Rapid Antigen Testing Questions and Answers

COVID-19 Testing Requirements

1.Who must be tested for COVID-19?

As per the Minister's Directive: COVID-19: Long-Term Care Home Surveillance Testing and Access to Homes (Minister's Directive) effective January 8, 2021, all staff, student placement and volunteers working in long-term care homes must be tested regularly in accordance with the Minister's Directive, unless the exception for individuals who have previously had laboratory confirmed COVID-19 applies.

The testing requirements in the Minister's Directive include all individuals working in long-term care homes who are:

- Staff as defined in the Long-Term Care Homes Act, 2007
- Volunteers as defined in the Long-Term Care Homes Act, 2007
- Student placement, meaning any person working in the long-term care home as part of a clinical placement requirement of an educational program of a college or university, and who does not meet the definition of "staff" or "volunteer" under the Long-Term Care Homes Act, 2007.

The Minister's Directive also includes additional testing and documentation requirements for general visitors, caregivers and support workers.

2. Are sales representatives or maintenance workers subject to the Minister's Directive?

A sales representative is a general visitor under the COVID-19 Visiting Policy and is subject to the same requirements that apply to general visitors under the Minister's Directive.

The long-term care home must determine if the maintenance worker is a "staff" member for the purposes of the *Long-Term Care Homes Act, 2007* or accessing the home as a visitor. If the long-term care home determines that the maintenance worker is a visitor, the individual would be considered a support worker and the home must follow the testing related requirements for support workers under the Minister's Directive. Alternatively, if the maintenance worker is a staff member, the long-term care home must follow the testing related requirements for staff under the Minister's Directive.

3. Does the Minister's Directive apply to government inspectors?

The Minister's Directive sets out testing and documentation requirements that every licensee must follow with respect to staff, volunteers, student placements, caregivers, support workers, and general visitors, as those terms are defined in the Minister's Directive, the Long-Term Care Homes Act, 2007, and Ontario Regulation 79/10.

As government inspectors do not fall under any of these categories, they are not subject to the testing requirements in the Minister's Directive. Examples of government inspectors include inspectors under the Long-Term Care Homes Act, 2007, the Health Protection and Promotion Act, and the Occupational Health and Safety Act.

4. Can homes ask a person visiting a very ill or palliative resident to demonstrate that they have received a negative PCR test result or take an Antigen test?

Homes may not ask a person who is visiting a very ill or palliative resident to demonstrate that they have received a negative PCR test result, verbally attest to not subsequently tested positive or take an Antigen test.

5. What type of test for COVID-19 can be done to meet the surveillance testing requirements?

Currently, COVID-19 testing can be done using a validated real-time polymerase chain reaction (PCR) assay laboratory test **or** a point-of-care rapid antigen screening test (antigen test) in accordance with the protocols and frequency contained in the <u>COVID-19 Guidance:</u> <u>Considerations for Rapid Antigen Screening</u> (Provincial Testing Guidance).

Long-term care homes are to transition to rapid antigen screening as soon as possible to make it simpler and faster to identify potential COVID-19 positive cases and to become fully operational under the mandatory Provincial Rapid Antigen Screening program in accordance with the following schedule:

Region	Transition Period	Provincial Rapid Antigen Screening Program in Place
Durham Region Health Department	February 8 to 15,	February 16, 2021
Ottawa Public Health	2021	
Peel Public Health		
Simcoe-Muskoka District Health Unit		
Toronto Public Health		
Windsor-Essex County Public Health Unit		
York Region Public Health Services		
All other public health units	February 16 to 21, 2021	February 22, 2021

6. What if a home is in outbreak? Does the transition schedule still apply?

Homes in outbreak are instructed to contact the ministry to discuss specific modified deadlines for mandatory transition to a fully operational Provincial Rapid Antigen Screening program and will be assessed on case by case basis.

7. What is the Panbio™ COVID-19 Ag Rapid Test?

The Panbio™ COVID-19 Ag Rapid Test is an antigen test that can be used for point of care testing to detect COVID-19 faster than the regular laboratory-based PCR test for COVID-19. Currently, all rapid antigen screening is being conducted using the Panbio™ test. In the future, additional devices may be used for rapid antigen screening, pending Health Canada approval and availability.

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

The Panbio™ COVID-19 Ag Rapid test should only be performed on asymptomatic individuals for screening purposes using a testing device that has been approved by Health Canada and is available in Ontario.

