

510(K) SUMMARY k 132256

SUBMITTED BY: BECTON, DICKINSON AND COMPANY
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CONTACT NAME: Gregory P. Payne, RAC, Director Regulatory Affairs

DATE PREPARED: July 17, 2013

DEVICE TRADE NAME: BD Veritor™ System Flu A+B assay Clinical kit

DEVICE COMMON NAME: Influenza virus serological reagents

DEVICE CLASSIFICATION: 21 CFR 866.3330

PREDICATE DEVICES : BD Veritor™ System for Rapid Detection of Flu A+B
POC (120049 and k121797)

INTENDED USE :

AUG 07 2013

Clinical Kit

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 nucleoprotein antigens from nasopharyngeal wash, aspirate and swab in transport media samples from symptomatic patients. The **BD Veritor** System for Rapid Detection of 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 nasopharyngeal (NP) washes/aspirates 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.

Performance characteristics for influenza A and B NP swabs in transport media were established during January through April of 2012 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, 2011-2012 Season, and Composition of the 2012-2013 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.

DEVICE DESCRIPTION :

The BD Flu A+B test is a chromatographic assay to qualitatively detect influenza A and B viral antigens in respiratory specimens. The patient specimen is mixed in a prefilled unitized tube containing RV Reagent D and added to the test device. RV Reagent C contains mucolytic agents that function to break down mucus in a patient specimen thereby exposing viral antigens and enhancing detection in the assay device. Processed specimens are expressed through a filter tip into a single sample well on the BD Flu A+B test device.

The specimen is mixed and added to the test device where influenza A or influenza B viral antigens bind to anti-influenza antibodies conjugated to detector particles on the BD Flu A+B test strip. The antigen-conjugate complex migrates across the test strip to the reaction area and is captured by an antibody line on the membrane. The assay utilizes a proprietary enhanced colloidal-gold particle at the test lines as the means for identifying the presence of influenza A or B viral antigens.

The BD Flu A+B test devices are 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 onboard negative control zone addresses non-specific signal generation and is not labeled on the test device. The remaining zone is used to measure the assay background and is also not labeled.

Positive Ctrl	C
Flu B test line	L4
Flu A test line	L3
Negative Ctrl	L2
Background	



The BD Flu A+B assay incorporates an active negative control feature in each test to identify and compensate for sample-related, nonspecific signal generation. The BD Veritor™ System Reader uses a proprietary algorithm which 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 test line signal is above a pre-selected assay cutoff, the specimen is scored as positive. If the resultant test line signal is below the cutoff, the specimen is scored as negative. Use of the active negative control feature allows the BD Veritor™ System reader 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.

DEVICE COMPARISON:

The modified device differs from the currently marketed BD Veritor™ System Flu A+ B in the following way:

The labeling has been changed to reflect the addition of Analytical Sensitivity (LOD) reactivity data for A/Anhui/1/2013 H7N9 and Strain Reactivity tables.

SUBSTANTIAL EQUIVALENCE:

The modified device BD Veritor™ System Flu A+ B is substantially equivalent to the current legally marketed device, BD Veritor™ System Flu A+B assay. Additions made to the labeling to add additional strain testing did not change the intended use of the device or the fundamental scientific technology.

Risk analysis was not conducted to add this analytical sensitivity information to the product insert as no new issues of safety and effectiveness were identified for this addition to the product insert.

Additions are as follows:

Change	Potential Impact of Change
Addition of data for Analytical Sensitivity and Strain reactivity tables for A/Anhui/1/2013 H7N9	Change to package insert to reflect this change along with addition of FDA required disclaimer. "Although this test has been shown to detect the novel avian influenza A(H7N9) cultured virus, the performance characteristics of this device with clinical specimens that are positive for the novel avian influenza A(H7N9) virus have not been established. The BD Veritor System Flu A+B test can distinguish between influenza A and B viruses, but it cannot differentiate influenza A subtypes."



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

GREGORY P. PAYNE
RAC, DIRECTOR REGULATORY AFFAIRS
BECTON, DICKINSON AND COMPANY
10865 ROAD TO THE CURE, SUITE 200
SAN DIEGO, CA 92121

August 7, 2013

Re: K132256
Trade/Device Name: BD Veritor™ System Flu A+B assay Clinical kit
Regulation Number: 21 CFR 866.3330
Regulation Name: Influenza virus serological reagents
Regulatory Class: I
Product Code: GNX
Dated: July 17, 2013
Received: July 19, 2013

Dear Mr. Payne:

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. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2—Mr. Payne

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Uwe Scherf -S^{for}

Sally Hojvat, M.Sc., Ph.D.
Director, Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K132256

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Prescription Use (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

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