CLIA Waiver by Application Approval Determination
Decision Summary

I. Document Number

CW240032

II. Parent Document Number

K243872

III. CLIA Waiver Type

Dual 510(k) and CLIA Waiver by Application (Dual Submission)

IV. Applicant

Becton, Dickinson and Company

V. Proprietary and Established Names

BD Veritor System for SARS-CoV-2

VI. Measurand (analyte)

SARS-CoV-2 nucleocapsid antigens

VII. Sample Type(s)

Direct anterior nasal specimen

VIII. Type of Test

Qualitative chromatographic digital immunoassay

IX. Test System Description

A Overview

Device Description:

The BD Veritor System for SARS-CoV-2 is a rapid (approximately 15 minutes) qualitative chromatographic digital immunoassay for the direct detection of nucleocapsid protein antigens from SARS-CoV-2 in direct anterior nasal swab specimens collected from patients with signs

and symptoms of COVID-19 by a healthcare provider. The test is intended for interpretation in laboratory and near patient testing environments only with the BD Veritor Plus Analyzer Instrument. The test is not intended to be interpreted visually.

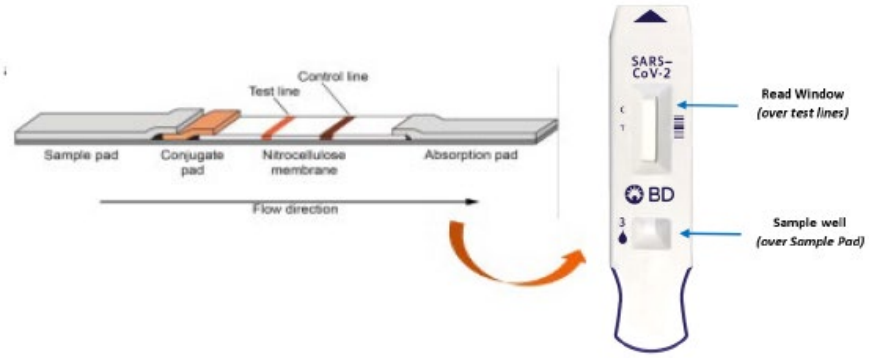

Figure 1: Test device

The test device is composed of a plastic housing, known as a cassette, that contains a test strip with the following parts: sample pad, conjugate pad, nitrocellulose membrane, and absorption pad. The patient sample is placed in the tube containing extraction buffer, where the virus particles in the sample are disrupted, exposing internal viral nucleoproteins. After disruption, the sample is dispensed into the sample well of the cassette.

When specimens are processed and added to the test device, SARS-CoV-2 antigens present in the specimen bind to biotinylated antibodies and antibodies conjugated to detector particles, colloidal gold nanoparticles, in the test strip. The biotinylated antibody-antigen-conjugate complexes migrate across the test strip to the reaction area and are captured by a line of streptavidin bound on the membrane.

The assay is intended for interpretation in both laboratory and near-patient testing environments only with an opto-electronic interpretation instrument, the BD Veritor Plus Analyzer Instrument and is not interpreted visually. The analyzer measures the amount of light reflected from various zones along the assay strip. The measurement of the assay background zone is an important factor during the test interpretation as the reflectance value is compared to that of the control and test zones. The instrument analyzes the reflectance data to provide the proper test interpretation.

The BD Veritor test devices are designed with four spatially distinct reaction zones (Figure 2).

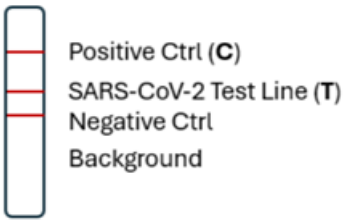

Figure 2: Reaction zones on the test device: positive control position (C), test line position for SARS-CoV-2 (T), negative control position, and a background zone.

