

COVID-19 Rapid Antigen Screening for Staff in Congregate Care Settings

TUESDAY, JANUARY 12TH

MODERATOR: REBECCA TRUSCOTT, ONTARIO HEALTH

SPEAKERS:

OLHA DOBUSH, MINISTRY OF LONG-TERM CARE

DR. SAMIR PATEL, PUBLIC HEALTH ONTARIO

DR. JULIE SHAW, EASTERN ONTARIO REGIONAL LAB ASSOCIATION

JENNIFER SMITH, EASTERN ONTARIO REGIONAL LAB ASSOCIATION

KEVIN THOMAS, ONTARIO HEALTH



Objectives

By the end of this session, you will understand:

- How rapid antigen screening will be used in congregate care settings
- How to collect the appropriate specimens for rapid antigen screening
- How to order and store Panbio™ COVID-19 antigen rapid test kits
- How to set up and run an antigen screening clinic
- How to interpret, communicate and document results



Updated MLTC Directive and Clinical Guidance on Use of Antigen Tests

Summary of Changes to Minister of Long-Term Care's Directive

- Long-term care homes are encouraged to implement rapid antigen tests for the purposes of surveillance testing of staff, student placements and volunteers in accordance with the protocols and frequency contained in the Ministry of Health's [COVID-19 Guidance: Considerations for Rapid Antigen Screening](#)
- The key requirements of the Rapid Antigen Screening Guidance include for asymptomatic individuals in long-term care homes that are not in outbreak and located in:
 - yellow/orange/red/grey zones, specimen collection and screening should be performed 2-3 times per week
 - green zone, specimen collection and screening should be performed 1-2 times per week.
- NOTE: For the duration of the Provincewide Shutdown, long-term care home licensees are required to implement testing frequency appropriate to the grey zone.
- To help long-term care homes prepare for implementation of rapid antigen tests, PCR tests may continue to be used for the surveillance testing purposes of the Directive, until a later date is confirmed.

Clinical Guidance (1/2)

- Rapid antigen testing is used for screening purposes only and should NOT be used for diagnosis of acute COVID-19 infection. Rapid antigen testing is performed on: a Nasopharyngeal swabs (NPS), a combined swab of throat and both nares, or a deep nasal swab.
- **Eligibility:**
 - Asymptomatic individuals in non-outbreak environment
 - Individuals who have previously been infected with and recovered from COVID-19 should not undergo repeat testing/antigen screening, unless otherwise directed by [local public health](#) or their health care provider as per their symptom and exposure history.
- **The *Laboratory Licensing and Specimen Collection Centre Act (LSCCLA)***
 - Regulates the operation of clinical labs and specimen collection centres by requiring a license to operate a laboratory and a license to operate a specimen collection centre.
 - ***Specimen Collection:*** Certain regulated health professionals (e.g., Physicians, Nurse Practitioners, Pharmacists, Dentists, Registered Nurses, Registered Practical Nurses, Paramedics and community paramedic practitioners) are exempt from Reg 682 of the LSCCLA and can collect a specimen without a license.
 - ***Conducting the Test:*** These same regulated health professionals (e.g., Physicians, Nurse Practitioners, Pharmacists, Dentists, Registered Nurses, Registered Practical Nurses, Paramedics and community paramedic practitioners) are exempt from Reg 683 of the LSCCLA and can perform a rapid COVID-19 test without a license.

Clinical Guidance (2/2)

- **Confirmatory Test for Positive Results:**
 - A positive result on a rapid antigen screening test is considered a preliminary positive and should be followed up with a laboratory-PCR test to act as a confirmatory test.
- **Negative Results:**
 - This is a screening test result, and only applies if the individual tested has no symptoms and no known exposure to COVID-19.
 - Individual should be counselled that the result is negative, and a false negative is possible
 - Individual should be directed to continue to follow infection prevention and control measures

Nasopharyngeal Specimen Collection and Procedure for Panbio™

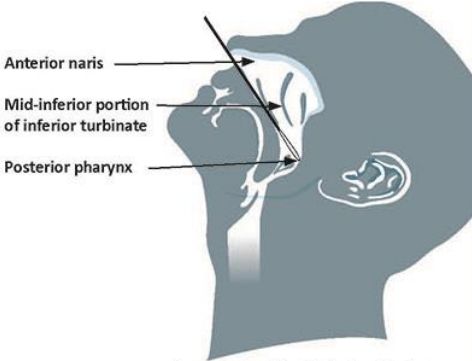


Specimen Collection for Panbio™

Nasopharyngeal Specimen Collection Instructions

Public Health Ontario | Santé publique Ontario

1. Tilt patient's head back 70°.
2. Insert flexible shaft mini-tip swab through nares parallel to palate (not upwards) until:
 - a. Resistance is met, OR
 - b. Distance is equivalent to half the distance from the patient's ear to their nostril.
3. Gently rub and roll the swab.
4. Leave swab in place for several seconds to absorb secretions.
5. Slowly remove the swab while rotating it and immediately place in sterile tube



In a seated position, tilt the head back at a 70° angle as illustrated in the picture

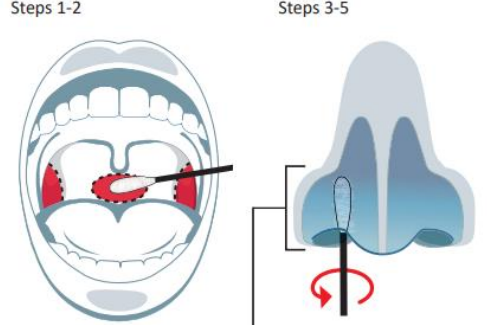
Ontario

<https://www.publichealthontario.ca/en/laboratory-services/kit-test-ordering-instructions/virus-respiratory-kit>

Oropharyngeal/Throat combined with Anterior Nares/Nostril

Public Health Ontario | Santé publique Ontario

1. Insert swab in posterior pharynx and tonsillar areas.
2. Rub swab over posterior pharynx and bilateral tonsillar pillars; avoid tongue, teeth, and gums.
3. Using the same swab, insert about 1 cm (0.5 in) inside nares.*
4. Rotate swab and leave in place for 10-15 seconds.
5. Using the same swab, repeat for the other nostril.



