IVD Rx Only 30 °C 2 °C

REF 256088
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2023-05

Quick Reference Instructions

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

BD

Quick Reference Instructions

REF 256088

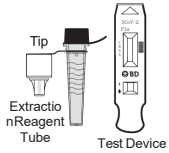
Use of BD Veritor™ System for Rapid Detection of SARS-CoV-2 & Flu A+B with the BD Veritor™ Plus Analyzer

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

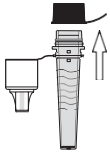
Read the complete test procedure, including recommended QC procedures before performing the test. Refer to the package insert for complete information about the test. Ensure ALL components are at room temperature (15–30 °C) when running the test. For use with anterior nasal swab samples.

Sample preparation

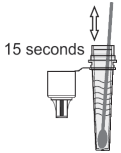
1 Gather test materials and label test device with specimen ID.



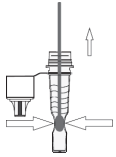
2 Remove cap from extraction reagent tube. Use only reagent tubes provided with this kit.



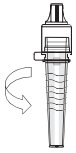
3 Taking care not to splash contents out of the tube, insert the swab into the tube and plunge the swab up and down in the fluid for a minimum of 15 seconds.



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



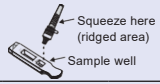
5 Press dispensing tip on the extraction reagent tube firmly. Mix the sample by flicking or swirling the bottom of the tube. Add sample to test device within 30 minutes.



Using the BD Veritor Plus Analyzer to read the assay device

ANALYZE NOW MODE

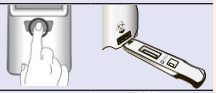
6 Add **3 drops** of the processed sample from the extraction reagent tube to the test device sample well, then properly dispose of the extraction reagent tube.



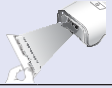
7 Allow test to develop for **15 minutes**. Do not disturb. Keep level.

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.



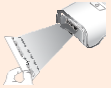
9 Result will appear on screen. Record result and remove test device. Properly dispose of test device. Do not re-read test devices.

OR

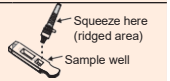
WALK AWAY MODE (instrument must be plugged in)

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.



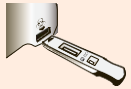
Add **3 drops** of the processed sample from the extraction reagent tube to the test device sample well, then properly dispose of the extraction reagent tube.



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.



Serial testing should be performed in symptomatic individuals with negative SARS-CoV-2 results at least twice over three days with 48 hours between tests.

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Quick Reference Instructions

REF 256088

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 SARS-CoV-2 test results: Repeat testing does not need to be performed if patients have a positive SARS-CoV-2 result at any time. A positive SARS-CoV-2 test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please instruct your patient to adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive SARS-CoV-2 result that is incorrect (a false positive). Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definitive cause of disease. Individuals who test positive for SARS-CoV-2 with the BD Veritor™ System for Rapid Detection of SARS-CoV-2 & Flu A+B should self-isolate. In some cases, additional confirmatory testing with a molecular test for positive SARS-CoV-2 results may also be necessary, if there is a low likelihood of COVID-19, such as individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection. Testing facilities within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.

Positive flu test results: Positive Flu A or Flu B results indicate the presence of influenza viral antigens, but correlation with patient history and other diagnostic information is necessary to determine infection status.

This test is not intended to detect influenza C antigens. 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 definitive cause of disease.

Negative SARS-CoV-2 test results: Negative SARS-CoV-2 results are presumptive.

To increase the chance that the negative result for SARS-CoV-2 is accurate, you should test again in 48 hours if the individual has symptoms on the first day of testing. A negative test result for SARS-CoV-2 indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

Negative flu test results: A negative test is presumptive for influenza A and B and it is recommended these results be confirmedby 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.

Test Invalid: If the test is invalid due to invalid internal positive or negative control lines, the BD Veritor™ Plus System Analyzer will display a "POSITIVE CONTROL INVALID" or "NEGATIVE CONTROL INVALID" and the patient specimen or control swab assay must then be repeated. Do not report results. Re-test with a new test device and collect a fresh patient specimen. If the "CONTROL INVALID" reading recurs, contact BD. Consult BD Veritor™ Plus Analyzer for more information.

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. Analyze control swabs using the same process and work flow as used for patient specimens. 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 andSARS-CoV-2. Repeat testing is required for negative SARS-CoV-2. Please follow table below when interpreting SARS-CoV-2 results.
Flu A: + Flu B: – CoV2: –	Positive test for Flu A (influenza A antigen detected) Repeat testing is required for negative SARS-CoV-2. Please follow table below when interpreting SARS-CoV-2 results.
Flu A: – Flu B: + CoV2: –	Positive test for Flu B (influenza B antigen detected) Repeat testing is required for negative SARS-CoV-2. Please follow table on next page when interpreting SARS-CoV-2 results.
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 with a new swab and test device.
CONTROL INVALID	Test Invalid. Repeat the test with a new swab and test device.

*Result Invalid – 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 with a new swab and test device.Upon retesting, if the specimen produces a "RESULT INVALID" again, the user may want to consider other methods to determine whether the sample is positive or negative for SARS-CoV-2 or influenza virus.

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

Status on first day of Testing	Day 0 (Test 1)	Day 2 (Test 2)
With Symptoms	**COVID-19 (-)** Serial testing recommended for COVID-19 **Flu A or B (-)** Flu A or B Result is Negative	**COVID-19 (-)** COVID Result is Negative **COVID-19 (+)** COVID-19 Result is Positive **Flu A or B (-)** Flu A or B Result is Negative **Flu A or B (+)** Flu A or B Result is Positive
	COVID-19 (-) Serial testing is recommended for COVID-19 **Flu A or B (+)** Flu A or B Result is Positive	**COVID-19 (-)** COVID-19 Result is Negative **COVID-19 (+)** COVID-19 Result is Positive **Flu A or B (-)** **Maintain Flu Positive Interpretation** **Flu A or B (+)** Flu A or B Result is Positive
	COVID-19 (+) COVID-19 Result is Positive **Flu A or B (-)** Flu A or B Result is Negative	No serial testing recommended
	COVID-19 (+) COVID-19 Result is Positive **Flu A or B (+)** Flu A or B Result is Positive	No serial testing recommended

