymptomatic individuals in various settings (facility transfers and hospitals) and fully vaccinated individuals. Please see the Ministry of Health guidance document for more information.

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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 athome self-collection for COVID-19 using antigen rapid 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 objective of this program is to reduce the spread of COVID-19 and to support essential and vulnerable workplaces to safely stay open. Through the program, rapid antigen tests will be distributed to employers in priority settings, to enhance existing routine screening measures for asymptomatic employees. Rapid antigen tests may allow for workplaces to proactively identify cases of COVID-19 that may have otherwise been missed, supporting employee safety and business continuity in a variety of settings. Screening for COVID-19 using a rapid antigen test takes about 15 to 20 minutes.



There are two types of rapid tests available in the PASP - Abbott Panbio™ and BD Veritor™. Abbott Panbio™ are single use test kits that meet the needs of most organizations. This test kit works well for low and high testing volumes and is recommended for organizations with multiple testing sites. This test kit can now be used for at-home self-screening of asymptomatic individuals. BD Veritor™ test kits require a small analyzer machine. This test kit is recommended for organizations with high testing volumes and a limited number of testing sites and not for at-home self-collection.

#### Resources

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



#### **Additional Resources:**

Document Name	Description
COVID-19 Guidance: Considerations for Rapid Antigen Screening	Provides participating sites with considerations on the use of antigen rapid for the purpose of asymptomatic screening programs. Please see the latest provincial testing guidance under the "Symptoms, Screening, and Testing Resources" section of the Ministry of Health's website.
<ul> <li>Ontario Health training modules:</li> <li>Overview of Provincial Antigen Screening Program</li> <li>Best Practices for Point-of-Care Testing</li> <li>Collecting Specimens</li> <li>Self-Collection</li> <li>Documenting and reporting results</li> <li>COVID-19 rapid antigen test results tracker</li> <li>Panbio™: implementing a rapid antigen clinic</li> <li>BD Veritor™: implementing a rapid antigen clinic</li> </ul>	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

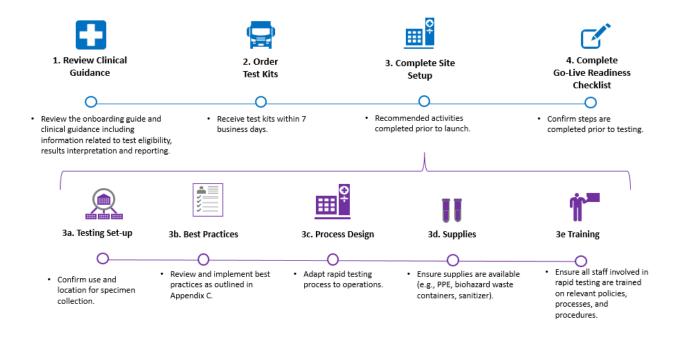
# **Onboarding Process Overview**

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

If you have questions during the onboarding process, please contact <a href="mailto:covid19testing@ontariohealth.ca">covid19testing@ontariohealth.ca</a>.



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 screening programs. Please see the latest provincial testing guidance under the "Symptoms, Screening, and Testing Resources" section of the <u>Ministry of Health's</u> website.

#### As of August 25, 2021:

- Antigen screening is no longer recommended for fully vaccinated individuals. Individuals are
  considered fully vaccinated 14 or more days after receiving their second dose of a two-dose COVID19 vaccine series or their first dose of a one-dose COVID-19 vaccine series.
- Effective September 7, 2021, all staff, volunteers, students, and contractors at public hospitals, home and community care service providers, Local Health Integration Networks, and ambulance services) will be required to undertake rapid antigen screening if they are not fully vaccinated.
- At-home self-swabbing is permitted. See <u>Considerations for Antigen Point-Of-Care Testing guidance</u>.

# 2. Order COVID-19 Antigen Rapid Testing Kits



Visit the Ontario Together website to check eligibility and apply for free rapid antigen tests <u>covid-</u>19.ontario.ca/get-free-rapid-tests.

