Ontario Health

COVID-19 Rapid Antigen Testing Onboarding Guide

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Note: Ontario Health will update this document on a regular basis as new information becomes available and provincial guidance changes.

Disclaimer: This document was developed by Ontario Health for training and guidance purposes. The application and use of this document are the responsibility of the user. Ontario Health assumes no liability resulting from any such application or use.

Purpose

This document provides planning and implementation guidance for workplaces and congregate living settings (e.g., shelters, retirement homes, and long-term care homes, etc.), as well as other sectors undertaking on-site or at-home testing for COVID-19 using rapid antigen tests (RATs) in Ontario. The Ministry of Health, Public Health Ontario and Ontario Health have contributed to this document.

Provincial Antigen Screening Program

The Provincial Antigen Screening Program (PASP) is a program being led by the Ministry of Health, with support from partner ministries, Public Health Ontario, and Ontario Health. The PASP allows organizations to add an additional safety measure in workplaces, congregate living settings, and other sectors to help reduce the spread of COVID-19. Through the program, RATs are distributed to enhance existing public health measures. RATs may allow workplaces, congregate living settings, and other sectors to proactively identify cases of COVID-19 that may have otherwise been missed, supporting employee safety and business continuity. Using a COVID-19 RAT takes about 15 to 20 minutes.

Resources

The documents listed below should be used to support implementation of COVID-19 rapid testing using RATs. Sites are also encouraged to develop internal resources to help introduce rapid antigen testing to their staff and external partners, as required.

Included in this Document:

Document Name	Description
COVID-19 RAT Program Frequently Asked Questions (Appendix A)	Provides participating sites with instructions regarding COVID-19 RATs, including when to use the test, the testing process, and interpreting test results.
Primer on Best Practices: COVID-19 RATs (Appendix B)	This checklist highlights the suggested approach to quality management for COVID-19 RAT use.
Repackaging RATs for At-Home Use (Appendix C)	Provides recommendations on repackaging RATs into smaller packages for home distribution.
COVID-19 RAT Go-Live Readiness Checklist (Appendix D)	Provides a list of essential steps to review prior to initiating testing using COVID-19 RATs.
RAT Technical Specifications (Appendix E)	Provides a list of items included in RAT shipments. Information on expiry extensions for RATs can be found on the Ontario Health website.

Additional Resources:

Document Name	Description
COVID-19 Provincial Testing Guidance	Provides guidance on the use of RATs.

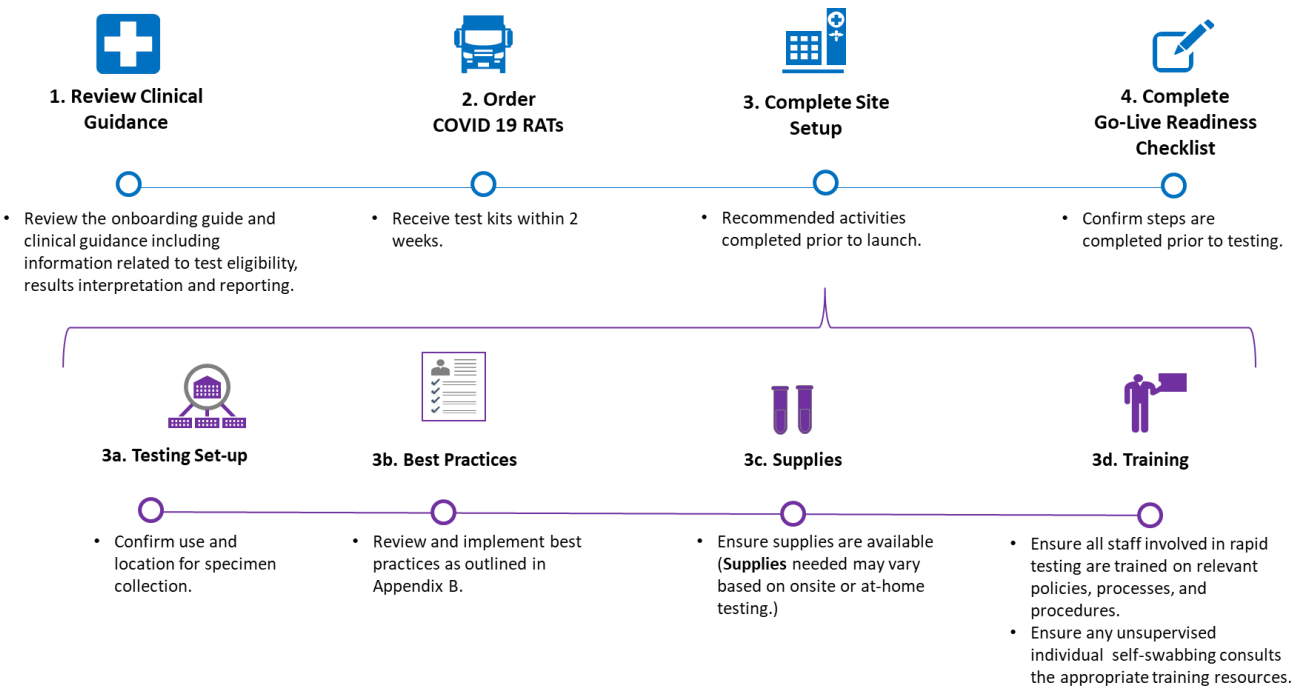
Ontario Health training documents:
 	
