sunbeam
COMMUNITY & DEVELOPMENTAL SERVICES

COVID-19 Rapid Antigen Testing

Team Training Guide

Version 1.0

Table of Contents

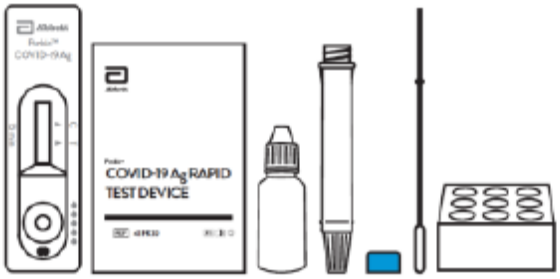
Section 1

General Information

Overview of the Abbott Panbio COVID-19 Rapid Test Device

Key Points

- The Abbot Panbio is a portable analyzer
- After a swab is taken, it is swirled in a tube with a buffer fluid for 15 seconds
- Drops from the tube are placed on a test device cartridge
- After 15 minutes, the cartridge can be read for results
- The screen on the cartridge will display lines to indicate the results



Abbott Panbio Training Video

https://www.globalpointofcare.abbott/en/product-details/panbio-covid-19-ag-antigen-test.html

- Scroll down to the bottom of the page to see "Videos" - watch the video titled "Nasal Swab Test Procedure Live Action"
- Runtime: 3 min

Watched Training Video	Date	Signature

Other Information

- Rapid testing is not as sensitive as a PCR test that is completed at a regional assessment centre, and results need to be interpreted with caution and care
- Use only the swabs provided in the kit
- Materials must be stored and used between 15-30°C

Overview of the Provincial Rapid Testing Program

Sunbeam Community Developmental Services is partnered with Ontario Health to run the COVID-19 rapid antigen screening program using the Abbot Panbio testing system.

The provincial antigen screening program is intended to:

- Reduce the spread of COVID-19 and support essential and vulnerable workplaces
- Enable workplaces to proactively identify cases of COVID-19 that may have been missed
- Support routine rapid testing to improve employee safety

Who is eligible to participate?

- All asymptomatic employees are encouraged to participate in rapid testing for COVID-19
- If an employee is experiencing symptoms of COVID-19, or have had an exposure to a case of COVID-19, they should not be tested via rapid testing and should seek testing at a regional assessment centre
- If an employee previously tested positive for COVID-19, they are excluded from the pilot
- If a site is in outbreak, then employees form that site are excluded from rapid testing for the duration of the outbreak

Ontario Health Training Resources

Webinar: Implementing Rapid Antigen Testing Surveillance

- Live webinar held on March 10, 2021
- This session provides an overview on how to implement a COVID-19 Rapid Antigen Screening Program
- **Access webinar recording: (run time 34 min)**
  https://www.youtube.com/watch?v=lkUrACOLsUY
- **Access webinar presentation slides:**
  - https://www.ontariohealth.ca/sites/ontariohealth/files/2021-03/Implementing_screening_program.pdf

Watched Training Video or Read Slides	Date	Signature

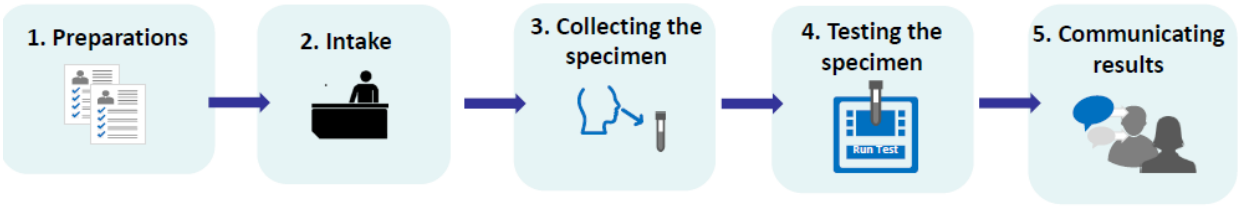
Overview of Clinic Set Up

Each clinic will have three or four stations:

1. Registration and Intake
2. Swab Collection
3. Specimen Testing
4. Waiting Area (optional)

The clinic space will also include environmental barriers to separate stations with ample room for physical distancing, and signage to indicate directional flow of participants.