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

See Table 1 for considerations when ordering the Panbio<sup>™</sup> COVID-19 Ag Rapid Test kits and Table 2 for considerations when ordering BD Veritor<sup>™</sup>.

**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.

# 3. Complete Site Set-Up

## 3a: 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 <u>local public health unit</u> to make them aware that the organization will be engaging in rapid antigen screening.



#### **3b: 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 <u>Appendix C</u> and found in the <u>training</u> 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 <u>Appendix C</u>.

#### **3c: Process Design**

The <u>Implementing a COVID-19 Rapid Antigen Screening Clinic webinars</u> provide suggestions on how to plan for, set-up and operate an on-site screening clinic using Panbio™ and BD Veritor™ tests. Sites will need to develop new or adapt their existing processes to integrate rapid testing based on their setting.

### 3d: Supplies

Table 3 lists the general supplies and equipment for COVID-19 antigen rapid tests. General supplies are to be obtained by sites on their own.

Table 4 lists the equipment found in the Panbio<sup>™</sup> and BD Veritor<sup>™</sup> rapid antigen tests kits. Visit the Ontario Together website to determine how to order tests for your site: <u>covid-19.ontario.ca/get-free-rapid-tests.</u>

Table 3: Supplies and equipment for COVID-19 antigen rapid 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 throughout the testing process.
2	Hand Sanitizer	Used by rapid-testing clinic staff throughout the testing process.



3	Disinfectant	Used by rapid-testing clinic staff throughout the testing process.
4	Plexiglass Shield	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 <sup>1</sup> .
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.

Table 4: Equipment for Panbio<sup>™</sup> and BD Veritor<sup>™</sup> COVID-19 antigen rapid tests

#	Supplies/Equipment	olies/Equipment Description and Use	
1	Panbio™ COVID-19 Ag Rapid Test Kit	Each testing kit includes:	
	COVID-19 Ag RAPID TOST DEVICE  See state 1-3.5	<ul> <li>25 test devices packaged in individual foil pouches</li> <li>9 ml bottle of buffer</li> <li>25 extraction tubes</li> <li>25 extraction tube caps</li> <li>1 positive control swab (for quality control testing)</li> <li>1 negative control swab (for quality control testing)</li> <li>25 sterilized swabs for sample collection</li> <li>1 tube rack</li> <li>1 quick reference guide</li> <li>1 set of instructions for use</li> </ul>	

<sup>&</sup>lt;sup>1</sup> Refer to the Ministry of the Environment and Climate Change for <u>Safe handling and management of rapid antigen</u> <u>COVID-19 testing waste</u>.



BD Veritor™ SARS-CoV-2
Antigen Test

BD Veritor™ SARS-CoV-2

Antigen Test

BD Veritor™ test kit.

BD Veritor™ test kit.

BD Veritor™ test kit.

# 3e: 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 <a href="https://ontariohealth.ca/antigen-test">ontariohealth.ca/antigen-test</a> 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 Covers staffing, materials and space required, how to collect and test samples, and how to interpret and communicate results. There are separate sessions for Panbio<sup>™</sup> and BD Veritor<sup>™</sup> COVID-19 antigen rapid tests.



- How to collect specimens for rapid antigen screening Teaches health professionals, or other
  individuals that have little experience with specimen collection, how to conduct swabbing techniques
  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.
- How to self-screen at home: Teaches participants how to swab their own nose and perform their own test for sites choosing to offer at-home self-screening.
- 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.

### **3f: Splitting Panbio™ Tests for At-Home Self-Screening**

Organizations should split a kit of 25 Panbio™ tests into mini screen kits for at-home screening to avoid test wastage.

