PHARMACISTS AND COVID-19: ASYMPTOMATIC TESTING IN COMMUNITY PHARMACY

A request from the New Brunswick provincial government was received by the New Brunswick College of Pharmacists (the College) in late January, 2021, to investigate the possible use of community pharmacists to assist New Brunswick Public Health with testing of asymptomatic individuals identified as “regular border crossers” into New Brunswick.

The following guidance provides an outline of the information which will initially guide practitioners involved in this part of practice. College staff will continue to collaborate with the office of Public Health in developing necessary tools for pharmacy professionals.

Participation in this testing program is not mandatory. Pharmacy managers must ensure that a decision to provide Panbio™ COVID-19 Ag Rapid Testing is made only after a thorough assessment of available resources. Pharmacies implementing COVID-19 testing must consider employee and public safety, and the feasibility of performing testing in the pharmacy environment.

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Disclaimer: This guidance document was developed and approved by the Council of the New Brunswick College of Pharmacists (the College) in response to needs identified by the office of New Brunswick Public Health. The College does not authorize its use by pharmacy professionals beyond this specific collaboration with NB Public Health for the stated purpose of the administration of the Panbio™ COVID-19 Ag Rapid Testing.
ADMINISTRATION OF PANBIO (COVID-19) TESTING

1. The pharmacy is to have a standard operating procedure (SOP), appropriate for their practice site.
   - A template for a policy and procedure is provided by the New Brunswick College of Pharmacists, to be populated by the pharmacy manager or their delegate, and appropriate for the needs and limitations of the practice site. [See Appendix 1].
   - The minimum requirements for the SOP document, which is the responsibility of the pharmacy manager or their delegate, will include:
     - title and purpose of the standard operating procedure.
     - limitations of the test.
     - performance specifications (sensitivity, specificity).
     - required equipment and reagents.
     - definition of sample and appropriate collection/handling techniques to support safe and effective immediate use of the sample in a POCT.
     - procedural steps on how to accurately complete the test.
     - device calibration and quality control.
     - information on interpretation of results.
     - result notification for patients.
     - result notification for Public Health.
     - instructions on the proper use, maintenance, and storage of the testing device and/or instruments.
     - instructions on safe working practices and specimen collection, including proper use of PPE.
     - requirements for training, ongoing competency assessment of individuals performing the tests and documentation of such training/assessments.

2. A pharmacist will be responsible for
   - supervising the testing process.
   - initiation and ongoing maintenance of SOPs and Quality Assurance.
   - initiation and monitoring of staff training.
   - interpretation and communication of presumptive positive results to patients.
   - notification of Public Health in the case of a presumptive positive result
   - any other supervisory functions related to this part of practice.

3. Pharmacy technicians and pharmacy assistants, after appropriate training will be able to take part in specimen collection, as well as other technical aspects of COVID-19 testing. Specimen collection from the anterior nares, particularly in a program where oversight is provided by a pharmacist, is a technical function which can be readily learned by both regulated and non-regulated pharmacy team members.
   Pharmacy Assistants, as well as pharmacists and technicians who lack current training in infection prevention control (IPC), must take that training prior to administering COVID-19 testing (see Training).
4. The pharmacy manager shall ensure that the pharmacy environment is clean and safe for sample collection, conducting the test, and device and supply storage. The environment shall comply with any conditions defined by the manufacturer of the test. Generally, tests shall be conducted in a separate room to provide privacy for the patient.

5. In the event of a presumptive positive test, a defined infection control and a response procedure must be in place, to prevent further risk of exposure.

6. Eligibility requirements for asymptomatic testing will be established by Public Health and may evolve over time. Changes in eligibility will be communicated by Public Health.

7. Testing may be performed on patients aged 3 years old and older.
   - This is consistent with direction from Public Health, and as age is not specifically addressed in supplementary Abbott materials, is not inappropriate.

