

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

- 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.



Objectives

1. Understand how to set up and use the BD Veritor™ Plus Analyzer
2. Understand the general workflow process for the BD Veritor™ System for Rapid Detection of SARS-CoV-2

BD Veritor™ Plus Analyzer Technology



- Handheld optoelectronic instrument
- One-touch button operation
- Clear liquid crystal display (LCD)
- One analyzer for multiple assays
- Maintenance-free
- Two Operation Modes: Analyze Now & Walk Away

Interpretation of the test results has only been validated using the BD Veritor™ Plus Analyzer.

BD Veritor™ Plus Analyzer Specifications

Ambient Temperatures (15-30 ° C)
Ambient Light (0-3000 lux uniform illumination)

Ambient Humidity (up to 85% RH)
Indoor Use only

Firmware version 5.40

Maximum lifetime of 3,500 tests or 24 months from first use, whichever comes first

Firmware version 5.50

Maximum lifetime of 10 000 tests or 24 months from first use, whichever comes first

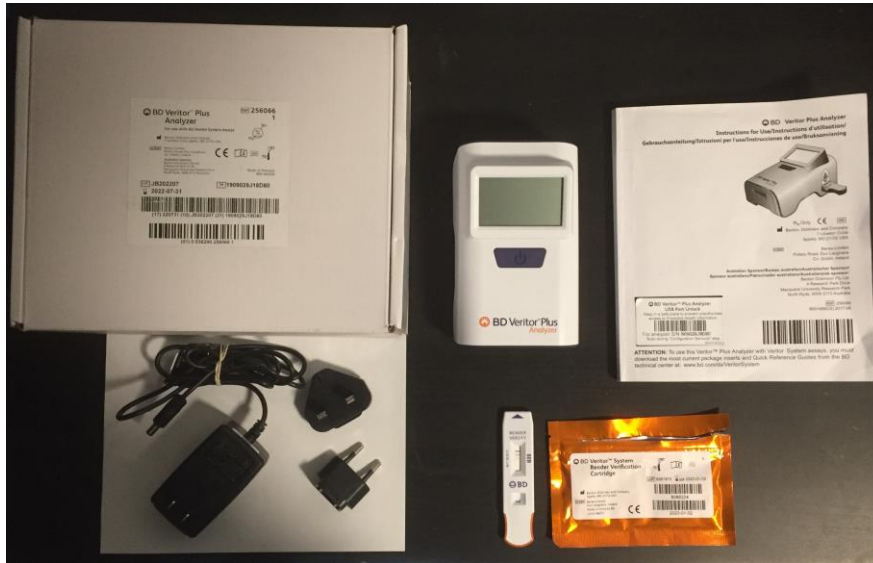
Both firmware versions have a maximum shelf life of 34 months from the manufacturing date



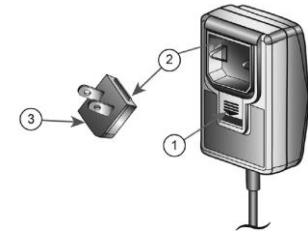
Analyzers with firmware v5.40 cannot be upgraded to v5.50

Analyzer will display a warning message when it gets to the last 300 tests or the last 60 days (whichever comes first)

BD Veritor™ Plus Analyzer – Box Contents



- 1 BD Veritor™ Plus Analyzer
- 1 User Manual (IFU)
- 1 USB Port Unlock Barcode label
- 1 power adapter with 3 blade adapters
- 1 orange Verification Cartridge



1. Assemble the power adapter using correct blade adaptor.
2. Affix the USB Port Unlock Barcode label on the cover of the User Manual.

BD Veritor™ Plus Analyzer – Verifications

1. Verify the battery strength symbol and charge the analyzer as needed.
2. Verify the analyzer self-test pass.

Only use the analyzer if the **SELF-TEST PASS**

3. Before the first use of the analyzer, perform a Verification Test.

- Insert the orange Verification Cartridge when the display shows:

INSERT TEST DEVICE OR DOUBLE-CLICK BUTTON FOR WALK AWAY MODE

Only use the analyzer if the Verification test indicates **VERIFY PASS**.

- Store the Verification Cartridge in its orange protective pouch.



