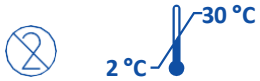

IVD

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BD Veritor™ At-Home COVID-19 Test

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

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

For *In Vitro* Diagnostic Use.

Healthcare Provider Instructions for Use

bd.com/e-labeling

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

BD Veritor™ At-Home COVID-19 Test

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

For *In Vitro* Diagnostic Use.
In the USA: For use under an Emergency Use Authorization only.
Please read these instructions completely before beginning to test specimens.

INTENDED USE

The BD Veritor™ At-Home COVID-19 Test is a chromatographic, digital immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests. The test results are interpreted by the Scanwell Health App and displayed on a compatible smartphone. This test is authorized for non-prescription, home use with self-collected (unobserved) direct anterior nasal swab specimens from individuals aged 14 years or older, or with adult collected anterior nasal swab specimens from individuals aged 2 years or older.

The BD Veritor™ At-Home COVID-19 Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the BD Veritor™ At-Home COVID-19 Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. 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 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.

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of COVID-19, such as, an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 and/or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary if there is a low likelihood of COVID-19 such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Individuals who test negative and continue to experience COVID-like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care from their healthcare provider.

Test results are reported to relevant public health authorities in accordance with local, state, and federal requirements, using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by the CDC. Test result reporting from the BD Veritor™ At-Home COVID-19 Test occurs via the Scanwell Health App software application. Individuals should also report their test result to their healthcare provider to receive appropriate medical care.

The BD Veritor™ At-Home COVID-19 Test is intended for non-prescription self-use and/or, as applicable for an adult lay user testing another person aged 2 years or older in a non-laboratory setting. BD Veritor™ At-Home COVID-19 Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION OF THE TEST

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

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

The BD Veritor™ At-Home COVID-19 Test is a system consisting of a rapid (approximately 15 minutes) single-use chromatographic immunoassay with results interpreted by the Scanwell Health App and displayed on a compatible smartphone. The BD Veritor™ At-Home COVID-19 Test is used for the direct and qualitative detection of the presence or absence of SARS-CoV-2 nucleocapsid antigens in anterior nasal (nares) specimens, taken from individuals symptomatic for COVID-19. It is also for use in individuals without symptoms when used in a serial testing program as described in the authorized intended use. The test is intended for non-prescription, home use with self-collected (14 years or older) or adult-collected (from 2 years or older) anterior nasal swabs.

PRINCIPLES OF THE PROCEDURE

The BD Veritor™ At-Home COVID-19 Test system consists of an immunochromatographic assay and smartphone app intended to detect the presence or absence of SARS-CoV-2 nucleocapsid antigens in anterior nasal specimens from individuals symptomatic for COVID-19 or for use in individuals without symptoms when used in a serial testing program. When a nasal specimen is added to the Tube containing extraction fluid and the extracted specimen is then added to the Test Stick, SARS-CoV-2 nucleocapsid 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 test reaction area and are captured by a line of antibodies bound to the membrane. The Test Sticks are designed with spatially distinct reaction zones which include distinct positive and negative control line positions, a sample adequacy line position and the test line position for SARS-CoV-2. The positive and negative control lines are internal reagent controls designed to assure the Test Stick reagents are

viable and that the test has been properly conducted. The sample adequacy line is designed to detect an endogenous biomarker, to assure human specimen is present. Interpretation and reporting of the correct test result, from the multiple lines deposited in the reaction zone, requires the use of the Scanwell Health App to process a scanned image of the Test Stick.

REAGENTS AND MATERIALS

MATERIALS SUPPLIED

The BD Veritor™ At-Home COVID-19 Test ("the Test kit") is a test system comprised of:

- Two rapid (approximately 15 minutes) single-use chromatographic immunoassays for the direct and qualitative detection of the presence or absence of SARS-CoV-2 antigens for use with self-collected (14 years or older) or adult-collected (from 2 years or older) anterior nasal swabs from individuals with, or without symptoms or other reasons to suspect a SARS-CoV-2 infection, when used as part of a serial testing program; and,
- The Scanwell Health App ("the app") installed on a compatible smartphone (supplied by the user) provides:
  - in-app step-by-step instructions on how to perform the test, from specimen collection to test device interpretation,
  - a built-in timer to alert the user when to progress in the testing steps,
  - a computer vision algorithm that performs image analysis of the captured test stick image and reports a Positive, Negative or Invalid test result to the user based on the presence or absence of test and control lines within the detected assay window.
  - test result reporting to relevant public health authorities in accordance with local, state, and federal requirements, using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by the CDC.

The BD Veritor™ At-Home COVID-19 Test kit includes the following components sufficient to perform two serial tests (pictured in **Figure 1** below):

- Box with Tube Holder,
- 2 - Nasal Swabs,
- 2 - Tubes containing extraction fluid,
- 2 - Test Sticks,
- 2 - Scan Cards (see description below in this section),
- Quick Start Guide,
- Product Information Leaflet, and
- Fact Sheet for Individuals.

Figure 1: Test kit contents

A description of the Test kit components is included in **Table 1.**

Table 1: Description of BD Veritor™ At-Home COVID-19 Test Components

BD Veritor™ At-Home COVID-19 Test Components	Description	Formulation
Tube (single use) with dispensing tip, filled with extraction reagent	Detergent solution with less than 0.1% sodium azide	Tris-HCL (buffer solution) Sodium Azide (preservative) Triton X-100 (detergent) NaCl
Swab (sterile, single use)	For self-collection of nasal specimen and transfer to Tube	Standard/regular nasal swab, nylon fiber and foam
Test Stick (single use)	Foil pouched Test Stick containing one reactive strip.	Bound on the nitrocellulose reaction membrane: - leporine (rabbit) anti-SARS coronavirus monoclonal antibody - biotin coupled to bovine protein - murine (mouse) anti-human protein monoclonal antibody Bound in the sample delivery area and conjugated to detector reagents: - murine Anti-Biotin antibody - murine Anti-SARS-CoV-2 antibody - murine Anti-human Serum Albumin antibody
Scan Card (single use)	The Test Stick is placed on the Scan Card to conduct a home lighting test and to help the user orient the Test Stick in preparation for image capture by the app.	
Instructions for Use	Quick Start Guide (QSG) Product Information Leaflet (PIL) Fact Sheet for Individuals	

MATERIALS NOT SUPPLIED

The following materials are required to perform the test but are not provided:

- Compatible Smartphone (supplied by the user) – Compatible smartphones are listed at: www.bdveritorathome.com/devices. BD will continue to evaluate and validate compatible smartphones and update this list as necessary.
- The minimum requirements are:
    - iPhone 7 or newer with iOS 10 or higher and a camera resolution of at least 1000 pixels in both dimensions, or
    - Android phones with Android 9 or higher and a camera resolution of at least 1000 pixels in both dimensions. Additionally, the camera should support RAW image capture, manual exposure and sensitivity settings.
- Scanwell Health App – Available for download from the app stores.

WARNINGS AND PRECAUTIONS

- For *in vitro* Diagnostic Use
- This product has not been FDA cleared or approved; but has been authorized by FDA under EUA.
- This product has been authorized only for the detection of proteins from SARS-CoV-2, 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 IVDs 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.
- Use only the contents provided in the test kit. Do not use test kit if it is past the expiration date.
- Follow the Scanwell Health App step-by-step directions exactly as presented. Failure to do so may affect test performance and/or produce incorrect results.
- Stay near your smartphone during the 15 minutes the test is running so you can hear the timer alarms. The Scanwell Health App will generate timing alerts during testing that are important to hear.
- Leave the swab inside its packaging until instructed to swab the nose. Keep the swab clean. Do not allow anything to touch the soft tip of the swab until instructed to swab the nose.
- Do not open any of the test kit contents until directed to do so by the Scanwell Health App.
- Perform the test as soon as possible after swabbing both nostrils, but no more than 1 hour after swabbing and within 30 minutes after adding the swab to the Tube.
- You must apply the 3 drops of sample to the marked location on the test stick within 5 minutes of opening the test stick packaging.
- Keep the test stick on a flat, well-lit surface during the test. Take care not to drop the test stick.
- Do not use the test if the liquid in the tube spills.
- Scan the test stick as soon as the 15-minute alert sounds. You have 5 minutes to complete your scan after the end of the 15-minute incubation, or the test becomes invalid.

- Do not force quit the Scanwell Health App until your result is available.
- Do not attempt to determine test results visually. Only use the Scanwell Health App, on a smartphone, to determine test results.
- Do not reuse any test kit components.
- Do not use this test kit beyond the expiration date printed on the outside of the box.
- Do not use if any of the test kit contents or packaging is damaged.
- The tube liquid contains sodium azide. Do not inhale, swallow, or expose to skin and eyes. If the liquid contacts skin, wash immediately with plenty of soap and water. If the liquid contacts eyes, flush with plenty of water. Do not flush the tube liquid down the drain
- Do not use the test on children under 2 years of age.

STORAGE

Store between 35°F - 86°F (2°C - 30°C) until use.

TEST PROCEDURE AND RESULTS INTERPRETATION

When opening of the BD Veritor™ At-Home COVID-19 Test kit, the user is instructed to first read the Quick Start Guide (QSG), download and open the Scanwell Health App from their app store, create or login to their Scanwell Account, and follow the step-by-step instructions provided in the app.

The app guides the user through the test, using audio as well as written and video instructions. The test procedure includes five main sections, outlined below.

1. Test Preparation
    a) The user is guided through a home lighting test using the Scan Card.
    b) Upon successful completion of the home lighting test, the user is instructed to wash their hands before proceeding to the next step.
    c) The user is instructed to take the components required for a single test out of the test kit box and arrange them on a clean, well-lit working surface.
    d) Instructions are provided for the preparation of the Tube and its placement in the Tube Holder.