• Collecting Specimens
• Self-Collection
• At-home self-testing Instructions
  ◦ Panbio™
  ◦ BTNX Rapid Response™
  ◦ BD Veritor™
  ◦ SD Biosensor
  ◦ Trimedic FaStep®
  ◦ Artron
	Provides planning and implementation guidance for organizations conducting on-site testing for COVID-19 using RATs as part of the PASP. The resources are available on the Ontario Health website at ontariohealth.ca/antigen-test.

Onboarding Process Overview

The onboarding process prepares sites to implement a testing program using COVID-19 RATs. Figure 1 describes the end-to-end onboarding process for sites.

If you have questions during the onboarding process, please contact covid19testing@ontariohealth.ca.

Figure 1: Onboarding Process Overview



1. Review Clinical Guidance

The COVID-19 Provincial Testing Guidance includes important information about the use of RATs.

2. Order COVID-19 RATs

Visit the Government of Ontario website to check eligibility and apply for free RATs.

Tests must be stored and transported between 2° to 30° Celsius. Tests cannot be frozen. Tests must also be protected from direct sunlight.

See Appendix E for a complete list of technical specifications by type of RATs. Information on **expiry extensions** for COVID-19 testing products, including RATs can be found on the Ontario Health website.

3. Complete Site Setup

3a. Setting Up Operations

Sites can choose the following modes of testing program operations:

1. Independently operate the program on-site (i.e., using existing staff or directly hired new staff).
2. Contract with a service provider of their choosing to operate the program on-site.
3. Operate a self-testing program, where employees either test themselves on-site or test at home before attending the workplace.

3b. Best Practices

Best practices are recommended procedures that have been shown by research and experience to produce optimal results. Sites using RATs should ensure that best practices are followed. Sites should designate a rapid testing lead (e.g., an administrator, director of care, or other lead) to oversee RAT activities at your organization. The rapid testing lead must take steps to ensure RAT use meets the best practices outlined in Appendix B.

If a service provider is contracted to deliver the program, the rapid testing lead can be the primary liaison with the service provider. The service provider should take steps to ensure rapid antigen testing meets the best practices as outlined in Appendix B. The Antigen Testing Services Directory provides a list of service providers who can perform rapid testing for the PASP.

Unsupervised self-testing enables employees to complete the RAT at home before they travel to the workplace. If individual employees are doing self-testing at home, they must consult the self-testing training resources developed by Ontario Health, in collaboration with Public Health Ontario, to ensure they have appropriate knowledge and skills to perform the test accurately.

3c. Supplies for Performing Testing

Table 1 lists the general supplies and equipment required to perform COVID-19 RAT. Sites needs to obtain general supplies and equipment on their own.