*Swab insertion distance will differ for paediatric patients.

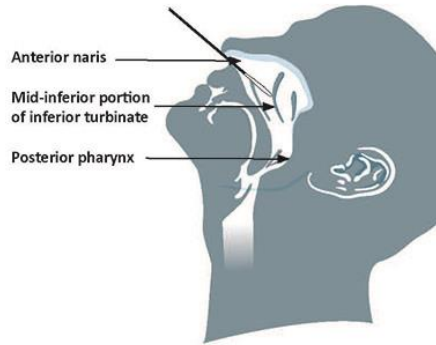
Ontario

<https://www.publichealthontario.ca/en/laboratory-services/kit-test-ordering-instructions/virus-respiratory-throat-nasal>

Deep Nasal Specimen Collection Instructions

Public Health Ontario | Santé publique Ontario

1. Tilt patient's head back 70°.
2. While gently rotating swab, insert swab about 2.5 cm (>1 in.)* straight back (not up) into nostril until the collar/safety stopping point touches the outside of the nose.
3. Rotate swab several times against the wall.
4. Leave swab in place for several seconds to absorb secretions.
5. Repeat for both nostrils using same swab.



In a seated position, tilt the head back at a 70° angle as illustrated in the picture

*Pediatrics: swab insertion distance will differ for pediatric patients.

Ontario

<https://www.publichealthontario.ca/en/laboratory-services/kit-test-ordering-instructions/virus-respiratory-kit-deep-nasal>



Panbio™ Ordering Process

Submitting a Request for Panbio

Requests for Panbio rapid tests can be submitted through the following link:

- <https://ehealthontario.on.ca/en/health-care-professionals/digital-health-services>

Central, East, North and Toronto Regions

Digital Health Services

Our suite of digital health services supports the delivery of modern, integrated, patient-centred care. Available to both individual clinicians and health care organizations, these robust, highly scalable services meet stringent privacy and security standards and enable the secure exchange of patient information across the province.

Coronavirus (COVID-19) Personal Protective Equipment & Vaccination Supplies Requests

Vaccination Supplies Requests

Critical Personal Protective Equipment (PPE) and/or Swab Kit Requests

Critical Personal Protective Equipment (PPE) and/or Swab Kit Requests with WEST LHIN(s)

Personal Protective Equipment (PPE) Product Concerns/Complaints

Should you have a concern/complaint about a product received from the Government of Ontario, please fully complete and submit this form.

West Region

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Note: If your LTC home is unsure which LHIN you reside in, it can be looked up by searching the postal code here: <http://www.lhins.on.ca>

Ontario Health West

WHICH PERSONAL PROTECTIVE EQUIPMENT (PPE) DO I USE?

Healthcare workers must assess which PPE to use before each patient interaction.

To protect yourself from exposure, refer to the suggested PPE guide at hmmscovid19.ca

Forms

PPE Order Forms →

Swab Order Form →


PPE Conservation Status →

Ordering Process for Panbio

- Submit requests for Panbio through the online intake form. Once all the relevant information is entered on the form (contact/shipping, details, etc.), requestors will enter 'Panbio' on the ordering portion of the form:

Central, East, North and Toronto Regions

Please indicate any swab kit types that you would prefer to receive for COVID-19 testing (e.g., % NP swabs vs. % Deep Nasal/Throat swabs vs. % Saliva Neat swabs, etc.). Please note that we cannot guarantee that a specific swab type will be provided for your request.

Specify  Panbio for testing <No. of Staff Members> across <No. of Homes>

Please include any additional comments

Include any relevant additional information here (e.g. approved pilot site, other product needs, etc.)

West Region

COVID 19 Swab Kit

All orders are to be placed in EACHES

Quantity of Swab Kits Requested

Enter eligible amount (e.g. 250)

Special Request or Comment:

Panbio for testing <No. of Staff Members> across <No. of Homes>

- Regional Supply Chain (RSC) team members will validate the requests.
- RSC team will then escalate the request to Public Health Ontario (PHO)
- PHO will enter orders into Stevens (i.e., distribution centre) and Stevens will ship these kits to the requesting entity

Winter Protocols for Swab Distribution

Background

- **Preparing for winter months:** Some items (kits, orphan media, etc.) require to be stored within a specific temperature (above “2° Celsius”). Shipment of such items will need to be temperature controlled (i.e. heat packs will be included in the packages).
- **Preparing for holiday season:** We anticipate our logistics providers to have an increased volume of deliveries during the holiday season and as such some delays in shipments may be experienced. Therefore, submitting orders well in advance will be important to ensure extra time for deliveries.

Winter Process

- The requesting entities will need to submit their requests **between Monday and Wednesday**. This will achieve a few objectives
 - give adequate packaging time to the warehouse to insert the heat-packs as required
 - ensure deliveries are completed ahead of the weekend and avoid prolonged shipment time in the event of unforeseen delays
- Unless **urgent**, requests / orders received on Thursday or Friday will be processed by the warehouse on Monday.



Readiness Assessment for Using Panbio™

- Kit content and set-up
- Staffing requirements
- Dedicated space
- Biosafety
- Conducting quality control

Rapid Antigen Screening Clinic Implementation Readiness Assessment

- Panbio™ rapid test kits
 - Check expiry date
 - Brought to 15-30° C
 - Extra tube holder (from another Panbio™ kit)
- Panbio™ implementation procedures and quality guidance understood by long-term care home administrator, physician and rapid test clinic staff
- 2-3 team members trained to operate rapid screening clinic (see slide 18 for staffing recommendations)
 - Registration, preparation of kits, labelling
 - Swabbing
 - Testing specimens and documenting results
- Confidentiality agreements signed by staff operating the rapid test clinic
- Dedicated, private space to test, read and record results