A positive result is determined by the analyzer when antigen-conjugate is deposited at the Test "T" position and a control conjugate is deposited at the Control "C" position on the assay device. Two of the four distinct zones on the test device, negative control and background, are not labeled. The active negative control feature in each test identifies and compensates for specimen-

related, nonspecific signal generation. The remaining zone is used to measure the assay background. The analyzer automatically scans the test strip, collects and analyzes the data, and then calculates and reports the result as either positive, negative, or invalid. The instrument analyzes and corrects for non-specific binding and detects positives not recognized by the unaided eye to provide an objective result. The analyzer uses a proprietary algorithm which subtracts nonspecific signal at the negative control line from the signal present at the test line. If the resultant test line signal is below the cutoff, the specimen is scored as negative. Use of the active negative control feature allows the BD Veritor System to correctly interpret test results that cannot be scored visually because the human eye is unable to accurately perform the subtraction of the nonspecific signal.

The analyzer is a portable, electronic instrument that uses a reflectance-based measurement method to evaluate line signal intensities on the assay test device. It applies assay-specific firmware algorithms to determine the presence or absence of target analyte(s). The analyzer is powered by a rechargeable Li-ion battery and compact wall transformer, is intended for tabletop or benchtop use, and follows the original BD Veritor instrument model of a calibration-free limited lifetime based on the number of tests performed, the number of days from first use, and/or the maximum shelf life from the date of manufacture. By design, the analyzer has few external means for user input or output. Operation requires minimal operator interaction to complete testing and to report results. analyzer workflow procedures depend on the instrument configuration selected by the user. In **Analyze Now** mode, the instrument evaluates test devices after the manual timing of the assay's development. In **Walk Away** mode, test devices are inserted into the analyzer immediately after the application of the specimen, and the timing of the assay development and the analysis is automated. In either case, assay results are provided to the operator on the liquid crystal display (LCD) display screen. Additional result documentation capabilities are possible with the use of a BD Veritor bar code scanning module, which can capture, display and/or integrate barcoded specimen, operator, or kit information in the test record.

The BD Veritor SARS-CoV-2 Control Swab Set is intended to be used as quality control samples representative of positive and negative test samples, to demonstrate that the reagents are functional and that the assay procedure is correctly performed.

B Test System Components

The assay kit contains all materials needed to run the test, including external controls. For a 30-test kit, this includes:

- Individually Packaged Test Cassettes (30): containing monoclonal anti-SARS antibodies
- Pre-filled Reagent tubes with integral dispensing tips (30): Detergent solution with less than 0.1 % sodium azide
- Specimen Sampling Nasal Swabs (30): Individually wrapped, sterile, single-use
- SARS-CoV-2 Positive Control Swab (1): Individually wrapped, single-use control swab containing non-infectious, recombinant viral protein antigen with less than 0.1% sodium azide
- SARS-CoV-2 Negative Control Swab (1): Individually wrapped, single-use control swab containing buffer with less than 0.1% sodium azide
- Instructions for use

- Quick Reference Instructions
- Nasal swab sampling instructions
- Tube tray

X. Specific Contents for CLIA Waiver

A Demonstrating "Simple":

Table 1: Demonstration of Simplicity for the BD Veritor System for SARS-CoV-2.

"Simple" Criteria	Device Characteristics
Is a fully automated instrument or a unitized or self-contained test.	• In WALK AWAY mode, the test does not require any operator intervention during the analysis step. User performs simple sample extraction steps prior to applying the extracted sample on the cassette and inserting into the analyzer. The BD Veritor Plus Analyzer completes the analysis automatically.
Uses direct unprocessed specimens, such as capillary blood (fingerstick), venous whole blood, nasal swabs, throat swabs, or urine.	• The test uses direct anterior nasal swab specimens.
Needs only basic, non-technique-dependent specimen manipulation, including any for decontamination.	• An untrained operator can conduct the test by performing simple steps without sample manipulation: 1) collect the anterior nasal swab, 2) insert the sample swab in the extraction reagent and plunge the swab up and down, 3) express excess liquid from the swab by squeezing the sides of the tube, 4) press the attached tip onto the tube, 5) apply 3 drops of the sample to the cartridge, and then 6) load the sample cartridge into the BD Veritor Plus Analyzer. • No specialized equipment is needed for sample processing.
Needs only basic, non-technique-dependent reagent manipulation, such as "mix reagent A and reagent B."	• The test requires only basic reagent handling to obtain accurate test results. No processing of reagents is needed prior to combining test reagent and sample. • The provided reagent is premeasured and provided in single-use vials. • The test cartridges are unitized and contain all the reagents required for analysis.
Needs no operator intervention during the analysis steps.	• The BD Veritor Plus Analyzer performs automated analysis of test results and eliminates subjectivity associated with visual reading of results by the end-user. • After insertion of the sample cartridge into the BD Veritor Plus Analyzer and the initiation of the test run, the test does not require any operator intervention during the analysis step.
Needs no technical or specialized training with respect to troubleshooting or interpretation of multiple or complex error codes.	• Error messages are unambiguous and include easy-to-interpret solutions. • No complex trouble shooting or interpretation of error codes are required to operate BD Veritor Plus Analyzer.