8. As part of SOPs, there must be adherence to requirements for disposal of biohazardous waste.
   - Biohazardous waste will be handled at the pharmacy level, similar to administration of injections or other testing.
   - The pharmacy must have sharps containers, labeled as “biohazardous”, as well as appropriately labelled waste containers. These must be stored appropriately and removed from the specimen collection and testing area in a timely manner.
   - As part of the pharmacist’s assessing resources available for provision of COVID-19 testing, ensure that there is adequate space for an increased volume of waste, and in particular, biohazardous waste.

9. Signage must be posted which informs the public that asymptomatic COVID-19 testing is occurring at this site (“warning”).

TRAINING REQUIREMENTS
10. The training required for use of the Panbio COVID-19 nasal tests will be made available from Abbott via scheduled virtual training sessions with Abbott trainers. These will be available in French and English. Abbott will also supply training materials as video and in written form.
   - This particular training is not a requirement, but pharmacists are reminded that they must have the knowledge, skills and competence to safely and accurately collect anterior nasal specimens, seeking additional training as required.
   - If pharmacists delegate specimen collection and running of tests to unregulated employees, these employees must be adequately trained and not performing tasks outside of that training.

11. Infection Prevention and Control (IPC) training will be provided by Public Health.
   - IPC procedures must be in place and followed. Pharmacy managers/pharmacists are responsible for ensuring that all team members involved in testing are appropriately trained.
12. Personal protective equipment (PPE) must include a gown, gloves, face shield and surgical/procedural mask, although N95 masks are not required.
   - Public Health reports that all PPE will be provided from provincial supplies, along with Abbott test kits.

QUALITY MANAGEMENT PROGRAM (QMP)

13. As part of the requirements of a Quality Management Program (QMP)\(^1\), and as required by Public Health, pharmacists must ensure a process for quality assurance be in place for COVID-19 testing of asymptomatic patients. See Appendix 2.

The pharmacy manager is responsible for the pharmacy’s quality assurance process for COVID-19 testing, which includes:
- ensuring standard operating procedures are established, maintained and their activities carried out as required by the standard operating procedure.
- initial and ongoing reagent validation prior to clinical use.
- proficiency testing to monitor overall testing practices at a pharmacy site.
- processes for error reporting.
- ensuring only trained and fully competent pharmacy team members conduct tests.
- monitoring the competence of pharmacy team members who conduct POCTs to ensure:
  ✓ adequate and appropriate initial and ongoing training, on standard operating procedures and safe work practice.s
  ✓ ongoing demonstration of: an understanding of the appropriate use of the device, its clinical utility and limitations and appropriate action when results fall outside predefined limits; an understanding of the technical limitations of the device, the stability and proper use of reagents, and recognition of error; the ability to consistently obtain a proper sample from the patient; and the skills required to follow quality procedures of a test and to assess and verify the validity of test results prior to reporting.
  ✓ processes for communicating negative test results.
  ✓ processes for communicating positive test results (pharmacists only).
  ✓ test documentation and follow-up requirements (pharmacists).
  ✓ troubleshooting issues with tests and/or devices.

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DOCUMENTATION OF PROCESS

14. Documentation of results for any testing performed must meet requirements outlined in Regulation 23.5(a) to (h). This includes (23.5 modified for COVID-19 Panbio test):

- Patient name and address.
- Type/name of test.
- Pharmacist name.
- Pharmacy technician/assistant performing test (if not the pharmacist).
- Date of testing.
- Date results were received by pharmacist.
- In the event of a negative result, date this was delivered to patient.
- In the event of a negative result, the method of delivery of that result to patient.
- In the event of a presumptive positive test, date and time of counselling with patient.
- In the event of a presumptive positive test, date and time of Public Health notification.