**Materials listed on
next slide**

Suggested Additional Materials for Panbio™ Screening

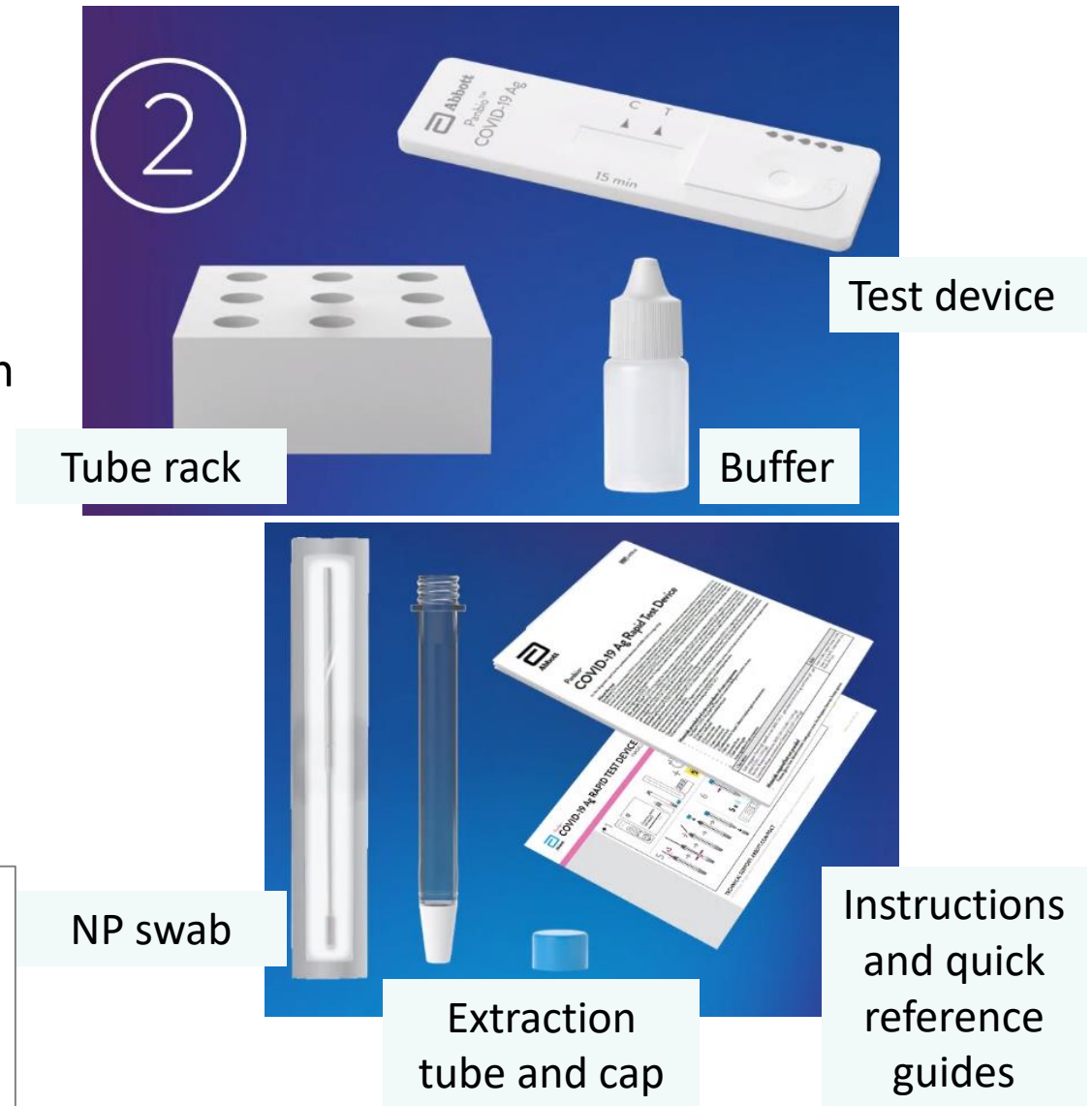


- PPE for clinic staff (mask, gown, face shield)
- 2 biohazard waste containers
- 2 sets pre-printed labels
- Masking tape
- Box of gloves
- Hand sanitizer
- Staff list
- Timer
- Disinfectant (clean spills, wipe down equipment pre/post clinic)
- Plexiglass shield

Panbio™ Kit

- 25 Test devices with desiccant in individual foil pouch
- 25 Extraction tubes
- 25 Extraction tube caps
- 25 Sterilized **nasopharyngeal swabs (NP)*** for specimen collection
- 1 Buffer (1 x 9 ml/bottle)
- 1 Positive control swab
- 1 Negative control swab
- 1 Tube rack
- 1 Quick reference guide (Nasopharyngeal)
- 1 Instructions for use

***NOTE: The proprietary Panbio™ swab can be used for the following acceptable alternate specimen collection techniques: deep nasal and combined throat + both nares.**



Storage Conditions for Panbio™ Kits

- Store Panbio™ between 15-30°C; DO NOT FREEZE
- Do not use test kit beyond expiration date
- Once test device is removed from foil pouch, it should be used immediately for testing
- Do not use test kit if foil pouch is damaged or seal is broken – discard immediately

Staffing Recommendations for Panbio™ Rapid Screening

Ideally, two-three designated staff members are needed for testing (if operating under exemption to the LSCCLA):

- **Person A** – to register staff, prepare kits and label tubes. Can be a non-RHP.
- **Person B** – an RHP, exempted under Reg 683, to collect the appropriate specimen. Person B will conduct the swab and place swab in extraction tube according to instructions.
 - Regulated health professionals that may conduct the swab: Physicians, Registered Nurses, Nurse Practitioners, Registered Practical Nurses, Pharmacists, Dentists, and Paramedics (including Community Paramedic Practitioners).
- **Person C** – must be RHP, exempted under Reg 683, to test the specimen and record and report results.
 - Regulated Health Professionals that may conduct the point of care test are: Physicians, Nurse Practitioners, Dentists, Pharmacists, RNs, RPNs, Paramedics (including Community Paramedic Practitioners).



