Ontario Health

BD Veritor™ COVID-19 Antigen Rapid Testing

Onboarding Guide

May 21, 2021

Contents

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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 testing, in accordance with the product manufacturer's label. Supervised self-swabbing for point-of-care antigen testing is now also permitted. Please see the Ministry of Health guidance document for more information.** **Disclaimer: This document was developed by Ontario Health for training and guidance purposes. The application and use of this document is the responsibility of the user. Ontario Health assumes no liability resulting from any such application or use. Last updated May 21, 2021.**

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Purpose

This document provides planning and implementation guidance for sites undertaking on-site screening for COVID-19 using the BD Veritor™ System, a SARS-CoV-2 antigen test. The Ministry of Health, Ministry of Long-Term Care, Public Health Ontario, and Ontario Health have contributed to this document.

Provincial Rapid Antigen Screening Program

The Provincial Antigen Screening Program (PASP) is a voluntary 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 individuals. Rapid antigen tests are intended to enable workplaces to identify cases of COVID-19 proactively, supporting employee safety and business continuity. The BD Veritor™ Antigen Test is used for point-of-care testing and detects COVID-19 in 15 minutes.

Resources

The documents listed below should be used to guide implementation of the BD Veritor™ Anitgen Test. 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
BD Veritor™ Antigen Test Surveillance Program Frequently Asked Questions (Appendix A)	Provides answers to questions staff might have regarding the BD Veritor™ Antigen Test.
BD Veritor™ Antigen Test Specimen Collection Tip Sheet (Appendix B)	Provides instructions to ensure the correct specimen collection method, swab type, and storage methods are used when using the BD Veritor™ Antigen Test.
What You Need to Know About Rapid Testing for COVID-19 (Appendix C)	Provides answers to questions individuals might have regarding the BD Veritor™ Antigen Test.
Primer on Best Practices for BD Veritor™ Antigen Test (Appendix D)	This checklist highlights the suggested approach to quality management for the BD Veritor™ Antigen Test.

Document Name	Description
Recommended Steps for Implementing a COVID-19 Rapid Antigen Screening Clinic (Appendix E)	Provides suggestions on how to plan for, set-up and operate an on-site screening clinic using the BD Veritor™ Antigen Test.
Site Readiness Checklist: BD Veritor System™ for Rapid Detection of SARS-CoV-2 (Appendix F)	Provides a list of essential steps to review prior to initiating testing using the BD Veritor™ Antigen Test.

Additional document(s)/links

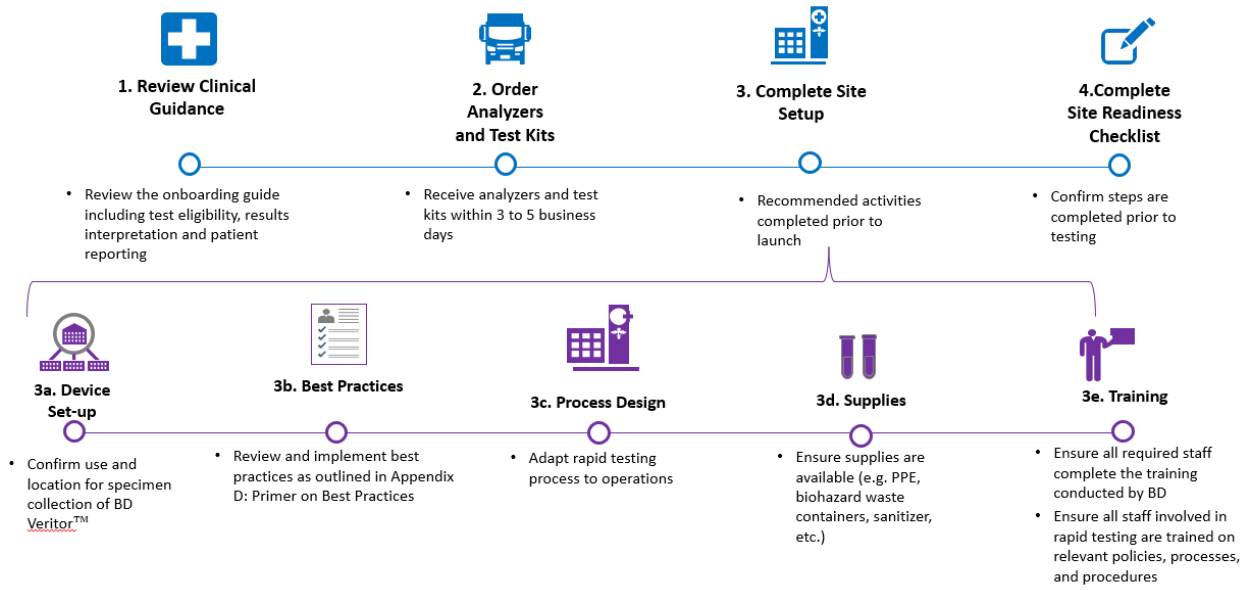
Document/Link Name	Description
COVID-19 Guidance: Considerations for Rapid Antigen Screening	Provides participating sites with considerations on the use of rapid antigen tests such as the BD Veritor™ Antigen Test for asymptomatic screening programs. Please also see the latest provincial testing guidance under the "Symptoms, Screening, and Testing Resources" section of the Ministry of Health's website.
Ordering BD Veritor™ Antigen Test Kits Through the eHealth Portal	Provides step-by-step instructions on how to order additional supplies (e.g., testing kits swabs, PPE) for point-of-care testing if needed. This process is currently under development.
BD Veritor™ Product Offering	Provides participating sites with details on BD Veritor™ such as product overview, features/benefits and details on how to use the antigen test. Videos produced by BD are also available.

Onboarding Process Overview

The onboarding process prepares sites to implement the BD Veritor™ System. 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's *COVID-19 Guidance: Considerations for Rapid Antigen Screening* includes information on the use of rapid antigen tests such as the BD Veritor™ 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.

