



Competency Check List: BD Veritor™ Plus System

Assay: BD Veritor™ System for Rapid Detection of SARS-CoV-2* (SKU 256089)

***Information about 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.

Instructions: Mark each task as ‘Met’ or ‘Unmet’ based on the Provider’s performance of the task and provide comments as necessary. After following general steps, follow Section A for “Analyze Now” mode, or Section B for “Walk Away Mode”. Refer to the IFU for the BD Veritor™ System for Rapid Detection of SARS-CoV-2 for comprehensive information about the test and procedure

Key Tasks	✓ Met	✓ Unmet	Notes
Check the expiration date.			
For each patient specimen, remove one extraction reagent tube/tip and one BD Veritor™ System for Rapid Detection of SARS-CoV-2 test device from its foil pouch immediately before testing. Label with patient’s name. Place the labeled extraction reagent tube(s) in the designated area of the tube rack.			
Insert the swab into one nostril of the patient. The swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril.			
Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected.			
Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.			

Please consult the Package Insert, BD Technical Support, or local sales representative with questions. Technical support can be reached at 1.800.638.8663 or technical.services@bd.com



Key Tasks	✓ Met	✓ Unmet	Notes
Withdraw the swab from the nasal cavity. The specimen is now ready for processing.			
Remove and discard the cap from the extraction reagent tube corresponding to the specimen to be tested.			
Insert the swab into the tube and plunge the swab up and down in the fluid for a minimum of 15 seconds, taking care not to splash contents out of the tube			
Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. Properly discard the swab in a biohazard bin.			
<p>Press the attached dispensing tip firmly onto the extraction reagent tube containing the processed specimen (threading/twisting not required). Mix thoroughly by swirling or flicking the bottom of the tube.</p> <p>NOTE: Do not use tips from any other product, including other products from BD or other manufacturers.</p>			
<p>To utilize the BD Veritor™ Plus Analyzer in “Analyze Now” mode, continue to section A. This mode allows for batch testing of multiple samples.</p> <p>To utilize the BD Veritor™ Plus Analyzer in “Walk Away” mode, continue to section B.</p>			



Section A: Analyze Now mode			
<p>Invert the extraction reagent tube and hold the tube vertically (approximately one inch above the BD Veritor™ System for Rapid Detection of SARS-CoV-2 test device sample well). Holding the tube at the ridged area, squeeze gently allowing three (3) drops of the processed specimen to be dispensed into the sample well of the appropriately labeled BD Veritor™ System for Rapid Detection of SARS-CoV-2 test device.</p> <p>NOTE: Squeezing the tube too close to the tip may cause leakage.</p> <p>NOTE: If utilizing batch testing via “Analyze Now” mode, wait at least 30 seconds before adding processed specimen into the sample well of the next test device.</p>			
<p>After adding the specimen, allow the test to run for 15 minutes before inserting into the BD Veritor™ Plus Analyzer. Devices used in a laminar flow hood or in areas with high air flow should be covered during test development.</p>			
<p>During incubation time, turn the BD Veritor™ Plus Analyzer on by pressing the blue power button once. The BD Veritor™ Plus Analyzer will complete a self-test before it is ready for use. After the self-test the display window shows “INSERT TEST DEVICE OR DOUBLE-CLICK BUTTON FOR WALK AWAY MODE”.</p>			
<p>Insert the BD Veritor™ System for Rapid Detection of SARS-CoV-2 test device when the 15-minute assay development time is complete.</p>			
<p>When analysis is complete, the test result appears in the display window.</p> <p>NOTE: Test results are NOT to be read from the test cartridge. Test results should be recorded as they appear on the Analyzer display screen.</p>			

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<p>Invalid Test – If the test is invalid, the BD Veritor™ Plus Analyzer will display a “RESULT INVALID” or “CONTROL INVALID” result and the test or control must then be repeated.</p>			
<p>Interpretation of Results: Operators should not attempt to interpret assay results directly from the assay test device.</p>			

Section B: Walk away mode			
<p>Turn on the BD Veritor™ Plus Analyzer by pressing the blue power button once. The BD Veritor™ Plus Analyzer will complete a self-test before it is ready for use. When the display window reads “INSERT TEST DEVICE OR DOUBLE-CLICK FOR WALK AWAY MODE”, double-click the blue power button.</p> <p>The display window reads “ADD SPECIMEN TO TEST DEVICE AND INSERT IMMEDIATELY:</p>			
<p>Invert the extraction reagent tube and hold the tube vertically (approximately one inch above the BD Veritor™ System for Rapid Detection of SARS-CoV-2 test device sample well). Holding the tube at the ridged area, squeeze gently allowing three (3) drops of the processed specimen to be dispensed into the sample well of the appropriately labeled BD Veritor™ System for Rapid Detection of SARS-CoV-2 test device.</p> <p>NOTE: Squeezing the tube too close to the tip may cause leakage.</p>			



Insert the test device into the slot of the right side of the BD Veritor™ Plus Analyzer. “DO NOT DISTURB TEST IN PROGRESS” appears in the display window. Automatic timing of the assay development, image processing and result analysis begins. The display window shows the remaining analysis time.			
When analysis is complete, the test result appears in the display window. Record the result and discard the test device appropriately.			

Health Care Provider:

Manager:
