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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

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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. 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 anterior nasal (nares) swab samples from individuals aged 14 years or older or adult-collected anterior nasal swab samples from individuals aged 2 years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 7 days of symptom onset when tested at least twice over 3 days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over 5 days with at least 48 hours between tests.

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, which is generally detectable in anterior nasal (nares) 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.

All negative results are 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 measures such as isolating from others and wearing masks. 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.

Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow-up care with their physician or 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 2 years or older in a non-laboratory setting. The BD Veritor™ At-Home COVID-19 Test is only for use under the Food and Drug Administration's Emergency Use Authorization. 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 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 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.

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 requiring serial (repeat) testing of negative results at least twice over 3 days or for use in individuals without symptoms when tested at least three times over 5 days. 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 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 confirm 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 ensure human specimen is present. Interpretation and reporting of the correct test result, from the multiple lines deposited in the reaction zone, require 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 symptomatic individuals requiring serial (repeat) testing of negative results at least twice over 3 days, or without symptoms when tested at least three times over 5 days 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 sample 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
- 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

BD Veritor™ At-Home COVID-19 Test Components	Description	Formulation
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.	N/A
Instructions for Use	Quick Start Guide (QSG) Product Information Leaflet (PIL) Fact Sheet for Individuals	N/A

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: bdveritorathome.com/devices. BD will continue to evaluate and validate compatible smartphones and update this list as necessary.
- The minimum requirements are:
  - iPhone 7 with iOS 11 and a camera resolution of at least 1000 pixels in both dimensions, or
  - Android phones with Android 9 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.
- Subsequent operating systems and phone models will be supported following performance evaluation.
- Scanwell® Health App – Available for download from the app stores.

WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

- Follow the Scanwell® Health App directions exactly as presented. Failure to do so may affect test performance and/or produce incorrect results.
- 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, 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.
- **Serial testing should be performed in individuals with negative results at least twice over 3 days (with 48 hours between tests) for symptomatic individuals and three times over 5 days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- **If you have had symptoms longer than 7 days you should consider testing at least three times over 5 days with at least 48 hours between tests.**
- An anterior nasal swab sample can be self-collected by an individual age 14 years and older. Children age 2 to 13 years should be tested by an adult.
- Do not use the test on anyone under 2 years of age.
- Wear a safety mask or other face covering when collecting a specimen from a child or another individual.
- Do not use if any of the test kit contents or packaging is damaged.
- Test components are single-use. Do not reuse.
- Use only the contents provided in the test kit.
- Do not use test kit if it is past the expiration date.
- Do not touch the swab tip.

- Follow the Scanwell® Health App step-by-step directions exactly as presented and read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test 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.
- 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.
- **Keep testing kit and kit components away from children and pets before and after use. Do not inhale, swallow or ingest any kit components. Avoid contact with your skin and eyes. The reagent solution contains harmful chemicals (see Table 2: Hazardous Ingredients 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 2: Hazardous Ingredients

Chemical Name/CAS	GHS Code	Concentration
Sodium Azide/26628-22-8	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310	0.095%
Triton X-100/9002-93-1	Causes skin irritation (H315) Causes serious eye irritation (H319)	2%

