510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K232434

B Applicant

BD

C Proprietary and Established Names

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

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
PSZ	Class II	21 CFR 866.3328 - Influenza Virus Antigen Detection Test System	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

This traditional 510(k) submission for the BD Veritor System for Rapid Detection of Flu A+B CLIA-Waived Kit was submitted by BD to obtain clearance (SE) for the device after making hardware modifications to the analyzer with associated updates to the instrument software (firmware).

There were no changes to the kit, reagents, procedure to perform the test and therefore no new analytical and clinical data were required with these revisions. The intended use of the device and its underlying scientific technology remain unchanged.

B Measurand:

Influenza A Nucleoprotein Antigen
Influenza B Nucleoprotein Antigen

C Type of Test:

Lateral flow immunochromatography

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The BD Veritor System for Rapid Detection of Flu A+B CLIA-Waived Kit 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 CLIA-Waived Kit (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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D 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.

IV Device/System Characteristics:

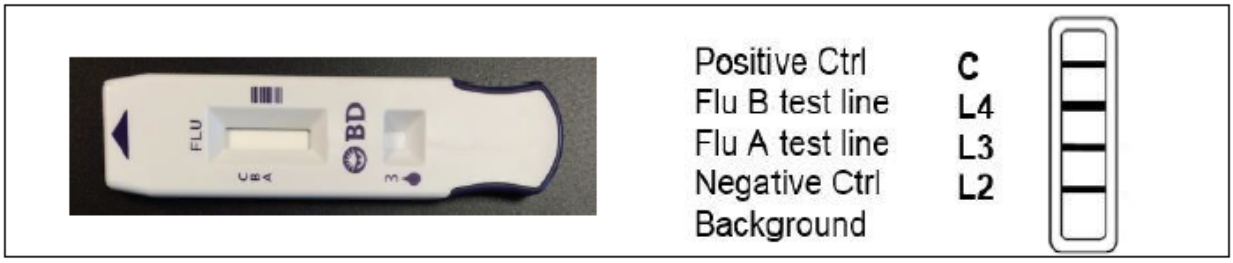
A Device Description:

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

When specimens are processed and added to the assay test device, any influenza A or B 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 complexes migrate 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 Veritor test devices are designed with five spatially distinct reaction zones including:

- a separate test line position for each target analyte (Flu A and Flu B),
- positive and negative control line positions, 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.



The BD Veritor System consists of a dedicated opto-electronic interpretation instrument and immunochromatographic assays for the qualitative detection of antigens from pathogenic organisms in samples processed from respiratory specimens. The assay included in this application is intended for interpretation in both laboratory and near-patient testing environments only with the BD Veritor Plus Analyzer Instrument ("the Analyzer") and is not interpreted visually.

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 assay test devices after manual timing of their incubation. In Walk Away mode, test devices are inserted immediately after application of the specimen, and timing of assay incubation and 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.

This 510(k) application includes validation of the changes made to the analyzer to add a plastic shield to the Analyzer's enclosure and in front of the LCD screen to protect the screen from being damaged when a high electrostatic discharge (ESD) voltage is applied. The main printed circuit board assembly (PCBA) was modified to add enhanced ESD and battery protection. A new firmware (V6.00) was developed to support the analyzer's new hardware features.

B Principle of Operation:

Immunochromatographic separation of influenza A or B antigen-antibody complexes detected via opto-electronic reader.

C Instrument Description Information:

1. Instrument Name:

   BD Veritor Plus Analyzer

2. Specimen Identification:

   Specimens ID's may be manually entered or scanned via the barcode scanner.

3. Specimen Sampling and Handling:

   Swab samples from nasopharyngeal or nasal swabs are manually transferred to test kit reagent tubes for elution and drop-wise addition to the test cassette. Freshly collected samples should be processed within 1 hour.

