

K121797

SEP 7 2012

510(k) SUMMARY

SUBMITTED BY: BECTON, DICKINSON AND COMPANY
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CONTACT NAME: Gregory Payne

DATE PREPARED: September 5, 2012

DEVICE TRADE NAME: BD Veritor™ System for Rapid Detection of Flu A+B

DEVICE COMMON NAME: Influenza virus serological reagents

DEVICE CLASSIFICATION: 21 CFR § 866.3330

PREDICATE DEVICES: Quidel QuickVue Influenza A+B

INTENDED USE:

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 samples in transport media 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) wash/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 February 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 samples processed from respiratory specimens. The processed specimen is added to the test device where influenza A or influenza B viral antigens bind to anti-influenza antibodies conjugated to detector particles on the 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. Results are interpreted by the BD Veritor™ System Reader, a portable electronic device which uses a reflectance-based measurement method to evaluate the line signal intensities on the assay test strip, and applies specific algorithms to determine the presence or absence of any target analyte(s). A liquid crystal display (LCD) on the instrument communicates the results to the operator.

DEVICE COMPARISON:

The BD Veritor™ System for Rapid Detection of Flu A+B was compared to the Quidel QuickVue Influenza A+B test (k053146 and k092698).

Product Feature	BD Veritor™ System for Flu A+B	Quidel QuickVue Influenza A+B (k053146)
Intended Use	<p>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 samples in transport media 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.</p> <p>Performance characteristics for influenza A and B nasopharyngeal (NP) wash/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 <i>Morbidity and Mortality Weekly Report</i> 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.</p> <p>Performance characteristics for influenza A and B NP swabs in transport media were established during February 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 <i>Morbidity and Mortality Weekly Report</i> 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.</p> <p>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.</p>	<p>The QuickVue® Influenza A+B test allows for the rapid, qualitative detection of influenza type A and type B antigens directly from nasal swab, nasopharyngeal swab, nasal aspirate, and nasal wash specimens. The test is intended for use as an aid in the rapid differential diagnosis of acute influenza type A and type B viral infections. The test is not intended to detect influenza C antigens. Negative results should be confirmed by cell culture; they do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions. The test is intended for professional and laboratory use.</p>
Specimen Types	Nasopharyngeal wash/aspirates and nasopharyngeal swabs in transport media	Nasal swab, nasopharyngeal swab, nasal wash/aspirate
Assay Technology	Immunochromatographic	Immunochromatographic
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 the scoring algorithm, and reports a positive, negative, or invalid result on the LCD screen based on pre-set thresholds.	Visual determination of presence or absence of pink-to-red Test Line and the appearance of a blue Procedural Control Line on the test strip indicate the presence of influenza A and/or B antigen.
Qualitative	Yes	Yes

Total Assay Time	Approximately 10 minutes	10 minutes
Control format	<ul style="list-style-type: none"> • Kit Flu A+/B- dry swab procedural control • Kit Flu B+/A- dry swab procedural control • Internal positive control • Internal negative control 	<ul style="list-style-type: none"> • Kit Flu A+ control swab • Kit Flu B+ control swab • Kit Negative control swab • Internal control lines
Detection of Flu A and B viruses	Differentiated influenza A and influenza B	Differentiated influenza A and influenza B

Summary of Performance Data from k120049:

Analytical Sensitivity

The limit of detection (LOD) for the BD Veritor System for Rapid Detection of Flu A+B test was established for a total of 7 influenza strains: 4 influenza A and 3 influenza B. The LOD for each strain represents the lowest concentration producing a positivity rate of approximately 95% based on testing 20 to 60 replicates.

Type	Influenza Viral Strain	Calculated LOD (TCID ₅₀ /mL)	No. Positive / Total	% Positive
A	A/Brisbane/10/2007 H3N2	7.27 x 10 ²	57/60	95%
A	A/Brisbane/59/2007 H1N1	3.30 x 10 ²	57/60	95%
A	A/California/7/2009 H1N1	5.00 x 10 ³	57/60	95%
A	A/Victoria/3/75 H3N2	3.11 x 10 ³	59/60	98.3%
B	B/Brisbane/60/2008	7.42 x 10 ³	58/60	96.7%
B	B/Florida/4/2006	1.30 x 10 ³	58/60	96.7%
B	B/Lee/40	4.44 x 10 ⁴	20/20	100%

TCID₅₀/mL = 50% Tissue Culture Infectious Dose

Analytical Specificity

A panel of 52 influenza viral strains including 20 Influenza A strains and 32 Influenza B strains were evaluated in triplicate with the BD Veritor™ System for Rapid Detection of Flu A+B test. All Influenza A viruses and all Influenza B viruses were correctly detected by the test.

Cross Reactivity

A total of 51 microorganisms (36 bacteria, one yeast and 14 viruses) were tested in triplicate with the BD Veritor™ System for Rapid Detection of Flu A+B test. None of the microorganisms tested were shown to be cross reactive with the test.