Rapid antigen screening clinic can be broken into 5 stages:



Safety Measures & Use of Personal Protective Equipment

Participants

- Provide medical mask for use while attending the clinic
- Provide hand sanitizer upon entry
- Encourage physical distancing throughout clinic space
- Provide disinfectant wipes for use at waiting area
- Environmental and plexiglass barriers to control flow of clinic and splash guards at testing areas

Testing Team

- Use of personal protective equipment varies between roles
- *Registration Role* – wears medical mask + eye protection at all times
- *Swab Collectors & Specimen Testers* – wear medical mask, face shield, gowns and gloves
    - Gloves are changed and hand hygiene performed after each swab is collected
    - Gloves are changed and hand hygiene performed after handling each extraction tube
    - Gowns, face shields and masks discarded if become contaminated, torn or wet

Cleaning & Disinfecting

- Intake table and pens used should be disinfected after each participant has attended
- Swab collection table and chair should be disinfected after each participant has attended if surfaces were touched
- Testing station table should be disinfected at the start and end of each day

Handling Biohazardous Waste

All testing materials, once used, are considered biohazardous waste.

All personal protective equipment, once used, is considered biohazardous waste.

<u>Extreme caution</u> must be used when handling and disposing of these items as they may contain live virus.

<u>Testing Materials</u>

The following items must be safely discarded in a biohazardous waste container once used:

- Swab
- Extraction tube
- Test device cartridge

<u>Personal Protective Equipment</u>

The following items must be safely discarded in a biohazardous waste container once used by a *Swab Collector* or *Specimen Tester*:

- Gloves
- Gown*
- Face shield*
- Mask*

*Note that the gown, face shield and mask only need to be discarded if they become contaminated, torn or wet; or at the end of the clinic day after the last specimen has been disposed.

<u>Cleaning Spills</u>

Clean up any spillage from swabs, extraction tubes or test device cartridges with disinfectant. Discard paper towels or wipes into biohazardous waste.

If a spill occurred on the laptop, use an alcohol swab to clean the spill. Discard alcohol swab into biohazardous waste.

Wear mask, face shield, gown and gloves when cleaning spills. Discard PPE into biohazardous waste.

<u>Mucous Membrane Exposure</u>

Portable eye wash stations will be available at the clinic for use if any sample materials are splashed into the eyes. Rinse thoroughly with affected eye(s) open and report incident to Rapid Testing Clinical Lead.

Frequently Asked Questions

1. **What is COVID-19 rapid antigen testing?**

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

2. **When should you perform a rapid antigen test?**

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

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

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

An individual who has previously had laboratory-confirmed COVID-19 AND was cleared by the local public health unit (PHU), should generally not be re-tested for surveillance purposes due to persistent shedding. Previously cleared individuals should continue to follow public health guidance for COVID-19 prevention, including self-isolating after high-risk exposures to cases.

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

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

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

The Abbott Panbio rapid antigen test kits come with a nasal swab that can be used to collect nasal specimens.

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

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

7. **Does a preliminary positive result on the Rapid Test mean the site is in outbreak?**

No, a preliminary positive result does not mean the site is in outbreak. The individual who tested positive is required to have a confirmatory PCR test. Local public health units will remain the authoritative body on the declaration of a COVID-19 outbreak, which will continue to be based on the presence of positive results on a confirmatory, lab-based PCR.

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

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

9. **If an individual has been vaccinated for COVID-19, do they still need to be tested?**

Individuals who have received a COVID-19 vaccine, regardless of whether they received one or two doses, are still able to receive an accurate result from a rapid antigen test. Vaccinated individuals should not be excluded from rapid antigen screening initiatives, as it is unknown at this time if they can still transmit COVID-19 despite being vaccinated.

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

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

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

After specimen collection, the swab should be stored in the capped extraction tube filled with buffer at room temperature (15-30˚C) until tested. For best results, testing should be done immediately. Instructions for how long a specimen can sit in the buffer vary for different test modalities. For example, specimens collected for testing with the Abbott Panbio can be used up to 2 hours from time of collection.

