June 16, 2025

Becton, Dickinson and Company
Colton Muraira
Senior Regulatory Affairs Manager
7 Loveton Cir.
Sparks, MD 21152

Re: K243872
Trade/Device Name: BD Veritor System for SARS-CoV-2
Regulation Number: 21 CFR 866.3982
Regulation Name: Simple Point-Of-Care Device To Directly Detect Sars-Cov-2 Viral Targets From Clinical Specimens In Near-Patient Settings
Regulatory Class: Class II
Product Code: QVF
Dated: December 17, 2024
Received: December 17, 2024

Dear Colton Muraira:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JOSEPH BRIGGS -S

Joseph Briggs, Ph.D.
Deputy Division Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K243872

Device Name
BD Veritor System for SARS-CoV-2

Indications for Use *(Describe)*

The BD Veritor System for SARS-CoV-2 is a chromatographic digital immunoassay for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal swab specimens from individuals with signs and symptoms of upper respiratory infection (i.e., symptomatic). The test is intended for use as an aid in the diagnosis of SARS-CoV-2 infections (COVID-19) in symptomatic individuals when either: tested at least twice over three days with at least 48 hours between tests; or when tested once, and negative by the BD Veritor System for SARS-CoV-2 and followed up with a molecular test.

A negative test result is presumptive and does not preclude SARS-CoV-2 infection; it is recommended these results be confirmed by a molecular SARS-CoV-2 assay.

Positive results do not rule out co-infection with other bacteria or viruses and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

Performance characteristics for SARS-CoV-2 were established between April 2024 and August 2024 when SARS-CoV-2 Omicron was the predominant SARS-CoV-2 variant in circulation. Performance characteristics may vary with newly emerging SARS-CoV-2 virus variants.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

BD Veritor™ System for SARS-CoV-2

Date prepared: 06/13/2025

Submitted by:
Becton, Dickinson and Company
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Sparks, MD 21152

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Device Trade Name: BD Veritor™ System for SARS-CoV-2

Common Name: Simple Point-Of-Care Device To Directly Detect SARS-CoV-2 Viral Targets From Clinical Specimens In Near-Patient Settings

Regulatory Information:

Regulation section:
866.3982 - Simple point-of-care device to directly detect SARS-CoV-2 viral targets from clinical specimens in near-patient settings

Classification:
Class II

Panel:
Microbiology

Product Code:
QVF

Predicate Device: Nano-Check™ COVID-19 Antigen Test (K231187)

Device Establishment:
Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152
Registration Number: 1119779

Standards/Guidance Documents

- Special controls for Simple point-of-care device to directly detect SARS-CoV-2 viral targets from clinical specimens in near-patient settings (Reclassification order for DEN220039 and special controls under 21 CFR 866.3982)
- CLSI EP05-A3:2019 Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition
- CLSI EP25 2nd Edition Evaluation of Stability of In Vitro Medical Laboratory Test Reagents
- IEC 62304 Edition 1.1 2015-06 Consolidated Version – Medical device software – Software life cycle processes
- ISO 14971 Third Edition 2019-12 – Medical devices – Application of risk management to medical devices
- IEC 62366-1 Edition 1.1 2020-06 Consolidated Version – Medical devices – Part 1: Application of usability engineering to medical devices
- ISO 15223-1 Fourth edition 2021-07 – Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1 General requirements
- ISO 20417 First edition 2021-04 Corrected version 2021-12 - Medical devices - Information to be supplied by the manufacturer

Intended Use

The BD Veritor™ System for SARS-CoV-2 is a chromatographic digital immunoassay for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal swab specimens from individuals with signs and symptoms of upper respiratory infection (i.e., symptomatic). The test is intended for use as an aid in the diagnosis of SARS-CoV-2 infections (COVID-19) in symptomatic individuals when either: tested at least twice over three days with at least 48 hours between tests; or when tested once, and negative by the BD Veritor™ System for SARS-CoV-2 and followed up with a molecular test.

