Implementing a COVID-19 Rapid Antigen Screening Program: BD Veritor™

Last updated: September 24, 2021

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

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Overview

By the end of this session, you will understand:

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

Readiness Assessment for Using BD Veritor™

- Kit content and set-up
- Staffing recommendations
- Dedicated space
- Biosafety
- Conducting quality control

Rapid Antigen Screening Clinic Implementation Readiness Assessment

- BD Veritor™ rapid test kits and analyzer(s)
  - Check expiry date
  - Brought to 15-30° C
- BD Veritor™ implementation procedures and quality guidance understood by rapid testing lead and test clinic staff.
- Team members trained to operate rapid screening clinic (see slide 13 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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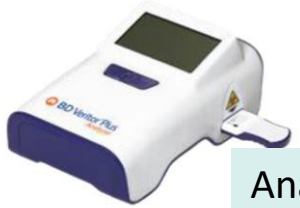
Suggested Additional Materials for BD Veritor™ Screening

- 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

BD Veritor™ COVID-19 Antigen Testing System

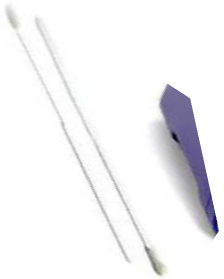
BD Veritor™



Analyzer

Test device

Positive and negative controls



Swabs

Extraction reagent

Type of Test	Antigen Test
Swab Type	Nasal
Specimen collection methods	Combined throat and both nares, Deep nasal or Nasal/both nares
Result TAT	15 mins
Performance (asymptomatic screening)	Sensitivity 50%*, Specificity 99.4%

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*Test sensitivity applies to asymptomatic screening use.

BD Veritor Analyzer

- Analyzers can perform between 3,500 to 10,000 tests
  - Analyzers with firmware version 5.40 can perform 3,500 tests.
  - Analyzers with firmware version 5.50 can perform 10,000 tests.
  - The firmware version is displayed on the analyzer digital display after it is turned on
- A user should be able to perform at least 300 tests on a single full charge.
  - A fully depleted battery will fully recharge in 7 hours or less after the power adapter is plugged in.
  - During use, the analyzer only needs to be plugged in if using Walk Away mode (unlikely use, as this mode can only process one test at a time).

Clinical Guidance

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

Dedicated Space for Antigen Screening

- Room temperature maintained at 15° C to 30° C
- Dedicated space should consist of a closed-off space with sufficient area to place a standard 6–8-foot (folding) table. Ensure that the table is set up such that it is not in direct sunlight.
- Accommodate for privacy to conduct swabbing and for reading and recording results.
- Allow for physical distancing and safety for 2-3 people to operate clinic
- Consider space on-hand for supply of PPE and test kits
- Access to a phone to contact the rapid testing lead regarding any preliminary positive results.

Biosafety Considerations for Antigen Screening

- Conduct a local risk assessment
- Wear appropriate personal protective equipment (PPE) when handling patient specimens and used devices (e.g., gloves, gowns, masks, and face shields)
- Dispose of specimens, kits, and other contaminated materials carefully in an appropriate biohazard container. All extraction tubes should have their caps in place prior to disposal. The biohazard waste container should be a yellow bag or container and labelled with the universal biohazard symbol. Refer to Safe Handling and Management of rapid antigen COVID-19 testing waste
- Maintain a safe work area

Conducting Quality Control Swabs

- Quality 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 kit
  - with any new kit lot number
  - by all newly trained operators before they begin testing individuals
  - for sites performing more than 30 tests/day, perform quality control swabs at the beginning of the day before testing begins
  - for sites performing less than 30 tests/day, perform quality control swabs each time a new kit box is
    opened or at least weekly, whoever is more frequent
- The process for running a control swab is the same as testing specimens.