Note that collected specimens for antigen testing should NOT be placed in the fridge. Please refer to the package insert of the test you are using for additional test-specific information.

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

At least 2 unique participant identifiers (e.g., name and date of birth) should be on both the test tube and corresponding test cartridge to avoid errors.

13. **Can you explain the importance of squeezing the swab?**

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

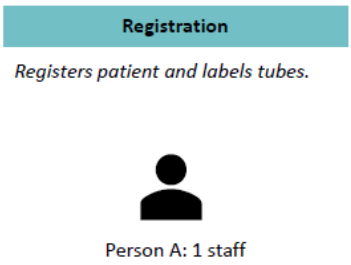
14. **If we are labelling the extraction tube and then disposing of the tube in a biohazard container, what happens to that staff personal health information?**

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

Section 2

Registration Role

Role Description

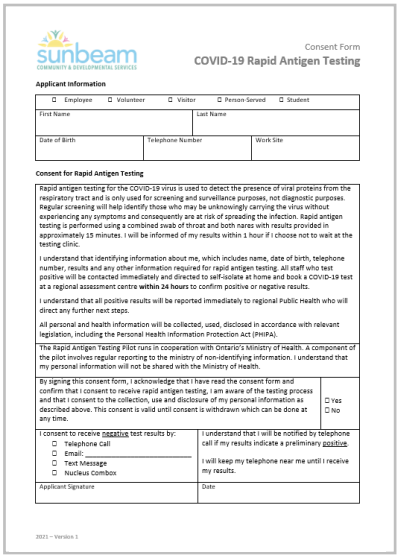


This person will:

- ✓ Prepare parking areas by putting out traffic cones to reserve a row of the parking lot
- ✓ Put out portable sign to indicate the entrance to the clinic
- ✓ Greet the participant and screen them in
- ✓ Review the consent form with the participant to inform them of the testing process
- ✓ Prepare swab labels with two unique identifiers
- ✓ Provide participant with the "What Happens Next" flyer
- ✓ Direct participant to the swab collection station

This role does not have to be a health professional.

Intake & Consent


Consent Form
COVID-19 Rapid Antigen Testing

Applicant Information

☐ Employee ☐ Volunteer ☐ Visitor ☐ Person Served ☐ Student

First Name | Last Name

Date of Birth | Telephone Number | Work Site

Consent for Rapid Antigen Testing

Rapid antigen testing for the COVID-19 virus is used to detect the presence of viral proteins from the respiratory tract and is only used for screening and surveillance purposes, not diagnostic purposes. Regular screening will help identify those who may be unknowingly carrying the virus without experiencing any symptoms and consequently are at risk of spreading the infection. Rapid antigen testing is performed using a combined swab of throat and both nares with results provided in approximately 15 minutes. I will be informed of my results within 1 hour if I choose not to wait at the testing clinic.

I understand that identifying information about me, which includes name, date of birth, telephone number, results and any other information required for rapid antigen testing. All staff who test positive will be contacted immediately and directed to self-isolate at home and book a COVID-19 test at a regional assessment centre **within 24 hours** to confirm positive or negative results.

I understand that all positive results will be reported immediately to regional Public Health who will direct any further next steps.

All personal and health information will be collected, used, disclosed in accordance with relevant legislation, including the Personal Health Information Protection Act (PHIPA).

The Rapid Antigen Testing Pilot runs in cooperation with Ontario's Ministry of Health. A component of the pilot involves regular reporting to the ministry of non-identifying information. I understand that my personal information will not be shared with the Ministry of Health.

By signing this consent form, I acknowledge that I have read the consent form and confirm that I consent to receive rapid antigen testing. I am aware of the testing process and that I consent to the collection, use and disclosure of my personal information as described above. This consent is valid until consent is withdrawn which can be done at any time. ☐ Yes ☐ No

I consent to receive negative test results by:
☐ Telephone call
☐ Email: _____
☐ Text Message
☐ Nucleus Combox

I understand that I will be notified by telephone call if my results indicate a preliminary positive.

I will keep my telephone near me until I receive my results.