The Panbio™ COVID-19 Ag Rapid test should NOT be used for diagnosis of COVID-19 infection. Any individual who is symptomatic or a contact of a confirmed case should be directed to their healthcare provider, an assessment centre, or participating licensed community lab to seek PCR testing.

9.Do long-term care homes have to conduct the rapid antigen tests themselves?

The ministry is exploring developing a Vendor of Record to connect LTC homes wishing to contract with providers to conduct surveillance screening clinics on their behalf in the LTC home. The ministry would look to developing and providing the necessary templates and service agreements to support licensees in making decisions regarding entering into contracts with providers and the terms and conditions on which services are provided. The Vendor of Record would be optional and would not prevent homes from contracting with a qualified vendor that is not on this roster.

10. How often must staff, student placement and volunteers be tested for COVID-19 with the antigen test?

Long-term care home licensees are required to conduct frequent COVID-19 testing of staff, student placements and volunteers in accordance with the protocols and frequency described in the Ministry of Health's Provincial Testing Guidance, unless the exception in the Minister's Directive for previous laboratory confirmed COVID-19 applies.

- Specimen collection and screening for asymptomatic individuals in high prevalence areas (Yellow/Orange/Red/Grey) should be performed 2-3 times per week.
- Specimen collection and screening for asymptomatic individuals in low prevalence areas (Green) should be performed 1-2 times per week.
 - The lower end of the frequency range would meet the compliance requirements of the Directive. However, homes are encouraged to test at a higher frequency to help reduce asymptomatic transmission of COVID-19.

Where a staff, student placement or volunteer enters a long-term care home less often than the frequency contemplated in the Provincial Testing Guidance, homes must ensure that the staff, student placement or volunteer takes an antigen test upon entry on the days on which they are entering the long-term care home in accordance with the protocols contained in the Provincial Testing Guidance.

11. Will long-term care homes be required to transition from the PCR test to an antigen test?

Yes, the ministry has announced start dates for homes to have fully operational antigen screening programs. The schedule is as follows:

- Public Health Unit: LTC Homes in:
 - Toronto Public Health, York Region Public Health Services, Peel Public Health, Windsor-Essex County Public Health Unit, Ottawa Public Health, Durham Region Health Department and Simcoe-Muskoka District Health Unit.

- Proposed Effective Date: Homes must be fully operational using the Panbio[™] rapid antigen test by February 16, 2021.
- Public Health Unit: LTC Homes in:
 - All other Public Health Units
 - Proposed Effective Date: Homes must be fully operational using the PanbioTM rapid antigen test by February 22, 2021.

12. Why are long-term care homes being asked to start using antigen tests for surveillance testing of staff, students and volunteers?

The Panbio™ COVID-19 Ag Rapid Test is an antigen test used for point-of-care testing that detects COVID-19 in 15 to 20 minutes and makes it simpler and faster to identify potential COVID-19 positive cases that otherwise may be missed. It also preserves the provincial lab network's capacity and ability to provide diagnostic test results in a timely manner.

13. If an individual previously tested positive for COVID-19, should they be tested again?

An individual who has previously had laboratory-PCR confirmed COVID-19 and was cleared by the local public health unit (PHU), should generally not be re-tested for surveillance purposes due to persistent shedding. Previously cleared individuals should continue to follow public health guidance for COVID-19 prevention, including self-isolating after high risk exposures to cases.

Re-testing after clearance should generally only be done with new the onset of new COVID-19 symptoms and can be considered if there is exposure to a confirmed case of COVID-19 or in an outbreak and/or at the direction of the local PHU. Individuals who have previously been infected with and recovered from COVID-19 should not undergo antigen testing.

14. How can long-term care homes determine that a person who has previously tested positive for COVID-19 has been cleared by the local public health unit?

A long-term care home should:

- 1. Ask the individual to demonstrate proof of their past laboratory confirmed positive COVID-19 test result.
- 2. Ensure that more than 10 days have passed since the date the test was administered.
- 3. Ask the individual to verbally attest that:
 - a. They have completed their isolation period as directed by a local public health unit; and,

b. Since completing their isolation period, they have not been identified as a COVID-19 case or a contact by the local public health unit.

15. If an individual has been vaccinated or immunized for COVID-19, do they still need to be tested prior to visiting a long-term care home?