15. Requirements for retentions of COVID-19 testing documentation are provided in Regulation 17.22.1(f), which states “A pharmacy shall retain the following records for a period of two years in written format (where applicable) and thereafter written or electronically for a period of not less than 15 years after the circumstances giving rise to the creation of the record:… (f) test ordering, results and interpretation record”

- Public Health advises that these records be readily retrievable in the event of future payment audits, and to provide evidence that presumptive positive cases were reported to public health or assessment centres.

DOCUMENTATION AND NOTIFICATION OF PATIENT

16. Prior to COVID-19 testing of eligible asymptomatic patients, the patient will provide informed consent.

- As part of informed consent, the pharmacy team member shall provide the patient with information that is understandable and sufficient to allow them to make an informed decision to accept or decline the testing service. To support their decision, the pharmacy team member shall provide the opportunity for the patient to ask questions of the pharmacist and obtain responses about the test. The information to be provided shall include the following:
  - name of the test
  - objective of the test (The test is used to identify people who may be asymptomatic COVID-19 positive individuals)
  - benefits and risks of testing
  - plan for follow-up, if appropriate, including timeline (A presumptive positive test will be reported to Public Health and second confirmatory test will be provided at a RHA Assessment Center. People who test positive will be informed to return to home and isolate until they hear from PUBLIC Health).
14. Patients are to be provided with proof that COVID-19 testing was performed, or that an appointment for testing has been made.

- Each patient is to be provided at time of testing with written or electronic confirmation of screening test performed including full name of individual, date, time test performed, name of responsible Pharmacist and Technician/Assistant who performed in a format not easily reproducible and bearing the pharmacy name and phone number.

15. Patients are to be encouraged to leave the pharmacy after specimen collection to await their results, in order to minimize contact time with staff and other patients. As part of SOPs, the pharmacist will develop a plan for patient notification of results.

- Notification of a patient for a negative COVID-19 test may be delivered via several mechanisms acceptable to the patient and pharmacist (in person, via text or telephone, or other electronic means).
- Use of electronic modes of communication must adhere to all privacy and confidentiality requirements.
- Notification of a patient for a presumptive positive COVID-19 test result must be delivered by the pharmacist. Notification must be delivered via telephone or using video technology.
- In the case of a presumptive positive COVID-19 test result, the patient must be counselled to remain in self-isolation until they are contacted by Public Health. The patient must be told that a second test using PCR testing will be scheduled to confirm what the screening test has revealed.

DOCUMENTATION AND NOTIFICATION OF PUBLIC HEALTH

17. Once the pharmacist undertakes testing, they are responsible for following up on the results and taking necessary actions until they have confirmed that another appropriate health care provider has assumed responsibility for the results.

- COVID-19 is a reportable disease which normally requires both a phone call and written report to local Public Health office
- Pharmacists will report to Public Health via 811 online, which will initiate a process for scheduling an appointment for additional PCR testing at an assessment site.
- The pharmacist’s notification via 811 online will generate an e-mail notification to Public Health for that patient. The patient will be contacted by the assessment centre to set up the appointment for PCR testing.

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2 In development. Link will be provided by Public Health when in place.
Appendix 1: Standard Operating Procedure Template

Lines are provided to indicate a process which may be tailored to the practice site. Pharmacists are encouraged to insert the steps of that process being used, such that the written SOP is complete.

Title: COVID-19 Antigen Testing: Asymptomatic Patients

Purpose: On behalf of Public Health in New Brunswick, community pharmacists and their teams will provide rapid testing for COVID-19, using Abbott Panbio COVID-19 Ag Rapid Test Device.

Limitations: Use of Panbio test kits in asymptomatic patients is not intended to be diagnostic, but is used as a screening tool. Negative test results do not preclude the possibility of the patient being COVID-19 positive. Positive test results are to be considered a “presumptive” positive, and must then be followed by PCR testing at a provincial assessment site for confirmation.

Testing does not replace current public health measures such as symptom screenings, physical distancing, use of personal protective equipment and frequent hand hygiene. Antigen Screening does not prevent someone from getting COVID-19 and does not completely rule out an active COVID-19 infection.