Applicant Signature | Date

2021 – Version 1

- Verbally read over the consent form with the participant
- Ensure they fill out each section and that all information is easy to read
- Add a star(*) to the top of the form if the person is a drop-in participant to flag this for later documentation
- Once completed, give the participant the consent form to take with them to the swab collection station

Label Preparation

Pre-printed labels will be provided with blanks to fill in for the following fields:

- Name/Initials
- Date of Birth
- Phone number

At the registration table, fill out two of these labels per participant:

- One will be for the extraction tube
- One will be for the test cartridge

When leaving the registration station, the participant will have with them:

Their signed consent form + "What Happens Next" flyer + 2 labels

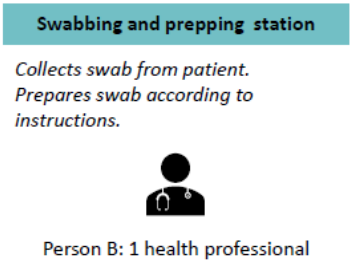
Section 3

Swab Collection Role

Role Description

This person will:

- ✓ Prepare extraction tubes with buffer solution
- ✓ Label the extraction tube
- ✓ Perform a deep nasal swab
- ✓ Place the swab in the labelled extraction tube
- ✓ Mix the specimen in the extraction tube
- ✓ Insert extraction tube into tube rack
- ✓ Direct participant to the specimen testing station



This role has to be a health professional.

Preparation of Extraction Tubes

Ahead of the first appointment at the clinic, prepare extraction tubes with buffer solution on a separate table than the specimen collection area. Prepare enough tubes for the booked appointments.

1. Hold the buffer bottle vertically above the tube.
2. Fill the extraction tube until it reaches the fill line.
    a. If the amount of buffer is excessive or insufficient, an improper test result may occur.
3. Cap the extraction tube and place in the tube rack.

Tip: To avoid contamination of the buffer bottle, ensure it is only handled with clean hands and gloves and that the bottle cap is kept firmly sealed between each use.

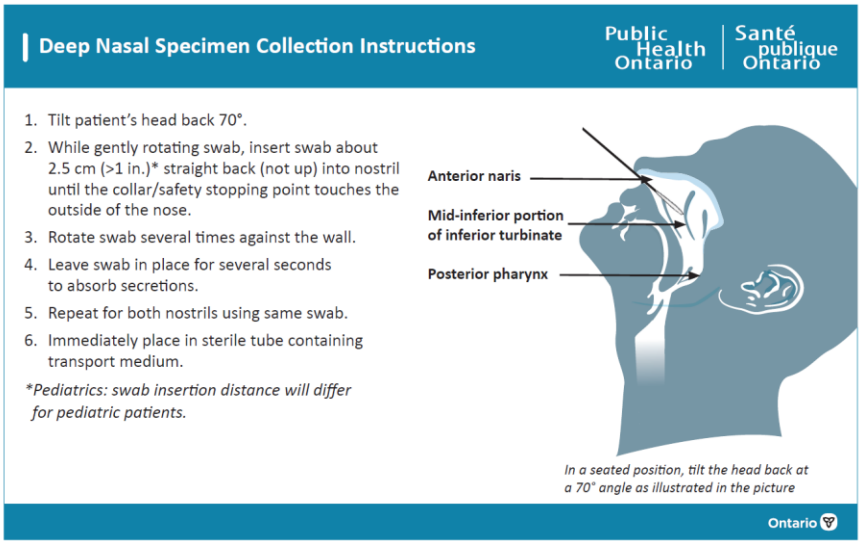
Quality Control

- At the beginning of each clinic day, check that the test kits and buffer solution are not expired.
- Do not mix buffer solution of different lot numbers together.
- Do not store test kits in direct sunlight.

Prior to Collecting the Swab

1. When the participant arrives at the station, label an extraction tube with their pre-filled label.
2. Put their signed consent form in a plastic transport container.

Collection Method



Note: if the swab breaks during specimen collection, repeat collection with a new swab.

