Implementing a COVID-19 Rapid Antigen Screening Program: Panbio

Last updated: September 24, 2021

Visit ontariohealth.ca/antigen-test to watch a training video on this topic.

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Overview

By the end of this session, you will understand:

1. Suggested site flow and set-up for a rapid antigen screening clinic
2. How to use Panbio™ tests

Readiness Assessment for Using Panbio™

- Kit content and set-up
- Staffing recommendations
- 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 rapid testing lead and test clinic staff.
- Team members trained to operate rapid screening clinic (see slide 10 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

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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

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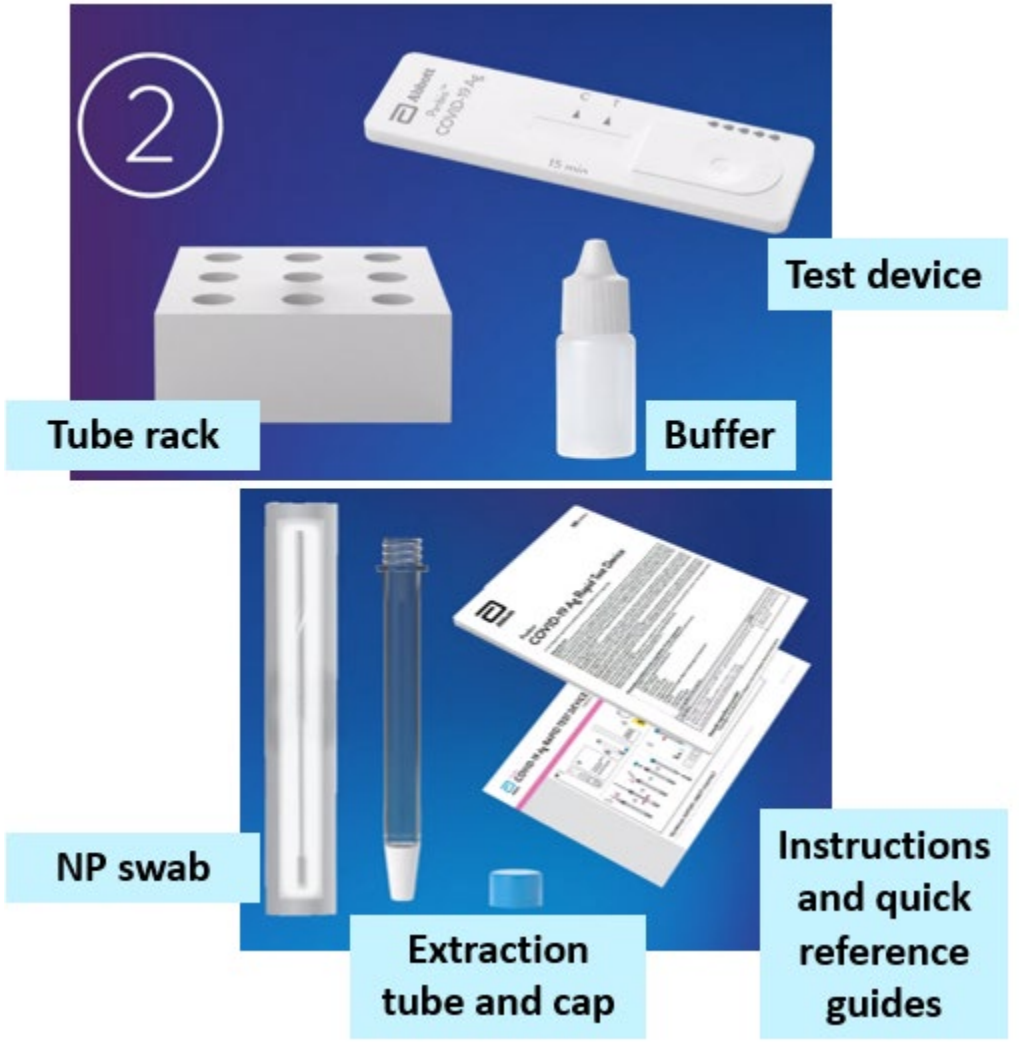
Panbio™ Kit

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



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Storage Conditions for Panbio™ Kits

- Store Panbio™ between 2-30°C; DO NOT FREEZE
- Track test lot numbers and expiry date. 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. Dispose of unused damaged or expired testing kits with biohazard waste.