"Simple" Criteria	Device Characteristics
Needs no electronic or mechanical maintenance beyond simple tasks, e.g., changing a battery or power cord.	• There is no maintenance required other than wiping of the external surface of the analyzer. • There are no user serviceable parts, and the instrument is to be returned to BD if maintenance is required.
Produces results that require no operator calibration, interpretation, or calculation.	• There is no instrument calibration, and the interpretation of results is automated.
Produces results that are easy to determine, such as 'positive' or 'negative,' a direct readout of numerical values, the clear presence or absence of a line, or obvious color gradations.	• Interpretation of results is automated. Results are displayed on the instrument screen as positive, negative, or invalid and no additional interpretation or calculations are required.
Contains a quick reference instruction sheet that is written at no higher than a 7th grade reading level.	• The test procedure is written at a 7th grade comprehension level.

B Demonstrating "Insignificant Risk of an Erroneous Result"- Failure Alerts and Fail-Safe Mechanisms

1. Risk Analysis:

   A comprehensive risk analysis of the BD Veritor System for SARS-CoV-2 has been conducted in accordance with ISO 14971, *"Medical devices-Application of risk management to medical devices"*. The sponsor utilized the Device Hazard Analysis and the Failure Mode Effects Analysis (FMEA) methods to assess the risks of failure that may occur during use or misuse of the device. The FMEAs included identification of potential failure modes and effect of the failure, potential causes, risk control measures and evaluation of severity and frequency of occurrence. The elements considered included operator errors (human factors), sample and device handling and storage, and environmental factors.

   Potential sources of errors that could adversely affect system performance were identified and mitigated first through system design and then through additional cautions in the labeling. The identified risks which could result in erroneous test results were evaluated in flex studies that stressed the functional limits of the test system (see Section VIII.B.3).

2. Fail-Safe and Failure Alert Mechanisms:

   The BD Veritor System for SARS-CoV-2 was designed to include numerous features and fail-safe mechanisms built into the system to prevent erroneous results.

   Design Features

   - Nasal swabs are supplied with the kit to facilitate optimal specimen collection and release.
   - Pre-filled unitized tube eliminates the need to measure or dispense reagents prior to testing.
   - Filter tip is attached to unitized tube provided for ease of use.
   - Graphics are clearly printed on the test device to indicate the sample addition well and the correct number of drops to be added.

- Each test device contains a negative control line. The BD Veritor Plus Analyzer algorithm evaluates the negative control line and compensates for any sample dependent non-specific binding.
- On-device barcode identifies the analyte being tested. The analyzer displays both the analyte that was tested and the results for each assay in the display widow.
- Objective, instrumented test interpretation eliminates errors due to end users with varying levels of visual acuity and allows use under variable lighting conditions.
- Light weight, portable BD Veritor Plus Analyzer is designed for simplicity with a single button operation, self-checks on electronics and optics and requires no maintenance or calibration by the operator.
- Option of operation on battery power or plugged into facility power provides flexibility for different usage situations.
- The BD Veritor Plus Analyzer displays the assay result in the display window for 15 minutes when operating on battery power or 60 minutes when plugged in or until the assay device is removed.