From Abbott (package insert):

1. The contents of this kit are to be used for the professional and qualitative detection of SARS-CoV-2 antigen from nasal swab. Other specimen types may lead to incorrect results and must not be used.
2. Failure to follow the instructions for test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
3. A negative test result may occur if the specimen was collected, extracted or transported improperly. A negative test result does not eliminate the possibility of SARS-CoV-2 infection and should be confirmed by viral culture or a molecular assay.
4. Positive test results do not rule out co-infections with other pathogens.
5. Test results must be evaluated in conjunction with other clinical data available to the physician.
6. Reading the test results earlier than 15 minutes or later than 20 minutes may give incorrect results.
7. Panbio™ COVID-19 Ag Rapid Test Device is not intended to detect from defective (non-infectious) virus during the later stages of viral shedding that might be detected by PCR molecular tests.
8. Positive results may occur in cases of infection with SARS-CoV.

Performance specifications:

External evaluation of Panbio™ COVID-19 Ag Rapid Test Device: Clinical performance of Panbio™ COVID-19 Ag Rapid Test Device was determined by testing 104 positive nasal swab specimens and 404 negative specimens for SARS-CoV-2 antigen (Ag) to have a sensitivity of 98.1% (95% CI: 93.2-99.8%) and a specificity of 99.8% (95% CI: 98.6-100.0%). Clinical specimens were determined to be positive or negative using an FDA EUA RT-PCR reference method.

Required equipment and reagents:

Provided in the Panbio test kits:

1. Test device with desiccant in individual foil pouch
2. Buffer
3. Extraction tube
4. Extraction tube cap
5. Positive control swab
6. Negative control swab
7. Sterilized nasal swabs for sample collection
8. Tube rack
9. Quick reference guide
10. Instructions for use

Items not provided in the test kit, but required:

1. PPE for user, as well as hand sanitizer
2. Biohazard waste receptacle
3. Timer (15 minutes)
4. Sanitation supplies

**Definition of sample and appropriate collection/handling techniques** to support safe and effective immediate use of the sample in a POCT:

Nasal sampling is less invasive and results in less patient discomfort than sampling from other upper respiratory anatomical sites.³

The procedure for nasal (anterior nasal) sampling is as follows: Using a flocked or spun polyester swab (provided with the Panbio test kit), insert the swab at least 1 cm (0.5 inch) inside the nostril (naris) and firmly sample the nasal membrane by rotating the swab and leaving in place for 10 to 15 seconds. Sample both nostrils with same swab.

**Making an appointment for asymptomatic COVID-19 testing**

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**Scheduling Walk-in COVID-19 testing patients**

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**Checking the patient in at the time of testing:**

1. Patient will arrive at the Pharmacy on the day of the screening
2. Pharmacy Team will validate Patient eligibility and identity

3. Pharmacy Team will retrieve the assessment form, fill out Patient Information, and review pre-screening questions on the form with Patient to ensure that they are asymptomatic.

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4. Patients must answer “No” to all questions to be eligible for the screening. If a patient answers “Yes” to any questions, document updated response on the Assessment Form and inform the patient that they need to self-isolate at home and contact 811 (by phone or online) to schedule an appointment at a local COVID-19 Assessment Centre.

5. If the patient is confirmed to be eligible for the screening:
   • Invite the Patient into the area dedicated for sample collection.
   • Minimize Patient contact with surfaces in the area as much as possible.

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Procedural steps for Panbio testing
(see: Abbott Panbio COVID-19 Ag Rapid Test Device Quick Reference Guide)
Test Preparation

1. Allow all kit components to reach a temperature between 15-30 °C prior to testing for 30 minutes.
2. Pharmacy team member performing the test must don (put on) PPE.
3. Remove the test device from the foil pouch prior to use. Place on a flat, horizontal and clean surface.
4. Hold the buffer bottle vertically and fill the extraction tube with buffer fluid until it flows up to the Fill-line of the extraction tube (300 μl). Caution: If the amount of buffer is excessive or insufficient, an improper test result may occur.
5. Place the extraction tube, labelled with the patient name and/or code number/bar code in the tube rack.