A negative test result is presumptive and does not preclude SARS-CoV-2 infection; it is recommended these results be confirmed by a molecular SARS-CoV-2 assay.

Positive results do not rule out co-infection with other bacteria or viruses and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

Performance characteristics for SARS-CoV-2 were established between April 2024 and August 2024 when SARS-CoV-2 Omicron was the predominant SARS-CoV-2 variant in circulation. Performance characteristics may vary with newly emerging SARS-CoV-2 virus variants.

Special Conditions for Use Statement

For Prescription Use only
For *in vitro* diagnostic use only

Special Instrument Requirements

BD Veritor™ System for SARS-CoV-2 is performed on BD Veritor™ Plus Analyzer (hardware v2.0, firmware v6.10 or later).

Device Description

The BD Veritor™ System for SARS-CoV-2 is a rapid (approximately 15 minutes) chromatographic digital immunoassay for the direct detection of the presence or absence of SARS-CoV-2 antigens in anterior nasal swab specimens taken from patients with signs and symptoms of upper respiratory infection (i.e., symptomatic) who are suspected of COVID-19 by their healthcare provider. The test is intended for use with an opto-electronic interpretation instrument, the BD Veritor™ Plus Analyzer Instrument and is not interpreted visually.

- 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 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.
- A positive result is determined by the BD Veritor™ Plus 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.
- The instrument analyzes and corrects for non-specific binding and detects positives not recognized by the unaided eye to provide an objective result.

Procedures to evaluate test devices depend on the BD Veritor™ Plus Analyzer workflow configuration chosen. In **Analyze Now** mode, the instrument evaluates assay devices after manual timing of their development. In **Walk Away mode**, devices are inserted immediately after application of the specimen, and timing of assay development and analysis is automated. Additionally, connection of a BD Veritor™ Plus Analyzer to a printer or IT system is possible if desired. Additional result documentation capabilities are possible with the integration of a BD Veritor™ barcode scanning enabled module.

The Analyzer uses a proprietary algorithm that subtracts the nonspecific signal at the negative control line from the signal present at the test line. If the resultant test line signal is above a preselected cutoff, the specimen is scored as positive. If the resultant test line signal is below or equal to the cutoff, the specimen is scored as negative. Use of the active negative control feature allows the BD Veritor™ Plus Analyzer 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 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.

Test Principle

Immunochromatographic SARS-CoV-2 antigen-antibody complexes detected via opto-electronic reader.

Substantial Equivalence

Indication for Use Comparison

The BD Veritor™ System for SARS-CoV-2 and the predicate (Nano-Check™ COVID-19 Antigen Test) have the same intended use (Table 1).

Technological Comparison

The BD Veritor™ System for SARS-CoV-2 has a similar principle of operation as the predicate, the Nano-Check™ COVID-19 Antigen Test (K231187). Both assays are qualitative and are based on lateral flow immunochromatography, use the same specimen type (direct anterior nasal swab), target the same analyte (SARS-CoV-2 nucleocapsid protein), and have the same type of use (prescription use) and population (individuals with signs and symptoms of upper respiratory infection). The test time is also the same (approx. 15 minutes). Both reagent kits contain all the test components required to perform the test.

The main difference between the BD Veritor™ System for SARS-CoV-2 and Nano-Check™ COVID-19 Antigen Test lies in their result interpretation method. The BD Veritor™ System for SARS-CoV-2 utilizes BD Veritor™ Plus Analyzer to read and interpret the results whereas the predicate relies on the user to visually read and interpret the results. The difference between the subject and predicate devices does not raise any new questions of safety or effectiveness.