Table 1: Supplies and equipment for COVID-19 rapid antigen testing

Supplies/ Equipment	Description and Use	Testing at home	Testing on site
COVID-19 RATs	RATs for COVID-19 as ordered through the Government of Ontario website. Note: If conducting at-home testing, sites can repackage RATs into smaller allotments. Suggested repackaging methods are provided in **Appendix C.**	X (See note)	X
Biohazard Waste Containers	Required to safely dispose of the swabs, test kits, and PPE after use if testing is done on site as per the Environmental Protection Act[1].		X
Disinfectant	Used to clean the test space between each test.	X	X
Garbage Bag	Can be used to safely dispose of the swabs, test kits, and PPE after use.	X	
Hand Sanitizer	Used by rapid testing clinic staff, as well as individuals undergoing testing on site or at home.	X	X
Masking Tape and Sharpie	Can be used by rapid testing clinic staff to record the time when testing the specimen.		X
Personal Protective Equipment (PPE)	Gloves, gowns, medical masks, and face shields will be needed for all individuals running the rapid testing clinic on site.		X
Plexiglass Shield (recommended)	Recommended to be used by rapid testing clinic staff while performing swabbing.		X
Timer	Used to monitor the testing time.	X	X

3d. Training

Ontario Health has developed complementary training resources for RAT. These training resources are available on the Ontario Health website at ontariohealth.ca/antigen-test and include topics such as:

- **How to collect specimens for RAT**: Provides information on how to conduct swabbing for RAT. This document is available in 26 languages.
- **At Home antigen self-screening video:** Provides general instructions for how to use RATs at home and perform self-testing.
- **How to use Antigen Test at Home:** Provides step by step written instructions for how to use RATs at home. There is a separate document available for each test type.

[1] Refer to the Ministry of the Environment and Climate Change for Safe handling and management of rapid antigen COVID-19 testing waste.

4. Complete the Go-live Readiness Checklist

The COVID-19 Rapid Antigen Test Go-live Readiness Checklist (Appendix D) provides a list of essential steps to review prior to initiating testing using COVID-19 RATs.

5. Issues Management

Please report any issues you experience to covid19testing@ontariohealth.ca with a description of your issue.

6. Acknowledgement

This onboarding guide was adapted by Ontario Health from the *COVID-19 Rapid Testing ID NOW™ Onboarding Package for New Sites*, which was developed by the ID NOW™ Rapid Testing Resources Committee.

Thank you to Abbott, BD, BTNX, SD Biosensor, Trimedic, and Artron for permission to use illustrations.

Appendix A: Frequently Asked Questions

What is a COVID-19 RAT?

- A rapid antigen test (RAT) is an easy-to-use test that looks for evidence of the COVID-19 virus. RATs do not replace other public health measures such as vaccination, symptom screening, physical distancing, masking, and hand hygiene. RATs do not replace requirements to protect the health and safety of workers.

When should you perform a COVID-19 RAT?

- RATs must be used in accordance with the COVID-19 Provincial Testing Guidance and PASP terms and conditions.

How should RATs be used?

- RATs can be performed by health professionals or trained individuals (i.e., any individual who has reviewed the training materials housed on the Ontario Health website and feels confident with carrying out the instructions).
- Specimen collection and use of RATs should follow the labelling instructions, provided by the manufacturer as approved by Health Canada.
- If the manufacturer's labelling instructions (as approved by Health Canada) do not already include combined oral and nasal sampling, users may voluntarily perform the combined oral and nasal sampling method following the RAT collection instructions found here as it may increase test sensitivity compared with nasal sampling alone.
- If the manufacturer's labelling instructions (as approved by Health Canada) do not already include self-swabbing and self-testing, voluntary self-swabbing and self-testing may be performed if the user has the appropriate knowledge, skills, and judgment to self-swab and self-test as per the training resources available here, including an instructional video.

How does a COVID-19 RAT compare to laboratory-based PCR tests?

- Compared to PCR tests, COVID-19 RATs have a higher risk of providing either a false negative result (a result that shows a person is not infected with COVID-19 when they are) or a false positive result (a result that shows a person is infected with COVID-19 when they are not).
- Interpretation of results varies based on specimen type collected, the prevalence of COVID-19 in the community, the presence of symptoms, and the COVID-19 exposure risk.

How often should someone be screened for COVID-19 using a RAT?

