

Long-Term Care Antigen Screening Pilot: Information Document

The Long-Term Care Antigen Screening Pilot is a voluntary program being led by the Ministry of Health, with support from the Ministry of Long-Term Care, Public Health Ontario, and Ontario Health.

The Long-Term Care Antigen Screening Pilot is in addition to, and does not replace, any screening and testing required in accordance with the *Long-Term Care Homes Act, 2007*, any Minister's Directive made under it or any other Ministry of Health and Ministry of Long-Term Care Directives and policy (including CMOH Directives requiring testing).

This information document is meant to outline the key information required to support the successful implementation of the provincial Long-Term Care Antigen Screening Pilot program and includes details on the following:

1) Pilot Program Guidance

- What is the Long-Term Care Antigen Screening Pilot?
- What is the Panbio™ COVID-19 Antigen Screening Test?
- What are the benefits of participating in the pilot?
- Who is eligible to participate in the pilot?
- What does participation in the pilot entail?
- What are the data collection and reporting requirements associated with the evaluation of this pilot?
- What are the financial considerations for this pilot?

2) Clinical Guidance: Parameters for the Use of the Panbio™ in the Long-Term Care Antigen Screening Pilot

- Who can Perform the Panbio™ Test?
- Parameters for the Use of the Panbio™ Antigen Screening Test in the long-term care pilot
 - i. Protocols for testing using the Panbio™ in long-term care homes
 - ii. Protocols for interpreting results
 - iii. Public health role in declaring an outbreak in the context of this pilot

Note

This document is intended for use by Panbio™ Screening Test Pilot program participants during the initial implementation of rapid antigen testing in Ontario. This is a **living document** and includes guidance supported by currently-available evidence. **As evidence evolves, this document will be updated accordingly.**

Pilot Program Guidance

What is the Long-Term Care Antigen Screening Pilot?

The Long-Term Care Antigen Screening Pilot is one arm of a broader antigen screening pilot program being rolled out to employers across the province. The overarching objective of the broad pilot program is to assess the value of the **Panbio™ antigen test** as a screening tool to support safety and business continuity in a variety of workplaces, including long-term care. In the long-term care setting specifically, the Panbio™ is intended for screening of long-term care staff, students, volunteers, caregivers and support workers, and general visitors. Results from this pilot will support an increased understanding of how rapid antigen testing could be deployed more broadly to support provincial COVID-19 response activities.

The long-term care-based pilot will be implemented beginning in November 2020. Participation is voluntary, and long-term care homes that participate in the pilot program will be provided with Panbio™ tests from the Ontario government at no cost to the homes.¹

What is the Panbio™ COVID-19 Antigen Screening Test?

The Panbio™ is a rapid point-of-care antigen test, meaning that it can be performed anywhere (i.e. on-site, at the long-term care facility) by a regulated health professional (see [Who Can Perform the Panbio™ test?](#)) and does not require shipping a specimen to a lab for processing. It is currently administered through a **nasopharyngeal swab** and takes approximately 15 minutes to yield results. An overview of how the test is performed can be found [here](#). Further information on instructions for use can be found [here](#).

Rapid antigen tests are less sensitive than the lab-based polymerase chain reaction (PCR) tests that are performed at COVID-19 Assessment Centres and pharmacies. Because it is a new test, data specifically related to Panbio™'s accuracy as a screening tool is primarily from lab-based studies, which may not be entirely reflective of real world experience. Data from Abbott, the company that developed the Panbio™, suggests that it has 93.3% sensitivity and 99.4% specificity. Other studies have shown sensitivity results ranging from 72.1% - 86.5%, and specificity of 95% and above.² Generally, these results indicate that the Panbio™ may inaccurately yield negative results (i.e. false negatives) in individuals who are infected approximately 30% of the time.

More details on the parameters for the use of the Panbio™ test in this long-term care-based pilot are outlined in the [Parameters for the Use of the Panbio™ in the Long-Term Care Antigen Screening Pilot](#) section of this document.

¹ The pilot program is using the Panbio™ tests provided to Ontario by the Federal government and is therefore dependent on the supply of Panbio™ COVID-19 tests from the Canadian federal government.

² Linares, M. et al., *Journal of Clinical Virology* 2020; Albert, E. et al., 2020; Gremmels, H. et al., 2020.

The Ontario government will continue to monitor Health Canada approval of additional rapid testing devices for potential implementation within this pilot program in the future.

What are the Benefits of Participating in the Pilot?

