BD

IVD

℞ Only

REF 256088
500051910(01)
2021-03
English

Veritor™ System

For Rapid Detection of SARS-CoV-2 & Flu A + B

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

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

30
Determinations

BD Veritor™ System

For Rapid Detection of SARS-CoV-2 & Flu A+B

For *In Vitro* Diagnostic Use
For use with the BD Veritor™ Plus Analyzer running firmware version 5.50 or later
in the United States, for use under an Emergency Use Authorization only

Please read these instructions completely before beginning testing of specimens.

INTENDED USE

The BD Veritor™ System for Rapid Detection of SARS-CoV-2 & Flu A+B is a rapid chromatographic digital immunoassay intended for the in vitro, simultaneous qualitative detection and differentiation of SARS-CoV-2 nucleocapsid antigen and/or influenza A and B nucleoprotein antigens directly from anterior nasal swab samples taken from individuals who are suspected of a viral respiratory infection consistent with COVID-19 by a healthcare provider, within the first six days of symptom onset. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar. In the USA, 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.

Performance characteristics for influenza A and B were established during January through March of 2011 when influenza viruses A/2009 H1N1, A/H3N2, B/Victoria lineage, and B/Yamagata lineage were the predominant influenza viruses in circulation according to the Morbidity and Mortality Weekly Report from the CDC entitled "Update: Influenza Activity—United States, 2010–2011 Season, and Composition of the 2011–2012 Influenza Vaccine." Minor changes were made to the BD Veritor System for Rapid Detection of Flu A+B device to accommodate the addition of SARS-CoV-2 detection reagents. Performance characteristics for influenza A and B were not re-established with the modified device and may vary from previous performance. Performance characteristics may vary against other emerging influenza viruses. This test is not intended to detect influenza C antigens.

Results are for the simultaneous identification of SARS-CoV-2 nucleocapsid protein and Influenza A and B viral nucleoproteins. These antigens are generally detectable in anterior nasal swabs 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 SARS-CoV-2 results to the appropriate public health authorities.

Negative results should be treated as presumptive, do not rule out either Influenza or SARS-CoV-2, 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 one of these infections. Negative results for SARS-CoV-2 should be confirmed with a molecular assay, if necessary, for patient management. Negative results for influenza A and B should be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay.

If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. A viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

The BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B is intended for use in point of care settings by trained healthcare professionals or other users specifically instructed in the use of BD Veritor Systems and proper infection control procedures. In the United States, the BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B 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 millions of confirmed human infections worldwide. Cases of severe illness and deaths have been widely 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, including influenza, and include fever, cough, myalgia and shortness of breath.

Influenza illness classically presents with sudden onset of fever, chills, headache, myalgias, and a non-productive cough Epidemics of influenza typically occur during winter months with estimated 114,000 hospitalizations[3] and 36,000 deaths[4] per year in the U.S. Influenza viruses can also cause pandemics, during which rates of illness and death from influenza-related complications can increase dramatically. Distinguishing between these two viral respiratory infections, as well as differentiating between influenza A and B, is important in determining appropriate interventions.

The BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B is designed as a rapid (15-minute test incubation time) chromatographic digital immunoassay for the direct detection of the presence or absence of influenza A, influenza B and SARS-CoV-2 antigens in anterior nasal swab specimens collected from patients with signs and symptoms who are suspected of

COVID-19 or influenza by their healthcare provider. 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 bar code scanning 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 & Flu A+B is designed to detect the presence or absence of SARS-CoV-2 nucleocapsid protein and Influenza A and B nucleoproteins in respiratory samples from patients with signs and symptoms of infection who are suspected of COVID-19 or Influenza. When specimens are processed and added to the test device, any SARS-CoV-2 or influenza A or B 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 and control material is deposited at any of the specific test positions ("B", "S" "A" or "C") on the assay device. The instrument analyzes and corrects for non-specific binding and detects positives and negatives 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 & Flu A+B 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 containing: • Murine anti-SARS coronavirus monoclonal antibodies • Murine anti-flu A monoclonal antibodies • Murine anti-flu B monoclonal antibodies • Biotin coupled to bovine protein • Murine and Leporine anti-SARS coronavirus, murine anti-flu A, anti-flu B and anti-biotin monoclonal antibodies conjugated to detector reagents are bound in the sample delivery area.
Reagent D	30 single use reaction tubes, each with 400 µL 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	SARS-CoV-2 antigen (inactive recombinant nucleocapsid protein) with less than 0.1% sodium azide.
Flu A (+) Control Swab	1 each – individually wrapped for single use	influenza A antigen (inactive recombinant nucleoprotein) with <0.1% sodium azide
Flu B (+) Control Swab	1 each – individually wrapped for single use	influenza B antigen (inactive recombinant nucleoprotein) with <0.1% sodium azide
Paperboard tube stands	3 each	Each stand has capacity for 10 extraction reagent tubes
Assay documentation	1 each - Instructions for use 1 each - Quick reference instruction card 1 each - Nasal Sampling guide	

Materials Required but not provided:

- BD Veritor™ Plus Analyzer running firmware v5.50 or later (Cat. No. 256066)
- timer
- specimen rack
- any necessary personal protective equipment

Optional Equipment:

- Veritor System Bar Code Scanning Module (Catalog No. 256068 or 445010)
- USB Printer cable for BD Veritor Plus Analyzer (Cat. No. 443907)
- Epson Printer model TM-T20 II
- BD Veritor Plus Connect (contact BD Technical Services for details).
- BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B Positive Control Swab set – 10 of each analyte (Cat. No 256090)

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
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. The 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, influenza A and influenza B, 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 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 any of the positive control swabs 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 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.
12. When collecting 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 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 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. This prevents evaporation of the sample which may lead to incomplete sample flow and erroneous false positive or control invalid results.
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.
24. If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, the specimen should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

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 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 six days of symptoms are more likely to produce negative results for SARS-CoV-2 when compared to an RT-PCR assay. 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

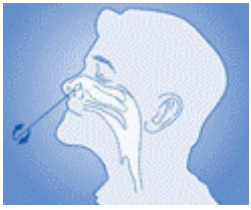
Freshly collected specimens should be processed as soon as possible, but no later than one hour after specimen collection. It is essential that correct specimen collection and preparation methods be followed.

Anterior Nasal Swab Specimen Collection

Note: The BD Veritor System Kit includes swabs for anterior nasal specimen collection.

1. 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. Take at least 15 seconds to collect the specimen.

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 & Flu A + B kit. The swab must be processed in the extraction reagent vial within one hour.

DOs 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.
- 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 of 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 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.

See section 5.1.2 in the BD Veritor Analyzer Instructions for Use for recommendations on instrument cleaning. 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.

Getting ready to test

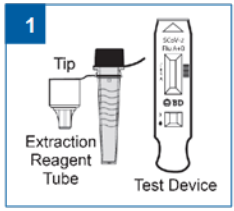
The following steps assume that the BD Veritor Plus Analyzer is ready to use. To choose or change any Veritor Plus Analyzer settings, see the BD Veritor Plus Analyzer Instructions for Use, section 4.7. A printer is not necessary to display results. **However, if your facility has chosen to connect the 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 one hour.