4. Calibration:

   Not Applicable

5. Quality Control:

   The test includes a positive control to ensure adequate migration of the reagents through the test membrane to the desired test line locations for the reader. The test also contains a negative control to test for non-specific binding and two background test regions to measure

assay background when calculating test line signal strength. Each kit also contains positive control swabs for Influenza A and Influenza B. It is the manufacturer's recommendation that positive controls be run after every new kit lot, a new operator performs the test, a new shipment of test kits is received, and as required by local, state, and federal regulations.

V Substantial Equivalence Information:

A Predicate Device Name(s):

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

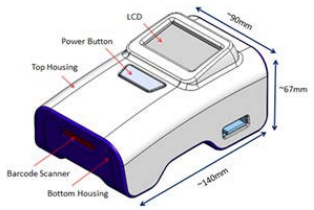
B Predicate 510(k) Number(s):

K223016

C Comparison with Predicate(s):

Device & Predicate Device(s):	K232434	K223016
Device Trade Name	BD Veritor System for Rapid Detection of Flu A+B CLIA-Waived Kit	BD Veritor System for Rapid Detection of Flu A+B CLIA-Waived Kit
General Device Characteristic Similarities		
Intended Use/ Indications For Use	The BD Veritor System for Rapid Detection of Flu A+B CLIA-Waived Kit 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 CLIA-Waived Kit (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	Same

	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.	
General Device Characteristic Differences		
Specimen Types	Nasal and nasopharyngeal swabs	Same
Assay Technology	Immunochromatographic	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
Instrument		
Instrument name	BD Veritor Plus Analyzer	Same

Appearances and dimensions		Same
Intended use	For use with BD Veritor System test devices	Same
Firmware functional verification	Verification cartridge supplied with each Analyzer	Same
Assay type determination	Internal camera reads barcode on test device	Same
Lifetime	10,000 tests 24 months from first use 34 months from date of manufacture	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.	Same
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	The BD Veritor InfoWiFi 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. Adds wireless	Same

	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		
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

VI Standards/Guidance Documents Referenced:

IEC 60601-1-2

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

This traditional 510(k) submission for the BD Veritor System for Rapid Detection of Flu A+B CLIA-Waived Kit was submitted by BD to obtain clearance (SE) for the device following hardware modifications to the analyzer and related updates to the instrument software (firmware). No new analytical studies were needed with these revisions because the kit, reagents, and the procedure to perform the test remain unchanged. Therefore, all the analytical performance characteristics hereafter are noted as "not applicable". Please refer to K223016 for the analytical performance data.

1. Precision/Reproducibility:

   Not applicable

2. Linearity:

   This is a qualitative test and linearity is not applicable.

3. Analytical Specificity/Interference:

   Not applicable

4. Assay Reportable Range:

   Not applicable

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Not applicable

6. Detection Limit:

   Not applicable

7. Assay Cut-Off:

   Not applicable

8. Accuracy (Instrument):

   Not applicable

9. Carry-Over:

   Not applicable

B Comparison Studies:

No changes were made to the kit, reagents, and procedure to perform the test since K220316. See K220316 for more information.

1. Method Comparison with Predicate Device:

   Not applicable

2. Matrix Comparison:

   Not applicable

C Clinical Studies:

This traditional 510(k) submission for the BD Veritor System for Rapid Detection of Flu A+B CLIA-Waived Kit was submitted by BD to obtain clearance (SE) for the device following hardware modifications to the analyzer and related updates to the instrument software (firmware). No new clinical study was needed with these revisions because the kit, reagents, and the procedure to perform the test remain unchanged. Therefore, all the clinical performance

characteristics hereafter are noted as “not applicable”. Please refer to K223016 for the clinical performance data.

1. Clinical Sensitivity:

   Not applicable

2. Clinical Specificity:

   Not applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   None

D Clinical Cut-Off:

The Clinical Cut-Off remains unchanged. See K220316 for more information.

E Expected Values/Reference Range:

Expected Values remain unchanged. See K220316 for more information.

F Other Supportive Instrument Performance Characteristics Data:

Not applicable

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.