January 27, 2023

BD
Dung Nguyen
Senior Staff, Regulatory Affairs
7 Loveton Cir
Sparks, Maryland 21152

Re: K223016
Trade/Device Name: BD Veritor System for Rapid Detection of Flu A+B CLIA-Waived Kit
Regulation Number: 21 CFR 866.3328
Regulation Name: Influenza Virus Antigen Detection Test System
Regulatory Class: Class II
Product Code: PSZ
Dated: September 27, 2022
Received: September 29, 2022

Dear Dung Nguyen:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Himani Bisht -S

Himani Bisht, Ph.D.
Assistant Director
Viral Respiratory and HPV Branch
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)*
K223016

Device Name
BD Veritor System for Rapid Detection of Flu A+B CLIA-Waived Kit

Indications for Use *(Describe)*

The BD Veritor System for Rapid Detection of Flu A+B CLIA waived assay is a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral nucleoprotein antigens from nasal and nasopharyngeal swabs of symptomatic patients. The BD Veritor System for Rapid Detection of Flu A+B (also referred to as the BD Veritor System and BD Veritor System Flu A+B) is a differentiated test, such that influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single device. The test is to be used as an aid in the diagnosis of influenza A and B viral infections. A negative test is presumptive and it is recommended that these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions. The test is not intended to detect influenza C antigens.

Performance characteristics for influenza A and B were established during January through March of 2011 when influenza viruses A/2009 H1N1, A/H3N2, B/Victoria lineage, and B/Yamagata lineage were the predominant influenza viruses in circulation according to the Morbidity and Mortality Weekly Report from the CDC entitled "Update: Influenza Activity-United States, 2010-2011 Season, and Composition of the 2011-2012 Influenza Vaccine." Performance characteristics may vary against other emerging influenza viruses.

If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to the state or local health department for testing. Virus culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

BD Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived Kit

Summary Preparation Date:
9/27/2022

Submitted by:
BD Diagnostic Systems
Becton, Dickinson and Company
7 Loveton Cir.
Sparks, MD 21152
Establishment Registration Number: 1119779

Primary Contact:
Dung Nguyen
Sr. Staff, Regulatory Affairs
Tel: 424-452-8128
Email: dung.nguyen3@bd.com

Alternate Contact:
Michelle Bowerman
Director, Regulatory Affairs
Tel: 269-254-4802
Email: michelle.bowerman@bd.com

Proprietary Names:
BD Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived Kit

Common Names:
Devices Detecting Influenza A, B, and C Virus Antigens

Regulatory Information
Regulation section: 21 CFR 866.3328
Classification Name: Devices Detecting Influenza A, B, and C Virus Antigens
Classification: Class 2
Panel: Microbiology
Product Code(s): PSZ

Predicate Device
BD Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived Kit (K112277, K132259, K132692, K151291, K160161, K180438)

Device Establishment

Becton, Dickinson and Company
7 Loveton Cir.
Sparks, MD 21152
Registration Number: 1119779

Performance Standards

Not applicable.

Intended Use

The BD Veritor™ System for Rapid Detection of Flu A+B CLIA waived assay is a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral nucleoprotein antigens from nasal and nasopharyngeal swabs of symptomatic patients. The BD Veritor System for Rapid Detection of Flu A+B (also referred to as the BD Veritor System and BD Veritor System Flu A+B) is a differentiated test, such that influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single device. The test is to be used as an aid in the diagnosis of influenza A and B viral infections. A negative test is presumptive and it is recommended that these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions.
The test is not intended to detect influenza C antigens.

Performance characteristics for influenza A and B were established during January through March of 2011 when influenza viruses A/2009 H1N1, A/H3N2, B/Victoria lineage, and B/Yamagata lineage were the predominant influenza viruses in circulation according to the Morbidity and Mortality Weekly Report from the CDC entitled "Update: Influenza Activity—United States, 2010-2011 Season, and Composition of the 2011- 2012 Influenza Vaccine." Performance characteristics may vary against other emerging influenza viruses.

If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to the state or local health department for testing. Virus culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Special Instrument Requirements:

The BD Veritor™ System for Rapid Detection of Flu A+B CLIA Waived Kit is intended for use with the BD Veritor™ Plus Analyzer.

Device Description

A. Summary

The BD Veritor™ System for Rapid Detection of Flu A+B is a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral antigens from

nasopharyngeal and nasal swabs of symptomatic patients. The test is to be used as an aid in the diagnosis of influenza A and B viral infections. It is a differentiated test, such that influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single test device. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other management decisions. All negative test results should be confirmed by another methodology, such as a nucleic acid-based method.