2. Order BD Veritor™ Analyzer and SARS-CoV-2 Antigen Tests

Sector-specific instructions on how to order BD Veritor™ analyzers and tests will be made available to participating sites. Please contact covid19testing@ontariohealth.ca if you need a copy.

Generally, it is recommended to order up to one month's supply for your site. Once an order is placed, it will take 2 to 5 days for a site to receive the shipment. Additional information can be found in the ordering instructions for your sector.

- Number of tests in a box = 30 single use test devices
- Number of tests in a pallet = 2,880
- Size of the analyzer = 248 mm x 202 mm x 152 mm
- Weight of the analyzer = 0.925 kg

3. Complete Site Set-Up

3a: Testing Set-Up

First, sites must confirm the population and clinical circumstances where COVID-19 testing with BD Veritor™ will be used, based on review of the Ministry of Health's COVID-19 Guidance: Considerations for Rapid Antigen Screening, the BD Veritor™ Antigen Test Surveillance Program FAQ (Appendix A) and local community needs.

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 they will be engaging in rapid screening.

3b: Best Practices

Sites conducting COVID-19 rapid testing using BD Veritor™ 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 rapid-testing implementation. The rapid testing lead must take steps to ensure rapid antigen testing meets the best practices outlined in Appendix D. 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 best practices.

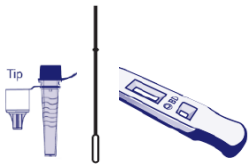
3c: Process Design

The *Recommended Steps for Implementing a COVID-19 Rapid Antigen Screening Clinic* document (Appendix E) provides suggestions on how to plan for, set up and operate an on-site screening clinic using the BD Veritor™ Plus Antigen Test. Sites will need to develop new processes or adapt their ones to integrate rapid testing based on their setting.

3d: Supplies

Table 1 lists the recommended supplies and equipment required for the BD Veritor™ Antigen Test.

Table 1: Recommended Supplies and Equipment to Operate a BD Veritor™ Antigen Test Clinic.

#	Supplies/Equipment	Description and Use	Ordering Process
1	BD Veritor™ Analyzer 	Used by point-of-care testing (POCT) staff for the direct and qualitative detection of SARS-CoV-2 antigens.	Specific step-by-step instructions on how to order BD Veritor™ Analyzers will be made available to participating sites.
2	BD Veritor™ SARS-CoV-2 Antigen Test 	Each testing kit includes: • 30 single use reaction tubes, each with 325 µL extraction reagent and having an integral dispensing tip 1 positive control swab • 30 test devices • 1 positive control swab • 1 negative control swab • 30 sterilized swabs for sample collection • 1 quick reference card • 1 instructions for use • 1 nasal sampling instructions • Disposable tube rack	Specific step-by-step instructions on how to order BD Veritor™ Antigen Test Kits will be made available to participating sites.

#	Supplies/Equipment	Description and Use	Ordering Process
3	Personal Protective Equipment (PPE)	Used by POCT staff throughout the testing process.	Sites to order through their regular process.
4	Hand Sanitizer	Used by POCT staff throughout the testing process.	Sites to order through their regular process.
5	Disinfectant	Used by POCT staff throughout the testing process.	Sites to order through their regular process.
6	Plexiglass Shield	Recommended to be used by POCT staff while performing swabbing.	Sites to order through their regular process.
7	Biohazard Waste Containers	Required to safely dispose of the swabs, test kits, and PPE after use as per the *Environmental Protection Act*. Refer to the Ministry of the Environment and Climate Change C-4: The Management of Biomedical Waste in Ontario for specifications around container labelling and disposal requirements.	Sites to order through their regular process.
8	Masking Tape	Can be used by POCT staff to record the time when testing the specimen.	Sites to order through their regular process.
9	Timer	Used by POCT staff to monitor the testing time to result.	Sites to order timer through their regular process.

3e: Training

All relevant staff should complete training following the Best Practices guidance.

4. Complete the Go-Live Readiness Checklist

The *BD Veritor™ Plus Antigen Test Go-Live Readiness Checklist* (Appendix F) provides a list of essential steps to review prior to initiating testing using the BD Veritor™ Plus Antigen Test.

5. Issues Management

Please send any issues to covid19testing@ontariohealth.ca (or your Ontario Health primary contact) with a description of your concerns.

Please contact BD Technical Support with any product-related technical questions or product complaints, by phone at 1-800-638-8663, option 2 or email Technical.Services@bd.com.

6. Acknowledgement

This onboarding guide was adapted by Ontario Health from the *Panbio™ COVID-19 Antigen Rapid Testing Onboarding Guide for Congregate Settings*, which was developed by the Panbio™ Implementation Team.

Appendix A: BD Veritor™ Antigen Test Surveillance Program Frequently Asked Questions

This tip sheet will answer common questions about the BD Veritor™ Antigen Test for program staff. Please note a separate general information sheet (Appendix C) will answer questions for individuals undergoing the rapid test. These questions and the answers provided may be updated as clinical evidence evolves.

What is the BD Veritor™ Antigen Test?

- It is an antigen test that can be used for point-of-care testing (POCT) to detect COVID-19 faster than the regular laboratory-based polymerase chain reaction (PCR) test for COVID-19.
- The way this test is used may evolve as more information about test performance becomes available.

Who should get a BD Veritor™ Antigen Test?

- The BD Veritor™ Antigen Test **should only be used on asymptomatic individuals** for screening purposes only.
- The BD Veritor™ Antigen Test **should not** be used for diagnosis of COVID-19 infection. They **should not** be used for symptomatic individuals, or individuals who have had close contact with known positive COVID-19 cases in the context of this program. Symptomatic individuals, or individuals who have had close contact with known positive cases should be directed to an Assessment Centre for testing.
- The BD Veritor™ Antigen Test **should not be used in either a confirmed or suspected outbreak setting.** The local Public Health Unit should be notified in such circumstances.
- Individuals screened with BD Veritor™ should have passed the regular screening protocol at your facility.
- Individuals will get more information about whether the BD Veritor™ SARS-CoV-2 Antigen Test is right for them when they arrive for their test.
- As more is learned about the BD Veritor™ Antigen Test, guidance on how and when rapid tests are used may evolve.
- See the Ontario Ministry of Health's COVID-19 Guidance: Considerations for Rapid Antigen Screening for details regarding the recommended use of the BD Veritor™ Antigen Test as a screening tool. Please see the latest provincial testing guidance under the "Symptoms, Screening, and Testing Resources" section of the Ministry of Health's website.