Panbio™ Kit Swab Type

- Ontario's current inventory of the Abbott Panbio™ test kits comes with either nasopharyngeal (NP) swabs or nasal swabs.
  - Either swab kit type may be distributed based on available inventory
  - Program participants should only specify the kit type in their order if they specifically wish to receive a kit with nasopharyngeal swabs
- NP swabs can be used for NP, combined throat + both nares, deep nasal or nasal specimen collection
- Nasal swabs can be used for combined throat + both nares, deep nasal or nasal specimen collection

Clinical Guidance

- All Health Canada approved point-of-care tests for COVID-19 can be performed in accordance with the product manufacturer's label, i.e., by health professional or trained operator.
- Specimen collection for antigen POCT may also be done under supervision of a trained individual or by the person being tested ('self-swabbing'). Self-swabbing for POCT antigen tests is not currently approved by Health Canada, but the Ministry of Health is of the opinion that it is appropriate, from a clinical perspective, to do voluntary self-swabbing for antigen POCTs in accordance with this guidance document under the following condition:
  - Any individual supervising self-swabbing or doing self-swabbing must consult the self-swabbing training resource (video and written instructions) developed by Ontario Health in collaboration with Public Health Ontario and ensure they have appropriate knowledge, skills and judgement to perform the test.
- Individuals and organizations are under no obligation to conduct antigen POCT using supervised self-swabbing; use of supervised and unsupervised self-swabbing as a means of specimen collection is to be done only on a voluntary basis.

Staffing Recommendations for Antigen Rapid Screening

Example staffing model of 2-3 designated staff members:

Staff Member	Role
Person A	Pre-testing: Register staff, prepare kits and label tubes.
Person B	Testing: Use swab to collect the specimen and place it in the extraction tube according to instructions.
Person C	Testing & Result Recording: Test the specimen and record and report results.

The suggested process flow in this deck, using batch testing, would accommodate approximately 30 tests per hour.

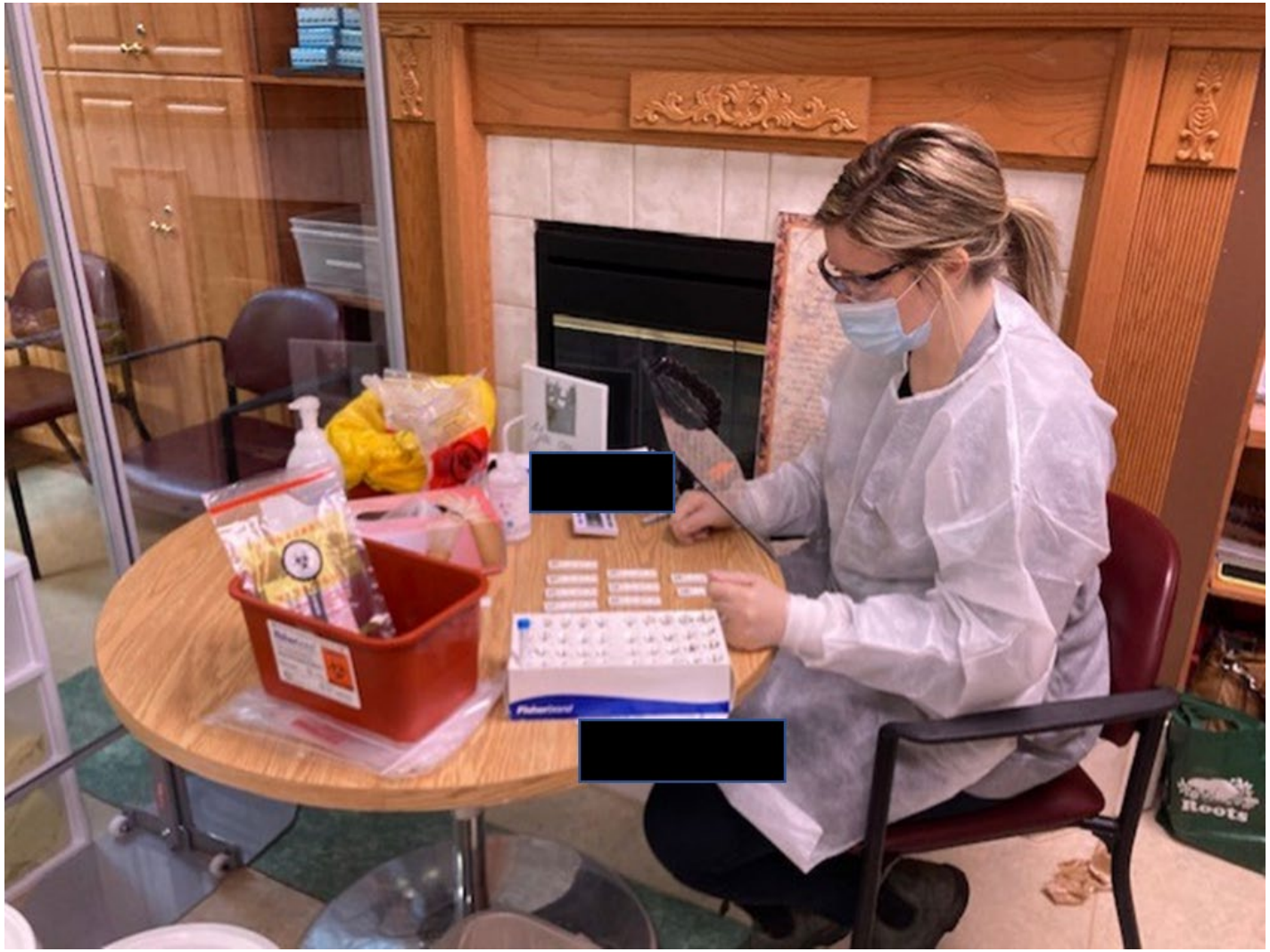
Note: Employers will be responsible for ensuring individuals delivering antigen tests have the knowledge, skills, and judgement to perform the test.

