Employer Antigen Screening Pilot: Information Document

The Employer Antigen Screening Pilot is a voluntary program being led by the Ministry of Health, with support from partner ministries, Public Health Ontario, and Ontario Health.

This Information Document is meant to outline the key information required to support the successful implementation of the provincial Employer Antigen Screening Pilot Program, and includes details on the following:

1. **An Overview of the Employer Antigen Screening Pilot**
    - What is the Employer 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 mean for my workplace?
    - What are the financial considerations for my workplace?

2. **Parameters for the Use of the Panbio™ in the Employer Antigen Screening Pilot**
    - How should the Panbio™ antigen screening test be used in this pilot?
    - Who can perform the Panbio™ test?
    - What are the key considerations for interpreting test results?

3. **Pilot Reporting Requirements**
    - What are the general reporting requirements for pilot participation?
    - What are the reporting requirements in the case of a positive Panbio™ test result?

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.

1. Pilot Overview

What is the Employer Antigen Screening Pilot?

The objective of this time-limited pilot program is 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. It aims to distribute Panbio™ COVID-19 antigen screening tests to employers in a range of settings for use among asymptomatic employees. 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 pilot will be 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). Employers can volunteer to participate in any one of the three phases, during which they will be provided Panbio™ tests for free from the Ontario government.[1] Each employer's participation period in the pilot will be 8 weeks long.

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 place of employment) 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. 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 in fact infected approximately 30% of the time.

More details on the parameters for the use of the Panbio™ test in this pilot program are outlined in the *Parameters for the Use of the Panbio™ in the Employer Antigen Screening Pilot* section of this document.

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.

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[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.

What are the Benefits of Participating in the Pilot?

A key benefit of participating in the Employer Antigen Screening Pilot is that it may facilitate the identification of an individual infected with COVID-19 infection in the workplace that regular screening protocols might otherwise miss through a rapid, on-site test. It may therefore prevent asymptomatic individuals from unknowingly spreading COVID-19 in the workplace.

Who is Eligible to Participate in this Pilot?

The pilot program is designed to learn about the effectiveness of the Panbio™ test as a screening tool in a variety of workplace settings. Therefore, the Ministry of Health will accept participants from the private, public, and non-profit sectors, as well as from a broad range of settings, including but not limited to four priority settings: health care, vulnerable (e.g. congregate) settings, essential services and industry. Employers that participated in targeted testing initiatives in the spring of 2020 are not exempt from applying to participate in this pilot.

Employers can apply to this pilot program by responding directly to their ministry's invitation, which was sent on November 11th, 2020 through a memo seeking participants. Employers who did not receive this memo can contact their respective ministries to inquire about participation.

Participants will be chosen based on their readiness to perform rapid antigen screening testing in accordance with the requirements set out by the Ministry of Health, as outlined in the *Parameters for the Use of the Panbio™ in the Employer Antigen Screening Pilot* section of this guidance document. The Ministry of Health will aim to ship tests to participating employers within 24 hours upon confirmation of an employer's readiness and pending provincial Panbio™ inventory. Employers can start testing once they are ready.

What Does Participation in the Pilot Mean for my Workplace?

If accepted to participate in this pilot program, the government will provide employers up to 3 Panbio™ tests per week, per participating employee, for a total of 8 weeks, pending available inventory. Large employers may be asked to identify a subset of their workforce as a test group for the pilot period based on overall demand for Panbio™ within this pilot program.

The tests distributed through this pilot program are to be used only for Ontario-based employers and must be used within the 8-week duration of the pilot (i.e. tests cannot be saved for future use). Following the 8-week pilot period, 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. Further information on the reporting requirements and data collection associated with pilot participation are outlined in the *Pilot Reporting Requirements* section of this guidance document.

Participation for each employer is limited to one phase of the pilot program. Employers should work with their respective ministry officials to determine an appropriate start-date, and therefore which phase of the pilot they would like to participate in.