BD Veritor™ System Flu A+B test devices are interpreted by a BD Veritor™ Plus Analyzer. When using the BD Veritor™ Plus Analyzer, workflow steps depend on the selected operational mode and the Analyzer configuration settings. 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. Depending on the configuration chosen by the operator, the instrument communicates status and results to the operator via a liquid crystal display (LCD) on the instrument, a connected printer, or through a secure connection to the facility's information system.

B. Test Principle

The BD Veritor™ Flu A+B test is an immuno-chromatographic assay for detection of influenza A and B viral antigens in samples processed from respiratory specimens. The viral antigens detected by the BD Flu A+B test are nucleoprotein, not hemagglutinin (HA) or neuraminidase (NA) proteins. Flu viruses are prone to minor point mutations (i.e., antigenic drift) in either one or both of the surface proteins (i.e., HA or NA). The BD Flu A+B test is not affected by antigenic drift or shift because it detects the highly conserved nucleoprotein of the influenza viruses. To perform the test, the patient specimen swab is treated in a supplied reaction tube prefilled with a lysing agent that serves to expose the target viral antigens, and then expressed through a filter tip into the sample well on a BD Veritor™ Flu A+B test device. Any influenza A or influenza B viral antigens present in the specimen bind to anti-influenza antibodies conjugated to colloidal gold micro-particles on the Veritor™ Flu A+B test strip. The antigen-conjugate complex then migrates across the test strip to the capture zone and reacts with either Anti-Flu A or Anti-Flu B antibodies that are immobilized on the two test lines on the membrane.

The BD Flu A+B test device shown in **Figure 1** is designed with five spatially distinct zones including positive and negative control line positions, separate test line positions for the target analytes, and a background zone. The test lines for the target analytes are labeled on the test device as 'A' for flu A position, and 'B' for flu B position. The onboard positive control ensures the sample has flowed correctly and is indicated on the test device as 'C'. Two of the five distinct zones on the test device are not labeled. These two zones are an onboard negative control line and an assay background zone. 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.

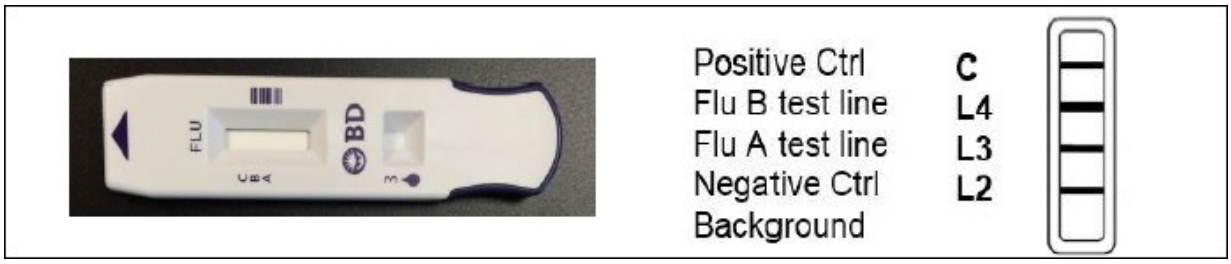


Figure 1. BD Veritor™ System Flu A+B Test Device

C. System Components

The Veritor™ System is made up of assay kits with analyte specific reagents and a portable optoelectronic interpretation instrument.

D. Flu A+B CLIA-Waived Kit Contents

The components included in the BD Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived test kit (Catalog # 256045) are detailed in **Table 1**.

Table 1: Contents of the Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived Kit

Component	Quantity	Description of Component
BD Veritor™ System Flu A+B Test Devices	30 Test Devices	Foil pouched device containing one reactive strip. Each strip has two test lines of antibodies specific to either influenza A or influenza B viral antigen, and positive and negative control lines.
RV Reagent D	30 tubes with 400 µL reagent	Detergent with < 0.1% sodium azide (preservative).
Flexible minitip flocked swab	30 each	Swab for nasopharyngeal or nasal collection.
Control A+/B-	1 each	Flu A positive and Flu B negative control swab, influenza A antigen (inactive recombinant nucleoprotein) with < 0.1% sodium azide.
Control B+/A-	1 each	Flu B positive and Flu A negative control swab, influenza B antigen (inactive recombinant nucleoprotein) with < 0.1% sodium azide.

E. Instrument

The instrument used with the BD Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived Kit is the BD Veritor™ Plus Analyzer (also referred to as the Analyzer).