WARNINGS AND PRECAUTIONS

1. Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
2. For *in vitro* diagnostic use.
3. All test results must be obtained using the BD Veritor Plus Analyzer.
4. **DO NOT** read the test results visually.
5. 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 poweradapter is connected).
6. Handle all specimens and related materials as if capable of transmitting infectious agents.
7. It is recommended to follow your institution's requirements for decontamination procedures or if spills occur. See the BD Veritor Analyzer Instructions for use forinstrument cleaning.
8. Dispose of used materials as biohazardous waste in accordance with federal, state and local requirements.
9. **Ensure all components are at room temperature (15–30 °C) when runningthe test.**
10. 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.
11. Please refer to package insert for detailed assay instructions, cautions, limitations and warnings.
12. **Serial testing should be performed in individuals with negative SARS-CoV-2 results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
13. Consistent with serial testing recommendations for SARS-CoV-2, for multi-analyte tests, symptomatic individuals who test positive for Influenza A or B on the initial test but negative for SARS-CoV-2 should be tested again in 48 hours to evaluate for co-infection with SARS-CoV-2 infection.

In the USA, this product has not been FDA cleared or approved; but has been authorizedby FDA under an Emergency Use Authorization. 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* diagnosticsfor detection and/or diagnosis of the virus that causes COVID-19 under Section 564(b)(1) of Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or theauthorization is revoked sooner.

This product is 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.

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

IVD Rx Only

2 °C 30 °C

REF 256088
500051910(03)
2023-05
English

BD

Veritor™ System

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

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

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

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Determinations

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

Please read these instructions completely before beginning to test specimens.

INTENDED USE

The BD Veritor™ System for Rapid Detection of SARS-CoV-2 & Flu A+B is a rapid chromatographic digital immunoassay intended for the simultaneous qualitative detection and differentiation of SARS-CoV-2 nucleocapsid protein antigen, influenza A, and influenza B nucleoprotein antigens directly from anterior nasal swab samples collected from individuals who are suspected of a viral respiratory infection consistent with COVID-19 by a healthcare provider within the first six (6) days of symptom onset when tested at least twice over 3 days with at least 48 hours between tests. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar. 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.

The BD Veritor™ System for Rapid Detection of SARS-CoV-2 & Flu A+B does not differentiate between SARS-CoV or SARS-CoV-2 viruses.

Results are for the simultaneous in vitro detection and differentiation of SARS-CoV-2 nucleocapsid protein and influenza A and B viral nucleoproteins and is not intended to detect influenza C antigens. 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. 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.

SARS-CoV-2, influenza A, and influenza B viral antigens are generally detectable in anterior nasal swab specimens 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 definitive 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.

All negative SARS-CoV-2 results are presumptive and should be confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control measures such as isolating from others and wearing masks. Negative results should be considered in the context of a patient’s recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

All negative influenza A and B test results are presumptive. It is recommended these results be confirmed by an FDA-cleared influenza A and B molecular assay. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions.

The BD Veritor™ System for Rapid Detection of SARS-CoV-2 & Flu A+B is intended for use by healthcare professionals or trained operators who are proficient in performing tests in point of care settings. The BD Veritor™ System for Rapid Detection of SARS-CoV-2 & Flu A+B is only for in vitro diagnostic use under the Food and Drug Administration’s Emergency Use Authorization (EUA). This product has not been FDA cleared or approved.

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™ barcode 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
Extraction Reagent	30 single use reaction tubes, each with 400 µL extraction reagent and having an integral dispensing tip	Detergent solution with less than 0.1% sodium azide (preservative)
Specimen sampling swabs	30 sterile, single use specimen sampling swabs	For sample collection and transfer
SARS-CoV-2 (+) Control Swab	1 each – individually wrapped for single use	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 less than 0.1% sodium azide

Materials Provided:

KIT COMPONENT	QUANTITY	DESCRIPTION
Flu B (+) Control Swab	1 each – individually wrapped for single use	Influenza B antigen (inactive recombinant nucleoprotein) with less than 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 instructions	

MATERIALS REQUIRED BUT NOT PROVIDED	OPTIONAL EQUIPMENT
• BD Veritor™ Plus Analyzer running firmware v5.50 or later (Catalog No. 256066) • Timer • Tube rack for specimens • Any necessary personal protective equipment	• BD Veritor™ System Barcode Scanning Module (Catalog No. 256068 or 445010) • USB Printer cable for BD Veritor™ Plus Analyzer (Catalog No. 443907) • Epson Printer model TM-T20 II • BD Veritor™ Plus Connect (contact your BD representative for details) • BD Veritor™ System for Rapid Detection of SARS-CoV-2 & Flu A+B Positive Control Swab set – 10 of each analyte (Catalog No. 256090)

WARNINGS AND PRECAUTIONS

1. Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
2. For in vitro diagnostic use.
3. For prescription use only.
4. In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use Authorization. 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. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
5. This product is 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.
6. **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing**.
7. Consistent with serial testing recommendations for SARS-CoV-2, for multi-analyte tests, symptomatic individuals who test positive for influenza A or B on the initial test but test negative for SARS-CoV-2 should be tested again in 48 hours to evaluate for co-infection with SARS-CoV-2 infection.
8. Do not use this kit beyond the expiration date printed on the outside carton.
9. The test device should remain in its original sealed pouch until ready for use. Do not use if any of the test kit contents or packaging is damaged. Once opened, the test device must be used within 5 minutes.
10. Do not use the kit to evaluate patient specimens if either the positive control swabs fail to give expected results.
11. When using the “Analyze Now” mode, do not read test results before 15 minutes or after 20 minutes. Results read before 15 minutes or after 20 minutes may lead to a false positive, false negative, or invalid result.
12. Test results are not meant to be visually determined. All test results must be determined using the BD Veritor™ Plus Analyzer.
13. Test components are for single use. Do not reuse any BD Veritor™ System test device or kit components.