Sites can explore partnering with additional community providers or engaging service providers by contract to conduct rapid antigen screening.

Dedicated Space for Antigen Screening

- Room temperature maintained at 15° C to 30° C
- Dedicated space should consist of a closed-off space with sufficient area to place a standard 6–8-foot (folding) table. Ensure that the table is set up such that it is not in direct sunlight.
- 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 the rapid testing lead regarding any preliminary positive results.

Dedicated Space for Panbio™ Screening



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Biosafety Considerations for Antigen Screening

- Conduct a local risk assessment
- Wear appropriate personal protective equipment (PPE) when handling patient specimens and used devices (e.g., gloves, gowns, masks, and face shields)
- Dispose of specimens, kits, and other contaminated materials carefully in an appropriate biohazard container. All extraction tubes should have their caps in place prior to disposal. The biohazard waste container should be a yellow bag or container and labelled with the universal biohazard symbol. Refer to Safe Handling and Management of rapid antigen COVID-19 testing waste
- For waste generated from **at-home** rapid antigen screening the regulatory requirements for managing the hazardous waste under the Environmental Protection Act do not apply.
    - People undertaking at-home screening should consult local municipal by-laws on the proper disposal of this waste to ensure if can be disposed of with household trash
- Maintain a safe work area
- For more information see Public Health Ontario's Biosafety Factsheet

Track Specimens

- Use an electronic tracker that records all staff working at the site who will be participating in the rapid antigen screening program. A laptop is helpful for maintaining accurate/real-time records
  - A password protected Excel spreadsheet will keep all information secure
  - If using paper, store in a safe, secure location
- Create 2 electronic labels per test for each staff member. Labels should include at least 2 personal unique identifiers (e.g., name and date of birth)

