Implementing a COVID-19 Rapid Antigen Screening Program

Last updated: May 21, 2021

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

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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^{o} C
  - Extra tube holder (from another Panbio™ kit)
- Panbio™ implementation procedures and quality guidance understood by rapid testing lead and test clinic staff.
- 2-3 team members trained to operate rapid screening clinic (see slide 9 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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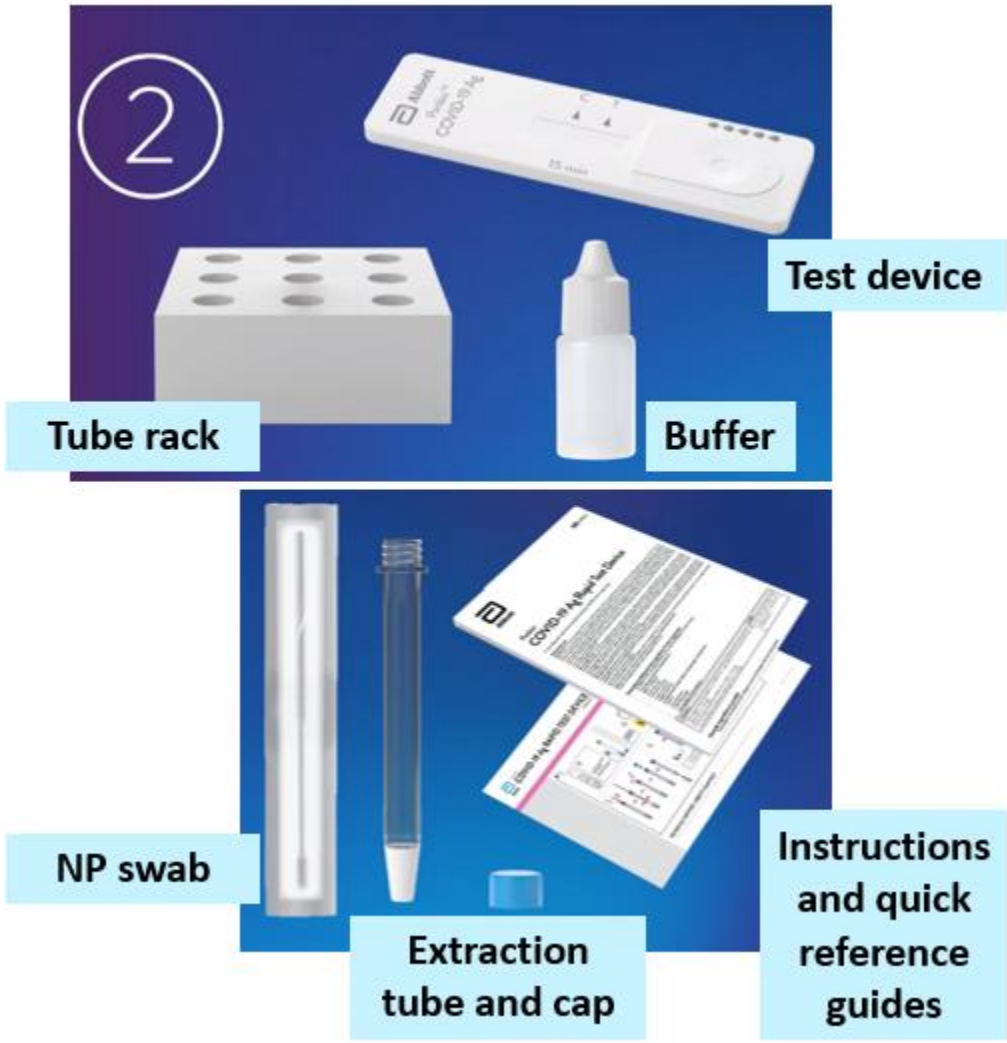
Panbio™ Kit

