REF 256082

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

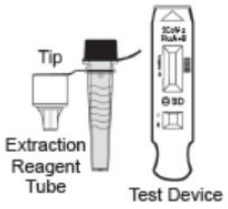
Use of BD Veritor™ System for Rapid Detection of SARS-CoV-2 with the BD Veritor™ Plus Analyzer

In the USA: For use under Emergency Use Authorization (EUA) Only

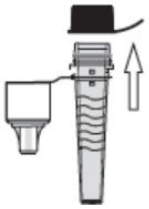
Read the complete test procedure, including recommended QC procedures before performing the test. Refer to the package insert for complete information about the test. Ensure ALL components are at room temperature (15–30 °C) when running the test. For use with direct anterior nasal swab samples.

Sample preparation

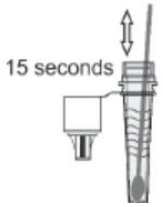
1 Gather test materials and label test device with specimen ID.



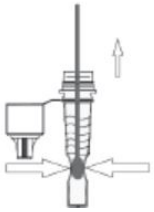
2 Remove cap from extraction reagent tube. Use only reagent tubes provided with this kit.



3 Insert patient sample swab and vigorously plunge the swab up and down for 15 seconds



4 Remove swab while squeezing extraction reagent tube to extract liquid. Properly dispose of swab.

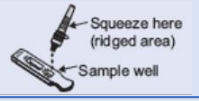


5 Press dispensing tip on the extraction reagent tube firmly. Mix the sample by flicking or swirling the bottom of the tube. Add sample to test device within 30 minutes.

Using the BD Veritor Plus Analyzer to read the assay device

ANALYZE NOW MODE

6 Add **3 drops** of the processed sample from the extraction reagent tube to the test device sample well.



7 Allow test to develop for **15 minutes**.
Do not disturb. Keep level.
CAUTION: False positive or false negative results can occur if test device is read before 15 minutes or after 20 minutes. Cover test device if working in a drafty environment to ensure proper sample flow.

8 When test is ready, power on instrument by pressing blue start button once. When prompted, insert test device to read.

Optional: If using the barcode scanning accessory, follow screen prompts to scan any required barcodes to start the test analysis.

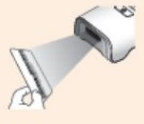
9 Result will appear on screen. Record result and remove test device. Properly dispose of test device. Do not re-read test devices.

OR

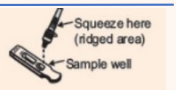
WALK AWAY MODE (instrument must be plugged in)

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.

Optional: If using the barcode scanning accessory, follow screen prompts to scan any required barcodes.



Add **3 drops** of the processed sample from the extraction reagent tube to the test device sample well.



Confirm timer is visible and Walk Away mode is activated before inserting device. Insert device immediately to start assay timing and analysis. Delay invalidates assay result and requires a repeated test with a new test device.

Do not touch instrument during analysis. Keep level.
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 test device is removed.

If used on asymptomatic individuals for serial testing, a second test should be performed with at least 24 hours (and no more than 48 hours) between tests.

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

In the USA: For use under Emergency Use Authorization (EUA) Only

IVD Rx Only 2 °C 30 °C

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

INTERPRETATION OF RESULTS

Test results must **NOT** be read visually. The BD Veritor Plus System Analyzer (purchased separately) must be used for interpretation of all test results. Refer to table above.

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. An initial negative test result in an asymptomatic individual should be the first of a minimum of two tests (serial testing) with at least 24 hours (and no more than 48 hours) between tests. An asymptomatic individual undergoing serial testing with a positive result indicates that SARS-CoV-2 antigen is present but does not rule out coinfection with other pathogens. Additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of SARS-CoV-2 infection, such in an individual with a close contract or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.

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

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 beginning at step 4. 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.

SPECIMEN COLLECTION AND HANDLING

Proper specimen collection and handling of direct anterior nasal swabs is required to ensure accurate results (see enclosed specimen collection guide). Additional training or guidance is recommended if operators are not experienced with specimen collection and handling procedures.

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. It is recommended to follow your institutions requirements for decontamination procedures or if spills occur. See the BD Veritor Analyzer Instructions for Use for instrument cleaning.
6. Dispose of used materials as biohazardous waste in accordance with federal, state and local requirements.
7. **Ensure all components are at room temperature (15–30 °C) when running the test.**
8. Keep devices and instrument level and undisturbed for duration of the 15-minute incubation. Cover test device if working in a drafty environment to prevent sample evaporation and incomplete sample flow which may produce an erroneous false positive result or control invalid result.
9. Please refer to the package insert for detailed assay instructions, cautions, limitations and warnings.

- In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an EUA for use by authorized laboratories:
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and,
- This product is only authorized for the duration of the declaration that circumst exist justifying the authorization of emergency use of *in vitro* diagnostics for de and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, D Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminate authorization is revoked sooner.

Technical Information: In the United States contact BD Technical Service and Support at 1.800.638.8663 or bd.com

Becton, Dickinson and Company
7 Loveton Circle
Sparks, Maryland 21152 USA

bd.com/e-labeling
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2021-03

IVD Rx Only 2 °C 30 °C

REF 256082
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2021-03

BD

Veritor™ System

For Rapid Detection of SARS-CoV-2

Kit configured for testing anterior nasal swab samples, processed, and dispensed directly onto the assay test device.

For use under an Emergency Use Authorization only, in the United States.

30
Determinations

bd.com/e-labeling

Becton, Dickinson and Company
7 Loveton Circle
Sparks, Maryland 21152 USA

BD Veritor™ System

For Rapid Detection of SARS-CoV-2

Kit configured for testing anterior nasal swab samples, processed, and dispensed directly onto the assay test device.

For *In Vitro* Diagnostic Use.
For use with the BD Veritor™ Plus Analyzer running firmware version 5.4 or later.
In the USA: For use under an Emergency Use Authorization only.

Please read these instructions completely before beginning to test specimens.

INTENDED USE

The BD Veritor™ System for Rapid Detection of SARS-CoV-2 is a chromatographic digital immunoassay intended for the direct and qualitative detection of SARS-CoV-2 nucleocapsid antigens in direct anterior nasal swabs from individuals who are either suspected of COVID-19 by their healthcare provider, within the first 5 days of the onset of symptoms, or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests. In the United States, testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high, or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the identification of SARS-CoV-2 nucleocapsid antigen. This antigen is generally detectable in upper respiratory samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results should be treated as presumptive, do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary, for patient management. For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.

The BD Veritor™ System for Rapid Detection of SARS-CoV-2 is intended for use in point of care settings and operated by healthcare professionals or trained users specifically instructed in the use of the BD Veritor™ System and proper infection control procedures. In the United States, the BD Veritor™ System for Rapid Detection of SARS-CoV-2 is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION OF THE TEST

A novel coronavirus (2019-nCoV) was identified in December 2019,[1] which has resulted in hundreds of thousands of confirmed human infections worldwide. Cases of severe illness and deaths have been reported. On February 11, 2020 the International Committee for Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2.

The median incubation time is estimated to be approximately 5 days[2] with symptoms estimated to be present within 12 days of infection. The symptoms of COVID-19 are similar to other viral respiratory diseases and include fever, cough, and shortness of breath.