Fail-safe Features

- Lock-out functions that do not allow output of results if internal controls or system checks are not successfully completed:
    - During power initialization, the BD Veritor Plus Analyzer performs a start-up self-test to check the following:
        - Functionality of the light source, the camera, and by confirming the firmware checksum. If the instrument fails the start-up self-test, a failure message will be displayed.
        - Upon completion of the self-test, the BD Veritor Plus Analyzer will perform a lifetime check and will display a lifetime warning if the analyzer is nearing expiration. This warning will continue to be displayed each time the analyzer is powered on until expiration is reached.
    - An external verification cartridge is provided with every BD Veritor Plus Analyzer to allow the operator to test the functionality of the system. In the event of failure, a message is displayed, and the instrument cannot be used to interpret any tests.

- Lock-out functions that do not allow output of results if the device was mishandled:
    - During instrument start-up, the functionality of the light source and the camera are checked. In the event of damage to the BD Veritor Plus Analyzer (i.e. dropped or mishandled), the self-test will fail, and the user will be locked out from performing test interpretation.
    - Each test device contains on-board controls to identify proper functioning of the assay. The BD Veritor Plus Analyzer identifies internal control failures and will not report results.

- Physical features to ensure correct placement of components, such as strips or cartridges:
    - Incorrect insertion of the cartridge (reverse, upside down etc.) is prevented by an asymmetric key design of the interface between the test device/analyzer, which does not allow the test device to be inserted into the analyzer incorrectly.

- A barcode on the test device identifies the assay being performed. The analyzer reports out the correct assay results for the analyte associated with that barcode.

- Battery checks:
  - The BD Veritor Plus Analyzer performs battery monitoring when it is powered up, before reading the test device, and after reading the test device. An alert will be issued before the battery capacity falls below the point at which performance is affected. This battery error will continue to be reported until the batteries are recharged. Once the batteries fall below this threshold level, no results can be reported.

- Internal procedural controls to flag procedural problems:
  - Use of control lines and an assay background zone detect improper sample flow. When this occurs, the Analyzer will not report a test result, but will report a Control Invalid result.
  - The negative control line and the background zone are incorporated on each test device to address problems with sample-dependent non-specific binding.
  - The BD Veritor Plus Analyzer evaluates control and test lines on each test device. If the control lines are not detected or are detected outside limits, test results will not be reported but a Control Invalid result will be reported.

- External control material
  - Positive and negative controls are supplied with each test kit and are supplied separately.
  - An analyzer verification cartridge is supplied to verify the analyzer is functioning within specifications.

3. Flex Studies:

The operational limits of the BD Veritor System for SARS-CoV-2 were evaluated in a series of experiments of "stress", including conditions outside of those recommended in the instructions for use. Flex testing was performed with contrived positive nasal swabs generated by diluting heat inactivated SARS-CoV-2 virus (Omicron variant, XBB) in negative clinical matrix (NCM) at 2x LoD ($1.19x10^4$ $TCID_{50}$/mL). The studies and data demonstrate that the test is robust in the claimed intended use condition with an insignificant risk of erroneous results. Results are summarized below.

Table 2: Flex Study Results.

Condition		**Positive Swab Samples (Positive/Total)**	**Negative Swab Samples (Negative/Total)**
Development/Read Time	10 minutes	5/5	5/5
	15 minutes	5/5	5/5
	20 minutes	5/5	5/5
	30 minutes	5/5	5/5
	40 minutes	5/5	5/5
	60 minutes	5/5	5/5
Specimen Volume on Swab	25 µL	5/5	5/5
	50 µL (control)	5/5	5/5

