Provincial Antigen Screening Program: Information Document

The Provincial Antigen Screening Program is being led by the Ministry of Health, with support from partner ministries, Public Health Ontario, and Ontario Health.

This document is meant to outline the key information required to support the successful implementation of the Provincial Antigen Screening Program, and includes details on the following:

1. Program Overview 2

What is the Provincial Antigen Screening Program? 2

What is a Rapid Antigen Test? 2

What are the Benefits of Participating in the Program? 3

How have Rapid Antigen Tests been used in workplaces in Ontario to date? 3

Who is Eligible to Participate in this Program? 4

What Does Participation in the Program Mean for my Workplace? 4

What are the Financial Considerations for my Workplace? 5

Will my Workplace Receive Training? 5

How does my Workplace Receive Tests Once Accepted into the Program? 5

What Considerations does my Workplace Need to Make for Storage and Handling of Antigen Tests? 6

2. Parameters for the Use of Rapid Antigen Tests in the Provincial Antigen Screening Program 6

How Should an Antigen Test be Used in this Program? 7

Who Can Perform a Rapid Antigen Test? 8

What are the Key Considerations for Interpreting Test Results? 9

Should Individuals Who have been Vaccinated for COVID-19 Receive a Rapid Antigen Test? 9

Can Rapid Antigen Tests Detect COVID-19 Variants of Concern? 10

3. Program Reporting Requirements 10

What are the General Reporting Requirements for Program Participation? 10

What are the Reporting Requirements in the Case of a Positive Antigen Test Result? 11

Note

This document is intended for use by Provincial Antigen Screening Program participants in Ontario. This is a living document and includes guidance supported by currently-available evidence. As evidence evolves, this document will be updated accordingly.

Individual ministries may have sector specific policies or directives related to rapid antigen testing, which must be considered in addition to the program information below.

While there are several rapid antigen tests available for use in Ontario, the information below primarily pertains to Abbott Panbio™ antigen tests.

1. Program Overview

What is the Provincial Antigen Screening Program?

The Provincial Antigen Screening Program is a newly launched program that allows employers in priority settings to add an additional safety measure in high-risk and essential workplaces, to help reduce the spread of COVID-19. Through the program, rapid antigen tests will be distributed to organizations in priority settings, to enhance existing routine screening measures for asymptomatic employees and other identified groups. 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 workplaces.

What is a Rapid Antigen Test?

A rapid antigen test (also known as a point-of-care test) can be performed anywhere (i.e. on-site, at the place of employment) by a health professional (see *Who Can Perform a Rapid Antigen Test?)* and does not require shipping a specimen to a lab for processing. It is currently administered through a nasopharyngeal, nasal, deep nasal, or combined nasal and throat swabs and takes approximately 15 minutes to yield results.

Currently, all provincially supported rapid antigen screening is being conducted using the Abbott Panbio™ test. In the future, additional devices such as the BD Veritor or the Sofia Quidel may be used as part of the Provincial Antigen Screening Program. All three tests perform similarly but may have different considerations in terms of optimal location and workflow.

An overview of how the Panbio™ test is performed can be found here. Further information on instructions for use can be found here.

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

Available evidence indicates that frequent screening with rapid antigen tests increases the chances of early identification of cases in otherwise asymptomatic individuals and mitigates the lower sensitivity of a single antigen test. 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. For example, field studies on Panbio™ have shown sensitivity results ranging from 72.1% - 86.5% for individuals within the first 7 days of symptom onset, and specificity of 95% and above.[1] Generally, these results indicate that the Panbio™ may inaccurately yield negative results (i.e. false negatives) in individuals who are infected

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

approximately 30% of the time, and may result in false positive results when screening asymptomatic individuals.

Information on testing frequency can be found in the COVID-19 Guidance: Considerations for Rapid Antigen Screening document.

More details on the parameters for the use of antigen tests in this program are outlined in the *Parameters for the Use of Antigen Tests in the Provincial Antigen Screening Program* section of this document.