The BD Veritor™ System for Rapid Detection of SARS-CoV-2 is a rapid (approximately 15 minutes) chromatographic digital immunoassay for the direct detection of the presence or absence of SARS-CoV-2 antigens in respiratory specimens taken from patients with signs and symptoms who are suspected of COVID-19, or taken from asymptomatic individuals being tested serially, as described in the authorized intended use. The test is intended for interpretation in both laboratory and near patient testing environments only with the BD Veritor™ Plus Analyzer Instrument. The test is not intended to be interpreted visually. Procedures to evaluate test devices depend on the BD Veritor™ Plus Analyzer workflow configuration chosen. In **Analyze Now mode**, the instrument evaluates assay devices after manual timing of their development. In **Walk Away mode**, devices are inserted immediately after application of the specimen, and timing of assay development and analysis is automated. Additionally, connection of a BD Veritor™ Plus Analyzer to a printer or IT system is possible if desired. Additional result documentation capabilities are possible with the integration of a BD Veritor™ barcode scanning enabled module. Please refer to the BD Veritor™ Plus Analyzer Instructions for Use for details on how to implement these features.

PRINCIPLES OF THE PROCEDURE

The BD Veritor™ System consists of a dedicated opto-electronic interpretation instrument and immunochromatographic assays for the qualitative detection of antigens from pathogenic organisms in samples processed from respiratory specimens. The BD Veritor™ System for Rapid Detection of SARS-CoV-2 is designed to detect the presence or absence of SARS-CoV-2 nucleocapsid proteins in respiratory samples from patients with signs and symptoms of infection who are suspected of COVID-19 by their healthcare provider, within the first 5 days of the onset of symptoms, or who are

asymptomatic and undergoing serial testing, as described in the intended use. When specimens are processed and added to the test device, SARS-CoV-2 antigens present in the specimen bind to antibodies conjugated to detector particles in the test strip. The antigen-conjugate complexes migrate across the test strip to the reaction area and are captured by a line of antibodies bound on the membrane. A positive result is determined by the BD Veritor™ Plus Analyzer when antigen-conjugate is deposited at the Test "T" position and the Control "C" position on the assay device. The instrument analyzes and corrects for non-specific binding and detects positives not recognized by the unaided eye to provide an objective result.

REAGENTS

The following components are included in the BD Veritor™ System for Rapid Detection of SARS-CoV-2 kit.

Materials Provided:

KIT COMPONENT	QUANTITY	DESCRIPTION
BD Veritor™ System Test Devices	30 single use test devices	Foil pouched test device containing one reactive strip. Each strip has one line of murine anti-SARS coronavirus monoclonal antibody on the test line, and one of biotin coupled to bovine protein on the positive control line. Murine and Leporine anti-SARS coronavirus and anti-biotin monoclonal antibodies conjugated to detector reagents are bound in the sample delivery area.
Extraction Reagent	30 single use reaction tubes, each with 325 µL extraction reagent and having an integral dispensing tip	Detergent solution with less than 0.1% sodium azide (preservative).
Specimen sampling swabs	30 sterile, single use specimen sampling swabs	For sample collection and transfer.
SARS-CoV-2 (+) Control Swab	1 each – individually wrapped for single use	Non-infectious, recombinant viral protein antigen with less than 0.1% sodium azide.
SARS-CoV-2 (–) Control Swab	1 each – individually wrapped for single use	Buffer with less than 0.1% sodium azide.
Assay documentation	1 each - Instructions for use 1 each - Quick reference instruction card 1 each - Nasal sampling instructions	

MATERIALS REQUIRED BUT NOT PROVIDED	OPTIONAL EQUIPMENT
• BD Veritor™ Plus Analyzer running firmware v5.40 or later (Catalog Number 256066) • BD Veritor™ System Barcode Scanning Module (Catalog Number 256068 or 445010)* • Timer • Tube rack for specimens • Any necessary personal protective equipment	• USB Printer cable for BD Veritor™ Plus Analyzer (Catalog Number 443907) • Epson Printer model TM-T20 II • BD Veritor™ Plus Connect (contact your BD representative for details)

* If required to configure instrument display language

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use. Only for use under an Emergency Use Authorization in the United States.
2. For prescription use only.
3. In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high, or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
4. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and, in the USA, the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
5. Do not use this kit beyond the expiration date printed on the outside carton.
6. The test device should remain in its original sealed pouch until ready for use. Do not use the test if the seal is broken or the pouch is damaged. Do not use the test if it is open for more than 5 minutes.
7. Do not use the kit to evaluate patient specimens if either the positive control swab or negative control swab fail to give expected results.
8. Test results are not meant to be visually determined. All test results must be determined using the BD Veritor™ Plus Analyzer.
9. To avoid erroneous results, specimens must be processed as indicated in the assay procedure section.

10. Do not reuse any BD Veritor™ System test device or kit components.
11. Do not use components from any other BD Veritor™ test with the BD Veritor™ System for Rapid Detection of SARS-CoV-2. While components from other BD Veritor™ tests may appear similar, they are not the same.
12. When collecting direct anterior nasal swab sample, use the nasal swab supplied in the kit.
13. Other than the swabs used for specimen collection, kit components should not contact the patient.
14. Proper specimen collection, storage and transport are critical to the performance of this test.
15. The test is intended to be used with direct anterior nasal swabs and is not validated for use with swabs in viral transport media.
16. Specific training or guidance is recommended if operators are not experienced with specimen collection and handling procedures. Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are collected and evaluated.
17. Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. Standard precautions and institutional guidelines should always be followed in handling, storing, and disposing of all specimens and all items contaminated with blood or other body fluids.
18. The SARS-CoV-2 positive control swabs have been prepared from recombinant viral proteins and do not contain infectious material.
19. Dispose of used BD Veritor™ System test devices and reagents as biohazardous waste in accordance with federal, state and local requirements.
20. Reagents contain sodium azide, which is harmful if inhaled, swallowed or exposed to skin. If there is contact with skin, wash immediately with plenty of water. Contact with acids produces very toxic gas. Dispose of used BD Veritor™ System test devices and reagents in accordance with federal, state and local requirements in an approved biohazard waste container. Do not flush reagents down the drain.
21. Test devices used in a laminar flow hood or in areas with high air flow should be covered during test development to ensure proper sample flow.
22. In environments likely to cause electrostatic charge buildup (dry air, synthetic floor coverings, synthetic clothing), touch a metal surface before using the BD Veritor Plus Analyzer.
23. For additional information on hazard symbols, safety, handling and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at bd.com.

STORAGE

Kits may be stored at 2–30 °C. DO NOT FREEZE. **Reagents and devices must be at room temperature (15–30 °C) when used for testing**.

SPECIMEN COLLECTION AND HANDLING

Specimen Collection and Preparation

Acceptable specimens for testing with this kit include direct anterior nasal swab specimens obtained by the dual nares collection method. It is essential that correct specimen collection and preparation methods be followed. Specimens obtained early during symptom onset will contain the highest viral titers; specimens obtained after five days of symptoms are more likely to produce negative results when compared to an RT-PCR assay. Specimens collected from asymptomatic individuals cannot be synchronized to onset of symptoms and should be evaluated as part of a serial testing program, Inadequate specimen collection, improper specimen handling and/or transport may yield a falsely negative result; therefore, training in specimen collection is highly recommended due to the importance of specimen quality for generating accurate test results.

Specimen Transport and Storage

Freshly collected specimens should be processed as soon as possible, but no later than one hour after specimen collection. It is essential that correct specimen collection and preparation methods be followed.

Anterior Nasal Swab Specimen Collection

1. Insert 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. Take approximately 15 seconds to collect the sample.
2. Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.
3. Withdraw the swab from the nasal cavity. The sample is now ready for processing using the BD Veritor™ System SARS-CoV-2 kit. The swab should be processed in the extraction reagent vial within 1 hour.

NOTE: The BD Veritor™ System Kit includes swabs for nasal specimen collection.