- Recommended use cases and frequency are outlined in the COVID-19 Provincial Testing Guidance.
- Some sectors may be required to perform testing at a pre-defined frequency.

When will individuals get their RAT results?

- RATs often provide results within 15 minutes.

- For testing done on site at the workplace, the individual tested should be notified if the test comes back positive according to the site's procedures, ideally within two hours.
- Although less ideal than communicating all results, some sites follow a "no news is good news approach," where individuals are not directly told if their result is negative.

What are the safety precautions that need to be taken while administering COVID-19 RATs?

- Please refer to Appendix B: Primer on Best Practices for COVID-19 RATs.

How should specimens be disposed of?

- Guidance on how waste from RATs should be handled in the workplace has been developed by the Ministry of Environment, Conservation and Parks, and can be found here: Safe Handling and Management of Rapid Antigen COVID-19 Testing Waste.
- For waste generated from at-home testing, the regulatory requirements for managing the hazardous waste under the Environmental Protection Act do not apply. Persons undertaking at-home RAT should consult their local municipality's by-laws on the proper disposal of this waste to ensure it can be disposed of with the household trash.

What should someone do if they test positive using a RAT?

- Please refer to the guidelines provided for what to do if you have been exposed to COVID-19 found here.

Do individuals who test positive on the RAT need to be confirmed with lab-based PCR testing?

- RAT results should be interpreted as advised in COVID-19 Provincial Testing Guidance.

If an individual previously tested positive for COVID-19, should they be tested with a RAT?

- Individuals who have previously been diagnosed with and cleared of COVID-19 infection can resume asymptomatic testing after 30 days from their COVID-19 infection (based on the date of their positive PCR or rapid antigen result). This 30-day window does not imply that the person is immune and protected against reinfection, and retesting may be done earlier if there is a concern for reinfection.

Does a positive result on the RAT mean the site is in outbreak?

- A positive RAT result does not necessarily mean that the site is to be declared in outbreak.
- Public health units will remain the authoritative body on the declaration of a COVID-19 outbreak.

Do you need more information?

- If you or anyone in the program has any questions or need more information about test results, please contact your local Public Health Unit.

Appendix B: Primer on Best Practices for On-Site Testing for COVID-19 RATs

This primer highlights key best practices for operating a COVID-19 rapid antigen testing program.

Quality Oversight, Personnel, and Training and Competency

- ☐ Identify a rapid testing lead, who will be accountable for the quality of the rapid testing program at your site.
- ☐ Identify health professionals, or other trained individuals who will collect specimens, perform testing, and communicate test results to individuals being tested, where needed, for on-site testing.
- ☐ Train and confirm the competency of all staff involved in the entire testing process: pre-testing (e.g., specimen collection, labelling), testing, and post-testing (e.g., result recording/notification) and re-train if the staff has not involved in the testing process in the last three months.

Facilities

- ☐ Ensure your rapid testing area is safe. Examples include having a closed-off room (if possible), allowing for physical distancing, access to hand hygiene products, access to clean running water in the event of spills, and avoiding absorbent floors (e.g., carpets), walls, tables, furniture, fans, and stand-alone air conditioners in the rapid testing area.
- ☐ Keep the RAT materials, specimens, discarded waste, and the test processing area as separate from one another as possible to avoid cross-contamination.

Equipment and Supplies

- ☐ When receiving new tests, inspect them and notify your distributor if tests are damaged or defective.
- ☐ Track kit lot numbers and expiry dates, being sure to use tests before they expire. If multiple individuals are using the tests, make sure to clearly communicate any shelf-life extensions with other users to avoid any confusion.

Specimen Collection, Testing, and Results Interpretation/Recording/Notification

- ☐ If not performing self-testing, confirm the tested individual's identification by checking at least two unique identifiers before collecting a sample. Track the individual's two unique identifiers on the test and confirm that they match those of the individual.
- ☐ Handle only one specimen at a time when setting up a test.
- ☐ Follow the product insert and/or provincial authorities when performing and interpreting the test.
- ☐ Record test results on paper or electronically with the name of the individual tested (with two unique identifiers), test result, test used, and date and time of testing.
- ☐ Ensure the following can be traced back to the testing result if necessary: who performed the test, who was notified of the test result, the kit lot number, and any quality control results where applicable.
- ☐ If not performing self-testing, communicate test results to the person being tested.