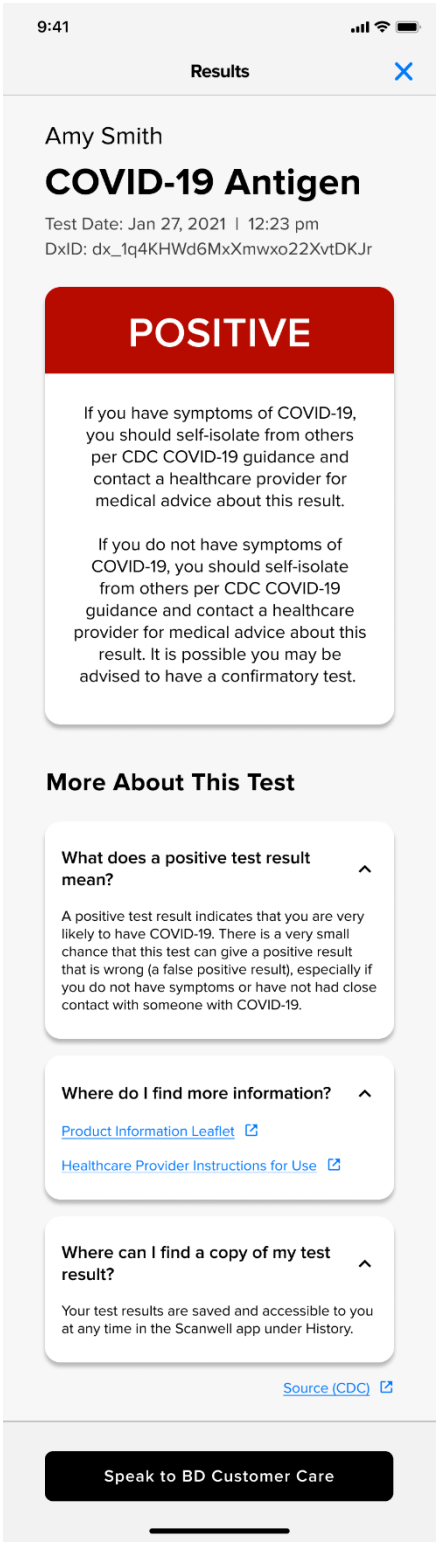
2. Nasal Swab Specimen Collection
    a) The user is guided through the proper collection of an anterior nasal swab specimen.
    b) Instructions are provided for adult self-collection or adult-collection (caregiver) of a specimen from a child or another adult (the appropriate workflow is displayed based on the profile the user selected in the app).
    c) The specimen collection is an anterior nasal swab collection.

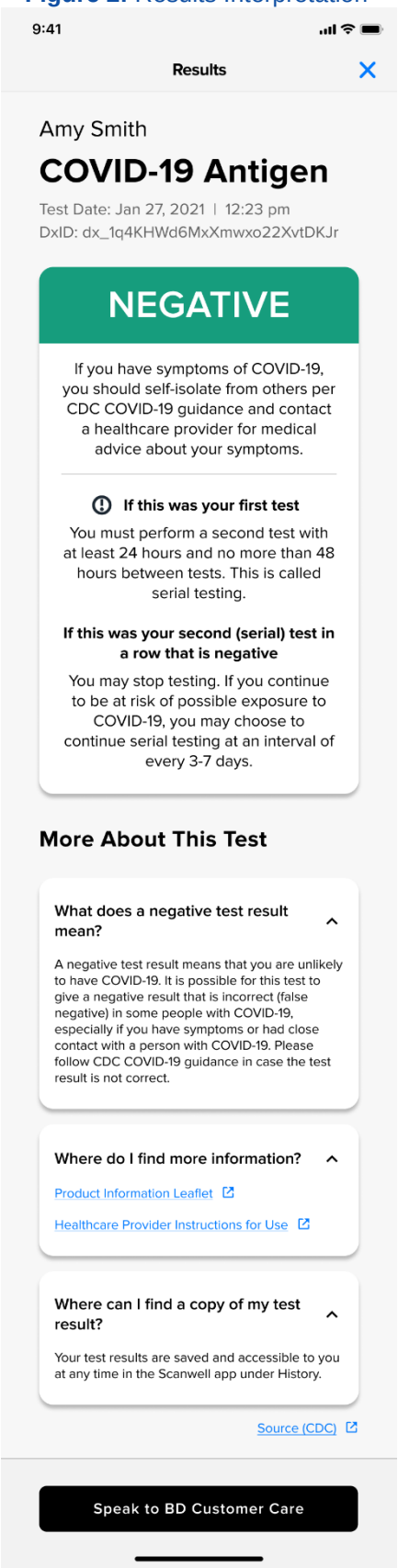
3. Specimen Extraction / Processing
    a) The user is guided through extraction of the specimen from the swab by plunging the swab into the provided Tube (with liquid).
    b) The user is instructed to discard the swab.