DO'S AND DON'TS OF SPECIMEN COLLECTION

- Use only swabs provided with the kit
- Do test sample immediately.
- In the United States, refer to: Interim Guidelines for Collecting, Handling and Testing Clinical Specimens from persons for COVID-19 at https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html.
- Outside the United States, refer to applicable guidelines from other national or local authorities

TEST PROCEDURE

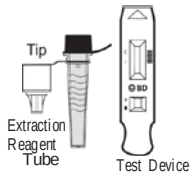
Reagents, specimens, and devices must be at room temperature (15–30 °C) for testing.
This BD Veritor™ System assay kit is only intended for anterior nasal swab specimens that are collected and tested directly (i.e., swabs that have NOT been placed in transport media). The kit includes a pre-diluted processing reagent in a ready to use "unitized" tube. Do not mix components from any other BD Veritor test with the components of this kit. While components from other BD Veritor tests may appear similar, they are not the same. This kit IS NOT INTENDED for testing liquid samples such as wash or aspirate samples or swabs in transport media as results can be compromised by over dilution.

Getting Ready to Test

The following steps assume that the BD Veritor™ Plus Analyzer is ready to use. To choose or change any BD Veritor™ Plus Analyzer settings, see the BD Veritor™ Plus Analyzer Instructions for Use, section 4.7. A printer is not necessary to display results. **However, if your facility has chosen to connect the BD Veritor™ Plus Analyzer to a printer, check that the BD Veritor™ Plus Analyzer is plugged into a power source, paper supply is adequate and any necessary network connections are enabled before testing.**
Once the anterior nasal swab has been collected from the nostrils, the swab should be processed within 1 hour.
Procedural steps for direct anterior nasal swabs or control swabs:

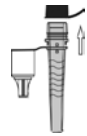
1

- Remove one extraction reagent tube/tip and one BD Veritor™ System test device from its foil pouch immediately before testing or within 5 minutes of opening. If uncovered, debris may land on the device read window and interfere with line interpretation causing false positive or invalid results.
- Label one test device and one extraction reagent tube for each specimen or control to be tested.
- Place the labeled extraction reagent tube(s) in a rack in the designated area of the workspace.



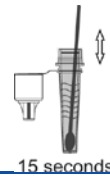
2

Remove and discard the cap from the extraction reagent tube.



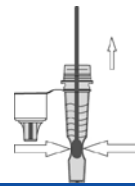
3

Carefully 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.



4

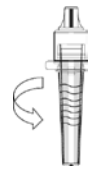
Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.



5

Press the attached tip firmly onto the extraction reagent tube containing the processed sample (threading or twisting is not required). Mix thoroughly by swirling or flicking the bottom of the tube.

NOTE: Do not use tubes or tips from any other product, including other products from BD or other manufacturers.



Once the swab has been processed in the extraction reagent and the tube has been capped, the sample should be added to the test device within 30 minutes.

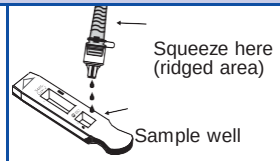
After step 5, choose from the BD Veritor™ Plus Analyzer workflow option below before continuing to step 6:				
	BD Veritor™ Plus Analyzer in **Analyze Now** mode	BD Veritor™ Plus Analyzer in **Walk Away** mode	BD Veritor™ Plus Analyzer with a barcode scanning module installed.	
			in **Analyze Now** mode	in **Walk Away** mode
Instructions in section:	**A**	**B**	**C**	**D**

A Using a BD Veritor™ Plus Analyzer in "*Analyze Now*" mode*:

6A **Adding the specimen to the test device (If testing in batches, jump to Step 6A Batch)**

- Invert the extraction reagent tube and hold it vertically (approximately one inch above the sample well).
- Gently squeeze the ridged body of the tube, dispensing three (3) drops of the processed specimen into the sample well.
- Excess volume remains for retesting if necessary.

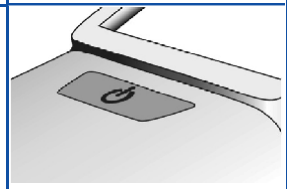
NOTE: Squeezing the tube too close to the tip may cause leakage. This could result in contamination or insufficient sample to run the assay, potentially resulting in a false positive or invalid result.



7A **Timing test development**

- After adding the sample, allow the test to run for **15 minutes but no longer than 20 minutes** before inserting the test device into the BD Veritor™ Plus Analyzer.
- During incubation time, turn the BD Veritor™ Plus Analyzer on by pressing the blue power button once.

NOTE: Test devices used in a laminar flow hood or in areas with high air flow should be covered during test development to prevent sample evaporation and incomplete sample flow which may produce an erroneous false negative, false positive result or control invalid result.



CAUTION: Incorrect results may occur if development time is less than 15 minutes. Some lines may appear on the device sooner. Do not read device visually. Do not read test devices before 15 minutes as this could result in a false negative or invalid result . Do not read devices after 20 minutes as false negative, false positive or invalid results may occur.

8A **Using the BD Veritor™ Plus Analyzer**

- 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".
- INSERT THE TEST DEVICE when the 15-minute assay development time is complete.
- The status of the assay analysis process appears in the display window. Follow the on-screen prompts to complete the procedure. Do not touch the instrument or remove the test device until the result appears.
- When analysis is complete, the test result appears in the display window.

9A **Record the result before removing the test device.**

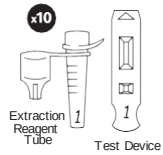
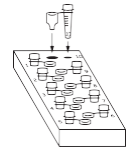
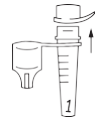
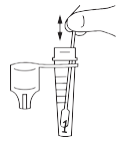
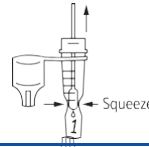
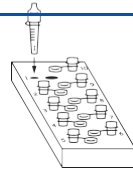
*ATTENTION: TEST Results are NOT maintained in the display window when the device is removed or if the BD Veritor™ Plus Analyzer is left unattended for more than 15 minutes (60 minutes if AC power adapter is connected).

Instructions for Batch Testing

Processing errors that result in false positive or false negative results may occur when inadequate time is planned between multiple specimens in batch mode. Allow adequate time for each specimen to process in the test device and for obtaining and recording Analyzer results. Follow CDC Guidelines for changing gloves and cleaning work area between specimen handling and processing. https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html. The following recommendations were developed based upon a single replicate of 12 specimens tested by professional operators within 30 minutes. Untrained or inexperienced operators may not be able to accurately process as many specimens in batch mode.

CAUTION: Each institution should develop a batch testing protocol to ensure that patient specimens can be tested accurately and in accordance with the instructions for use.

A-Batch Batch Sample Collection (10 Tests):

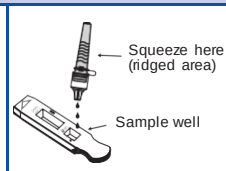
6A Batch	**Gather 10 sets of test materials.** • Open test device pouches. • Label each set with patient ID (extraction reagent tube and test device).	
7A Batch	**Label the tube tray with the patient ID.** • Set each tube in the tray with the matching patient ID.	
8A Batch	Select extraction reagent tube and remove cap.	
9A Batch	**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.	
10A Batch	**Remove swab** while squeezing to extract liquid. Properly dispose of swab.	
11A Batch	Press dispensing tip on the tube firmly. **Mix** the sample by swirling the bottom of the tube.	
12A Batch	Place tube back in tray with matching patient ID. • Repeat steps 8A–12A until all remaining tubes have been prepared. • Specimen processed in the reagent vial must be **run within 30 minutes** on the test device.	

A-Batch Batch Preparation and Analysis (10 Tests):

13A Batch

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.

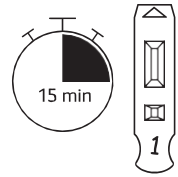
NOTE: Squeezing the tube too close to the tip may cause leakage. This could result in contamination or insufficient sample to run the assay.



14A Batch

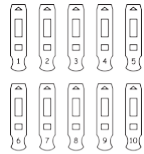
Activate a 15-minute timer. Each test device **must incubate for 15 minutes** before it can be analyzed.

