Ontario Health

COVID-19 Rapid Antigen Screening Program

Frequently Asked Questions

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Clinical Guidance on Rapid Antigen Testing

1. What is COVID-19 rapid antigen testing?

Antigen tests can be used for point-of-care testing to detect COVID-19 faster than the regular laboratory-based polymerase chain reaction (PCR) test for COVID-19 providing results in 15-20 minutes.

2. When should you perform a rapid antigen test?

Antigen testing should only be performed on asymptomatic individuals for screening purposes only using a testing device that has been approved by Health Canada and is available in Ontario.

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

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

An individual who has previously had laboratory-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.

Repeat laboratory-based PCR testing after clearance should generally only be done with the onset of new COVID-19 symptoms and can be considered if there is exposure to a confirmed case of COVID-19, in an outbreak scenario, and/or at the direction of the local public health unit. Generally, individuals who have previously been infected with and recovered from COVID-19 should not undergo antigen testing, unless otherwise directed by local public health or their health care provider as per their symptom and exposure history.

4. How does an antigen test compare to regular laboratory-based PCR tests?

Compared to the regular laboratory-based PCR test, an antigen test has a higher risk of a false negative and a false positive result.

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

5. What are the rates of false positives and false negatives for antigen tests?

Rates of false positives and false negatives vary slight from one antigen testing modality to another and vary depending on the population being tested. For one antigen test, the Abbott Panbio™, the false positive rate is less than 1% (i.e., specificity is >99%) and the false negative rate is anywhere between 30-75% (i.e., sensitivity is between 25-70%). However, in practice, the likelihood of a result being true or false (predictive value) varies according to the population tested. In populations not expected to have COVID (i.e., asymptomatic screening program with a community prevalence rate < 3%), a significant portion of

positives may be false positives (low positive predictive value), and therefore a positive rapid antigen test should be confirmed with a laboratory-based PCR test. On the other hand, the negative predictive value usually remains around 99% or greater, meaning that less than 1 out of 100 negatives would be false negatives.

6. Are there concerns about 30% of positive cases being missed?

In relative percentages, with the lower sensitivity of antigen testing compared to laboratory-based PCR testing, it is possible that antigen testing may be missing 30% of cases. However, for example, the risk of missing 30% of 50 out of 100 individuals (i.e., 15 individuals) with COVID in a hospital emergency department is quite significant, whereas the risk of missing 30% of 1 out of 100 individuals (i.e., 0.3 individual) with COVID in the screening program suggests lower total numbers of false negatives, and may be furthermore reduced by repeating testing frequently to increase the overall capture rate and to find that 0.3 out of 100 individuals that could be missed.

7. What type of swabbing technique can be used to perform a rapid antigen test?

Rapid antigen testing is performed using one of the following specimen collections:

- a nasopharyngeal specimen (highest sensitivity),
- a combined specimen of throat and both nares,
- a deep nasal specimen,
- or a nasal specimen.

A nasopharyngeal specimen collection has the highest sensitivity compared to other specimen collection techniques. Alternative acceptable specimen collection techniques in the provincial clinical guidance include a combined swab of throat and both nares, or a deep nasal swab, or a nasal swab using the swab included in the test kit.

A nasopharyngeal swab can be used to collect specimens from all four sites – nasopharynx; combined throat and both nares; nasal; or a deep nasal. Nasopharyngeal specimen collection is a controlled act and can only be conducted by certain regulated health professionals.

A nasal swab can be used to collect specimens from only three sites – combined throat and both nares; nasal; or a deep nasal. A nasal swab cannot be used to collect a nasopharyngeal specimen.

Nasal and throat specimen collection may be slightly less sensitive than nasopharyngeal specimen collection for the detection of COVID-19. For more details of the effect of specimen collection on sensitivity please see the Public Health Ontario website by clicking here.

8. Who can collect the specimen and conduct the test?

Recent changes to the Ministry of Health guidance and amendments to Regulation 682 and Regulation 683 under the Laboratory and Specimen Collection Centre Licensing Act (LSCCLA) allow for all Health Canada approved point-of-care tests for COVID-19 to be performed (specimen collection and conducting the test) by health professionals, or other trained individuals, in accordance with the manufacturer's label. Sites can determine the appropriate individual to collect the specimens and operate the tests based upon their staffing capacities.

In the case of rapid antigen testing only, 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.

For more information on how to collect specimens, please refer to Public Health Ontario website

9. What type of swabs are included in the rapid antigen test kits?

Ontario's current inventory of Panbio™ rapid antigen test kits come with either nasopharyngeal (NP) swabs, or nasal swabs.

- NP swabs can be used for NP, combined throat + both nares, deep nasal and nasal specimen collections.
- Nasal swabs can be used for combined throat + both nares, deep nasal and nasal specimen collections.

