Training session

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.
Training Objectives

1. Learn how to set up and use the BD Veritor™ Plus Analyzer

2. Understand the proper sample collection techniques

3. Familiarize with the general workflow procedures 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 BD Veritor™ test results have been validated using the BD Veritor™ Plus Analyzer instrument only.
**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

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BD Veritor™ Plus Analyzer – Set-Up & Use
BD Veritor™ Plus Analyzer – Box Contents

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

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

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BD Veritor™ Plus Analyzer – Verifications

• Press the blue power button once to turn on the analyzer.
• 1. Verify the battery strength symbol and charge the analyzer as needed.
• 2. The analyzer will display the BD logo and perform a self-test.

![Image of BD logo]

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:

![Image of Verification Cartridge insertion]

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

The verification test result will display

**VERIFY PASS** or **VERIFY FAIL**

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

• Do not use the analyzer if an error message is shown on the display.
• Store the Verification Cartridge in its orange protective pouch.
BD Veritor™ Plus Analyzer - Set-Up & Use

Key Takeaways

- Insert the Verification Cartridge only when the display shows: INSERT TEST DEVICE OR DOUBLE-CLICK FOR WALK AWAY MODE

- The Verification Test can only be run in the Analyze Now mode.

- Record results before removing the test device or within 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
  o Outer case and display may be wiped with a clean towel, lightly moistened with 70% isopropyl alcohol (IPA) or 10% bleach solution.

• Disposal
  o Expired BD Veritor™ Plus Analyzers should be disposed of as biohazardous waste and according to local environmental electronic waste disposal regulation.
  o Analyzer contains a lithium ion battery
### 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
Sample Collection – Nasal swab
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.
- Squeeze sides of tube when removing the swab from the extraction reagent tube to extract excess liquid.
- Process freshly collected specimens as soon as possible.

**DO**

- Don’t insert collected swabs back into their peel-pouch.
- Don’t process samples more than 1 hour after collection.
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

* Source: www.bd.com/bd-Veritor-plus-system-for-rapid-covid-19-sars-cov-2-testing

Simple Use Section  20/08/2020
BD Veritor™ System for Rapid Detection of SARS-CoV-2
Sample Processing

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

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 entrap 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

<table>
<thead>
<tr>
<th>ANALYZE NOW MODE</th>
<th>OR</th>
<th>WALK AWAY MODE (instrument must be plugged in)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. Add 3 drops of the processed sample to the test device sample well.</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>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 dusty environment.</td>
<td>Optional: If using the barcode scanning accessory, follow screen prompts to scan any required barcodes.</td>
<td></td>
</tr>
<tr>
<td>8. When test is ready, power on instrument by pressing blue start button once. When prompted, insert test device to read.</td>
<td>Add 3 drops of the processed sample to the test device sample well.</td>
<td>Confirm tester 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.</td>
</tr>
<tr>
<td>Optional: If using the barcode scanning accessory, follow screen prompts to scan any required barcodes to start the test analysis.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Result will appear on screen. Record result and remove test device.</td>
<td>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</td>
<td></td>
</tr>
</tbody>
</table>
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 – Analyze Now Mode

**Key Takeaways**

- Label extraction reagent tubes and test devices properly.
- 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); **60 minutes** (power adapter).
- Use the Analyze Now mode to run the Verification Cartridge.

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- Don’t process nasal swabs more than **1 hour** after collection.
- Don’t read the test device multiple times in the analyzer.
- Don’t determine the results by visually inspecting the test device.
BD Veritor™ System for Rapid Detection of SARS-CoV2
Sample Processing – Walk Away Mode
**BD Veritor™ System for Rapid Detection of SARS-CoV-2**

**Sample Processing – Walk Away Mode**

**Key Takeaways**

- 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.

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- Don’t press the power button more than twice when entering the Walk Away mode.
- Don’t squeeze the reagent tube too close to the tip when dispensing the 3 drops to the test device.
- Don’t disturb the analyzer or remove the test device during the 15 minutes incubation time.
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).

https://youtu.be/wJJRPS7pu44
BD Technical Support: 1(800) 638-8663

Thank you!