- 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 15-30°C; DO NOT FREEZE
- Do not use test kit beyond expiration date
- Once test device is removed from foil pouch, it should be used immediately for testing
- Do not use test kit if foil pouch is damaged or seal is broken – discard immediately. 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 Update – March 5, 2021

- Changes to Ministry of Health guidance to allow for all Health Canada approved point-of-care tests for COVID-19 to be performed in accordance with the product manufacturer's label, i.e., by health professional or trained operator.
- Specimen collection for antigen testing may also be done by the person being tested ('self-swabbing') under the following specific circumstances:
  - If a trained individual, including a health care professional (regulated or unregulated) is supervising the self-swabbing
  - Any individual supervising self-swabbing must consult the self-swabbing training resource developed by Ontario Health in collaboration with Public Health Ontario and ensure they have the appropriate knowledge, skills, and judgment to provide appropriate self-swabbing oversight, including how to operate the device, PPE requirements, and how to safely dispose of waste

Staffing Recommendations for Panbio™ Rapid Screening

Example staffing model of 2-3 designated staff members:

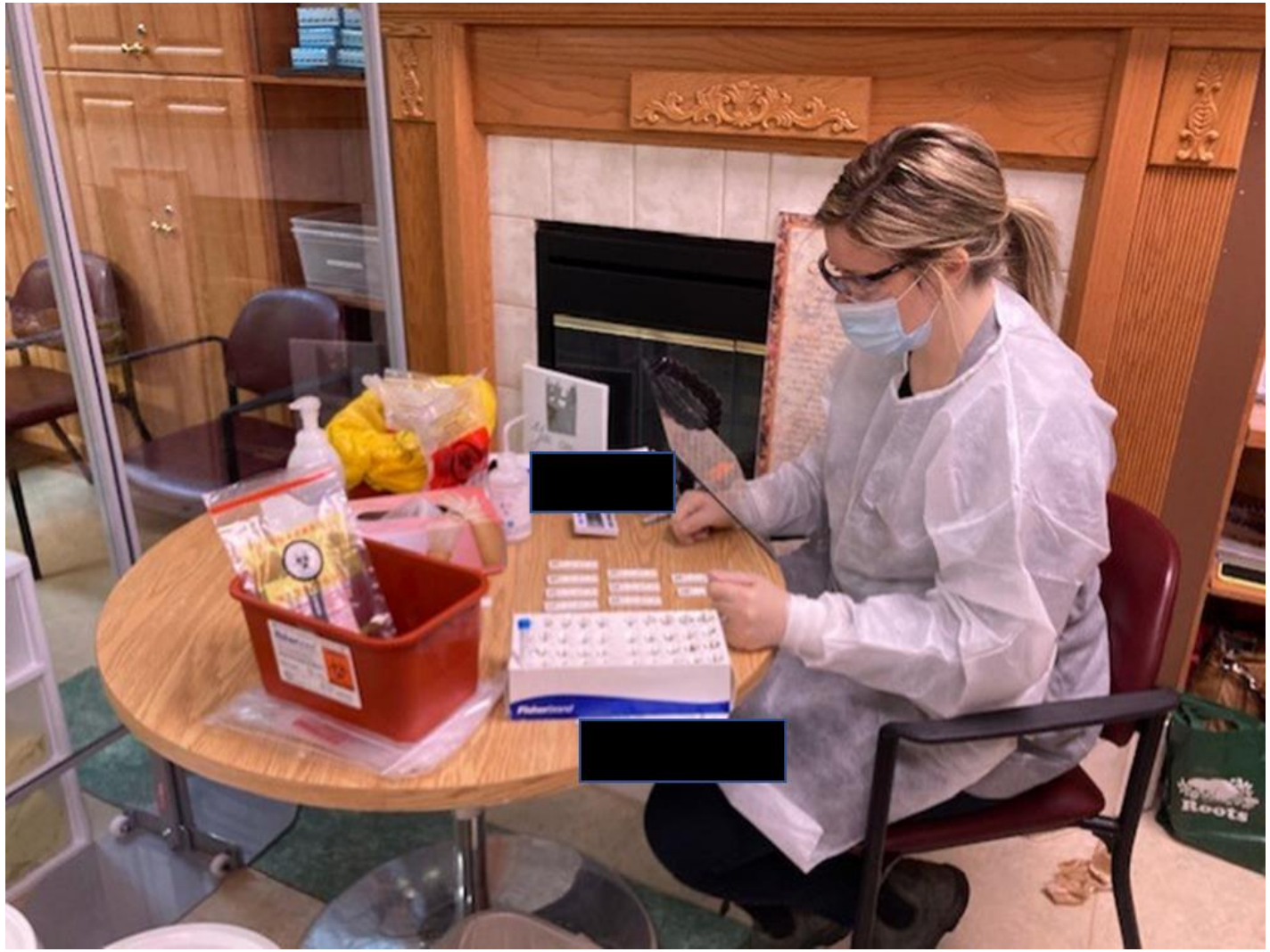
Staff Member	Role
Person A	**Pre-testing**: Register staff, prepare kits and label tubes.
Person B	**Testing**: Use swab to collect the specimen and place it in the extraction tube according to instructions.
Person C	**Testing & Result Recording**: Test the specimen and record and report results.