NOTE: Do not read test devices before 15 minutes as this could result in a false negative or invalid result. Do not read devices after 20 minutes as false positive, false negative or invalid results may occur.



15A Batch

Repeat steps 13A–14A until all remaining devices **have been prepared and are incubating,** with a timer running staggering each test by 30 seconds.

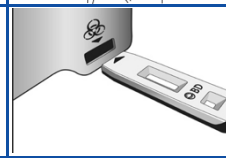


16A Batch

Power on the BD Veritor™ Plus Analyzer by pressing the blue start button once. The device is now ready to be inserted into the Analyzer. Analyzer may remain on until all testing is completed.

17A Batch

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



18A Batch

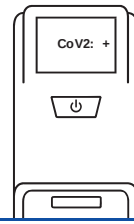
If using the optional **barcode reader module,** follow the screen prompts to scan operator ID and kit lot number to start the test analysis.

After scans are completed, the BD Veritor™ Plus Analyzer displays a countdown time and test analysis begins.

19A Batch

Result will appear on screen and will be stored in the BD Veritor™ Plus Analyzer.

- Record result.
- Remove test device and properly dispose.
- Continue with the next device once it has incubated for 15 minutes.



*ATTENTION: TEST Results are NOT maintained in the display window when the device is removed or if the BD Veritor™ Plus Analyzer is left unattended for more than 15 minutes (60 minutes if AC power adapter is connected).

B Using the BD Veritor™ Plus Analyzer in "*Walk Away* " mode*: with no barcode scanning module installed

To use Walk Away mode - connect the AC power adapter to the Analyzer and a power source

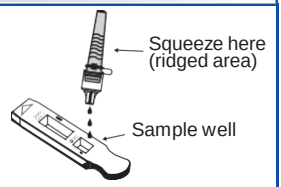
6B **Starting Walk Away Mode**

- Turn the BD Veritor™ Plus Analyzer on by pressing the blue power button once
- When the display window reads: "INSERT TEST DEVICE OR DOUBLE-CLICK FOR WALKAWAY MODE", Double-click the blue power button.
- The display window reads "ADD SPECIMEN TO TEST DEVICE AND INSERT IMMEDIATELY".

7B **Adding the specimen to the test device**

- Invert the extraction reagent tube and hold it vertically (approximately one inch above the sample well).
- Gently squeeze the ridged body of the tube, dispensing three (3) drops of the processed specimen into the sample well.
- Excess volume remains for retesting if necessary.

NOTE: Squeezing the tube too close to the tip may cause leakage. This could result in contamination or insufficient sample to run the assay, potentially resulting in a false positive or invalid result.



CAUTION: A countdown timer displays the time remaining for test insertion. Walk Away mode must be activated again when this timer expires. Confirm timer is visible and Walk Away mode is activated before inserting test device.

8B **Starting the development and reading sequence**

- Insert the test device into the slot on the right side of the BD Veritor™ Plus Analyzer.

The test device must remain horizontal to prevent spilling the specimen out of the sample well, potentially contaminating the workspace and compromising the integrity of the result.

- "DO NOT DISTURB TEST IN PROGRESS" appears in the display window. Automatic timing of the assay development, image processing and result analysis begins. The status of the assay analysis process appears in the display window. Follow the on-screen prompts to complete the procedure. Do not touch the instrument or remove the test device until the result appears.
- The display window shows the remaining analysis time.

Do not touch the BD Veritor™ Plus Analyzer or remove the test device during this process. Doing so will abort the assay analysis. If this happens within 5 minutes of starting the assay, restart the BD Veritor™ Plus Analyzer, select Walk Away Now mode and insert the device again for a 15-minute read. If this occurs after 5 minutes and if there is sufficient remaining extracted sample, re-apply the extracted sample to a new device and re-analyze after 15 minutes. If there is insufficient extracted sample, a new swab specimen will be needed.

9B **Record the result before removing the test device.**

- When analysis is complete, the test result appears in the display window. Record the result and discard the test device appropriately.

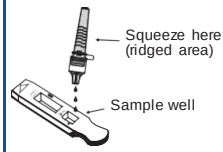
*ATTENTION: TEST Results are NOT maintained in the display window when the device is removed or if the BD Veritor™ Plus Analyzer is left unattended for more than 15 minutes (60 minutes if AC power adapter is connected).

C Using the BD Veritor™ Plus Analyzer In "*Analyze Now*" mode with a barcode scanning module installed

6C **Adding the specimen to the test device**

- Invert the extraction reagent tube and hold it vertically (approximately one inch above the sample well).
- Gently squeeze the ridged body of the tube, dispensing three (3) drops of the processed specimen into the sample well.
- Excess volume remains for retesting if necessary.

NOTE: Squeezing the tube too close to the tip may cause leakage. This could result in contamination or insufficient sample to run the assay, potentially resulting in a false positive or invalid result.



7C **Timing test development**

- After adding the sample, allow the test to run for **15 minutes but no longer than 20 minutes** before inserting the test device into the BD Veritor™ Plus Analyzer.

NOTE: Test devices used in a laminar flow hood or in areas with high air flow should be covered during test development to prevent sample evaporation and incomplete sample flow which may produce an erroneous false negative, false positive result or control invalid result.

CAUTION: Do not read test device visually. Some lines may appear on the device before the end of the incubation time. Do not read test devices before 15 minutes as this could result in a false negative or invalid result . Do not read devices after 20 minutes as false negative, false positive or invalid results may occur.

8C **Using the BD Veritor™ Plus Analyzer**

During the test device incubation time, turn on the BD Veritor™ Plus Analyzer by pressing the blue button once.

The display window briefly shows "SCAN CONFIG BARCODE." This is an opportunity to change the configuration of the BD Veritor™ Plus Analyzer. Ignore this message and postpone this process when an assay is awaiting analysis. Please refer to the BD Veritor™ Plus Analyzer Instructions for Use for configuration steps.

- When assay development time is complete and the BD Veritor™ Plus Analyzer display window reads "INSERT TEST DEVICE OR DOUBLE-CLICK FOR WALK AWAY MODE", insert the BD Veritor™ System SARS-CoV-2 device into the slot on the right side of the BD Veritor™ Plus Analyzer.

9C **Using the barcode scanner**

Follow the prompts on the display screen to complete any required barcode scans of:

— OPERATOR ID
— SPECIMEN ID and/or
— KIT LOT NUMBER

- **Prompts for each scanning step appear in the display window for only 30 seconds. Failure to complete scans during that time will cause the BD Veritor™ Plus Analyzer to default to the beginning of step 8C. To restart this step, remove and reinsert the test device to initiate a new reading sequence.**
- **Move barcodes slowly toward the window until a confirmation tone sounds. The scanned barcode value appears in the next display window.**
- **The BD Veritor™ Plus Analyzer can record the Kit Lot Number and expiration date in the test record but does not restrict the use of expired or inappropriate reagents. Management of expired materials is the responsibility of the user.**

After required scans are completed, the BD Veritor™ Plus Analyzer displays a countdown timer and test analysis begins.

- **Do not touch the BD Veritor™ Plus Analyzer or remove the test device during this process. Doing so will abort the assay analysis.**
- When analysis is complete a result appears in the display window. If configured to display, the specimen ID barcode value also appears. If a printer is connected, specimen ID and result are automatically printed.

If the printer is not connected, record the result before removing the assay device.

ATTENTION: TEST Results are NOT maintained in the display window when the device is removed or if the BD Veritor™ Plus Analyzer is left unattended for more than 15 minutes (60 minutes if AC power adapter is connected).

10C **Removing the test device**

Remove and then discard the test device appropriately. The display will show "INSERT TEST DEVICE OR DOUBLE-CLICK BUTTON FOR WALK AWAY MODE" to indicate the BD Veritor™ Plus Analyzer is ready to perform another test.