Dedicated Space for Panbio™ Screening

- Dedicated space should consist of a closed-off space with sufficient area to place a standard 6–8-foot (folding) table.
- Accommodate for privacy to conduct swabbing and for reading and recording results.
- Allow for physical distancing and safety for 2-3 people to operate clinic
- Consider space on-hand for supply of PPE and test kits
- Access to a phone to contact director of care/administrator or physician regarding any preliminary positive results.

Biosafety Considerations for Panbio™ Screening

- Conduct a local risk assessment
- Wear appropriate personal protective equipment (PPE) when handling patient specimens and used devices
- Dispose of specimens, kits, and other contaminated materials carefully in an appropriate biohazard container
- Maintain a safe work area

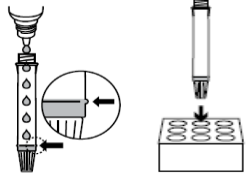
For more information: <https://www.publichealthontario.ca/-/media/documents/lab/covid-19-abbott-panbio-antigen-rapid-test-biosafety.pdf?la=en>

Conducting Control Swabs

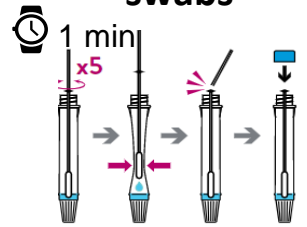
Control swabs should be tested by staff who will be operating the testing station. Quality control swabs should be tested with each new shipment of kits, with any new lot numbers of kits and done at least weekly. It is important to time the control test for the full 15 minutes.

Process Flow for Testing Kit with Controls

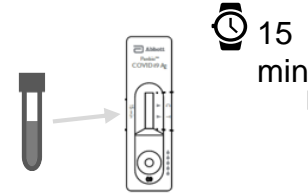
1. Fill tube with buffer



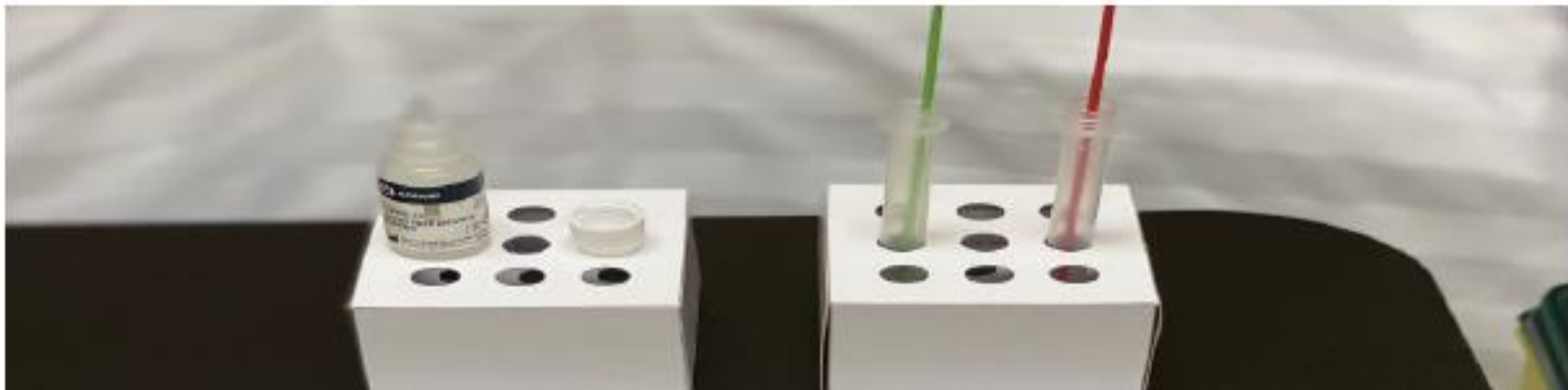
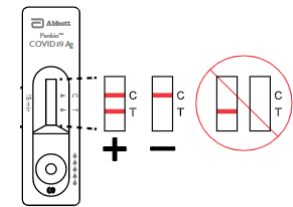
2. Insert control swabs



3. Process test



4. Read result





Operational Process for using Panbio™

- Preparations
- Intake
- Specimen collection
- Testing the specimen
- Reading results
- Communicating results

Operational Procedures

Rapid antigen screening clinic can be broken into 5 stages:

1. Preparations
2. Intake
3. Collecting the specimen
4. Testing the specimen
5. Reading the result
6. Communicating results

1. Preparations

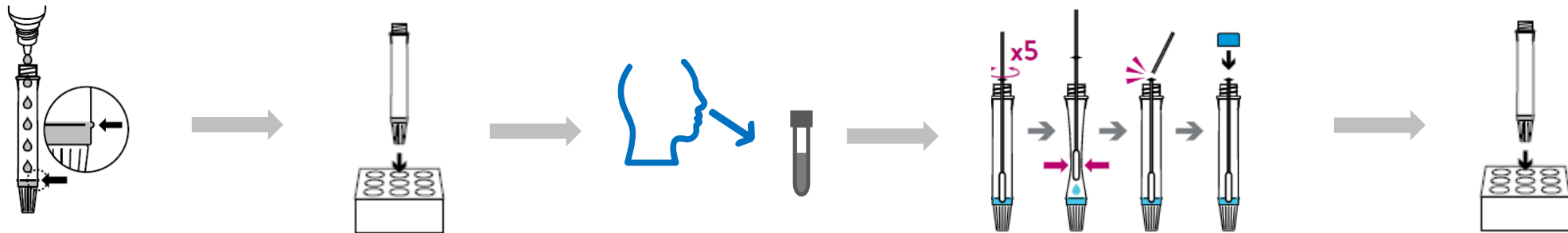
1. Panbio™ test kits should be prepared in advance and should contain the following:
 - Extraction tubes, pre-filled with **buffer fluid**, as per manufacturer's directions:
 - The **buffer bottle** should be held vertically, and the **extraction tube** filled with **buffer fluid** until it reaches the fill-line of the extraction tube (300µl).
 - **If the amount of buffer is excessive or insufficient, an improper test result may occur.**
 - Test cartridge
 - NP swab
2. Determine how test tubes and cartridges will be labelled with participant information (e.g., name and DOB) to avoid mix-ups.
 - Suggest to pre-print two labels containing participant information: One for Panbio™ extraction tube, one for cartridge/device.