- For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

STORAGE

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

TEST PROCEDURE AND RESULTS INTERPRETATION

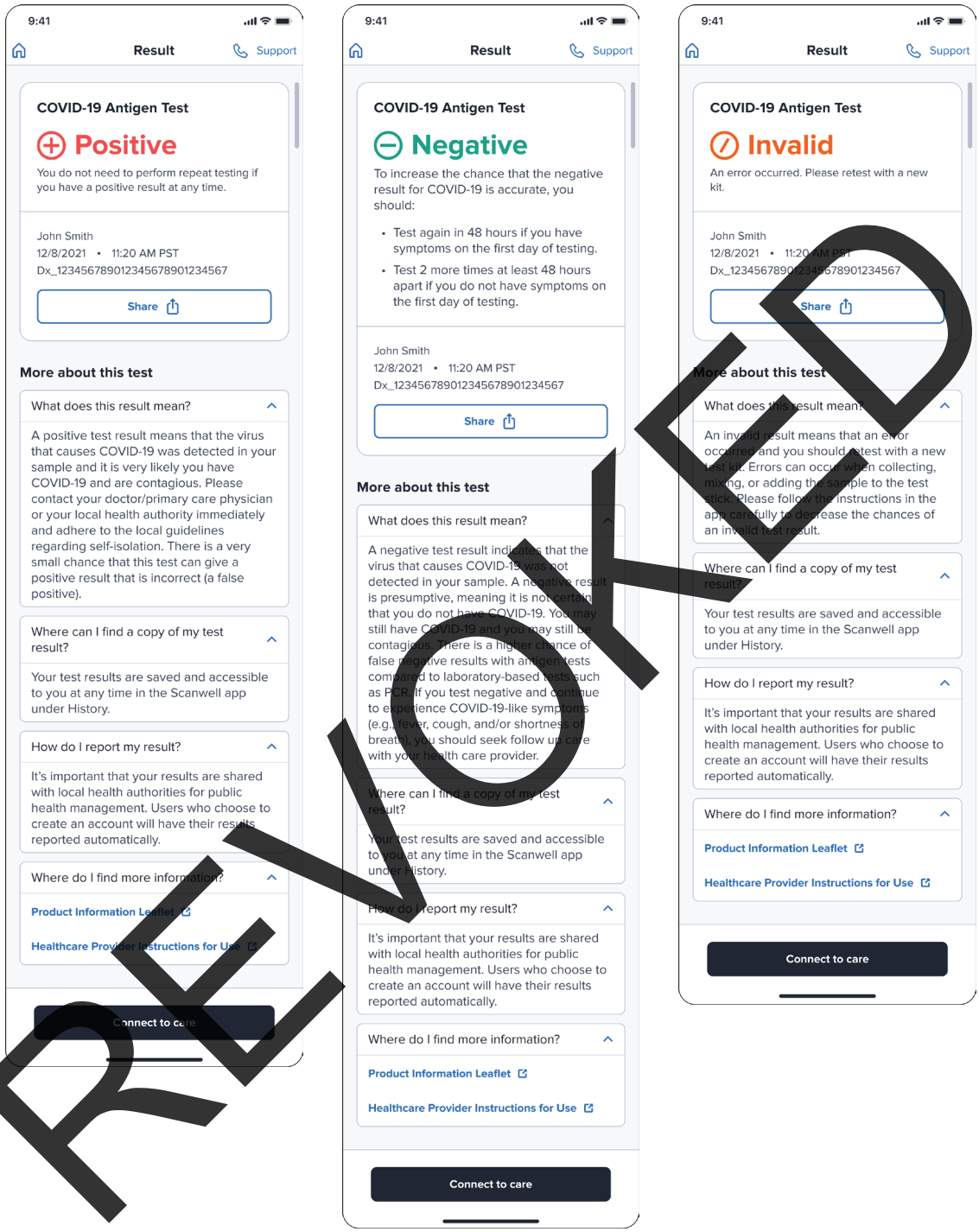
When opening of the BD Veritor™ At-Home COVID-19 Test kit, the user is instructed to first read the Quick Start Guide (QSG), download and open the Scanwell® Health App from their app store, create or log in to their Scanwell® Account, and follow the step-by-step instructions provided in the app.

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 Sample 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 sample 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 Results 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



TEST INTERPRETATION

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting tests results.

Table 3: Test Results Interpretation

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

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.

COVID-19 Positive (+)

Repeat testing does not need to be performed if patients have a positive result at any time.

A positive 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 contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and 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 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 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 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.

COVID-19 Negative (-)

To increase the chance that the negative result for COVID-19 is accurate, you should:

- **Test again in 48 hours if the individual has symptoms on the first day of testing.**
- **Test two more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.**

A negative test result 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 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.

Invalid

An invalid result means that an error has occurred. Re-test with a new swab and new test device.

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 ensure 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 ensure 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 that result in the reporting of the test as Negative, Positive, or Invalid are outlined in Table 4.

Table 4: 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 failsafe against any possible missed detections.

Other Failure Alert and Failsafe Controls

The test also incorporates failure alert and failsafe controls that ensure 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, or a user attempts to use a different manufacturer's Test Stick.

LIMITATIONS

- 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.
- 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.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.
- If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, 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.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- This test detects both viable (live) and nonviable SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
- 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.

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 10 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 site, unassisted by the study staff and according to the product labeling in 11 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 compliant reference RT-PCR result, leaving 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 5.

Table 5: 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% (99.0%, 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 6.

Table 6: 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 BD 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 7 demonstrating similar performance of the assay through 7 days post symptoms onset. Additional information for a small number of specimens collected from days 7 to 10 are provided as a supplemental analysis.

Table 7: 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%)				

		Reference RT-PCR Results for detection of SARS-CoV-2 by CT category		
Symptoms Onset Day	BD Veritor™ Result	Positive	Negative	Total
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%)				

		Reference RT-PCR Results for detection of SARS-CoV-2 by CT category		
Symptoms Onset Day	BD Veritor™ Result	Positive	Negative	Total
0–9 days	Positive	33	1	34
	Negative	6	551	557
	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%)				

CLINICAL PERFORMANCE: PROSPECTIVE SERIAL TESTING STUDY AT NATIONAL INSTITUTE OF HEALTH

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 3 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 5 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 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing.

Performance of the antigen test with serial testing in individuals is described in Table 8.

Table 8: Data Establishing PPA of COVID-19 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 PCR POSITIVE TEST RESULT	ASYMPTOMATIC ON FIRST DAY OF TESTING			SYMPTOMATIC ON FIRST DAY OF TESTING		
	Ag Positive/PCR Positive (Antigen Test Performance % PPA)					
	1 Test	2 Tests	3 Tests	1 Test	2 Tests	3 Tests
0	9/97 (9.3%)	35/89 (39.3%)	44/78 (56.4%)	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	17/34 (50.0%)	23/34 (67.6%)	25/32 (78.1%)	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	16/21 (76.2%)	15/20 (75.0%)	13/15 (86.7%)	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	20/28 (71.4%)	21/27 (77.8%)	16/18 (88.9%)	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	13/23 (56.5%)	13/22 (59.1%)	4/11 (36.4%)	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	5/9 (55.6%)	5/8 (62.5%)	N/A	4/9 (44.4%)	3/7 (42.9%)	N/A

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 (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 2.8×10^5 $TCID_{50}$/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 9.

