Ontario Health

Panbio™ COVID-19 Antigen Rapid Testing

Onboarding Guide

Version 3 – May 21, 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 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.

Purpose

This document provides planning and implementation guidance for congregate settings (e.g., workplaces, shelters, retirement and long-term care homes, etc.) undertaking on-site screening for COVID-19 using the Panbio™ COVID-19 Ag Rapid Test 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 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 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. The Panbio™ COVID-19 Ag Rapid Test is an antigen test used for point-of-care testing (POCT) that detects COVID-19 in 15 to 20 minutes.

Resources

The documents listed below should be used to support implementation of the Panbio™ COVID-19 Ag Rapid 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
Panbio™ COVID-19 Ag Rapid Test Surveillance Program Frequently Asked Questions (Appendix A)	Provides participating sites with instructions regarding the Panbio™ COVID-19 Ag Rapid Test, including when to use the test, the testing process, and interpreting test results.
Panbio™ COVID-19 Ag Rapid Test Specimen Collection Tip Sheet (Appendix B)	Provides instructions to ensure that the correct specimen collection method, swab type, and storage methods are used with the Panbio™ COVID-19 Ag Rapid Test.
Panbio™ COVID-19 Ag Rapid Test Information Sheet (Appendix C)	Provides answers to questions about the Panbio™ COVID-19 Ag Rapid Test for individuals being screened.
Primer on Best Practices: Panbio™ COVID-19 Ag Rapid Test (Appendix D)	This checklist highlights the suggested approach to quality management for the Panbio™ COVID-19 Ag Rapid Test.
Recommended Approach 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 Panbio™ COVID-19 Ag Rapid Test.
Panbio™ COVID-19 Ag Rapid Test Go-Live Readiness Checklist (Appendix F)	Provides a list of essential steps to review prior to initiating testing using the Panbio™ COVID-19 Ag Rapid Test.

Additional Resource:

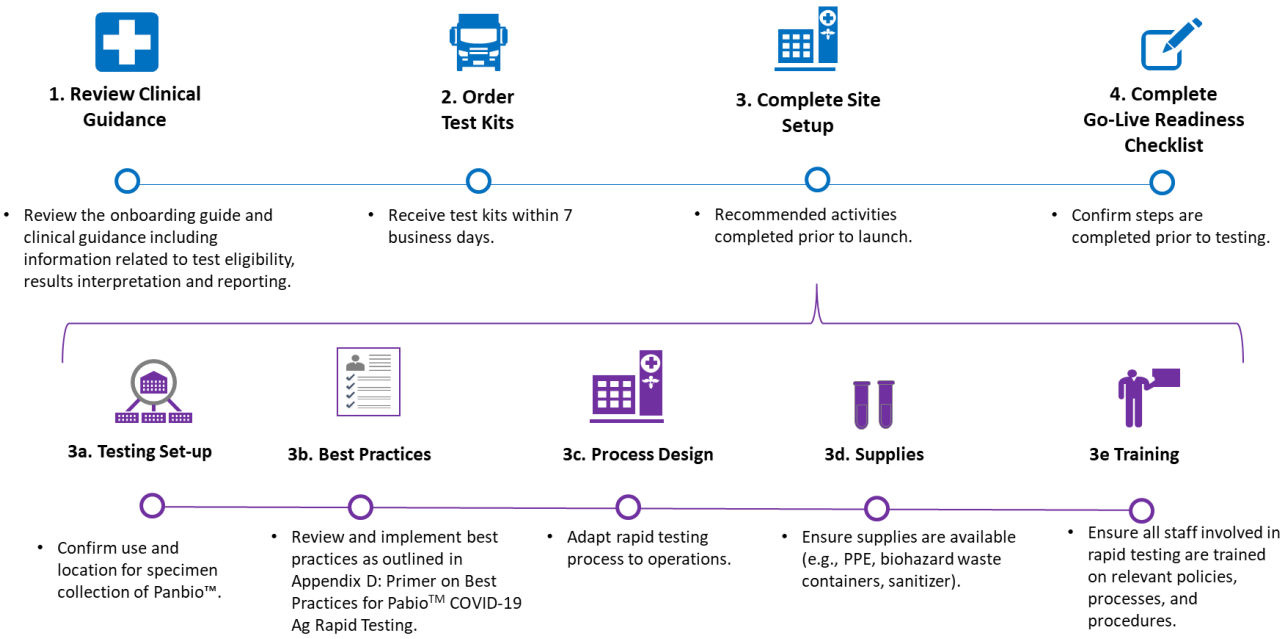
Document Name	Description
COVID-19 Guidance: Considerations for Rapid Antigen Screening	Provides participating sites with considerations on the use of rapid antigen tests such as Panbio™ COVID-19 Ag Rapid Test for the purpose of asymptomatic screening programs. Please see the latest provincial testing guidance under the "Symptoms, Screening, and Testing Resources" section of the Ministry of Health's website.

Onboarding Process Overview

The onboarding process prepares sites to implement the Panbio™ COVID-19 Ag Rapid Test. Figure 1 describes the end-to-end onboarding process for sites.

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

Figure 1: Onboarding process overview



1. Review Clinical Guidance

The Ministry of Health COVID-19 Guidance: Considerations for Rapid Antigen Screening includes information on the use of rapid antigen tests such as the Panbio™ COVID-19 Ag Rapid Test 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. Public Health Ontario and Ontario Health have also developed Panbio™ COVID-19 Ag Rapid Test Surveillance Program Frequently Asked Questions (Appendix A), and a specimen collection tip sheet (Appendix B) to provide additional guidance.

2. Order Panbio™ COVID-19 Ag Rapid Testing Kits

Sector-specific step-by-step instructions on how to order Panbio™ Rapid Antigen Test Kits through an online intake form will be circulated with this onboarding guide. 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. Additional information can be found in the ordering instructions for your sector.

See Figure 2 below for additional consideration when ordering the Panbio™ COVID-19 Ag Rapid Test kits.

Note: If the number of tests your site is ordering is close to a master case amount, please try to round up if storage space permits, to help speed up shipments. For example,

- If you need 750 tests, order 800 tests (1 case)
- If you 2,200 tests, order 2,400 tests (3 cases)

Figure 2: Product information sheet.