Designing Clinic Hours for your Setting

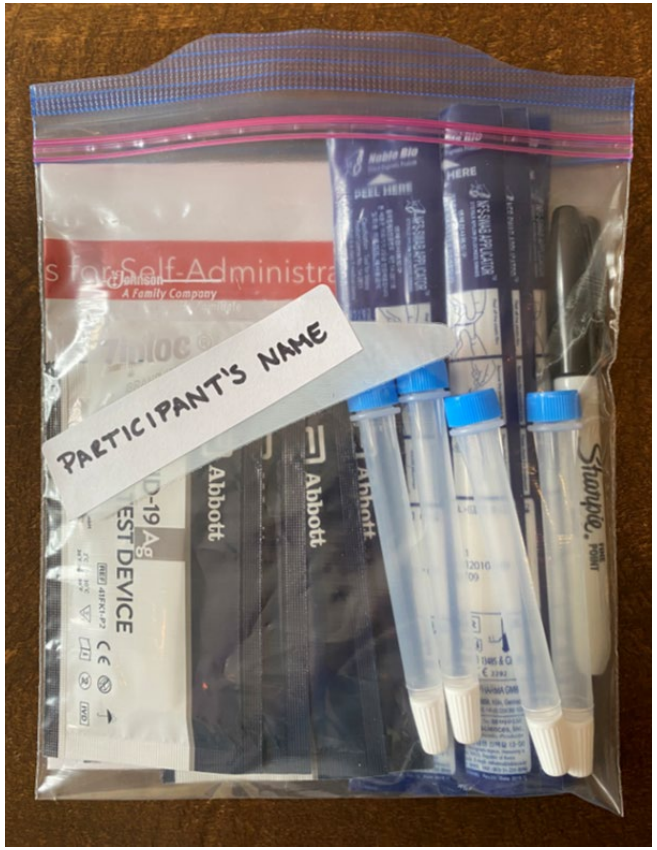
- Clinic hours may be defined based upon the hours of work at the site of testing, the start and end times of any shifts and the frequency of testing as outlined in the Ministry of Health – COVID-19 Guidance: Considerations for Antigen Point-of-Care Testing

Splitting Panbio™ Tests for At-Home Self-Screening

- **Organizations should split a kit of 25 tests into mini screen kits for at-home screening to avoid test wastage.**
  - Mini screen kits should contain all the supplies needed for up to 4 weeks worth of screening for each participant
- **How to create mini kits:**
  1. The organization should conduct the positive and negative control swabs on each new lot of rapid antigen tests for quality assurance purposes.
  2. Collect all the supplies needed for the chosen frequency of screening, including packaged swabs, tubes, test cartridges, a permanent marker for labelling the tubes with the correct date, and any written documentation about the at-home screening process (see attached image).

Splitting Panbio™ Tests for At-Home Self-Screening

3. Pre-fill all tubes with the buffer solution to the fill line (approximately ten drops).
    - If you use too little or too much liquid, you may get an incorrect test result.
    - Do not touch the liquid itself, the bottle dispenser tip, or the test tube opening with your hands.
    - Use only the liquid provided in the kit. Do not replace the liquid any other liquids (e.g. tap water) otherwise the results may correct.
    - Note that the buffer solution will last in the tubes until the expiration date of the test.



4. Ensure the caps on both ends of the tube are securely fastened.
5. Put supplies into a ziploc bag or another container and label with the participant's name (if desired).

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Refer to: Making Mini Screen Kits for @Home Screening - YouTube for a short video on how to split the Panbio™ kits.

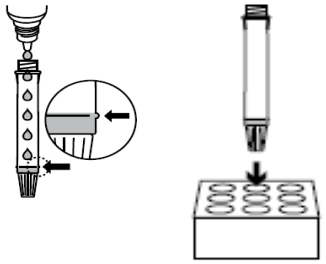
Conducting Control Swabs

- 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 with any new lot numbers of kits.
- For sites performing:
  - >25 tests/day: Conduct control swabs at the beginning of the day before patient testing begins
  - <25 tests/day: Conduct control swab 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.