Yes, the testing requirements of the Minister's Directive continue to apply to individuals who have been vaccinated, in addition to continuing to follow public health measures including masking, physical distancing, hand hygiene, and symptom screening. This includes active screening on entry to the long-term care home for symptoms and exposures for COVID-19, including temperature checks, attesting to not be experiencing any of the typical and atypical symptoms of COVID-19 (in accordance with Directive #3 issued by the Chief Medical Officer of Health).

Rapid Antigen Testing

16. 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 patient populations varies based on specimen type collected and pre-test probability of COVID-19 in the patient being tested.

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

A positive test result on the rapid antigen test should be considered a preliminary positive and requires a confirmatory laboratory-based PCR test. The following actions should be taken:

- 1. Counsel individual that the result is preliminary positive and PCR confirmation is required.
- 2. Issue guidance to return home and self-isolate until receipt of confirmatory laboratory PCR test result.
- 3. Ensure confirmatory laboratory-based PCR testing is performed within 24 hours.
- 4. Report the preliminary positive result to the local Public Health unit as soon as possible.

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

A new specimen is required from the individual that tests positive on the rapid antigen test for the confirmatory laboratory-based PCR test.

19. Does a preliminary positive result on the Panbio™ COVID-19 Ag Rapid Test mean the long-term care home is in outbreak?

No, a preliminary positive result does not mean the long-term care home 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 a positive result on a confirmatory, labbased PCR.

Conducting the Test

20. Do individuals need to provide consent every time they are tested?

The health practitioner administering the COVID-19 test must obtain the consent of the individual in accordance with the *Health Care Consent Act, 1996*. An individual must consent to a test for COVID-19 before the test can be administered—this includes staff, student placements, volunteers, caregivers, support workers and general visitors.

21. Can rapid antigen testing be conducted throughout a shift/visit or will individuals need to be screened prior to entry?

During the transition period, homes should be screening staff in accordance with the protocols and frequency described in the Ministry of Health's Provincial Testing Guidance, prior to starting their shift or beginning their visit— to identify possible positive COVID-19 test results before congregating with other staff and residents.

When rapid antigen testing programs are fully operational, homes must ensure that only staff, student placements, volunteers, caregivers, support workers and general visitors that have received negative antigen test results are granted entry into the LTC home.

22. What happens if individuals refuse to be tested?

The health and safety of individuals in long-term care homes is a top concern. Testing results help protect individuals in the home (e.g., staff, student placement, volunteers, residents) from exposure to infectious diseases. As provided in the Minister's Directive, every licensee of a long-term care home must ensure that no staff, student placements, volunteers, caregivers, support workers or general visitors enter the long-term care home unless the requirements contained in the Minister's Directive for testing have been met.

Pursuant to the Minister's Directive, long-term care homes must refuse entry to staff, student placements, volunteers, caregivers, support workers or general visitors if the requirements in

the Minister's Directive, including for testing are not met.

23. Can a long-term care home determine their own testing dates for staff, student placements and volunteers, or will these dates be assigned from Ontario Health?

Currently, testing dates for staff, student placements and volunteers can be determined by long-term care homes, but must comply with the required testing frequency in accordance with the protocols contained in the Provincial Testing Guidance and that PCR tests be taken in accordance with the frequency contained in the Minister's Directive (dated January 8, 2021).

As homes transition to become fully operational under the mandatory Provincial Rapid Antigen Screening program, the Minister's Directive will be updated and will be prescribing the testing frequency which will be performed three times per week, on non-consecutive days for staff, students and volunteers entering a LTC home two or more days in a 7-day period. For staff entering a home only once in a 7-day period, the test must be performed on the "day of". Homes are responsible for ensuring only those with a negative antigen test result are allowed to interact with residents and congregate with other staff.

24. What are the testing requirements for staff, student placements and volunteers who occasionally enter the long-term care home?

Where a staff, student placement or volunteer enters a long-term care home less often than the frequency contemplated in the Provincial Testing Guidance, homes must ensure that the staff, student placement or volunteer takes an antigen test upon entry on the days on which they are entering the long-term care home in accordance with the protocols contained in the Provincial Testing Guidance.

25. What are the testing requirements for caregivers, support workers and general visitors?

Licensees are required to ensure that caregivers, support workers and general visitors are tested in accordance with the requirements in the Minister's Directive.