Document Management

☐ Ensure there are rapid testing program procedures at your site and that the most recent version is used.

Quality Assurance

☐ If performing testing on site, perform quality control checks regularly, including when a new person is trained to perform testing, when a new shipment is received, when there is a change in lot number, when recommended by the manufacturer and (where relevant), provincial authorities.
☐ Investigate failed quality control checks and stop new specimen testing until the cause of the failure has been corrected.

Infection Prevention, Occupational Health, and Safety

☐ Do not eat, drink, smoke, vape, handle contact lenses, or apply cosmetics during testing.
☐ Use infection prevention and safety precautions recommended by the manufacturer or provincial authorities.
☐ Clean and disinfect the rapid-testing area regularly and as soon as any spills occur.

Ethical Conduct

☐ Treat all heath information as confidential following the *Personal Health Information Protection Act* (PHIPA).

Appendix C: Repackaging RATs for At-Home Use

Organizations may decide to repackage tests for individuals who are self-testing at home in order to avoid test wastage. Instructions on how to create mini kits for each test type are provided below. If providing asymptomatic testing kits, mini kits should ideally contain all the supplies needed for up to four weeks' worth of testing for each participant.

If the original box of tests comes with a control swab (usually packaged and labelled separately from the sterile swabs used for specimen collection), the organization should test the positive and negative control swabs on each new lot or shipment of boxes for quality assurance purposes. **Control swabs should not be included in the mini kit.**

In order to make the mini-kits, follow these recommended steps:

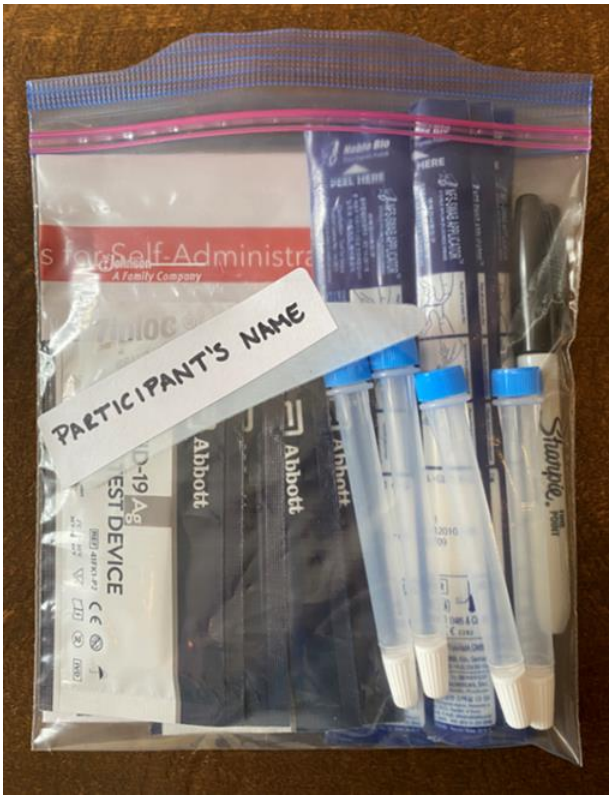
1. Perform hand hygiene before handling test components to avoid contamination.
2. Collect all the supplies needed for the chosen frequency of testing, including sterile swabs, tubes, caps/nozzles, unopened test cartridges, and any written documentation about the at-home testing process.

   A) For kits with multi-use buffer bottle only (Abbott Panbio™): Pre-fill all tubes with the buffer solution to the fill line. (See Picture 1)
   - If you use too little or too much liquid, you may get an incorrect test result.
   - Do not touch the liquid itself, the bottle dispenser tip, or the test tube opening with your hands.
   - Use only the liquid provided with the tests. Do not replace the liquid with any other liquids (e.g., tap water) otherwise the results may not be correct.
   - Note that the buffer solution will last in the tubes until the expiration date of the test.
   - Ensure the caps on both ends of the tube are securely fastened to prevent leakage or evaporation.