What are the Benefits of Participating in the Program?

A key benefit of participating in the Provincial Antigen Screening Program is that rapid, on-site testing may facilitate the identification of an individual infected with COVID-19 infection in the workplace that regular screening protocols might otherwise miss. It may therefore help prevent asymptomatic individuals from unknowingly spreading COVID-19 in the workplace and helps to break the chain of transmission for COVID-19.

How have Rapid Antigen Tests been used in workplaces in Ontario to date?

Ontario began a time-limited employer pilot project in November 2020 to assess the value of the Panbio™ antigen test as a screening tool to support employee safety and business continuity in a variety of workplaces. Results from this pilot support an increased understanding of how rapid antigen testing could be deployed more broadly to support provincial COVID-19 response activities.

The pilot was implemented in three phases, beginning in November 2020 and ending on March 31st, 2021 (or until all participants in phase 3 have completed their 8-week pilot). Over 160 employers are participating in the pilot across four priority settings: healthcare, congregate living, essential workplaces and industry settings.

Most employers and employees surveyed felt that the pilot increased the sense of protection and security in the workplace. Additionally, employers perceived benefits to the workplace including the provision of test results in a timely manner, and a contribution to reducing the overall transmission of COVID-19. Most employers (90%) felt that implementation went smoothly. Most employees (85%) had no concerns with participating; for those who did have concerns, the largest concern was the impact on the ability to work in the event of a positive test result.

Early pilot data shows a positivity rate of approximately 0.25%. This means that of all the rapid antigen tests performed, approximately 0.25% were positive. While this number demonstrates a low overall number of positives and therefore minimal disruption to a workplace, it also indicates the ability of asymptomatic screening with antigen tests to find COVID-19 cases that otherwise would have otherwise gone undetected.

Who is Eligible to Participate in this Program?

Ontario is committed to providing Ontarians with more access to innovative testing options to help stop the spread of COVID-19. The province is expanding the use of rapid antigen tests for more people in more priority settings to quickly identify cases of COVID-19 as a measure of enhanced public health and safety. Sectors prioritized for the Provincial Antigen Screening Program include:

- All long-term care homes across the province
- Retirement homes
- Essential industry
- Congregate living
- Schools
- High priority communities

Partner ministries will be reaching out to priority sectors to confirm interest and participation. Organizations can apply to this program by responding directly to their ministry's invitation. Organizations who did not receive this memo can contact their respective ministries to inquire about participation in the Provincial Antigen Screening Program.

Employers that participated in targeted testing initiatives in the spring of 2020 or in the Employer Rapid Antigen Screening Pilot are not exempt from applying to participate in this program.

What Does Participation in the Program Mean for my Workplace?

If accepted to participate in this program, the government will provide employers with free rapid antigen test kits, pending available inventory. In most instances, this will be up to 2 to 3 tests, per employee, per week, and will be guided by sector-specific policy or directives. Large employers may be asked to identify a subset of their workforce who are eligible for testing based on overall demand for antigen tests within this program or prioritization for higher-risk settings.

All participating workplaces will be required to enter into a Program Agreement. The Program Agreement outlines the parameters for participation in the Provincial Antigen Screening Program. Participating workplaces must adhere to the parameters outlined in the Program Agreement in order to continue receiving a supply of rapid antigen tests and to avoid having their participation in the program terminated by the province.

The free test kits distributed through this program are to be used only for Ontario-based employers and must be used within the duration of the program (i.e. tests cannot be saved for future use). Tests must be used on an employer's own employees or other identified groups; an employer cannot distribute or sell tests to any third party (e.g. a client company). This does not preclude employers from using a contracted agency to deliver the tests.

For the duration of the program, the government will be collecting data from participating sites to support the evaluation of the program and the value of point-of-care antigen testing as an effective and accurate screening tool for COVID-19. Further information on the reporting requirements and data collection associated with program participation are outlined in the *Program Reporting Requirements* section of this guidance document.

What are the Financial Considerations for my Workplace?