Manufacturer: Abbott

Product Description: Level 4 Rapid Test Medical Device

Key Technical Specifications:

Product Details	Specification
Tests per Inner Case (each)	25 tests
Inner Case Weight (in lbs)	2 lbs
Inner Case Dimensions (in cm)	23 x 12.5 x 9
Inner Cases per Master Case (each)	32 cases
Tests per Master Case (each)	800 tests
Master Case Weight (in lbs)	33 lbs
Master Case Dimensions (in cm)	47 x 53 x 39
Master Cases per Pallet (each)	12 cases
Tests per Pallet (each)	9,600 tests
Temperature Considerations	Transportation and storage must contain products between 2° to 30° Celsius
Additional Details	Product cannot be frozen

3. Complete Site Set-Up

3a: Testing Set-Up

Confirm population and clinical circumstances where COVID-19 rapid testing with Panbio™ will be used based on a review of the Ministry of Health's COVID-19 Guidance: Considerations for Rapid Antigen Screening, the Panbio™ COVID-19 Ag Rapid Test Surveillance Program Frequently Asked Questions (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 the organization will be engaging in rapid screening.

3b: Best Practices

Sites conducting COVID-19 rapid testing using Panbio™ should ensure that best practices for point-of-care testing are in place. Please see Appendix D for more information. 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 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 the best practices as outlined in Appendix D.

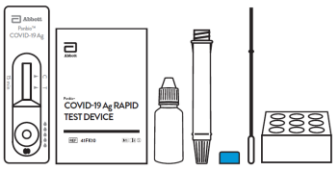
3c: Process Design

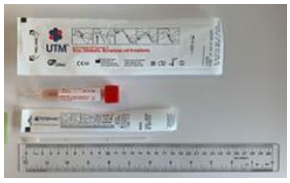
The Recommended Steps for Implementing a COVID-19 Rapid Antigen Screening Clinic document (Appendix E) provides suggestions on how to plan for, set-up and operate an on-site screening clinic using the Panbio™ COVID-19 Ag Rapid Test. Sites will need to develop new or adapt their existing processes to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

3d: Supplies

Table 1 lists the recommended supplies and equipment required for Panbio™ COVID-19 Ag Rapid Test.

Table 1: Supplies and equipment required for Panbio™ COVID-19 Ag Rapid Test

#	Supplies/Equipment	Description and Use	Ordering Process
1	Panbio™ COVID-19 Ag Rapid Test Kit 	Each testing kit includes: • 25 test devices packaged in individual foil pouches • 9 ml bottle of buffer • 25 extraction tubes • 25 extraction tube caps • 1 positive control swab (for quality control testing) • 1 negative control swab (for quality control testing) • 25 sterilized swabs for sample collection • 1 tube rack • 1 quick reference guide • 1 set of instructions for use	Sector specific step-by-step instructions on how to order Panbio™ Rapid Antigen Test Kits through an online intake form will be circulated with this onboarding guide. Please contact covid19testing@ontariohealth.ca if you need a copy.

2	Swab Kits for Confirmatory PCR Testing (if conducting confirmation PCR swabs on-site) 	Swab kits (nasopharyngeal, nasal, or throat) are used to collect a specimen for confirmatory laboratory PCR testing of positive Panbio™ results. Swab kits typically contain a swab, transport media, and a biohazard bag. *Image is for illustration purposes only.*	Sites to order through their regular process.
3	Personal Protective Equipment (PPE) for clinic staff	Gloves, gowns, medical masks and face shields will be needed for all individuals running the rapid-testing clinic throughout the testing process.	Sites to order through their regular process.
4	Hand Sanitizer	Used by rapid-testing clinic staff throughout the testing process.	Sites to order through their regular process.
5	Disinfectant	Used by rapid-testing clinic staff throughout the testing process.	Sites to order through their regular process.
6	Plexiglass Shield	Recommended to be used by rapid-testing clinic 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[1].	Sites to order through their regular process.
8	Masking Tape	Can be used by rapid-testing clinic staff to record the time when testing the specimen.	Sites to order through their regular process.

[1] 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.

9	Timer	Used by rapid-testing clinic staff to monitor the testing time to result. E.g., VWR's traceable four-channel alarm timer; catalogue 62344-641.	Sites to order timer through their regular process.

3e: Training

Ontario Health has developed training resources, in addition to this onboarding guide, for Panbio™ COVID-19 Ag rapid testing. These training resources are available on the Ontario Health website at ontariohealth.ca/panbio and include topics such as:

- **How to implement the Provincial Rapid Antigen Screening Program: Running a rapid testing clinic** - Covers staffing, materials and space required, how to collect and test samples, and how to interpret and communicate results for Panbio™ COVID-19 Ag rapid testing.
- **How to collect specimens for rapid antigen testing -** Teaches health professionals, or other individuals that have little experience with specimen collection, how to conduct swabbing techniques that are appropriate for Panbio™ COVID-19 Ag rapid testing.
- **Following best practices for quality rapid-testing implementation** - Provides more detail on how to run the quality control testing, the frequency of quality control testing and reviews biosafety considerations for Panbio™ COVID-19 rapid antigen testing.
- **How to document and report rapid antigen testing results** - Provides guidance on how to collect, store and report data for Panbio™ COVID-19 rapid antigen testing.

4. Complete the Go-Live Readiness Checklist

The Panbio™ COVID-19 Ag Rapid Test Go-Live Readiness Checklist (Appendix F) provides a list of essential steps to review prior to initiating testing using the Panbio™ COVID-19 Ag Rapid Test.

5. Issues Management

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

6. Acknowledgement

This onboarding guide was adapted by Ontario Health from the *COVID-19 Rapid Testing ID NOW™ Onboarding Package for New Sites*, which was developed by the ID NOW™ Rapid Testing Resources Committee. We would like to thank committee members for their invaluable insights and feedback on rapid testing. The Committee was chaired by Chris Simpson (Queen's University) and was composed of the following members: Kathleen Carlin (Patient Family Advisor), Antoine Corbeil (Public Health Ontario), Jennifer Everson (Ontario Health, West), Lee Fairclough (St. Mary's Hospital), Gary Garber (Public Health Ontario), Jonathan Gubbay (Public Health Ontario), Shelley Leigh (Orillia Soldiers' Memorial Hospital), Jane Liu (Patient Family Advisor), Michelle Murti (Public Health Ontario), Janice Nolan (Institute for Quality Management in Healthcare), Jacqueline Park (Thunder Bay Regional Health Science Centre), Lisa Thomas (Ontario Health) and Daniel Warshafsky (Ministry of Health).
Thank you to Abbott, Extendicare Canada and Public Health Ontario for permission to use illustrations.