The Analyzer is a digital immunoassay instrument that uses a reflectance-based measurement method and applies assay specific algorithms to determine the presence or absence of the target analyte. The Analyzer supports the use of different assays by reading an assay-specific barcode on the test device. Depending on the configuration chosen by the operator, the instrument communicates status and results to the operator via a liquid crystal display (LCD) on the instrument, a connected printer, or through a secure connection to the facility's information system.

In the case of the Flu A + B test, the BD Veritor™ Plus Analyzer subtracts nonspecific signal at the negative control line from the signal present at both the Flu A and Flu B test lines. If the resultant line signal is above a pre-selected assay cutoff, the specimen scores as positive. If the resultant line signal is below the cutoff, the specimen scores 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 measurement of the assay background zone is an important factor during test interpretation as the reflectance is compared to that of the control and test zones. A background area that is white to light pink indicates the device has performed correctly. The instrument does not require calibration. A BD Veritor™ Plus Analyzer can be identified by the image in **Figure 2**.

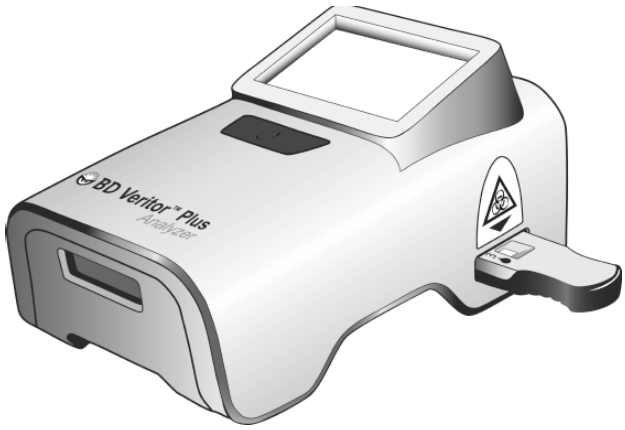


Figure 2. BD Veritor™ Plus Analyzer

The BD Veritor™ Plus Analyzer has the flexibility of an optional bar code scanning module and connectivity module designed to facilitate record keeping as well as the addition of a "Walk Away" workflow mode. Depending on the configuration chosen by the operator, the BD Veritor™ Plus Analyzer communicates status and results to the operator via a liquid crystal display (LCD) on the instrument, a connected printer, or through a secure connection to the facility's information system.

Table 2 lists the components that are included with the BD Veritor™ Plus Analyzer, which is purchased separately from the BD Veritor™ assays.

Table 2: BD Veritor™ Plus Analyzer Components

BD Veritor™ Plus Analyzer	1 each	Portable, rechargeable instrument for interpretation of BD Veritor™ System test devices
Instructions for Use	1 each	Printed instructions for use
USB Port Unlock Label	1 each	Adhesive label used to unlock the USB port
Compact AC power adapter with blades for USA, Japan, UK, and EU	1 each	Used to charge the internal rechargeable battery power source.
BD Veritor™ Verification Cartridge	1 each	Used to verify the proper functionality of the Analyzer.

The BD Veritor™ Plus system features a modular architecture that allows users to customize the system to meet their needs. Operators who wish to include data capture and/or secure transmission features may expand the functionality of the system by using optional accessories as described below.

BD Veritor™ InfoScan Module

The BD Veritor™ InfoScan module is inserted into the BD Veritor™ Plus Analyzer to add the capability of reading specimen identification, operator identification, reagent lot information, reagent expiration date, and modifying the on-screen display language of the BD Veritor™ Plus Analyzer. With the BD Veritor™ InfoScan module, users can unlock the unit's data storage to download test information to a connected computer over a USB connection. A BD Veritor™ Plus Analyzer configured with a BD Veritor™ InfoScan module can be identified by the label on its underside, shown in **Figure 3**.

Figure 3. BD Veritor™ Plus Analyzer Configured with BD Veritor™ InfoScan

BD Veritor™ Plus Connect

When implemented with BD Synapsys™ Informatics Solution, BD Veritor™ Plus Connect enables BD Veritor™ Plus Analyzers equipped with a BD Veritor™ barcode scanning module to securely transmit test results to a facility's information system via an Ethernet connection. The Connect software runs on a separate dedicated computer networked to the BD Veritor™ Plus Analyzer with the USB cable provided with the BD Veritor™ barcode scanning module. This is shown schematically in **Figure 4**.