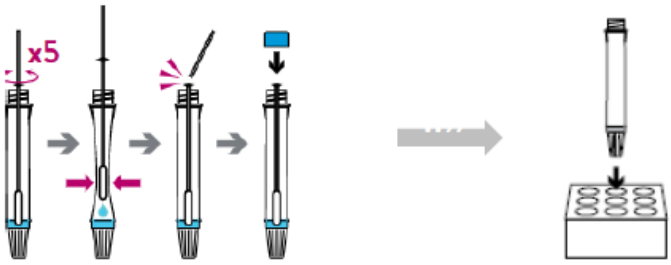
Participants may also **self-swab**. Please see below resources about how to support this.

- https://www.youtube.com/watch?v=RXIEz1YZFDQ (5 minutes)
- https://www.ontariohealth.ca/sites/ontariohealth/files/2021-03/How_to_Nasal_Swab_2-pager.pdf

Preparing Swabs for Testing

As soon as the swab has been collected:

1. Place the swab in the labelled extraction tube.
2. Swirl the swab tip in the buffer fluid then push into the wall of the extraction tube at least five times for a minimum of 15 seconds, being careful not to splash contents out of the tube.
3. Squeeze out the swab by squeezing the outside of the extraction tube.
4. Break the swab at the breakpoint and place the tube cap on.
   - Discard broken part of the swab in a biohazardous waste container.
5. Place the extraction tube (with swab inside) in the tube rack.
6. Place the tube rack in the plastic transport container.
7. Write the time the swab was taken on a piece of masking tape with your initials. Mark the plastic transport container with the masking tape.
   - *Once the swab is placed in an extraction tube, the sample should be read within 2 hours*
8. Reminder: Participant consent form to also be placed in the transport container.



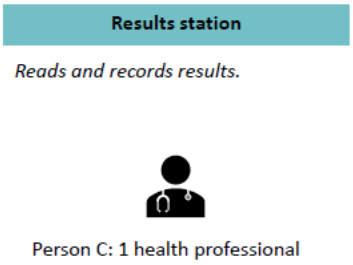
Section 4

Specimen Testing Role

Role Description

This person will:

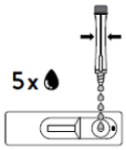
- ✓ Receive plastic transport container from participant
- ✓ Direct participant to waiting area or to the exit
- ✓ Prepare test device cartridge with label and specimen
- ✓ Set 15 min timer
- ✓ Interpret results
- ✓ Communicate results
- ✓ Document results
- ✓ Perform quality control checks

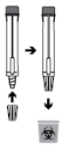


Specimen Testing Method

Once the plastic transport container is received at the station:

1. Open a test device cartridge and place the unused pre-printed label on the device to correspond with the participant's information on the extraction tube that will be tested.
   - *Once cartridge is removed from foil pouch, it should be used immediately*
2. Place the cartridge on a flat, horizontal and clean surface.
3. Do not re-use test device cartridges.
4. Take the extraction tube (with specimen in it) from the tube rack and remove the nozzle cap from the bottom.
5. Hold the tube vertically (approx. 1 inch above the sample well) and gently squeeze the body of the tube, dispensing **5 drops** of the processed specimen into the sample well.
6. *For batch testing, repeat steps 1-3 for up to 10 specimens. Place each test device on a different section of the table (distanced apart from each other).*
7. Start a 15 min timer. DO NOT move the test device cartridge until the test is complete.
8. Discard extraction tube with nozzle cap on in the biohazard bin.
9. Change gloves and perform hand hygiene after handling each extraction tube. Gloves to be discarded in the biohazard bin.
10. During the 15 minute wait period, add participant information into the results tracking spreadsheet (see details in *Documentation* section)
11. After 15-20 minutes, record the result before disposing the cartridge into the biohazard bin.