The provincial government will provide participating employers with the appropriate number of rapid antigen test kits to meet sector-specific testing guidelines, for free, dependent on available inventory. Additional financial support may be provided at the discretion of participating employers' respective ministries. Otherwise, participating employers will assume all additional program implementation costs (e.g. health professional expenses, supplies, and the implementation of physical safety measures).

Participating employers may work with a privately-contracted service delivery partner to administer the Provincial Antigen Screening Program, but are not required to.

Will my Workplace Receive Training?

Training materials will be made available from Ontario Health in an online format and will include a sector-specific kick-off webinar and a suite of written materials and pre-recorded training modules. As your sector begins to implement, participating workplaces will receive information on upcoming training opportunities.

Participation in training is not a mandatory requirement of this program but it will help build confidence and competence for those performing the testing and will assist your workplace in understanding program logistics and planning for implementation.

How does my Workplace Receive Tests Once Accepted into the Program?

Approved workplaces that have entered into a Program Agreement will be provided with information from their ministries on how to request test kits.

- Health stakeholders will order rapid antigen tests through an online ordering system called Remedy, which is managed by Ontario Health.
- Non-health stakeholders will order rapid antigen tests online through the PPE Supply Portal, which is managed by the Ministry of Government and Consumer Services.

Current inventory of the Abbott Panbio™ test kits come with either nasopharyngeal swabs or nasal swabs. Either swab kit type may be distributed based on available inventory. Program participants should only specify the kit type if they wish to receive a kit with nasopharyngeal swabs.

Health professionals performing a rapid antigen test may collect a specimen in accordance with Provincial Rapid Antigen Testing Guidance. Nasopharyngeal swabs can be used to collect nasopharyngeal, nasal, deep nasal or combined dual nares and throat specimens. Nasal swabs can be used to collect deep nasal, nasal or combined dual nares and throat specimens. Ordering separate swabs or new kits is not necessary to support alternate specimen collection types.

Nasopharyngeal swabbing is a restricted act, and this specimen type may only be collected by physicians, nurse practitioners, or their delegate.

What Considerations does my Workplace Need to Make for Storage and Handling of Antigen Tests?

Participating employers will need to be able to store any rapid antigen tests received. Below are some key space and storage requirements:

For Abbott Panbio™ Rapid Antigen Tests:

1. No. of Tests in a Box = 25
    a. Box Dimensions = 23cm x 12.5cm x 9cm
    b. Box Weight = 2lbs
2. No. Tests in a Case = 800 (32 inner boxes)
    a. Case Dimensions = 47cm x 53 cm x 39 cm
    b. Case Weight = 33lbs
3. No. of Tests per Pallet = 9,600 (12 cases)
4. During transportation and storage, test kits need to remain between 2 and 30 degrees Celsius and are not to be frozen.

For more details, please visit the manufacturer's website.

2. Parameters for the Use of Rapid Antigen Tests in the Provincial Antigen Screening Program

Participating employers will have significant flexibility in the implementation of rapid antigen testing within their respective workplaces. The government is not being prescriptive about the operational decisions related to program implementation, so long as they adhere to the terms of the Provincial Antigen Screening Program agreement, including compliance with provincial guidance. Sector specific policy or directives may further outline any required implementation parameters, including frequency of testing and populations to test.

Unused tests cannot be returned due to quality control and infection prevention control considerations. Before ordering test kits, participating employers should assess their readiness to implement, including:

- The availability of health professionals to administer the test.
- Anticipated uptake among employees (and other identified groups) if testing is voluntary.
- Informing the local Public Health Unit about the intent to implement a rapid testing screening initiative. A local Public Health Unit is not required to approve a rapid testing screening initiative.

If employers withdraw from the program or have unused tests, they should contact their ministry representative to determine next steps.

How Should an Antigen Test be Used in this Program?