Mini screen kits should contain all the supplies needed for up to 4 weeks worth of screening for each participant



#### To make the mini screen kits, do the following:

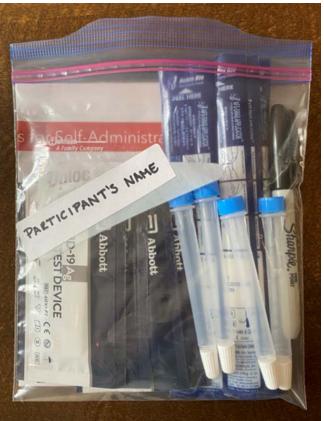
- The organization should conduct the positive and negative control swabs on each new lot of Panbio™ tests for quality assurance purposes.
- Collect all the supplies needed for the chosen frequency of screening, including packaged swabs, tubes, test cartridges, a permanent marker for labelling the tubes with the correct date, and any written documentation about the at-home screening process (see attached image).
- 3. 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.
- 4. Ensure the caps on both ends of the tube are securely fastened.
- 5. Put supplies into a ziploc bag or another container and label with the participant's name (if desired).

# 4. Complete the Go-Live Readiness Checklist

The COVID-19 Antigen Rapid Test Go-Live Readiness Checklist (Appendix D) provides a list of essential steps to review prior to initiating testing using COVID-19 Antigen Rapid 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*<sup>TM</sup> *Onboarding Package for New Sites*, which was developed by the ID NOW<sup>TM</sup> Rapid Testing Resources Committee.

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



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

#### What is a COVID-19 antigen rapid 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 should not replace public health measures such as
  vaccination, symptom screening, physical distancing, masking and hand hygiene. It should not replace
  requirements to protect the health and safety of workers.
- The way this test is used may evolve as more information about test performance becomes available.

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

- See the Ontario Ministry of Health's <u>COVID-19 Guidance</u>: <u>Considerations for Rapid Antigen Screening</u> for details regarding the recommended use of COVID-19 Antigen Rapid Tests as a screening tool.
- Although the manufacturer instructions mention that the tests can be used to diagnose symptomatic
  patients with COVID-19, the province recommends that COVID-19 antigen rapid tests should only be
  used on asymptomatic individuals without a close contact to a known COVID-19 case for screening
  purposes only.
- Symptomatic individuals, or individuals who have had close contact with known positive cases should be directed to an Assessment Centre, participating licensed community lab or specimen collection centre, where available, for a diagnostic molecular test instead of antigen POCT.
- COVID-19 antigen rapid tests should not be used in either a confirmed or suspected outbreak setting, unless it is being conducted under the guidance and direction of a local <u>Public Health Unit</u> and it is being conducted only in addition to, not as replacement for, diagnostic testing of individuals within the outbreak setting as outline in the <u>provincial testing guidance</u>.
- 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
  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 antigen rapid test?

- Specimen collection and test processing for rapid antigen screening is to be conducted by trained individuals (including self-swabbing and/or self-testing).
- Specimen collection may also be done by the person being tested ("self-swabbing") under the following conditions:



- Any individual supervising self-swabbing or doing self-swabbing must consult the <u>self-swabbing training resources</u> developed by Ontario Health in collaboration with Public Health Ontario.
- 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 (<u>video</u> and <u>written instructions</u>) 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 antigen rapid test compare to regular laboratory-based PCR tests?

- Compared to the regular laboratory-based PCR test, COVID-19 antigen rapid tests have a higher risk of a false negative and 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 antigen rapid test?

• Antigen screening may be performed at minimum one time per week in low prevalence communities, and up to 2-3 times per week for individuals who are not fully vaccinated.

#### When will individuals get their antigen rapid test results?

- If the COVID-19 antigen rapid test is positive, the individual should be notified according to the site's procedures, usually within about 2 hours.
- At the appointment, the patient will find out more information about how to receive negative or invalid results, based on the site's protocol.
- Many 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 antigen rapid tests?

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

- A positive result on a rapid antigen test is considered a preliminary positive and require a confirmatory laboratory-based PCR test or rapid molecular test within 48 hours.
- The individual should self-isolate immediately, follow local public health guidance and receive a lab-based confirmatory PCR test or confirmatory rapid molecular test within 48 hours. If the individual receives a negative result from a laboratory-based PCR test, they may be able to return to work before 10 days at the direction of their public health unit. If the individual receives a negative result from the rapid molecular test, they should seek additional confirmatory testing using a laboratory-based PCR test. If the individual does not get a confirmatory test, they should remain self-isolated until 10 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.