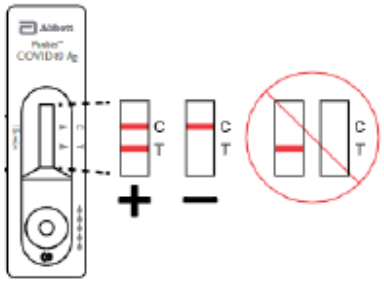


Cautions

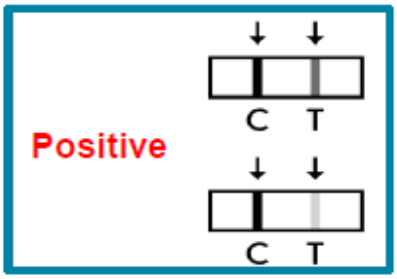
- Squeezing the tube too close to the tip may cause leakage
- Bubbles in the extraction tube can lead to inaccurate results. If unable to create sufficient drops, this may be caused by clogging in the dispensing nozzle. Shake the tube gently to release the blockage.
- If there is a lot of air movement around the cartridge during the 15 min waiting period, cover with a plastic container to avoid inconsistent flow

Interpreting Results

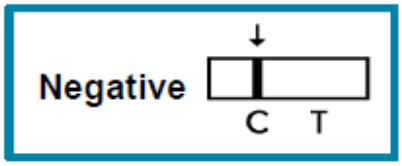
Results will be displayed in the result window:



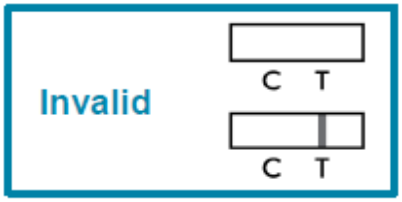
Legend:
C = Control line
T = Test line



Positive = the presence of the **control line (C) and the test line (T)** in 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.

Note: Results are also invalid if more than 20 minutes has elapsed.

"Invalid" result	If test results are invalid, the test must be repeated with a new swab collected. The same cartridge that received an invalid result should not be re-used. If a second invalid test result is obtained, stop staff testing until the cause of the failures is identified. Contact distributor if problems persist.

Troubleshooting

Communicating Results

Test Result is Negative (-)

Notify the participant of their results by their preferred method of communication indicated on the consent form.

Counsel the participant that the result is negative, but a false negative is still possible. Continue to follow public health measures for symptom screening, appropriate distancing, use of PPE and hand hygiene.

Test Result is a Preliminary Positive (+)

Notify the participant immediately and privately by telephone or in-person if the participant is in the waiting area.

- If the call goes to voicemail, continue calling at regular intervals until able to talk to the person directly.

Counsel the participant that the positive result is considered a preliminary positive, and to confirm a test result, the participant must book a COVID-19 test at a regional testing or assessment **centre within 24 hours**. The participant must go immediately home to start self-isolation until results are received from this confirmatory repeat test. Remember to be kind and considerate about this news.

Notify the Rapid Testing Clinical Lead as soon as possible of the preliminary positive results.

- Rapid Testing Clinical Lead will report the results to the local Public Health Unit
- Rapid Testing Clinical Lead will notify supervisor of the affected location

Test Result is Invalid

Notify the participant of their results by their preferred method of communication indicated on the consent form.

Counsel the participant that they will need to repeat their test to retrieve an accurate result.

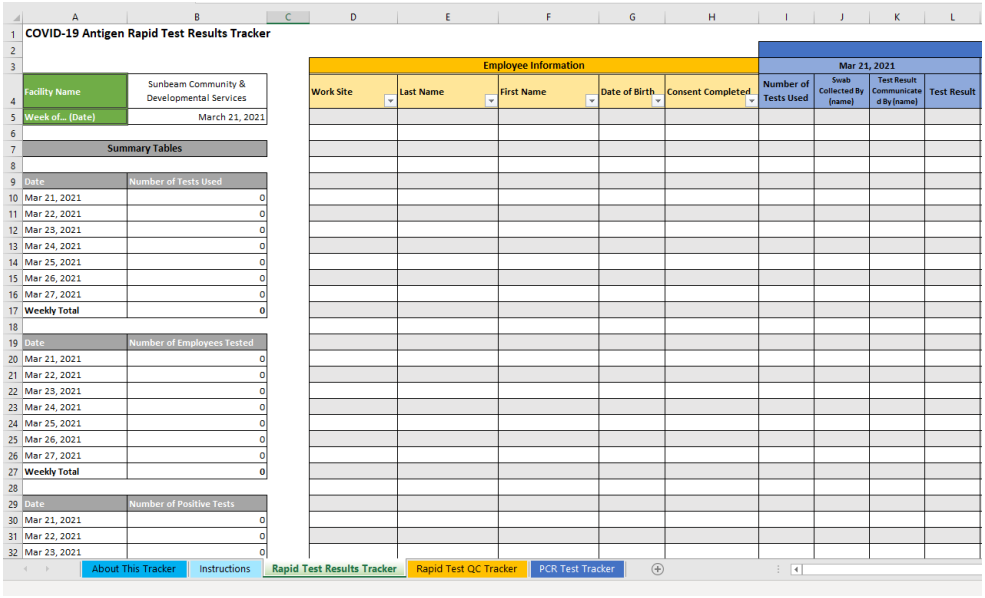
- As testing is voluntary, it is not mandatory for the person to re-test if they choose not to do so

