

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k121797

B. Purpose for Submission:

To add a new sample type to the already cleared device K120049

C. Measurand:

Influenza A and B nucleoprotein antigens in nasopharyngeal wash/aspirate and swab samples in transport media

D. Type of Test:

Qualitative immunochromatogenic assay

E. Applicant:

Becton Dickinson and Company

F. Proprietary and Established Names:

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

G. Regulatory Information:

1. Regulation section:

21 CFR § 866.3330, Influenza Serological Reagents

2. Classification:

Class I

3. Product code:

GNX, Antigens, including CF controls, Influenza A, B, and C

4. Panel:

Microbiology (83)

H. Intended Use:

1. Intended use(s):

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.

2. Indication(s) for use:

Same as Intended Use

3. Special conditions for use statement(s):

The device is for prescription use only

4. Special instrument requirements:

Requires the use of the BD Veritor System Reader

I. Device Description:

The BD Flu A+B test is a chromatographic assay to qualitatively detect influenza A and B viral nucleoprotein antigens in samples processed from respiratory specimens (NP wash/aspirates and NP swab samples in transport media). The patient specimen is mixed in a prefilled unitized tube containing mucolytic agents that function to break down mucus in a patient specimen thereby exposing viral antigens. 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.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Quidel QuickVue Influenza A+B

2. Predicate 510(k) number(s):

k053146

3. Comparison with predicate:

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

Product Feature	BD Veritor™ System for Flu A+B	Quidel QuickVue Influenza A+B (k053146)
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<p>Intended Use</p>	<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 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.</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 Morbidity and Mortality Weekly Report from the CDC entitled “Update: Influenza Activity—United States, 2011-2012 Season, and Composition of the 2012-2013</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>
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	<p>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>	
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

K. Standard/Guidance Document Reference (if applicable):

Not Applicable

L. Test Principle:

The BD Flu A+B test is a chromatographic assay to qualitatively detect influenza A and B viral antigens (nucleoproteins) in NP wash/aspirates specimens and NP swabs in transport media. The patient specimen is mixed in a prefilled unitized tube containing RV Reagent C 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 processed specimen flows through 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. 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 and requires the use of the BD Flu A+B Veritor System Reader.

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.

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. The BD Veritor™ System Reader measures the amount of light reflected from various zones along the assay strip. 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 analyzes the reflectance data to provide the proper interpretation.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

Analytical performance was assessed based on the data submitted with the two previously FDA cleared 510(k)s for BD Veritor System for Rapid Detection of Flu A+B in nasopharyngeal and nasal swabs (k112277) and nasopharyngeal wash/aspirate samples (k120049). It is sufficient to assess the analytical performance of the additional specimen type, nasopharyngeal swab samples in transport media, claimed in the current submission. Please refer to decision summaries of k112277 and k120049 for detailed information.

2. Comparison studies:

a. Method comparison with predicate device:

Not Applicable

b. Matrix comparison:

A matrix comparison study was conducted previously to address concerns regarding matrix effects on the assay's performance. Please refer to decision summary of k120049.

3. Clinical studies:

Clinical Performance NP Wash/Aspirates 2010-2011 (k120049):

Performance characteristics for the BD Veritor System for Rapid Detection of Flu A+B test were established using NP wash/aspirate specimens in multi-center clinical studies conducted at two U.S. trial sites and one Hong Kong trial site during the 2010-2011 respiratory season. A total of 1502 prospective specimens (1002 in the U.S and 500 in Hong Kong) were evaluated using the BD Veritor System for Rapid Detection of Flu A+B test and PCR. Five specimens were not evaluable because of data reconciliation issues, an additional 13 were excluded because of insufficient sample volume for reference method testing and 13 samples were excluded as "Result Invalid" (for an invalid rate of 0.9% [13/1484]).

The prospective specimens consisted of NP washes and aspirates from symptomatic patients. 49% of the samples were from females and 51% from males. 56.6% were from patients less than or equal to 5 years of age, 21.9% of the patients tested were in the 6-21 year age group, 5.7% were from 22-59 years of age, and 15.8% were obtained from persons greater than or equal to 60 years (the patient age was not provided for 0.1% of samples). 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).