Track Specimens

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

Testing Process & Staffing

Example staffing model of 2-3 designated staff members:

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

- The suggested process flow in this deck, using batch testing, would accommodate approximately 20 swabs an hour

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

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

Designing Clinic Hours for your Setting

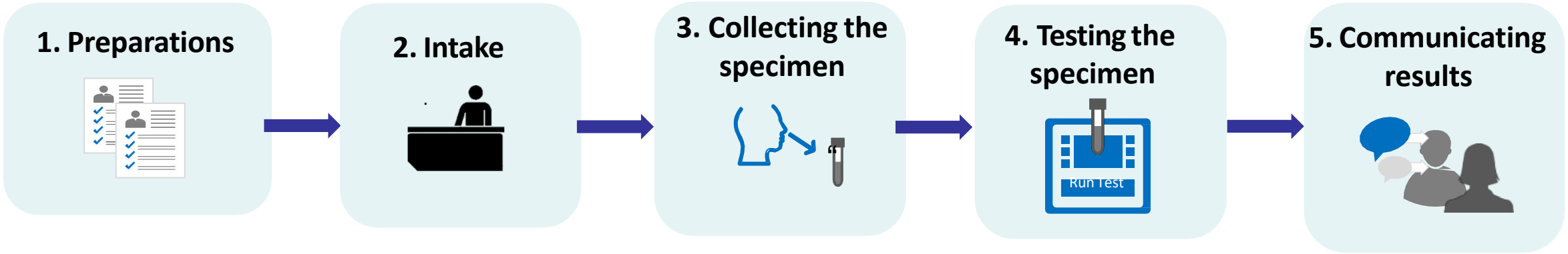
- Depending on the frequency of hours of work at the site, the start and end times of any shifts and the frequency of testing, you may want to choose one of the following approaches:
  - In settings with shift workers, conduct a 12-hour clinic on 3 to 4 days each week. For example, this could be from 6 a.m. to 6 p.m. This schedule would allow for employees who are working any of the three main shifts (i.e., days, evenings, nights) to be tested on-site.
  - For larger workplaces, conduct a 4-hour clinic most days of the week, as staff arrive. The timing of the clinic can vary to capture all shifts.
  - For smaller workplaces, with fewer employees, conduct a clinic 2 days per week, where all participating staff are tested each day the clinic is offered.

Operational Process for using BD Veritor™

- Preparations
- Intake
- Specimen collection
- Testing the specimen
- Reading results
- Communicating results

Operational Procedures

Rapid antigen screening clinic can be broken into 5 stages:



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1. Preparations

1. Confidentiality agreements signed by staff operating the rapid test clinic.
2. BD Veritor™ test kits should be ready for use and contain the following:
   - Extraction tubes, pre-filled with buffer fluid (325µl)
   - Test devices
   - Nasal swab
   - BD Veritor Plus Analyzer (plugged in or charged overnight)
3. Confirm test kits have not expired. Test kits should be at 15-30° C prior to use.
4. Determine how test tubes and cartridges will be labelled with at least two unique identifiers to avoid mix-ups.

2. Intake

1. Inform participant of testing process.
2. Record the participant's 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 of intake and results.
3. Label a BD Veritor™ tube with two unique identifiers for tracking.
4. Direct participant to the rapid test station.

3. Specimen Collection and Processing

1. **Person A** places pre-printed label with two unique identifiers on extraction tube.

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.

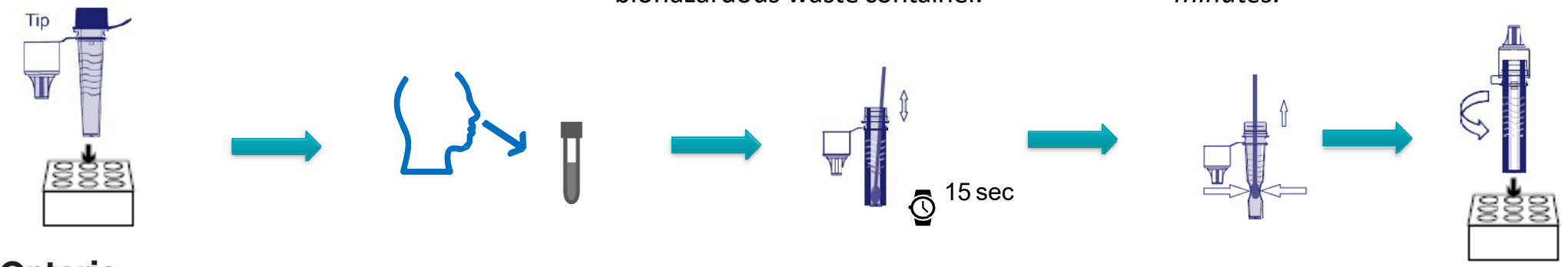
4. **Person B** plunges the swab up and down in the fluid for a minimum of 15 seconds, taking care not to splash contents out of the tube.