Table 1 - BD Veritor™ System for SARS-CoV-2 Substantial Equivalence Comparison

Device and Predicate	**Subject Device**	**Predicate (K231187)**
Device Trade Name	BD Veritor™ System for SARS-CoV-2	Nano-Check™ COVID-19 Antigen Test
General Device Characteristic Similarities		
Intended Use / Indications for Use	The BD Veritor™ System for SARS-CoV-2 is a chromatographic digital immunoassay for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal swab specimens from individuals with signs and symptoms of upper respiratory infection (i.e., symptomatic). The test is intended for use as an aid in the diagnosis of SARS-CoV-2 infections (COVID-19) in symptomatic individuals when either: tested at least twice over three days with at least 48 hours between tests; or when tested once, and negative by the BD Veritor™ System for SARS-CoV-2 and followed up with a molecular test.	The Nano-Check COVID-19 Antigen Test is a lateral flow immunochromatographic assay for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal swab specimens from individuals with signs and symptoms of upper respiratory infection (i.e., symptomatic) when testing is started within 4 days of symptom onset. The test is intended for use as an aid in the diagnosis of SARS-CoV-2 infections (COVID-19) in symptomatic individuals when either: tested at least twice over three days with at least 48 hours between tests; or when tested once, and negative by the Nano-Check COVID-19 Antigen

	A negative test result is presumptive and does not preclude SARS-CoV-2 infection; it is recommended these results be confirmed by a molecular SARS-CoV-2 assay. Positive results do not rule out co-infection with other bacteria or viruses and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Performance characteristics for SARS-CoV-2 were established between April 2024 and August 2024 when SARS-CoV-2 Omicron was the predominant SARS-CoV-2 variant in circulation. Performance characteristics may vary with newly emerging SARS-CoV-2 virus variants.	Test and followed up with a molecular test. The test does not differentiate between SARS-CoV and SARSCoV-2. A negative test result is presumptive, and it is recommended these results be confirmed by a molecular SARS-CoV-2 assay. Positive results do not rule out co-infection with other bacteria or viruses and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Performance characteristics for SARS-CoV-2 were established during the 2022 SARS-CoV-2 pandemic when SARS-CoV-2 Omicron was the predominant SARS-CoV-2 variant in circulation. When other SARS-CoV-2 virus variants are emerging, performance characteristics may vary. This test is intended for prescription use only and can be used in Point-of-Care settings.
Specimen Type	Direct anterior nasal swab	Same
Analyte	SARS-CoV-2 nucleocapsid protein	Same
Test type	Lateral flow immunochromatographic	Same
Test result Type	Qualitative	Same
Test Time	15-20 minutes	Same
General Device Characteristics Differences		
Instrumentation	BD Veritor™ Plus Analyzer	None
Result Interpretation	Instrument read - BD Veritor™ Plus Analyzer scans the test strip and analyzes the reflectance data to provide the proper test interpretation. The Analyzer displays the test results (Positive, Negative, or Invalid) on the screen.	Visually read - visual interpretation of the presence or absence of colored line(s) on the control and test line(s) of the test strip is used to determine Positive, Negative, or Invalid results.

Analytical performance

Repeatability and Lot-to-Lot Precision

The lot-to-lot precision and repeatability studies evaluated the following sample types: negative, a low positive (2x LoD) and a moderate positive sample (5x LoD). The study was conducted by two operators for two runs per day for a total of 10 nonconsecutive days. The first run of each day included 3 independently manufactured lots of each kit component, and the second run of each day included 1 lot of each kit component.

For the repeatability requirements, results were reproducible in the hands of two in-house trained operators when tested over a period of 10 days with two runs per operator per day using one manufactured kit lot. Acceptance was met based on agreement with expected result. Negative samples produced an overall 100% negative result (0% positive), low positive samples (2x LoD) produced 100% positive results, and moderately positive samples (5x LoD) produced 100% positive results.

For the lot-to-lot precision requirements, results were reproducible over multiple lots (3) when tested over the course of 10 days with multiple operators. Acceptance was met based on agreement with expected result. Negative samples produced an overall 100% negative result (0% positive), low positive samples (2x LoD) produced 100% positive results, and moderately positive samples (5x LoD) produced 100% positive results.