   B) For kits with single use vials (BTNX Rapid Response™): Include the single use vials in the provided supplies. Do NOT create mini kits by pre-filling extraction tubes with buffer solution as the nozzle is not hermetic (sealed or leakproof) and the buffer will leak. (See Picture 3)

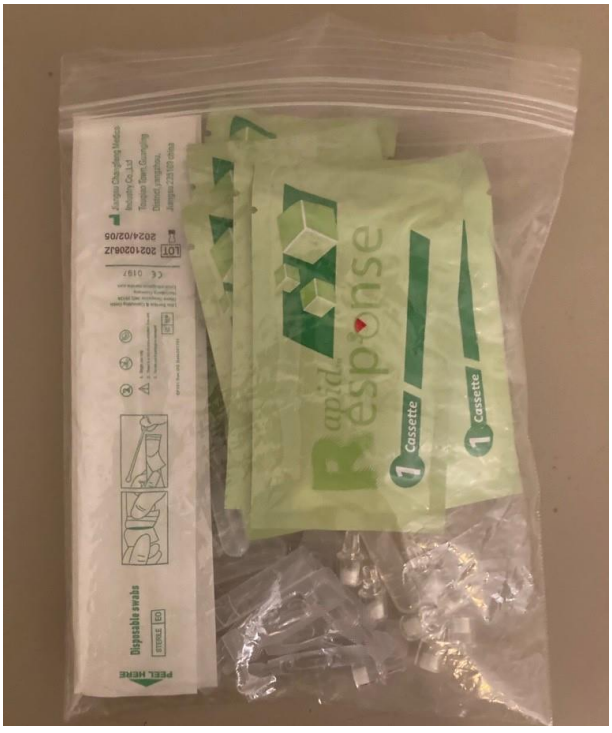
   C) For kits with pre-filled test tubes (BD Veritor™, SD Biosensor, Trimedic FaStep): Include the necessary amount of sealed test tubes with pre-filled buffer. (See Picture 2 for BD Veritor)

3. Put supplies into a Ziploc® bag or another container and label with the participant's name (if desired) and expiry date of supplies included in the mini-kit.



Picture 1: Panbio™ mini kit example

Picture 2: BD Veritor™ mini kit example



Picture 3: BTNX mini kit example

Appendix D: COVID-19 RAT Go-live Readiness Checklist for Testing Sites

#	Activity	Completed
1	Reviewed the Ministry of Health's COVID-19 Provincial Testing Guidance.	
2	Reviewed the COVID-19 Rapid Antigen Testing Onboarding Guide.	
3	COVID-19 rapid antigen testing implementation procedures have been reviewed and are understood by the staff involved in testing.	
4	Staff identified and trained to operate testing on site or at home: • Registration, preparation of kits, labelling; • Swabbing; and, • Testing specimens and documenting results.	
5	Confidentiality agreements signed by staff involved in testing.	
6	Ordered and received COVID-19 RATs.	
7	Additional materials required for testing are available.	
8	Full testing process established and documented (e.g., on site testing, home testing, result documentation, etc.).	

Appendix E: RAT Technical Specifications

Table 1: Key Technical Specifications for Abbott Panbio™

Product Details	**Specification**
Tests per Inner Case (each)	25 tests
Inner Case Dimensions (in cm)	23 x 12.5 x 9 cm
Tests per Master Case (each)	800 tests
Tests per Pallet (each)	9,600 tests
Content per Test	**Specification**
Test devices packaged in individual foil pouches	25 devices
Extraction buffer	1 x 9 ml bottle or 25 x 325 µL vials
Extraction tubes	25 tubes
Extraction tube caps	25 caps
Sterilized swabs for sample collection	25 swabs
Disposable tube rack	1 rack
Positive control swab (for quality control testing)	1 swab
Negative control swab (for quality control testing)	1 swab
Quick reference guide	1 guide
Instructions for use	1 set