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How does the BD Veritor™ Antigen Test compare to regular laboratory-based PCR tests?

- Compared to the regular laboratory-based polymerase chain reaction (PCR) test, the BD Veritor™ Antigen Test has 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 individual being tested.

How often should someone be screened for COVID-19 using the BD Veritor™ Antigen Test?

- Frequency of specimen collection and screening is dependent upon which public health zone the organization is situated within.
    - For asymptomatic individuals in high prevalence areas (Yellow/Orange/Red/Grey zones), specimen collection and screening should be performed 2 to 3 times per week.
    - For low prevalence areas (Green), specimen collection and screening should be performed 1 to 2 times per week.

How is the BD Veritor™ Antigen Test conducted?

- Appropriate biosafety precautions must be taken when using the BD Veritor™ Antigen Test.
- Inform the individual or their substitute decision-maker about the procedure. An individual can withdraw their consent at any time during the process.
- Collect one specimen for the BD Veritor™ Antigen Test:
    - Combined swabbing of throat and both nares, is the preferred specimen collection method for asymptomatic screening given its expected higher sensitivity
    - In descending preference, deep nasal (both nares) and nasal (both nares) are acceptable specimen collection methods
- Process the test according to manufacturer's instructions.
- Inform the individual that the BD Veritor™ Antigen Test results will not be available through the Ontario COVID-19 Test Results viewer.
    - Instead, let the individual know how they can access their BD Veritor™ Antigen Test results following the site's protocol.
    - If the results of the BD Veritor™ Antigen Test are positive, they are considered preliminary positive and the tested individual will need a regular laboratory-based PCR COVID-19 test to confirm the results. The individual who received the preliminary positive result should be counselled to immediately self-isolate and book an appointment at the nearest COVID-19 Assessment Centre for a laboratory-based PCR test within 24 hours.

- Specimen collection may be done by the person being tested ('self-swabbing') if a health care professional (regulated or unregulated), or 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, personal protective equipment requirements, and how to safely dispose of waste.

When will individuals get their BD Veritor™ Antigen Test Results?

- If the BD Veritor™ Antigen Test is positive, the individual should find out within 1 to 2 hours.
- Based on site protocol, the individual will find out more information about how to receive negative or invalid results, prior to receiving their COVID-19 rapid test.
- Reporting all negative results to staff is best practice. Some sites follow a "no news is good news approach" where individuals are not directly told if their result is negative.

How can individuals access their BD Veritor™ Antigen Test Results?

- At their appointment, the individual will get information on how to access results.
- Each site has a process for following up with individuals tested. Staff are asked to talk to them at their appointment about how to get test results.

Do individuals need to book an appointment for the BD Veritor™ Antigen Test?

- Procedures for scheduling appointments (if applicable) for COVID-19 rapid testing will be determined by the site operator.

What are the safety precautions that need to be taken while administering the BD Veritor™ Antigen Test?

- Sites should conduct a local risk assessment to ensure the safety of personnel performing the BD Veritor™ Antigen Test. Given that a clinical specimen is being handled, there is the potential for splashing with use of the BD Veritor™ Antigen Test. At minimum, gloves, gowns, medical masks, and face shields are required. A plexiglass shield should also be in place for the point-of-care test operator to perform testing behind.

How should specimens be disposed of?

- The test kits, swabs, and PPE should be handled with caution and safely disposed of in a biohazard waste after use as per the *Environmental Protection Act*. Refer to the Ministry of the Environment and Climate Change C-4: The Management of Biomedical Waste in Ontario for specifications around container labelling and disposal requirements. All extraction tubes should have their caps in place prior to disposal.

If an individual has been vaccinated for COVID-19 do they still need to be tested?

- Individuals who have received a COVID-19 vaccine, regardless of whether they received one or two doses, are still able to receive an accurate result from a rapid antigen test. Vaccinated individuals should not be excluded from rapid antigen screening initiatives, as it is unknown at this time if they can still transmit COVID-19 despite being vaccinated.

Does a preliminary positive result on the BD Veritor™ Antigen Test mean the site is in outbreak?

- No, a preliminary positive result does not mean the site is in outbreak. Any individual who tested positive is required to have a confirmatory PCR test and must self-isolate and follow local public health guidance until the result of the confirmatory, laboratory-based PCR test is known. 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 laboratory-based PCR tests.

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

- A positive result on a rapid antigen test is considered a preliminary positive and should be followed up with a laboratory-based PCR test to act as a confirmatory test within 24 hours.
- The following actions should be taken:
    - Tell the individual that the result is preliminary positive and PCR confirmation is required.
    - Issue guidance that the individual must self-isolate and follow local public health guidance until the result of the confirmatory, laboratory-based PCR test is known.
    - Ensure confirmatory laboratory-based PCR testing is performed within 24 hours.

Is a new specimen required for the confirmatory laboratory-based PCR test when an individual tests positive on the rapid antigen test?

- Individuals who have received a preliminary positive result using BD Veritor™ should not undergo a second BD Veritor™ test. Instead, as noted above, they should be told that they should self-isolate immediately, follow local public health guidance, and receive a laboratory-based confirmatory PCR test within 24 hours.

- A second swab must be collected for a confirmatory laboratory-based PCR test. If the site has capacity to perform swabbing for PCR testing on-site, then proceed to do so; otherwise, the individual should be directed to an Assessment Centre.

Which results are considered final if results from BD Veritor™ Antigen Test and laboratory-based PCR testing differ?