Caregivers and Support Workers

Subject to exceptions in the Minister's Directive, every licensee shall ensure that all caregivers and support workers demonstrate that they have received a negative COVID-19 test result before granting them entry as a visitor, whether the visit will take place indoors or outdoors:

a. Green and Yellow Levels. For long-term care homes located in PHU regions in green-prevent or yellow-protect levels, licensees shall ensure that caregivers and support workers demonstrate that they have received a negative PCR Test result in the past two weeks and verbally attest to not subsequently having tested positive OR have a negative Antigen Test result on the day of the visit.

b. Orange, Red and Grey Levels. For long-term care homes located in PHU regions in orange-restrict, red-control or grey-lockdown levels, licensees shall ensure that caregivers and support workers demonstrate that they have received a negative PCR Test result in the past week and verbally attest to not subsequently having tested positive OR have a negative Antigen Test result on the day of the visit.

General Visitors

Subject to exceptions in the Minister's Directive, every licensee shall ensure that for general visitors:

- a. Green and Yellow Levels. For long-term care homes located in PHU regions in green-prevent or yellow-protect levels, licensees shall ensure that general visitors demonstrate that they have received a negative PCR Test result in the past two weeks and verbally attest to not subsequently having tested positive OR have a negative antigen test result on the day of the visit.
- b. Orange, Red and Grey Levels. No general visitors are permitted in long-term care homes located in PHU regions in orange-restrict, red-control or grey-Lockdown levels.

26. Do staff, student placements and volunteers have the option to get tested at assessment centres or other facilities?

Antigen testing is to be completed on site at the long-term care home, while PCR testing (where available) is conducted at the assessment centres, community labs and pharmacies.

Requisition

27. How should the order to conduct rapid antigen testing be documented?

No requisition form is required for health care providers performing antigen testing. Health care providers are responsible for meeting their professional obligations and ensuring proper documentation is in place when performing antigen testing.

Swabs and Testing Kits

28. How often should homes perform quality control testing?

For long-term care homes performing rapid testing under the licensing exemption model (no lab oversight), quality control swabs should be tested with each new shipment of kits, with any new lot numbers of kits and done at least weekly. It is important to time the control test for the full 15 minutes. Testing should be completed by staff who will be operating the testing station.

29. What type of swab technique can be used to perform a rapid antigen test?

Health Canada has approved three different modes of specimen collection for use with the Abbott PanbioTM rapid antigen screening test: nasopharyngeal swab (NPS), combined swab of throat and both nares, or a deep nasal swab.

For more details of the effect of specimen collection on sensitivity please see the Public Health Ontario website by clicking <u>here</u>.

30. Where can I find instructions on how to properly collect specimen samples?

Instruction on how to properly collect specimen samples using the nasopharyngeal, combined throat and nares, and deep nasal technique can be found on the Public Health Ontario website by clicking here.

31. What type of swabs are included in the Panbio™ COVID-19 Ag Rapid Test kit?

The test kits include 1 positive and 1 negative control swab for quality control testing and 25 sterilized nasopharyngeal swabs for sample collection. It is acceptable to use the nasopharyngeal swabs for alternate specimen collection techniques, i.e., combined throat and both nares and deep nasal.

32. How long can you keep a swab in the solution before applying it to a cartridge?

After specimen collection, the swab should be stored in the capped extraction tube filled with buffer at room temperature (15-30°C) until tested. Testing can be done immediately or within 2 hours of collection.

33. What information needs to be included on the pre-printed staff labels while conducting the rapid antigen test?

We recommend including at least 2 participant identifiers (e.g., name and date of birth) on both the test tube and corresponding test cartridge to avoid errors.

34. What should be done if the control line is not visible when reading the test result?

If the control line is not visible when reading the test result, the test is considered invalid. Conduct repeat testing with a second specimen using the Panbio™ COVID-19 Ag Rapid Test.

Additional Support for Long-Term Care Homes

35. Will the Ministry provide financial support/resources to support home in implementing rapid antigen testing?

Costs, including for additional staffing or sector support, that are incurred for the purposes of surveillance testing including point of care testing, are eligible expenses under the Prevention and Containment Fund.

36. My long-term care home doesn't have the resources or capacity to establish antigen testing at the home; what additional support can a long-term care home rely on?

Long-term care homes continue to be responsible for implementing the requirements under the Minister's Directive, including for antigen testing.