Procedure for Anterior Nasal Swabs or positive control swabs:

Step 1:

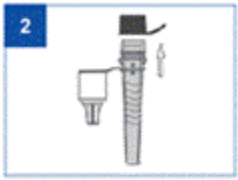
- Remove one extraction reagent tube/tip and one BD Veritor System test device from its foil pouch immediately before testing. If left uncovered, debris may land on the device read window and interfere with line interpretation causing false positive, false negative or invalid results.
- Label one test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



Process the Specimen or Positive Control Swab

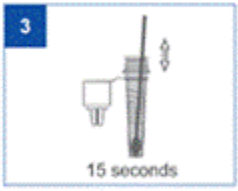
Step 2:

- Remove and discard the cap from the extraction reagent tube.



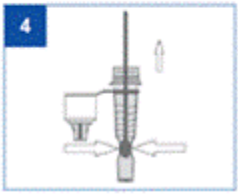
Step 3:

- Taking care not to splash contents out of the tube, insert the swab into the tube and plunge the swab up and down in the fluid for a minimum of 15 seconds.



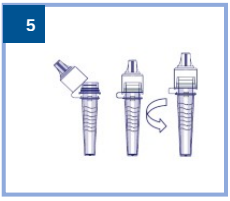
Step 4:

- While firmly squeezing the sides of the tube to extract the specimen from the head of the swab, remove the swab from the extraction reagent. Ensure Swab is above liquid level before squeezing and twist as you remove swab.



Step 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.

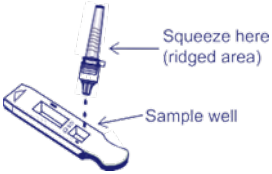
After the swab has been processed in the extraction reagent and the tube has been capped, the sample must be added to the test device within 30 minutes

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 BD Veritor bar code scanning module	
			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:

Step 6A: Adding the specimen to the test device (If testing in batches, see Step 6A-Batch, below)

- 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.

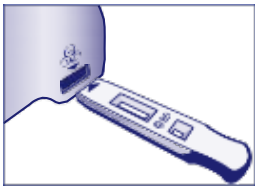


NOTE: Squeezing the tube too close to the tip may cause leakage. This could result in contamination or insufficient sample to run the assay, potentially resulting in a false positive or invalid result.

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

Step 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.

Step 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 in Analyze Now mode

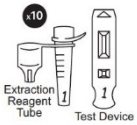
Processing errors that result in false positive or false negative results may occur when inadequate time is planned between multiple specimens in batch mode. Allow adequate time for each specimen to process in the test device and for obtaining and recording Analyzer results. Follow CDC Guidelines for 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 - Before implementing batch testing processes, each site should develop a batch testing protocol to confirm that patient specimens can be tested accurately and in accordance with the instructions for use.

Batch Sample Collection (Example below includes 10 Tests)

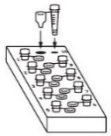
Step 6A-Batch

- **Gather 10 sets of test materials.**
- Open test device pouches
- Label each set with patient ID (extraction reagent tube and corresponding test device).



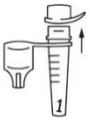
Step 7A-Batch

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



Step 8A-Batch

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

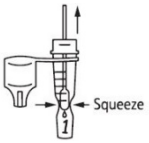


Step 9A-Batch

- **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

Step 10A-Batch

- While firmly squeezing the sides of the tube to extract the specimen from the head of the swab, remove the swab from the extraction reagent. Ensure Swab is above liquid level before squeezing and twist as you remove swab.
- Properly dispose of swab.

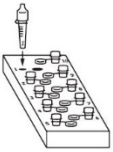


Step 11A-Batch

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

Step 12A-Batch

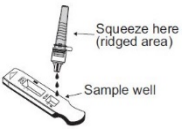
- Place tube back in tray with matching patient ID.
- Repeat steps 8A – 12A until all remaining tubes have been prepared. Specimen processed in the reagent vial must be added to the test device **within 30 minutes**.



Batch Preparation and Analysis (10 tests)

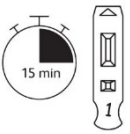
Step 13A-Batch

- 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.**
- **Stagger the addition of subsequent specimens by approx. 30 seconds.**



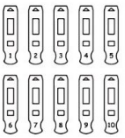
Step 14A-Batch

- 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, false positive or invalid result. Do not read devices after 20 minutes as false positive or invalid results may occur.



Step 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.



Step 16A-Batch

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

Step 17A-Batch

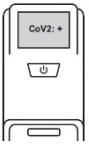
- When prompted, insert the test device to read.

Step 18A-Batch

- If using the optional **bar code reader module**, follow the screen prompts to scan operator ID and/or kit lot number to start the test analysis.
- After scans are completed, the Analyzer displays a countdown timer and test analysis begins.

Step 19A-Batch

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



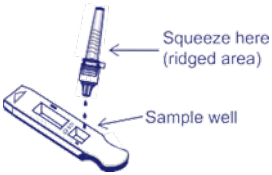
B Using the BD Veritor Plus Analyzer in "*Walk Away*" mode: with no barcode scanning module installed

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

Step 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 WALK AWAY MODE, Double-click the blue power button.
- The display window reads "ADD SPECIMEN TO TEST DEVICE AND INSERT IMMEDIATELY"

Step 7B: Adding the specimen to the test device



- Invert the tube, holding it vertically (approximately one inch above the BD Veritor System test device 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.

Step 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 your 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 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 addition of the extracted sample to the test device, restart the Analyzer, select Walk-Away Now mode and insert the device again for a 15-minute read. If this happens after 5 minutes have elapsed, discard the test device and begin the assay process again from step 7B above. This may require a new patient specimen if insufficient volume remains.

Step 9B: Record the Result

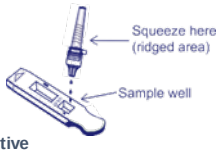
- When analysis is complete, the test result appears in the display window. Record the result and discard the test device appropriately.

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 BD Veritor bar code scanning module installed

Step 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.

Step 7C: Timing development

- Allow the test to develop for **15 minutes but no longer than 20 minutes.**

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.

- **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 positive or control invalid result.**

Step 8C: Using the BD Veritor Plus Analyzer

During the 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 test device into the slot on the right side of the BD Veritor Plus Analyzer.

Step 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 a printer is not connected, record the result before removing the assay device.**

Step 10C: Remove 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.

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

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

Step 6D: Starting Walk Away mode

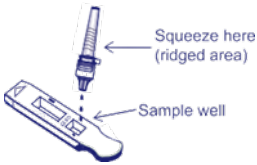
- Turn on the BD Veritor Plus Analyzer by pressing the blue power button once. The display window will briefly show "SCAN CONFIG BARCODE". This is an opportunity to change the configuration of the BD Veritor Plus Analyzer. Please refer to the BD Veritor Plus Analyzer Instructions for Use for configuration 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.

Step 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.**

Step 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 test 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 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.

Step 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 a 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).

Step 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
Flu A: - Flu B: - CoV2: -	Negative Test for Flu A, Flu B and SARS-CoV-2 (no antigen detected)
Flu A: + Flu B: - CoV2: -	Positive test for Flu A (influenza A antigen detected)
Flu A: - Flu B: + CoV2: -	Positive test for Flu B (influenza B antigen detected)
Flu A: - Flu B: - CoV2: +	Positive test for SARS-CoV-2 (SARS-CoV-2 antigen detected)
Flu A: + Flu B: - CoV2: +	Positive Test for Flu A and SARS-CoV-2 (Flu A and SARS-CoV-2 antigens detected)
Flu A: - Flu B: + CoV2: +	Positive Test for Flu B and SARS-CoV-2 (Flu B and SARS-CoV-2 antigens detected)
RESULT INVALID	Result invalid. Repeat the test
POSITIVE CONTROL INVALID	Test Invalid.* Repeat the test.
NEGATIVE CONTROL INVALID	Test Invalid.* Repeat the test.