Reproducibility

A multi-site reproducibility study was conducted to determine between-site, between-operator, between-run, between-day and total reproducibility calculations. Two operators at three sites tested contrived SARS-CoV-2 positive samples and SARS-CoV-2 negative samples across 5 days using one lot of materials. Samples were prepared, randomized, and blinded before testing. Three sample levels were tested each day (1x LoD, 5x LoD, and negative, contrived in the negative nasal fluid). Three replicates per operator per day were tested 2 hours apart by two operators per site at three total sites. This exact testing scheme was carried out over 5 days (same three sample levels tested, on the same lot, by the same two operators, at the same three sites). All samples tested in the reproducibility study generated 100% agreement at all sites.

Table 2 - Reproducibility Analysis Results by Site

Site	% Agreement (Number in Agreement/Number of Samples)		
	Negative	Low Positive	Positive
Site 1	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)
Site 2	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)
Site 3	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)
Overall	100.0% (90/90)	100.0% (90/90)	100.0% (90/90)
Overall 95% C.I.	(95.9%, 100%)	(95.9%, 100%)	(95.9%, 100%)

Linearity

Not applicable. This is a qualitative assay.

Analytical Sensitivity/Detection Limit

The SARS-CoV-2 limit of detection (LoD) for the BD Veritor™ System for SARS-CoV-2 a was established using limiting dilutions of a sample of heat-inactivated SARS-CoV-2 Omicron XBB obtained from Zeptometrix. This material was supplied at a concentration of 5.95 x 10^6 $TCID_{50}$/mL and diluted in confirmed-negative clinical matrix derived from nasal swab specimens that had been extracted in a Phosphate Buffered Saline solution. This study is designed to estimate the LoD of the assay when using a direct nasal swab; 50 µL of each dilution was transferred to a swab and tested with the BD Veritor™ System for SARS-CoV-2 using a procedure appropriate for patient nasal swab specimens. After an initial range-finding 10-fold dilution series, the tentative LoD was identified as the lowest dilution to give positive results in 100% of three replicates. At this tentative LoD, 20 replicates per lot were prepared and tested on three unique kit lots (total of 60 replicates) to confirm the LoD by demonstrating ≥95% positivity.

Table 3 - LoD Summary with Heat-Inactivated SARS-CoV-2 Omicron XBB

Starting Material Concentration ($TCID_{50}$/mL)	Estimated LoD Concentration ($TCID_{50}$/mL)	Estimated LoD Concentration per Swab ($TCID_{50}$/swab)	No. Positive/Total	% Positive
5.95×10^6	5.95×10^3	298	60/60	100

Furthermore, the LoD was established with the first WHO International Standard for SARS-CoV-2 Antigen, NIBSC 21/368, using a limiting dilution series in negative clinical matrix. This study is designed to estimate the LoD of the assay when using a direct nasal swab; 50 µL of each dilution was transferred to a swab and tested with the BD Veritor™ System for SARS-CoV-2 using the procedure appropriate for patient nasal swab specimens. After an initial range-finding 2-fold dilution series, the tentative LoD was identified as the lowest dilution to give positive results in 100% of three replicates. At this tentative LoD, 20 replicates were prepared and tested on one unique kit lot to confirm the LoD by demonstrating ≥95% positivity.

Table 4 - WHO SARS-CoV-2 Standard Antigen LoD

Description	Source	NIBSC No.	Concentration (IU/mL)	IU/Swab	No. of Positives/ No. Tested
WHO International Standard	NIBSC	21/368	250	12.5	20/20

NIBSC: National Institute for Biological Standards and Control

Assay Measuring Range

Not applicable. This is a qualitative assay.