If the BD Veritor™ Plus Analyzer is connected to an LIS, a steady ENVELOPE symbol will appear to indicate that results are awaiting transmission. If a network connection is not detected while the ENVELOPE symbol is still displayed, the BD Veritor™ Plus Analyzer will queue all untransmitted results and attempt to transmit them when reconnected. If it is powered off during this time, it will attempt to transmit as soon as power is restored, and connection is re-established. A flashing envelope indicates that data are in the process of being transmitted.

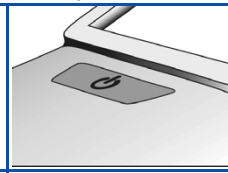
D Using the BD Veritor™ Plus Analyzer In "*Walk Away* " mode with a barcode scanning module installed

To use Walk Away mode - connect the AC power adapter to the BD Veritor™ Plus Analyzer and a power source

6D

Starting Walk Away Mode

- Turn the BD Veritor™ Plus Analyzer on by pressing the blue power button once. The display window will briefly show "SCAN CONFIG BARCODE". This is an opportunity to change the configuration of the BD Veritor™ Plus Analyzer. Please refer to the BD Veritor™ Plus Analyzer Instructions for Use for configuration steps. Ignore this message and postpone this process when an assay is awaiting analysis.
- When the display window reads: "INSERT TEST DEVICE OR DOUBLE-CLICK FOR WALK AWAY MODE", Double-click the blue power button.



7D

Using the barcode scanner

- Follow the prompts on the display screen to complete any required barcode scans of:

— OPERATOR ID
— SPECIMEN ID and/or
— KIT LOT NUMBER

- **Prompts for each scanning step appear in the display window for only 30 seconds. Failure to complete scans during that time will cause the BD Veritor™ Plus Analyzer to default to the beginning of step 6D. To restart this step, remove and reinsert the test device to initiate a new reading sequence.**
- **Move barcodes slowly toward the window until a confirmation tone sounds. The scanned barcode value appears in the next display window.**
- **The BD Veritor™ Plus Analyzer can record the Kit Lot Number and expiration date in the test record but does not restrict the use of expired or inappropriate reagents. Management of expired materials is the responsibility of the user.**

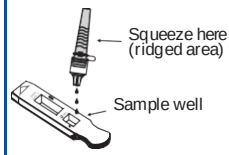
8D

Adding the specimen to the test device

- When the display window reads: "ADD SPECIMEN TO TEST DEVICE AND INSERT IMMEDIATELY":

— Invert the tube, holding it vertically (approximately one inch above the BD Veritor™ System SARS-CoV-2 device sample well).
— Gently squeeze the ridged portion of the tube, dispensing three (3) drops of the processed specimen into the sample well.
— Excess volume remains for retesting if necessary.

NOTE: Squeezing the tube too close to the tip may cause leakage. This could result in contamination or insufficient sample to run the assay, potentially resulting in a false positive or invalid result.



CAUTION: A countdown timer displays the time remaining for test insertion. Walk Away mode must be activated again when this timer expires. Confirm timer is visible and Walk Away mode is activated before inserting test device.

9D

Starting the development and reading sequence

- Insert the test device into the slot on the right side of the BD Veritor™ Plus Analyzer. The test device must remain horizontal to prevent spilling the specimen out of the sample well.
- "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.

Do not touch the BD Veritor™ Plus Analyzer or remove the test device during this process. Doing so will abort the assay analysis.

- When analysis is complete, a result appears in the display window. If configured to display, the Specimen ID barcode value also appears. If a printer is connected, specimen ID and result are automatically printed.

If the printer is not connected, record the result before removing the assay device.

ATTENTION: TEST Results are NOT maintained in the display window when the device is removed or if the BD Veritor™ Plus Analyzer is left unattended for more than 15 minutes (60 minutes if AC power adapter is connected).

10D

Removing the test device

Remove and then discard the test device appropriately. The display will show "INSERT TEST DEVICE OR DOUBLE-CLICK BUTTON FOR WALK AWAY MODE" to indicate the BD Veritor™ Plus Analyzer is ready to perform another test. Note that the BD Veritor™ Plus Analyzer returns to Analyze Now mode at the conclusion of each read sequence.

If the BD Veritor™ Plus Analyzer is connected to an LIS, a steady ENVELOPE symbol will appear to indicate that results are awaiting transmission. If a network connection is not detected while the ENVELOPE symbol is still displayed, the BD Veritor™ Plus Analyzer will queue all untransmitted results and attempt to transmit them when reconnected. If it is powered off during this time, it will attempt to transmit as soon as power is restored, and connection is re-established. A flashing envelope indicates that data are in the process of being transmitted.

INTERPRETATION OF RESULTS

The BD Veritor™ Plus Analyzer (provided separately) must be used for interpretation of all test results. Operators should not attempt to interpret assay results directly from the test strip contained within the BD Veritor™ assay device.

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

*Invalid Test – If the test is invalid, the BD Veritor™ System Instrument will display "CONTROL INVALID" and the test or control must then be repeated. If the "CONTROL INVALID" reading recurs, contact BD.

REPORTING OF RESULTS

Positive Test – Positive for the presence of SARS-CoV-2 antigen. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative Test – 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. For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary after second negative result for asymptomatic patients, if there is a high likelihood of SARS-CoV-2 infection, such in an individual with as a close contract with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.

Control Invalid – Do not report results. Repeat the test. It may be necessary to collect a fresh patient specimen, if more than 1 hour has passed since specimen collection, or more than 30 minutes since the specimen was placed into extraction buffer.

Batch Testing – Processing errors, including false positive or false negative results, may occur when inadequate time is planned between multiple specimens in batch mode. Allow adequate time for each specimen to process in the test device and for obtaining and recording Analyzer results.

See section 5.1.2 in the BD Veritor Analyzer Instructions for Use for recommendations on instrument cleaning.
Follow CDC Guidelines for changing gloves and cleaning work area between specimen handling and processing.
It is recommended to follow your institution's requirements for decontamination procedures or if a spill occurs.
Follow CDC guidelines for best practices to limit contamination. https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html.

QUALITY CONTROL

Each BD Veritor™ System SARS-CoV-2 test device contains both positive and negative internal/procedural controls:

- The internal positive control line validates the immunological integrity of the device, proper reagent function, and assures correct test procedure.
- The membrane area surrounding test lines functions as a background check on the assay device.

The BD Veritor™ System Instrument evaluates the positive and negative internal/procedural controls after insertion of each test device. The BD Veritor™ Plus Analyzer prompts the operator if a quality issue occurs during assay analysis. Failure of the internal/procedural controls will generate an invalid test result.

NOTE: The internal controls do not assess proper sample collection technique.

External Positive and Negative Controls

Positive and Negative control swabs are supplied with each kit. These controls provide additional quality control material to assess that the test reagents and the BD Veritor™ System Instrument perform as expected. Prepare kit control swabs and test using the same procedure as used for patient specimens.

BD recommends controls be run once for:

- each new kit lot,
- each new operator,
- as required by internal quality control procedures and in accordance with local, state and federal regulations or accreditation requirements.

If the kit controls do not perform as expected, do not report patient results. Contact your local BD representative.