The BD Veritor Plus System Analyzer reports dual positive influenza A and influenza B results as "RESULT INVALID" including if the SARS-CoV-2 result is also positive. Specimens generating "RESULT INVALID" should be retested. Upon retesting of the same specimen, if the specimen produces "RESULT INVALID" again, the user should retest using other methods (e.g., molecular testing) to determine whether the sample is positive or negative for SARS-CoV-2 or influenza virus.

Test Invalid – If the test is invalid, the BD Veritor System Instrument will display "POSITIVE CONTROL INVALID" or "NEGATIVE CONTROL INVALID" and the patient specimen or control swab assay must then be repeated. Do not report results. Repeat the test. It may be necessary to collect a fresh patient specimen, if more than one hour has passed since specimen collection, or more than 30 minutes since the specimen was placed into extraction buffer. If the "CONTROL INVALID" reading recurs, contact BD. Consult BD Veritor Plus Analyzer for more information.

REPORTING OF RESULTS

Positive Tests – Positive results indicate the presence of SARS-CoV-2 or influenza 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 not measured by this test. The agent detected may not be the definite cause of disease. Testing facilities within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.

Negative SARS-CoV-2 Results – Negative SARS-CoV-2 results should be treated as 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. Testing facilities within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.

Negative Flu Results - A negative test is presumptive for influenza A and B and it is recommended these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative results do not preclude influenza virus infections and should not be used as the sole basis for treatment or other patient management decisions.

Batch Testing - Processing errors may occur when inadequate time is planned between multiple specimens in batch mode, resulting in false positive or false negative results. 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. (Refer to *Guidance for SARS-CoV-2 Point-of-Care Testing*: https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html)

QUALITY CONTROL

Each BD Veritor System 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 use of the test device.
- The Negative control line (not marked on device) controls for sample specific non-specific signal.
- 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 CONTROL SWABS

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

BD recommends positive 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 BD Technical Services at 1.800.638.8663.

LIMITATIONS OF THE PROCEDURE

- Clinical performance was evaluated with frozen samples, and test performance may be different with fresh samples.
- Users should test specimens as quickly as possible after specimen collection and always process the swab within one hour of specimen collection and within 30 minutes of placing the swab into the extraction reagent.
- The performance of this test was not evaluated for SARS-CoV-2, influenza A or B detection with samples collected in viral transport media and should not be used with this test.
- 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 & Flu A+B 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 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. Between specimens and after batch testing, instruments should be carefully cleaned following recommended disinfection procedures. (Refer to *Guidance for SARS-CoV-2 Point-of-Care Testing*: https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html).
- Do not analyze test devices before 15 minutes as this could result in a false negative or invalid result. Do not analyze devices after 20 minutes as false positive or invalid results may occur. When processing multiple samples in batch testing, users should take extra care to monitor proper timing for each specimen.
- The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 6 of illness are more likely to be negative when compared to an 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 and influenza antigens from nasal swab specimens only. This test can detect both viable and non-viable viral material. The BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A + B 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 any infections due to analytes not included on this test.
- Positive and negative predictive values are highly dependent on prevalence rates. Positive test results are more likely to represent false positive results during periods when disease prevalence is low. False negative test results are more likely when prevalence of disease caused by SARS-CoV-2 or influenza 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 or influenza viruses that have undergone minor amino acid changes in the target epitope region.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected in October 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.

- Minor changes were made to the BD Veritor System for Rapid Detection of Flu A+B device to accommodate the addition of SARS-CoV-2 detection reagents. Performance characteristics for influenza A and B were not re-established with the modified device and may vary from previous performance.
- The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection and performance may differ in asymptomatic individuals.
- Negative results for SARS-CoV-2, influenza A, or influenza B should be treated as presumptive and confirmed with an FDA authorized or cleared 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.
- Users should test specimens as quickly as possible after specimen collection, always within one hour after specimen collection and within 30 minutes of placing swab into extraction reagent.
- The validity of the BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A + B 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 & Flu A + B 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 & Flu A + B ("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 authorized labeling -"BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A + B" Instructions for Use and Quick Reference Instructions. 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 must 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

Performance of the BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B compared to RT-PCR for SARS-CoV-2 detection

The performance of the BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B was established with 278 direct nasal swabs prospectively collected and enrolled from individual symptomatic patients (within six days of symptom onset) who were suspected of COVID-19. As with all antigen tests, performance may decrease as days since symptom onset increase. Samples were collected by qualified personnel in six geographically diverse areas across the United States.

Two nasal swabs were collected simultaneously 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 frozen until tested. Specimens enrolled at the six sites were selected based on a specified date range; specimens were tested sequentially by site in a blinded fashion. The performance of the BD Veritor System Assay was compared to results of a nasal swab stored in 3 mL viral transport media tested with an Emergency Use Authorized molecular (RT-PCR) test for detection of SARS-CoV-2.

Table 1: Summary of the Performance of the BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B Assay compared to RT-PCR for Nasal Swabs for detection of SARS-CoV-2

BD Veritor Results for Detection of SARS-CoV-2	Reference RT-PCR Results for detection of SARS-CoV-2		
	POS	NEG	Total
POS	52*	1	53
NEG	8	217**	225
Total	60	218	278

PPA: 86.7% (C.I. 75.8%, 93.1%)
NPA: 99.5% (C.I. 97.4%, 99.9%)

*Of the 52 concordant SARS-CoV-2 positive samples, BD Veritor identified 1 dual positive (Flu B false positive and SARS-CoV-2 true positive) test result from one sample.
**Of the 217 concordant SARS-CoV-2 negative samples, BD Veritor identified 1 Flu B false positive sample and 1 Flu A false positive sample.

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

Table 2: Demographics for the 278 specimens used in the study above

	Subject Demographics for nasal swabs BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B Assay result		
Age Group	Total #	Total Positive	Prevalence
18 - 21 Years	10	4	40.0%
22 - 49 Years	147	25	17.0%
50 - 59 Years	63	11	17.5%
60 - 69 Years	42	7	16.7%
70 - 79 Years	13	5	38.5%
>=80 Years	3	1	33.3%

Agreement of the BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B with the BD Veritor System for Rapid Detection of Flu A+B (previously cleared device)

The clinical performance of the influenza detection portion of the BD Veritor™ System for the Rapid Detection of SARS-CoV-2 & Flu A+B assay was performed with a total of 75 influenza positive clinical remnant specimens (40 influenza A positive, and 35 influenza B positive) and 40 influenza A+B influenza negative specimens. These clinical specimens were remnants of NP swabs collected in an original volume of 3.0 mL UVT media. All specimens were stored frozen at -70°C before analysis. The remnant samples were tested in a randomized, blinded fashion in both the BD Veritor™ System for the Rapid Detection of SARS-CoV-2 & Flu A+B and the BD Veritor™ System for the Rapid Detection of Flu A+B assays.

Results presented in the two tables below demonstrate the concordance between the previously cleared BD Veritor System Flu A+B assay and the Flu A+B detection capability of the BD Veritor SARS-CoV-2 & Flu A+B assay. Results presented here are also 100% concordant with historical reference RT-PCR results for all 115 specimens.