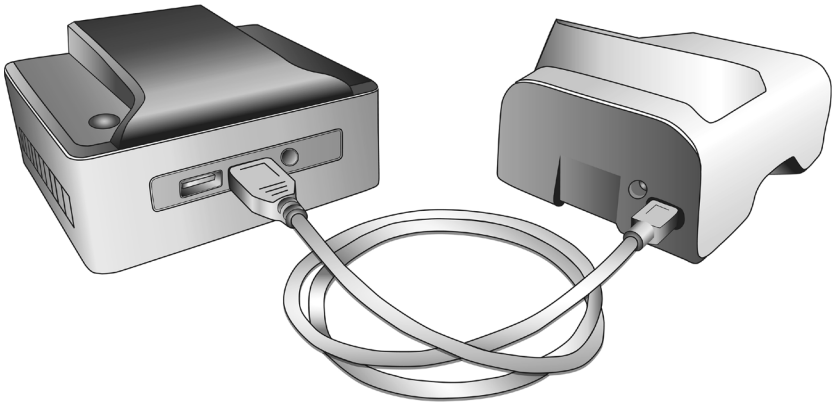


Figure 4: BD Veritor™ Plus Analyzer Connected to BD Veritor™ Plus Barcode Scanning Module

BD Veritor™ InfoWiFi Module

The BD Veritor™ InfoWiFi module provides the same functional features as the BD Veritor™ InfoScan module and adds wireless communication capability. Once configured, the BD Veritor™ InfoWiFi module can connect to a local wireless network and transmit test results to the BD Synapsys™ Informatics Solution. An additional BD Synapsys™ Informatics subscription is required. A BD Veritor™ Plus Analyzer configured with a BD Veritor™ InfoWiFi module can be identified by the label on its underside, shown **Figure 5**.

Figure 5. BD Veritor™ Plus Analyzer Configured with BD Veritor™ InfoWiFi Module

Substantial Equivalence –

The subject device, BD Veritor™ System for Rapid Detection of Flu A+B CLIA Waived Kit is a modified version of the current legally marketed device, BD Veritor™ System for Rapid Detection of Flu A+B CLIA Waived Kit. The predicate 510(k) numbers are K112277, K132259, K132692, K151291, K160161, K180438.

Table 3 provides a comparison between the two versions. In accordance with FDA's Guidance, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications* (July 28, 2014), the modified device is substantially equivalent to the predicate device as described in K180438. There are no changes to the device kit components. The following changes have been made to the Veritor™ Plus Analyzer:

- The Analyzer's trigger board was modified to incorporate additional circuitry for protection against overvoltage conditions which can occur when a non-BD power supply is used. The trigger board is a secondary board, separate from the main board where all assay-related functionality of the Analyzer is located. The trigger board supports a trigger switch for detection of an inserted assay cartridge and supplies DC power to the Analyzer.
- The lifetime number of tests that can be performed on the Veritor™ Plus Analyzer was extended from 3,500 tests to 10,000 tests.
- The optional InfoWiFi module was added to operate as part of the Veritor™ -to-BD Synapsys™ Informatics connectivity solution. Previously, the BD Veritor™ InfoScan module was available as an optional module to add the capability of reading specimen identification, operator identification, reagent lot information, reagent expiration date, and modifying the on-screen display language of the Analyzer. The BD Veritor™ InfoWiFi module was developed as an optional module to provide the same functional features as the previously available BD Veritor™ InfoScan module and adds wireless communication capability.

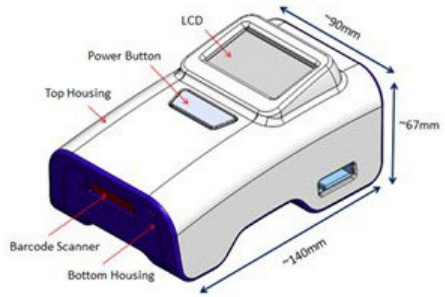
The claim of substantial equivalence is based on the determination that the predicate device is a legally marketed device; the modifications to the Analyzer do not result in a new intended use or different technological characteristics; and the changes do not raise different questions of safety and effectiveness. Non-clinical testing was performed to verify overvoltage protection, lifetime number of tests extension, and the functionalities of the BD Veritor™ InfoWiFi module.