Specimen Collection & Extraction

Ask the Patient to lower their mask below their nose but still covering their mouth and use the swab to collect the sample following the shallow nasal technique.
1. Tilt the patient’s head back 70 degrees. While gently rotating the swab, insert swab less than one inch (about 2 cm) into nostril (until resistance is met at the turbinates).
2. Rotate the swab five times against the nasal wall then slowly remove from the nostril.
3. Using the same swab repeat the collection procedure with the second nostril. Caution: If the swab stick breaks during specimen collection, repeat specimen collection with a new swab.
4. Swirl the swab tip in the buffer fluid inside the extraction tube, pushing into the wall of the extraction tube at least five times and then squeeze out the swab by squeezing the extraction tube with your fingers.
5. Break the swab at the breakpoint and close the cap of extraction tube.
6. Ensure extraction tube is labelled with the patient name and/or code number/bar code.

Reaction with Test Device

1. Open the dropping nozzle cap at the bottom of the extraction tube.
2. Dispense 5 drops of extracted specimens vertically into the specimen well (S) on the device. Do not handle or move the test device until the test is complete and ready for reading. Caution: Bubbles that occur in the extraction tube can lead to inaccurate results. If you are unable to create sufficient drops, this may be caused by clogging in the dispensing nozzle. Shake the tube gently to release the blockage until you observe free drop formation.
3. Ensure testing device is labelled with the same patient name and/or code number/bar code as the extraction tube.
4. Close the nozzle and dispose of the extraction tube containing the used swab according to your local regulations and biohazard waste disposal protocol.
5. Start timer. Read result at 15 minutes. Do not read results after 20 minutes. Screening results will be available 15 minutes after specimen collection and will only be viewable for 5 minutes. Important: If the rapid screening results are not viewed and documented during the results viewing window, the Patient will need to return to the Pharmacy to conduct another screening.
6. Dispose of the used device according to your local regulations and biohazard waste disposal protocol.

Sanitization of the counselling room should occur prior to doffing (taking off) PPE.

After every screening is completed, all Patient-contact surfaces (i.e., areas within 2 meters of the
Patient, including specimen collection area) should be cleaned and disinfected as soon as possible and in between patients, allowing for sufficient contact time for the disinfectant used.

**Interpretation of results:**

1. **Negative result:** The presence of only the control line (C) and no test line (T) within the result window indicates a negative result.

2. **Positive result:** The presence of the test line (T) and the control line (C) within the result window, regardless of which line appears first, indicates a positive result. Caution: The presence of any test line (T), no matter how faint, indicates a positive result.

3. **Invalid result:** If the control line (C) is not visible within the result window after performing the test, the result is considered invalid.

**Device Calibration and Quality Assurance:**

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**Internal Quality Control:**

The test device has a test line (T) and a control line (C) on the surface of the test device. Neither the test line nor the control line are visible in the result window before applying a specimen. The control line is used for procedural control and should always appear if the test procedure is performed properly and the test reagents of the control line are working.

**External Quality Control:**

The controls are specifically formulated and manufactured to ensure performance of the Panbio™ COVID-19 Ag Rapid Test Device and are used to verify the user’s ability to properly perform the test and interpret the results. The Positive Control will produce a positive test result and has been manufactured to produce a visible test line (T). The Negative Control will produce a negative test result.

Good laboratory practice suggests the use of positive and negative controls to ensure that:

- Test reagents are working.
- The test is correctly performed.

The external controls can be run under any of the following circumstances:

- By a new operator prior to performing testing on patient specimens.
- When receiving a new test shipment.
• At periodic intervals as dictated by local requirements, and/or by the user’s Quality Control procedures.