Table 3: Agreement between the BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A + B and the BD Veritor System for Rapid Detection of Flu A+B for Detection of Flu A

FLU A detection:	BD Veritor System for Rapid Detection of Flu A+B Assay result		
BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B Assay result	FLU A POS	FLU A NEG (Flu B positives + Flu A+B negatives)	Total
POS	40	0	40
NEG	0	75	75
Total	40	75	115
PPA: 100% (C.I. 91.2%, 100%) NPA: 100% (C.I. 95.2%, 100%)			

Table 4: Agreement between the BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A + B and the BD Veritor System for Rapid Detection of Flu A+B for Detection of Flu B

FLU B detection:	BD Veritor System for Rapid Detection of Flu A+B Assay result		
BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B Assay Result	Flu B POS	Flu B NEG (Flu A positives + Flu A+B negatives)	Total
POS	35	0	35
NEG	0	80	80
Total	35	80	115
PPA: 100% (C.I. 90.0%, 100%) NPA: 100% (C.I. 95.5%, 100%)			

Flu A+B detection performance estimation

Performance characteristics of the BD Veritor System for Rapid Detection of Flu A+B test were established in prospective, multi-center, Point-of-Care (POC) studies conducted during the 2010–2011 Flu season. The specimens consisted of nasal and nasopharyngeal swabs from patients symptomatic for Influenza. Performance of the BD Veritor Flu A+B assay was compared to an FDA cleared RT-PCR method. The BD Veritor System for the Rapid Detection of Flu A+B test initially demonstrated a PPA of 83.6% and NPA of 97.5% for influenza A, and a PPA of 81.3% and NPA of 98.2% for influenza B in the clinical studies conducted during the 2010-2011 Flu season. The BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B represents the addition of SARS-CoV-2 detection reagents to the previously cleared Flu A+B assay product. Minor modifications were made to accommodate this change and to optimize SARS-CoV-2 detection. No prospective clinical trial was performed to re-establish Flu A+B performance claims with the modified device. Instead, a retrospective analysis of previously submitted Flu A+B performance data modeling the possible impact of these changes was performed. The tables below present this analysis. While a small performance difference is shown here, an analysis of the two data sets confirm that this difference is not statistically significant.

Table 5: Flu A Detection

	RT-PCR Reference results		
BD Veritor System for Rapid Detection of Flu A+B	Flu A POS	Flu A NEG (Flu B positives + Flu A+B negatives)	Total
POS	187	13	200
NEG	39	497	536
Total	226	510	736
Reference Method: PCR PPA: 82.7% (C.I. 74.9%, 88.5%) NPA: 97.5% (C.I. 95.7%, 98.5%)		Wald 95% Confidence intervals corrected for over-dispersion, where needed, due to potential variability between sites.	

Table 6: Flu B Detection

	RT-PCR Reference results		
BD Veritor System for Rapid Detection of Flu A+B	Flu B POS	Flu B NEG (Flu A positives + Flu A+B negatives)	Total
POS	138	10	149
NEG	33	555	587
Total	171	565	736
Reference Method: PCR PPA: 80.7% (C.I. 70.3%, 88.1%) NPA: 98.2% (C.I. 95.7%, 99.3%)		Wald 95% Confidence intervals corrected for over-dispersion, where needed, due to potential variability between sites.	

ANALYTICAL PERFORMANCE

Limit of detection for SARS-CoV-2 (Analytical Sensitivity)

The SARS-CoV-2 limit of detection (LoD) for the BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B was established using limiting dilutions of a sample of SARS-CoV-2 USA-WA1/2020 inactivated by gamma irradiation obtained from BEI Resources. This material was supplied at a concentration of 2.8 x 10^5 $TCID_{50}$/mL and diluted in confirmed-negative clinical matrix derived from nasal or nasopharyngeal swab specimens that had been expressed in viral transport media. In this study, designed to estimate the LoD of the assay when using a direct nasal swab, 50 µL of each dilution was transferred to a swab and tested in the BD Veritor assay using the procedure appropriate for patient nasal swab specimens. After an initial range-finding 10-fold dilution series, the tentative LoD was identified as the lowest 2-fold dilution to give positive results in 100% of three replicates. At this tentative LoD, 20 replicates were prepared and tested to confirm the LoD by demonstrating ≥95% positivity.

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

Limit of detection for influenza (Analytical Sensitivity):

Flu A and Flu B analytical sensitivity were established as part of the FDA clearance of the BD Veritor System for the Rapid Detection of Flu A+B (K112277 and K151291). To confirm equivalent analytical sensitivity between this BD Veritor SARS-CoV-2 & Flu A+B assay and the previously cleared Flu A+B assay, an LoD study was conducted in which each dilution in a two-fold series was tested on both assays simultaneously. Dilutions were created with live virus in confirmed-negative clinical matrix and tested by transferring 50 µL to a swab and following the procedure appropriate for patient nasal swab specimens. The tentative LoD was identified as the lowest 2-fold dilution to give positive results for all of three replicates, and the LoD was confirmed when ≥95% of 20 replicates tested positive. For the two Flu A strains and one of the two Flu B strains tested in this side-by-side study, the LoD of the SARS-CoV-2 & Flu A+B assay was confirmed at the same dilution as the previously cleared BD Veritor Flu A+B assay. For the B/Brisbane/60/2008 strain, the LoD of the SARS-CoV-2 & Flu A+B assay was confirmed at one two-fold dilution lower than the previous cleared BD Veritor Flu A+B assay.

Table 7: Limit of Detection

Influenza virus (Type/Subtype)	Virus Strain name	Starting Material Concentration	Estimated LoD for SARS-CoV-2 & Flu A+B Assay	Estimated LoD for Flu A+B Assay using direct-swab workflow*
H1N1	A/California/07/2009	1 x 10^8 $TCID_{50}$/mL	5.0 x 10^4 $TCID_{50}$/mL	5.0 x 10^4 $TCID_{50}$/mL
H3N2	A/Victoria/3/75	4.11 x 10^7 $TCID_{50}$/mL	4.11 x 10^4 $TCID_{50}$/mL	4.11 x 10^4 $TCID_{50}$/mL
Yamagata lineage	B/Phuket/3073/2013	1 x $10^{9.9}$ EID_{50}/mL	3.97 x 10^7 EID_{50}/mL	3.97 x 10^7 EID_{50}/mL
Victoria lineage	B/Brisbane/60/2008	1 x $10^{9.9}$ EID_{50}/mL	7.94 x 10^6 EID_{50}/mL	1.59 x 10^7 EID_{50}/mL

* Note: The LoD values generated in this study cannot be compared directly to LoD values reported in the instructions for use for the BD Veritor System for Rapid Detection of Flu A+B (8087667) because of differences in testing protocol.

Strain Reactivity - Influenza:

The analytical reactivity of the monoclonal antibodies targeting Flu A and Flu B used in this product has been demonstrated as part of previous FDA review of the BD Veritor System for the Rapid Detection of Flu A+B. To augment these established performance results, the BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B was evaluated using a panel of contemporary influenza virus strains provided by the US Centers for Disease Control and Prevention as representative of strains circulating in 2020. After an initial set of range-finding 10-fold dilutions, each strain was tested with the swab workflow in a series of 2-fold dilutions with five replicates at each dilution until a point at which all the replicates were negative.