Condition		Positive Swab Samples (Positive/Total)	Negative Swab Samples (Negative/Total)
	100 µL	5/5	5/5
Extracted Sample Amount	1 drop	15/21 (6 invalid)	2/5 (3 invalid)
	2 drops	5/5	5/5
	3 drops	5/5	5/5
	4 drops	5/5	5/5
	5 drops	5/5	5/5
	Entire tube volume	5/5	5/5
Incorrect Sample Application	Add sample to sample well	5/5	5/5
	Add sample to reading window	Invalid	Invalid
Extraction Buffer Volume	150 µL	1/5 (4 invalid)	0/5 (5 invalid)
	285 µL	5/5	5/5
	325 µL	5/5	5/5
Swab Elution	15 s. plunge with pinching (control)	5/5	5/5
	15 s. plunge no pinching	5/5	5/5
	No plunge no pinching	5/5	5/5
Non-level Surface	Leveled surface (control)	5/5	5/5
	30° angle tilted vertically with reading window higher	5/5	5/5
	30° angle tilted vertically with sample well higher	5/5	5/5
	30° angle tilted on a side (side-laying devices)	5/5	5/5
	Devices laid upside-down for 1 min immediately followed by 14 min right side-up	5/5	5/5
	Devices laid upside-down for 5 min immediately followed by 10 min right side-up	5/5	20/21[1] (1 invalid)
	Devices laid upside-down for 10 min immediately	5/5	5/5

Condition		Positive Swab Samples (Positive/Total)	Negative Swab Samples (Negative/Total)
	followed by 5 min right side-up		
	Devices laid upside-down for 15 min	5/5	5/5
Device Drop (Time before device drop from 3 ft.)	No drop (control)	5/5	5/5
	1 min	5/5	5/5
	2 min	5/5	5/5
	5 min	5/5	5/5
	10 min	5/5	5/5
	15 min	5/5	5/5
Environmental Tolerance	High temperature High humidity (45°C / 95% RH)	5/5	5/5
	Low temperature High humidity (5°C / 95% RH)	5/5	5/5
	High temperature Low humidity (45°C / 5% RH)	20/21[2] (1 invalid)	5/5
	Low temperature Low humidity (5°C / 5% RH)	5/5	5/5
	Ambient temperature Ambient humidity (25°C / 50% RH)	5/5	5/5
Drafty Conditions	Inside flow hood, ventilation on, covered	5/5	5/5
	Inside flow hood, ventilation on, uncovered	5/5	5/5
	Benchtop, uncovered	5/5	5/5
Incorrect reagent and kit storage	2-30°C (Control)	5/5	5/5
	-20°C for 24 hours followed by 60°C for 24 hours (Stressed)	5/5	5/5
Inadequate Temperature Equilibration of Test Kit	Equilibrated to room temperature 30 min (Control)	5/5	5/5
	Cold Kits (No equilibration)	5/5	5/5

Condition		Positive Swab Samples (Positive/Total)	Negative Swab Samples (Negative/Total)
Vibrational Effects	No Vibration	5/5	5/5
	21.5 cm away from operating centrifuge	5/5	5/5
	112.0 cm away from operating centrifuge	5/5	5/5
Geographical Altitude Effects (above sea level)	100 m	5/5	5/5
	1000 m	5/5	5/5
	3000 m	5/5	5/5
Bubbles in Sample Chamber	No bubbles or foaming	5/5	5/5
	Bubbles or foaming	5/5	5/5
Specimen Stability[3]	Room Temp. (Control), 0 hr.	5/5	5/5
	High Room Temp. 30±1°C, 26.4 hrs.	5/5	5/5
	35±2°C, 4.4 hrs.	5/5	5/5
	Refrigerated 4±1°C, 26.4 hrs.	5/5	5/5
	Frozen -20±4°C, 26.4 hrs.	5/5	5/5
Open-pouch stability	0 min	5/5	5/5
	5 min	5/5	5/5
	15 min	5/5	5/5
	30 min	5/5	5/5
	1 hr.	5/5	5/5
	2 hrs.	5/5	5/5
	4 hrs.	5/5	5/5
	24 hrs.	5/5	5/5

[1] The test devices set at 30° angle tilted vertically with sample well higher produced one "Positive Control Line Invalid" due to sample flowing on top of nitrocellulose leaving conjugate behind during testing (first 5 replicates). 16 additional replicates were tested, all of which provided the expected results.
[2] One replicate tested produced a "Positive Control Line Invalid" result in the first 5 replicates. 16 additional replicates were tested in the chamber at 45°C/5% RH and all 16 replicates produced expected results.
[3] The swabs were stored 30°C±1°C, 35°C±2°C, 4°C±1°C, and at -20°C±4°C for the duration of the study. To account for the worst-case scenario, after the extraction of samples from the swabs, the extracts were stored at 30°C±1°C, 35°C±2°C, 4°C±1°C, and at -20°C±4°C as well.

