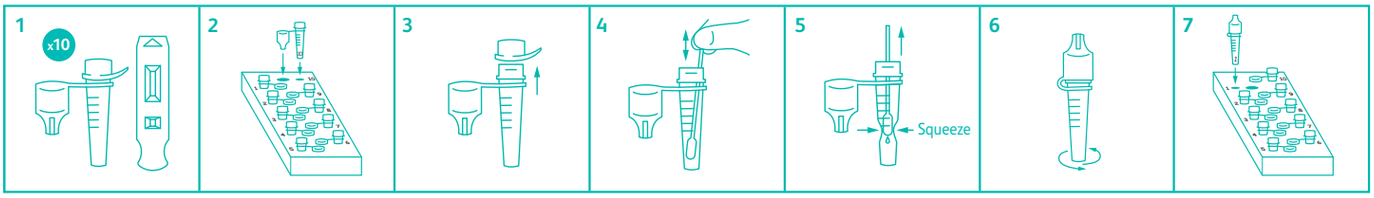
Analyze Now mode provides a batch testing option

BD Veritor™ System for Rapid Detection of SARS-CoV-2*

Review the complete instructions for use for information and procedural steps; including recommended quality control procedures before performing the sample collection and analysis. Ensure all components are at room temperature (15–30 °C) when performing the test.

Example below demonstrates processing of 10 samples in 25 minutes. Using this workflow, up to 24 tests may be run in an hour (beginning after specimen collection, including steps 3-14).**

Batch sample collection (10 tests)



1
- **Gather 10 sets of test materials.**
- Label each set with patient ID.

2
- Label the tube tray with patient ID.
- **Set each tube in the tray** with matching patient ID.

3
- Select extraction reagent tube and **remove cap**.

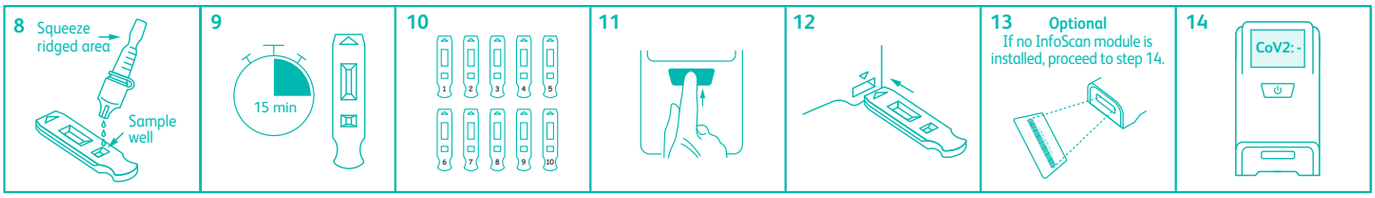
4
- **Insert patient sample swab** and vigorously plunge the swab up and down for 15 seconds taking care not to splash contents out of the tube.

5
- **Remove swab** while squeezing to extract liquid.
- Properly dispose of swab.

6
- Press dispensing tip on the tube firmly.
- **Mix the sample** by swirling the bottom of the tube.

7
- **Place tube back in tray** with matching patient ID.
- Repeat steps 3-7 until all remaining tubes have been prepared.
- Specimen processed in the reagent vial must be **run within 30 minutes** on the test device.

Batch preparation and analysis (10 tests)



8
- Select the extracted sample and the matching test device for each specimen.
- **Add 3 drops of the processed sample** to the test device sample well.

9
- Activate a 15 minute timer.
- **Each test device must incubate for 15 minutes***** before it can be analyzed.

10
- Repeat steps 8-9 until **all remaining test devices have been prepared and are incubating,** each with their timers running.

11
- When first test is ready, **power on the Analyzer** by pressing the blue start button once.
- Analyzer may remain on until all testing is completed.

12
- When prompted, **insert the test device to read.**

13
- If using the **BD Veritor™ InfoScan module,** follow the screen prompts to scan operator ID, specimen ID and kit lot number to start the test analysis.
- After required scans are completed, the Analyzer displays a countdown timer and test analysis begins.

14
- **Result will appear on screen,** and will be stored in the Analyzer.
- Test results are NOT maintained in the display window when the device is removed or if the Analyzer is left unattended for more than 15 minutes (60 minutes if AC power adapter is connected).
- Record result.
- Remove test device and properly dispose.
- Continue with the next test device once it has incubated for 15 minutes.

Interpretation of results

Display	Interpretation
CoV2: +	Positive Test for SARS-CoV-2 (antigen present)
CoV2: –	Presumptive Negative Test for SARS-CoV-2 (no antigen)
CONTROL INVALID	Test Invalid. Repeat the test.

*For use under Interim Order Authorization only

**BD Veritor for Rapid Detection of SARS-CoV-2 Batching workflow study, September 2020

Mesich B., Faron M., Gerstbrein D., Mashock M., Buchan B., and Ledeboer N. Time of Motion Analysis for Three Point of Care Flu Assays Comparing Single and Batch Test Methods. Poster presented at American Society for Microbiology Microbe annual meeting; June 20-24, 2019; San Francisco, CA.

***CAUTION: Incorrect results may occur if development time is less than 15 minutes. Cover test device if working in a drafty environment.

BD

Interpretation of results

Test results must **NOT** be read visually. The BD Veritor™ Plus Analyzer (purchased separately) must be used for interpretation of all test results. Refer to the reverse side of this card.

Positive Test Results: SARS-CoV-2 antigen present; does not rule out coinfection with other pathogens.

Negative Test Results: Negative results are presumptive. Negative test results do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions, including infection control decisions, particularly in the presence of clinical signs and symptoms consistent with COVID-19, or in those who have been in contact with the virus. It is recommended that these results be confirmed by a molecular testing method, if necessary for patient management.

Invalid Test: If the test is invalid the BD Veritor™ Plus Analyzer will display a "CONTROL INVALID" result and the test or control must then be repeated.

Warnings and precautions

1. For *in vitro* Diagnostic use only.
2. All test results must be obtained using the BD Veritor™ Plus Analyzer.
3. **DO NOT** read the test results visually.
4. Handle all specimens and related materials as if capable of transmitting infectious agents.
5. Dispose of used materials as biohazardous waste in accordance with federal, provincial and local requirements.
6. Ensure all components are at room temperature (15–30 °C) when running the test.
7. Please refer to the package insert for detailed assay instructions cautions, limitations and warnings.

Specimen collection and handling

Proper specimen collection and handling is required to ensure accurate results. Additional training or guidance is recommended if operators are not experienced with specimen collection and handling procedures.

External quality control procedure

Swab controls are supplied with each kit. These swab controls should be used to ensure that the test reagents work properly and that the test procedure is performed correctly. For kit swab controls, insert the control swab into the extraction reagent tube and vigorously plunge the swab up and down for 15 seconds. Process according to the test procedures on the reverse side of this card using the same workflow as used for patient samples. BD recommends running controls for each new kit lot, each new operator, and each new shipment of test kits or at periodic intervals required by your facility. If the kit controls do not perform as expected, do not report patient results and contact BD Technical Support at 1.800.638.8663.

Technical Information:
Contact BD Technical Service and Support at
1.800.638.8663 or bd.com

- This test has been authorized for sale in Canada by Health Canada under Interim Order
- This test is only authorized for the duration of the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19, unless the authorization is terminated or revoked sooner;
- This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.

BD, 2100 Derry Road West,
Suite 100, Mississauga, ON,
L5N 0B3
866.979.9408

Visit bd.com/en-ca