Table 8: Flu Strain Reactivity for the BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B

Influenza Virus (Type/Subtype)	Virus Strain Name	Virus Serial Dilution Concentration (EID_{50}/mL) and Number of Positive Results at Each Dilution (N=5)					
A(H3N2)	A/Perth/16/2009	EID_{50}/mL	2.00×10^6	9.98×10^5	**4.99×10^5**	2.49×10^5	N/A
		# Detected	5	5	**5**	0	N/A
		% Detected	100	100	**100**	0	N/A
A(H3N2)	A/Hong Kong/2671/2019	EID_{50}/mL	3.16×10^6	1.58×10^6	**7.91×10^5**	3.95×10^5	N/A
		# Detected	5	5	**5**	0	N/A
		% Detected	100	100	**100**	0	N/A
A(H1N1)pdm09	A/Christ Church/16/2010	EID_{50}/mL	1.58×10^7	**7.92×10^6**	3.96×10^6	N/A	N/A
		# Detected	5	**5**	0	N/A	N/A
		% Detected	100	**100**	0	N/A	N/A
A(H1N1)pdm09	A/Guandong-Maonan/1536/2019	EID_{50}/mL	1.26×10^7	6.29×10^6	3.15×10^6	**1.57×10^6**	1.26×10^6
		# Detected	5	5	3	**1**	0
		% Detected	100	100	60	**20**	0
B (Victoria Lineage)	B/Michigan/09/2011	EID_{50}/mL	7.94×10^4	**3.97×10^4**	1.99×10^4	N/A	N/A
		# Detected	5	**4**	0	N/A	N/A
		% Detected	100	**80**	0	N/A	N/A
B (Victoria Lineage)	B/Washington/02/2019	EID_{50}/mL	1.58×10^6	**7.92×10^5**	3.96×10^5	N/A	N/A
		# Detected	5	**1**	0	N/A	N/A
		% Detected	100	**20**	0	N/A	N/A
B (Yamagata Lineage)	B/Texas/81/2016	EID_{50}/mL	2.00×10^5	**9.98×10^4**	4.99×10^4	N/A	N/A
		# Detected	5	**5**	0	N/A	N/A
		% Detected	100	**100**	0	N/A	N/A
B (Yamagata Lineage)	B/Phuket/3073/2013	EID_{50}/mL	7.94×10^7	3.97×10^7	1.99×10^7	**9.93×10^6**	7.94×10^6
		# Detected	5	5	5	**2**	0
		% Detected	100	100	100	**40**	0

To comply with FDA Class 2 Special Controls applicable to rapid influenza detection tests, flu strain reactivity of the BD Veritor System for Rapid Detection of Flu A+B assay was demonstrated for the same influenza strains as shown in Table 8 above using the protocol recommended by the US Centers for Disease Control. Starting material is tested in 5-fold serial dilutions until two consecutive dilutions are negative. The BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B assay detected the tested strains at lower concentrations compared to the previously 510(K) cleared BD Veritor Flu A+B assay. However, these experiments were carried out at different times and represent different evaluation protocols, so side-by-side comparisons are not applicable.

Table 9: Flu Strain Reactivity for the BD Veritor System for Rapid Detection of Flu A+B

Influenza Virus (Type/Subtype)	Virus Strain Name	Virus Serial Dilution Concentration (EID_{50}/mL) and Number of Positive Results at Each Dilution (N=5)					
A(H3N2)	A/Perth/16/2009	EID_{50}/mL	$8.0x10^7$	$1.6x10^7$	**$3.2x10^6$**	$6.4x10^5$	$1.3x10^5$
		# Detected	5/5	5/5	**5/5**	0/5	0/5
		% Detected	100%	100%	**100%**	0%	0%
A(H3N2)	A/Hong Kong/2671/2019	EID_{50}/mL	$6.3x10^6$	**$1.3x10^6$**	$2.5x10^5$	$5.1x10^4$	$1.0x10^4$
		# Detected	5/5	**4/5**	0/5	0/5	0/5
		% Detected	100%	**80%**	0%	0%	0%
A(H1N1)pdm09	A/Christ Church/16/2010	EID_{50}/mL	$6.3x10^8$	$1.3x10^8$	**$2.5x10^7$**	$5.1x10^6$	$1.0x10^6$
		# Detected	5/5	5/5	**5/5**	0/5	0/5
		% Detected	100%	100%	**100%**	0%	0%
A(H1N1)pdm09	A/Guandong-Maonan/1536/2019	EID_{50}/mL	$2.5x10^8$	$5.0x10^7$	**$1.0x10^7$**	$2.0x10^6$	$4.0x10^5$
		# Detected	5/5	5/5	**3/5**	0/5	0/5
		% Detected	100%	100%	**60%**	0%	0%
B (Victoria Lineage)	B/Michigan/09/2011	EID_{50}/mL	$1.6x10^6$	$3.2x10^5$	**$6.4x10^4$**	$1.3x10^4$	$2.5x10^3$
		# Detected	5/5	5/5	**1/5**	0/5	0/5
		% Detected	100%	100%	**20%**	0%	0%
B (Victoria Lineage)	B/Washington/02/2019	EID_{50}/mL	$6.3x10^7$	$1.3x10^7$	**$2.5x10^6$**	$5.1x10^5$	$1.0x10^5$
		# Detected	5/5	5/5	**5/5**	0/5	0/5
		% Detected	100%	100%	**100%**	0%	0%
B (Yamagata Lineage)	B/Texas/81/2016	EID_{50}/mL	$8.0x10^6$	$1.6x10^6$	**$3.2x10^5$**	$6.4x10^4$	$1.3x10^4$
		# Detected	5/5	5/5	**5/5**	0/5	0/5
		% Detected	100%	100%	**100%**	0%	0%
B (Yamagata Lineage)	B/Phuket/3073/2013	EID_{50}/mL	$1.6x10^9$	$3.2x10^8$	**$6.4x10^7$**	$1.3x10^7$	$2.5x10^6$
		# Detected	5/5	5/5	**5/5**	0/5	0/5
		% Detected	100%	100%	**100%**	0%	0%

The influenza strains previously demonstrated to show analytical reactivity with the monoclonal antibodies targeting Flu A and Flu B used in this product are shown in the following tables. Additional information detailing this testing can be found in the Instructions for Use for the BD Veritor System for Rapid Detection of Flu A+B (BD document 8087667)..

Table 10: Previously Demonstrated Flu A Strain Reactivity (BD SKU 256045)