2. Intake

1. Inform staff member of testing process.
2. Record the staff member name that will be tested and store the record in a safe, secure location (e.g., password protected Excel spreadsheet). This will form the basis of the “results tracker”. A laptop is helpful for maintaining accurate/real-time records (intake and results).
3. Label a Panbio™ tube with the appropriate participant information for tracking (e.g., pre-printed label).
4. Label a corresponding Panbio™ test cartridge.
5. Direct staff member to the rapid test station.

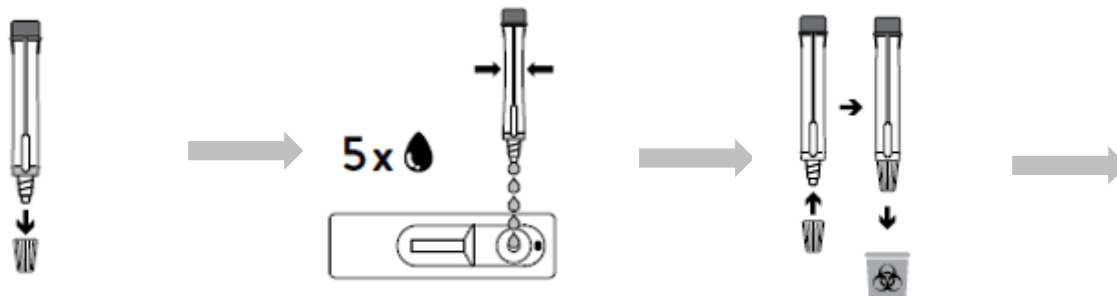
3. Specimen Collection

1. **Person A (can be non-RHP)** places pre-printed label with name of the staff member on extraction tube.
2. **Person A** places a pre-filled extraction tube in the tube rack.
3. **Person B (RHP trained to collect swab)** collects specimen **with dedicated rapid test swab** and places the **swab** in labelled extraction tube.
4. **Person B** swirls swab tip in **buffer fluid** then push into the wall of the extraction tube at least five times.
5. **Person B** squeezes out the swab by squeezing the outside of **extraction tube** with their fingers.
6. **Person B** breaks the **swab** at the breakpoint and places the **tube cap** on. The broken part of the swab is disposed of in the **biohazard container**.
7. The **extraction tube** with the **swab** is placed in a 2nd tube holder.
8. **Person B** changes gloves and performs hand hygiene after each swab.



4. Testing the Specimen – Option 1

1. **Person C (designated RHP)** opens a **test device** and places a pre-printed label on the device to correspond with the staff member's name on **extraction tube** that will be tested.
2. Each **extraction tube** that will be tested should have a corresponding **test device**. **DO NOT** re-use test devices.
3. **Person C** takes **extraction tube** (with specimen in it) from the 2nd tube holder, removes the nozzle cap from the bottom, and **dispenses 5 drops** into the well of the **test kit**.
4. Discard extraction tube with nozzle cap in the biohazard bin
5. **Person C** checks the time on the clock, **adds 15 mins, writes this on a piece of masking tape** and places **masking tape next to the test device** (i.e., if time is 12:00, then 12:15 written on masking tape). **The time of the tape indicates when the test device should be checked, and the result recorded.**

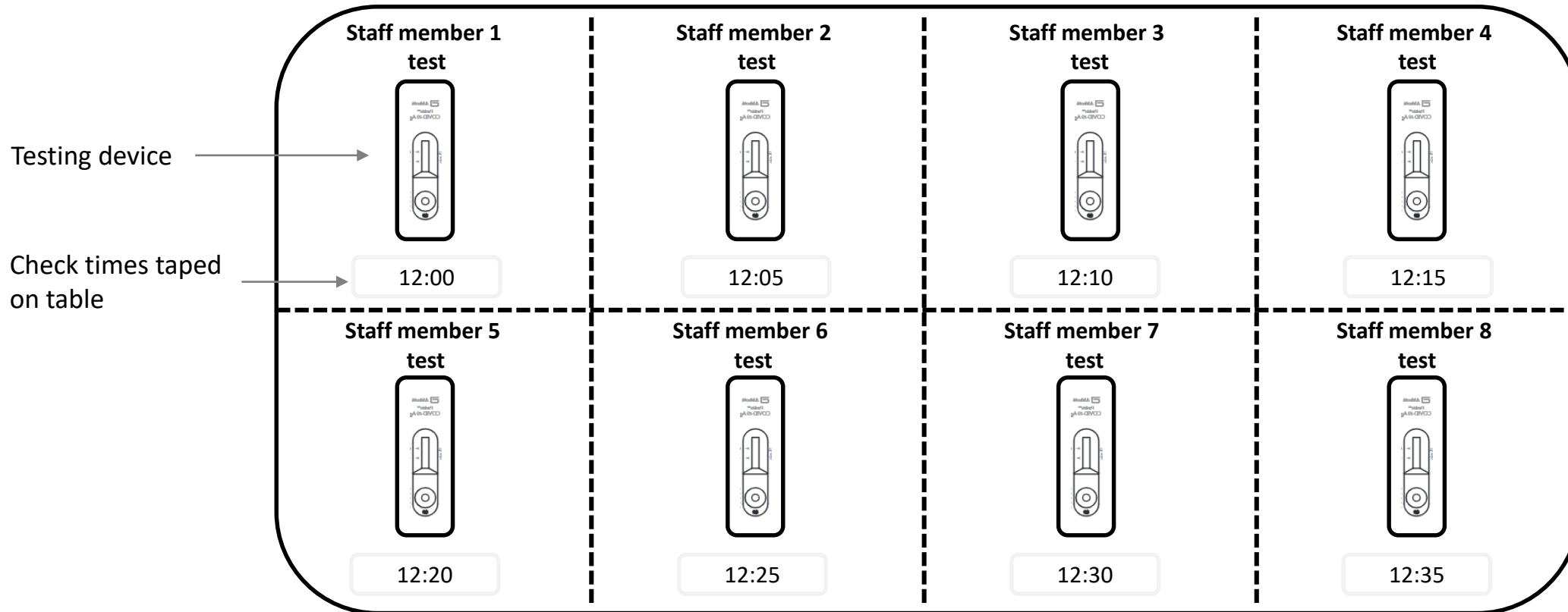


Person C repeats steps 1-5 for the next extraction tube to be tested and places each testing device and masking tape on different sections of the table.