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

Dedicated Space for Panbio™ Screening

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

Dedicated Space for Panbio™ Screening



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Biosafety Considerations for Panbio™ Screening

- Conduct a local risk assessment
- Wear appropriate personal protective equipment (PPE) when handling patient specimens and used devices
- Dispose of specimens, kits, and other contaminated materials carefully in an appropriate biohazard container. 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.
- Maintain a safe work area
- For more information see Public Health Ontario's Biosafety Factsheet

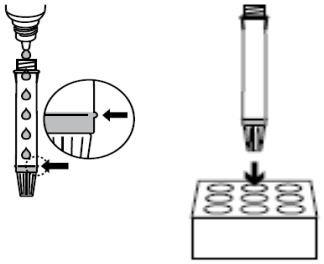
Conducting Control Swabs

- 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.

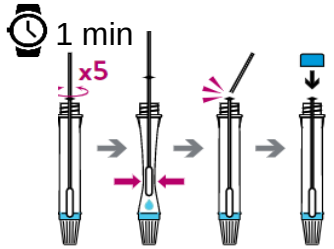
Conducting Control Swabs

Process Flow for Testing Kit with Controls

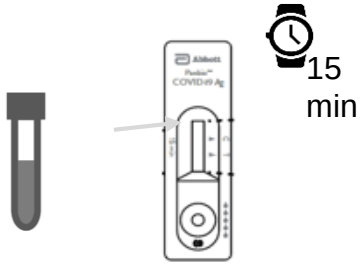
1. Fill tube with buffer



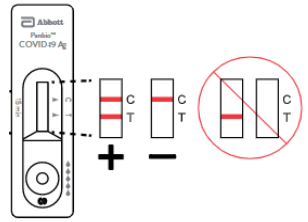
2. Insert control swabs

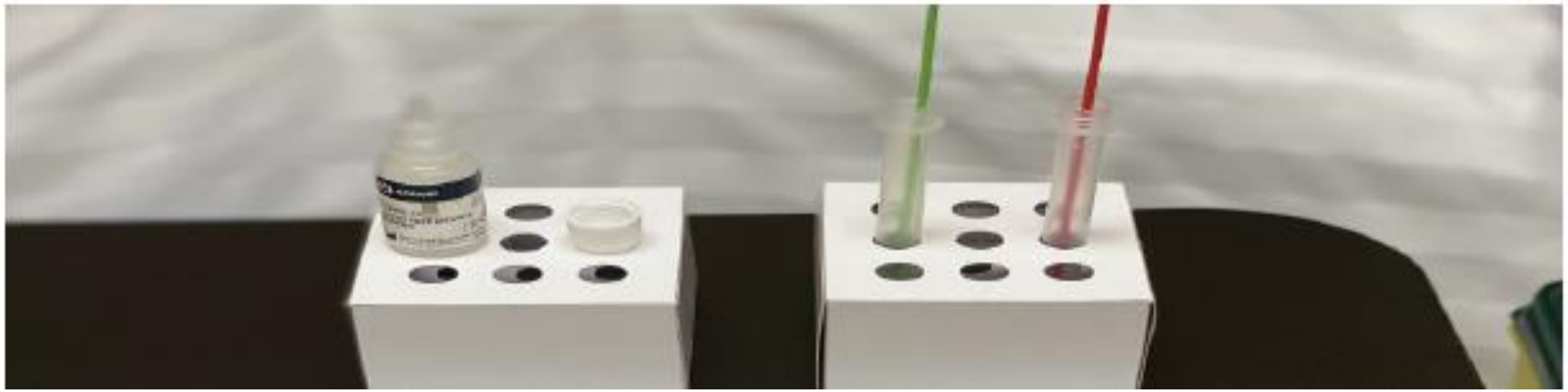


3. Process test



4. Read result





Panbio™ buffer and control swabs

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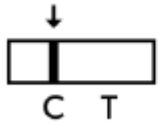
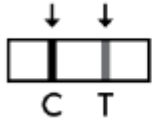
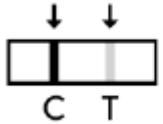
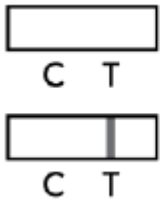
Interpreting Results of Control Swabs

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

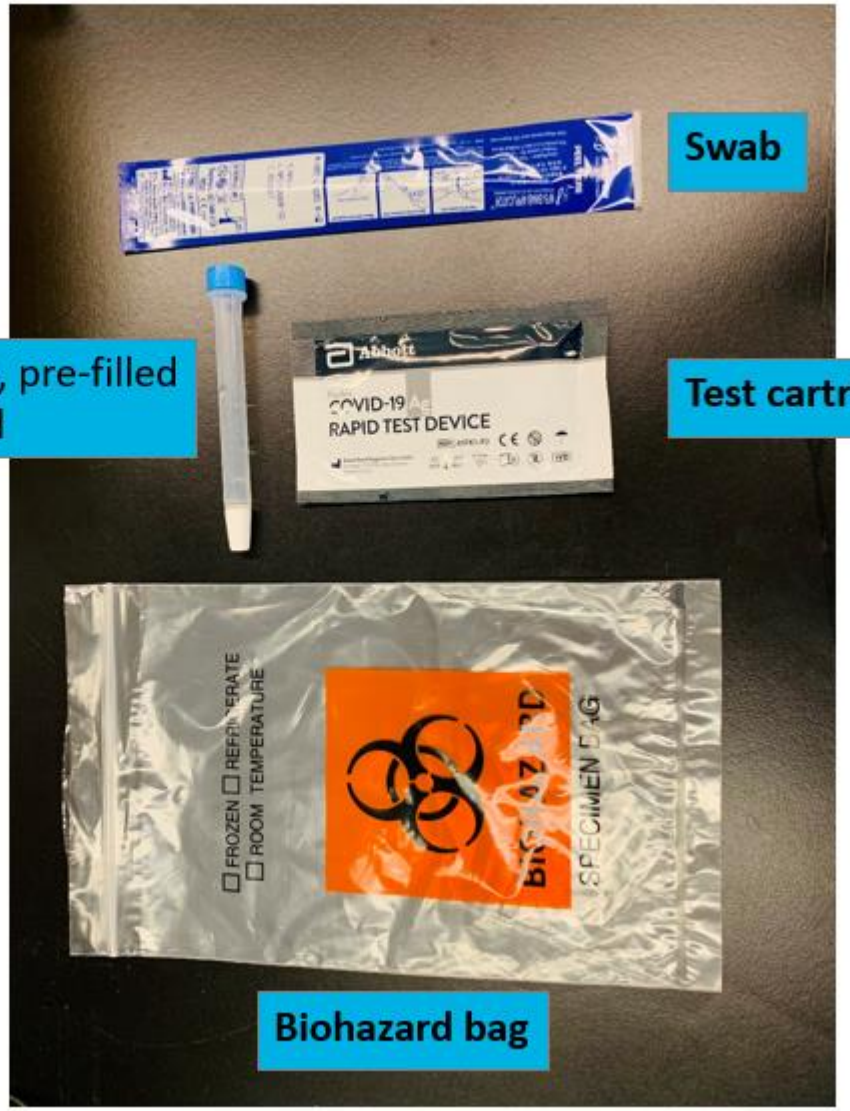
Rapid antigen screening clinic can be broken into 6 stages:

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.**
   - Test cartridge
   - NP 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 3 labels containing participant information: One for Panbio™ extraction tube, one for cartridge/device.

1. Preparations



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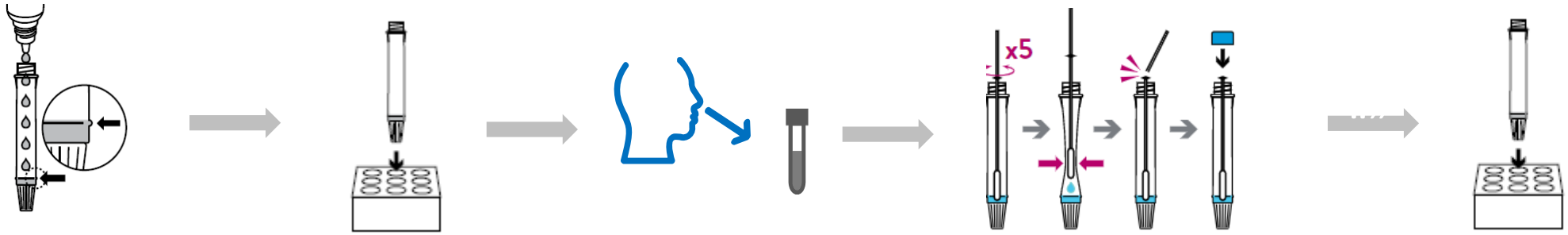
2. Intake

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.