To ensure the antigen test is used in accordance with its intended purpose as a screening tool (i.e. not a diagnostic tool), and to ensure accurate data collection and evaluation of its effectiveness, through this program, **participating employers must adhere to the following parameters of use throughout the program**:

1. Antigen tests must be used in **accordance with Provincial Antigen Screening Program agreement.**

2. Antigen tests **do not replace infection prevention and control measures such as** symptom screening, appropriate distancing, use of personal protective equipment (PPE), and hand-hygiene activities. Testing is not required under the *Occupational Health and Safety Act, 1990,* nor does it replace any duties under the *Occupational Health and Safety Act* to take all precautions reasonable in the circumstances to protect the health and safety of workers. These measures are essential to *prevent* the transmission of COVID-19, whereas testing can only identify individuals after transmission has occurred.

3. Antigen tests **should only be used on asymptomatic individuals** who have passed the initial standard screening conducted within the workplace. They 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 individual who have had close contact with known positive cases should be directed to an Assessment Centre for testing.

4. Antigen tests **should not be used in either a confirmed or suspected outbreak in a workplace setting**, per provincial testing guidance.

5. 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 program.

6. As per Provincial Testing Guidance, 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. Participation in the Provincial Antigen Screening Program does not provide participants with priority access to confirmatory lab-based PCR tests.

7. As per Provincial Testing Guidance, an individual who receives a positive antigen test result **must self-isolate, as must their close contacts, until the result of the confirmatory, lab-based PCR test is known**.

8. Ensure **considerations have been made for biosafety** as per Public Health Ontario guidance.

Who Can Perform a Rapid Antigen Test?

A temporary exemption to Regulation 682 and Regulation 683 under the *Laboratory and Specimen Collection Centre Licensing Act*, *1990* ("LSCCLA") and key requirements of the LSCCLA has been made for anyone participating in the Provincial Antigen Screening Program. In order to be eligible for this exemption, a participating employer must have entered into a Program Agreement with the province and be in compliance with that Program Agreement.

This exemption allows for a broad range of health professionals to perform rapid antigen screening as part of the Provincial Antigen Screening Program, so long as they have the knowledge, skills, training and judgement required to perform the test.

Health professionals may include both regulated health professionals, as well as non-regulated health professionals, which could include, but are not limited to:

- Personal support workers
- Physician assistants
- Physiotherapy assistants
- Speech language therapists
- Osteopaths

The overseeing ministry may have discretion in adding or removing health professionals from the list based on the knowledge, skills, judgement and training required to perform the swab and test in particular settings.

While any of the health professionals listed above can perform the point-of-care antigen test, the collection of nasopharyngeal specimens is limited to physicians, nurse practitioners, or their delegates.

Health professionals can perform rapid antigen testing for COVID-19 for their patients and individuals who are not their patients. Requisition forms are not required for health professionals performing a rapid antigen test as part of this program.

If applicable, health professionals are responsible for satisfying all applicable legislative and regulatory requirements, including those under the *Health Protection and Promotion Act* (HPPA), *Personal Health*

Information Protection Act (PHIPA), *Health Care Consent Act* (HCCA), and the *Regulated Health Professions Act* (RHPA). Health professionals must ensure proper documentation is in place when performing COVID-19 rapid antigen testing.

At this point in time, self-swabbing is not enabled under the Provincial Antigen Screening Program. The Ontario government will continue to monitor Health Canada approval of self-swabbing technologies for potential implementation in the future.

What are the Key Considerations for Interpreting Test Results?

Because rapid antigen tests are less sensitive and specific than lab-based PCR tests, results are not as accurate. As such, rapid antigen tests may 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 to a lesser extent, some false positive test results (i.e. a result that indicates the individual is infected with COVID-19 when in fact they are not). Results should therefore be interpreted with caution.

For example, in the instance that an employee tested with a rapid antigen test receives a negative result, they should be reminded of the possibility that the test result may be inaccurate. Participating employers should reinforce the importance of continuing to adhere to the necessary COVID-19 infection prevention and control measures, such as appropriate distancing, use of PPE, and hand washing, to reduce the risk of infection.