NOTES:

- **Tip** -Testing station table should be cleaned and sectioned off prior to start of clinic.
- **DO NOT** move the test device until the test is complete.
- **Caution** - Bubbles in the extraction tube can lead to inaccurate results. If unable to create sufficient drops, this may be caused by clogging in the dispensing nozzle. Simply recap your extraction tube and invert the tube. This will release the blockage.
- Clean up any spillage with appropriate disinfectant.
- **Change gloves and perform hand hygiene after handling each extraction tube**

Testing Station Table Visual Representation – Option 1

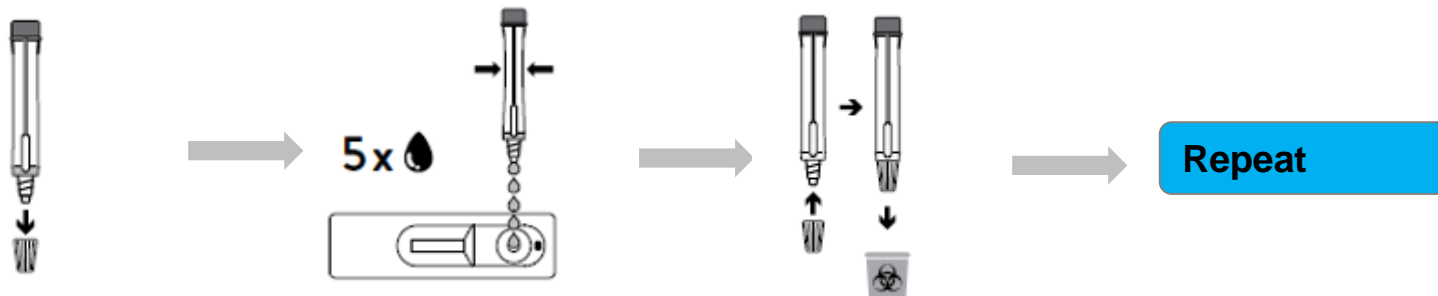


4. Testing the Specimen – Option 2

1. **Person C (designated RHP)** sets out **5-10 test cartridges** (depending on number of staff to be tested).
2. **Person C** opens **all test devices for the batch** and places a pre-printed label on each device to correspond with the staff member's information on **extraction tube** that will be tested .

Each **extraction tube** that will be tested should have a corresponding **test device**. **DO NOT** re-use test devices.

3. **Person C** takes **extraction tube** (with specimen in it) from the 2nd tube holder, holds it vertically, removes the nozzle cap from the bottom, and **dispenses 5 drops** into the well of the **test kit**.
4. Discard extraction tube with nozzle cap in the biohazard bin
5. **Person C repeats steps 2-4** for the next **extraction tube** to be tested.



NOTES:

- **Caution** - Bubbles in the extraction tube can lead to inaccurate results. If unable to create sufficient drops, this may be caused by clogging in the dispensing nozzle. Simply recap your extraction tube and invert the tube. This will release the blockage.
- Clean up any spillage with appropriate disinfectant.
- **DO NOT** move the test device until the test is complete
- **Tip:** Testing station table should be cleaned prior to start of clinic.
- **Change gloves and perform hand hygiene after handling each extraction tube**

Testing Station Table Visual Representation – Option 2



5. Reading Results

1. When check time has been reached **Person C** records each result on the results tracker. The result is found in the rectangular window of the test device. Results need to be checked within 5 mins of time on the masking tape.

If using **option 2**, results need to be checked 15-20 minutes after sample was dropped into well.

2. Interpret results:

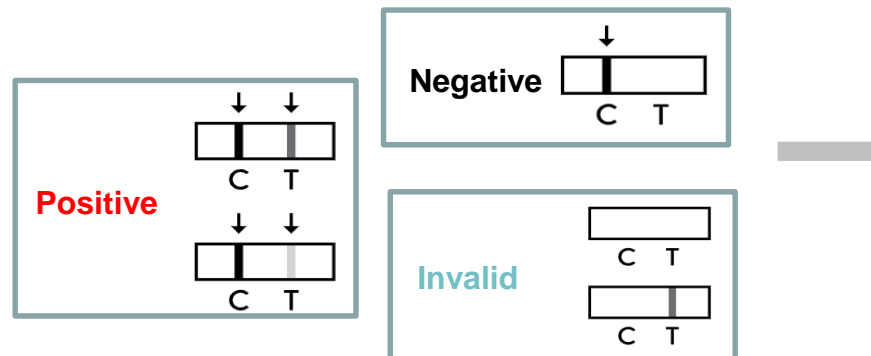
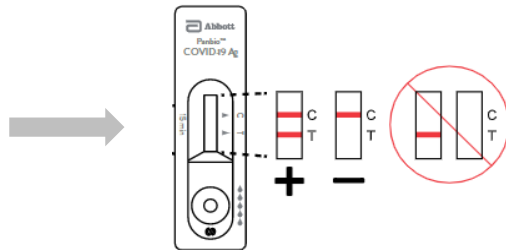
Positive = the presence of **the control line (C) and the test line (T)** within the result window. The presence of any test line (T), no matter how faint, indicates a positive result

Negative = the presence of **only the control line (C)** and no test line (T) within the result window

Invalid = if the **control line (C) is not visible** within the result window. Instructions may not have been followed correctly or sample was too viscous. It is recommended to read the instructions again before conducting repeat testing with a new specimen.

3. Dispose of used device in **biohazard container**
4. Remove and dispose of corresponding masking tape label from table
5. At the end of rapid antigen screening clinic Person C checks that all results have been **recorded on results tracker** and saves and stores the file securely.