LIMITATIONS OF THE PROCEDURE

- The performance of this test has not yet been clinically validated for use in patients without signs and symptoms of respiratory infection, or for serial screening applications and performance may differ in these populations.
- Clinical performance was evaluated with frozen samples, from symptomatic patients and test performance may be different with fresh samples.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected during the month of June, 2020. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- Users should test specimens as quickly as possible after specimen collection and always within 1 hour of specimen collection or 30 minutes after placement of swab into the extraction reagent.
- Positive test results do not rule out co-infections with other pathogens.
- Results from the BD Veritor™ System for Rapid Detection of SARS-CoV-2 test should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.
- A false-negative test result may occur if the level of viral antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly; therefore, a negative test result does not eliminate the possibility of SARS-CoV-2 infection.
- Based on *in vitro* testing, false positive results cannot be ruled out if patients with rheumatoid factor higher than 12.5 IU/mL in nasal fluid, although it is unclear if such concentrations are clinically relevant.
- False positive results can occur due to contamination. Users should disinfect instrument between specimens and batch testing and follow careful disinfection procedures to limit contamination.
- Do not read test devices before 15 minutes as this could result in a false negative or invalid result. Do not read devices after 20 minutes as false positive, false negative or invalid results may occur.
- The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 5 of illness are more likely to be negative compared to a RT-PCR assay.
- Failure to follow the test procedure may adversely affect test performance and/or invalidate the test result.
- The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 antigens from nasal swab specimens only.
- The BD Veritor™ System for Rapid Detection of SARS-CoV-2 can detect both viable and non-viable SARS-CoV-2 material. The BD Veritor™ System for Rapid Detection of SARS-CoV-2 performance depends on antigen load and may not correlate with other diagnostic methods performed on the same specimen.
- Negative test results are not intended to rule in other non-SARS-CoV-2 viral or bacterial infections.
- Positive and negative predictive values are highly dependent on prevalence rates. Positive test results are more likely to represent false positive results during periods of little/no SARS-CoV-2 activity when disease prevalence is low. False negative test results are more likely when prevalence of disease caused by SARS-CoV-2 is high.
- This device has been evaluated for use with human specimen material only.
- Monoclonal antibodies may fail to detect, or detect with less sensitivity, SARS-CoV-2 viruses that have undergone minor amino acid changes in the target epitope region.
- Sensitivity of the test after the first five days of the onset of symptoms has been demonstrated to decrease as compared to a RT-PCR SARS-CoV-2 assay.
- Negative results should be treated as presumptive and confirmed with an FDA authorized molecular assay, if necessary, for clinical management, including infection control. Outside the United States, a molecular assay cleared for diagnostic use in the country of use is recommended.
- The validity of the BD Veritor™ System for Rapid Detection of SARS-CoV-2 test has not been proven for identification/confirmation of tissue culture isolates and should not be used in this capacity.

CONDITIONS OF AUTHORIZATION FOR THE LABORATORY (APPLICABLE IN THE USA)

The BD Veritor™ System for Rapid Detection of SARS-CoV-2 Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

However, to assist clinical laboratories using the BD Veritor™ System for Rapid Detection of SARS-CoV-2 ("your product" in the conditions below), the relevant Conditions of Authorization are listed below.

- Authorized laboratories* using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using your product must use your product as outlined in the BD Veritor™ System for Rapid Detection of SARS-CoV-2 Instructions for Use. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
- Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and to BD by contacting BD Customer Support Services at 800.638.8663 (in the U.S.) any suspected occurrence of false positive or false negative results and

significant deviations from the established performance characteristics of your product of which they become aware.

- All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.
- Becton, Dickinson and Co., authorized distributors, and authorized laboratories and patient care settings using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

*The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate, or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation as "authorized laboratories".

CLINICAL PERFORMANCE

The performance of the BD Veritor™ System for Rapid Detection of SARS-CoV-2 was established with 226 direct nasal swabs prospectively collected and enrolled from individual symptomatic patients[a] (within 5 days of onset) who were suspected of COVID-19. As with all antigen tests, performance may decrease as days since symptom onset increases due to lower viral loads later in the patient's disease course. , The inability to synchronize asymptomatic individuals with onset of infection may impact performance as specimens may be tested when viral loads are below the assay's limit of detection. Clinical studies in asymptomatic patients undergoing serial testing are ongoing to establish the clinical performance. Samples were collected by qualified personnel in 21 geographically diverse areas across the United States.

Nasal swabs were collected following the dual nares method and handled as described in the package insert of the collection device. Specimens were frozen within 30 minutes of collection and stored until tested. All specimens within a pre-specified date range were selected and then sequentially tested in a blinded fashion. The performance of the BD Veritor™ System Assay was compared to results of a nasopharyngeal or oropharyngeal swab stored in 3 mL viral transport media tested with an Emergency Use Authorized molecular (RT-PCR) test for detection of SARS-CoV-2.

[a]Symptoms included new loss of taste or smell, fever, shortness of breath or difficulty breathing, headache, cough, sore throat, muscle pain, chills and repeated shaking with chills.

Table 1: Summary of the Performance of the BD Veritor™ System for Rapid Detection of SARS-CoV-2 Compared to RT-PCR for Nasal Swabs

BD Veritor™ Results	Reference RT-PCR Results		
	POS	NEG	Total
POS	26	0	26
NEG	5	195	200
Total	31	195	226

PPA: 84% (C.I. 67%–93%)
NPA: 100% (C.I. 98%–100%)
PPV: 100% (C.I. 89%–100%)
NPV: 97.5% (C.I. 95%–99

The performance of this test has not yet been clinically validated for use in patients without signs and symptoms of respiratory infection or for serial screening applications, and performance may differ in these populations

While the clinical performance of BD Veritor System for Rapid Detection of SARS-CoV-2 does not meet the 95% confidence interval lower bound of 70%, supplemental clinical data was submitted for the BD Veritor System for the Rapid Detection of SARS-CoV-2 and Flu A+B, in which the clinical performance did exceed the 95% confidence interval lower bound of 70% to support serial testing.

EXPLANATION OF TERMS:
C.I.: Confidence Interval
PPA: Positive Percent Agreement = True Positives / (True Positives + False Negatives)
NPA: Negative Percent Agreement = True Negatives / (True Negatives + False Positives)
PPV: Positive Predictive Value = True Positives / (True Positives + False Positives)
NPV: Negative Predictive Value = True Negatives / (True Negatives + False Negatives)

Hypothetical Predictive Values

The positive predictive value (PPV) point estimate was 100% with a 95% Confidence Interval of 89%–100%. This PPV was obtained with 13.7% observed prevalence. The PPV (percentage of positive test results that are true positives) varies with disease prevalence. As disease prevalence decreases, the percent of test result that are false positive increase. With a hypothetical prevalence of 1% the PPV point estimate remains at 100% but the Confidence Interval increases to 33.2%–100%. The PPV will also decrease as the Specificity (Negative Percent Agreement or NPA) decreases. The observed NPA in this study was 100% with a 95% Confidence Interval of 98%–100%, which means that the false positive rate could be between 0–2% of all the test performed.

The local SARS-CoV-2 prevalence should be taken into consideration when interpreting diagnostic test results.

Table 2: Hypothetical Positive and Negative Predictive Values for the BD Veritor™ System for Rapid Detection of SARS-CoV-2 compared to RT-PCR for Varying Prevalence of COVID-19 in the Population.