14. 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.
15. When collecting an anterior nasal swab sample, use the nasal swab supplied in the kit. Do not touch the swab tip.
16. Other than the swabs used for specimen collection, kit components should not make contact with the patient.
17. Proper specimen collection, storage and transport are critical to the performance of this test.
18. The test is intended to be used with direct nasal swabs and is not validated for use with swabs in viral transport media.
19. 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. Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
20. 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.
21. The positive control swabs have been prepared from recombinant viral proteins and do not contain infectious material.
22. Collect and dispose of all used and unused reagents and any other contaminated disposable materials following procedures for biohazardous or potentially biohazardous waste. It is the responsibility of each laboratory to handle solid and liquid waste according to their nature and degree of hazardousness and to adequately treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations. Do not discharge liquid waste down the drain where prohibited.
23. 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.
24. Do not inhale, swallow or ingest any kit components. Avoid contact with your skin and eyes. The reagent solution contains harmful chemicals (see Hazardous Ingredients Table 1 below). If the solution contacts your eyes, flush with large amounts of water. **If irritation persists, seek medical advice:**
    https://www.poisonhelp.org or 1-800-222-1222

Table 1: Hazardous Ingredients

GHS Hazard Statement for mixture	Labeling of Harm(s)	Hazardous Ingredients (%)
Skin irritation	Causes mild skin irritation (H316)	• Triton X-100 (CAS# 9036-19-5): 2.08% (w/w) • Sodium Azide (CAS# 26628-22-8): 0.0927% (w/w)
Serious eye irritation	Causes serious eye irritation (H319)	• Triton X-100 (CAS# 9036-19-5): 2.08% (w/w) • Sodium Azide (CAS# 26628-22-8): 0.0927% (w/w)

25. 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.
26. 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.
27. 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.
28. 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.
29. The performance of this device has not been assessed in a population vaccinated against COVID-19.
30. For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
31. For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

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 6 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 1 hour after specimen collection. It is essential that correct specimen collection and preparation methods be followed.

Anterior Nasal Swab Specimen Collection

The BD Veritor™ System for Rapid Detection of SARS-CoV-2 & Flu A+B includes swabs for nasal specimen collection.

1. Carefully insert the entire collection tip of the swab (usually 1/2 to 3/4", or 1 to 1.5 cm) into one nostril of the patient. 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 should be processed in the extraction reagent vial within 1 hour.

DO'S AND DON'TS OF SPECIMEN 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 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 the BD Veritor™ Plus 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

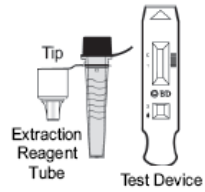
The following steps assume that the BD Veritor™ Plus Analyzer is ready to use. To choose or change any BD Veritor™ Plus Analyzer settings, see the BD Veritor™ Plus Analyzer Instructions for Use. A printer is not necessary to display results. **However, if your facility has chosen to connect the BD Veritor™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

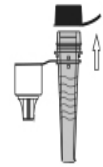
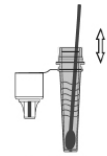
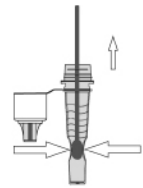
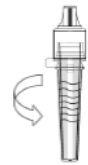
Once the nasal swab has been collected from the nostrils, the swab should be processed within 1 hour.

Procedural steps for Nasal Swabs or positive control swabs:

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.



2 Remove and discard the cap from the extraction reagent tube.	
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.	 15 seconds
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 the swab.	
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 should be added to the test device within 30 minutes.

After step 5, choose from the BD Veritor™ Plus Analyzer workflow option below before continuing to step 6:				
	BD Veritor™ Plus Analyzer in **Analyze Now** mode	BD Veritor™ Plus Analyzer in **Walk Away** mode	BD Veritor™ Plus Analyzer with the BD Veritor™ Barcode Scanning Enabled Module	
			in **Analyze Now** mode	in **Walk Away** mode
Instructions in section:	**A**	**B**	**C**	**D**

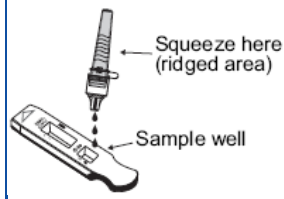
A Using a BD Veritor™ Plus Analyzer in "*Analyze Now*" mode*:

6A

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

- Invert the extraction reagent tube and hold it vertically (approximately 1 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.
- Properly dispose of the extraction reagent tube.

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 false or invalid results.

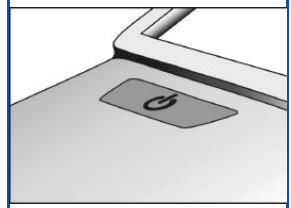


7A

Timing test development

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

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



CAUTION: 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.

8A

Using the BD Veritor™ Plus Analyzer

- The BD Veritor™ Plus Analyzer will complete a self-test before it is ready for use. After the self-test the display window shows "INSERT TEST DEVICE OR DOUBLE-CLICK BUTTON FOR WALK AWAY MODE".
- INSERT THE TEST DEVICE when the 15-minute assay development time is complete.
- The status of the assay analysis process appears in the display window. Follow the on-screen prompts to complete the procedure. Do not touch the instrument or remove the test device until the result appears.
- When analysis is complete, the test result appears in the display window.

9A

Record the result before removing the test device.

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

Instructions for Batch Testing 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.

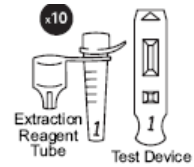
Batch Sample Collection (Example below includes 10 Tests)

A-Batch — Batch Sample Collection (10 Tests):

6A Batch

Gather 10 sets of test materials.

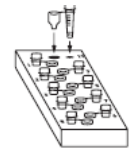
- Open test device pouches.
- Label each set with patient ID (extraction reagent tube and test device).



7A Batch

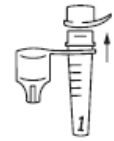
Label the tube tray with the patient ID.

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



8A Batch

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



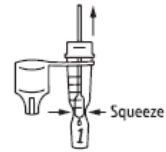
9A Batch

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

10A Batch

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.