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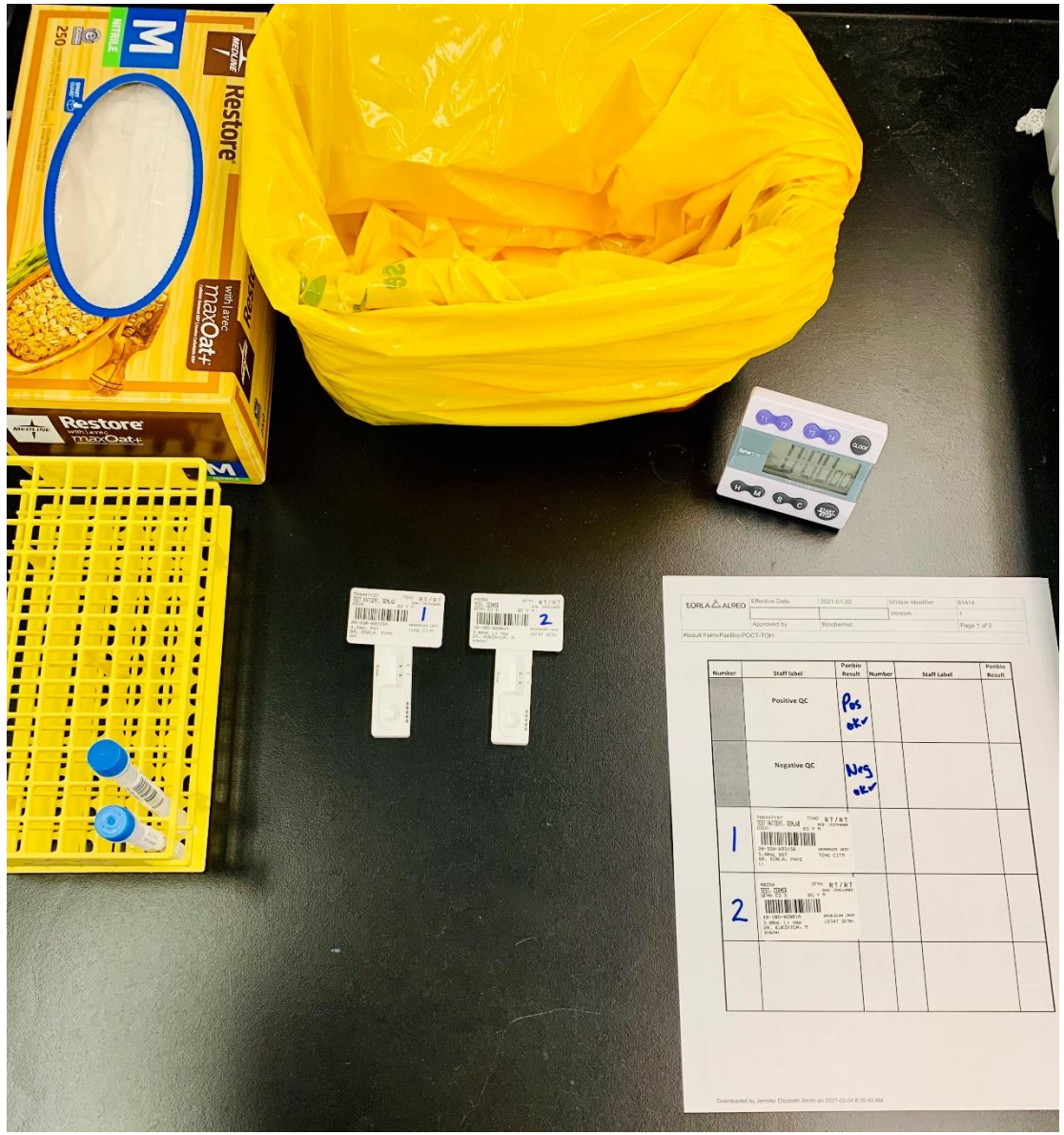
4. Testing the Specimen (batch testing)



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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).

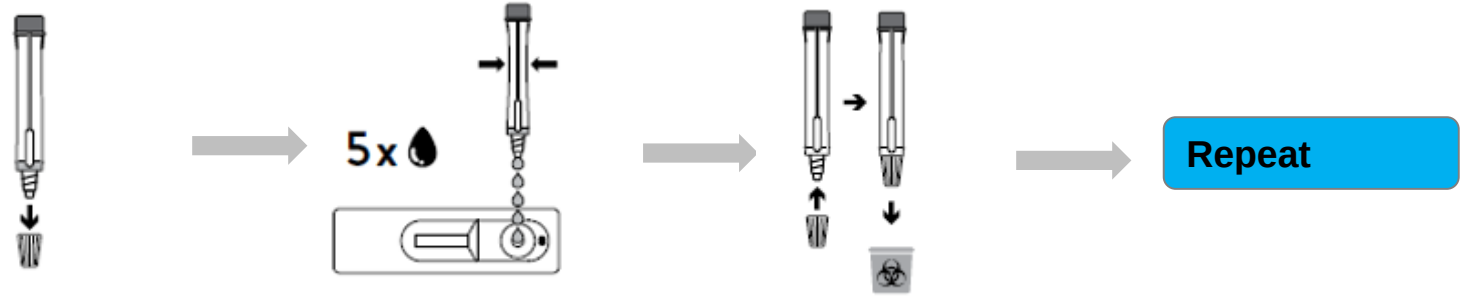
2. **Person C** opens **all test devices for the batch** and places a pre-printed label on each device to correspond with the staff member's information on **extraction tube** that will be tested .