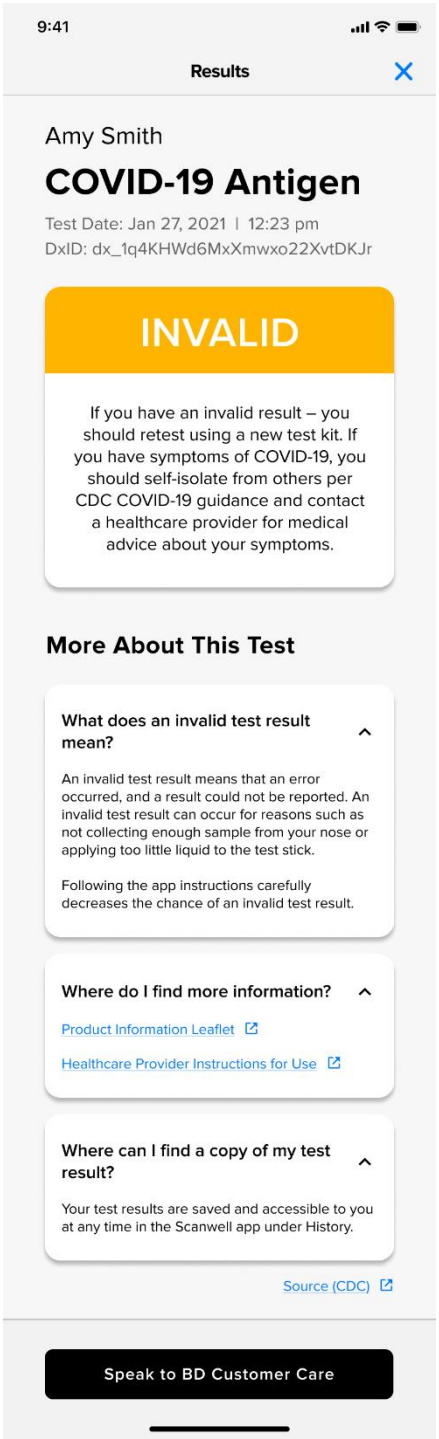
4. Sample Application to the test stick
    a) The user is instructed to close the top on the dispensing Tube.
    b) The user is guided through the application of three (3) drops of sample to the Test Stick.

5. Test Stick Scanning and Result Interpretation with the Scanwell Health App
    a) After sample application, the user is prompted in the app to progress to the next step. This actuates an in-app 15-minute incubation timer.
    b) When the timer sounds on the cell phone, the user is prompted to scan the Test Stick (the Test Stick must be placed on the Scan Card). The user has 5 minutes to complete the scanning step, after which the test is voided, and the user is instructed to try again with a new test or to contact customer service.
    c) Several pre-image capture quality checks are built into the scanning step to ensure the image captured is of sufficient quality for analysis. These include checks for low lighting, shadow, Test Stick detection and proximity to the Scan Card, among others. User feedback notifications appear at the top of the screen, instructing the user in real-time how to capture a good image. The app only accepts and analyzes an image if all pre-image capture quality checks are passed.
    d) On the subsequent screen, the interpreted result is displayed. Negative, Positive and Invalid test results are possible (see **Figure 2**). An invalid test may occur for several reasons, including the absence of a positive control line, presence of negative control line with intensity above predefined threshold, or sample adequacy line below a predefined threshold.

Figure 2: Results Interpretation







QUALITY CONTROL

The Test Sticks are designed with spatially distinct reaction zones which include positive and negative control line positions, a sample adequacy line position and the test line position for SARS-CoV-2.

Internal Controls

The positive and negative control lines are internal reagent controls designed to assure the Test Stick reagents are viable and that the test has been properly conducted. The sample adequacy line is designed to assess whether the collected nasal specimen is suitable for analysis by detection of an endogenous biomarker, to assure sample validity.

To properly interpret and report the test outcome from multiple lines deposited in the reaction zone, the test system requires the use of the smartphone app to process a scanned image of the Test Stick. There are no markings on the Test Stick housing identifying the different reaction zones, nor are these described in the labeling.

The app interpretation logic factors in the presence or absence of the control lines to determine if the overall result is valid or invalid. If the result is deemed valid, a determination is made to report the test as Negative or Positive. Invalid results may be caused by the absence of a Positive Control Line or Sample Adequacy line below a predetermined threshold, or the presence of a Negative Control Line above a predetermined threshold. The possible combinations of test and control lines result in the reporting of the test as Negative, Positive or Invalid are outlined below in **Table 2**.

Table 2: Test and Control Line Combinations

Display	Positive Control	Negative Control	Sample Adequacy	SARS-CoV-2 Result
Positive	Present	Valid	Present	Positive
Negative	Present	Valid	Present	Negative
Positive*	Present	Valid	Absent	Positive
Invalid	Present	Valid	Absent	Negative
Invalid	Present	Invalid	N/A	N/A
Invalid	Absent	N/A	N/A	N/A

*In the case of a positive SARS-CoV-2 result in the absence of an adequate Sample Adequacy line, the app returns a positive result as a fail-safe against any possible missed detections.

Other Failure Alert and Failsafe Controls

The test also incorporates failure alert and failsafe controls that assure the user is not allowed to continue with the test, rather than receive an invalid result, in the event:

- Home lighting is not appropriate prior to initiation of the test,
- Too much time has elapsed since sample was added to the Test Stick,
- Too much time has elapsed between Test Stick development and scanning,
- Scanning conditions are not conducive to ensure the image captured is of sufficient quality for analysis including low lighting, shadow, Test Stick detection and proximity to the Scan Card, and
- A user attempts to use a different manufacturer's test stick.