Time check

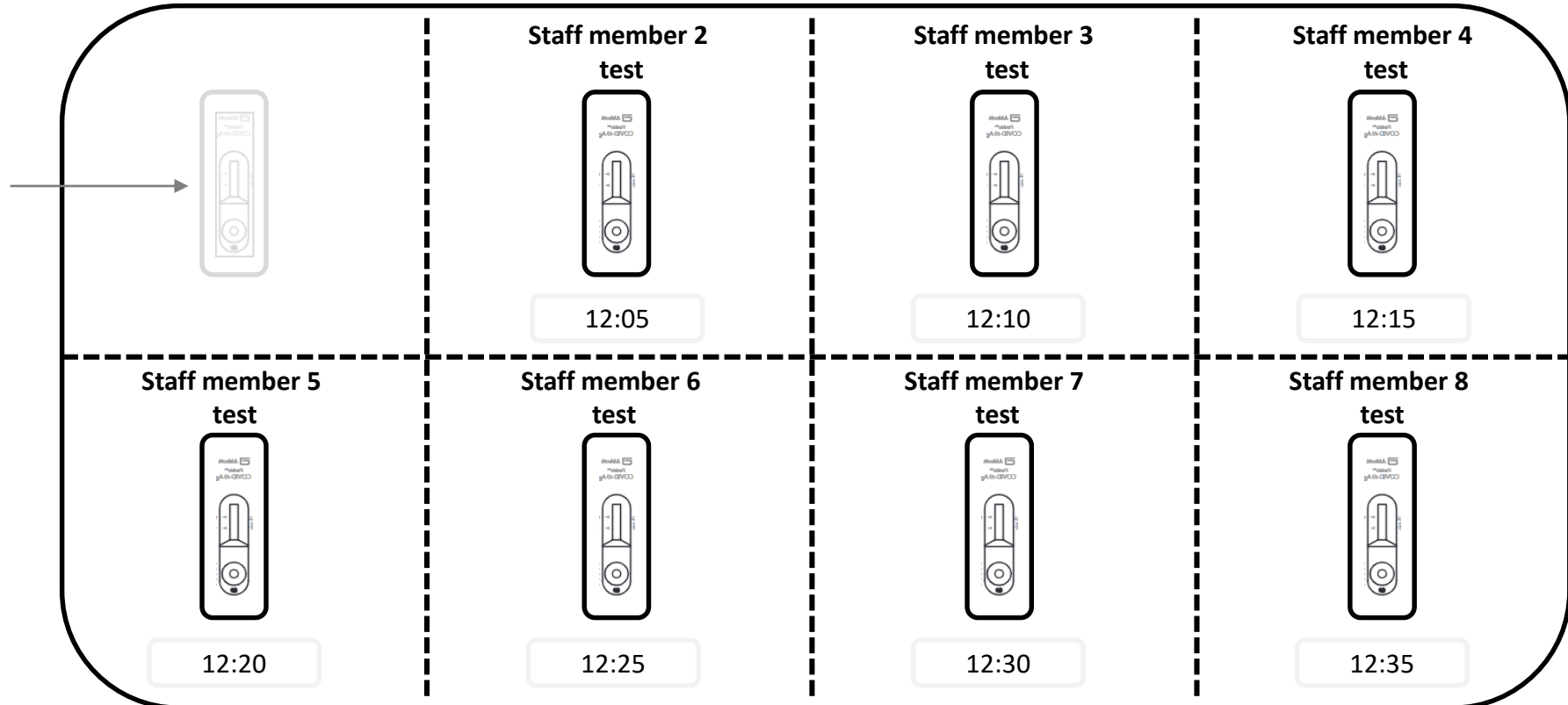


Person C repeats steps 1-4 for the next test device

Preparing for Next Set of Tests – Option 1

Once result is recorded, used device and masking tape is removed and replaced with next device and masking tape with new check time

Used device should be discarded immediately into biohazard bin



6. Communicating Results (1/2)

Negative Results

- Most organizations that are conducting frequent rapid antigen screening do not communicate negative results and follow a “no news is good news approach”
- Continue to follow public health measures for symptom screening, appropriate distancing, use of PPE and hand-washing

Preliminary Positive Results

- Follow all public health guidance for handling preliminary positive case
- Report preliminary positive result to local public health unit
- Require that employee receive confirmatory lab PCR test within 24 hours

6. Communicating Results (2/2)

Preliminary positive results roles and responsibilities

At the Rapid Test Station:

- **Person C** communicates the positive result to the **physician** (or Admin if physician not available) in a private manner; typically, by telephone. **Person C** takes steps to maintain confidentiality of the results, i.e., results should not be communicated in a manner that exposes the identity of the staff to individuals other than physician or Admin.
- Once the positive result has been communicated to physician, **Person C** informs **Person B** to restart the intake process.

Director of Care, Senior Administrator or Physician

- Staff member is informed of preliminary positive result and a confirmatory PCR test is completed by an RHP.
- Staff member is asked leave the workplace and return to their residence, where they should remain in self-isolation until contacted by Public Health and provided further instructions.
- Follow internal protocols to inform administration of home of positive result, e.g., leaving voicemail message with their contact number for follow-up.



Documenting Results

Documenting Results (1/2)

- A staff list (“results tracker”) should be created to document results of staff screened for COVID-19 using antigen test.
- This list should document:
 - Staff (student placements, volunteers) who have been tested
 - Staff (student placements, volunteers) who have been tested using antigen rapid/lab-based PCR test
 - Staff (student placements, volunteers) who refused the antigen rapid/ lab-based PCR test
 - Staff (student placements, volunteers) who received negative antigen rapid/lab-based PCR test results
 - Staff (student placements, volunteers) who received positive antigen rapid/lab-based PCR test results
 - Staff (student placements, volunteers) who received confirmatory positive lab-based PCR test result
 - Staff (student placements, volunteers) who received confirmatory negative lab-based PCR test result
- All preliminary positive COVID-19 tests performed must be reported to the local public health unit in accordance with the [LSCCLA](#) and the [HPPA](#).
- Health care professionals must ensure that all personal and health information will be collected, used, disclosed in accordance with relevant legislation, including the [Personal Health Information Protection Act \(PHIPA\)](#).