It is important to remember that all test results are confidential. Only the testing team member working at the Specimen Testing station and the Rapid Testing Clinical Lead should be aware of who has tested positive. (ie. results should not be communicated in a manner that exposes the identity of the staff member to other individuals).

Documentation

An excel spreadsheet will be used to document and track COVID-19 Rapid Testing results.

A laptop will be kept at the Specimen Testing station to record results as they are received on this spreadsheet.



COVID-19 Antigen Rapid Test Results Tracker

Facility Name	Sunbeam Community & Developmental Services
Week of... (Date)	March 21, 2021

Summary Tables

Date	Number of Tests Used
Mar 21, 2021	0
Mar 22, 2021	0
Mar 23, 2021	0
Mar 24, 2021	0
Mar 25, 2021	0
Mar 26, 2021	0
Mar 27, 2021	0
Weekly Total	0

Date	Number of Employees Tested
Mar 21, 2021	0
Mar 22, 2021	0
Mar 23, 2021	0
Mar 24, 2021	0
Mar 25, 2021	0
Mar 26, 2021	0
Mar 27, 2021	0
Weekly Total	0

Date	Number of Positive Tests
Mar 21, 2021	0
Mar 22, 2021	0
Mar 23, 2021	0

Employee Information					Mar 21, 2021			
Work Site	Last Name	First Name	Date of Birth	Consent Completed	Number of Tests Used	Swab Collected By (name)	Test Result Communicated By (name)	Test Result

About This Tracker | Instructions | Rapid Test Results Tracker | Rapid Test QC Tracker | PCR Test Tracker

Rapid Test Results will be tracked under the Green tab.

Quality Control results will be tracked under the Yellow tab.

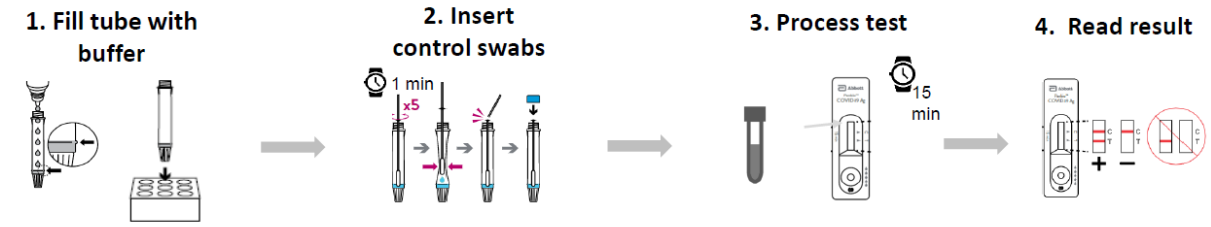
Quality Control

Quality control swabs should be tested by staff who will be operating the Specimen Testing station.

Quality control swabs should be tested:

- ☐ With each new shipment of kit
- ☐ With any new kit lot number
- ☐ By all newly trained operators before they begin testing individuals
- ☐ For sites performing more than 25 tests/day, perform quality control swabs at the beginning of the day
- ☐ For sites performing less than 25 tests/day, perform quality control swabs each time a new kit box is opened or at least weekly, whichever is more frequent

Record results of Quality Control testing on the excel spreadsheet (above).


1. Fill tube with buffer
2. Insert control swabs
1 min
x5
3. Process test
15 min
4. Read result
+
−