11A Batch

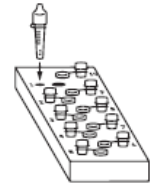
Press dispensing tip on the tube firmly.

- **Mix the sample** by swirling the bottom of the tube.

12A Batch

Place tube back in tray with matching patient ID.

- Repeat steps 8A–12A until all remaining tubes have been prepared.
- Specimen processed in the reagent vial must be **run within 30 minutes** on the test device.



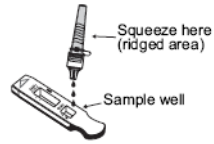
A-Batch — Batch Sample Collection (10 Tests):

13A Batch

Select the extracted Sample and the matching test device for each specimen. **Add 3 drops of the processed sample** to the test device sample well, then properly dispose of the extraction reagent tube.

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 false or invalid results.

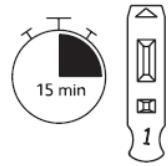
NOTE: Stagger the addition of subsequent specimens by approximately 30 seconds.



14A Batch

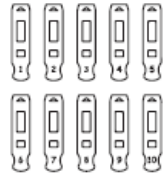
Activate a 15-minute timer. Each test device must incubate for 15 minutes before it can be analyzed.

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.



15A Batch

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

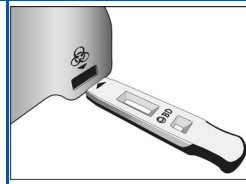


16A Batch

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

17A Batch

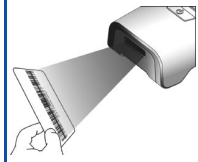
When prompted, **insert the test device to read.**



18A Batch

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

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

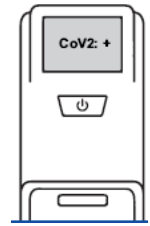


A-Batch Batch Sample Collection (10 Tests):

19A Batch

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

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



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

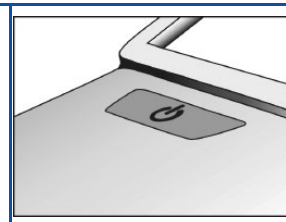
B Using the BD Veritor™ Plus Analyzer in "*Walk Away*" mode*: with no barcode scanning module installed

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

6B

Starting Walk Away Mode

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

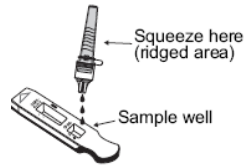


7B

Adding the specimen to the test device

- Invert the extraction reagent tube and hold it vertically (approximately 1 inch above the BD Veritor™ System test sample well).
- Gently squeeze the ridged body of the tube, dispensing three (3) drops of the processed specimen into the sample well.
- Properly dispose of the extraction reagent tube.

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 false or invalid results.

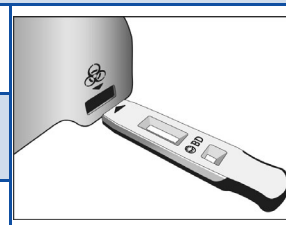


CAUTION: A countdown timer displays the time remaining for test insertion. Walk Away mode must be activated again when this timer expires. Confirm timer is visible and Walk Away mode is activated before inserting test device.

8B

Starting the development and reading sequence

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



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

- "DO NOT DISTURB TEST IN PROGRESS" appears in the display window. Automatic timing of the assay development, image processing and result analysis begins. The status of the assay analysis process appears in the display window. Follow the on-screen prompts to

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

complete the procedure. Do not touch the instrument or remove the test device until the result appears.

- The display window shows the remaining analysis time.

Do not touch the BD Veritor™ Plus Analyzer or remove the test device during this process. Doing so will abort the assay analysis. If this happens within 5 minutes of starting the assay, restart the BD Veritor™ Plus Analyzer, select Walk Away Now mode and insert the device again for a 15-minute read. If this occurs after 5 minutes 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.

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

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

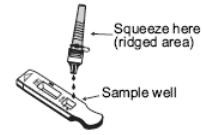
***ATTENTION: TEST Results are NOT maintained in the display window when the device is removed or if the BD Veritor™ Plus Analyzer is left unattended for more than 15 minutes (60 minutes if AC power adapter is connected).**

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

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

- Invert the extraction reagent tube and hold it vertically (approximately 1 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.
- Properly dispose of the extraction reagent tube.

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 false or invalid results.



7C **Timing test development**

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

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

CAUTION: Incorrect results may occur if development time is less than 15 minutes. Some lines may appear on the device sooner. Do not read test 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.

8C

Using the BD Veritor™ Plus Analyzer

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

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

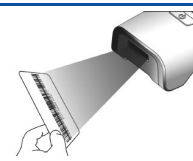
- When assay development time is complete and the BD Veritor™ Plus Analyzer display window reads "INSERT TEST DEVICE OR DOUBLE-CLICK FOR WALK AWAY MODE", insert the BD Veritor™ System SARS-CoV-2 & Flu A+B device into the slot on the right side of the BD Veritor™ Plus Analyzer.

9C

Using the barcode scanner

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

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



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

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

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

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

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

10C

Removing the test device

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

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

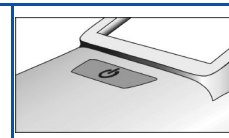
D Using the BD Veritor™ Plus Analyzer In "*Walk Away*" mode with a barcode scanning module installed

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

6D

Starting Walk Away Mode

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

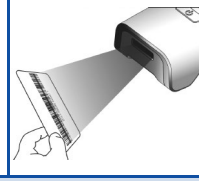


7D

Using the barcode scanner

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

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



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

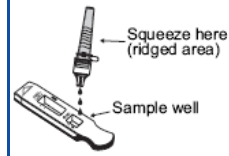
8D

Adding the specimen to the test device

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

— Invert the tube, holding it vertically (approximately 1 inch above the BD Veritor™ System SARS-CoV-2 test device sample well).
— Gently squeeze the ridged portion of the tube, dispensing three (3) drops of the processed specimen into the sample well.
— Properly dispose of the extraction reagent tube.

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 false or invalid results.