LIMITATIONS

- For emergency use only
- For *in vitro* diagnostic use.
- Do not use the test on children under 2 years of age.
- The test has only been tested in children age 2 and above.
- For children ages 2-13 years, specimens must be collected and tested by an adult (18+ years old).
- Failure to follow the test directions may affect test performance and/or provide incorrect results.
- False negative results are a possible concern, especially if you have symptoms or recently had significant close contact with a person with COVID-19 and when local disease prevalence is high.
- False positive results are a possible concern, especially if you do not have any symptoms when local disease prevalence is low.
- The test performance has only been assessed for use with human nasal swabs.
- Samples collected in viral transport media should not be used with this test.
- Perform the testing of the sample as soon as possible after swabbing the nose.
- Positive test results do not rule out co-infections with other pathogens.
- Negative test results do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions, including infection control decisions, particularly in the presence of clinical signs and symptoms consistent with COVID-19, or in those who have been in contact with the virus.
- Negative results are presumptive, do not rule out COVID-19 infection and it may be necessary to obtain additional testing with a molecular assay, if needed for patient management.
- The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 antigens from nasal swab specimens only. This test can detect both viable and non-viable viral material. The detection of SARS-CoV-2 antigens depends on antigen load and may not correlate with other diagnostic methods.
- Use only the nasal swab provided in the test kit to collect the test specimen.
- Do not re-use any of the test kit components, including the nasal swab.
- The performance of this test has not yet been clinically validated for use in patients without signs and symptoms of respiratory infection, or for serial screening applications and performance may differ in these populations.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected in Spring of 2021. 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.

CLINICAL PERFORMANCE

The performance of the BD Veritor™ At-Home COVID-19 Test was established with 597 direct nasal swabs prospectively collected and enrolled from symptomatic individuals (within ten days of symptom onset) who were suspected of COVID-19. As with all antigen tests, performance may decrease as days since symptom onset increase. Specimen collection and testing was performed by the subject (age 14 and older) or their Parent/Legal Guardian/Companion (age 2 and older) at the testing site, unassisted by the study staff and according to the product labeling in eleven geographically diverse areas across the United States. Reference nasal swabs were collected by a healthcare professional and tested with the comparator method in a blinded fashion. The performance of the BD Veritor™ At-Home COVID-19 Test 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.

A total of 648 compliant subjects were enrolled into the study, of which 638 had a compliant BD Veritor app result for the invalid rate analysis. The invalid rate for the BD Veritor™ At-Home COVID-19 Test was calculated to be 1.6% (10/638). The invalid rate was calculated by the number of invalid results over the total number of compliant BD Veritor app results. Of the 638 compliant BD Veritor app results, those with an invalid result were removed (10) as well as 31 subjects who were missing a complaint reference RT-PCR result, leave 597 subjects for performance calculation. The performance of this test has not yet been clinically validated for use in patients without signs and symptoms of respiratory infection, or for serial screening applications and performance may differ in these populations.

Performance of the BD Veritor™ At-Home COVID-19 Test is presented in **Table 3**.

Table 3: Summary of the Performance of the BD Veritor™ At-Home COVID-19 Test compared to RT-PCR for Nasal Swabs for detection of SARS-CoV-2

BD Veritor™ At-Home COVID-19 Test Results for Detection of SARS-CoV-2	**Reference RT-PCR Results for detection of SARS-CoV-2**		
	POS	**NEG**	**Total**
POS	33	1	34
NEG	6*	557	563
Total	39	558	597
PPA: 84.6% (70.3%, 92.8%) NPA: 99.8% (99%, 100%)			

*One (1) specimen negative by the At-Home Test and positive by the reference RT-PCR was negative by a second RT-PCR assay.

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

Age demographics for the subjects that participated in the clinical performance study are presented in **Table 4**.

Table 4: Demographics of the 597 specimens in the Clinical Performance Study

Subject Demographics for nasal swabs BD Veritor™ At-Home COVID-19 Test result	
Age Group	**Positivity Rate***
2 - 13	5.0% (1/20)
14 – 24	5.8% (7/120)
25 – 64	7.2% (29/401)
≥ 65	3.6% (2/56)
Overall	6.5% (39/597)
* Positivity rate is based on RT-PCR results. Subjects with compliant and reportable results from both Veritor and RT-PCR tests are included in the analysis.	

The PPA and NPA stratified by days since onset of symptoms is presented in **Table 5** demonstrating similar performance of the assay through ten days post symptoms onset.

Table 5: PPA and NPA between the BD Veritor™ At-Home COVID-19 Test compared to RT-PCR for Nasal Swabs for detection of SARS-CoV-2 stratified by Days of Symptoms Onset

		Reference RT-PCR Results for detection of SARS-CoV-2 by CT category		
Symptoms Onset Day	**BD Veritor Result**	**Positive**	**Negative**	**Total**
Day 0	Positive	0	0	0
	Negative	0	4	4
	Total	0	4	4
PPA: Not Available NPA: 100% (51%, 100%)				
0 - 1 day	Positive	2	0	2
	Negative	1	56	57
	Total	3	56	59
PPA: 66.7% (20.8%, 93.9%) NPA: 100% (93.6%, 100%)				
0 - 2 days	Positive	8	0	8
	Negative	2	162	164
	Total	10	162	172
PPA: 80.0% (49.0%, 94.3%) NPA: 100.0% (97.7%, 100.0%)				
0 - 3 days	Positive	21	0	21
	Negative	2	263	265
	Total	23	263	286