BD Veritor™ Plus Analyzer – Set-Up & Use



BD Veritor™ Plus Analyzer - Set-Up & Use

Key Takeaways



- The Verification Test can only be run in the Analyze Now mode.
- The analyzer will automatically turn off after **15 minutes** when operating on battery or **60 minutes** when operating on power adapter.
- Remove any inserted test device from the analyzer before powering the instrument.



- Don't use the analyzer if the self-verify or Verification Test fail.
- Don't confuse the Verification Cartridge with a test device.
- Don't power the analyzer through its USB micro port.
- Don't press or hold the power button while inserting a test device.

BD Veritor™ Plus Analyzer Cleaning and Disposal

- **Cleaning**
 - Outer case and display may be wiped with a clean towel, lightly moistened with 70% isopropyl alcohol (IPA) or 10% bleach solution.
- **Disposal**
 - Expired BD Veritor™ Plus Analyzers should be disposed of as biohazardous waste and according to local environmental electronic waste disposal regulation.
 - Analyzer contains a lithium ion battery

BD Veritor™ Plus Analyzer

Error codes

Result Number	Message	Possible Cause(s)	Corrective Action(s)
02	POSITIVE CONTROL LINE INVALID CONSULT MANUAL	The positive assay control line is outside the normal range.	On first occurrence, repeat the assay. On subsequent occurrences, contact BD.
03	TEST WAS REMOVED REINSERT TEST DEVICE	The test device was removed while the run was in progress.	That run is invalidated. The device may be re-inserted to begin a new run.
05	BACKGROUND INVALID CONSULT MANUAL ERROR 05	The assay background area is outside of the normal range.	Remove the device and cycle the instrument power. <ul style="list-style-type: none"> • If the instrument displays an error during power-on, contact BD. • If no error message appears, obtain an additional sample and repeat the assay. If the issue recurs, contact BD.
06	ANALYZER FAILURE CALL BD ERROR 06	A hardware anomaly has occurred.	Contact BD.

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

Kit Contents

- 30 individually wrapped Test Devices
- 30 pre-filled reagent tubes
- 30 individually wrapped sterile nasal swabs
- 1 Positive and 1 negative control swabs
- Instructions for use
- Quick reference instructions
- Nasal sample quick reference instructions

What is not included in the kit, but needed to perform the test:

- BD Veritor™ Plus System Analyzer (Cat. No 256066)
- Timer(s) (workflow dependent)
- Appropriate PPE



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

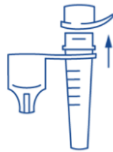
Workflow Overview

Detection of SARS-CoV-2 antigens in samples processed from nasal swabs

Assay time of 15 minutes, with 1 minute of hands on-time*



STEP 1
Collect patient sample
(mid-nasal)



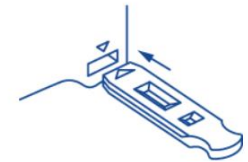
STEP 2
Remove cap & insert
swab into tube



STEP 3
Mix sample for 15 sec
with reagent, then
remove swab



STEP 4
Close dispensing cap,
then dispense sample
into test device



STEP 5
Insert test device into the
analyzer
For Walk Away mode, insert
immediately
For Analyze Now mode, insert
after timing the assay
development

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

Sample Collection – Nasal swab

Key Takeaways

- Collect samples using the swabs provided with the kits.
- Collect samples from both nostrils.
- Process freshly collected specimens within 1 hour after collection.
- BD has not validated any storage or transport method for the collected samples.

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

Sample Processing



Quick Reference Instructions for BD Veritor™ SARS-CoV-2

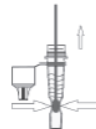
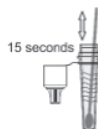
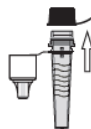
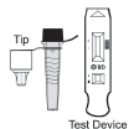
REF 256089

Use of BD Veritor™ System for Rapid Detection of SARS-CoV-2 with the BD Veritor™ Plus Analyzer

Read the complete test procedure, including recommended QC procedures before performing the test. Refer to the package insert for complete information about the test. Ensure ALL components are at room temperature (15–30 °C) when running the test.

Sample preparation

- 1 Gather test materials and label test device with specimen ID.
- 2 Remove cap from extraction reagent tube.
- 3 Insert patient sample swab and vigorously plunge the swab up and down for 15 seconds.
- 4 Remove swab while squeezing tube to extract liquid. Properly dispose of swab.
- 5 Press dispensing tip on the tube firmly. Mix the sample by flicking or swirling the bottom of the tube.