5. **Person B** removes the swab while squeezing the sides of the tube to extract the liquid from the swab. The swabs should be safely discarded in biohazardous waste container.

6. **Person B** press the attached tip firmly onto the extraction reagent tube containing the processed sample (threading or twisting is not required). They then mix thoroughly by swirling or flicking the bottom of the tube. The **extraction tube** is placed in a 2nd tube holder.

7. **Person B** changes gloves and performs hand hygiene after each swab.

Once the swab is placed in extraction tube, the sample should be read within 30 minutes.



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4. Testing the Specimen

1. **Person C** opens a **test device** and places a pre-printed label on the device to correspond with the participant's name on **extraction tube** that will be tested.

2. 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, inverts the extraction reagent tube and hold it vertically (approximately one inch above the sample well) and gently squeezes the ridged body of the tube, dispensing **three (3) drops** of the processed specimen **into the sample well**.

4. *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).*

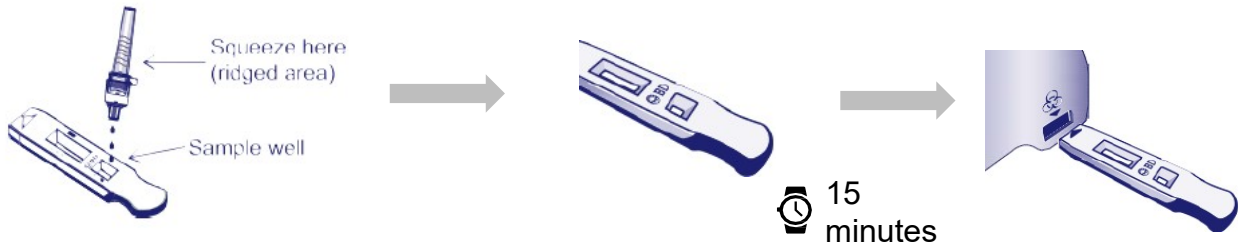
5. Person C started a 15-minute timer.

6. Discard extraction tube with nozzle cap in the biohazard bin

7. During the 15 minutes, Person C powers on the analyzer by pressing the blue button. The **BD Veritor Plus Analyzer will complete a self-test before it is ready for use.**

8. After the self-test the display window shows **INSERT TEST DEVICE OR DOUBLE-CLICK BUTTON FOR WALK AWAY MODE. Insert the test device when the 15-minute assay development time is complete.** *For batch testing, repeat for all specimens.*

9. Record the result before removing the device.



NOTES:

- **Tip -**Testing station table should be cleaned and sectioned off prior to start of clinic and cleaned again at the end of the day.
- **DO NOT** move the test device until the test is complete.
- Clean up any spillage with appropriate disinfectant.
- **Change gloves and perform hand hygiene after handling each extraction tube**

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5. Communicating Results (1/2)

Negative Results

- Many organizations that are conducting frequent rapid antigen screening do not communicate negative results and follow a “no news is good news” approach. Reporting all negative results to staff being tested is best practice.
- Continue to follow public health measures for symptom screening, appropriate distancing, use of PPE and hand-washing

Preliminary Positive Results

- Follow all public health guidance for handling preliminary positive case
- Counsel individual that the positive result is considered preliminary positive and recommend they obtain a second swab for confirmatory lab-based PCR test or undergo a rapid molecular test as soon as possible (ideally within 48 hours). Do not re-test with rapid antigen test.
- Further details for employees on ***What to do*** if you have a positive COVID-19 rapid antigen test, can be found in Ministry of Health – COVID-19 Guidance: Considerations for Antigen Point-of-Care Testing

5. Communicating Results (2/2)

Preliminary positive results roles & responsibilities:

At the Rapid Test Station
• **Person C** communicates the positive result to the **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 participation to individuals other than staff who are part of the testing team.