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

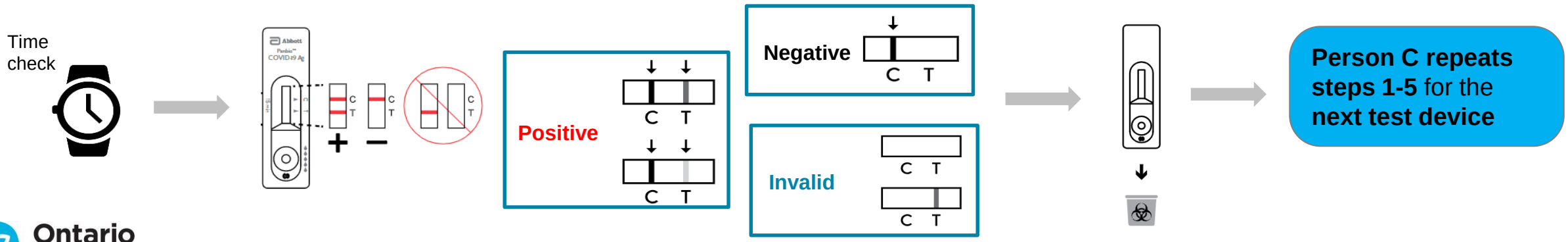
Invalid = if the **control line (C) is not visible** within the result window. Instructions may not have been followed correctly or sample was too viscous. It is recommended to read the instructions again before conducting repeat testing with a new specimen.

3. Record result for each cartridge on the results tracker

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

5. Remove and dispose of corresponding masking tape label from table

6. 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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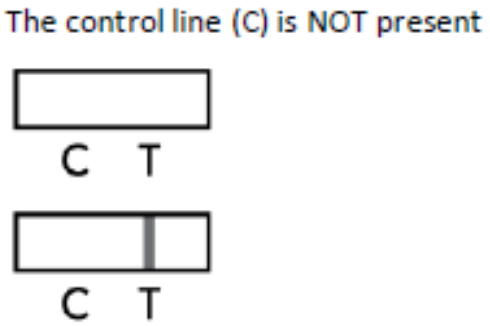
6. Communicating Results - Invalid

- 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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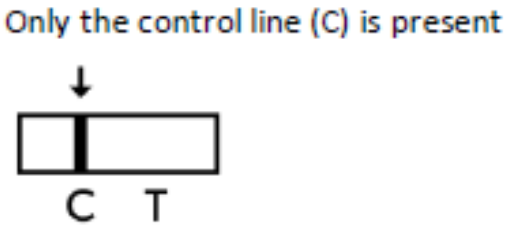
6. Communicating Results - Negative

- 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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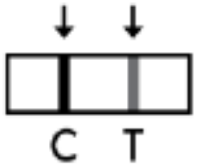
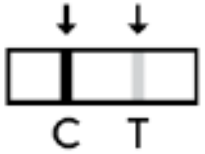
6. Communicating Results - Positive

- Counsel individual that the positive result is considered preliminary positive and they will need to have a second swab within 24 hours for confirmation.
- Require that the individual receive confirmatory lab-based PCR test within 24 hours. Do not re-test with rapid antigen test.

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



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



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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 ensures a confirmatory PCR test is completed within 24 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.

Key Site Requirements, Available Resources and Additional Support

Key Site Requirements for Rapid Antigen Screening

Rapid testing lead:
An administrator, director of care or other lead to oversee the rapid testing implementation at your organization.

Testing Personnel: Health professionals, or other trained individuals, to perform the swabbing and operating the rapid testing device.

Confirmatory testing: The ability to collect PCR swabs or process in place to direct individuals with preliminary positive results from the rapid testing to closest assessment centre or participating community lab for confirmatory lab-based testing.