The BD Veritor™ rapid antigen test kits come with a nasal swab that can be used to collect combined throat + both nares, deep nasal, and nasal specimens.

10. Do you use one swab to collect specimens from the throat and both nares?

Yes, the same swab is used to collect both the throat samples and the nasal samples. See Virus Respiratory (Throat + Nasal) Specimen Collection Instructions.

11. 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.

12. Is there risk to the nose from nasal swabbing 2-3 times per week?

Specimens can be collected using a nasopharyngeal swab (the optimal method), or a combined swab of throat and both nares, nasal or a deep nasal swab. A throat-only swab for antigen testing may be acceptable under the rare circumstances where a combined throat and nares approach is unfeasible, understanding the risks associated with the lower sensitivity of throat-only collection.

13. What are the licensing requirements to operate rapid antigen testing?

Amendments to Regulation 682 and Regulation 683, under the Laboratory and Specimen Collection Centre Licensing Act (LSCCLA) have been made to reduce implementation barriers and enable widespread uptake across the province to support continued reporting of COVID-19 point-of care-test results. These amendments became effective on March 3rd, 2021 and include:

- Amendments to Regulation 682 under the LSCCLA
    - Exempting a person who performs COVID-19 testing using a device authorized by Health Canada for point-of-care use from the licensing requirements of the LSCCLA.
- Amendments to Regulation 683 under the LSCCLA:
    - Exempting a person who collects specimens for COVID-19 testing using a device authorized by Health Canada for point-of-care use from the licensing requirements of the LSCCLA.

A corresponding amendment to Regulation 569, under the Health Protection and Promotion Act (HPPA) was also made to support continued reporting of COVID-19 point-of care-test results as a Disease of Public Health Significance, including results obtained through point-of-care testing within the context of the above-noted changes under the LSCCLA. This amendment became effective on March 3rd, 2021 and requires that any person who performs a COVID-19 point-of-care test, who is not otherwise already required to report under the HPPA, report the following to the medical officer of health of the public health unit within which the person being tested resides:

- Positive results from a COVID-19 molecular (nucleic acid) point-of-care test.
    - The amendment requires that, where possible, results from COVID-19 molecular (nucleic acid) point-of-care tests be entered into the Ontario Laboratories Information System (OLIS) as the mechanism for reporting positive results to public health.
    - Otherwise, positive results from molecular (nucleic acid) point-of-care tests must be reported to the medical officer of health by other secure means.
- Preliminary positive results from a COVID-19 antigen point-of-care test.

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

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

15. **Should confirmatory PCR-testing occur on-site or at an assessment centre?**

    Individuals who have received a preliminary positive result using a rapid antigen test need to receive a lab-based confirmatory PCR test within 24 hours. If there is capacity to perform the PCR test on-site, a new specimen is required from the individual that tested positive on the rapid antigen test. A second swab must be used to collect a specimen for the confirmatory laboratory-based PCR test. If there isn't capacity to perform the confirmatory PCR test, the individual should book an appointment at the nearest assessment centre, participating community lab or specimen collection centre.

16. **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.

17. **Do COVID-19 rapid antigen tests detect the variants of concern?**

    Antigen tests detect the nucleocapsid protein rather than the spike protein (where the mutation typically exists in the variants of concern) and therefore is not expected to be affected by a mutation in the spike protein. With this, antigen tests should be able to detect COVID-19 infection caused by a variant of concern.

18. **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.

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19. **Is a requisition required to conduct a rapid antigen test?**

    No requisition form is required to perform antigen testing. However, registered health professionals are responsible for meeting their professional obligations and ensuring proper documentation is in place when performing antigen testing.

20. Do staff operating the rapid antigen testing clinics need to sign confidentiality agreements?

Sites conducting rapid antigen testing must treat all heath information as confidential following the Personal Health Information Protection Act (PHIPA). Confidentiality agreements must be signed by staff operating the rapid-test clinic.

21. Our test kits arrived in the back of a truck this morning when the outdoor temperature was -25ºC. The box was very cold but the solution was not frozen. Should I be concerned?

Storage and transportation of test kits between 2°C to 30°C is acceptable, and kits are more likely to be at the lower temperatures during the winter months. Kits will be shipped with appropriate temperature control to prevent freezing. At the on-site clinic, store antigen 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. Do not freeze the kits or their components. Freezing kits renders the tests invalid. If you receive a shipment of frozen test kits, please contact your distribution centre.

22. How often should sites perform quality control testing?

Quality control swabs should be tested with each new shipment of kits, with any new lot numbers of kits and by all newly trained operators before they begin testing individuals. Sites using more than 1 box of tests per day, should perform quality control swabs at the beginning of the day before testing begins. Sites performing less than 1 box of tests per day, should perform quality control swabs each time a new kit box is opened or at least weekly, whichever is more frequent. 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.