Interfering Substances

A variety of substances including whole blood, prescription medications and over-the-counter (OTC) medications, were tested with the BD Veritor™ System for Rapid Detection of Flu A+B test in triplicate at concentration levels comparable to or greater than levels that may be present in patient respiratory samples. None of the substances evaluated were shown to interfere with the performance of the test.

Media Compatibility

Ten different types of transport media commonly used for the preservation and transport of respiratory specimens were evaluated for compatibility with the BD Veritor™ System for Rapid Detection of Flu A+B test. The effects of frozen storage of transport media samples on the stability of the antigen were also evaluated in this study.

Reproducibility

The reproducibility of the BD Veritor System for Rapid Detection of Flu A+B test was evaluated at three clinical laboratory sites. The reproducibility panel was composed of 30 simulated influenza A or B samples. These included moderate positive samples, low positive samples (near the assay limit of detection), high negative samples (i.e., containing very low concentrations of virus such that positive results occur ~5% of the time) and negative samples. The results are summarized below.

Reproducibility Results – Percent of Flu A Positives				
Sample	Site 1	Site 2	Site 3	Total
High negative H1N1 A	3.3% (1/30) (0.6%,16.7%)	0.0% (0/30) (0.0%,11.3%)	0.0% (0/30) (0.0%,11.3%)	1.1% (1/90) (0.2%,6.0%)
Low positive H1N1 A	93.3% (28/30) (78.7%,98.2%)	86.7% (26/30) (70.3%,94.7%)	93.3% (28/30) (78.7%,98.2%)	91.1% (82/90) (83.4%,95.4%)
Moderate positive H1N1 A	100.0% (30/30) (88.6%,100.0%)	96.7% (29/30) (83.3%,99.4%)	100.0% (30/30) (88.6%,100.0%)	98.9% (89/90) (94.0%,99.8%)
High negative H3N2 A	16.7% (5/30) (7.3%,33.6%)	3.3% (1/30) (0.6%,16.7%)	0.0% (0/30) (0.0%,11.3%)	6.7% (6/90) (3.1%,13.8%)
Low positive H3N2 A	93.3% (28/30) (78.7%,98.2%)	86.7% (26/30) (70.3%,94.7%)	93.3% (28/30) (78.7%,98.2%)	91.1% (82/90) (83.4%,95.4%)
Moderate positive H3N2 A	100.0% (30/30) (88.6%,100.0%)	100.0% (30/30) (88.6%,100.0%)	96.7% (29/30) (83.3%,99.4%)	98.9% (89/90) (94.0%,99.8%)
Flu A Negatives	0.8% (1/120) (0.1%,4.6%)	0.0% (0/120) (0.0%,3.1%)	0.0% (0/119) (0.0%,3.1%)	0.3% (1/359) (0.0%,1.6%)

Reproducibility Results – Percent of Flu B Positives				
Sample	Site 1	Site 2	Site 3	Total
High negative B	3.3% (1/30) (0.6%,16.7%)	0.0% (0/30) (0.0%,11.3%)	0.0% (0/30) (0.0%,11.3%)	1.1% (1/90) (0.2%,6.0%)
Low positive B	90.0% (27/30) (74.4%,96.5%)	63.3% (19/30) (45.5%,78.1%)	82.8% (24/29) (65.5%,92.4%)	78.7% (70/89) (69.0%,85.9%)

Reproducibility Results – Percent of Flu B Positives				
Sample	Site 1	Site 2	Site 3	Total
Moderate positive B	96.7% (29/30) (83.3%,99.4%)	100.0% (30/30) (88.6%,100.0%)	100.0% (30/30) (88.6%,100.0%)	98.9% (89/90) (94.0%,99.8%)
Flu B Negatives	0.0% (0/210) (0%,1.8.0%)	0.0% (0/210) (0.0%,1.8%)	0.0% (0/210) (0.0%,1.8%)	0.0% (0/630) (0.0%,0.6%)

Clinical Performance Data for NP Swabs in Transport Media 2011-2012

EXPECTED VALUES

The rate of positivity observed in respiratory testing will vary depending on the method of specimen collection, handling/transport system employed, detection method utilized, the time of year, age of the patient, geographic location and most importantly, local disease prevalence. The overall prevalence observed with an FDA-cleared influenza A and B molecular assay in the U.S. during the 2011-2012 clinical study was 31.7% for influenza A and 4.5% for influenza B. At the clinical sites located in Japan, the prevalence observed with the same FDA-cleared influenza A and B molecular assay was 0% for influenza A and 89 % for influenza B.

Clinical Performance NP Swab in Transport Media 2011-2012; U.S. and Japan Combined

Performance characteristics for the BD Veritor System for Rapid Detection of Flu A+B test were established using NP swabs in transport media in multi-center studies conducted at six clinical trial sites located in geographically diverse areas within the United States and five clinical sites in Japan using a total of 292 samples.