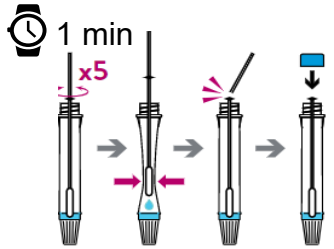
Conducting Control Swabs

Process Flow for Testing Kit with Controls

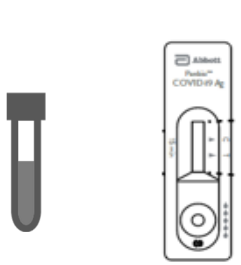
1. Fill tubes with buffer



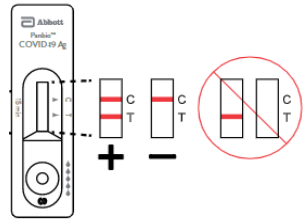
2. Insert control swabs

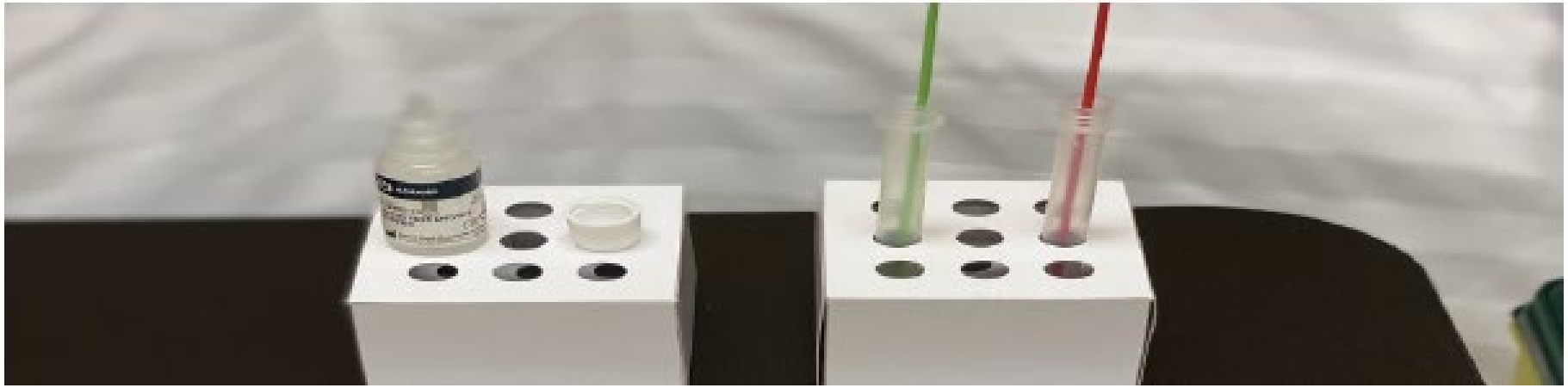


3. Process tests



4. Read results





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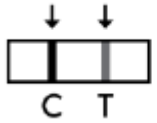
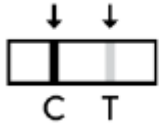
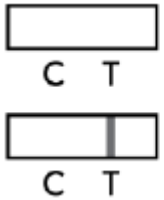
Interpreting Results of Control Swabs

Result:	Interpretation:
	**The result is negative** The presence of only the control line (C) and no test line (T) within the result window indicates a negative result.
	**The result is positive** The presence of the control line (C) and the test line (T) within the result window, regardless of which line appears first, indicates a positive result.
	**The result is positive** The presence of any test line (T), no matter how faint, indicates a positive result.
	**The result is invalid** If the control line (C) is not visible within the result window after performing the test, the result is considered invalid. Instructions may not have been followed correctly or the sample was too viscous. It is recommended to test a new lot and review the instructions again before conducting tests on patient specimens. Contact the distributor if problems persist.

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 6 stages:

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

1. Preparations

1. Panbio™ test kits should be prepared in advance and placed in a small clear biohazard bag. The bag 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.**
     - Buffer bottle should be kept separate from specimens.
     - The buffer cap should be firmly sealed between each use.
   - Test cartridge
   - NP or nasal swab
2. Determine how test tubes and cartridges will be labelled with participant information (e.g., name and date of birth) to avoid mix-ups.
   - Pre-print 2-3 labels containing participant information: One for Panbio™ extraction tube, one for cartridge/device, one for results sheet (if using paper).

1. Preparations

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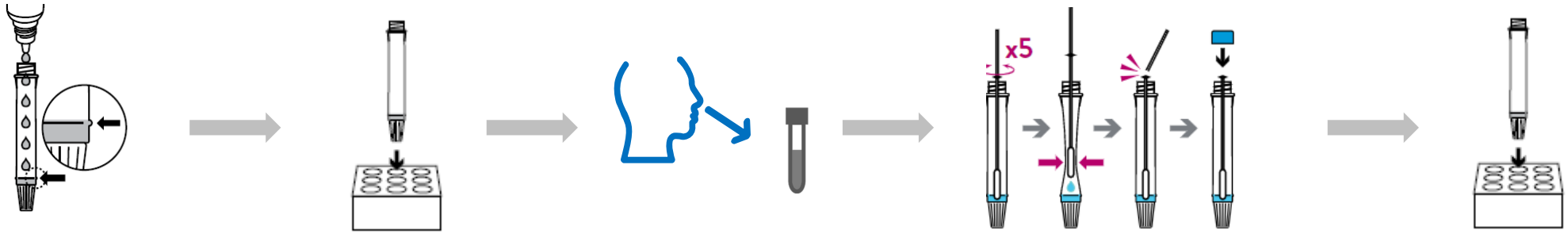
2. Intake

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** places pre-printed label with name of the staff member on extraction tube found in prepared testing kit.
2. **Person A** places a pre-filled extraction tube in the tube rack.
3. **Person B** 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.