Employee participation in this pilot is not mandatory. Rather, employers participating in this pilot program must seek consent from their employees on a voluntary basis before administering the Panbio™ test. Employees are under no obligation to undergo screening.

What are the Financial Considerations for my Workplace?

The provincial government will provide participating employers with the appropriate number of Panbio™ tests kits to last the duration of the 8-week pilot period 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 pilot program implementation costs (e.g. health care provider expenses, and the implementation of physical safety measures).

2. Parameters for the Use of the Panbio™ in the Employer Antigen Screening Pilot

Participating employers will have significant flexibility in the frequency of Panbio™ testing within their respective workplaces. For example, employers could decide to use the tests for regular screening of employees before the beginning of a shift, or they could decide to use the tests for one-time screening of asymptomatic employees. As long as the tests are used within the maximum allotment (i.e. up to 3 tests per participating employee, per week, for 8 weeks), the government is not being prescriptive about the operational decisions related to pilot implementation.

How Should the Panbio™ Antigen Screening Test be Used in this Pilot?

To ensure the Panbio™ 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 as a screening tool through this pilot program, **participating employers must adhere to the following parameters of use throughout the pilot**:

1. The Panbio™ test must be used in **accordance with the manufacturer's instructions**.

2. The Panbio™ screening test **should not replace infection prevention and control measures such as** symptom screening, appropriate distancing, use of personal protective equipment (PPE), and hand-washing 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. The Panbio™ screening test **should only be used on asymptomatic individuals** who have passed the initial standard screening conducted within the workplace. It should not be used for symptomatic

individuals, or individuals who have had close contact with known positive cases in the context of this pilot. Symptomatic individuals, or individual who have had close contact with known positive cases should be directed to an Assessment Centre for testing.

4. The Panbio™ screening test **should not be used in either a confirmed or suspected outbreak in a workplace setting**. The local Public Health Unit should be notified in such circumstances.

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 pilot program.

6. As per Provincial Testing Guidance, a positive result on the PanbioTM is considered a **preliminary positive and should be followed up with a laboratory-PCR test** to act as a confirmatory test within 24 hours.

Who Can Perform the Panbio™ Test?

In accordance with recent regulatory changes under the *Laboratory and Specimen Collection Centre Licensing Act*, *1990* in addition to physicians, the following health care providers can also perform the Panbio™ test: nurse practitioners, registered nurses, registered practical nurses, pharmacists, dentists, paramedics, and community paramedicine practitioners, if they are also permitted by their college or other professional regulator. These health care providers are able to perform rapid antigen testing for COVID-19 for their patients and individuals who are not their patients.

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* (PHIPA), *Health Care Consent Act* (HCCA), and the *Regulated Health Professions Act* (RHPA).

What are the Key Considerations for Interpreting Test Results?

Because the Panbio™ rapid antigen test is less sensitive and specific than lab-based PCR tests, results are not as accurate. As such, the Panbio™ will 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 the Panbio™ 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 the Panbio™ 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.

Further information regarding reporting requirements associated with a positive test result on the Panbio™ during this pilot are outlined in the *What are the Reporting Requirements in the Case of a Positive Panbio™ Test Result* section of this document.

3. Pilot Reporting Requirements

What are the General Reporting Requirements for Pilot 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:

- Number of Panbio™ tests used
- Number of employees 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

A centralized database for reporting of pilot data is currently being developed. In the meantime, the Ministry of Health will provide phase 1 participants with a reporting template to use for manual data entry until the centralized pilot reporting database comes online.

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 workplace settings. Future phases of the pilot program may collect a different set of information from

participating employers, and this guidance document will be updated to reflect those reporting requirements accordingly.

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

A positive result on a Panbio™ test is considered a preliminary positive. Public health direction requires that the local Public Health Unit be notified 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 that had a positive result on the Panbio™ screening test through the pilot 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 Panbio™ test during this pilot can be found in the COVID-19 Guidance: Considerations for Employer Antigen Screening Pilot document.