Flu A Strain	Subtype	Minimal Detected Concentration on the Flu A+B Assay using a liquid-sample workflow
A/Brisbane/59/2007	H1N1	3.3 x 10^2 $TCID_{50}$/mL
A/California/7/2009	H1N1	5.0 x 10^3 $TCID_{50}$/mL
A/Denver/1/57	H1N1	4.45 x 10^4 $CEID_{50}$/mL
A/FM/1/47	H1N1	7.91 x 10^4 $CEID_{50}$/mL
A/Fujian-Gulou/1896/2009	H1N1	4.5 x 10^5 $CEID_{50}$/mL
A/Mal/302/54	H1N1	2.22 x 10^5 $CEID_{50}$/mL
A/New Caledonia/20/1999	H1N1	2.5 x 10^3 $TCID_{50}$/mL
A/New Jersey/8/76	H1N1	1.58 x 10^3 $CEID_{50}$/mL
A/NWS/33	H1N1	1.58 x 10^4 $CEID_{50}$/mL
A/PR/8/34	H1N1	6.31 x 10^2 $TCID_{50}$/mL
A/Solomon Island/03/2006	H1N1	2.5 x 10^3 $TCID_{50}$/mL
A/Washington/24/2012	H1N1	3.16 x 10^4 EID_{50}/mL
A/Weiss/43	H1N1	7.03 x 10^6 $CEID_{50}$/mL
A/WS/33	H1N1	7.91 x 10^2 $CEID_{50}$/mL
A/Aichi/2/68	H3N2	7.91 x 10^3 $CEID_{50}$/mL
A/Brisbane/10/2007	H3N2	7.27 x 10^2 $TCID_{50}$/mL
A/California/02/2014	H3N2	1.45 x 10^2 $TCID_{50}$/mL
A/Hong Kong/8/68	H3N2	8.89 x 10^4 $CEID_{50}$/mL
A/Moscow/10/99	H3N2	5.8 x 10^5 $TCID_{50}$/mL
A/Perth/16/2009	H3N2	1.0 x 10^6 $TCID_{50}$/mL
A/Port Chalmers/1/73	H3N2	3.95 x 10^4 $CEID_{50}$/mL
A/Switzerland/9715293/2013	H3N2	3.25 x 10^2 $TCID_{50}$/mL
A/Texas/50/2012	H3N2	1.75 x 10^3 $TCID_{50}$/mL
A/Wisconsin/67/2005	H3N2	2.5 x 10^5 $TCID_{50}$/mL
A/Victoria/3/75	H3N2	3.11 x 10^3 $TCID_{50}$/mL
A/Indiana/08/2011	H3N2v	1 x 10^4 $TCID_{50}$/mL
A/Indiana/10/2011	H3N2v	7.9 x 10^6 $CEID_{50}$/mL
A/Kansas/13/2009	H3N2v	1.0 x 10^3 $TCID_{50}$/mL
A/Minnesota/11/2010	H3N2v	7.9 x 10^5 $CEID_{50}$/mL
A/Pennsylvania/14/2010	H3N2v	1.26 x 10^6 $CEID_{50}$/mL
A/West Virginia/06/2011	H3N2v	7.9 x 10^3 $TCID_{50}$/mL
A/Anhui/01/2005	H5N1	0.512 HA
A/Vietnam/1203/2004	H5N1	0.512 HA
A/Northern	H5N2	6.28 x 10^5 EID_{50}/mL
A/Pheasant/NewJersey/1355/1998	H5N2	0.256 HA
A/Gyrfalcon/Washington/41088-	H5N8	1.98 x 10^6 EID_{50}/mL
A/Mallard/Netherlands/12/2000	H7N7	0.256 HA
A/Anhui/1/2013	H7N9	5.42 x 10^6 $CEID_{50}$/mL
A/Chicken/HongKong/G9/1997	H9N2	1.024 HA

EID_{50} = 50% Egg Infectious Dose
$TCID_{50}$ = 50% Tissue Culture Infectious Dose
$CEID_{50}$ = 50% Chicken Embryo Infectious Dose
HA = Hemagglutination Assay

Table 11: Previously Demonstrated Flu B Strain Reactivity (BD SKU 256045)

Flu B Strain	Minimal Detected Concentration on the Flu A+B Assay using a liquid-sample workflow
B/Brazil/178/96	2.32×10^4 $TCID_{50}$/mL
B/Brisbane/33/2008 (Victoria Lineage)	2.45×10^5 $CEID_{50}$/mL
B/Brisbane/60/2008	7.42×10^3 $TCID_{50}$/mL
B/Brisbane/72/97	1.00×10^4 $TCID_{50}$/mL
B/Canada/548/99	>0.64 HA
B/Egypt/393/99	>1.28 HA
B/Florida/2/2006	1.08×10^4 $TCID_{50}$/mL
B/Florida/4/2006	1.30×10^3 $TCID_{50}$/mL
B/Fujian/93/97	3.95×10^5 $TCID_{50}$/mL
B/Fukushima/220/99	9.33×10^2 $TCID_{50}$/mL
B/Guangdong-Liwan/1133/2014 (Yamagata Lineage)	9.0×10^5 $CEID_{50}$/mL
B/GuangXi/547/98	2.32×10^5 $TCID_{50}$/mL
B/Hawaii/01/97	>6.4 HA
B/Hong Kong/5/72	1.11×10^4 $CEID_{50}$/mL
B/Hong Kong/219/98	>1 HA
B/Hong Kong/259/2010(Victoria Lineage)	1.35×10^6 $CEID_{50}$/mL
B/Jiangsu/10/2003	1.16×10^4 $TCID_{50}$/mL
B/Johannesburg/5/99	3.95×10^4 $TCID_{50}$/mL
B/Lee/40	4.44×10^4 $CEID_{50}$/mL
B/Lisbon/03/96	>0.08 HA
B/Malaysia/2506/2004	5.0×10^4 $TCID_{50}$/mL
B/Maryland/1/59	3.51×10^2 $CEID_{50}$/mL
B/Massachusetts/2/2012 (Yamagata Lineage)	1.25×10^6 $CEID_{50}$/mL
B/Mass/3/66	1.58×10^5 $CEID_{50}$/mL
B/Montana/5/2012	3.14×10^5 EID_{50}/mL
B/Ohio/11/96	>0.16 HA
B/Ohio/1/05	1.34×10^5 $TCID_{50}$/mL
B/Phuket/3073/2013	6.08×10^3 $TCID_{50}$/mL
B/Puerto Mont/10427/98	0.02 HA
B/Russia/69	3.9×10^2 $TCID_{50}$/mL
B/Shandong/7/97	1.58×10^6 $TCID_{50}$/mL
B/Shanghai/04/97	1.58×10^5 $TCID_{50}$/mL
B/Shenzhen/135/97	3.16×10^4 $TCID_{50}$/mL
B/Sichuan/116/96	0.016 HA
B/Taiwan/2/62	2.81×10^2 $CEID_{50}$/mL
B/Texas/06/2011 (Yamagata Lineage)	6.2×10^5 $CEID_{50}$/mL
B/Texas/02/2013 (Victoria Lineage)	2.75×10^4 $CEID_{50}$/mL
B/Utah/09/2014 (Yamagata Lineage)	6.3×10^3 $CEID_{50}$/mL
B/Victoria/504/00	4.64×10^4 $TCID_{50}$/mL
B/Wisconsin/01/2010 (Yamagata Lineage)	7.0×10^2 $CEID_{50}$/mL
B/Yamagata/16/88	9.75×10^3 $TCID_{50}$/mL
B/Yamanashi/166/98	4.88×10^4 $TCID_{50}$/mL

EID_{50} = 50% Egg Infectious Dose
$TCID_{50}$ = 50% Tissue Culture Infectious Dose
$CEID_{50}$ = 50% Chicken Embryo Infectious Dose
HA = Hemagglutination Assay

HIGH DOSE HOOK EFFECT

No high dose hook effect was observed with up to 2.8×10^6 $TCID_{50}$/mL of gamma-inactivated SARS-CoV-2, up to 2.0×10^9 EID_{50}/mL of Flu A virus, or up to 7.9×10^9 EID_{50}/mL of Flu B virus with the BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B test.

ENDOGENOUS INTERFERING SUBSTANCES

Because the specific monoclonal antibodies targeting SARS-CoV-2 utilized in this assay are identical to those used in the BD Veritor System for Rapid Detection of SARS-CoV-2 assay, the endogenous and microbial interfering substance testing was not repeated. The results in Tables 12 and 13 were generated with the previously authorized product.