Rapid Testing Lead
• Participant is informed of preliminary positive result and a confirmatory PCR test or rapid molecular test is completed (ideally within 48 hours). • Participant is asked to self-isolate until contacted by Public Health and provided further instructions.

Documenting and reporting

- Health professionals, or other trained individuals, are responsible for satisfying all applicable legislative and regulatory requirements, including those under the *Health Protection and Promotion Act* (HPPA), *Personal Health Information Protection Act* (PHIPA), *Health Care Consent Act* (HCCA), and the *Regulated Health Professions Act* (RHPA).
- Health professionals, or other trained individuals, must ensure proper documentation is in place when performing COVID-19 rapid antigen testing.
- Treat all heath information as confidential following the Personal Health Information Protection Act.

Available Resources and Additional Support

Resources

- BD Veritor – Helpful documents and video demonstrations: https://bdveritor.bd.com/en-us/rapid-antigen-testing/covid-19
- Safe Handling and Management of rapid antigen COVID-19 testing waste

Training Resources Available from Ontario Health

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

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Questions

Please e-mail covid19testing@ontariohealth.ca with any questions

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Appendix

Test kit expiry (1/2)

Some lots of BD Veritor™ test kits now have an extended shelf-life (expiration date) of up to 12 months. For these lots, the product Unique Device Identifier (UDI) barcode on the kit box will display the original expiry date until you receive kits with the updated labeling. Please see below for the list of lot numbers with the extended shelf-life.

Lot	Original Expiry	New Expiry	Lot	Original Expiry	New Expiry
0340740	5/20/2021	11/20/2021	1029376	7/6/2021	01/06/2022
0343900	5/20/2021	11/20/2021	1032077	7/6/2021	01/06/2022
0346215	5/22/2021	11/22/2021	1035279	7/6/2021	01/06/2022
0349155	5/26/2021	11/26/2021	1027050	7/7/2021	01/07/2022
0357565	5/31/2021	11/31/2021	1033798	7/7/2021	01/07/2022
0358634	6/2/2021	12/02/2021	1035122	7/7/2021	01/07/2022
0356935	6/4/2021	12/04/2021	1028825	7/9/2021	01/09/2022
0364277	6/7/2021	12/07/2021	1031666	7/9/2021	01/09/2022
0365333	6/9/2021	12/09/2021	1036924	7/10/2021	01/10/2022
0361837	6/10/2021	12/10/2021	1046484	7/10/2021	01/10/2022
1002327	6/11/2021	12/11/2021	1038934	7/12/2021	01/12/2022

Test kit expiry (2/2)

Lot	Original Expiry	New Expiry	Lot	Original Expiry	New Expiry
1003502	6/14/2021	12/14/2021	1038689	7/13/2021	01/13/2022
1007570	6/16/2021	12/16/2021	1041056	7/15/2021	01/15/2022
1013906	6/22/2021	12/22/2021	1042874	7/15/2021	01/15/2022
1017995	6/22/2021	12/22/2021	1040092	7/16/2021	01/16/2022
1014710	6/24/2021	12/24/2021	1045248	7/16/2021	01/16/2022
1022146	6/24/2021	12/24/2021	1044778	7/19/2021	01/19/2022
1016642	6/25/2021	12/25/2021	1047008	7/19/2021	01/19/2022
1020841	6/25/2021	12/25/2021	1050036	7/19/2021	01/19/2022
1019883	6/29/2021	12/29/2021	1050033	7/19/2021	01/19/2022
1018218	6/30/2021	12/30/2021	1047060	7/20/2021	01/20/2022
1026113	6/30/2021	12/30/2021	1050617	7/20/2021	01/20/2022
1021217	7/1/2021	01/02/2022	1047054	7/21/2021	01/21/2022
1022997	7/2/2021	01/02/2022	1047064	7/21/2021	01/21/2022
1024065	7/4/2021	01/04/2022	1050591	7/21/2021	01/21/2022