Endogenous and Exogenous Interfering Substances

A study was performed to demonstrate that endogenous or exogenous substances that may be found in the upper respiratory tract do not interfere with the detection of SARS-CoV-2 in the BD Veritor™ System for SARS-CoV-2. Each substance was tested in triplicate with negative and positive contrived samples using negative clinical matrix and SARS-CoV-2 Omicron XBB at a concentration of 1.785×10^4 $TCID_{50}$/mL in the case of positive contrived samples. No interference was noted for any of the substances tested at the concentrations listed.

Table 5 - Interfering Substances Summary

Substance	**Concentration Tested**	**Interference (Yes/No)**	
		Negative Sample	Positive Sample
Benzocaine and Menthol (Chloraseptic max)	3 mg/mL	No	No
Throat Spray with Phenol	5% w/v	No	No
Neo Synephrine (Phenylephrine)	15% v/v	No	No
CVS Nasal Spray (Cromolyn)	15% v/v	No	No
Afrin (Oxymetazoline)	15% v/v	No	No
Sodium chloride with preservatives	15% v/v	No	No
Beclomethasone	15% v/v	No	No
Dexamethasone	15% v/v	No	No
Nasarel (Flunisolide)	15% v/v	No	No
Nasacort (Triamcinolone)	15% v/v	No	No
Rhinocort (Budesonide)	15% v/v	No	No
Nasonex (Mometasone)	15% v/v	No	No
Flonase (Fluticasone)	15% v/v	No	No
Zicam Cold Remedy (Galphimia glauca, Luffa Opperculata, Sulphur)	15% v/v	No	No
Alkalol	15% v/v	No	No
NasoGel	1.25% v/v	No	No
Tamiflu (Oseltamivir)	500 ng/mL	No	No
Hand sanitizer (ethyl alcohol)	1% v/v	No	No
Hand Soap (Benzalkonium chloride)	1% v/v	No	No
Biotin	3.5 µg/mL	No	No
Bactroban (Mupirocin)	10 mg/mL	No	No
Whole Blood (human)	2.5% v/v	No	No
Mucin	2.5 mg/mL	No	No
Histaminum hydrochloricum	15% v/v	No	No
Remdesivir	6 µg/mL	No	No
Molnupiravir	3 µg/mL	No	No
Leukocytes	2.50×10^6 cells/mL	No	No

Cross reactivity

Cross-reactivity of the BD Veritor™ System for SARS-CoV-2 was evaluated by testing various pathogens, high prevalence disease agents, and normal or pathogenic flora. Each organism was tested in triplicate in negative clinical matrix. Testing showed no evidence of cross-reactivity at the concentrations tested.