Appendix A: Panbio™ COVID-19 Ag Rapid Test Surveillance Program Frequently Asked Questions

This tip sheet will answer common questions about the Panbio™ COVID-19 Ag Rapid Test for program staff. Please note a separate information sheet (Appendix C) will answer questions for individuals undergoing rapid testing. The questions and the answers provided may be updated as clinical evidence evolves.

What is the Panbio™ COVID-19 Ag Rapid 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.

When should you perform the Panbio™ COVID-19 Ag Rapid Test?

- See the Ontario Ministry of Health's COVID-19 Guidance: Considerations for Rapid Antigen Screening for details regarding the recommended use of the Panbio™ COVID-19 Ag Rapid 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.
- The Panbio™ COVID-19 Ag Rapid test **should only be used on asymptomatic individuals** for screening purposes only.
- The Panbio™ COVID-19 Ag Rapid test **should not** be used for diagnosis of COVID-19 infection. It **should not** be used for symptomatic individuals, or individuals who have had close contact with known positive 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, participating licensed community lab or specimen collection centre, where available, for testing.
- The Panbio™ COVID-19 Ag Rapid Test **should not be used in either a confirmed or suspected outbreak setting.** The local Public Health Unit should be notified in such circumstances.

Who can perform the Panbio™ COVID-19 Ag Rapid Test?

- Specimen collection and test processing for rapid antigen testing is to be conducted by health professionals, or other trained individuals, in accordance with the manufacturer's label.
- 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.

- Nasopharyngeal specimen collection is a controlled act and can only be conducted by a regulated health professional.

How does the Panbio™ COVID-19 Ag Rapid Test compare to regular laboratory-based PCR tests?

- Compared to the regular laboratory-based PCR test, the Panbio™ COVID-19 Ag Rapid 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 patient being tested.

- For individuals with **very low likelihood of COVID-19** (e.g., asymptomatic individuals with no known exposure to a patient with COVID-19),

    - a positive result is likely to be a false positive (i.e., the test has a low positive predictive value in this population).
    - a negative result is likely to be a true negative (i.e., the test has a high negative predictive value in this population).
    - a nasopharyngeal swab or alternate upper respiratory tract swab (e.g., combined throat and dual nares swab) does not significantly impact the negative predictive value.

How often should someone be screened for COVID-19 using the Panbio™ COVID-19 Ag Rapid Test?

- The recommended frequency of rapid antigen testing is dependent upon the community prevalence of COVID-19.

    - 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 Panbio™ COVID-19 Ag Rapid Test conducted?

- First, appropriate biosafety considerations must be addressed when using the Panbio™ COVID-19 Ag Rapid Test. Refer to Public Health Ontario's Abbott Panbio COVID-19 Antigen Rapid Test: Biosafety Considerations fact sheet for further details.
- Inform the individual or their substitute decision-maker about the procedure. An individual can withdraw their consent at any time during the process.
- Collect a specimen for the Panbio™ COVID-19 Ag Rapid Test.
    - Nasopharyngeal (NP) swabbing, nasal swabbing, combined swabbing of throat and both nares, and deep nasal swabbing are accepted specimen collection methods for asymptomatic screening.
- Process the test according to manufacturer's instructions.
- Inform the individual that the Panbio™ COVID-19 Ag Rapid Test results will not be available through the Ontario COVID-19 Test Results viewer.
    - Instead, let the individual know how they can access their Panbio™ COVID-19 Ag Rapid Test rapid results following the site's protocol.
    - If the results of the Panbio™ COVID-19 Ag Rapid 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 within 24 hours. If the site has the capacity to conduct the PCR swab on-site, this is preferred. If this is not possible, 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, participating licensed community lab or specimen collection centre, where available, for a laboratory-based PCR test within 24 hours.

When will individuals get their Panbio™ COVID-19 Ag Rapid Test results?

- If the Panbio™ COVID-19 Ag 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.

Do patients need to book an appointment for the Panbio™ COVID-19 Ag Rapid Test?

- Procedures for scheduling appointments for COVID-19 testing will be determined by each site implementing a rapid antigen screening clinic.

What are the safety precautions that need to be taken while administering the Panbio™ COVID-19 Ag Rapid Test?

- Sites should conduct a local risk assessment to ensure the safety of personnel performing the Panbio™ COVID-19 Ag Rapid Test. Given that a clinical specimen is being handled, there is the potential for splashing with use of Panbio™. At minimum, gloves, gowns, medical masks, and face shields are required. A plexiglass shield should also be in place to perform testing behind. Refer to Public Health Ontario's Abbott Panbio COVID-19 Antigen Rapid Test: Biosafety Considerations fact sheet for further details**.**

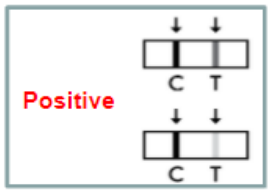
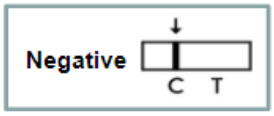
- The Panbio™ rapid test buffer is not effective at inactivating SARS-CoV-2. The test kits and swabs should be handled with caution and disposed of in a biohazard waste container. All extraction tubes should have their caps in place prior to disposal in a biohazard waste container. The biohazard waste container should be a yellow bag or container and labelled with the universal biohazard symbol.

  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.

How do you interpret the Panbio™ COVID-19 Ag Rapid Test results?

- Table 2 below provides a summary of how to interpret Panbio™ COVID-19 Ag Rapid Test results and the appropriate follow-up action.

Table 2: Panbio™ COVID-19 Ag Rapid Test Interpretation Summary

Displayed Result	Test Result	Test Interpretation	Follow-up Action
 Control line is **visible** Test line is **visible**	Preliminary Positive	SARS-CoV-2 detected. • This is a **preliminary positive result**. • Confirmatory testing using laboratory-based PCR test is **required within 24 hours**.	a. Tell individual that the result is preliminary positive and PCR testing is required for confirmation. b. Tell the individual that they must self-isolate and follow public health guidance until the result of the confirmatory, lab-based PCR test is known. c. Ensure confirmatory laboratory-based PCR testing is performed within 24 hours.
 Control line is **visible** Test line is **NOT visible**	Negative	SARS-CoV-2 NOT detected. • This is a **screening test** result, and only applies if the individual tested has no symptoms and no known exposure to COVID-19.	a. Tell individual that the result is negative but a false negative is still possible. b. Individuals should continue to follow all infection prevention and control measures in place.
 Control line is **NOT visible**	Invalid	Test is uninterpretable due to test failure; no result is available.	a. Let individual know that the test result was invalid. b. Conduct repeat testing with a second specimen using the Panbio™ COVID-19 Ag Rapid Test.