Note: If unable to process immediately, keep specimens in the capped extraction tube filled with buffer at room temperature (15˚-30˚C) for up to two (2) hours from time of collection.



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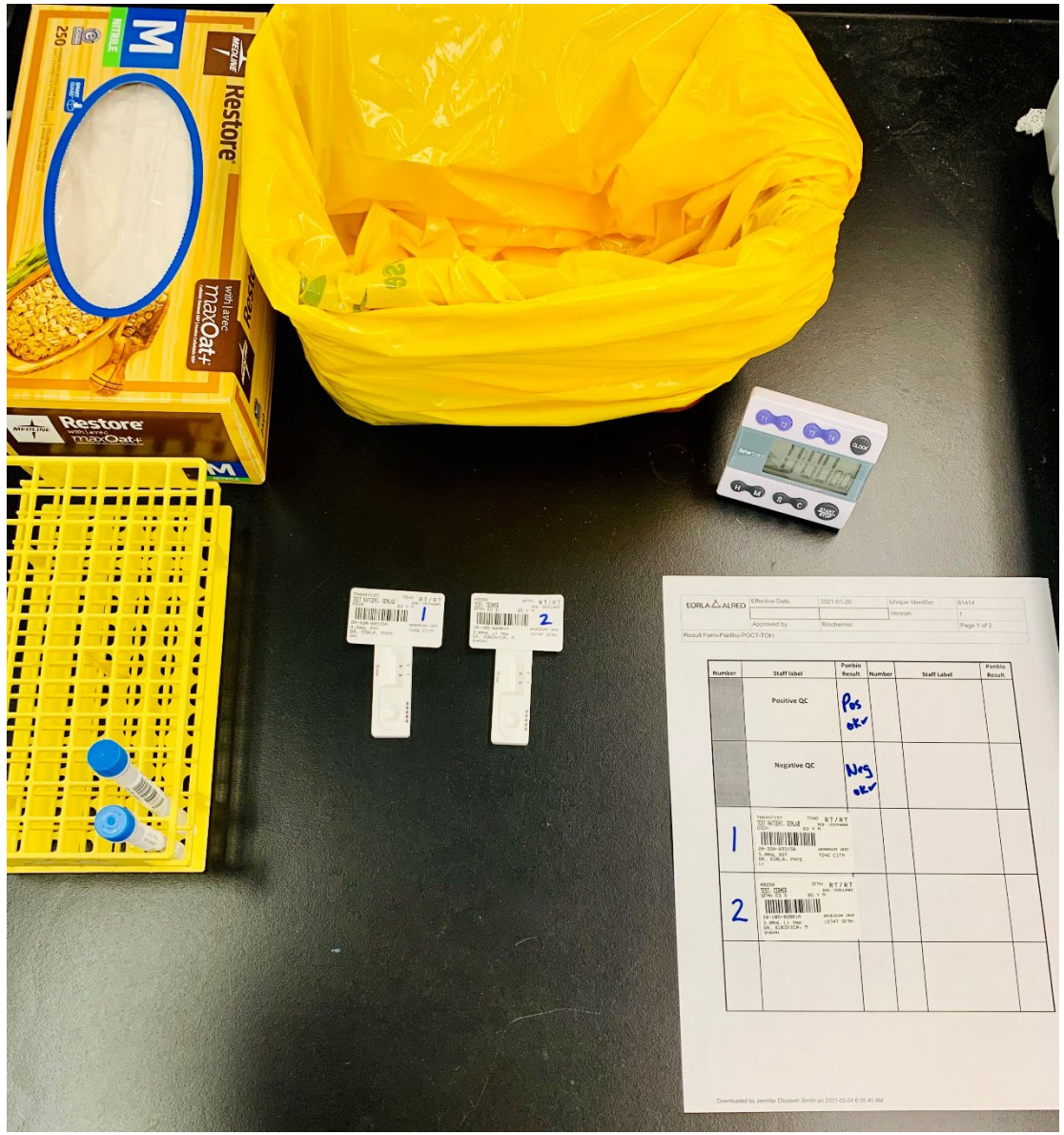
4. Testing the Specimen (batch testing)



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4. Testing the Specimen (batch testing)

1. **Person C** sets out **5-10 test cartridges** (depending on number of staff to be tested).