Control Test Procedure:

Positive / Negative Control Swab
Caution: Control use only. Do not use the positive or negative control swab for specimen collection.

1. Hold the buffer bottle vertically and fill the extraction tube with buffer fluid until it flows up to the Fill-line of the extraction tube (300 μl). Caution: If the amount of buffer is excessive or insufficient, an improper test result may occur.
2. Place the extraction tube in the tube rack.
3. Insert the positive or negative control swab in the buffer fluid inside of the extraction tube and soak the swab for 1 minute. Swirl the control swab tip in the buffer fluid inside of the extraction tube, pushing into the wall of the extraction tube at least five times and then squeeze out the swab by squeezing the extraction tube with your fingers.
4. Dispose of the used control swab in accordance with your biohazard waste disposal protocol.
5. Close the cap of the extraction tube.
6. Follow the above test procedure [Reaction with Test Device].

Processes for notification of patient:

For negative results
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Suggested content to share with patients (negative):
Important:
• While COVID-19 antigen screening is faster than COVID-19 polymerase chain reaction (PCR) tests, they may be less sensitive. Someone with an active COVID-19 infection could get a negative result.
• Rapid antigen screening is used for screening purposes only and is not used to diagnose COVID-19
• Antigen screening does NOT prevent someone from getting COVID-19, does NOT completely rule out an active COVID-19 infection and should NOT be used as a diagnostic tool
• Screening is an extra health and safety step, to be used along with existing measures like physical distancing, hand washing, personal protective equipment and enhanced cleaning.
• Do a health screening of COVID symptoms on a daily basis and staying home when symptoms are present.
• Rapid antigen screening does NOT replace any of above health and safety measures.

For positive results
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Suggested content to share with patients (positive):

Important:

- A positive rapid COVID-19 antigen screening is considered a “preliminary positive”, so you will need a follow-up PCR test. Public Health will contact you to book an appointment at a local COVID-19 Assessment Centre. This test is needed to confirm a diagnosis.
- While COVID-19 antigen screening is faster than COVID-19 polymerase chain reaction (PCR) tests, they may be less sensitive. Someone who does not have an active COVID-19 infection could get a positive result.
- For this reason, a follow-up PCR test is required within 24 hours, or as directed by Public Health.
- In the meantime, self-isolate at home (except for a medical emergency) and do not come into contact with others until the PCR test results are available and you are cleared to return to work.
- In the meantime, continue to take precautionary measures as outlined by current public health guidelines. Also, continue to practice physical distancing, wash your hands often, and continue to use a facial covering.
- Rapid antigen screening is used for screening purposes only and is not used to diagnose COVID-19.
- Antigen screening does NOT prevent someone from getting COVID-19, does NOT completely rule out an active COVID-19 infection and should NOT be used as a diagnostic tool.
- Screening is an extra health and safety step, to be used along with existing measures like physical distancing, hand washing, personal protective equipment (like masks) and enhanced cleaning. Do a health screening of COVID symptoms on a daily basis and stay home when symptoms are present.
- Rapid antigen screening does NOT replace any of above health and safety measures.
- Please note that the Pharmacist is required to report the preliminary positive antigen screening result to the local public health unit.

For inconclusive results

Suggested content to share with patients (inconclusive):

- You need to be re-screened at the Pharmacy today as your results were inconclusive (no results were found).
- While COVID-19 antigen screening is faster than COVID-19 polymerase chain reaction (PCR) tests, they may be less sensitive, and occasionally may not display a result. For this reason, you need to be screened once again.
- Important: Please contact the pharmacy to arrange for re-screening today. In the meantime, continue to take precautionary measures as outlined by current public health guidelines. Do a health screening of COVID symptoms on a daily basis and staying home when symptoms are present. Continue to practice physical distancing, wash your hands often and use personal protective equipment.
- Do not come into contact with others and self-isolate at home except for a medical emergency or until you are able to go to your re-screening appointment.
- Rapid antigen screening is used for screening purposes only and is not used to diagnose COVID-19.
- Antigen screening does NOT prevent someone from getting COVID-19, does NOT completely rule out an active COVID-19 infection and should NOT be used as a diagnostic tool.
- Screening is an extra health and safety step, to be used along with existing measures like physical distancing, hand washing, personal protective equipment and enhanced cleaning.
- Rapid antigen screening does NOT replace any of above health and safety measures.