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 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, lab-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 Panbio™ should not undergo a second Panbio™ test. Instead, as noted above, the individual should be told that they should self-isolate immediately, follow local public health guidance and receive a lab-based confirmatory PCR test within 24 hours.

- If the site has capacity to perform swabbing for PCR testing on-site, a new specimen is required from the individual who tests positive on the rapid antigen test. A second swab must be used to collect a specimen for the confirmatory laboratory-based PCR test.

Which results are considered final if results from Panbio™ COVID-19 Ag Rapid Testing and laboratory-based PCR testing differ?

- If the Panbio™ COVID-19 Ag Rapid Test conflicts with the regular laboratory-based PCR test result, **the regular laboratory-based PCR test provides the final COVID-19 result.**

- A patient 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 Panbio™ COVID-19 Ag Rapid 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.

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 Panbio™ COVID-19 Ag 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 PCR 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, lab-based PCR.

Appendix B: Panbio™ COVID-19 Ag Rapid 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 Panbio™ COVID-19 Ag Rapid Test.

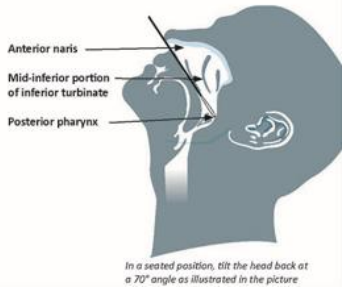
Specimen collection

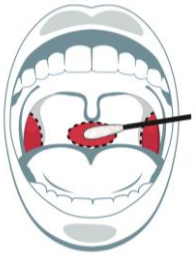
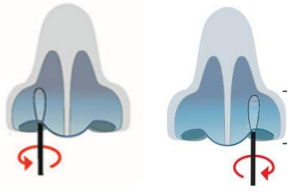
- Refer to Table 3 below for a list of acceptable specimens for asymptomatic screening, collection instructions and diagrams. For more information on specimen collection, refer to the Public Health Ontario (PHO) website.

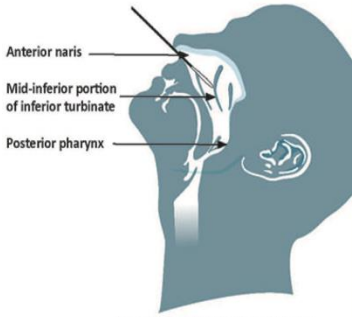
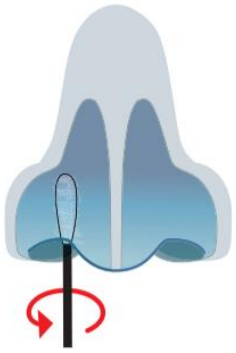
- Contrary to the regular laboratory-based PCR test, the Panbio™ COVID-19 Ag Rapid Test only accepts freshly collected specimens. Do not dilute with any solution (e.g., viral or other transport media) except for the extraction buffer provided in the kit.

- If transportation is required, pre-label an extraction tube provided with the kit with at least two (2) unique patient identifiers (e.g., name and date of birth), as well as the date and time of collection, fill the extraction tube with extraction buffer up to the fill line (300 µL), then collect and keep the swab in the extraction tube filled with buffer at room temperature (15˚-30˚C) for up to 2 hours from the time of collection.

Table 3: Panbio™ COVID-19 Ag Rapid Test Specimen Collection

Specimen Collection Site	Collection Instructions	Diagram
Nasopharyngeal swab • A nasopharyngeal (NP) swab is a controlled act and can only be conducted by a regulated health professional. • It is the specimen collection method with the highest sensitivity. • Use the swab provided in the manufacturer's kit.	1. Tilt patient's head back 70°. 2. Insert flexible shaft mini-tip swab through nares parallel to palate (not upwards) until: a. Resistance is met, OR b. Distance is equivalent to half the distance from the patient's ear to their nostril. 3. Gently rub and roll the swab. 4. Leave the swab in place for several seconds to absorb secretions. 5. Slowly remove the swab while rotating it and immediately place in pre-labelled tube containing buffer.	

Combined swab of throat and both nares ● A combined swab of the throat and both nares is an acceptable specimen collection method, although less sensitive than a NP specimen. ● 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 the swab several times against the nasal wall. 5. Leave the swab in place for several seconds to absorb secretions. 6. Using the same swab, repeat for the other nostril. Immediately place in pre-labelled tube containing buffer. *Swab insertion distance will differ for paediatric patients.	Steps 1-2:  Steps 3-5: 

Deep nasal swab ● A deep nasal swab is an acceptable specimen collection method, although slightly less sensitive than a NP specimen. ● Use the swab provided in the manufacturer's kit.	1. Tilt patient's head back 70°. 2. Insert the swab about 2.5 cm (approximately 1 in.)* straight back (not up) into nostril – stop when you meet resistance (at turbinates). 3. Rotate the swab several times against the nasal wall. 4. Leave the swab in place for several seconds to absorb secretions. 5. Repeat for both nostrils using the same swab. 6. Immediately place in pre-labelled tube containing buffer. *Swab insertion distance will differ for paediatric patients	 *In a seated position, tilt the head back at a 70° angle as illustrated in the picture*
Nasal swab ● A nasal swab is an acceptable specimen collection method, although less sensitive than a NP specimen. ● Use the swab provided in the manufacturer's kit.	1. Insert swab about 1 cm (0.5 in) inside the nares.* 2. Rotate the swab several times against the nasal wall. 3. Leave the swab in place for several seconds to absorb secretions. 4. Using the same swab, repeat for the other nostril. 5. Immediately place in pre-labelled tube containing buffer *Swab insertion distance will differ for pediatric patients.	

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

This information sheet includes questions commonly asked by individuals being tested with the Panbio™ COVID-19 Ag Rapid Test.