The flex studies to support the CLIA Waiver Application for the BD Veritor System for SARS-CoV-2 and the risk control measures are listed in the table below:

Table 3: Summary of Flex Studies and the risk control measures.

Category	Study	Study Results and Conclusion	Risk Control Measure
Operator Errors	Development and read time variability	The assay produces accurate results when read between 10-60 minutes after sample application. The entire workflow is 20 minutes or less.	For Analyze Now mode, the package insert instructs users "After adding the sample, allow the test to run for 15 minutes but no longer than 20 minutes before inserting the test device into the BD Veritor Plus Analyzer." For Walk Away mode, the analyzer instructs the users on the display window to "Add specimen to the test device and insert immediately". The analyzer interprets results after 15 minutes automatically. The package insert has the limitation "Do not read test devices before 15 minutes or after 20 minutes as a false or invalid result might occur."
	Incorrect sample application	The assay produces a Positive Control Line invalid result when the sample is applied to the reading window on the cassette instead of the sample window.	The assay produces Control Invalid result when a negative or a positive extracted sample is added to the reading window (also referred to as the device strip window) of test devices.
	Device drop	The assay produced acceptable results when dropped from 3 feet at 1 minute, 2 minutes, 5 minutes, 10 minutes, and 15 minutes after sample incubation.	The Package Insert contains a warning statement to "Keep devices and instrument level and undisturbed for duration of the 15-minute incubation."
	Extraction buffer volume variability	All conditions met the specifications except for 150µL of extraction reagent condition that resulted in mostly invalid results.	The Package Insert contains a warning statement, "Do not use if any of the test kit components or packaging is damaged." If insufficient volume of sample is added, the assay is designed such that the positive control on the device should fail to develop properly and therefore the analyzer should report a Control Invalid result.
	Specimen volume variability	The assay is capable of producing acceptable results with 25-100 µL specimen.	Not applicable as the specimen volume is not measured in the test.
	Extracted sample volume variability	All conditions met the specifications except for the 1 drop condition.	1. The Package Insert specify the addition of three drops to the test device. 2. The sample well on the device is marked with a graphic symbol indicating the correct number of drops to be added. 3. If insufficient volume of sample is added, the assay is designed such that the positive control on the device should fail to develop properly and

Category	Study	Study Results and Conclusion	Risk Control Measure
			therefore the analyzer should report a Control Invalid result.
	Sample elution technique variability	All replicates for each of the testing conditions produced the expected result. Therefore, plunging and/or pinching during sample elution does not impact sample elution.	The package insert instructs users "[..]plunge the swab up and down in the fluid" and "While firmly squeezing the sides of the tube to extract the liquid from the swab, remove the swab from the extraction reagent."
	Bubbles in Sample Chamber	The assay produces acceptable results when a negative or a positive extracted sample is added with bubbles or foaming present.	N/A
Reagent Integrity	Open-pouch stability	The assay produces accurate results when exposed for 0 minutes to 24 hours in this open pouch study.	The Package Insert instructs users to "Remove one extraction reagent tube/tip and one BD Veritor System test device from its foil pouch immediately before testing or within 5 minutes of opening."
	Incorrect reagent and kit storage	The assay produces acceptable results when the kit (including sample collection swab) was stored at 2 – 30° C (control), -20 °C for 24 hours followed by 60°C for 24 hours.	The Package Insert states "Kits may be stored at 2–30 °C. DO NOT FREEZE."
	Inadequate temperature equilibrium	The assay is capable of producing acceptable results when the test is performed immediately after removal from storage at 2-8°C.	The Package Insert states "Reagents and devices must be at room temperature (15–30 °C) when used for testing."
Environmental Factors	Surface stability	All conditions passed acceptance criteria with >95% agreement. The test devices set at 30° angle tilted vertically with sample well higher produced one Positive Control Line invalid due to sample flowing on top of nitrocellulose leaving conjugate behind.	The Package Insert contains a warning statement to "Keep devices and instrument level and undisturbed for duration of the 15-minute incubation."
	Temperature and humidity variability	Clinical negative matrix sample, low positive (2x LoD) sample, positive control swab, and negative control swab were tested at nominal and extreme temperature and relative humidity variations. One invalid result was observed at high temperature and low humidity. All other results were acceptable at other conditions.	The Package Insert states "Kits may be stored at 2–30 °C. DO NOT FREEZE."