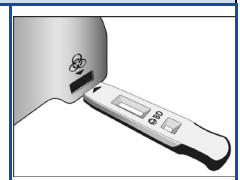
CAUTION: A countdown timer displays the time remaining for test insertion. Walk Away mode must be activated again when this timer expires. Confirm timer is visible and Walk Away mode is activated before inserting test device.

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

9D

Starting the development and reading sequence

- Insert the test device into the slot on the right side of the BD Veritor™ Plus Analyzer. The test device must remain horizontal to prevent spilling the specimen out of the sample well.
- "DO NOT DISTURB TEST IN PROGRESS" appears in the display window. Automatic timing of the assay development, image processing and result analysis begins.
- The display window shows the remaining analysis time.



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

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

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

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

10D

Removing the test device

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

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

INTERPRETATION OF RESULTS

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

Display	Interpretation
Flu A: - Flu B: - CoV2: -	Negative Test for Flu A, Flu B and SARS-CoV-2 (no antigen detected) Repeat testing is required to improve test accuracy for SARS-CoV-2. Please follow Table 2 below when interpreting SARS-CoV-2 results.
Flu A: + Flu B: - CoV2: -	Positive test for Flu A (influenza A antigen detected) Repeat testing is required to improve test accuracy for SARS-CoV-2. Please follow Table 2 below when interpreting SARS-CoV-2 results.
Flu A: - Flu B: + CoV2: -	Positive test for Flu B (influenza B antigen detected) Repeat testing is required to improve test accuracy for SARS-CoV-2. Please follow Table 2 below when interpreting SARS-CoV-2 results.
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 (influenza A and SARS-CoV-2 antigens detected)
Flu A: - Flu B: + CoV2: +	Positive Test for Flu B and SARS-CoV-2 (influenza B and SARS-CoV-2 antigens detected)
RESULT INVALID	Result invalid*. Repeat the test with a new swab and test device.
POSITIVE CONTROL INVALID	Test Invalid†. Repeat the test with a new swab and test device.

Display	Interpretation
NEGATIVE CONTROL INVALID	Test Invalid†. Repeat the test with a new swab and test device.

*Result Invalid -- The BD Veritor™ Plus 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 with a new swab and test device. Upon retesting, if the specimen produces "RESULT INVALID" again, the user may want to consider other methods to determine whether the sample is positive or negative for SARS-CoV-2 or influenza virus.

†Test Invalid – If the test is invalid due to invalid internal positive or negative control lines, the BD Veritor™ Plus Analyzer 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. Re-test with a new test device and collect a fresh patient specimen. If the "CONTROL INVALID" reading recurs, contact BD. Consult BD Veritor™ Plus Analyzer for more information.

Repeat testing is needed to improve test accuracy. Please follow Table 2 below when interpreting test results.

Table 2: SARS-CoV-2 Test Results Interpretation

Status on first day of Testing	Day 0 (Test 1)	Day 2 (Test 2)
With Symptoms	**COVID-19 (-)** Serial testing recommended for COVID-19 **Flu A or B (-)** Flu A or B Result is Negative	**COVID-19 (-)** COVID Result is Negative **COVID-19 (+)** COVID-19 Result is Positive **Flu A or B (-)** Flu A or B Result is Negative **Flu A or B (+)** Flu A or B Result is Positive
	COVID-19 (-) Serial testing is recommended for COVID-19 **Flu A or B (+)** Flu A or B Result is Positive	**COVID-19 (-)** COVID-19 Result is Negative **COVID-19 (+)** COVID-19 Result is Positive **Flu A or B (-)** **Maintain Flu Positive Interpretation** **Flu A or B (+)** Flu A or B Result is Positive
	COVID-19 (+) COVID-19 Result is Positive **Flu A or B (-)** Flu A or B Result is Negative	No serial testing recommended
	COVID-19 (+) COVID-19 Result is Positive **Flu A or B (+)** Flu A or B Result is Positive	No serial testing recommended

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

REPORTING OF RESULTS

Positive SARS-CoV-2 Result– Repeat testing does not need to be performed if patients have a positive SARS-CoV-2 result at any time.

A positive SARS-CoV-2 test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please instruct your patient to adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive SARS-CoV-2 result that is incorrect (a false positive).

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definitive cause of disease. Individuals who test positive for SARS-CoV-2 with the BD Veritor™ System for Rapid Detection of SARS-CoV-2 & Flu A+B should self-isolate. In some cases, additional confirmatory testing with a molecular test for positive SARS-CoV-2 results may also be necessary, if there is a low likelihood of COVID-19, such as individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection. Testing facilities within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.

Positive Flu Results - Positive Flu A or Flu B results indicate the presence influenza viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status.

This test is not intended to detect influenza C antigens. Positive results do not rule out bacterial infection or coinfection with other viruses not measured by this test. The agent detected may not be the definitive cause of disease.

Negative SARS-CoV-2 Results – Negative SARS-CoV-2 results are presumptive.

To increase the chance that the negative result for SARS-CoV-2 is accurate, you should test again in 48 hours if the individual has symptoms on the first day of testing.

A negative test result for SARS-CoV-2 indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as RT-PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary healthcare provider.

All negative SARS-CoV-2 results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

Negative Flu Results – 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.

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

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 CONTROLS 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 your local BD representative.

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 1 hour of specimen collection or 30 minutes since placement of swab into the extraction reagent.
- The performance of this test was not evaluated for detection of SARS-CoV-2, influenza A or B in samples collected in viral transport media. Transport media 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.

- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- 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.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. Based on in vitro testing, false positive results cannot be ruled out in 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)
- 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 a RT-PCR assay.
- Incorrect test results may occur if a specimen is incorrectly collected or handled. 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 (live) and nonviable viral material. The BD Veritor™ System for Rapid Detection of SARS-CoV-2 & Flu A+B performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample.
- 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 reestablished 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.
- All SARS-CoV-2 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. Outside the United States, a molecular assay cleared for diagnostic use in the country of use is recommended.
- If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative for SARS-CoV-2, the patient may not have COVID-19, however additional follow-up may be needed.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and the individual likely has COVID-19.
- Users should test specimens as quickly as possible after specimen collection, always within 1 hour after specimen collection and within 30 minutes of placing the swab into the 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/in-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 "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/OHT7OIR/OPEQ/CDRH (via email: CDRHEUAReporting@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 Company, 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 3: 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[a]	1	53
NEG	8	217[b]	225
Total	60	218	278

PPA: 86.7% (C.I. 75.8%–93.1%)
NPA: 99.5% (C.I. 97.4%–99.9%)
[a] 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.
[b] 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 4: 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%

Table 4: 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
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. The table below presents the performance agreement between the two BD Veritor™ 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 5: 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 SARS-CoV-2 & Flu A+B Assay Result	BD Veritor™ System for Rapid Detection of 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 6: 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 SARS-CoV-2 & Flu A+B Assay Result	BD Veritor™ System for Rapid Detection of 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%)			

Table 5: 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 SARS-CoV-2 & Flu A+B Assay Result	BD Veritor™ System for Rapid Detection of Flu A+B Assay result		
	Flu A POS	Flu A NEG (Flu B Positives + Flu A+B Negatives)	Total

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 7: Flu A Detection

BD Veritor™ System for Rapid Detection of Flu A+B	RT-PCR Reference results		
	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: RT-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 8: Flu B Detection

BD Veritor™ System for Rapid Detection of Flu A+B	RT-PCR Reference results		
	Flu B POS	Flu B NEG (Flu A Positives + Flu A+B Negatives)	Total
POS	138	10	148
NEG	33	555	588
Total	171	565	736
Reference Method: RT-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.	

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx®) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test

was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36–48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT-PCR, of which 57 (39%) reported symptoms on the first day of infection.

Performance of the antigen test with serial testing in symptomatic individuals is described in Table 9.

Table 9: Data establishing PPA of SARS-CoV-2 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

DAYS AFTER FIRST RT-PCR POSITIVE TEST RESULT	SYMPTOMATIC ON FIRST DAY OF TESTING		
	1 TEST	2 TESTS	3 TESTS
0	34/57 59.6%	47/51 92.2%	44/47 93.6%
2	58/62 93.5%	59/60 98.3%	43/43 100%
4	55/58 94.8%	53/54 98.1%	39/40 97.5%
6	27/34 79.4%	26/33 78.8%	22/27 81.5%
8	12/17 70.6%	12/17 70.6%	7/11 63.6%
10	4/9 44.4%	3/7 42.9%	-

1 Test = one (1) test performed on the noted days after first RT-PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.
2 Tests = two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.
3 Tests = three (3) tests performed an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

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 2.8×10^5 $TCID_{50}$/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
2.8×10^5 $TCID_{50}$/mL	2.8×10^2 $TCID_{50}$/mL 14 $TCID_{50}$/swab	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 BD Veritor™ 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 10: 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 (BD document 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 11: 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 (EID50/mL) and Number of Positive Results at Each Dilution (N=5) when tested with the SARS-CoV-2 & Flu A+B Assay					
A(H3N2)	A/Perth/16/2009	EID_{50}/mL	2.00 x 10^6	9.98 x 10^5	**4.99 x 10^5**	2.49 x 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 x 10^6	1.58 x 10^6	**7.91 x 10^5**	3.95 x 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 x 10^7	**7.92 x 10^6**	3.96 x 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 x 10^7	6.29 x 10^6	3.15 x 10^6	**1.57 x 10^6**	1.26 x 10^6
		# Detected	5	5	3	**1**	0
		% Detected	100	100	60	**20**	0
B (Victoria	B/Michigan/09/2011	EID_{50}/mL	7.94 x 10^4	**3.97 x 10^4**	1.99 x 10^4	N/A	N/A

Table 11: 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 (EID50/mL) and Number of Positive Results at Each Dilution (N=5) when tested with the SARS-CoV-2 & Flu A+B Assay					
Lineage)		# 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 11 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 12: 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	8.0×10^7	1.6×10^7	**3.2×10^6**	6.4×10^5	1.3×10^5
		# 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	6.3×10^6	**1.3×10^6**	2.5×10^5	5.1×10^4	1.0×10^4
		# 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	6.3×10^8	1.3×10^8	**2.5×10^7**	5.1×10^6	1.0×10^6
		# Detected	5/5	5/5	**5/5**	0/5	0/5
		% Detected	100%	100%	**100%**	0%	0%

Table 12: 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(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 13: 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	3.3×10^2 $TCID_{50}$/mL
A/California/7/2009	H1N1	5.0×10^3 $TCID_{50}$/mL
A/Denver/1/57	H1N1	4.45×10^4 $CEID_{50}$/mL
A/FM/1/47	H1N1	7.91×10^4 $CEID_{50}$/mL
A/Fujian-Gulou/1896/2009	H1N1	4.5×10^5 $CEID_{50}$/mL
A/Mal/302/54	H1N1	2.22×10^5 $CEID_{50}$/mL