Table 6 - Cross-Reactivity Summary

Potential Cross-Reacting Organism	Concentration Tested	Cross-Reactivity (Yes/No)
Human coronavirus 229E (inactivated)	1.00×10^5 $TCID_{50}$/mL	No
Human coronavirus OC43	1.00×10^5 $TCID_{50}$/mL	No
Human coronavirus NL63	1.00×10^5 $TCID_{50}$/mL	No
Human coronavirus HKU1*	1.00×10^5 cp/mL	No
MERS-coronavirus (inactivated)	1.00×10^5 $TCID_{50}$/mL	No
SARS-coronavirus	1.00×10^5 $TCID_{50}$/mL	No
Adenovirus Type 1	1.00×10^5 $TCID_{50}$/mL	No
Adenovirus Type 3	1.00×10^5 $TCID_{50}$/mL	No
Adenovirus Type 7	1.00×10^5 $TCID_{50}$/mL	No
Human Metapneumovirus (HMPV), A2	1.00×10^5 $TCID_{50}$/mL	No
Parainfluenza virus 1	1.00×10^5 $TCID_{50}$/mL	No
Parainfluenza virus 2	1.00×10^5 $TCID_{50}$/mL	No
Parainfluenza virus 3	1.00×10^5 $TCID_{50}$/mL	No
Parainfluenza virus 4A	1.00×10^5 $TCID_{50}$/mL	No
Influenza A (H1N1)pdm90	1.00×10^5 EID_{50}/mL	No
Influenza B (Victoria Lineage)	1.00×10^5 EID_{50}/mL	No
Enterovirus D68	1.00×10^5 $TCID_{50}$/mL	No
Respiratory syncytial virus, strain Long	1.00×10^5 $TCID_{50}$/mL	No
Rhinovirus 3	1.00×10^5 PFU/mL	No
Haemophilus influenzae	1.00×10^6 CFU/mL	No
Streptococcus pneumoniae	1.00×10^6 CFU/mL	No
Streptococcus pyogenes	1.00×10^6 CFU/mL	No
Candida albicans	1.00×10^6 CFU/mL	No
Pooled human nasal wash	N/A	No
Bordetella pertussis	1.00×10^6 CFU/mL	No
Mycoplasma pneumoniae	1.00×10^6 CCU/mL	No
Chlamydia pneumoniae	1.00×10^6 IFU/mL	No
Legionella pneumophila	1.00×10^6 CFU/mL	No
Staphylococcus aureus (MSSA)	1.00×10^6 CFU/mL	No
Staphylococcus aureus (MRSA)	1.00×10^6 CFU/mL	No
Staphylococcus epidermidis	1.00×10^6 CFU/mL	No

*Five different clinical samples were tested in replicates of three. Concentrations of each clinical sample was 1.00 x 10E+05 copies/mL based on standard curve/quantitative analysis targeting detection of the RDRP region.
TCID: Tissue Culture Infectious Dose
CCU: Colony Changing Units
CFU: Colony-Forming Units
EID: Egg Infectious Dose
IFU: Inclusion-Forming Units
PFU: Plaque-Forming Units
cp: copies

Microbial Interference

Microbial Interference for the BD Veritor™ System for SARS-CoV-2 was evaluated by testing various pathogens, high prevalence disease agents, and normal or pathogenic flora with the BD Veritor™ SARS-CoV-2 assay. Each organism was tested in triplicate in the presence of heat-inactivated SARS-CoV-2 Omicron XBB at a concentration of 1.785 x 10^4 $TCID_{50}$/mL in negative clinical matrix. Testing showed no evidence of microbial interference at the concentrations tested.

Table 7 - Microbial Interference Summary

Potential Microbial Interferent	Concentration Tested	Interference (Yes/No)
Human coronavirus 229E (inactivated)	1.00×10^5 $TCID_{50}$/mL	No
Human coronavirus OC43	1.00×10^5 $TCID_{50}$/mL	No
Human coronavirus NL63	1.00×10^5 $TCID_{50}$/mL	No
Human coronavirus HKU1*	1.00×10^5 cp/mL	No
MERS-coronavirus (inactivated)	1.00×10^5 $TCID_{50}$/mL	No
SARS-coronavirus	1.00×10^5 $TCID_{50}$/mL	No
Adenovirus Type 1	1.00×10^5 $TCID_{50}$/mL	No
Adenovirus Type 3	1.00×10^5 $TCID_{50}$/mL	No
Adenovirus Type 7	1.00×10^5 $TCID_{50}$/mL	No
Human Metapneumovirus (HMPV), A2	1.00×10^5 $TCID_{50}$/mL	No
Parainfluenza virus 1	1.00×10^5 $TCID_{50}$/mL	No
Parainfluenza virus 2	1.00×10^5 $TCID_{50}$/mL	No
Parainfluenza virus 3	1.00×10^5 $TCID_{50}$/mL	No
Parainfluenza virus 4A	1.00×10^5 $TCID_{50}$/mL	No
Influenza A (H1N1)	1.00×10^5 EID_{50}/mL	No
Influenza B (Victoria Lineage)	1.00×10^5 EID_{50}/mL	No
Enterovirus D68	1.00×10^5 $TCID_{50}$/mL	No
Respiratory syncytial virus, strain Long	1.00×10^5 $TCID_{50}$/mL	No
Rhinovirus 3	1.00×10^5 PFU/mL	No
Haemophilus influenzae	1.00×10^6 CFU/mL	No
Streptococcus pneumoniae	1.00×10^6 CFU/mL	No
Streptococcus pyogenes	1.00×10^6 CFU/mL	No
Candida albicans	1.00×10^6 CFU/mL	No
Pooled human nasal wash	N/A	No
Bordetella pertussis	1.00×10^6 CFU/mL	No
Mycoplasma pneumoniae	1.00×10^6 CCU/mL	No
Chlamydia pneumoniae	1.00×10^6 IFU/mL	No
Legionella pneumophila	1.00×10^6 CFU/mL	No
Staphylococcus aureus (MSSA)	1.00×10^6 CFU/mL	No
Staphylococcus aureus (MRSA)	1.00×10^6 CFU/mL	No
Staphylococcus epidermidis	1.00×10^6 CFU/mL	No