What is the Panbio™ COVID-19 Rapid Test?

- The Panbio™ COVID-19 Ag Rapid Test is a test for COVID-19 that gives results faster than a regular test (between 15 minutes and 2 hours).
- The test shows if you have a protein of the COVID-19 virus.
- It helps identify people who do not have symptoms but who have COVID-19.
- Compared to a regular COVID-19 test, Panbio™ has 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 testing 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 Panbio™ COVID-19 Ag Rapid Test?

- You may be offered a Panbio™ COVID-19 Ag Rapid Test if:
    - You have no symptoms
    - You haven't been in contact with someone who has COVID-19
    - You have passed regular COVID-19 screening
    - There are no suspected or confirmed outbreaks of COVID-19 at your facility

What will happen during my appointment?

- A health care provider will swab inside of your nose or both your nose and throat to take a sample for the rapid test.
- 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, (unless your workplace can do a swab for lab-based testing on-site) you will need to go to an assessment centre, 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 get 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 Panbio™ COVID-19 Ag 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 within 24 hours for a regular (laboratory-based) 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.
    - 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 Panbio™ COVID-19 Ag 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.

What happens if my Panbio™ COVID-19 Ag Rapid 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 have 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/

Appendix D: Primer on Best Practices for Panbio™ COVID-19 Ag Rapid Test

This primer highlights key best practices for the Panbio™ COVID-19 Ag Rapid Test.

Quality Oversight, Personnel, and Training and Competency

- ☐ Identify a rapid testing lead, who will be accountable for the quality of the rapid-testing program at your site.
- ☐ Identify health professionals, or other trained individuals who will collect specimens, perform testing, and communicate test results to individuals being tested.
- ☐ Train and confirm the competency of all staff involved in the entire testing process: pre-testing (e.g., specimen collection, labelling), testing, and post-testing (e.g., result recording/notification) and re-train if not involved in testing clinics in the last 3 months.

Facilities

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

Equipment and Supplies

- ☐ When receiving new kits, inspect and 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

☐ 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 Approach for Implementing a COVID-19 Rapid Antigen Screening Clinic

Prepare to Implement a COVID-19 Rapid Antigen Screening Clinic

Staffing Recommendations:

- Rapid antigen screening tests can be performed by health professionals, or other trained individuals (i.e., swab, process antigen test, and read and communicate screening result). Sites will typically require 2 to 3 staff members to operate a clinic.

- Changes have been made to Regulation 682 and Regulation 683 under *the Laboratory and Specimen Collection Centre Licensing Act* (LSCCLA) to broaden appropriate access to COVID-19 tests that are authorized by Health Canada for point-of-care use across the province. These changes allow a person to collect specimens and perform a COVID-19 point-of-care COVID-19 antigen test without the need for a laboratory licence.

- By exempting COVID-19 tests that are approved by Health Canada for point-of-care use from the LSCCLA, the list of who can perform the tests is much broader, enabling greater flexibility for implementation.

- Specimen collection for antigen testing may also be done by the person being tested ('self-swabbing') under the following specific circumstances:

    - If a trained individual, including a health care professional (regulated or unregulated) is supervising the self-swabbing
    - Any individual supervising self-swabbing must consult the self-swabbing training resource developed by Ontario Health in collaboration with Public Health Ontario and ensure they have the appropriate knowledge, skills, and judgment to provide appropriate self-swabbing oversight, including how to operate the device, PPE requirements, and how to safely dispose of waste

- Health professionals, or other trained individuals, are responsible for satisfying all applicable legislative and regulatory requirements, including those under the *Laboratory and Specimen Collection Centre Licensing Act* (LSCCLA), *Health Protection and Promotion Act* (HPPA), *Personal Health Information Protection Act* (PHIPA), *Health Care Consent Act* (HCCA), and the *Regulated Health Professions Act* (RHPA). Health professionals, or other trained individuals, 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 4: Example staffing model

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

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 (room temperature) 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 6- to 8-foot table (e.g., folding table with a non-absorbent surface that is easy to clean). 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.
- 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 3 people to operate and move around the clinic.

- Consider having sufficient space for an ample supply of hand-hygiene products, 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 testing lead of a preliminary positive result.

Considerations for Infection Prevention, Occupational Health, and Safety

- Sites should conduct a local risk assessment to ensure the safety of personnel performing the Panbio™ COVID-19 assay. At minimum, gloves, gowns, masks, and face shields are required, and a plexiglass shield should also be in place when a test is being conducted or a clinical specimen is being handled.

- Please note the Panbio™ COVID-19 buffer does not inactivate the virus[2] and the Panbio™ COVID-19 buffer contains substances that are eye and skin irritants and can be acutely toxic if ingested.[3]

Equipment and Supplies

- When receiving new kits, track test lot numbers and expiry date, being sure to use tests before they expire. Unused damaged or expired testing kits can be disposed of with regular waste.

- At the on-site clinic, store Panbio™ COVID-19 test kits at 15°C to 30°C (room temperature) and leave them sealed in their foil pouches until just before use. Kits must be at room temperature before use. Note that the storage and transportation of test kits between 2°C to 30°C is acceptable. Do not freeze the kits or their components. Freezing kits renders the tests invalid.

- Ensure Panbio™ COVID-19 buffers with different lot numbers or those for other products are not used together.

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[2] See Abbott Panbio™ COVID-19 Rapid Antigen Test: Biosafety Considerations for details and guidance from Public Health Ontario. https://www.publichealthontario.ca/-/media/documents/lab/covid-19-abbott-panbio-antigen-rapid-test-biosafety.pdf?la=en

[3] The Panbio™ COVID-19 device buffer contains < 0.1% sodium azide and chemicals that are eye and skin irritants. Refer to the Panbio™ COVID-19 Ag Rapid Test Device Safety Data Sheet for details and first aid measures and discard any leftover Panbio™ COVID-19 device buffer following the *Ontario Environmental Protection Act*.

Materials to Carefully Track Specimens During the Clinic

- Use an electronic tracker that records all staff working at the site who will be participating in the rapid antigen screening program. A laptop is helpful for maintaining accurate/real-time records (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 unique identifiers (e.g., name and date of birth).

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.
- Some congregate care settings with experience implementing rapid antigen testing clinics using Panbio™ have typically found that they can administer approximately 30 tests per hour.
- 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 schedule 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 each day the clinic is offered.