23. When conducting quality control testing, are we required to test both the negative and positive swab?

Quality control testing must be conducted regularly with each swab type. The positive control will produce a positive test result and has been manufactured to produce a visible test line (T). The negative control will produce a negative test result. Good laboratory practice suggests the use of positive and negative controls to ensure that:

- Test reagents are working, and
- The test is correctly performed.

24. Is there a validation process as there is for rapid antigen tests in addition to the quality control swabs that come with each box?

There is no separate validation process for antigen testing. The quality control swabs provided with each box is sufficient.

25. How do you document your quality control/lot numbers?

Ontario Health has developed a results tracker for sites implementing COVID-19 rapid antigen testing. This tracker includes a sheet for lot numbers and quality control results. The COVID-19 Rapid Test Results

Tracker can be accessed on the Ontario Health website. Sites can create their own trackers or modify the tracker developed by Ontario Health to meet their needs.

26. How long can you keep a swab in the buffer solution before testing the specimen?

After specimen collection, the swab should be stored in the capped extraction tube filled with buffer at room temperature (15-30˚C) until tested. For best results, testing should be done immediately. Instructions for how long a specimen can sit in the buffer vary for different test modalities. For example, specimens collected for testing with the BD Veritor™ can be stored in the extraction solution for a maximum of 30 minutes and specimens collected for testing with Panbio™ can be stored in the capped extraction tube with buffer for a maximum of 2 hours. Note that collected specimens for antigen testing should NOT be placed in the fridge. Please refer to the package insert of the test you are using for additional test-specific information.

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

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

28. What type of timer is recommended for us during testing?

Test results need to be checked 15-20 minutes after the sample was dropped into the well. It is recommended to use a timer to keep track of time, although some sites use a wall clock and write the time the sample was added to the on a piece of masking tape beside the cartridge. You can use just one timer as long as you are able to read results within 15-20 minutes.

Timers can be ordered through your regular equipment and supplies ordering process. One example of a timer is the traceable four-channel alarm timer, available through VWR (catalogue 62344-641).

29. What type of test tube rack is required?

A disposable tube rack is provided with each kit and the tube rack can be re-used with other test kits if necessary. There is no need to order a separate test tube rack, although some sites do prefer to use a separate plastic tube rack.

30. Can you explain the importance of squeezing the swab?

When you insert the swab into the extraction tube, you must immerse the swab into the buffer. The tube is flexible, and you should squeeze the tube and pull the swab up through your squeezed fingers. This helps release the sample into the buffer.

31. How do we dispose of the test kits?

Public Health Ontario advises, as per the manufacturer's instructions, to decontaminate and dispose of all specimens, used extraction tubes (with dispensing nozzle closed), used test devices, and other potentially

contaminated materials in a biohazard container as infectious waste, and to dispose of the biohazard container according to applicable local regulations.

32. What type of biohazard waste containers are required?

The biohazard waste container should be a yellow container and labelled with the universal biohazard symbol. Biohazard bags and biohazard waste containers do not come with the kits and need to be ordered separately, through your regular ordering process.

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.

33. If we are labelling the extraction tube and then disposing of the tube in a biohazard container, what happens to that staff PHI?

The extraction tubes should be labelled with 2 unique participant identifiers (e.g. name and date of birth). It is standard practice for tubes with these health identifiers do go into biohazard bags and disposed of according to local regulations.

34. Does personal protective equipment need to be changed between each person being swabbed and between processing each test?

Gloves, gowns, medical masks and face shields will be needed for all individuals running the rapid testing clinic throughout the testing process. The person collecting samples should change gloves and perform hand hygiene after each swab. The person performing the test should change gloves and perform hand hygiene after handling each extraction tube.

35. With all the logistics involved in planning and implementing rapid antigen testing is it anticipated that there will be a consistent supply of test kits available for the foreseeable future?

The province has acquired a sufficient supply of rapid antigen tests to support the Provincial Antigen Screening Program. There is no current concern regarding a consistent supply of the kits.

36. How do I order rapid antigen tests?

Sector-specific step-by-step instructions on how to order rapid antigen test kits through an online intake form will be provided by your supporting ministry after you complete the Provincial Antigen Screening Program Agreement.

37. How long does it take to receive a shipment of rapid antigen tests?

Orders are typically sent out within 3-5 business days. Orders should be placed when there is between 7 and 14 days of supplies left.

38. Who can I contact if I have additional questions?

Please email any rapid antigen questions to covid19testing@ontariohealth.ca.

For questions pertaining to data collection and reporting please email AskHealthData@ontario.ca with the subject line, “Antigen Testing Data Collection”.