Category	Study	Study Results and Conclusion	Risk Control Measure
	Vibrational variability	The assay is capable of producing acceptable results when the test device is positioned in close proximity (21.5 cm and 112.0 cm away) of an operating centrifuge at 14,000 rpm for up to 15 min after sample addition.	The Package Insert contains a warning statement to "Keep devices and instrument level and undisturbed for duration of the 15-minute incubation."
	Geographical altitude	The assay is capable of producing acceptable results when the test is performed at the altitude of sea level up to 3000 m.	N/A
	Drafty conditions	The assay produces acceptable results when sample addition and assay development take place in areas away from high air flow/in a laminar flow hood, as well as in areas with high air flow/in a laminar flow hood.	The Package Insert contains a note in instructions: "Test devices used in a laminar flow hood or in areas with high air flow should be covered during test development to prevent sample evaporation and incomplete sample flow, which may cause a false or invalid result to occur."
Specimen Integrity	Specimen stability	The assay produces acceptable results when a negative or positive sample is stored at the tested temperatures and durations: • at 4°C for up to 24 hours. • at 35 °C for up to 4 hours. • at -20 °C up to 24 hours. • at room temperature (15–30 °C) for up to 24 hours.	The Package Insert contains: 1. Warnings statement, "Samples should be tested as soon as possible after collection, but no later than one hour when stored at room temperature, or 12 hours when stored at 2° to 8 °C or -20 °C." 2. Specimen storage, "Freshly collected specimens should be processed as soon as possible after collection, but no later than one hour when stored at room temperature. Swab samples that will be stored at 2° to 8 °C or at -20 °C for 12 hours should be stored in a sterile container."

C Demonstrating "Insignificant Risk of an Erroneous Result" – Accuracy

Comparison Study

The clinical performance of the BD Veritor System for SARS-CoV-2 was evaluated in a multi-center, prospective clinical study in the U.S. between April 2024 and August 2024, during a period when the SARS-CoV-2 Omicron variant was the predominant strain. The study only enrolled subjects with symptoms of respiratory infection consistent with a SARS-CoV-2 infection. A total of 1168 subjects were consecutively enrolled and tested by thirty-eight (38) operators across fifteen (15) different CLIA-waived sites. Of those, 136 specimens were excluded due to protocol deviations, shipping issues, sample leakage, and not meeting inclusion/exclusion criteria. Two anterior nasal (AN) swabs were collected from each study subject during the same visit. The first AN swab sample from both nostrils was collected by the operators and was then added into the Universal Viral Transport (UVT) media containing 1 mL

media and stored in dry ice until it was shipped to a reference laboratory and tested with an FDA cleared SARS-CoV-2 RT-PCR Test as comparator. The second AN swab sample was collected from both nostrils using the provided swab and was tested immediately using the BD Veritor System for SARS-CoV-2 by 38 users who are representative of a CLIA-waived operator (e.g., administrative personnel, medical assistants, nurses) across the 15 sites.

There were 1032 samples evaluated, 7.7% collected from patients aged 6 months - 5 years, 10.3% from patients aged 6 - 21 years, 13.5% from patients aged 22 - 59 years, and 18.5% from patients aged 60 years or older. Among the subjects, 61.5% were from female patients, while 38.5% were from male patients. Results obtained with the BD Veritor System for SARS-CoV-2 were compared to the results obtained with the RT-PCR comparator test to determine clinical sensitivity and specificity. The study cohort included 14.6% low-positive samples. The BD Veritor System for SARS-CoV-2 demonstrated a Positive Percent Agreement of 84.0% (C.I. 95%: 77.2%, 89.1%) and Negative Percent Agreement 99.7% (C.I. 95%: 99.0%, 99.9%).