COVID-19 Prevalence	All Values Expressed as 95% Confidence Interval							
	Sensitivity (PPA)	Specificity (NPA)	PPV	Theoretical False Positives Out of 100 Positive Results	Theoretical False Positives Out of 100 Total Results	NPV	Theoretical False Negatives Out of 100 Negative Results	Theoretical False Negatives Out of 100 Total Results
0.1%	67%–93%	98%–100%	(4.7%–100%)	0–95	0–2	100%	0	0
1.0%			(33.2%–100%)	0–67	0–2	(99.7%–99.9%)	0	0
2.0%			(50.1%–100%)	0–50	0–2	(99.3%–99.9%)	0–1	0
5.0%			(72.1%–100%)	0–28	0–2	(98.3%–99.7%)	0–2	0–1
10.0%			(84.5%–100%)	0–17	0–2	(96.4%–99.4%)	1–4	0–2
13.7%			(88.6%–100%)	0–11	0–1	(94.9%–99.1%)	1–5	0–2
15.0%			(89.7%–100%)	0–10	0–1	(94.4%–99.0%)	1–6	0–2
20.0%			(92.5%–100%)	0–8	0–1	(92.2%–98.7%)	1–8	0–3
25.0%			(94.2%–100%)	0–6	0–1	(89.9%–98.2%)	2–10	0–4

EXPLANATION OF TERMS:
PPV: Positive Predictive Value = True Positives / (True Positives + False Positives)
NPV: Negative Predictive Value = True Negatives / (True Negatives + False Negatives)

The Positive Predictive Value (percentage of positive test results that are true positives) varies with disease prevalence. As disease prevalence decreases, the confidence interval of the PPV gets wider and the percent of test results that are false positive increases. Table 2 contains PPV confidence interval estimates for the BD Veritor™ assay at other prevalence levels of SARS-CoV-2 in a population. Based on the specificity at 1% prevalence, PPV could be as low as 33.2%. This means that the false positives may be as high as 66.8%, meaning that 67 out of 100 positive results may be false positives. If you look at 100 total results, including both positive and negative results, you could see two or fewer false positive results, with the expectation of seeing a single true positive result. Similarly, in a population with 0.1% prevalence, the PPV could be as low as 4.7% meaning that approximately 95 out of 100 positive results would be false positive.

ANALYTICAL PERFORMANCE

LIMIT OF DETECTION (ANALYTICAL SENSITIVITY)

The LOD for the BD Veritor™ System for Rapid Detection of SARS-CoV-2 was established using limiting dilutions of a viral sample inactivated by gamma irradiation. The material was supplied at a concentration of 2.8 x 10^5 $TCID_{50}$/mL. In this study, designed to estimate the LOD of the assay when using a direct nasal swab, the starting material was spiked into a volume of pooled human nasal matrix obtained from healthy donors and confirmed negative for SARS-CoV-2. An initial range finding study was performed testing devices in triplicate using a 10-fold dilution series. At each dilution, 50 µL samples were added to swabs and then tested in the BD Veritor™ assay using the procedure appropriate for patient nasal swab specimens. A concentration was chosen between the last dilution to give three positive results and the first to give three negative results. Using this concentration, the LOD was further refined with a 2-fold dilution series. The last dilution demonstrating 100% positivity was then tested in an additional 20 replicates tested in the same way.

Starting Material Concentration	Estimated LOD	No. Positive/Total	% Positive
2.8 x 10^5 $TCID_{50}$/mL	1.4 x 10^2 $TCID_{50}$/mL	19/20	95%

CROSS REACTIVITY (ANALYTICAL SPECIFICITY)

Cross-reactivity of the BD Veritor™ System for Rapid Detection of SARS-CoV-2 was evaluated by testing a panel of high prevalence respiratory pathogens that could potentially cross-react with the BD Veritor™ System for Rapid Detection of SARS-CoV-2 in a negative and a 5x LOD sample. Each organism and virus was tested in triplicate. The final concentration of each organism is documented in the following table.

Potential Cross-Reactant	Concentration Tested	Cross-Reactivity (Yes/No)
Human coronavirus 229E (heat inactivated)	1.0 x 10^5 U/mL	No
Human coronavirus OC43	1.0 x 10^5 $TCID_{50}$/mL	No
Human coronavirus NL63	1.0 x 10^5 $TCID_{50}$/mL	No
Adenovirus	1.0 x 10^5 $TCID_{50}$/mL	No
Human Metapneumovirus	1.0 x 10^5 $TCID_{50}$/mL	No
Parainfluenza virus 1	1.0 x 10^5 $TCID_{50}$/mL	No
Parainfluenza virus 2	1.0 x 10^5 $TCID_{50}$/mL	No
Parainfluenza virus 3	5.2 x 10^5 $TCID_{50}$/mL	No
Parainfluenza virus 4	1.6 x 10^4 $TCID_{50}$/mL	No
Influenza A	2.5 x 10^5 $TCID_{50}$/mL	No
Influenza B	2.9 x 10^5 $TCID_{50}$/mL	No
Enterovirus	4.0 x 10^5 $TCID_{50}$/mL	No
Respiratory syncytial virus	4.0 x 10^5 $TCID_{50}$/mL	No
Rhinovirus	1.1 x 10^5 PFU/mL	No
SARS-coronavirus	4.5 x 10^5 PFU/mL	No
MERS-coronavirus	1.5 x 10^5 $TCID_{50}$/mL	No
Haemophilus influenzae	1.4 x 10^6 CFU/mL	No
Streptococcus pneumoniae	1.0 x 10^6 CFU/mL	No
Streptococcus pyogenes	1.6 x 10^6 CFU/mL	No
Candida albicans	1.8 x 10^6 CFU/mL	No
Pooled human nasal wash	100%	No
Bordetella pertussis	1.4 x 10^6 CFU/mL	No
Mycoplasma pneumoniae	1.0 x 10^6 CFU/mL	No
Chlamydia pneumoniae	1.0 x 10^6 IFU/mL	No
Legionella pneumophila	1.0 x 10^6 CFU/mL	No

To estimate the likelihood of cross-reactivity with SARS-CoV-2 of organisms that were not available for wet testing, *in silico* analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was used to assess the degree of protein sequence homology.

- For *P. jirovecii* one area of sequence similarity shows 45.4% homology across 9% of the sequence, making cross-reactivity in the BD Veritor™ sandwich immunoassay highly unlikely.
- No protein sequence homology was found between SARS-CoV-2 and *M. tuberculosis*, and thus homology-based cross-reactivity can be ruled out.
- The comparison between SARS-CoV-2 nucleocapsid protein and human coronavirus HKU1 revealed that the only potential for homology is with the HKU1 nucleocapsid phosphoprotein. Homology is relatively low, at 36.7% across 82% of sequences, but cross-reactivity cannot be ruled out.

ENDOGENOUS INTERFERING SUBSTANCES

Various substances were evaluated with the BD Veritor™ System for Rapid Detection of SARS-CoV-2. The substances tested included whole blood 4%, mucin and various medications. No interference was noted with this assay for any of the substances tested.

Substance	Concentration Tested	Interference (Yes/No)
Afrin Nasal Spray (Oxymetazoline)	5% v/v	No
Flonase (Fluticasone)	5% v/v	No
Nasacort (Triamcinolone)	5% v/v	No
Neo-Synephrine (Phenylephrine hydrochloride)	5% v/v	No
Oseltamivir	2.2 µg/mL	No
Mucin protein	2.5 mg/mL	No
Rhinocort (Budesonide)	5% v/v	No
Saline nasal spray	15% v/v	No
Zanamivir	282 ng/mL	No
Zicam Cold Remedy (Galphimia glauca, Luffa operculata, Sabadilla)	5% v/v	No
Whole blood	4% v/v	No
Cepacol (Menthol/Benzocaine)	1.5 mg/mL	No
Ricola (menthol)	1.5 mg/mL	No
Tobramycin	4 µg/mL	No
Sucrets (Dydonine/Menthol)	1.5 mg/mL	No
NeilMed Naso Gel	5% v/v	No
Zicam nasal spray (Oxymetazoline)	10% v/v	No
Alkalol nasal wash	10% v/v	No
Fisherman's Friend (menthol)	1.5 mg/mL	No
Chloraseptic (Phenol Spray)	15% v/v	No
Mupirocin	10 mg/mL	No

Additionally, the following were tested for interference in a negative and a 3x LOD sample. No interference was noted at the levels tested.