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

Table 12:

Substance	Concentration Tested	Interference (Yes/No)
Afrin Nasal Spray (Oxymetazoline)	15% v/v	No
Flonase (Fluticasone)	5% v/v	No
Nasacort (Triamcinolone)	5% v/v	No
Neo-Synephrine (Phenylephrine hydrochloride)	15% v/v	No
Oseltamivir	2.2 µg/mL	No
Mucin protein	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 (Dyclonine/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
Rheumatoid Factor*	12.5 IU/mL	No

*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 unknown 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 sample and 5x LoD sample. No interference was observed.

Table 13:

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 influenza	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 IFU/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 sample and a sample spiked with SARS-CoV-2 at approximately three times the assay limit of detection. At the following levels, no interference was noted.		
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 influenza	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

CROSS REACTIVITY (ANALYTICAL SPECIFICITY)

Cross-reactivity of the BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B was evaluated by testing a panel of respiratory pathogens that could potentially cross-react with the analyte detection reagents in the test device. Each microorganism, virus or negative matrix was tested in triplicate. Testing showed no evidence of cross-reactivity at the concentrations tested.

Potential Cross-Reactant	Concentration Tested	Cross-Reactivity with SARS-CoV-2 test line (Yes/No)	Cross-Reactivity with Flu A test line (Yes/No)	Cross-Reactivity with Flu B test line (Yes/No)
Human coronavirus 229E (Heat inactivated)	1.0×10^5 U/mL	No	No	No
Human coronavirus OC43	1.0×10^5 $TCID_{50}$/mL	No	No	No
Human coronavirus NL63	1.0×10^5 $TCID_{50}$/mL	No	No	No
Adenovirus Type 3	1.0×10^5 $TCID_{50}$/mL	No	No	No
Human Metapneumovirus (HMPV), A2	1.0×10^5 $TCID_{50}$/mL	No	No	No
Parainfluenza virus 1	1.0×10^5 $TCID_{50}$/mL	No	No	No
Parainfluenza virus 2	1.0×10^5 $TCID_{50}$/mL	No	No	No
Parainfluenza virus 3	1.6×10^6 $TCID_{50}$/mL	No	No	No
Parainfluenza virus 4a	1.6×10^4 $TCID_{50}$/mL	No	No	No
Influenza A H1N1	2.5×10^5 $TCID_{50}$/mL	No	N/A	No
Influenza B	1.6×10^5 $TCID_{50}$/mL	No	No	N/A
Enterovirus D68	4.0×10^5 $TCID_{50}$/mL	No	No	No
Respiratory syncytial virus, strain Long	3.9×10^5 $TCID_{50}$/mL	No	No	No
Rhinovirus 3	1.0×10^5 PFU/mL	No	No	No
SARS-coronavirus (gamma irradiated)	2.5×10^5 $TCID_{50}$/mL	No	No	No
MERS-coronavirus (Heat inactivated)	1.5×10^5 $TCID_{50}$/mL	No	No	No
SARS-CoV-2 (gamma irradiated)	1.0×10^5 $TCID_{50}$/mL	N/A	No	No
Haemophilus influenzae	1.0×10^6 CFU/mL	No	No	No
Streptococcus pneumoniae	1.0×10^6 CFU/mL	No	No	No
Streptococcus pyogenes	1.0×10^6 CFU/mL	No	No	No
Bordetella pertussis	1.0×10^6 CFU/mL	No	No	No
Mycoplasma pneumoniae	1.0×10^6 CFU/mL	No	No	No
Chlamydia pneumoniae	1.0×10^6 IFU/mL	No	No	No
Legionella pneumophila	1.0×10^6 CFU/mL	No	No	No
Staphylococcus aureus	1.3×10^6 CFU/mL	No	No	No
Staphylococcus epidermidis	1.0×10^6 CFU/mL	No	No	No
Pooled human nasal wash	100%	No	No	No
Candida albicans	1.0×10^6 CFU/mL	No	No	No

To estimate the likelihood of SARS-CoV-2 cross-reactivity with 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 is highly unlikely.

COMPETITIVE INHIBITION

A competitive inhibition study was conducted to evaluate whether the presence of Flu A or Flu B virus will inhibit the detection of SARS-CoV-2 virus, and whether the presence of SARS-CoV-2 virus will inhibit the detection of Flu A or Flu B virus due to competition on the assay. For this study, contrived specimens were generated that contained both the potential inhibitor at clinically relevant concentration (at least 1 x 10^5 $TCID_{50}$/mL) and the target analyte at low concentration (no more than 3x LoD). Each condition was tested in triplicate, and all replicates were positive, demonstrating a low probability of false negatives under circumstances expected during co-infection. Testing results are presented in the table below.

Competitive virus	Concentration of competitor	Test target virus	Concentration of test target	Target signal inhibition (Y/N)
SARS-CoV-2 (gamma irradiated)	1.0 x 10^6 $TCID_{50}$/mL	Influenza A H1N1	7.5 x 10^4 $TCID_{50}$/mL	No
SARS-CoV-2 (gamma irradiated)	1.0 x10^5 $TCID_{50}$/mL	Influenza B	6.0 x 10^6 $TCID_{50}$/mL	No
Influenza A H1N1	1.0 x 10^5 $TCID_{50}$/mL	SARS-CoV-2 (gamma irradiated)	8.4 x 10^2 $TCID_{50}$/mL	No
Influenza B	1.3 x 10^7 $TCID_{50}$/mL	SARS-CoV-2 (gamma irradiated)	8.4 x 10^2 $TCID_{50}$/mL	No

TECHNICAL SUPPORT

For questions, or to report a problem, please call Technical Support at 1.800.638.8663. 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 http://www.fda.gov/medwatch).

Outside the USA, contact your local BD representative.

REFERENCES

1. Centers for Disease Control and Prevention. Accessed March 30, 2020.
2. https://www.cdc.gov/flu/symptoms/flu-vs-covid19.htm
3. Simonsen L., Fukuda K, Schonberger LB, Cox NJ. Impact of influenza epidemics on hospitalizations. J. Infect. Dis. 2000;181:831-7
4. Thompson WW, Shay DK, Weintraub E, et al. Mortality associated with influenza and respiratory syncytial virus in the United States. JAMA 2003: 289:179-86

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

Change History

Revision	Date	Change Summary
01	2020-12	Initial release.