A key benefit of participating in the Long-Term Care Antigen Screening Pilot is that, in combination with core prevention methods, it may serve as a tool to provide early identification of an individual infected with COVID-19.

Who is Eligible to Participate in this Pilot?

The Long-Term Care Antigen Screening Pilot is one arm of a broader antigen screening pilot being implemented across the province. The overarching goal of the broader antigen screening program is to learn about the effectiveness of the Panbio™ test as a screening tool in a variety of settings, including long-term care as one specific sector/setting.

Long-term care homes can apply to this pilot program by contacting the Ministry of Long-Term Care at Ltc.Info@ontario.ca.

What Does Participation in the Pilot Entail?

Participating long-term care homes will have flexibility in the frequency and targeting of individuals for Panbio™ testing. Eligible populations for testing include long-term care staff, volunteers, students, caregivers and support workers, and general visitors. A participating long-term care home may choose to phase pilot testing by targeting staff first and then expand testing to include other eligible populations.

Participation in screening on the part of eligible populations as part of this pilot is entirely voluntary. Long-term care homes must seek consent from those participating in the screening test on a voluntary basis before administering the Panbio™ test.

Participating long-term care homes will be provided Panbio™ tests from the provincial government at no cost to the homes, pending available inventory. Homes may receive up to three Panbio™ tests per week, per participating individual for the foreseeable future, pending available inventory. Homes must request the number of tests they require.

The tests distributed through this pilot program are to be used only for Ontario-based long-term care homes.

What are the Data Collection and Reporting Requirements Associated with the Evaluation of this Pilot?

The government will be collecting data from participating sites to support the evaluation of the pilot program and the value of the Panbio™ test as an effective and accurate screening tool for COVID-19. The information

gathered will inform future decision-making regarding its continued and/or expanded use in the long-term care sector.

The government will request information from participating long-term care homes every week (i.e. every seven days), and the reporting period for each week will run from Saturday to Friday. The following information will be required from participating long-term care homes:

- Number of Panbio™ tests used
- Number of individuals tested
- Number of positive Panbio™ test results
- Number of negative Panbio™ test results
- If known, the number of positive Panbio™ tests that resulted in a confirmed positive COVID-19 result through a follow-up, lab-based PCR test
- If known, the number of positive Panbio™ tests that resulted in a negative COVID-19 result through a follow-up, lab-based PCR test

The government will provide an update to long-term care homes in the upcoming weeks regarding the length of time for which these data points must be collected and reported to inform the evaluation. For now, long-term care homes will be required to report the above information on a weekly basis until otherwise notified.

The government may request additional information throughout the course of the pilot program as it evolves in order to inform future use cases for these rapid tests, and the impact of antigen screening in a range of settings, at which time, this guidance document will be updated to reflect those reporting requirements accordingly.

What are the Financial Considerations for this Pilot?

The provincial government will provide participating long-term care homes with the appropriate number of Panbio™ tests kits at no cost to the homes, dependent on available inventory.

Clinical Guidance:

Parameters for the Use of the Panbio™ in the Long-Term Care Antigen Screening Pilot

Who Can Perform the Panbio™ Test?

Health care providers should refer to the manufacturer's instructions to ensure the test is conducted appropriately.

In accordance with recent regulatory changes under the *Laboratory and Specimen Collection Centre Licensing Act*, the following healthcare providers may swab a patient and/or perform the Panbio™ test if they can perform any controlled acts as required to do so: physicians, nurse practitioners, registered nurses, registered practical nurses, pharmacists, dentists, paramedics, and community paramedicine practitioners.

Requisition forms are not required for health care providers performing the Panbio™ point-of-care test as part of this pilot program. Health care providers are responsible for meeting their professional obligations and ensuring proper documentation is in place when performing COVID-19 rapid antigen testing.

Health care providers 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, 2004 \(PHIPA\)](#), [Health Care Consent Act, 1996 \(HCCA\)](#), and the [Regulated Health Professions Act, 1991 \(RHPA\)](#).

Parameters for the Use of the Panbio™ Antigen Screening Test in the Long-Term Care Pilot

Because the Panbio™ rapid antigen test is less sensitive and specific than lab-based PCR tests, results do not perform with the same individual diagnostic accuracy as lab-based tests. As such, the Panbio™ can yield some false negative test results (i.e. a result that indicates the individual is not infected with COVID-19 when in fact they are), and false positive test results (i.e. a result that indicates the individual is infected with COVID-19 when in fact they are not).