The government has recently made regulatory amendments under the *Laboratory and Specimen Collection Centre Licensing Act* (LSCCLA) allowing for a time-limited exemption from the LSCCLA for persons who perform point-of-care antigen testing and who are participating in the Provincial Antigen Screening Program and are in compliance with its conditions. This change allows a broader range of health professionals to collect specimens and perform COVID-19 point-of-care antigen testing, e.g., Personal Support Workers and Occupational Therapists. The federal government has only approved the test for use by a health professional consistent with the manufacturer's instructions.

Recognizing that the transition to antigen testing will require additional preparation, capacity and support, the Ministry of Long-Term Care and Ontario Health will continue to work with long-term care homes and with members of the health care sector to identify local supports (e.g., from pharmacies, community labs, paramedics) that could help conduct antigen testing at long-term care homes.

Long-term care homes are encouraged to build on their existing relationships within the health sector to aid the implementation of antigen testing.

37. How many Panbio kits should long-term care homes order?

Long-term care homes will need to acquire the necessary kits for each round of testing from their local/regional distribution source (or from Ontario Health using an online request form, available here). Please note that swabs should be ordered 7-14 days in advance, to ensure timely delivery. Homes are encouraged to pre-order testing kits for multiple rounds of testing (e.g., bulk order).

Ontario Health recommends that long-term care homes order approximately one month's supply of testing kits at a time. Where possible, Ontario Health encourages head offices to place and receive orders for multiple homes.

Data and Reporting

38. Are long-term care homes required to collect or disclose any statistical information under the Directive?

The Minister's Directive requires long-term care home licensees to collect and maintain statistical data on:

- The number of staff, student placements and volunteers tested.
- The number of staff, student placements and volunteers who refused a test.
- The dates on which staff, student placements and volunteers were tested (either at the long-term care home or another testing location).
- The number of general visitors, caregivers and support workers tested in the home and the date on which they were tested

Long-term care homes must submit this information on a weekly basis to the Ministry of Health and, upon request, to the Ministry of Long-Term Care, the local PHU and to Ontario Health.

The Service Area Offices (SAO)will monitor the weekly testing data reports and will be following up with homes that have reported less than 100% testing of staff or have not reported any data. The SAO will confirm compliance with the Minister's Directive and determine if an inspection is required.

In collecting, using or disclosing this information, long-term care homes must continue to adhere to all applicable requirements of the *Freedom of Information and Protection of Privacy Act* and the *Personal Health Information Protection Act*. 2004.

39. Are there any other reporting requirements related to positive test results?

If the head ("superintendent", as defined under the *Health Protection and Promotion Act*) of the long-term care home becomes aware of diseases of public health significance in the home, including COVID-19, they have a duty to report to the local medical officer of health under the *Health Protection and Promotion Act*.

Health care providers and licensed laboratories have the duty to report positive results of diseases of public health significance to the local PHU under the *Health Protection and Promotion Act*), and the *Laboratory and Specimen Collection Centre Licensing Act*, respectively.

Public health direction requires that a preliminary positive on the Panbio[™] also be reported to the local PHU immediately.

If a long-term care home is advised that a worker has tested positive for COVID-19 due to exposure at the workplace, or that a claim has been filed with the Workplace Safety and Insurance Board (WSIB), the employer is required to give notice in writing within four days to:

- The Ministry of Labour, Training and Skills Development.
- The workplace's joint health and safety committee or a health and safety representative.
- The worker's trade union (if applicable).

Additionally, the employer must report any instances of occupationally acquired illnesses to the WSIB within three days of receiving notification of said illness.

Other Questions

40. Will the Minister's Directive on rapid antigen testing and other supporting documents be made available in French?

Click here to read Minister's Directive in French.

41. Will Panbio be implemented in additional settings (e.g., hospitals, retirements home, etc.)?

Ontario's Ministry of Health has launched Panbio™ COVID-19 Ag Rapid Test pilot programs in long-term care, industry, essential services, and other congregate settings. Broad implementation of screening using the Panbio™ COVID-19 Ag Rapid Test in other priority settings will continue to be reviewed by the Ministry of Health, Ontario Health, Public Health Ontario and local PHUs.

How many staff can be tested an hour in a Panbio Clinic? On average, how many clinics are required per week to test staff in small, medium and large long-term care homes?

Long-term care homes with experience implementing rapid antigen testing clinics using PanbioTM have typically found that they can administer approximately 30 tests per hour.

42. Who can I contact if I have any issues?

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