Table 13: 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/New Caledonia/20/1999	H1N1	2.5×10^3 $TCID_{50}$/mL
A/New Jersey/8/76	H1N1	1.58×10^3 $CEID_{50}$/mL
A/NWS/33	H1N1	1.58×10^4 $CEID_{50}$/mL
A/PR/8/34	H1N1	6.31×10^2 $TCID_{50}$/mL
A/Solomon Island/03/2006	H1N1	2.5×10^3 $TCID_{50}$/mL
A/Washington/24/2012	H1N1	3.16×10^4 EID_{50}/mL
A/Weiss/43	H1N1	7.03×10^6 $CEID_{50}$/mL
A/WS/33	H1N1	7.91×10^2 $CEID_{50}$/mL
A/Aichi/2/68	H3N2	7.91×10^3 $CEID_{50}$/mL
A/Brisbane/10/2007	H3N2	7.27×10^2 $TCID_{50}$/mL
A/California/02/2014	H3N2	1.45×10^2 $TCID_{50}$/mL
A/Hong Kong/8/68	H3N2	8.89×10^4 $CEID_{50}$/mL
A/Moscow/10/99	H3N2	5.8×10^6 $TCID_{50}$/mL
A/Perth/16/2009	H3N2	1.0×10^6 $TCID_{50}$/mL
A/Port Chalmers/1/73	H3N2	3.95×10^4 $CEID_{50}$/mL
A/Switzerland/9715293/2013	H3N2	3.25×10^2 $TCID_{50}$/mL
A/Texas/50/2012	H3N2	1.75×10^3 $TCID_{50}$/mL
A/Wisconsin/67/2005	H3N2	2.5×10^5 $TCID_{50}$/mL
A/Victoria/3/75	H3N2	3.11×10^3 $TCID_{50}$/mL
A/Indiana/08/2011	H3N2v	1×10^4 $TCID_{50}$/mL
A/Indiana/10/2011	H3N2v	7.9×10^6 $CEID_{50}$/mL
A/Kansas/13/2009	H3N2v	1.0×10^3 $TCID_{50}$/mL
A/Minnesota/11/2010	H3N2v	7.9×10^5 $CEID_{50}$/mL
A/Pennsylvania/14/2010	H3N2v	1.26×10^6 $CEID_{50}$/mL
A/West Virginia/06/2011	H3N2v	7.9×10^3 $TCID_{50}$/mL
A/Anhui/01/2005	H5N1	0.512 HA
A/Vietnam/1203/2004	H5N1	0.512 HA
A/Northern Pintail/Washington/40964/2014	H5N2	6.28×10^5 EID_{50}/mL
A/Pheasant/NewJersey/1355/1998	H5N2	0.256 HA
A/Gyrfalcon/Washington/41088-6/2014	H5N8	1.98×10^6 EID_{50}/mL

Table 13: 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/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 14: 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 x 10^4 $TCID_{50}$/mL
B/Brisbane/33/2008 (Victoria Lineage)	2.45 x 10^5 $CEID_{50}$/mL
B/Brisbane/60/2008	7.42 x 10^3 $TCID_{50}$/mL
B/Brisbane/72/97	1.00 x 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 x 10^4 $TCID_{50}$/mL
B/Florida/4/2006	1.30 x 10^3 $TCID_{50}$/mL
B/Fujian/93/97	3.95 x 10^5 $TCID_{50}$/mL
B/Fukushima/220/99	9.33 x 10^2 $TCID_{50}$/mL
B/Guangdong-Liwan/1133/2014 (Yamagata Lineage)	9.0 x 10^5 $CEID_{50}$/mL
B/GuangXi/547/98	2.32 x 10^5 $TCID_{50}$/mL
B/Hawaii/01/97	>6.4 HA
B/Hong Kong/5/72	1.11 x 10^4 $CEID_{50}$/mL
B/Hong Kong/219/98	>1 HA
B/Hong Kong/259/2010(Victoria Lineage)	1.35 x 10^6 $CEID_{50}$/mL
B/Jiangsu/10/2003	1.16 x 10^4 $TCID_{50}$/mL
B/Johannesburg/5/99	3.95 x 10^4 $TCID_{50}$/mL
B/Lee/40	4.44 x 10^4 $CEID_{50}$/mL
B/Lisbon/03/96	>0.08 HA
B/Malaysia/2506/2004	5.0 x 10^4 $TCID_{50}$/mL
B/Maryland/1/59	3.51 x 10^2 $CEID_{50}$/mL

Table 14: 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/Massachusetts/2/2012 (Yamagata Lineage)	1.25 x 10^6 $CEID_{50}$/mL
B/Mass/3/66	1.58 x 10^5 $CEID_{50}$/mL
B/Montana/5/2012	3.14 x 10^5 EID_{50}/mL
B/Ohio/11/96	>0.16 HA
B/Ohio/1/05	1.34 x 10^5 $TCID_{50}$/mL
B/Phuket/3073/2013	6.08 x 10^3 $TCID_{50}$/mL
B/Puerto Mont/10427/98	0.02 HA
B/Russia/69	3.9 x 10^2 $TCID_{50}$/mL
B/Shandong/7/97	1.58 x 10^6 $TCID_{50}$/mL
B/Shanghai/04/97	1.58 x 10^5 $TCID_{50}$/mL
B/Shenzhen/135/97	3.16 x 10^4 $TCID_{50}$/mL
B/Sichuan/116/96	0.016 HA
B/Taiwan/2/62	2.81 x 10^2 $CEID_{50}$/mL
B/Texas/06/2011 (Yamagata Lineage)	6.2 x 10^5 $CEID_{50}$/mL
B/Texas/02/2013 (Victoria Lineage)	2.75 x 10^4 $CEID_{50}$/mL
B/Utah/09/2014 (Yamagata Lineage)	6.3 x 10^3 $CEID_{50}$/mL
B/Victoria/504/00	4.64 x 10^4 $TCID_{50}$/mL
B/Wisconsin/01/2010 (Yamagata Lineage)	7.0 x 10^2 $CEID_{50}$/mL
B/Yamagata/16/88	9.75 x 10^3 $TCID_{50}$/mL
B/Yamanashi/166/98	4.88 x 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 x 10^6 $TCID_{50}$/mL of gamma-inactivated SARS-CoV-2, up to 2.0 x 10^9 EID_{50}/mL of Flu A virus, or up to 7.9 x 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 (BD SKU 256082), the endogenous and microbial interfering substance testing was not repeated. The results in Tables 15 and 16 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 15: Endogenous Interfering Substances

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 16: Microbial Interference

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

Table 16: Microbial Interference

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

NIH/RADx® VARIANT TESTING

The performance of this test device in the detection of the Omicron variant of SARS-CoV-2 was evaluated in a dilution series of clinical specimens which were positive for the Omicron variant. This testing was conducted by the National

Institutes of Health (NIH) as a component of the Rapid Acceleration of Diagnostics (RADx®) initiative. Specimen pools were prepared by the RADx® team using clinical pooled samples from currently circulating Omicron strains and tested by RADx® to assess performance with the Omicron variant. Results from this dilution series cannot be compared to other specimen pools and do not indicate that a test will have different clinical performance compared to other EUA authorized tests. Compared to an EUA authorized RT-PCR method, this test detected 100% of live virus Omicron samples at a Ct-value of 22.7 (n=5). Testing was also compared to two additional EUA authorized OTC antigen tests (Assay #1 and Assay #2). Omicron dilutions at lower viral concentrations (Ct-values greater than 23.6) were not detected by this test in this study.