Using the BD Veritor Plus Analyzer to read the assay device

ANALYZE NOW MODE		OR	WALK AWAY MODE (instrument must be plugged in)	
6	Add 3 drops of the processed sample to the test device sample well.		Press blue start button once to power on. When prompt appears, double click to enter Walk-Away mode. Three minute countdown timer displays time remaining for test device insertion.	
7	Allow test to develop for 15 minutes. CAUTION: incorrect results may occur if development time is less than 15 minutes. Cover test device if working in a drafty environment.		Optional: If using the barcode scanning accessory, follow screen prompts to scan any required barcodes.	
8	When test is ready, power on instrument by pressing blue start button once. When prompted, insert test device to read.		Add 3 drops of the processed sample to the test device sample well.	
	Optional: If using the barcode scanning accessory, follow screen prompts to scan any required barcodes to start the test analysis.		Confirm timer is visible and Walk Away mode is activated before inserting device. Insert device to start assay timing and analysis. Do not touch instrument during analysis. Keep level.	
9	Result will appear on screen. Record result and remove test device. Properly dispose of test device.		Result will appear on the screen after analysis is complete (15 minutes). Record result, remove test device and discard properly. Instrument returns to Analyze Now mode when	



BD Veritor™ System for Rapid Detection of SARS-CoV2 Sample Processing – Analyze Now Mode



BD Veritor™ System for Rapid Detection of
SARS-CoV-2 – Sample processing and analysis -
Analyze Now mode

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

Sample Processing – Analyze Now Mode

Key Takeaways



- Reagents and test devices must be at room temperature (15-30° C) before use.
 - Extracted samples must be added to the test device within **30 minutes**.
 - Add 3 free-falling drops to the test device by gently squeezing the ridged body of the tube.
 - Incubate test device for **15 minutes**.
 - Cover test device to avoid inconsistent flow when incubating in areas with high air flow.
 - Record the result before removing the test device or within **15 minutes** (battery) or **60 minutes** (power adapter).
-



- It is not recommended to read the test device multiple times in the analyzer.
- It is not recommended to interpret the results visually.

BD Veritor™ System for Rapid Detection of SARS-CoV-2 Sample Processing – Walk Away Mode

Key Takeaways

DO

- Connect the analyzer to a power source when using the Walk Away mode.
- Enter the Walk Away mode before dispensing the 3 drops to the test device.
- Keep the test device horizontal when inserting in the analyzer.
- Record the result before removing the test device from the analyzer.
- Dispose of all BD Veritor™ kit components as biohazardous waste according to local requirements.

DON'T

- Don't press the power button more than twice when entering the Walk Away mode.
- Don't disturb the analyzer or remove the test device during the 15 minutes incubation time.

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

Batch Testing Option – Analyze Now Mode

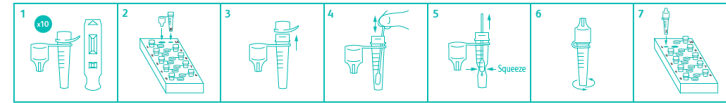
Key Takeaways

- Allows for maximization of the number of samples that can be processed (analyze up to 24 tests in 1 hour).
- Dedicated operator is recommended for batching
- Requires a minimum of two timers to monitor the 15 minutes incubation time and the stagger time in between inoculating test devices (30 secs suggested).
- Quick Reference Guide and training video available for further information.

<https://youtu.be/wJJRPS7pu44>

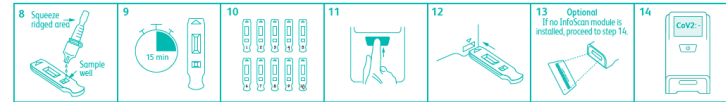
Example below demonstrates processing of 10 samples in 25 minutes. Using this workflow, up to 24 tests may be run in an hour (beginning after specimen collection, including steps 3-14).*

Batch sample collection (10 tests)



- Gather 10 sets of test materials.
• Label each set with patient ID.
- Label the tube tray with patient ID.
• Set each tube in the tray with matching patient ID.
- Select extraction reagent tube and remove cap.
- 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.
- Remove swab while squeezing tip to extract liquid.
• Properly dispose of swab.
- Press dispensing tip on the tube firmly.
• Mix the sample by swirling the bottom of the tube.
- 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)