- If the BD Veritor™ Antigen Test conflicts with the regular laboratory-based PCR test result, **the regular laboratory-based PCR test provides the final COVID-19 result.**
- Individuals should follow public health guidance and may need to return for repeat laboratory-based PCR testing as soon as possible if:
    - The regular laboratory-based PCR result is indeterminate or invalid.
    - A swab for the regular laboratory-based PCR testing was NOT collected within 24 hours of the BD Veritor™ Antigen Test swab collection.

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

- Individuals who have previously been diagnosed with and cleared of COVID-19 infection should resume asymptomatic surveillance testing 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 surveillance testing immediately.
- Individuals who were previously a probable case or other situations where it is uncertain if the individual was a 'true' case should continue to participate in asymptomatic surveillance/screening testing.

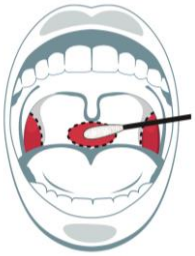
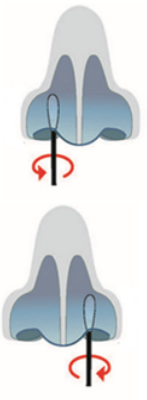
Appendix B: BD Veritor™ Antigen Test Specimen Collection Tip Sheet

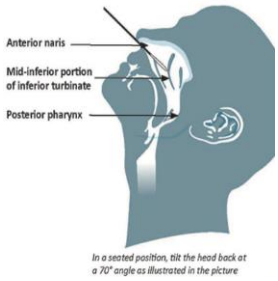
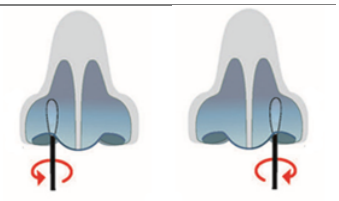
This tip sheet provides instructions to ensure that the correct specimen collection method and storage methods are used when using the BD Veritor™ Antigen Test.

Specimen collection

- Refer to Table 2 for a list of acceptable specimens for asymptomatic screening, collection instructions and diagrams for the BD Veritor™ Antigen Test. A combined swab of throat and both nares is preferred given its higher sensitivity, but a deep nasal swab (both sides), or an anterior nasal swab (both nares) is also acceptable. For more information on specimen collection, refer to the Public Health Ontario (PHO) Laboratory COVID-19 Test Information Sheet.
- Contrary to the regular laboratory-based PCR test, the BD Veritor™ Antigen Test only accepts freshly collected specimens. Do not dilute with any solution (e.g., viral or other transport media) except for the extraction buffer provided in the kit.

Table 2 – BD Veritor™ Antigen Test Specimen Collection:

Specimen Collection Site	Collection Instructions	Diagram
Combined swab of throat and both nares ● A combined swab of the throat and both nares is a preferred specimen collection method. ● Use the swab provided in the manufacturer's kit.	1. Insert swab in posterior pharynx and tonsillar areas. 2. Rub swab over posterior pharynx and bilateral tonsillar pillars; avoid tongue, teeth, and gums. 3. Using the same swab, insert about 1 cm (0.5 in.) inside nares.* 4. Rotate swab and leave in place for 10 to 15 seconds. 5. Using the same swab, repeat for the other nostril. 6. Immediately test or place in extraction tube. *Swab insertion distance will differ for paediatric patients.	Steps 1-2:  Steps 3-5: 

Specimen Collection Site	Collection Instructions	Diagram
Deep nasal swab ● A deep nasal swab is a preferred specimen collection method. ● Use the swab provided in the manufacturer's kit.	1. Tilt patient's head back 70° 2. While gently rotating swab, insert swab about 2.5 cm (> 1 in.) straight back (not up) into nostril. 3. Rotate swab several times against the wall. 4. Leave swab in place for several seconds to absorb secretions. 5. Repeat for both nostrils using the same swab. 6. Immediately place in extraction tube.	
Nasal swab ● A nasal swab is an acceptable specimen collection method although less sensitive than a deep nasal or combined throat and both nares specimen. ● Use the swab provided in the manufacturer's kit.	1. Insert swab about 2.5 cm (1 in) inside nares*. 2. Roll the swab 5 times along the mucosa inside the nostril. 3. Using same swab, repeat for other nostril. 4. Withdraw the swab from the nasal cavity. The sample is now ready for processing using the BD Veritor System™ SARS-CoV-2 kit.	

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

This sheet is about the BD Veritor™ Antigen Test and it will answer questions you might have.

What is the BD Veritor™ Antigen Test?

- The BD Veritor™ Antigen Test is used to detect a protein of the virus causing COVID-19 and can be done immediately, or very soon after collection (within 1 hour).
- Knowing your rapid test results will guide your next steps to keep yourself and others safe, including following public health precautions (e.g. staying home, keeping distant from other people/self-isolating).
- Right now, the BD Veritor™ Antigen Test is being used as a screening test for persons without symptoms who are not considered at high risk of having COVID-19.
- Because the BD Veritor™ Antigen Test has a higher risk of false positive and false negative results, testing needs to be done at regular intervals (e.g., 1 to 3 times per week).

How is the BD Veritor™ Antigen Test used in Ontario?

- BD Veritor is being implemented as part of Ontario's Provincial Antigen Screening Program. Targeted testing using the BD Veritor™ Antigen Test may be offered in settings as organized by the Ministry of Health, Ontario Health, local public health units, or as part of an evaluation.
- The test is used in Ontario for individuals with no symptoms or those who have not been exposed to COVID-19. Individuals with symptoms or who have been exposed should be tested with a molecular lab-based COVID-19 test.

Who can get a BD Veritor™ Antigen Test?

- You may be offered a BD Veritor™ Antigen Test at your facility if:
    - You have no symptoms
    - You have not been in contact with someone who had COVID-19
    - You have passed your regular screening protocol at your facility
    - There are no suspected or confirmed outbreaks at your facility
- Right now, rapid tests may not yet be available in all communities as rapid tests are being deployed to priority populations/settings.

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What will happen during my appointment?