Alternatively, in the instance that an employee tested with a rapid antigen test receives a positive result, they should be reminded that the test result should be interpreted as a *preliminary* positive and that it may be inaccurate, in order to reduce potential anxiety on the part of that individual and among other employees. Additionally, in accordance with Provincial Testing Guidance, that employee must seek a lab-based PCR test within 24 hours to act as a confirmatory test, and should be advised to self-isolate until a confirmatory test result is received.

Further information regarding reporting requirements associated with a positive test result on a rapid antigen tests during this program are outlined in the *What are the Reporting Requirements in the Case of a Positive Antigen Test Result* section of this document.

Should Individuals Who have been Vaccinated for COVID-19 Receive a Rapid Antigen Test?

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.

Can Rapid Antigen Tests Detect COVID-19 Variants of Concern?

It is believed that rapid antigen tests are still able to detect COVID-19 caused by a Variant of Concern (e.g. the U.K., South African or Brazilian variants), however, a rapid antigen test can not tell if a COVID-19 infection has been caused by a Variant of Concern.

If an individual tests positive with a rapid antigen test, they will be required to seek a confirmatory, lab-based PCR test within 24 hours. At present, all positive lab-based PCR samples in Ontario are undergoing screening for any of the known Variants of Concern.

3. Program Reporting Requirements

What are the General Reporting Requirements for Program Participation?

The government will request information from participating employers every week (i.e. every 7 days), and the reporting period for each week will run from Saturday to Friday. The following information will be required from participating employers:

1. The type of rapid test used.
2. Number of rapid antigen tests used.
3. Number of invalid rapid antigen test results.
4. Number of individuals who tested positive with a rapid antigen test
5. Number of individuals who tested negative with a rapid antigen test
6. Number of positive rapid antigen tests that were:
    a. Confirmed positive for COVID-19 through a follow-up, lab-based PCR test
    b. Confirmed negative for COVID-19 through a follow-up, lab-based PCR test
    c. Unconfirmed through a follow-up, lab-based PCR test because results are pending or unknown

A centralized database, the Health Data Collection Service, will support required weekly online reporting by participating sites. Once an employer is accepted to participate, they will be onboarded on to the Health Data Collection Service and will be provided information and training on how to submit data. 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 must be entered for each participating site i.e. it cannot be reported collectively at the organization or chain level.

All data is reported and stored at the aggregate level; no patient identifiable data is collected.

The province may, at its discretion, terminate an employer's participation in the program and stop supplying test kits to employers that fail to comply with reporting or other program requirements.

Training materials and other supporting documents will be made available. Questions related specifically to data submission for the Provincial Antigen Screening Program can be emailed to AskHealthData@ontario.ca with the subject line "Antigen Testing Data Collection".

The government may request additional information throughout the course of the 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 workplace settings.

Long-term care homes should follow the reporting requirements specified by the Ministry of Long-Term Care.

What are the Reporting Requirements in the Case of a Positive Antigen Test Result?

A positive result on a rapid antigen test is considered a preliminary positive. Public health direction requires that the local Public Health Unit be notified by the health professional performing the test of a preliminary positive result, and that the individual who was tested receive a follow-up, confirmatory lab-based PCR test at a COVID-19 Assessment Centre within 24 hours.

In the instance that you are advised that one of your employees who had a positive result on an antigen screening test through the program has also received a positive result through a confirmatory, lab-based PCR test (i.e. a confirmed case of COVID-19 in that employee/individual) and that the infection was due to exposure at the workplace, in accordance with the *Occupational Health and Safety Act, 1990*, the employer must 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 health and safety representative
- The worker's trade union (if applicable)

Additionally, you must report any occupationally acquired illnesses to the Workplace Safety and Insurance Board within three days of receiving notification of the illness, in accordance with the *Workplace Safety and Insurance Act, 1997*.

Further information on what is required when a positive result is detected on a rapid antigen test during this program can be found in the COVID-19 Guidance: Considerations for Rapid Antigen Screening document.