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

I Background Information:

A 510(k) Number

K223016

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:

To establish Substantial Equivalence to a predicate device and to obtain 510(k) clearance following modifications to the previously 510(k)-cleared BD Veritor System for Rapid Detection of Flu A+B.

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 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.

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 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 antibodies conjugated to detector reagents in the test strip. The antigen-conjugate complexes migrate across the test strip to the reaction area and are captured by a line of antibodies bound on the reaction membrane. The BD Veritor test devices are designed with spatially distinct reaction zones including:

- a test line position for each target analyte,
- positive and negative control line positions, and
- a background zone

The measurement of the background zone compensates for background reflectance on the test strip, while the onboard negative control zone identifies and compensates for sample-related, nonspecific signal.

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 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 a new accessory module for the Analyzer that enables communication of test results to a facility WiFi network and integration into a secure data depository and then delivery to a facility LIS system.

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:
   Dry 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.

4. Calibration:
   Calibration is not recommended.

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.

This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this application, if the product has functions that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.

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):
K180438

C Comparison with Predicate(s):

Device & Predicate Device(s):	K223016	K180438
Device Trade Name	BD Veritor System for Rapid Detection of Flu A+B CLIA waived assay (modified)	BD Veritor System for Rapid Detection of Flu A+B CLIA waived assay
General Device Characteristic Similarities		

Intended Use/Indications For 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-	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. 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

	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.	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.
Specimen Types	Same	NPS and NS
Assay Technology	Same	Chromatographic Immunoassay
Detection Format	Same	Opto-electronic reader
Type of test	Same	Qualitative
Analyte detection	Same	Detection and differentiation of Influenza A and Influenza B antigens
Instrument	Same	BD Veritor Plus Analyzer
Analzyer software	Same	Version 5.70
Assay positivity algorithm	Same	Original
Assay cutoff threshold determination	Same	Original
General Device Characteristic Differences		
Analyzer trigger board	Original plus overvoltage protection	Original

Instrument Lifetime	10,000 Tests 24 months from first use 34 months from date of manufacture	3,500 Tests 24 months from first use 34 months from date of manufacture
Supplemental modules or software	InfoScan module PlusConnect software InfoWifi software	InfoScan module PlusConnect software

VI Standards/Guidance Documents Referenced:

No Standard/Special Control/Guidance Documents were referenced.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

Not applicable. Please refer to Decision Summary K180438.

B Comparison Studies:

Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

   Clinical Sensitivity remains unchanged since K180438. See K180438 for more information.

2. Clinical Specificity:

   Clinical Specificity remains unchanged since K180438. See K180438 for more information.

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

   None.

D Clinical Cut-Off:

The Clinical Cut-Off remains unchanged since K180438. See K180438 for more information.

E Expected Values/Reference Range:

Expected Values remains unchanged since K180438. See K180438 for more information

F Other Supportive Instrument Performance Characteristics Data:

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.