- A health professional or trained individual will swab inside of your nose **or** both your nose and throat to take a sample for the rapid test. Specimen collection may also be done by the person being tested ('self-swabbing') if a health care professional or trained individual, is supervising the self-swabbing.
- If your result is negative, you do not need to do anything special. You do need to keep following the infection prevention and control measures at your organization.
- If the result is positive, you will need to go to an Assessment Centre, participating licensed community lab or specimen collection centre, where available, where a second swab will be taken from your nose (or both your nose and throat) for a regular COVID-19 test. The regular test will confirm your result. You will need to self-isolate until the laboratory result for your regular test comes back.

How will I find out my COVID-19 rapid test results?

- A staff member at your appointment will let you know what to expect if your test result is negative or invalid.
- If the BD Veritor™ Antigen Test result is positive, you will be notified according to the procedures at your congregate care facility, usually within about 2 hours.
    - You will need to have a second swab within 24 hours for a regular (laboratory-based) COVID-19 test. This may occur at a local COVID-19 Assessment Centre, participating licensed community lab or a specimen collection centre, where available. The result from the regular test will confirm if you have truly tested positive for COVID-19.
- If your regular 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 regular COVID-19 test results at http://covid-19.ontario.ca/.

What if my BD Veritor™ Antigen Test result is different from my regular COVID-19 test result?

- The regular laboratory-based COVID-19 test is the final test result.

What happens if my BD Veritor™ Antigen Test is positive?

- **Whether you have symptoms or not**, stay home and keep your distance from others in your household (self-isolate). If you did not receive a second swab for a regular COVID-19 test at your rapid-testing site, please book an appointment at the nearest COVID-19 Assessment Centre so a regular COVID-19 test can be conducted within 24 hours. Your public health unit will let you know how long to self-isolate.

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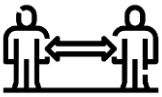
- Continue to follow all public health guidance. Wait for the regular COVID-19 test results to confirm your rapid result. Follow advice from your health care providers and public health unit.
- See Public Health Ontario's handout on "How to Self-Isolate": https://www.publichealthontario.ca/-/media/documents/ncov/factsheet-covid-19-how-to-self-isolate.pdf?la=en

What happens if my BD Veritor™ Antigen Test 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've recently had a rapid antigen test, you should have a laboratory-based PCR test done at a COVID-19 Assessment Centre.

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/

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Appendix D: Primer on Best Practices for BD Veritor™ Antigen Test

This primer highlights key best practices for the BD Veritor™ Antigen Test based on the Ontario Health Best Practices for Point-of-Care Testing document. Refer to the full document for a complete list of best practices.

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 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.

Facilities

- ☐ Ensure your rapid testing area is safe. Examples include having a closed-off room (if possible), allowing for physical distancing, having 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 notify Ontario Health if kits are damaged or defective.
- ☐ Track kit lot numbers and expiry dates, being sure to use tests before they expire.

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

☐ Ensure there are point-of-care testing program procedures at your site and that the most recent version is used.

☐ 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 E: Recommended Steps for Implementing a COVID-19 Rapid Antigen Screening Clinic (if operating under exemption to the Laboratory and Specimen Collection Centre Licensing Act)

Prepare to Implement a COVID-19 Rapid Antigen Screening Clinic

Staffing Recommendations:

- Specimen collection for point-of-care antigen tests may be done by health professionals, or other trained individuals, in accordance with the manufacturer's label. Requisition forms are not required for health professionals performing a rapid antigen test as part of this program.
- All persons conducting a COVID-19 point-of-care test (POCT) using a device that was approved by Health Canada for point-of-care use, including an antigen POCT device, are now exempt from the *Laboratory and Specimen Collection Centre Licensing Act* (LSCCLA).
- Sites will typically require three (3) staff members to operate a clinic.
- All persons conducting a COVID-19 POCT must ensure compliance with any applicable legislation related to the collection of personal health information, including PHIPA, and that proper documentation is in place when performing COVID-19 rapid antigen testing.
- Confidentiality agreements must be signed by staff operating the rapid test clinic.

Table 3 - Staffing Requirements to Run BD Veritor Antigen Clinic :

Staff Member	Role
Person A	Register staff, prepare kits, and label tubes.
Person B	Collects the swab and place swab in extraction tube according to instructions.
Person C	Test the specimen and record and report results.

The above staffing model is expected to yield an approximately 20 swabs collected and processed per hour.

Ontario Health can assist sites in identifying staffing models that support operating an antigen screening clinic on site. However, sites can explore partnering with additional community providers or engaging service providers by contract to conduct rapid antigen screening. A good place to start is by examining

existing relationships, for example, with community labs, local pharmacies, and/or paramedics to determine if these can be leveraged.

Physical Space Recommendations:

- A dedicated space maintained at 15°C to 30°C is needed to set up and run the rapid antigen testing clinic.
- Ideally, the dedicated area should consist of a closed-off space with sufficient area to place a standard level 6- by 8-foot table (e.g., folding table with a non-absorbent surface). Having a closed-off room helps to mitigate any potential transmission that could be caused by spillage of extracted specimens that may contain live virus. Once set up, the table will be used as a surface upon which the rapid tests will be placed to be processed. Ensure that the table is set up such that it is not in direct sunlight and near a supply outlet to plug in the analyzer.
- The space should accommodate for privacy to conduct the swabbing and privacy for reading and recording the results.
- The space should also allow for physical distancing and safety for three (3) people to operate and move around the clinic.
- Consider having sufficient space for an ample supply of personal protective equipment (PPE) and test kits to be kept close-at-hand.
- A phone should also be available to Person C, to notify the rapid antigen testing lead of a preliminary positive result.

Considerations for Infection Prevention, Occupational Health, and Safety

- Sites should conduct a local risk assessment to assure safety of personnel performing the BD Veritor™ Antigen Test. At minimum, gloves, gowns, masks, and face shields are required and a plexiglass shield should also be in place, behind which testing is conducted. These minimum requirements are in place because:
    - A clinical specimen is being handled.
    - The BD Veritor™ Antigen Test extraction buffer contains substances that are eye and skin irritants and can be acutely toxic if ingested.[1]

[1] The BD Veritor™ Antigen Test extraction buffer contains < 0.1% sodium azide that are eye and skin irritants. Refer to the BD Veritor™ System for Rapid Detection of SARS-CoV-2 Safety Data Sheet for details and first aid measures and discard any leftover BD Veritor™ extraction buffer following the Ontario Environmental Protection Act.