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:

To ensure that the test kits are functioning as they should, quality checks need to be done before starting to use the test kits and at regular intervals. Each box of 25 test kits comes with two control swabs: one positive control swab and one negative control swab to be used for quality checks. The control swabs contain samples so that when the quality checks are performed as per the process below, they will show either

positive or negative results, i.e., positive control swabs should yield positive results and negative control swabs should yield negative results.

For sites performing more than 25 tests/day, (i.e., more than one box of Panbio™ kits) perform quality checks with the control swabs at the beginning of the day before testing begins. For sites performing fewer than 25 tests/day, (i.e., less than one box of Panbio™ kits) perform control swabs each time a new kit box is opened or at least weekly, whichever is more frequent. In addition, control swabs should be tested with each new shipment of kits and with any new lot numbers of kits.

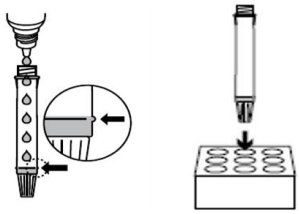
Follow the steps below to perform quality control checks:

1. Fill tube with buffer:

    - Hold buffer bottle and fill the extraction tube with buffer fluid until it reaches the fill-line (300 µl).

> **Caution:** If the amount of buffer is excessive or insufficient, an improper test result may occur.

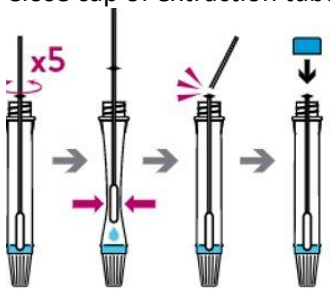
    - Place extraction tube in tube rack.
    - Put cap on buffer bottle and separate it from the testing area to avoid contaminating the buffer.



2. Insert control swabs:

    - Insert the positive or negative control swab in buffer fluid inside of the extraction tube and soak the swab for 1 minute.
    - Swirl the control swab tip in buffer fluid inside of the extraction tube, pushing into the wall of the tube at least 5 times. Squeeze the swab by squeezing the extraction tube.
    - Break the swab with the tip still in the tube; the broken end of the swab must be disposed of in a biohazard container.

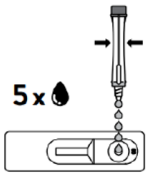
- Close cap of extraction tube.



3. Process control swab:
    - Open dropping nozzle cap and dispense 5 drops of the liquid onto the test kit.

> **Tip:** Bubbles in the extraction tube can lead to inaccurate results. If there is no free drop formation when dispensing the extracted control material onto the Panbio™ COVID-19 device specimen well, investigate for bubbles or blockage caused by the swab in the dispensing nozzle and shake the tube gently to displace the bubbles and/or swab.

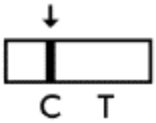
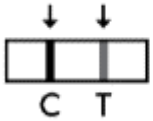
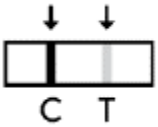
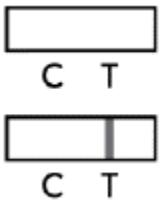
    - Place the test device on a flat surface and do not move the test device until the test is complete.
    - Discard the extraction tube recapped with a nozzle cap in a biohazard bin.
    - Set timer for 15 minutes to let extraction fluid react with test kit.



> **Reminder:** It is important to read the control test after at least 15 minutes and no more than 20 minutes.

4. Read and document result:

If:	**Then:**
Only the control line (C) is present.	The result is negative.

	The presence of only the control line (C) and no test line (T) within the result window indicates a negative result.
The control line (C) and the test line (T) are present. 	The result is positive. The presence of the control line (C) and the test line (T) within the result window, regardless of which line appears first, indicates a positive result.
The control line (C) is clearly present but the test line (T) is faint. 	The result is positive. The presence of any test line (T), no matter how faint, indicates a positive result.
The control line (C) is NOT present. 	The result is invalid. If the control line (C) is not visible within the result window after performing the test, the result is considered invalid. Instructions may not have been followed correctly or the sample was too viscous. It is recommended to read the instructions again before conducting repeat testing with a new specimen and a new test device.

Caution: If quality control swabs pass, proceed to testing. If quality control swabs are invalid, repeat quality checks with new control swabs. This will involve testing procedures with control swabs from a new box and reviewing your procedures. If problems persist, you can file a concern on the Ontario Health Digital Health Services Portal.

Workflow Recommendations:

Clinic operations should align, as best as possible, with the physical space recommendations provided above and allow for physical distancing (approximately 2 meters) between individuals operating the clinic. The workflow to implement a Panbio™ rapid antigen testing clinic for COVID-19 can be grouped into 6 stages:

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

1. Preparation

- Before preparing the test kits, conduct quality control testing, as described in the section above.
- Panbio™ test kits should be prepared in advance and should contain the following:
    - Extraction tubes, pre-filled with buffer fluid, as per the manufacturer's directions:
        - The buffer bottle should be held vertically, and the extraction tube filled with buffer fluid until it reaches the fill-line of the extraction tube (300µl).

> **Caution:** If the amount of buffer is excessive or insufficient, an improper test result may occur.
>
> **Tip:** To avoid contamination of the multi-use Panbio™ COVID-19 buffer bottle, ensure that the buffer bottle is kept separate from clinical specimens and the immediate testing area, that it is only handled with clean hands and gloves, and that the bottle cap is kept firmly sealed between each use.

    - Test cartridge(s)
    - Nasopharyngeal or nasal swab(s)
- Determine how test tubes and cartridges will be labelled with at least 2 participant identifiers that are unique (e.g., name and date of birth) to avoid errors.
    - The suggested process is to pre-print three labels containing staff information, one for the Panbio™ extraction tube and one for the test cartridge/device and one for a printed results sheet (if using).

Tip:	- Some congregate care settings with experience implementing on-site rapid antigen screening with Panbio™ have found it helpful to prepare extraction tubes with the buffer in small batches (e.g., 5 to 10 tests at a time).

2. Intake

- Inform staff member of the testing process.
- Record that the staff member will be tested in the electronic or paper tracker.
- Label a Panbio™ tube with the appropriate participant information for tracking using a pre-printed label.
- Label a corresponding Panbio™ test cartridge.
- Direct the staff member to the rapid-test station.