*Five different clinical samples were tested in replicates of three. Concentrations of each clinical sample was 1.00 x 10E+05 copies/mL based on standard curve/quantitative analysis targeting detection of the RDRP region.
TCID: Tissue Culture Infectious Dose
CCU: Colony Changing Units
CFU: Colony-Forming Units
EID: Egg Infectious Dose
IFU: Inclusion-Forming Units
PFU: Plaque-Forming Units
cp: copies

Metrological Traceability

Not applicable. The assay does not require calibration of any reference material or reference measurement procedures.

Specimen Stability

Negative samples (pooled negative matrix from nasal swab eluted in a Phosphate Buffered Saline solution) and low positive contrived samples in clinical matrix (2x LoD) were prepared for the specimen stability study. Swabs were spiked with 50 µL of each sample and exposed to various storage conditions. The swabs were tested in 5 replicates for each exposure time. The BD Veritor™ System for SARS-CoV-2 produces acceptable results when a sample on swab and extracted specimen is stored at the tested temperatures and durations:

- Sample on swab and extracted specimen stored at refrigerated temperature (2 - 8 °C) for up to 24 hours.
- Sample on swab and extracted specimen stored at 35 °C for up to 4 hours.
- Sample on swab and extracted specimen stored frozen at -20 °C for up to 24 hours.
- Sample on swab and extracted specimen stored at room temperature (15 - 30 °C) for up to 24 hours.

The results support a storage claim of 12 hours for unprocessed specimens when stored at room temperature, refrigerated at 2 - 8 °C, and frozen at -20 °C when stored in a sterile container.

Hook Effect

No hook effect was observed for heat-inactivated SARS-CoV-2 Omicron XBB for the BD Veritor™ System for SARS-CoV-2 up to a concentration of 5.95 x 10^6 $TCID_{50}$/mL.

Inclusivity

An inclusivity study was performed to demonstrate the analytical reactivity of the BD Veritor™ System for SARS-CoV-2 to detect current circulating SARS-CoV-2 variants of concern identified by CDC within the past year. Four (4) stock strains were included (Table 8). A preliminary study was conducted with ten-fold dilution series to determine a near cutoff concentration for each strain/isolate tested in 5 replicates with one lot of test kit. Then, two-fold dilution series using the preliminary LoD were prepared, and five (5) replicates were tested to identify the dilution at which assay reactivity decreased for each strain. Results are summarized below. All tested viral strains were detected.

Table 8 - Inclusivity Study Result

Lineage/Variant Type	Isolate	Level of Inclusivity
BA.5	hCoV-19/USA/COR-22-063113/2022	2.40×10^2 $TCID_{50}$/mL
BQ.1.1	hCoV-19/USA/MD-HP38861/2022	1.45×10^2 $TCID_{50}$/mL
BF.7	hCoV-19/USA/MD-HP38288/2022	2.40×10^2 $TCID_{50}$/mL
JN.1	hCoV-19/USA/New York/PV96109/2023	2.20×10^2 $TCID_{50}$/mL

Comparison studies

Method Comparison

Method Comparison Study was performed under the Clinical Study and not as part of the analytical studies. Please refer to the Clinical Study section for additional information.