PPA: 91.3% (73.2%, 97.6%) NPA: 100.0% (98.6%, 100.0%)				
0 - 4 days	Positive	25	1	26
	Negative	3	342	345
	Total	28	343	371
PPA: 89.3% (72.8%, 96.3%) NPA: 99.7% (98.4%, 99.9%)				
0 - 5 days	Positive	27	1	28
	Negative	5	408	413
	Total	32	409	441
PPA: 84.4% (68.2%, 93.1%) NPA: 99.8% (98.6%, 100.0%)				
0 - 6 days	Positive	28	1	29
	Negative	5	458	463
	Total	33	459	492
PPA: 84.8% (69.1%, 93.3%) NPA: 99.8% (98.8%, 100.0%)				
0 - 7 days	Positive	30	1	31
	Negative	5	501	506
	Total	35	502	537
PPA: 85.7% (70.6%, 93.7%) NPA: 99.8% (98.9%, 100.0%)				
0 - 8 days	Positive	31	1	32
	Negative	6	533	539
	Total	37	534	571
PPA: 83.8% (68.9%, 92.3%) NPA: 99.8% (98.9%, 100.0%)				
0 - 9 days	Positive	33	1	34
	Negative	6	551	457
	Total	39	552	591
PPA: 84.6% (70.3%, 92.8%) NPA: 99.8% (99.0%, 100.0%)				
0 - 10 days	Positive	33	1	34
	Negative	6	557	563
	Total	39	558	597
PPA: 84.6% (70.3%, 92.8%) NPA: 99.8% (99.0%, 100.0%)				

ANALYTICAL PERFORMANCE

LIMIT OF DETECTION (ANALYTICAL SENSITIVITY)

The LoD for the BD Veritor™ At-Home COVID-19 Test was established using limiting dilutions of a viral sample inactivated by gamma irradiation. The material was supplied at a concentration of 2.8 x 10^5 $TCID_{50}$/mL.

In this study, designed to estimate the LoD of the test when using nasal clinical matrix, an initial range finding study was performed testing devices in triplicate using a 10-fold dilution series. At each dilution, 50 µL samples were added to swabs and then tested through the full assay workflow, from processing in the extraction reagent to interpretation by the Scanwell Health App.

A concentration was chosen between the last dilution to give three positive results and the first to give three negative results. Using this concentration, the LoD was further refined with a 2-fold dilution series. The last dilution demonstrating 100% positivity was then tested in an additional 20 replicates tested in the same way. The BD Veritor™ At-Home COVID-19 Test LoD is shown in **Table 6**.

Table 6: BD Veritor™ At-Home COVID-19 Test Limit of Detection

Starting Material Concentration	Estimated LoD	No. Positive/ Total	% Positive
2.8 x 10^5 $TCID_{50}$/mL	1.87 x 10^2 $TCID_{50}$/mL	19/20	95%

CROSS REACTIVITY (ANALYTICAL SPECIFICITY)

A cross-reactivity study was conducted to demonstrate that the BD Veritor™ At-Home COVID-19 Test does not react with related pathogens, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in the respiratory tract. The starting material was spiked into a volume of pooled clinical matrix obtained from healthy donors and confirmed negative for SARS-CoV-2. Samples were added to swabs and then tested through the full assay workflow, from processing in the extraction reagent to interpretation by the Scanwell Health App. Each organism and virus was tested in triplicate. Testing of the following related and high prevalence disease agents showed no evidence of cross-reactivity at the concentrations tested except for SARS-Coronavirus at a concentration of 3.3 x 10^5 PFU/mL (see **Table 7**). Two lower concentrations of SARS-Coronavirus were tested, and cross reactivity was not observed at the lower concentrations.

Table 7: BD Veritor™ At-Home COVID-19 Test Cross Reactivity Testing Results

Potential Cross-Reactant	Concentration Tested	Cross-Reactivity (Yes/No)
Human coronavirus 229E	1.0 x 10^5 $TCID_{50}$/mL	No
Human coronavirus OC43	1.0 x 10^5 $TCID_{50}$/mL	No
Human coronavirus NL63	1.0 x 10^5 $TCID_{50}$/mL	No
Adenovirus Type 3	1.0 x 10^5 $TCID_{50}$/mL	No
Human Metapneumovirus (HMPV), A2	1.0 x 10^5 $TCID_{50}$/mL	No
Parainfluenza virus 1	1.0 x 10^5 $TCID_{50}$/mL	No
Parainfluenza virus 2	1.0 x 10^5 $TCID_{50}$/mL	No
Parainfluenza virus 3	2.1 x 10^6 $TCID_{50}$/mL	No
Parainfluenza virus 4a	1.6 x 10^4 $TCID_{50}$/mL	No

Potential Cross-Reactant	Concentration Tested	Cross-Reactivity (Yes/No)
Influenza A (H1N1 subtype A/Christ Church/16/2010)	5.3 x 10^7 EID_{50}/mL	No
Influenza A (H3N2 subtype A/Perth/16/2009)	6.6 x 10^6 EID_{50}/mL	No
Influenza B (Yamataga lineage B/Texas/81/2016)	6.6 x 10^5 EID_{50}/mL	No
Influenza B (Victoria lineage B/Washington/02/2019)	5.3 x 10^6 EID_{50}/mL	No
Enterovirus D68	5.3 x 10^5 $TCID_{50}$/mL	No
Respiratory syncytial virus, strain Long	5.3 x 10^5 $TCID_{50}$/mL	No
Rhinovirus 3	1.0 x 10^5 PFU/mL	No
MERS-coronavirus (Heat activated)	1.0 x 10^5 $TCID_{50}$/mL	No
Haemophilus influenzae	1.0 x 10^6 CFU/mL	No
Streptococcus pneumoniae	1.0 x 10^6 CFU/mL	No
Streptococcus pyogenes	1.2 x 10^6 CFU/mL	No
Candida albicans	1.3 x 10^6 CFU/mL	No
Bordetella pertussis	1.0 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
Staphylococcus aureus (MSSA)	1.8 x 10^7 CFU/mL	No
Staphylococcus aureus (MRSA)	2.1 x 10^7 CFU/mL	No
Staphylococcus epidermidis	1.7 x 10^6 CFU/mL	No
Candida albicans	1.3 x 10^6 CFU/mL	No
Pooled human nasal wash	N/A	No
Pneumocystis jirovercii-S. cerevisiae Recombinant	2.1 x 10^6 CFU/mL	No
SARS-coronavirus (gamma irradiated)	3.3 x 10^5 PFU/mL	Yes
SARS-coronavirus (gamma irradiated)	1.7 x 10^5 PFU/mL	No
SARS-coronavirus (gamma irradiated)	8.3 x 10^4 PFU/mL	No