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

SYMBOL GLOSSARY / GLOSSAR DER SYMBOLE / GLOSARIO DE SÍMBOLOS / GLOSSAIRE DES SYMBOLES / LEGENDA DEI SIMBOLI / SYMBOLFÖRTECKNING	
EC REP	Authorized Representative / Autorisierte Vertretung / Representante autorizado / Représentant autorisé / Rappresentante autorizzato / Auktoriserad representant
LOT	Batch Code / Chargenbezeichnung / Código de lote / Code de lot / Codice di lotto / Batchkod
	Biological Risk / Biologisches Risiko / Riesgo biológico / Risque biologique / Rischio biologico / Biologisk risk
	CE Marking / CE-Zeichen / Marcado CE / Marquage CE / Marcatura CE / CE-märkning
REF	Catalogue Number / Artikelnummer / Número de catálogo / Référence du catalogue / Numero di catalogo / Katalognummer
	Caution / Achtung / Precaución / Attention / Attenzione / Viktigt!
	Consult Instructions for Use / Gebrauchsanweisung beachten / Consultar instrucciones de uso / Consulter la notice d'utilisation / Consultare le istruzioni per l'uso / Se bruksanvisningen
	Contains sufficient for <n> tests / Inhalt ausreichend für <n> Tests / Contenido suficiente para <n> pruebas / Contenu suffisant pour <n> tests / Contenuto sufficiente per <n> test / Innehåller tillräckligt för <n> analyser
CONTROL +	Control, Positive / Kontrolle, positiv / Control, positivo / Contrôle, positif / Controllo positivo / Kontroll, positiv
CONTROL -	Control, Negative / Kontrolle, negativ / Control, negativo / Contrôle, négatif / Controllo negativo / Kontroll, negativ
	Date of Manufacture / Herstellungsdatum / Fecha de fabricación / Date de fabrication / Data di produzione / Tillverkningsdatum
	Do Not Reuse / Nicht wiederverwenden / No reutilizar / Ne pas réutiliser / Non riutilizzare / Får inte återanvändas
	Fragile, Handle with Care / Zerbrechlich, bitte mit Vorsicht handhaben / Frágil, manejar con cuidado / Fragile, manipuler avec soin / Fragile, maneggiare con cura / Ömtåligt, hanteras varsamt
IVD	In Vitro Diagnostic / In-vitro-Diagnostikum / Diagnóstico in vitro / Diagnostic in vitro / Diagnostica in vitro / In vitro-diagnostik
	Manufacturer / Hersteller / Fabricante / Fabricant / Produttore / Tillverkare
	Recyclable / Wiederverwertbar / Reciclable / Recyclable / Riciclabile / Återvinningsbart
SN	Serial Number / Seriennummer / Número de serie / Numéro de série / Numero di serie / Serienummer
	Temperature Limitation / Temperaturbegrenzung / Límite de temperatura / Limitation de température / Limite di temperatura / Temperaturbegränsning
	This End Up / Oben / Este lado hacia arriba/ Haut / Lato alto / Den här sidan upp
	Use By Date / Verwendbar bis / Fecha de caducidad / Date de péremption / Data di scadenza / Förbrukningsdag

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

bd.com/e-labeling

IVD Rx Only 2 °C 30 °C

REF 256088
L012430(02)
2021-02

Quick Reference Instructions for SARS-CoV-2 & Flu A+B

Use of BD Veritor™ System for Rapid Detection of SARS-CoV-2 & Flu A+B with the BD Veritor™ Plus Analyzer

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

REF 256088

Quick Reference Instructions for SARS-CoV-2 & Flu A+B

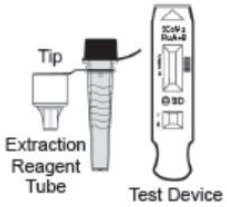
Use of BD Veritor™ System for Rapid Detection of SARS-CoV-2 & Flu A+B with the BD Veritor™ Plus Analyzer

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

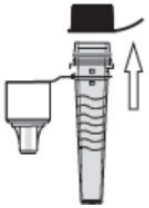
Read the complete test procedure, including recommended QC procedures before performing the test. Refer to the package insert for complete information about the test. Ensure ALL components are at room temperature (15–30 °C) when running the test. For use with anterior nasal swab samples.

Sample preparation

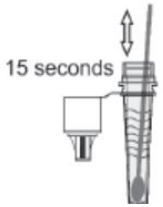
1 Gather test materials and label test device with specimen ID.



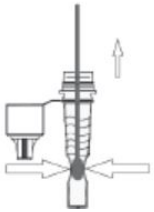
2 Remove cap from extraction reagent tube. Use only reagent tubes provided with this kit.



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



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

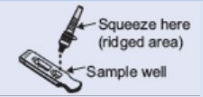


5 Press dispensing tip on the extraction reagent tube firmly. Mix the sample by flicking or swirling the bottom of the tube. Add sample to test device within 30 minutes.

Using the BD Veritor Plus Analyzer to read the assay device

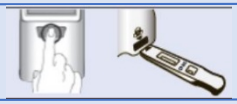
ANALYZE NOW MODE

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.

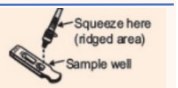
OR

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

REF 256088

Quick Reference Instructions for SARS-CoV-2 & Flu A+B

Use of BD Veritor™ System for Rapid Detection of SARS-CoV-2 & Flu A+B with the BD Veritor™ Plus Analyzer

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

SPECIMEN COLLECTION AND HANDLING

Proper specimen collection and handling of 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

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 Test Results table at right.

Positive test results: 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 SARS-CoV-2results to the appropriate public health authorities.

Negative test results: Negative SARS-CoV-2 results should be treated as 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. A negative test is presumptive for influenza A and B and it is recommended these results be confirmed by an FDA-cleared influenza A and B molecular assay. Negative results do not preclude influenza virus infections and should not be used as the sole basis for treatment or other patient management decisions.

Invalid Test: If the test is invalid the BD Veritor Plus System Analyzer will display a "RESULT INVALID" or "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. Process according to the test procedures on the reverse side of this card. 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.

DEVICE TEST RESULTS

Analyzer Display	Interpretation
Flu A: – Flu B: – CoV2: –	Presumptive negative test for Flu A, Flu B and SARS-CoV-2 (no antigen detected)
Flu A: + Flu B: – CoV2: –	Positive test for Flu A (influenza A antigen detected)
Flu A: – Flu B: + CoV2: –	Positive test for Flu B (influenza B antigen detected)
Flu A: – Flu B: – CoV2: +	Positive test for SARS-CoV-2 (SARS-CoV-2 antigen detected)
Flu A: + Flu B: – CoV2: +	Positive test for Flu A and SARS-CoV-2 (Flu A and SARS-CoV-2 antigens detected)
Flu A: – Flu B: + CoV2: +	Positive test for Flu B and SARS-CoV-2 (Flu B and SARS-CoV-2 antigens detected)
RESULT INVALID*	Result invalid. Repeat the test
CONTROL INVALID	Test Invalid. Repeat the test

*The BD Veritor Plus System Analyzer reports dual positive influenza A and influenza B results as "Result Invalid". Specimens generating a "Result Invalid" should be retested. Upon retesting, if the specimen produces a "Result Invalid", the user may want to consider other methods to determine whether the sample is positive or negative for influenza virus.

Quick Reference Instructions for SARS-CoV-2 & Flu A+B
Use of BD Veritor™ System for Rapid Detection of SARS-CoV-2 & Flu A+B with the BD Veritor™ Plus Analyzer
In the USA: For use under Emergency Use Authorization (EUA) Only

REF 256088

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. Test results are NOT maintained in the display window when the device is removed or if the Analyzer is left unattended for more than 15 minutes (60 minutes if AC power adapter is connected).
5. Handle all specimens and related materials as if capable of transmitting infectious agents.
6. It is recommended to follow your institution's requirements for decontamination procedures or if spills occur. See the BD Veritor Analyzer Instructions for use for instrument cleaning.
7. Dispose of used materials as biohazardous waste in accordance with federal, state and local requirements.
8. **Ensure all components are at room temperature (15–30 °C) when running the test.**
9. 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.
10. 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; 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, influenza A and influenza B, 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the authorization is revoked sooner.

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

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

bd.com/e-labeling

Veritor™ System for Rapid Detection of SARS-CoV-2 & Flu A+B

Proper Nasal Swab Sample Collection

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

REF 256088

1

This BD Veritor System SARS-CoV-2 & Flu A+B 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

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 & Flu A+B Kit.

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

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

- 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, influenza and B, 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the authorization is revoked sooner.

2021-03
L012385(02)

bd.com/e-labeling