Ongoing quality support and capacity: Staff conducting the screening clinic should review the training session to ensure the antigen testing is run appropriately and the required quality checks are performed on the test kits.

Data reporting: Sites are required to submit minimum data elements requested on a regular basis (e.g. weekly reporting of volumes).

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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#
- Ontario Health's online ordering system for Panbio™ kits: ehealthontario.on.ca/en/health-care-professionals/digital-health-services

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Panelists for Q&A:

- Dr. Julie Shaw, Division Head, Biochemistry, and Director, Point of Care Testing
  The Ottawa Hospital and Eastern Ontario Regional Lab Association
- Renee Mahalanobis, Director, Long-Term Care Projects and Stabilization, Ministry of Long-Term Care
- Dr. Antoine Corbeil, Medical Microbiology Resident, Public Health Ontario

Additional resources and training materials are available at ontariohealth.ca/antigen-test.

If you have questions about Panbio™ COVID-19 Antigen Rapid Testing, please contact Ontario Health at:

covid19testing@ontariohealth.ca

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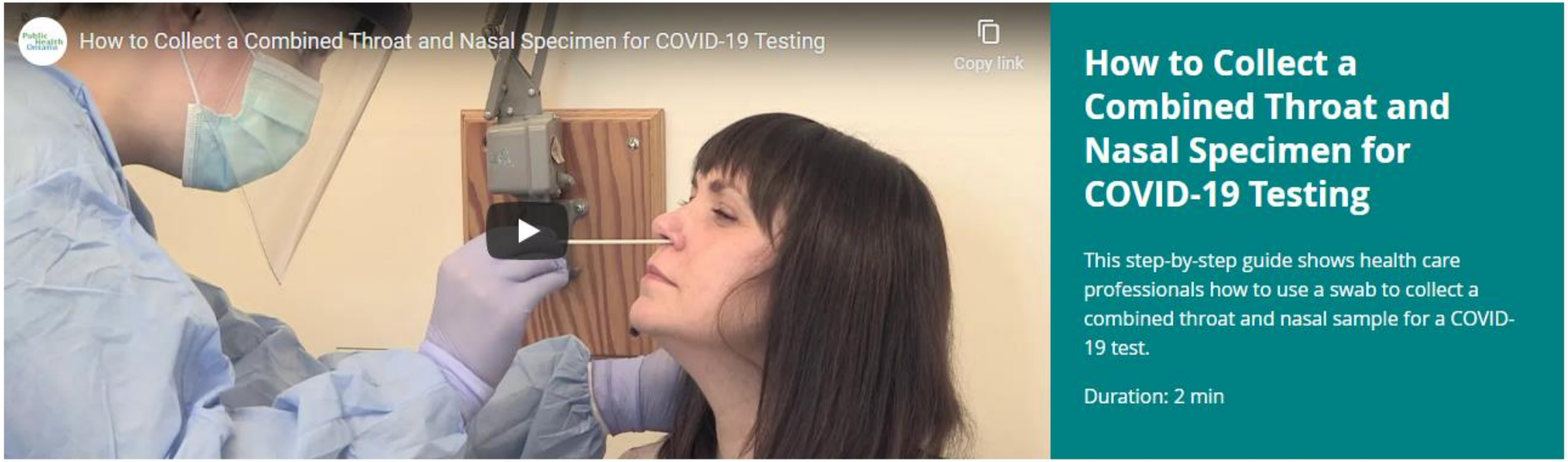
Appendix

Combined Throat and Nasal Specimen Collection



Source: Ontario Agency for Health Protection and Promotion (Public Health Ontario). Oropharyngeal/throat combined with anterior nares/nostril [Internet].
Toronto, ON: Queen's Printer for Ontario; 2020. Available from: www.publichealthontario.ca/en/laboratory-services/kit-test-ordering-instructions/virus-respiratory-throat-nasal

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Storage Conditions for Panbio™ Kits

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