Using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI), in silico analysis was conducted for those organisms that could not be sourced for wet testing. Two blast searches were performed, each of which compared the SARS-CoV-2 nucleocapsid protein sequence against sequence database information from one other microorganism listed below. The degree of sequence homology was then assessed to estimate the likelihood of cross-reactivity with SARS-CoV-2.

- No protein sequence homology was found between SARS-CoV-2 and *M. tuberculosis*, and thus homology-based cross-reactivity while unlikely, cannot be completely ruled out.
- The comparison between SARS-CoV-2 nucleocapsid protein and human coronavirus HKU1 revealed that the only potential for homology is with the HKU1 nucleocapsid phosphoprotein. Homology is relatively low, at 36.7% across 82% of sequences, but cross-reactivity cannot be ruled out.

ENDOGENOUS INTERFERING SUBSTANCES

An endogenous interference study was conducted to evaluate whether various substances that might be present in the respiratory tract or might be artificially introduced onto the nasal swab in the home environment, interfere with the BD Veritor™ At-Home COVID-19 Test. The

substances tested included whole blood 4%, mucin and various medications and cleaning agents. The study results demonstrate that at the concentrations tested none of the potential interfering substances produced false positive results when present in SARS-CoV-2 negative samples or false negative results when present in SARS-CoV-2 positive samples. No invalid results were produced in either condition. (see **Table 8**).

Table 8: BD Veritor™ At-Home COVID-19 Test Endogenous Interfering Substances Testing Results

Substance	Concentration Tested	False positive results (Yes/No)	False negative results (Yes/No)
Afrin (Oxymetazoline)	15% v/v	No	No
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	No	No
Chloraseptic Phenol Spray	15% v/v	No	No
CVS Nasal Drops (Phenylephrine)	15% v/v	No	No
CVS Nasal Spray (Cromolyn)	15% v/v	No	No
Fisherman's Friend (menthol)	1.5 mg/mL	No	No
Flonase (Fluticasone Propionate)	5% v/v	No	No
Homeopathic (Alkalol)	10% v/v	No	No
Mucin	5 mg/mL	No	No
Mupirocin	10 mg/mL	No	No
Nasacort (Triamcinolone)	5 % v/v	No	No
Naso GEL (NeilMed)	5% v/v	No	No
Neo-Synephrine (Phenylephrine HCl) (Spray)	15% v/v	No	No
Tamiflu (Oseltamivir Phosphate)	2.5 mg/mL	No	No
Rhinocort (Budesonide)	5% v/v	No	No
Ricola (menthol)	1.5 mg/mL	No	No
Saline nasal spray	15% v/v	No	No
Sucrets (Dyclonine/Menthol)	1.5 mg/mL	No	No
Tobramycin	4 µg/mL	No	No
Whole blood	4% v/v	No	No
Zanamivir	282 ng/mL	No	No
Zicam Cold Remedy (Galphimia glauca, Luffa)	5% v/v	No	No
Zicam nasal spray (Oxymetazoline)	10% v/v	No	No
Bleach (Sodium Hypochlorite)	1% v/v	No	No
Dish-washing Liquid (Sodium lauryl sulfate)	1% v/v	No	No
Hand sanitizer (ethyl alcohol)	1% v/v	No	No
Hand Soap (Benzalkonium chloride)	1% v/v	No	No
Laundry detergent (C12-15 pareth-7 and sodium laureth-12 sulfate)	1% v/v	No	No
Surface Sanitizer (Citric Acid)	1% v/v	No	No
Vicks VapoRub (Camphor, Eucalyptus oil, Menthol)	4.7% w/w, 1.2% w/w, 2.6% w/w	No	No

Substance	Concentration Tested	False positive results (Yes/No)	False negative results (Yes/No)
Biotin	12 µg/mL	No	No
Biotin	1.2 µg/mL	No	No

MICROBIAL INTERFERENCE

The purpose of this study was to evaluate whether microbes that are likely to be encountered in the respiratory tract, either as disease agents or as normal pathogenic flora, will interfere with the BD Veritor™ At-Home COVID-19 Test. The study demonstrated that false negatives will not occur when SARS-CoV-2 is present in a specimen at 3x LOD with the following related and high prevalence disease agents at the concentrations tested. No microbial interference was observed (see **Table 9**).