- Testing station tables should be cleaned and disinfected prior to the start of clinic, after every batch, and at the end of the day.
- Be sure to clean up any spillage with appropriate disinfectant as soon as possible after the spill.

Equipment and Supplies

- When receiving new kits, track the test lot numbers and expiry date to ensure tests are not used after they expire. Please note, some lots of BD Veritor™ now have an extended shelf-life (expiration date) of up to 12 months. 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 see below for the list of lot numbers with the extended shelf-life.

Table 4 - BD Veritor™ System for Rapid Detection of SARS-CoV-2 kit, material number: 256089 lots with extended shelf-life :

Lot Number	Original Expiry	New Expiry
0294803	3/25/2021	09/25/2021
0295733	3/26/2021	09/26/2021
0331698	4/1/2021	10/01/2021
0332652	4/2/2021	10/02/2021
0311781	4/6/2021	10/06/2021
0303674	4/7/2021	10/07/2021
0314005	4/8/2021	10/08/2021
0309513	4/9/2021	10/09/2021
0331906	4/12/2021	10/12/2021
0333772	4/13/2021	10/13/2021
0342239	4/16/2021	10/16/2021
0335228	4/19/2021	10/19/2021
1013902	5/17/2021	11/17/2021
1010086	5/18/2021	11/18/2021
0340740	5/20/2021	11/20/2021
0343900	5/20/2021	11/20/2021
0346215	5/22/2021	11/22/2021
0349155	5/26/2021	11/26/2021

Lot Number	Original Expiry	New Expiry
0357565	5/31/2021	11/31/2021
0358634	6/2/2021	12/02/2021
0356935	6/4/2021	12/04/2021
0364277	6/7/2021	12/07/2021
0365333	6/9/2021	12/09/2021
0361837	6/10/2021	12/10/2021
1002327	6/11/2021	12/11/2021
1003502	6/14/2021	12/14/2021
1007570	6/16/2021	12/16/2021
1013906	6/22/2021	12/22/2021
1017995	6/22/2021	12/22/2021
1014710	6/24/2021	12/24/2021
1022146	6/24/2021	12/24/2021
1016642	6/25/2021	12/25/2021
1020841	6/25/2021	12/25/2021
1019883	6/29/2021	12/29/2021
1018218	6/30/2021	12/30/2021
1026113	6/30/2021	12/30/2021
1021217	7/1/2021	01/02/2022
1022997	7/2/2021	01/02/2022
1024065	7/4/2021	01/04/2022
1029376	7/6/2021	01/06/2022
1032077	7/6/2021	01/06/2022
1035279	7/6/2021	01/06/2022
1027050	7/7/2021	01/07/2022
1033798	7/7/2021	01/07/2022
1035122	7/7/2021	01/07/2022
1028825	7/9/2021	01/09/2022
1031666	7/9/2021	01/09/2022

Lot Number	Original Expiry	New Expiry
1036924	7/10/2021	01/10/2022
1046484	7/10/2021	01/10/2022
1038934	7/12/2021	01/12/2022
1038689	7/13/2021	01/13/2022
1041056	7/15/2021	01/15/2022
1042874	7/15/2021	01/15/2022
1040092	7/16/2021	01/16/2022
1045248	7/16/2021	01/16/2022
1044778	7/19/2021	01/19/2022
1047008	7/19/2021	01/19/2022
1050036	7/19/2021	01/19/2022
1050033	7/19/2021	01/19/2022
1047060	7/20/2021	01/20/2022
1050617	7/20/2021	01/20/2022
1047054	7/21/2021	01/21/2022
1047064	7/21/2021	01/21/2022
1050591	7/21/2021	01/21/2022

- The analyzers have a set number of tests that they can perform, ranging from 3,500 to 10,000.
    - The number of tests that the analyzer can perform before expiry is dependent on the firmware version that it is running. The firmware version is displayed on the analyzer digital display after it is turned on. Analyzers with firmware version 5.40 can perform 3,500 tests. Analyzers with firmware version 5.50 can perform 10,000 tests.
- At the on-site clinic, store BD Veritor™ test kits at 2°C to 30°C and leave them sealed in their foil pouches until just before use. Kits must be at room temperature before use. Transportation of test kits between 2°C to 30°C is also acceptable. Do not freeze the kits or their components.
- A user should be able to perform at least 300 tests on a single full charge. This specification is written assuming that the user turns off the analyzer in between tests. In actual use, if they do not use the InfoScan module and use the batch testing option (which will be the likely case in Ontario), they will be able to perform well over 300 tests on a single charge. Also, a fully depleted battery will fully recharge in 7 hours or less after the power adapter is plugged in. The analyzer only needs to be

plugged in if the user wants to use the Walk Away mode (unlikely use, as this mode can only process one test at a time).

Materials to Carefully Track Specimens During the Clinic

- Use an electronic tracker that records all staff working at the site that will be participating in the rapid antigen screening program. A laptop is helpful for maintaining accurate/real-time records of intake and results. If you are using a laptop to record the staff list electronically, a password protected Excel spreadsheet will keep all information secure; consider the use of encryption software to provide more security. If using paper, store the form and staff list in a safe, secure location.
- Create electronic labels (2 labels for each staff member every time they are to be tested). Labels should include at least 2 personal identifiers.

Design a COVID-19 Rapid Antigen Screening Clinic That Will Work for Your Setting

- Determine how many individuals will need to be tested on a regular basis.
- Depending on the frequency of hours of work at the site, the start and end times of any shifts, and the frequency of testing described in the Ministry of Health's COVID-19 Guidance: Considerations for Rapid Antigen Screening, you may want to choose one of the following approaches:

    1. In settings with shift workers, conduct a **12-hour clinic on 3 to 4 days each week**. For example, this could be from 6 a.m. to 6 p.m. This would allow for employees who are working any of the three main shifts (i.e., days, evenings, nights) to be tested on-site.