3. Specimen Collection

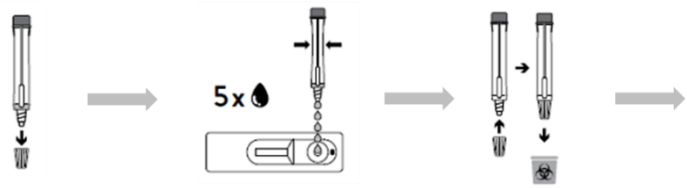
- **Person A** places a label (with two unique identifiers) of the staff member being tested (if possible, use pre-printed labels) on an extraction tube.
- **Person A** places the pre-filled labelled extraction tube in the tube rack.
- **Person B** collects a swab with the dedicated rapid-test swab and places the swab in the labelled extraction tube. Do not dilute the collected swab with any solution expect for the provided extraction buffer.
- The swab tip is swirled in the buffer fluid inside the extraction tube then pushed into the wall of the extraction tube at least five (5) times.
- **Person B** squeezes out the swab by squeezing the extraction tube with their fingers.
- **Person B** breaks the swab at the breakpoint and places the extraction tube cap on. The broken part of the swab is disposed of in the biohazard container.
- The extraction tube with the swab is placed in a second tube holder.

Tip: For optimal test performance, test specimens immediately after collection; if not possible, keep specimens in the capped extraction tube filled with the Panbio™ COVID-19 extraction buffer at room temperature (15˚-30˚C) for up to two (2) hours from time of collection.

- **Person B** changes gloves and performs hand hygiene after each swab.

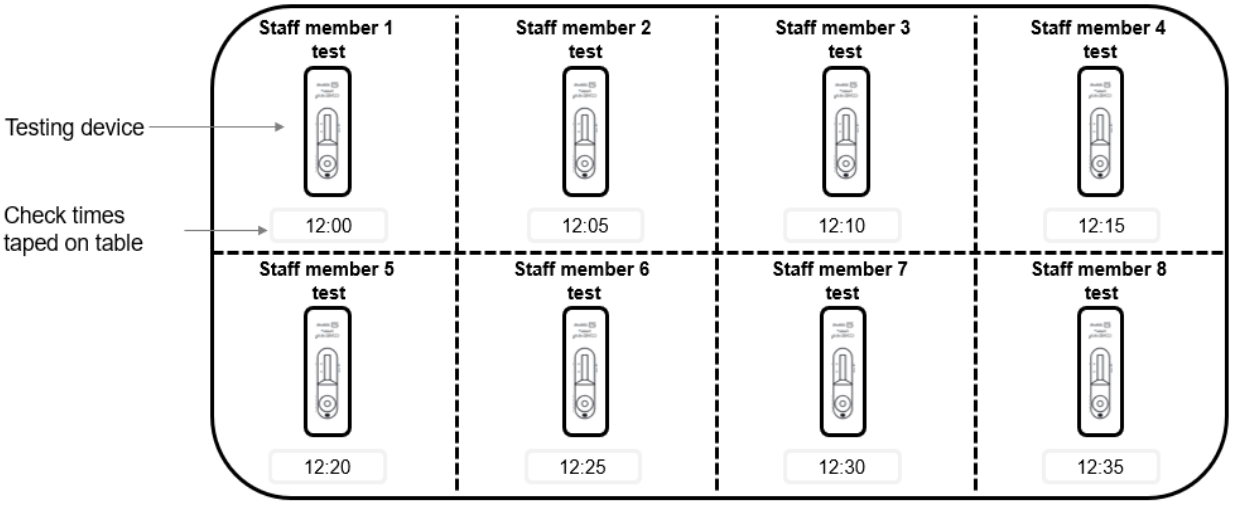
4a. Testing the specimen - Option 1

- **Person C** opens a test device and places a pre-printed label on the device to correspond with the staff member's name on the extraction tube that will be tested (i.e., if John Smith's extraction tube is to be tested, John Smith's label should be placed on the test kit).
- Each extraction tube that will be tested should have a corresponding test device. DO NOT re-use test devices.
- **Person C** takes the extraction tube (with specimen in it) from the second tube holder, holds it vertically, removes the nozzle cap from the bottom, and dispenses 5 drops into the well of the test kit.
- Discard the extraction tube with the nozzle cap in place in the biohazard bin.
- **Person C** checks the time on the clock, adds 15 minutes, writes this on a piece of masking tape and places the masking tape next to the test device (i.e., if time is 12:00, then 12:15 is written on masking tape). The time on the tape indicates when the test device should be checked, and the result recorded.



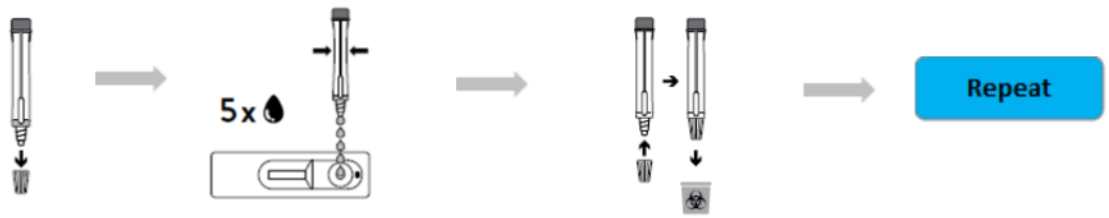
Person C repeats steps A-E for the **next extraction tube** to be tested and places each **testing device** and **masking tape** on different sections of the table.

Figure 2: Testing Station Visual Representation for Option 1



4b. Testing the Specimen – Option 2

- **Person C** sets out 5 to 10 test cartridges (depending on number of staff to be tested).
- **Person C** opens all test devices for the batch and places a pre-printed label on each device to correspond with the staff member's unique identifiers on the extraction tube that will be tested (i.e., if John Smith's extraction tube is to be tested, John Smith's label should be placed on John Smith's test kit).
- **Person C** takes the extraction tube (with specimen in it) from the second tube holder, holds it vertically, removes the nozzle cap from the bottom, and dispenses 5 drops into the well of the test kit.
- Discard the extraction tube with the nozzle cap in place in the biohazard bin.
- **Person C** repeats steps B through D for the next extraction tube to be tested.