Table 13: Clinical Performance of BD Veritor System for SARS-CoV-2 Compared to RT-PCR

BD Veritor System for SARS-CoV-2	**RT-PCR Comparator**		**Total**
	Positive	**Negative**	
Positive	121	3[a]	124
Negative	23[b]	885	908
Total	144	888	1032
Positive Percent Agreement (PPA) = 84.0% (77.2%, 89.1%)			
Negative Percent Agreement (NPA) = 99.7% (99.0%, 99.9%)			

[a] The three BD Veritor SARS-CoV-2 false positive results were retested with a second RT-PCR method and were confirmed negative.
[b] Of the 23 Veritor SARS-CoV-2 negatives, a second RT-PCR method agreed with the Veritor results in 9 cases, while it agreed with the primary RT-PCR method in 14 cases.

Table 14: Positive Results Stratified by Days Post-Symptom Onset

DPSO	**# Samples**	**BD Veritor System SARS-CoV-2 Positive Results**	**Reference RT-PCR SARS-CoV-2 Positives Results**	**PPA (%)**	**95% C.I. (%)**
Day 0	37	6	6	100.0	61.0 - 100.0
Day 1	84	12	14	85.7	60.1 – 96.0
Day 2	276	37	46	80.4	66.8 – 89.3
Day 3	286	31	38	81.6	66.6 – 90.8
Day 4	181	25	27	92.6	76.6 – 97.9
Day 5	125	7	10	70.0	39.7 – 89.2
Day 6	43	3	3	100.0	43.9 – 100.0

Operator Questionnaire:

At the end of the study, each operator that participated in the clinical evaluation and reproducibility studies was given a questionnaire to provide feedback on the ease of use of the BD Veritor System for SARS-CoV-2. The questionnaire had 12 questions on:

- Ease of use
- Design of the test
- Clarity of the instructions

Based on the operators' feedback, the overall BD Veritor System for SARS-CoV-2 was found to be easy to use without the help of an expert. Processing the sample, applying it to the cassette correctly, and seeing and understanding the results were easy. Operators also found the written instructions for the BD Veritor System for SARS-CoV-2 clear and easy to follow.

D Labeling for Waived Devices

The labeling submitted for the BD Veritor System for SARS-CoV-2 consists of:

1. Quick Reference Instructions:
    - Use of BD Veritor System for SARS-CoV-2 with the BD Veritor Plus Analyzer
    - BD Veritor System for SARS-CoV-2, Proper Nasal Swab Sample Collection

2. Instructions for Use:
    - BD Veritor System for SARS-CoV-2 Package Insert
    - BD Veritor Plus Analyzer, Instructions for Use

3. Package labeling: Shipping box, carton, carton barcode label, foil pouch (test device, extraction reagent unitized tubes), sample collection swab, positive control swab foil pouch, negative control swab foil pouch.

4. Package labeling of the control swabs sold separately: control swab set bag label (10 positives and 10 negatives controls); control swab set shelf pack Label (24 sets).

The following elements are appropriately present:

- The Quick Reference Guide and the Instructions for Use are written at no higher than a 7th grade reading level.
- The Instructions for Use and Quick Reference Guide identify the test as CLIA waived.
- The Instructions for Use and test cartridge package insert contain a statement that a Certificate of Waiver is required to perform the test in a waived setting.
- The Instructions for Use and Quick Reference Guide contain a statement that laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test. 42 CFR 493.15(e)(1).
- The Instructions for Use contains a statement that any modification to the test or the manufacturer's instructions will result in the test being classified as high complexity. 4 2 CFR 493.17(c)(4).
- The Instructions for Use and Quick Reference Guide provide instructions for conducting quality control procedures.

- The labeling is sufficient and satisfies the requirements of 21 CFR Part 809.10.

XI. Conclusion

The submitted information in this CLIA waiver application supports a CLIA waiver approval decision.