Documenting Results (2/2)

- The following statistical information will be required to be collected:
 - 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 volunteer testing was conducted; and
 - the number of visitors, caregivers and support workers tested in the home and the date on which they were tested.
- This information will be required to be submitted to the Ministry of Long-Term Care through the electronic Health Data Collection Tool that all homes have access to.



Available Resources and Additional Support

Resources

- Abbott – Helpful documents and video demonstrations:
<https://www.globalpointofcare.abbott/en/product-details/panbio-covid-19-ag-antigen-test.html#>
- Ontario Health’s online ordering system for Panbio™ kits:
<https://ehealthontario.on.ca/en/health-care-professionals/digital-health-services>
- Public Health Ontario long-term care resources:
<https://www.publichealthontario.ca/en/diseases-and-conditions/infectious-diseases/respiratory-diseases/novel-coronavirus/long-term-care-resources>
- Public Health Ontario fact sheet: Abbott Panbio™ COVID-19 Antigen Rapid Test: Biosafety Considerations: <https://www.publichealthontario.ca/-/media/documents/lab/covid-19-abbott-panbio-antigen-rapid-test-biosafety.pdf?la=en>



Additional Resources

- Later this week, all participants will be emailed:
 - Link to the recording of this webinar
 - Ontario Health Onboarding Guide for Panbio™ COVID-19 Ag Rapid Test
 - Link to a post-webinar survey
- Participants should have already received (posted on Itchomes.net):
 - Minister’s Directive COVID-19: Long-Term Care Home Surveillance Testing and Access to Homes
 - Clinical Guidance from the Office of the Chief Medical Officer of Health
 - FAQs
 - Ontario Health instructions on how to order Panbio™ test kits
 - Copy of the slide deck from this webinar

Questions?

- For more information about this presentation contact covid19testing@ontariohealth.ca
- For questions related to the Minister of Long-Term Care's Directive or Ministry of Health's, *Clinical COVID-19 Guidance: Considerations for Rapid Antigen Screening*, you may contact Ltc.Info@Ontario.ca



Appendix

Combined Throat and Nasal Specimen Collection



Public Health Ontario

How to Collect a Combined Throat and Nasal Specimen for COVID-19 Testing

Copy link

How to Collect a Combined Throat and Nasal Specimen for COVID-19 Testing

This step-by-step guide shows health care professionals how to use a swab to collect a combined throat and nasal sample for a COVID-19 test.

Duration: 2 min

Source: Ontario Agency for Health Protection and Promotion (Public Health Ontario). Oropharyngeal/throat combined with anterior nares/nostril [Internet].

Toronto, ON: Queen's Printer for Ontario; 2020. Available from: <https://www.publichealthontario.ca/en/laboratory-services/kit-test-ordering-instructions/virus-respiratory-throat-nasal>

Storage Conditions for Panbio™ Kits

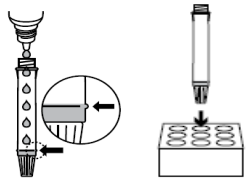
- The test kit should be **stored at temperatures between 2-30 °C. DO NOT FREEZE** the kit or its components.
 - If stored in a refrigerator, **all kit components must be brought to room temperature (15-30 °C) for a minimum of 30 minutes prior to performing the test.** DO NOT open the pouch while components come to room temperature.
- The buffer bottle may be opened and resealed for each assay. The buffer cap should be firmly sealed between each use. The buffer is stable until expiration date if kept at 2-30 °C.
- **DO NOT** use the test kit beyond its expiration date. The shelf life of the kit is as indicated on the outer package.
- **DO NOT** use the test kit if the pouch is damaged or the seal is broken.
- Direct swab specimens should be tested immediately after collection. **If immediate testing is not possible, the swab specimen can be kept in an extraction tube filled with extraction buffer (300 µl) at room temperature (15-30 °C) for up to two hours prior to testing.**
 - **Caution:** If the amount of buffer is excessive or insufficient, an improper test result may occur.
- Once a test device is removed from the foil pouch it should be used immediately for testing

Conducting Control Swabs

Control swabs should be tested by staff who will be operating the testing station. Quality control swabs should be tested with each new shipment of kits and done at least weekly.

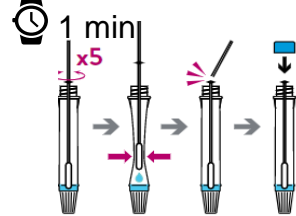
Process Flow for Testing Kit with Controls

1. Fill tube with buffer



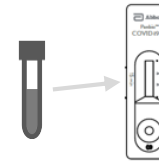
- Hold buffer bottle and fill extraction tube with buffer fluid until it reaches fill-line (300 µl). **If the amount of buffer is excessive or insufficient, an improper test result may occur.**
- Place extraction tube in tube rack

2. Insert control swabs



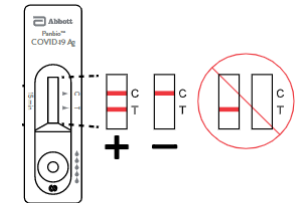
- Insert the positive or negative control swab in buffer fluid inside of the extraction tube and soak swab for 1 minute.
- Swirl control swab tip in buffer fluid inside of extraction tube, pushing into wall of the tube at least 5 times. Squeeze swab by squeezing extraction tube.
- Break the swab with the tip still in the tube; broken end of the swab is disposed of in biohazard container.
- Close cap of extraction tube.

3. Process test



- Open dropping nozzle cap and dispense 5 drops of the liquid onto the test kit. **Caution:** Bubbles in the extraction tube can lead to inaccurate results. If unable to create sufficient drops, this may be caused by clogging in the dispensing nozzle. Shake tube gently (or invert) to release the blockage.
- Do not move** the test device until the test is complete
- Discard extraction tube and nozzle cap in biohazard bin
- Set timer for 15 mins to let extraction fluid react with test kit.

4. Read result



- Read result
- Document test results