Results from the Panbio™ must therefore be interpreted with caution, **and the following protocols for its use, including the specific scenarios for its use, must be adhered to throughout the duration of the pilot** among all participating long-term care homes.

i. Protocols for Testing Using the Panbio™ in Long-Term Care Homes

- For the purpose of this pilot, the Panbio™ is to be used in long-term care homes ([inclusive of homes in green, yellow, orange, red, and lockdown zones](#)) that are **not in outbreak**.

- The Panbio™ screening test should be used **only on asymptomatic individuals** who have passed initial standard screening. It should not be used for symptomatic individuals, or individuals who have had close contact with a known positive case in the past 14 days. Symptomatic individuals, or individuals who have had close contact with a known positive case, should be directed to a COVID-19 Assessment Centre for testing.
- As per provincial testing guidance, **individuals who have previously been infected with and recovered from COVID-19 should generally not undergo repeat testing**, including by rapid antigen testing as part of this pilot program.
- The Panbio™ screening test **does not replace infection prevention and control measures** such as symptom screening, appropriate distancing, use of personal protective equipment (PPE), and hand-washing activities. These measures are essential to *prevent* the transmission of COVID-19, whereas testing can only identify individuals after transmission has occurred.
- The Panbio™ antigen test **does not replace routine, lab-based PCR testing of staff, students, or volunteers, or satisfy requirements under the Minister’s Directive: COVID-19: Long-Term Care Home Surveillance Testing And Access To Homes, effective November 23 for long-term care home licensees to ensure lab-based PCR testing of staff, students and volunteers, as required by the Directive, and to ensure that caregivers, support workers and general visitors provide proof of a negative PCR result and an attestation to not having subsequently tested positive, as required by the Directive.**
- The Panbio™ test must be used in **accordance with the manufacturer’s instructions**.

ii. **Protocols for Interpreting Results**

A. **In the case of a positive result on the Panbio™**

A positive result on the Panbio™ is considered a preliminary positive, and the following actions must be taken:

- The individual must receive a confirmatory PCR test immediately, at the long-term care home (i.e. a dual swab protocol of both Panbio™ and immediate PCR test).
 - A confirmatory PCR swab to validate all preliminary positive results from the Panbio™ will be required for a minimum of three weeks, to inform the evaluation of this pilot program. A comparison of results from the Panbio™ and the confirmatory PCR will serve to validate the Panbio™’s accuracy in this setting, and the potential to expand its use across the province in the future. Long-term care homes will be notified when the protocol for dual, confirmatory PCR swabbing changes.
- The individual and their close contacts must isolate immediately, pending results of the confirmatory, lab-based PCR test.
- Where daily COVID-19 specimen collection has been put in place the long-term care facility may submit the specimen through that channel. In cases where standing routing has not been

established the long-term care facility is asked to schedule a pickup with their regular specimen collection partner for COVID-19 specimens or to contact Covid-19.diagnostics@ontariohealth.ca for routing support.

- Public health direction requires that a preliminary positive on the Panbio™ be reported to the local [Public Health Unit](#) immediately.
- Individuals tested with the Panbio™ who receive a positive result should be informed that Panbio™ antigen screening does not yield accurate results 100% of the time. As such, they should be reminded that the test result should be interpreted as a *preliminary* positive and that the result may be inaccurate, in order to reduce potential anxiety on the part of that individual.
- Ensure the Panbio™ result is recorded as part of the mandatory data collection and reporting requirements for this pilot.

B. In the case of a negative result on the Panbio™

A negative result on the Panbio™ does not require further confirmatory testing. However, the following actions must be taken:

- The individual tested should be reminded of the possibility that the result may be inaccurate. Participating long-term care homes should reinforce the mandated COVID-19 infection prevention and control measures, such as appropriate distancing, use of PPE, and hand washing, to reduce the risk of infection.
- Ensure the Panbio™ result is recorded as part of the mandatory data collection and reporting requirements for this pilot.

C. Public Health Role in Declaring an Outbreak in the Context of the Pilot

Panbio™ results will not be used to determine the presence of a COVID-19 outbreak. Additionally, long-term care homes are not responsible for determining whether they are in a suspected or confirmed outbreak. Rather, 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 a positive result on a confirmatory, lab-based PCR.

Quick Reference: Guide for Interpreting Panbio™ Results

Interpreting Panbio™ Results in a Non-Outbreak Scenario, for Long-Term Care Homes

Rapid testing **does not replace** routine, lab-based PCR testing of long-term care staff, students, and volunteers under Minister's Directive under the *Long-Term Care Homes Act*.

What is the protocol if I see a...