Clinical study

The performance of the BD Veritor™ System for SARS-CoV-2 was established with 1,032 direct anterior nasal swabs prospectively collected and enrolled from individual symptomatic patients (within 6 days of onset) who were suspected of COVID-19 between April and August 2024. Samples were collected by qualified personnel in 15 geographically diverse areas across the United States.

Anterior nasal swabs were collected following the dual nares method and handled as described in the package insert of the collection device. Specimens were tested with the BD Veritor™ System for SARS-CoV-2. The performance of the BD Veritor™ System for SARS-CoV-2 was compared to the results obtained from an FDA-cleared SARS-CoV-2 RT-PCR test. The BD Veritor™ System for SARS-CoV-2 assay was performed by operators who had no prior experience in the laboratory testing and were representative of users who work in a CLIA Waived setting. Samples were randomized and blinded before testing.

Out of the 144 samples that tested positive with the comparator RT-PCR test, 121 were positive and 23 were negative using the BD Veritor™ System for SARS-CoV-2. Additionally, 885 out of 888 samples that were negative on RT-PCR were also negative on the BD Veritor™ System assay. The agreement between the BD Veritor™ System assay and RT-PCR is presented below.

Table 9 - Overall Percent Agreement for Nasal Swabs of the BD Veritor™ System for SARS-CoV-2 at 0-6 Days of Symptoms Onset Versus a Reference RT-PCR Test

BD Veritor™ System forSARS-CoV-2	Reference RT-PCR		
	Positive	**Negative**	**Total**
Positive	121	3[a]	124
Negative	23[b]	885	908
Total	144	888	1032
PPA: 84.0% (C.I.: 77.2%, 89.1%) NPA: 99.7% (C.I.: 99.0%, 99.9%)			

[a] The three BD Veritor™ System for SARS-CoV-2 false positive results were retested with a second RT-PCR method and were confirmed negative.

[b] The 23 BD Veritor™ System for SARS-CoV-2 false negative results were retested with a second RT-PCR method in which 14 were confirmed positive and 9 were negative.

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 10** below.

Table 10 - Prevalence Rates as Measured by Evaluable Reference RT-PCR and Veritor™ SARS-COV-2 Assay Observed During the Clinical Study Conducted with the BD Veritor™ System for SARS-CoV-2

Age Group	Reference RT-PCR SARS-CoV-2 Prevalence Rate % (Positive/Samples)
6 months to 5 years	7.7% (3/39)
6–21 years	10.3% (10/97)
22–59 years	13.5% (93/691)
≥60 years	18.5% (38/205)

The PPA and NPA stratified by days since onset of symptoms is presented in **Table 11**, demonstrating similar performance of the assay through 7 days post symptoms onset.

Table 11 - Percent Agreement of the BD Veritor™ System for SARS-CoV-2 Versus a Reference RT-PCR SARS-CoV-2 Test by Symptoms Onset Day

Day Post Symptom Onset	Total Number of Samples	BD Veritor™ System for 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

* The number of BD Veritor™ System SARS-CoV-2 positives that are in agreement with the reference SARS-CoV-2 positives.

EXPLANATION OF TERMS
C.I.: Confidence Interval

Conclusion

The submitted information in this premarket notification is complete and supports a substantial equivalence decision. Based on the comparison of technological features and intended use, and as a result of the non-clinical and clinical performance testing completed on the Veritor™ System for SARS-CoV-2, the proposed device does not raise new questions of safety and effectiveness and supports the conclusion that the proposed device is substantially equivalent to the predicate device.