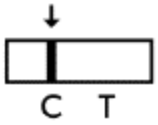
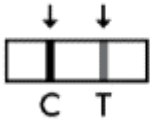
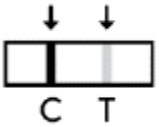
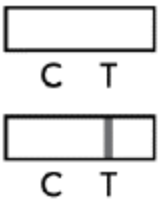


Notes on Specimen Testing:	- **Tip**: Bubbles in the extraction tube can lead to inaccurate results. If there is no free drop formation when dispensing the extracted control material onto the Panbio™ COVID-19 device specimen well, investigate for bubbles or blockage caused by the swab in the dispensing nozzle and shake the tube gently to displace the bubbles and/or swab. - Each extraction tube that will be tested should have a corresponding test device. DO NOT re-use test devices. - Testing table should be cleaned and sectioned off prior to the start of the clinic. - Clean up any spillage with appropriate disinfectant. - DO NOT move the test device until the test is complete. - Change gloves and perform hand hygiene after handling each extraction tube.

5. Reading the Results

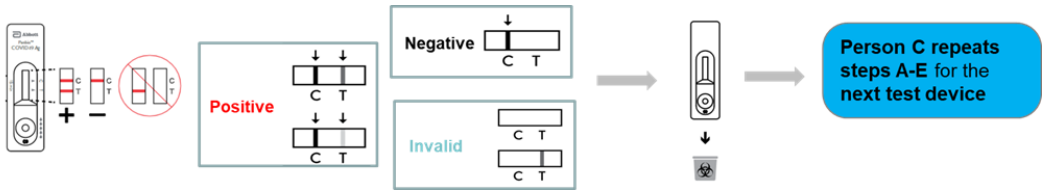
- **Person C** checks the times on the masking tapes (if using option 1). When the check time has been reached, **Person C** records each result on the staff list or electronic results tracker. The result is found in the rectangular window of the test device. Results need to be checked within 5 minutes of the time on the masking tape.
- If using option 2, results need to be checked 15 to 20 minutes after the sample was dropped into the well. Do not read the results after 20 minutes has passed.

- Interpreting results:

If:	Then:
Only the control line (C) is present. 	The result is negative. The presence of only the control line (C) and no test line (T) within the result window indicates a negative result.
The control line (C) and the test line (T) are present. 	The result is positive. The presence of the control line (C) and the test line (T) within the result window, regardless of which line appears first, indicates a positive result.
The control line (C) is clearly present but the test line (T) is faint. 	The result is positive. The presence of any test line (T), no matter how faint, indicates a positive result.
The control line (C) is NOT present. 	The result is invalid. If the control line (C) is not visible within the result window after performing the test, the result is considered invalid. Instructions may not have been followed correctly or the sample was too viscous. It is recommended to read the instructions again before conducting repeat testing with a new specimen and a new test device.

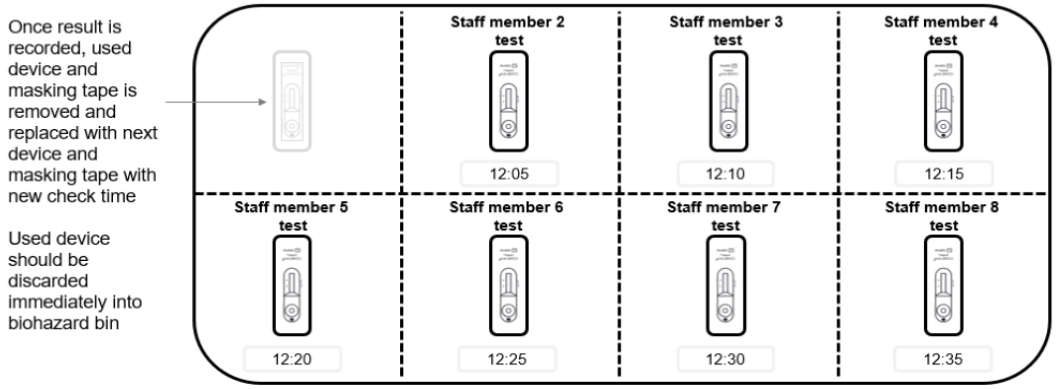
Caution: Temporarily pause testing while waiting for repeat testing results after an invalid test result. If an invalid result is obtained a second time, stop all staff testing until the cause of the control failures has been determined and corrected. This will involve testing procedures with a new lot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

- Dispose of the used device in the biohazard container.
- Remove and dispose of the corresponding masking tape label from the table.
- At the end of rapid testing clinic, **Person C** checks that all results have been recorded on the staff list or electronic results tracker and saves and stores the file securely.



- Prepare for the next set of tests.

Figure 3: Visual Representation for Option 2



7. Communicating and Documenting Results

Note: All personnel must ensure that all personal and health information are collected, used, disclosed in accordance with relevant legislation, including the *Personal Health Information Protection Act* (PHIPA).

- **Communicating Results**
  - If a Test Result is Negative:
    - Key message: Counsel individuals 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 directly 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.
  - If a Test Result is Positive:
    - Key message: Counsel individuals that the positive result is considered preliminary positive, and they will need to have a PCR test within 24 hours for confirmation.
    - Require that the individual receive confirmatory lab-based PCR test within 24 hours.
  - 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.

- **Documenting and Reporting Results**

  - If applicable, health professionals, or other trained individuals, 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). Health professionals, or other trained individuals, must ensure proper documentation is in place when performing COVID-19 rapid antigen testing.

  - 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 employees who tested positive with a rapid antigen test
    - Number of employees 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: Panbio™ COVID-19 Ag Rapid Test Site Go-Live Readiness Checklist

#	Requirement	Completed
1	Reviewed the Ministry of Health's COVID-19 Guidance: Considerations for Rapid Antigen Screening.	
2	Reviewed the Panbio™ COVID-19 Antigen Rapid Testing Onboarding Guide for Congregate Settings.	
3	Panbio™ COVID-19 Antigen Rapid Testing implementation procedures have been reviewed and are understood by the staff conducting rapid antigen testing.	
4	Two to three (2 to 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 Panbio™ COVID-19 Ag Rapid Test kits.	
7	Additional materials required for testing are available: ● PPE for clinic staff (mask, gown, face shield); ● Plexiglass shield to perform test behind; ● 2 biohazard waste containers; ● Masking tape; ● Box of gloves; ● Clock; ● Disinfectant (clean spills, wipe down equipment pre/post clinic); and ● Hand sanitizer.	
8	Dedicated space for testing identified.	
9	Process for documenting results established.	