**Process for notification of Public Health:**

**Note:** Notification of Public Health is only required for presumptive positive results

- Pharmacists obligations to report: COVID-19 is a designated disease of public health significance and thus reportable under the Mandatory Order.
- Pharmacists, as regulated health professionals, must contact their local public health unit to report preliminary positive antigen screening result. They must disclose, name, date of birth (if available), Medicare number (if available) and antigen screening result.
- Pharmacies will continue to report any presumptive positive cases to Public Health, using the protocol outlined by Public Health.⁴
- Important: A positive result on a rapid antigen screening test is considered a preliminary positive and should be followed up with a Laboratory-PCR test within 24 hours (or as directed by Public Health).

**Storage and Stability:**

From Abbott:
1. The test kit should be stored at a temperature between 2-30 °C. Do not freeze the kit or its components. Note: When 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.

   **Recommendation:** Testing supplies should be stored at room temperature, as room temperature does not lead to loss of testing integrity and it means there is no wait time for materials to come to room temperature prior to use.

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⁴ In development. Link will be provided by Public Health when in place.
2. 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.

3. Perform the test immediately after removing the test device from the foil pouch.

4. Do not use the test kit beyond its expiration date.

5. The shelf life of the kit is as indicated on the outer package.

6. Do not use the test kit if the pouch is damaged or the seal is broken.

7. 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.

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**Safety Instructions**: (including proper use of PPE)

**Warnings**

1. For *in vitro* diagnostic use only. Do not reuse the test device and kit components.

2. These instructions must be strictly followed by a trained healthcare professional to achieve accurate results. All users have to read the instruction prior to performing a test.

3. Do not eat or smoke while handling specimens.

4. Wear protective gloves while handling specimens and wash hands thoroughly afterwards.

5. Avoid splashing or aerosol formation of specimen and buffer.

6. Clean up spills thoroughly using an appropriate disinfectant.

7. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials (i.e. swab, extraction tube, test device) in a biohazard container as if they were infectious waste and dispose according to applicable local regulations.

8. Do not mix or interchange different specimens.

9. Do not mix reagent of different lots or those for other products.

10. Do not store the test kit in direct sunlight.

11. To avoid contamination, do not touch the head of provided swab when opening the swab pouch.

12. The sterilized swabs should be used only for nasal specimen collection.

13. To avoid cross-contamination, do not reuse the sterilized swabs for specimen collection.

14. Do not dilute the collected swab with any solution except for the provided extraction buffer.

15. The buffer contains <0.1% sodium azide as a preservative which may be toxic if ingested. When disposed of through a sink, flush with a large volume of water.

16. Do not use the positive or negative control swab for specimen collection.

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**Training Requirements**: (including ongoing competency assessment of individuals performing the tests and documentation of such training/assessments)

Pharmacists and any other pharmacy team members performing specimen collection must be familiar with the anterior nasal swab technique for COVID-19 testing and screening.
Nasal/Nostril/Nose Specimen Collection Instructions

1. Insert swab about 1 cm (0.5 in) inside nares*.
2. Rotate swab and leave in place for 10-15 seconds.
3. Using same swab, repeat for other nostril.
4. Immediately place in sterile tube containing transport medium.

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

Panbio Nasal Movie
-Live test.mp4
Appendix 2: Quality Assurance for Panbio (Abbott) COVID-19 testing

Requirements from Public Health, along with the pharmacy’s Quality Management Program (QMP)\(^5\), outlines the need for a quality assurance process, to be in place for COVID-19 testing of asymptomatic patients. This is also listed as one of the responsibilities of the pharmacist included in the SOP (Appendix 1).