Table 9: BD Veritor™ At-Home COVID-19 Test Microbial Interference Testing Results

Potential Cross-Reactant	Concentration Tested	Interference (Yes/No)
Human coronavirus 229E	1.0×10^5 $TCID_{50}$/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 Type 3	1.0×10^5 $TCID_{50}$/mL	No
Human Metapneumovirus (hMPV-27 A2)	1.0×10^5 $TCID_{50}$/mL	No
Parainfluenza virus 1	1.0×10^5 $TCID_{50}$/mL	No
Parainfluenza virus 2	1.0×10^5 $TCID_{50}$/mL	No
Parainfluenza virus 3	3.16×10^5 $TCID_{50}$/mL	No
Parainfluenza virus 4a	1.51×10^4 $TCID_{50}$/mL	No
Influenza A (H1N1 subtype A/Christ Church/16/2010)	7.92×10^6 $TCID_{50}$/mL	No
Influenza A (H3N2 subtype A/Perth/16/2009)	9.98×10^5 $TCID_{50}$/mL	No
Influenza B (Yamagata lineage B/Texas/81/2016)	2.49×10^5 $TCID_{50}$/mL	No
Influenza B (Victoria lineage B/Washington/02/2019)	7.92×10^5 $TCID_{50}$/mL	No
Enterovirus D68	2.00×10^5 $TCID_{50}$/mL	No
Respiratory syncytial virus, strain long	1.98×10^5 $TCID_{50}$/mL	No
Rhinovirus 3	1.00×10^5 PFU/mL	No
SARS-coronavirus (gamma-irradiated)	1.25×10^5 PFU/mL	No
MERS-coronavirus (Heat-inactivated)	1.00×10^5 $TCID_{50}$/mL	No
Haemophilus influenza	1.00×10^6 CFU/mL	No
Streptococcus pneumoniae	1.00×10^6 CFU/mL	No
Streptococcus pyogenes	1.13×10^6 CFU/mL	No
Bordetella pertussis	1.00×10^6 CFU/mL	No
Mycoplasma pneumoniae	1.00×10^6 CFU/mL	No
Chlamydia pneumoniae	1.00×10^6 IFU/mL	No
Legionella pneumophila	1.00×10^6 CFU/mL	No
Staphylococcus aureus (MSSA)	6.88×10^6 CFU/mL	No
Staphylococcus aureus (MRSA)	3.23×10^6 CFU/mL	No
Candida albicans	1.25×10^6 CFU/mL	No
Pneumocystis jirovecii-S. cerevisiae Recombinant	1.98×10^6 CFU/mL	No
Pooled human nasal wash	N/A	No

HIGH DOSE HOOK EFFECT

A high-dose hook effect study was conducted to evaluate if false negative or invalid results can be observed on the BD Veritor™ At-Home COVID-19 Test with very high levels of SARS-CoV-2 or human serum albumin (HSA).

No high-dose hook effect was observed on the BD Veritor™ At-Home COVID-19 Test when tested with gamma-irradiated SARS-CoV-2 and HSA, at concentrations of 2.8 $\times 10^6$ $TCID_{50}$/mL and 1.021 $\times$ 10^3 µg/mL, respectively.

HUMAN USABILITY & USER COMPREHENSION STUDY

BD conducted a study to evaluate the usability of the BD Veritor™ At-Home COVID-19 Test and home user comprehension of the intended use and results interpretation. The human usability and user comprehension study included participants from the multi-site clinical trial and a supplemental caregiver collection study. User satisfaction with the BD Veritor™ At-Home COVID-19 Test workflow, materials, and overall safety were also evaluated.

Seven hundred sixty-eight (768) home users, including self-collection participants (n=693) and caregivers (n=75) took part in the study. The study was conducted with home users in a simulated home use setting where the participant/caregiver performed the test using only the materials in the BD Veritor™ At-Home COVID-19 Test kit box (Test Stick, Tube, Scan Card, Swab, Quick Start Guide, and Product Information Leaflet) and the Scanwell Health App.

For all participants (self-collection and caregiver) in the study, all but one of the critical tasks had a success rate over 94%. The task “Rotate the swab in first nostril for 5 times” had a success rate of 85.7% (658 of 768), however the task “Rotate the swab in second nostril for 5 times” which is an identical task, had 94.1% (723 of 768) success rate, demonstrating an improvement in the task from the initial task learning.

All study participants were asked to fill out a satisfaction questionnaire rating the ease-of-use, quality of the instructions for use, safety concerns, and their confidence in the test result. All 10 questions presented in the questionnaire received a rating of 4.2 or above (on a scale of 1 to 5).

TECHNICAL SUPPORT

For questions, or to report a problem, please call 844-4Veritor (844-438-7486) or visit www.bdveritorathome.com. This document, The Fact Sheet for Healthcare Providers, the Fact Sheet for Individuals, the Quick Start Guide and the Patient Information Leaflet are available at bd.com/e-labeling.

The BD Veritor At-Home COVID-19 Test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Professionals and the authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas.

REFERENCES

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

Change History

Revision	Date	Change Summary
01	2021-08	Initial release

SYMBOL GLOSSARY	
	Catalog Number
	Consult Instructions for Use
	Do Not Reuse
	In Vitro Diagnostic
	Manufacturer
	Temperature Limitation

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