    2. For larger workplaces, conduct a **4-hour clinic most days of the week**, as staff arrive. The timing of the clinic can vary to capture all shifts.

    3. For smaller workplaces, with fewer employees, conduct a **clinic 2 days per week**, where all participating staff are tested at each day the clinic is offered.

The above suggestions apply to testing staff, but similar approaches could be considered for testing other individuals.

Implement the COVID-19 Rapid Antigen Screening Clinic

The following section outlines a recommended step-by-step process to operate a COVID-19 rapid antigen screening clinic.

Conducting Quality Control Testing:

Quality control swabs should be tested by staff who will be operating the testing station. For sites performing more than 30 tests/day, perform quality control swabs at the beginning of the day, before testing begins. For sites performing less than 30 tests/day, perform quality control swabs each time a new kit box is opened or at least weekly, whichever is more frequent. In addition, quality control swabs should be tested with each new shipment of kits, with any new kit lot number, and by all newly trained operators before they begin testing individuals.

Follow the steps to performing a regular test with the BD Veritor™ Plus Analyzer.

- If test results are invalid, review testing instructions and repeat the quality control swab on a new device.

Caution: Temporarily pause testing while waiting for repeat testing results after an invalid test result. If an invalid result is obtained a second time, stop all staff testing until the cause of the control failures has been determined and corrected. This will involve testing procedures with a new lot and reviewing your procedures. If problems persist, you can file a concern on the Ontario Health Digital Health Services Portal.

Workflow Recommendations:

The workflow to implement a BD Veritor™ antigen testing clinic for COVID-19 can be grouped into 6 stages:

1. Preparation
2. Intake
3. Specimen collection and processing
4. Testing the specimen
5. Interpreting results
6. Communicating and documenting results

1. Preparation

- BD Veritor™ test kits should be prepared in advance and should contain the following:

- Extraction tubes, pre-filled with buffer fluid (325µl)
- Test devices
- Swab
- BD Veritor Plus Analyzer (plugged in or charged overnight)

- Confirm test kits have not expired. Test kits should be at 15-30^{o} C prior to using.
- Determine how test tubes and cartridges will be labelled with two unique identifiers to avoid mix-ups

2. Intake

a. Inform participant of testing process.

b. Record the staff member name that will be tested and store the record in a safe, secure location (e.g., password protected Excel spreadsheet). This will form the basis of the "results tracker." A laptop is helpful for maintaining accurate/real-time records of intake and results.

c. Label a BD Veritor™ tube with the appropriate participant information for tracking (e.g., pre-printed label with two unique identifiers).

d. Direct staff member/resident to the rapid test station.

3. Specimen Collection

a. **Person A** places pre-printed label with two unique identifiers of the staff member/congregate care resident on extraction tube.

b. **Person A** places a pre-filled extraction tube in the tube rack.

c. **Person B** collects specimen with dedicated rapid- test swab (i.e., the swab supplied in the BD Veritor™ kit) and places the swab immediately in labelled extraction tube.

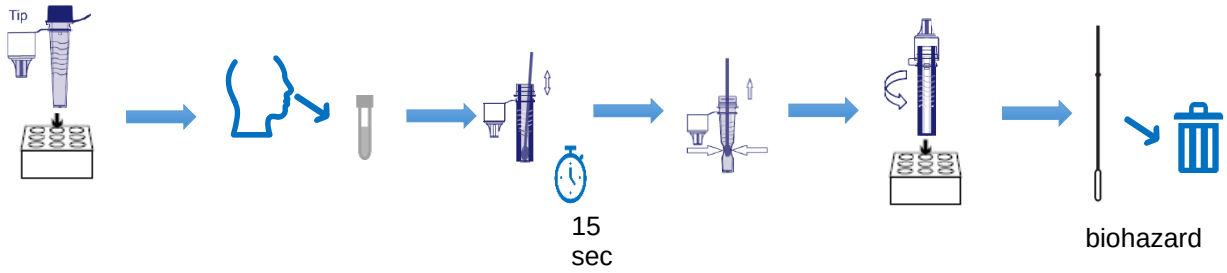
d. **Person B** plunges the swab up and down in the fluid for a minimum of 15 seconds, taking care not to splash contents out of the tube.

e. **Person B** removes the swab while squeezing the sides of the tube to extract the liquid from the swab. The swab should be discarded as biohazardous waste.

f. **Person B** presses the attached tip firmly onto the extraction reagent tube containing the processed sample (threading or twisting is not required). They then mix thoroughly by swirling or flicking the bottom of the tube. The **extraction tube** is placed in a 2nd tube holder.

g. **Person B** changes gloves and performs hand hygiene after each swab has been processed in the extraction reagent.

h. Once the swab has been processed in the extraction reagent and the tube has been capped, the sample should be added to the test device within 30 minutes.



- Specimen collection may also be done by the person being tested ('self-swabbing') if a health care professional (regulated or unregulated), or 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, personal protective equipment requirements, and how to safely dispose of waste.

4. Testing the specimen

a. **Person C** opens a **test device** and places a pre-printed label on the device to correspond with two unique identifiers on the **extraction tube** that will be tested.

b. Each **extraction tube** that will be tested should have a corresponding **test device**. **DO NOT re-use** test devices.

c. **Person C** takes **extraction tube** (with specimen in it) from the 2nd tube holder and mixes thoroughly by swirling or flicking the bottom of the tube. Then, invert the extraction reagent tube and hold it vertically (approximately one inch above the sample well) and gently squeeze the ridged body of the tube, dispensing **three (3) drops** of the processed specimen **into the sample well** of the test device. Person C changes gloves.