Omicron Pool 2 - Live Omicron Clinical Samples	Average N2 Ct (n = 9)	Assay #1 Percent Positive (n = 5)	Assay #2 Percent Positive (n = 5)	BD Veritor™ System for Rapid Detection of SARS-CoV-2 & Flu A+B Test * Percent Positive (n=5)
Dilution 1	**19.8**	100	100	100
Dilution 2	**20.8**	100	100	100
Dilution 3	**21.5**	100	100	100
Dilution 4	**22.7**	100	100	100
Dilution 5	**23.6**	100	0	20
Dilution 6	**24.0**	60	0	0
Dilution 7	**24.8**	0	0	0
Dilution 8	**25.8**	0	0	0
Dilution 9	**27.4**	0	0	0
Dilution 10	**28.1**	0	0	0
Dilution 11	**29.1**	0	0	0

*Testing was conducted using the BD Veritor™ Pro Rapid Detection of SARS-CoV-2 Test, which comprises the same SARS-CoV-2 test design and components.

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	1.0×10^5 $TCID_{50}$/mL	No	No	No
Human Metapneumovirus	1.0×10^5 $TCID_{50}$/mL	No	No	No

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)
Parainfluenza virus 1	1.0 x 10^5 $TCID_{50}$/mL	No	No	No
Parainfluenza virus 2	1.0 x 10^5 $TCID_{50}$/mL	No	No	No
Parainfluenza virus 3	1.6 x 10^6 $TCID_{50}$/mL	No	No	No
Parainfluenza virus 4a	1.6 x 10^4 $TCID_{50}$/mL	No	No	No
Influenza A H1N1	2.5 x 10^5 $TCID_{50}$/mL	No	N/A	No
Influenza B	1.6 x 10^5 $TCID_{50}$/mL	No	No	N/A
Enterovirus D68	4.0 x 10^5 $TCID_{50}$/mL	No	No	No
Respiratory syncytial virus, strain Long	3.9 x 10^5 $TCID_{50}$/mL	No	No	No
Rhinovirus 3	1.0 x 10^5 PFU/mL	No	No	No
SARS-coronavirus (gamma irradiated)	2.5 x 10^5 PFU/mL	No	No	No
MERS-coronavirus (heat inactivated)	1.5 x 10^5 $TCID_{50}$/mL	No	No	No
SARS-CoV-2 (gamma irradiated)	1.0 x 10^5 $TCID_{50}$/mL	N/A	No	No
Haemophilus influenzae	1.0 x 10^6 CFU/mL	No	No	No
Streptococcus pneumoniae	1.0 x 10^6 CFU/mL	No	No	No
Streptococcus pyogenes	1.0 x 10^6 CFU/mL	No	No	No
Bordetella pertussis	1.0 x 10^6 CFU/mL	No	No	No
Mycoplasma pneumoniae	1.0 x 10^6 CFU/mL	No	No	No
Chlamydia pneumoniae	1.0 x 10^6 IFU/mL	No	No	No
Legionella pneumophila	1.0 x 10^6 CFU/mL	No	No	No
Staphylococcus aureus	1.3 x 10^6 CFU/mL	No	No	No
Staphylococcus epidermidis	1.0 x 10^6 CFU/mL	No	No	No
Pooled human nasal wash	100%	No	No	No
Candida albicans	1.0 x 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 (Yes/No)
SARS-CoV-2 (gamma irradiated)	1.0 x 10^5 $TCID_{50}$/mL	Influenza A H1N1	7.5 x 10^4 $TCID_{50}$/mL	No
SARS-CoV-2 (gamma irradiated)	1.0 x 10^5 $TCID_{50}$/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.

Change History

Revision	Date	Change Summary
01*	2021-04	Initial release.
02*	2021-12	Added statement to Warnings and Precautions section that the performance of this device has not been assessed in a population vaccinated against COVID-19.
03	2023-05	Corrections made to Intended Use, Test Procedures, Quality Control, Conditions of Authorization for the Laboratory, Analytical Performance tables, LoD value, Cross-Reactivity table, and Change History table to align with the initial FDA-authorized labeling and clarify the changes. Serial testing labeling updates made to align with revised Letter of Authorization (dated 1 November 2022) and to include RADx® data. Updated anterior nasal swab specimen collection procedure to comply with depth of insertion change in nasal specimen collection guideline published by the CDC. Updated hazardous ingredients table and disposal instructions in the Warnings & Precautions section. Corrected minor typographical errors.

* Revisions 01 and 02 have not been authorized by the FDA. A different revision 01 document was authorized by the FDA on 24 March 2021, referred to as the "initial FDA-authorized labeling" in the Revision 03 Change Summary above.

SYMBOLS GLOSSARY

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

Symbol	Meaning
EC REP	Authorized representative in the European Community
LOT	Batch code
	Biological risks
REF	Catalogue number

Symbol	Meaning
	Caution
	Consult *instructions for use* or consult electronic *instructions for use*
	Contains sufficient for <*n*> tests
	Negative control
	Positive control
	Date of manufacture
	Do not re-use
	Fragile, handle with care
	In vitro diagnostic medical device
	Manufacturer
	This only applies to US: “Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.”
	Recyclable
	Serial number
	Temperature limit
	This way up
	Use-by date

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BD 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.

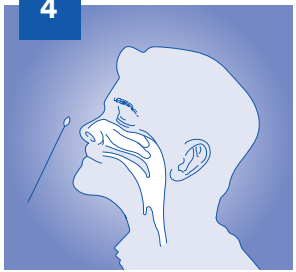
2

Carefully insert the entire collection tip of the swab (usually 1/2 to 3/4", or 1 to 1.5 cm) into one nostril. Roll the swab 5 times along the mucosa inside the nostrils to ensure that both mucus and cells are collected. Take at least 15 seconds to collect the specimen.

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. The swab should be processed in the extraction reagent vial within 1 hour.

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.
- Do not touch swab tip.
- 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

IVD Rx Only

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

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

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