Table 9: BD Veritor™ At-Home COVID-19 Test Limit of Detection

Starting Material Concentration	Estimated LoD	No. Positive/Total	% Positive
2.8×10^5 $TCID_{50}$/mL	1.87×10^2 $TCID_{50}$/mL 9.35 $TCID_{50}$/swab	19/20	95%

NIH/RADX® VARIANT TESTING

The performance of this 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 24.0 (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 24.0) were not detected by the BD Veritor™ At-Home COVID-19 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™ At-Home COVID-19 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	100
Dilution 6	24.0	60	0	100
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

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 UVT 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 3.3×10^5 PFU/mL (see Table 10). Two lower concentrations of SARS-Coronavirus were tested, and cross-reactivity was not observed at the lower concentrations.

Table 10: BD Veritor™ At-Home COVID-19 Test Cross-Reactivity Testing Results

Potential Cross-Reactant	Concentration Tested	Cross-Reactivity (Yes/No)
Human coronavirus 229E	1.0×10^5 $TCID_{50}$/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), A2	1.0×10^5 $TCID_{50}$/mL	No

Potential Cross-Reactant	Concentration Tested	Cross-Reactivity (Yes/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	2.1×10^6 $TCID_{50}$/mL	No
Parainfluenza virus 4a	1.6×10^4 $TCID_{50}$/mL	No
Influenza A (H1N1 subtype A/Christ Church/16/2010)	5.3×10^7 EID_{50}/mL	No
Influenza A (H3N2 subtype A/Perth/16/2009)	6.6×10^6 EID_{50}/mL	No
Influenza B (Yamataga lineage B/ Texas/81/2016)	6.6×10^5 EID_{50}/mL	No
Influenza B (Victoria lineage B/ Washington/02/2019)	5.3×10^6 EID_{50}/mL	No
Enterovirus D68	5.3×10^5 $TCID_{50}$/mL	No
Respiratory syncytial virus, strain Long	5.3×10^5 $TCID_{50}$/mL	No
Rhinovirus 3	1.0×10^5 PFU/mL	No
MERS-coronavirus (Heat activated)	1.0×10^5 $TCID_{50}$/mL	No
Haemophilus influenzae	1.0×10^6 CFU/mL	No
Streptococcus pneumoniae	1.0×10^6 CFU/mL	No
Streptococcus pyogenes	1.2×10^6 CFU/mL	No
Candida albicans	1.3×10^6 CFU/mL	No
Bordetella pertussis	1.0×10^6 CFU/mL	No
Mycoplasma pneumoniae	1.0×10^6 CFU/mL	No
Chlamydia pneumoniae	1.0×10^6 IFU/mL	No
Legionella pneumophila	1.0×10^6 CFU/mL	No
Staphylococcus aureus (MSSA)	1.8×10^7 CFU/mL	No
Staphylococcus aureus (MRSA)	2.1×10^7 CFU/mL	No
Staphylococcus epidermidis	1.7×10^6 CFU/mL	No
Pooled human nasal wash	N/A	No
Pneumocystis jirovecii-S. cerevisiae Recombinant	2.1×10^6 CFU/mL	No
SARS-coronavirus (gamma irradiated)	3.3×10^5 PFU/mL	Yes
SARS-coronavirus (gamma irradiated)	1.7×10^5 PFU/mL	No
SARS-coronavirus (gamma irradiated)	8.3×10^4 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 11).

Table 11: 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

Substance	Concentration Tested	False Positive Results (Yes/No)	False Negative Results (Yes/No)
Vicks VapoRub (Camphor, Eucalyptus oil, Menthol)	4.7% w/w, 1.2% w/w, 2.6% w/w	No	No
Biotin	12 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 3× LoD with the following related and high prevalence disease agents at the concentrations tested. No microbial interference was observed (see Table 12).

Table 12: 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 influenzae	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 2.8×10^6 $TCID_{50}$/mL and 1.021×10^3 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 (844-483-7486) or visit 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/in-vitro-diagnostics-euas

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Change History

Revision	Date	Change Summary
02	2022-03	Updates from the FDA following Intended Use changes for testing in symptomatic populations or serial testing in asymptomatic populations.
03	2023-03	Updates based on FDA revisions related to serial (repeat) testing for EUAs of antigen IVDs, received in a letter of authorization dated November 1, 2022.
04	2023-04	Minor typographical corrections were made to Intended Use and Clinical Performance Serial Testing Study sections.

SYMBOLS GLOSSARY

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

Symbol	Meaning
REF	Catalogue number
	Consult *instructions for use* or consult electronic *instructions for use*.
	Contains sufficient for <*n*> tests
	Do not re-use
IVD	*In vitro* diagnostic medical device
	Manufacturer
	Temperature limit