Table 3: Comparison of Modified Device to Predicate Device

Feature	BD Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived Kit (K180438)	Modified BD Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived Kit
Intended Use	The BD Veritor™ System for Rapid Detection of Flu A+B CLIA waived assay is a rapid chromatographic	Same

Feature	BD Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived Kit (K180438)	Modified BD Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived Kit
	immunoassay for the direct and qualitative detection of influenza A and B viral nucleoprotein antigens from nasal and nasopharyngeal swabs of symptomatic patients. The BD Veritor™ System for Rapid Detection of Flu A+B (also referred to as the BD Veritor™ System and BD Veritor™ System Flu A+B) is a differentiated test, such that influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single device. The test is to be used as an aid in the diagnosis of influenza A and B viral infections. A negative test is presumptive and it is recommended that these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Outside the U.S., a negative test is presumptive and it is recommended that these results be confirmed by viral culture or a molecular assay cleared for diagnostic use in the country of use. FDA has not cleared this device for use outside of the U.S. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions. The test is not intended to detect influenza C antigens. Performance characteristics for influenza A and B were established during January through March of 2011 when influenza viruses A/2009 H1N1, A/H3N2, B/Victoria lineage, and B/Yamagata lineage were the predominant influenza viruses in circulation according to the Morbidity and Mortality Weekly Report from the CDC entitled "Update: Influenza Activity—United States, 2010-2011 Season, and Composition of the 2011-2012 Influenza Vaccine." Performance characteristics may vary against other emerging influenza viruses.	

Feature	BD Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived Kit (K180438)	Modified BD Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived Kit
	If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to the state or local health department for testing. Virus culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.	
Specimen Types	Nasal and nasopharyngeal swabs	Same
Assay Technology	Chromatographic immunoassay	Same
Detection Format	An opto-electronic reader determines the line intensity at each of the spatially defined test and control line positions, interprets the results using a scoring algorithm and reports a positive, negative or invalid result on the LCD screen based on pre-set thresholds.	Same
Qualitative or Quantitative	Qualitative	Same
Assay Run Time	Approximately 10 minutes	Same
Control Format	• Kit Flu A+/B- dry swab procedural control • Kit Flu A-/B+ dry swab procedural control • Internal positive control • Internal negative control	Same
Detection of Flu A and B Viruses	Differentiation of Flu A vs. Flu B	Same
INSTRUMENT		
Instrument Name	BD Veritor™ Plus Analyzer	Same

Feature	BD Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived Kit (K180438)	Modified BD Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived Kit
Appearance and dimensions		Same
Intended Use	For use with BD Veritor™ System test devices	Same
Firmware Functional Verification	Verification cartridge supplied with each Analyzer	Same
Analyzer Trigger Board	Original	Original + overvoltage protection circuitry
Assay type determination	Internal camera reads barcode on test device	Same
Lifetime	3500 tests 24 months from first use 34 months from date of manufacture	10,000 tests 24 months from first use 34 months from date of manufacture
Assay workflow options	Analyze Now mode: Assay device is prepared with processed patient sample; user manually times the assay development and inserts assay device when development time is complete. Walk Away mode: Assay device is prepared with processed patient sample, inserted into the Analyzer immediately. Assay development is automatically timed by the instrument and result is displayed when development time is complete.	Same
Optional Modules for Data Capture and Transmission	InfoScan: reads specimen identification, operator identification, reagent lot information, reagent expiration date, and modifying the on-screen display language; download test information to a connected computer over a USB connection.	InfoWiFi: same functional features as the InfoScan. InfoWifi adds wireless communication capability through a secure connection to the facility's information system.
Electrical		
Batteries	Lithium-ion rechargeable battery	Same
AC power adapter	To charge the lithium-ion battery and/or operate the analyzer from facility power	Same
Firmware		

Feature	BD Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived Kit (K180438)	Modified BD Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived Kit
Assay positivity algorithm	Original	Same
Assay cutoff thresholds	Original	Same
Cybersecurity controls	To meet requirements for data privacy and anti-hacking protection	Same
USB On-The-Go port	To connect to printer or to a computer to display or print results. Input firmware or menu updates from flash drive.	Same

Analytical Performance

There have been no changes to the analytical performance of the BD Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived Kit since the assay was last cleared in K180438. The modifications to the Analyzer do not have an impact on the assay-specific analytical performance. Testing was performed to confirm (1) that the added overprotection circuity does not affect the function of the trigger board (recognition of a cartridge and the USB connection) (2) that the Analyzer performs up to 10,000 cycles within the current specifications, and (3) to verify general functionalities of the InfoWiFi module.

Clinical Performance Studies

There have been no changes to the clinical performance of the BD Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived Kit since the assay was last cleared in K180438. The modifications to the Analyzer do not have an impact on the assay-specific clinical performance.