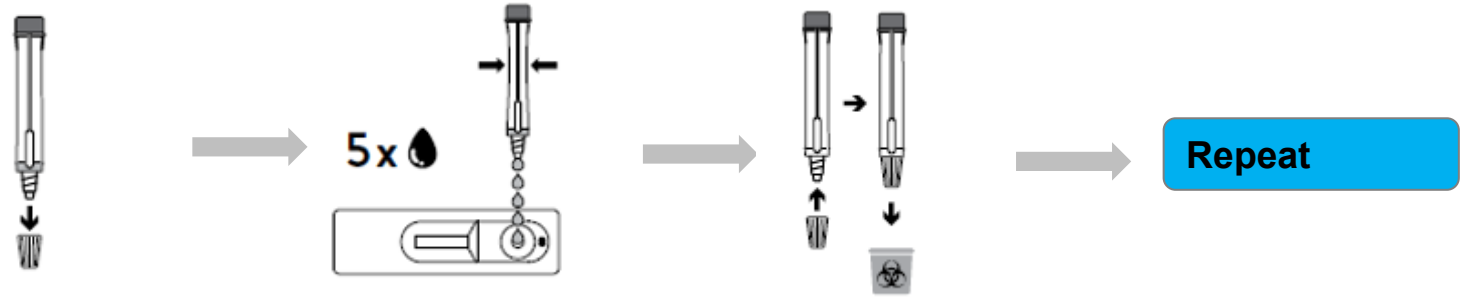
2. **Person C** opens **all test devices for the batch** and places a pre-printed label on each device to correspond with the staff member's information on **extraction tube** that will be tested.

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. Shake the tube gently to 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**

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Testing Station

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5. Reading Results

1. After 15-20 minutes, **Person C** interprets the result on each cartridge.

NOTE: Results are invalid if 20 or more minutes has elapsed

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

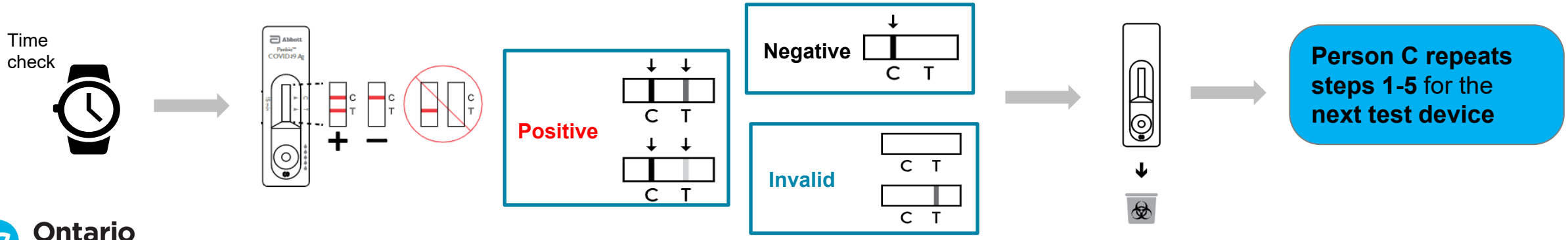
Negative = the presence of **only the control line (C)** and no test line (T) within the result window

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. Record result for each cartridge on the results tracker

4. Dispose of used device in **biohazard container**

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.



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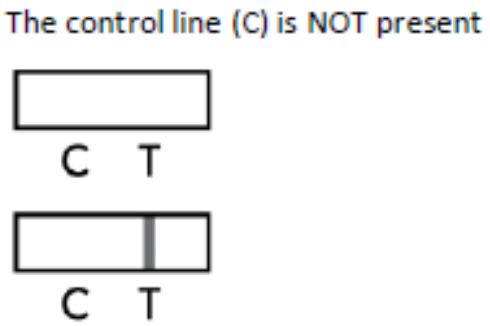
6. Communicating Results - Invalid

- If the control line (C) is not visible within the result window after performing the test, the result is considered invalid. Instructions may not have been followed correctly or the sample was too viscous.
- It is recommended to read the instructions again before conducting repeat testing with a new specimen and a new test device.
- If a second invalid result is obtained, you should stop staff testing until the cause of the failures has been determined. Contact the distributor if problems persist.