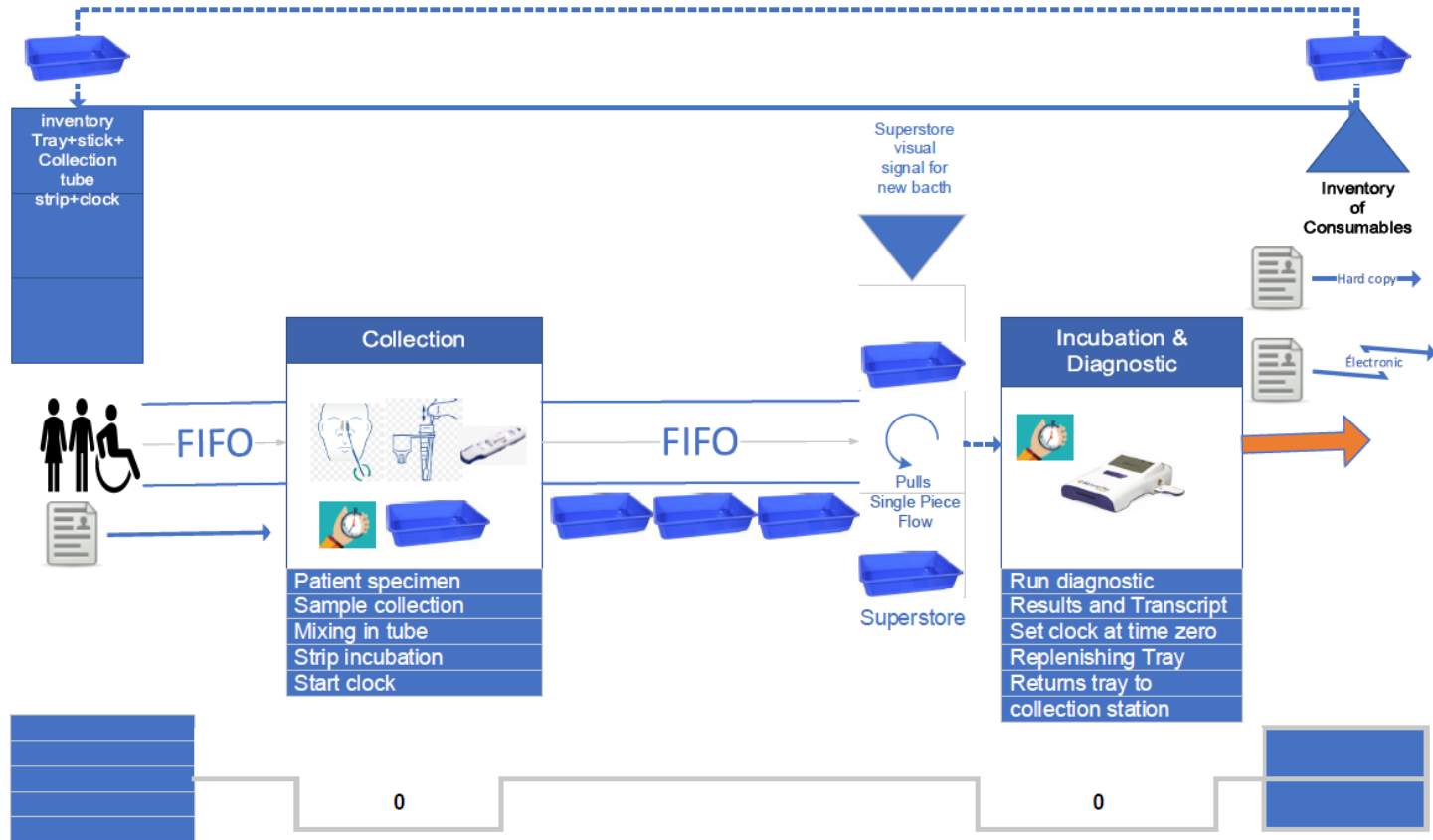


- Select the extracted sample and the matching test device for each specimen.
• Add 3 drops of the processed sample to the test device sample well.
- Activate a 15 minute timer.
• Each test device must incubate for 15 minutes*** before it can be analyzed.
- Repeat steps 8-9 until all remaining test devices have been prepared and are incubating, each with their timers running.
- 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.
- When prompted, insert the test device to read.
- 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.
- 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.







BD Technical Support:
1(800) 638-8663

Thank you!