This Quality Assurance process must include, at a minimum, the following items:

- **Initial and ongoing reagent validation prior to clinical use**
  - See SOP template (Appendix 1), under Device Calibration and Quality Assurance, Internal Quality Control, External Quality Control and Control Test Procedure.
  - Abbott recommends a control test for each Lot Number and delivery. For example, if 2 boxes of tests arrive in a delivery with the same lot number, only one control test is required. If the same lot number appears in a subsequent delivery, perform another control test (in case, for example, a change in conditions in transit for the second delivery).
  - More frequent control testing may also be undertaken, based on, for example, changes in personnel (shift changes) or other factors which may affect testing performance.

Template for External Control Testing: (Pharmacy team members are encouraged to create a document that meets the needs of the practice site.)

<table>
<thead>
<tr>
<th>Date of Control Testing</th>
<th>Lot # and Expiry date of Kit tested</th>
<th>Delivery date to the pharmacy</th>
<th>Team member performing the test</th>
<th>Positive control test result</th>
<th>Negative control test result</th>
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Proficiency testing to monitor overall testing practices at a pharmacy site. Pharmacists must ensure that only trained and fully competent pharmacy team members conduct tests.

- Pharmacists must review training with pharmacy team members and perform an initial check of all processes while the team member performs a test. This must be documented.
- Pharmacists must review IPC training and ensure appropriate use of PPE (including donning and doffing), disposal of biohazardous waste and sanitization of the specimen collection and testing area is done. This must be documented.
- Pharmacists may continue to monitor proficiency and safety of employees administering COVID-19 tests. This should also be documented.

  ✓ Monitoring may include ongoing demonstration of: an understanding of the appropriate use of the device, its clinical utility and limitations and appropriate action when results fall outside predefined limits; an understanding of the technical limitations of the device, the stability and proper use of reagents, and recognition of error; the ability to consistently obtain a proper sample from the patient; the skills required to follow quality procedures of a test and to assess and verify the validity of test results prior to reporting.

Template for Proficiency Testing: (Pharmacy team members are encouraged to create a document that meets the needs of the practice site.)

<table>
<thead>
<tr>
<th>Date of Proficiency Monitoring</th>
<th>Name of team member observed and assessor</th>
<th>Use of PPE (meets requirements or requires retraining)</th>
<th>Specimen Collection (meets requirements or requires retraining)</th>
<th>Testing Procedure (meets requirements or requires retraining)</th>
<th>Waste disposal and sanitation (meets requirement or requires retraining)</th>
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• **Processes for error reporting**
  
  - Mandatory reporting to an external agency is not required. However, a paper-based error reporting system must be in place.
  - In the event of an error, a root cause analysis must be performed and an action plan, with monitoring, developed.

Template for Error Reporting: (Pharmacy team members are encouraged to create a document that meets the needs of the practice site.)

<table>
<thead>
<tr>
<th>Date of Event</th>
<th>Identifier (patient initials, transaction #, etc)</th>
<th>Description of Error</th>
<th>Root Cause Analysis</th>
<th>Improve ment Action Items</th>
<th>Follow up and monitoring parameters</th>
<th>Comments</th>
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• Monitoring the competence of pharmacy team members who conduct Panbio COVID-19 testing will also include:
  
  - Review of processes for communicating negative test results (any pharmacy team member). Deficiencies and improvement plans could be reported using the Error Reporting mechanism.
  - Review of processes for communicating test results (pharmacists only). Deficiencies and improvement plans could be reported using the Error Reporting mechanism.
  - Review of appropriate test documentation and follow-up requirements (pharmacists). Deficiencies and improvement plans could be reported using the Error Reporting mechanism.
  - Troubleshooting issues with tests and/or devices.