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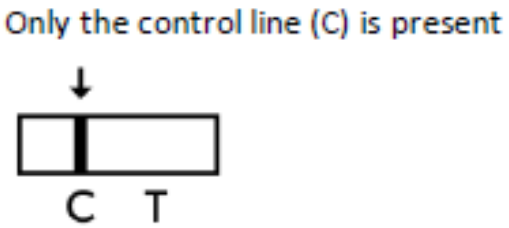
6. Communicating Results - Negative

- Counsel individual that the result is negative but a false negative is possible. Continue to follow public health measures for symptom screening, appropriate distancing, use of PPE and hand-washing.
- Reporting all negative results to staff being tested is best practice. Some organizations do not communicate negative results and follow a “no news is good news approach.”
- If requested by the local public health unit to report negative results, ensure that negative results are reported.



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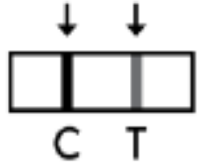
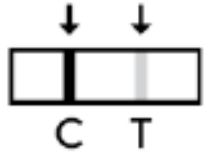
6. Communicating Results - Positive

- Counsel individual that the positive result is considered preliminary positive and recommend they obtain a second swab for confirmatory lab-based PCR test or undergo a rapid molecular test as soon as possible (ideally within 48 hours). Do not re-test with rapid antigen test.
- If confirmatory PCR testing is not done, the individual should remain self-isolated for 10 days, from the date of positive antigen test result. They should also inform everyone they were in close contact with in the last 48 hours before the antigen test result to also self-isolate and get tested unless fully vaccinated* or previously positive and asymptomatic.
- Further details for employees on **What to do** if you have a positive COVID-19 rapid antigen test, can be found in Ministry of Health – COVID-19 Guidance: Considerations for Antigen Point-of-Care Testing

The control line (C) and the test line (T) are present



The control line (C) but the test line (T) is faint



** Fully vaccinated defined as ≥14 days after receiving their second dose of a two-dose COVID-19 vaccine series or their first dose of a one-dose COVID-19 vaccine series*

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6. Roles and Responsibilities when Communicating Positive Results

Rapid Antigen Testing Station Staff

- **Person C** communicates the positive result to the **Rapid Testing Lead** 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 Rapid Testing Lead.

Rapid Testing Lead

- Ensures the staff member is informed of preliminary positive result and recommend and provide information about confirmatory PCR testing or rapid molecular testing. The employee should be tested as soon as possible (ideally within 48 hours).
- Follows internal protocols to inform administration of preliminary positive result, e.g., leaving voicemail message with their contact number for follow-up.
- Informs the staff that they will need to self-isolate until the laboratory test result comes back.

Documenting and reporting

- If applicable, health professionals, or other trained individuals, 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, or other trained individuals, must ensure proper documentation is in place when performing COVID-19 rapid antigen testing.

Available Resources and Additional Support

Resources

- Public Health Ontario fact sheet: Abbott Panbio™ COVID-19 Antigen Rapid Test: Biosafety Considerations: publichealthontario.ca/-/media/documents/lab/covid-19-abbott-panbio-antigen-rapid-test-biosafety.pdf?la=en
- Abbott – Helpful documents and video demonstrations: globalpointofcare.abbott/en/product-details/panbio-covid-19-ag-antigen-test.html#
- Safe Handling and Management of rapid antigen COVID-19 testing waste

Training Resources Available from Ontario Health

- Ontario Health website - ontariohealth.ca/antigen-test
  - COVID-19 Antigen Rapid Testing Onboarding Guides (Panbio and BD Veritor), which contain:
    - Frequently Asked Questions
    - Rapid Test Information Sheet
    - Primer on Best Practices
    - Go-Live Readiness Checklist
  - Training modules:
    - Implementing a Rapid Antigen Screening Clinic with Panbio™ COVID-19 Antigen Rapid Test
    - Implementing a Rapid Antigen Screening Clinic with BD Veritor™ COVID-19 Antigen Rapid Test
    - Best Practices for Point-of-Care Testing
    - Specimen Collection
    - Documenting and Reporting Results
    - Self-Collection
    - At-home Self-Screening

Questions?

- For more information about this presentation contact covid19testing@ontariohealth.ca