Cautions:

- **Squeezing the tube too close to the tip may cause leakage.**
- **If running test under laminar flow hood, cover test device to avoid inconsistent flow.**
- **DO NOT move the test device until the test is complete. When inserting the device into the analyzer, the test device must remain horizontal to prevent spilling of any non-absorbed specimen out of the sample well.**

d. *For **batch testing**, repeat steps a through c for up to 10 specimens using the same stagger time in between inoculation of each test device. Place each test device on a different section of the table.*

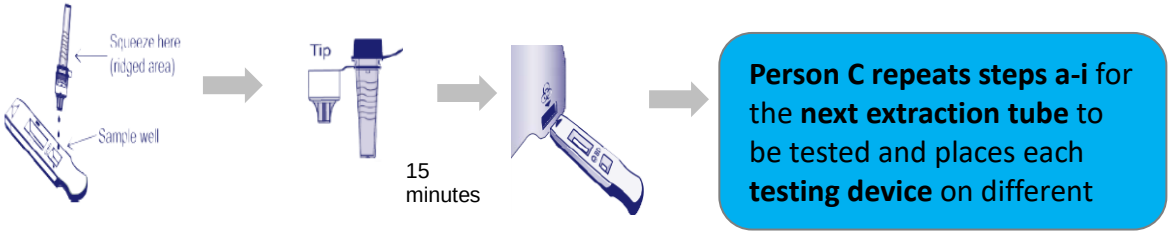
e. Person C starts a 15-minute timer.

f. Discard extraction tube with nozzle cap in the biohazard bin.

g. During the 15 minutes, Person C powers on the analyzer by pressing the blue button. The **BD Veritor™ Plus Analyzer will complete a self-test before it is ready for use.**

h. After the self-test, the display window shows **INSERT TEST DEVICE OR DOUBLE-CLICK BUTTON FOR WALK AWAY MODE. Insert the test device when the 15-minute assay development time is complete.** *For batch testing, repeat for all specimens using the stagger time established in step e, in between reading of each test devices.*

i. Record the result **before removing** the device.



5. Interpreting the Results

- Test results are not meant to be visually interpreted. Only use the interpretations provided by the BD Veritor™ Plus Analyzer.
- The BD Veritor™ Plus Analyzer will provide results as follows:

Display	Interpretation
CoV2: +	Preliminary positive
CoV2: -	Negative
CONTROL INVALID	Invalid

- If test results are interpreted as positive or negative, follow instructions in Section 6.
- If test results are invalid, review testing instructions and repeat the test on a new specimen and new test device.

6. Communicating and Documenting Results

- **Communicating Results**

  At the testing station, staff operating the clinic assume the following roles and responsibilities:

  - Rapid antigen clinic staff member communicates the preliminary positive result to the rapid-testing lead in a private manner. The staff member takes steps to maintain confidentiality of the results (i.e., results should not be communicated in a manner that exposes the identity of the staff to individuals other than the rapid- testing lead).

  Rapid testing lead assumes the following roles and responsibilities:

  - Ensures the individual is informed of preliminary positive result and ensures a confirmatory PCR test is completed within 24 hours.
  - Ensures the individual is asked to leave and return to their residence, where they should remain in self-isolation until contacted by Public Health and provided further instructions.
  - Follows internal protocols to inform administration of the preliminary positive result, e.g., leaving voicemail message with their contact number for follow-up.

a. If a Test Result is Negative (CoV2: -)

  - Key message: Counsel individual that the result is negative, but a false negative is still possible. Continue to follow public health measures for symptom screening, appropriate distancing, use of PPE and handwashing.
  - Reporting all negative results to staff being tested is a best practice. Some organizations that are conducting frequent rapid antigen testing do not communicate negative results and follow a “no news is good news approach.”
  - If requested by the local public health unit to report negative results, ensure that negative results are reported.

b. If a Test Result is a Preliminary Positive Result (CoV2: +)

  - Key message to individuals being tested: Counsel individual that the positive result is considered preliminary positive, and they will need to have a second swab within 24 hours for confirmation and self-isolate until a confirmatory test result is received.
  - Require that the individual receive confirmatory lab-based PCR test within 24 hours.

c. If a Test Result in Invalid (CONTROL INVALID) Repeat the test.

- **Documenting Results**

  - 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 the *Regulated Health Professions Act* (RHPA).

  - A participant list ("results tracker") should be created to document:
    - Who has been tested
    - The result of their test (positive, negative, invalid)
    - Individuals who refused the antigen rapid/ laboratory-based PCR test
    - Individuals who received a confirmatory positive laboratory-based PCR test and the result of the test (positive, negative)

  - The following statistical information will be required to be collected and submitted:
    - The type of rapid test used.
    - Number of rapid antigen tests used.
    - Number of invalid rapid antigen test results.
    - Number of individuals who tested positive with a rapid antigen test.
    - Number of individuals who tested negative with a rapid antigen test.

  - The method for reporting data may vary depending on how sites have received antigen screening tests:

    - Organizations who are shipped tests directly will be required to report into a centralized database, the Health Data Collection Service. Once an employer is accepted to participate, they will be onboarded on to the Health Data Collection Service and provided information and training on how to submit data and register data entry persons. Data must be entered weekly by Friday at 11:59pm EST. For participating employers that have more than one site participating in the program, data should be entered for each participating site.

    - For organizations that pick-up tests from a distribution hub (e.g., a local Chamber of Commerce), required data should be reported in the manner indicated by the pick-up location.

Appendix F: Site Readiness Checklist: BD Veritor System™ for Rapid Detection of SARS-CoV-2

#	Requirement	Completed
1	Reviewed the Ministry of Health's COVID-19 Guidance: Considerations for Rapid Antigen Screening.	
2	Reviewed the BD Veritor™ Antigen Testing Onboarding Guide.	
3	BD Veritor™ Antigen Testing implementation procedures have been reviewed and are understood by the staff conducting rapid antigen testing.	
4	Two to three (2-3) team members 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 BD Veritor™ Antigen Test kits.	
7	Additional materials required for testing are available: ● PPE for clinic staff (mask, gown, face shield); ● Plexiglass shield to perform test behind; ● Biohazard 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.	