Substance	Concentration Tested	Interference (Yes/No)
Afrin Nasal Spray (Oxymetazoline)	15% v/v	No
Neo-Synephrine (Phenylephrine hydrochloride)	15% v/v	No
Oseltamivir	2.2 µg/mL	No
Mucin protein	5 mg/mL	No
Mupirocin	10 mg/mL	No
Rheumatoid Factor	12.5 IU/mL	No

NOTE: Based on *in vitro* testing, false positive results may occur in patients with rheumatoid factor higher than 12.5 IU/mL in nasal fluid, although it is unclear if such concentrations are clinically relevant.

MICROBIAL INTERFERENCE

The BD Veritor™ System for Rapid Detection of SARS-CoV-2 assay was evaluated with various organisms at the concentrations indicated below in a negative and 5x LOD sample. No interference was noted.

Potential Microbial Interferent	Concentration Tested	Interference (Yes/No)
Human coronavirus 229E	1.0×10^5 U/mL	No
Human coronavirus OC43	1.0×10^5 $TCID_{50}$/mL	No
Human coronavirus NL63	1.0×10^5 $TCID_{50}$/mL	No
Adenovirus	1.0×10^5 $TCID_{50}$/mL	No
Human Metapneumovirus	1.0×10^5 $TCID_{50}$/mL	No
Parainfluenza virus 1	1.0×10^5 $TCID_{50}$/mL	No
Parainfluenza virus 2	1.0×10^5 $TCID_{50}$/mL	No
Parainfluenza virus 3	5.2×10^5 $TCID_{50}$/mL	No
Parainfluenza virus 4a	1.5×10^4 $TCID_{50}$/mL	No
Influenza A	2.5×10^5 $TCID_{50}$/mL	No
Influenza B	2.9×10^5 $TCID_{50}$/mL	No
Enterovirus D68	4.0×10^5 $TCID_{50}$/mL	No
Respiratory syncytial virus	4.0×10^5 $TCID_{50}$/mL	No
Rhinovirus 3	1.1×10^5 PFU/mL	No
SARS-coronavirus	4.5×10^5 PFU/mL	No
MERS-coronavirus	1.5×10^5 $TCID_{50}$/mL	No
Haemophilus influenzae	1.4×10^6 CFU/mL	No
Streptococcus pneumoniae	1.0×10^6 CFU/mL	No
Streptococcus pyogenes	1.6×10^6 CFU/mL	No
Bordetella pertussis	1.4×10^6 CFU/mL	No
Mycoplasma pneumoniae	1.0×10^6 CFU/mL	No
Chlamydia pneumoniae	1.0×10^6 CFU/mL	No
Legionella pneumophila	1.0×10^6 CFU/mL	No
Pooled human nasal wash	N/A	No
Candida albicans	1.8×10^6 CFU/mL	No

Additionally, the following potential cross-reacting organisms were tested using a negative and 3x LOD sample at the following levels. No interference was noted.

Potential Microbial Interferent	Concentration Tested	Interference (Yes/No)
Rhinovirus 3	1.1×10^5 PFU/mL	No
SARS-coronavirus	4.5×10^5 PFU/mL	No
MERS-coronavirus	1.5×10^5 $TCID_{50}$/mL	No
Haemophilus influenzae	1.4×10^6 CFU/mL	No
Streptococcus pneumoniae	1.0×10^6 CFU/mL	No
Streptococcus pyogenes	1.6×10^6 CFU/mL	No
Bordetella pertussis	1.4×10^6 CFU/mL	No

INTRA-SITE VARIABILITY

Another study was designed to assess the capability of users to test seeded swab samples across the range of the assay with three (3) users, over three (3) days, with three (3) lots of devices. The following table shows the performance.

Sample	Operator #1		Operator #2		Operator #3		Total	
	% Positive	95% C.I.	% Positive	95% C.I.	% Positive	95% C.I.	% Positive	95% C.I.
Negative	0% (0/27)	(0.0%,12.5%)	0% (0/27)	(0.0%,12.5%)	0% (0/27)	(0.0%,12.5%)	0% (0/81)	(0.0%,4.5%)
Low Positive (3x LOD)	100% (27/27)	(87.5%,100%)	100% (27/27)	(87.5%,100%)	100% (27/27)	(87.5%,100%)	100% (81/81)	(95.5%, 100%)
Low Positive (5x LOD)	100% (27/27)	(87.5%,100%)	100% (27/27)	(87.5%,100%)	100% (27/27)	(87.5%,100%)	100% (81/81)	(95.5%, 100%)
Moderate Positive (10x LOD)	100% (27/27)	(87.5%,100%)	100% (27/27)	(87.5%,100%)	100% (27/27)	(87.5%,100%)	100% (81/81)	(95.5%, 100%)
High Positive (40x LOD)	100% (27/27)	(87.5%,100%)	100% (27/27)	(87.5%,100%)	100% (27/27)	(87.5%,100%)	100% (81/81)	(95.5%, 100%)

HIGH DOSE HOOK EFFECT

No high dose hook effect was observed up to 2.8 x 10^5 $TCID_{50}$/mL of gamma-inactivated SARS-CoV-2 with the BD Veritor™ System for Rapid Detection of SARS-CoV-2 test.

TECHNICAL SUPPORT

For questions, or to report a problem, please call Technical Support at 1.800.638.8663 or visit bd.com. Test system problems may also be reported to the FDA using the MedWatch reporting system:
Phone: 1.800.FDA.1088; Fax: 1.800.FDA.1078 or visit http://www.fda.gov/medwatch.

Outside the United States, contact your local BD representative.

REFERENCES

1. Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-ncov/index.html. Accessed March 30, 2020.
2. https://www.cdc.gov/flu/symptoms/flu-vs-covid19.htm

Change History

Revision	Date	Change Summary
03	2020-08	Added statement that kit components (other than swabs) should not make contact with the patient. Removed https://www.biorxiv.org/content/10 reference.
04	2020-11	Minor typographical corrections.
05	2021-02	Added warning not to use components from other kits. Modified Sodium Azide warning language, description of intended user, added endogenous, microbial interference data tables and intra-site variability testing results.
06	2021-03	Modified intended use to allow for use in serial screening of asymptomatic individuals.

US Customers only: For symbol glossary, refer to bd.com/symbols-glossary

SYMBOL GLOSSARY	
EC REP	Authorized Representative
LOT	Batch Code
	Biological Risk
REF	Catalogue Number
	Caution
	Consult Instructions for Use
	Contains sufficient for <n> tests
CONTROL +	Control, Positive
CONTROL -	Control, Negative
	Date of Manufacture
	Do Not Reuse
	Fragile, Handle with Care
IVD	In Vitro Diagnostic
	Manufacturer
Rx Only	Prescription Use Only
	Recyclable
SN	Serial Number
	Temperature Limitation
	This End Up
	Use By Date

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bd.com/e-labeling

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

Proper Anterior Nasal Swab Sample Collection

In the USA: For use under Emergency Use Authorization (EUA) Only

REF 256082

1

This BD Veritor™ System SARS-CoV-2 Kit includes swabs for nasal specimen collection.

2

Carefully insert the swab into one nostril. 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 nostrils to ensure that both mucous and cells are collected. Take approximately 15 seconds to collect the sample

3

Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities

4

Withdraw the swab from the nasal cavity. The sample is now ready for processing using the BD Veritor System SARS-CoV-2.

IVD R_x Only

Do's and Don'ts of Sample Collection

- Do collect sample as soon as possible after onset of symptoms.
- Do test sample immediately.
- Use only swabs provided with the kit.
- Refer to: Interim Guidelines for Collecting, Handling and Testing Clinical Specimens from persons for COVID-19 at https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

US Customers only: For symbol glossary, refer to bd.com/symbols-glossary
Technical Information: In the United States contact BD Technical Service and Support at 1.800.638.8663 or bd.com

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- In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- This product has been authorized only for the detection of proteins from SARS-CoV-2 and not for any other viruses or pathogens; and,
- In the USA, the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of the virus that causes COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the authorization is revoked sooner.

2021-03
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