Table 2: Key Technical Specifications for BD Veritor™

Product Details	**Specification**
Tests per Inner Case (each)	30 tests
Tests per Pallet (each)	2,880 tests
Size of the analyzer (mm)*	248 mm x 202 mm x 152 mm
Weight of the analyzer (kg)*	0.925 kg
Content per Test	**Specification**
Test devices packaged in individual foil pouches	30 devices
Extraction tubes with buffer and dispensing tip (pre-filled)	30 tubes x 325 µL buffer
Sterilized swabs for sample collection	30 swabs
Disposable tube rack	1 rack
Positive control swab (for quality control testing)	1 swab
Negative control swab (for quality control testing)	1 swab
Quick reference guide	1 guide
Instructions for use	1 set
BD Veritor™ Analyzer*	1 instrument

*Optional (not required for testing). May be used to interpret the result of the BD Veritor™ test.

Ontario has endorsed the off-label use of BD Veritor™ as a self-read device. In addition, Health Canada approved the use of the BD Veritor™ RAT as a visually-read device (see COVID-19 testing device applications authorized by Health Canada), without the use of an analyzer machine. The use of BD Veritor™ as a visually-read device is particularly helpful for enabling at-home testing.

Table 3: Key Technical Specifications for BTNX Rapid Response™

Product Details	**Specification**
Tests per Inner Case (each)	25 or 5 tests (two versions)
Inner Case Dimensions (in cm)	21 x 13 x 8 cm
Tests per Master Case (each)	650 tests
Tests per Pallet (each)	13,000 tests
Content per Test	**Specification**
Test devices packaged in individual foil pouches	25 or 5 devices
Extraction tubes	25 or 5 tubes
Extraction buffer	2 x 4.5 ml bottle, and 25 or 1 x 325 µL buffer vials
Extraction tube nozzle caps with filter	25 or 5 nozzle caps
Sterilized swabs for sample collection	25 or 5 swabs
Disposable tube stand	1 stand
Instructions for use	1 set

Table 4: Key Technical Specifications for SD Biosensor Rapid Antigen Test Nasal

Product Details	**Specification**
Tests per Inner Case (each)	25 tests/box
Inner Case Dimensions (in cm)	56 x 48 x 43 cm
Tests per Master Case (each)	750 tests/case (30 boxes/case)
Tests per Pallet (each)	9000 tests per pallet
Content per Test	**Specification**
Test devices packaged in individual foil pouches	23, 5 or 2 devices
Extraction tubes with buffer	23, 5 or 2 tubes x 325 µL buffer
Extraction tube nozzle caps with filter	23, 5 or 2 nozzle caps
Sterilized swabs for sample collection	23, 5 or 2 swabs
Disposable tube rack	1 rack
Positive control swab (for quality control testing)	1 swab
Negative control swab (for quality control testing)	1 swab
Quick reference guide	1 guide
Instructions for use	1 set

Table 5: Key Technical Specifications for Trimedic FaStep®

Product Details	**Specification**
Tests per Inner Case (each)	20 tests
Inner Case Dimensions (in cm)	63 x 37 x 30 cm
Tests per Master Case (each)	540 tests
Tests per Pallet (each)	Not exact as 4 different pallet sizes available
Content per Test	**Specification**
Test devices packaged in individual foil pouches	20 devices
Extraction tubes with buffer and dispensing tip (pre-filled)	20 tubes x 325 µL buffer
Sterilized swabs for sample collection	20 swabs
Disposable tube stand	1 stand
Quick reference guide	1 guide
Instructions for use	1 set

Table 6 – Key Technical Specifications for Artron

Product Details	**Specification**
Tests per Inner Case (each)	5 tests per box
Inner Case Dimensions (in cm)	59*41*37cm
Tests per Master Case (each)	700 tests (140 boxes /case)
Tests per Pallet (each)	17,500 tests per pallet
Content per Test	**Specification**
Test devices packaged in individual foil pouches	5 devices
Extraction tubes with buffer	5 tubes with 300µL buffer
Extraction tube nozzle caps with filter	5 nozzle caps
Sterilized swabs for sample collection	5 nasals swabs (sterilized)
Disposable tube rack	Box has been adapted to be used as a rack for 3 tubes at a time.
Positive control swab (for quality control testing)	Not Included
Negative control swab (for quality control testing)	Not Included
Quick reference guide	Not Included
Instructions for use	1 set