The combined results are presented in the Table below.

Summary of the Performance of the BD Veritor System for Rapid Detection of Flu A+B Test Compared to PCR for NP swab in Transport Media-U.S. and Japan Combined

BD Flu A	Reference PCR		Total		BD Flu B	Reference PCR		Total
	P	N				P	N	
P	52	6	58		P	77	2	79
N	12	222	234		N	13	200	213
Total	64	228	292		Total	90	202	292
Reference Method: PCR PPA: 81.3% (70.0%, 88.9%) NPA: 97.4% (94.4%, 98.8%)					Reference Method: PCR PPA: 85.6% (76.8%, 91.4%) NPA: 99.0% (96.5%, 99.7%)			

Clinical Performance NP Swab in Transport Media 2011-2012; U.S

Performance characteristics for the BD Veritor System for Rapid Detection of Flu A+B test were established using NP swabs in transport media in multi-center studies conducted at six clinical trial sites located in geographically diverse areas within the United States. A total of 217 prospective specimens were evaluated using the BD Veritor System for Rapid Detection of Flu A+B test and PCR. Two specimens could not be evaluated because of data reconciliation issues, one was eliminated because of an invalid control reading and 13 were excluded because the PCR results were unresolved.

The specimens consisted of NP Swab in transport media from symptomatic patients. 55.8% of the samples were from females and 44.2% from males. 16.1% were from patients less than or equal to 5 years of age, 25.3% were from patients 6-21 years of age, 47.5% were from patients 22-59 years of age and 11.1% were obtained from patients greater than or equal to 60 years of age.

The performance of the **BD Veritor System for Rapid Detection of Flu A+B test** was compared to an FDA-cleared Influenza A and B molecular assay (PCR).

The results are represented in the Table below.

Summary of the Performance of the BD Veritor System for Rapid Detection of Flu A+B Test Compared to PCR for NP Swab in Transport Media Specimens – U. S.

Clinical kit: BD Flu A	Reference PCR		Total
	P	N	
P	52	6	58
N	12	131	143
Total	64	137	201
Reference Method: Reference PCR PPA: 81.3% (95% CI: 70.0%, 88.9%) NPA: 95.6% (95% CI: 90.8%, 98.0%)			

Clinical kit: BD Flu B	Reference PCR		Total
	P	N	
P	7	0	7
N	2	192	194
Total	9	192	201
Reference Method: Reference PCR PPA: 77.8% (95% CI: 45.3%, 93.7%) NPA: 100% (95% CI: 98.0%, 100%)			

Clinical Performance NP Swab in Transport Media 2011-2012; Japan

Performance characteristics for the BD Veritor System for Rapid Detection of Flu A+B test were established using NP swabs in transport media in multi-center studies conducted at five clinical trial sites in Japan. A total of 93 prospective specimens were evaluated using the BD Veritor System for Rapid Detection of Flu A+B test and PCR. Two specimens were excluded as the results were undetermined with the comparator assay.

The specimens consisted of NP Swab in transport media from symptomatic patients. 49.5% of the samples were from females and 50.5% from males. 31.2% were from patients less than or equal to 5 years of age, 63.4% were from patients 6-21 years of age and 5.4% were from patients 22-59 years of age.

(there were no specimens from patients greater than or equal to 60 years of age).

The results are represented in the Table below.

Summary of the Performance of the BD Veritor System for Rapid Detection of Flu A+B Test Compared to PCR for NP Swab in transport media specimens – Japan.

Clinical kit: BD Flu A	Reference PCR		<i>Total</i>
	P	N	
P	0	0	0
N	0	91	91
<i>Total</i>	0	91	91
Reference Method: Reference PCR No Data for PPA Calculation NPA: 100% (95% CI: 95.9%, 100%)			

Clinical kit: BD Flu B	Reference PCR		<i>Total</i>
	P	N	
P	70	2	72
N	11	8	19
<i>Total</i>	81	10	91
Reference Method: Reference PCR PPA: 86.4% (95% CI: 77.3%, 92.2%) NPA: 80.0% (95% CI: 49.0%, 94.3%)			



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Becton, Dickinson and Company
c/o Gregory P. Payne, RAC
Director, Quality Systems and Regulatory Affairs
10865 Road to the Cure, Suite 200
San Diego, CA 92121

SEP 7 2012

Re: k121797
Trade Name: BD Veritor™ System for Rapid Detection of Flu A+B
Regulation Number: 21 CFR §866.3330
Regulation Name: Influenza virus serological reagents
Regulatory Class: Class I
Product Codes: GNX
Dated: June 15, 2012
Received: June 19, 2012

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.

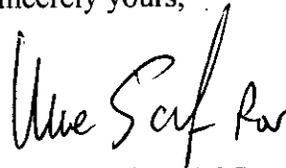
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number: k121797 _____

Device Name: BD Veritor™ System for Rapid Detection of Flu A+B

Indications for Use:

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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.

Prescription Use ✓ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k121797