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

- 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 rapid molecular test.

# 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 positive result).
- If there is uncertainty about the validity of the COVID-19 infection (e.g., asymptomatic infection with high cycle threshold value result), resume asymptomatic screening immediately.

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

- No, a preliminary positive result does not mean the site is in outbreak. The individual who tested positive is required to have a confirmatory molecular test.
- Local public health units will remain the authoritative body on the declaration of a COVID-19 outbreak, which will continue to be based on the presence of positive results on a confirmatory molecular test.



### 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 antigen rapid tests.

#### What is a COVID-19 rapid test?

- An antigen rapid test is a test for COVID-19 that gives results faster than a molecular 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, antigen rapid 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 needs to be done at regular intervals, (i.e., 1 to 3 times per week, at the discretion of the on-site rapid testing lead and dependent on the prevalence of COVID-19 in the community).

#### Who can get a COVID-19 antigen rapid test?

- You may be offered a COVID-19 antigen rapid test if:
  - You have no symptoms
  - o You are unvaccinated
  - o You haven't been in contact with someone who has COVID-19
  - o You have passed regular COVID-19 screening
  - There are no suspected or confirmed outbreaks of COVID-19 at your facility

### What will happen during my appointment?

- A trained individual will swab inside of your nose or both your nose and throat to take a sample for the rapid test. At-home self-swabbing is also permitted. See <u>Considerations for Antigen Point-Of-Care</u> <u>Testing guidance</u>.
- If your result is negative, you do not need to do anything special. You will keep following the infection prevention and control and screening rules at your workplace.
- If the result is positive, you will need to have a second swab taken from your nose (or both your nose and throat) for a regular ("molecular") COVID-19 test, either on site or at an Assessment Centre. The regular test will confirm your result. You will need to <u>self-isolate</u> until the laboratory result for your regular test comes back.



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

- If you are self-swabbing at home, you must read the results between 15-20 minutes after putting the liquid in the cartridge. 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.
  - o If the COVID-19 antigen rapid test result is **positive**, you will be notified according to the procedures at your workplace, usually within about 2 hours. You will need to have a second swab taken within 48 hours for a regular "molecular" COVID-19 test. This may occur on-site or at a local COVID-19 assessment centre, participating licensed community lab or specimen collection centre, where available. The result from the regular test will confirm if you have truly tested positive for COVID-19.
    - o 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 <a href="http://covid-19.ontario.ca/">http://covid-19.ontario.ca/</a>.
    - If your second test is a rapid molecular test and is negative, you will need to have another labbased 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.
  - o If the COVID-19 antigen rapid 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.
    - o 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 COVID-19 Assessment Centre.

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

• The results of the regular laboratory-based COVID-19 test is the final 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: <a href="https://www.phdapps.health.gov.on.ca/PHULocator/">https://www.phdapps.health.gov.on.ca/PHULocator/</a>



# **Appendix C: Primer on Best Practices in the Workplace for COVID-19 Antigen Rapid Tests**

This primer highlights key best practices for COVID-19 Antigen Rapid Tests.

Qu	ality 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 3 months.
Fac	ilities
	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.
Equ	uipment and Supplies
	When receiving new kits, inspect and notify Ontario Health if kits are damaged or defective. Track kit lot numbers and expiry dates, being sure to use tests before they expire.
Spe	ecimen 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.
Qu	ality 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.
Inf	ection 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.
Eth	ical Conduct
	Treat all heath information as confidential following the <u>Personal Health Information Protection Act</u> (PHIPA).



# **Appendix D: COVID-19 Antigen Rapid Test Work Site Go-Live Readiness Checklist**

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

Further testing was conducted on BD Veritor<sup>TM</sup> Kits to support a shelf-life of 12 months. There are some lots of BD Veritor<sup>TM</sup> 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. 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