Performance of the BD Veritor System for Rapid Detection of Flu A+B Test Compared to PCR for All NP Wash/Aspirate Specimens – All Sites

	Reference PCR		
Clinical kit: BD Flu A	P	N	Total
P	224	29	253
N	46	1172	1218
Total	270	1201	1471
Reference Method: PCR PPA: 83.0% (95% C.I. 78.0%- 87.0%) NPA: 97.6% (95% C.I. 96.6%- 98.3%)			

	Reference PCR		
Clinical kit: BD Flu B	P	N	Total
P	74	3	77
N	17	1377	1394
Total	91	1380	1471
Reference Method: PCR PPA: 81.3% (95% C.I. 72.1%- 88.0%) NPA: 99.8% (95% C.I. 99.4%- 99.9%)			

An additional 263 frozen retrospective specimens were evaluated with the BD Veritor System for Rapid Detection of Flu A+B test. Twelve samples were excluded because there was insufficient sample volume for reference method testing, one sample was excluded as a PCR “Unresolved” and one sample was excluded as “Result Invalid” (for an invalid rate of 0.4% [1/250]). The retrospective specimens consisted of NP washes and aspirates from symptomatic patients. 44.9% of the samples were from females and 55.1% from males. 87.5% were from patients less than or equal to 5 years of age.

Performance of the BD Veritor System for Rapid Detection of Flu A+B Test Compared to PCR for Retrospective NP Wash/Aspirate Specimens

	Reference PCR		
Clinical kit: BD Flu A	P	N	Total
P	58	2	60
N	5	184	189
Total	63	186	249
Reference Method: PCR PPA: 92.1% (95% C.I. 82.7%- 96.6%) NPA: 98.9% (95% C.I. 96.2%- 99.7%)			

	Reference PCR		
Clinical kit: BD Flu B	P	N	Total
P	29	2	31
N	10	208	218
Total	39	210	249
Reference Method: PCR PPA: 74.0% (95% C.I. 58.9%- 85.4%) NPA: 99.0% (95% C.I. 96.6%-99.7%)			

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.

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		<i>Total</i>		BD Flu B	Reference PCR		<i>Total</i>
	P	N				P	N	
P	52	6	58		P	77	2	79
N	12	222	234		N	13	200	213
<i>Total</i>	64	228	292		<i>Total</i>	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 were not evaluable 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.

For testing specimens with the BD Veritor Flu A+B test, sites were instructed to follow the procedures outlined in the draft package insert. Briefly, NP swab in 1 mL of transport media was vortexed or thoroughly mixed and 300 µL of the specimen was transferred into the unitized tube containing RV Reagent C using the exact volume disposable pipette. The attached filter tip was snapped in place and three drops of the mixture were added to the sample well of the BD Flu A+B device. After 10 minutes at room temperature the device was inserted into the BD Veritor™ System Reader for interpretation. Visual interpretation of results was not permitted from the device.

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). Briefly, nucleic acids were extracted from specimens using the indicated extraction system according to the package insert. An internal control (IC) was added to each specimen prior to extraction in order to monitor for inhibitors of PCR present in the extracted samples. Amplification was carried out for 50 cycles using the indicated instrument according to the assay procedure described in the package insert. Interpretation of PCR results for all

specimens and controls was determined using the device software and according to the protocol outlined in the package insert.

Test results were analyzed based on positive and negative Influenza A or B results with the BD Flu A+B assay. The data were tabulated using reference method (an FDA-cleared Influenza A and B molecular assay) results to categorize the BD Flu A+B test results into the following categories:

1. True Positive: Any BD Flu A+B test result which exhibits a positive result and has a paired reference method positive result shall be deemed a true positive.
2. False Positive: Any BD Flu A+B test result which exhibits a positive result but the paired reference method is negative shall be deemed a false positive.
3. True Negative: Any BD Flu A+B test result which exhibits a negative result for which reference method is negative shall be deemed a true negative.
4. False Negative: Any BD Flu A+B test result that exhibits a negative result but for which the reference method is positive shall be deemed false negative.

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		<i>Total</i>
	P	N	
P	52	6	58
N	12	131	143
<i>Total</i>	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		<i>Total</i>
	P	N	
P	7	0	7
N	2	192	194
<i>Total</i>	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 collected 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 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).

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		Total	Clinical kit: BD Flu B	Reference PCR		Total
	P	N			P	N	
P	0	0	0	P	70	2	72
N	0	91	91	N	11	8	19
Total	0	91	91	Total	81	10	91
Reference Method: Reference PCR No Data for PPA Calculation NPA: 100% (95% CI: 95.9%, 100%)				Reference Method: Reference PCR PPA: 86.4% (95% CI: 77.3%, 92.2%) NPA: 80.0% (95% CI: 49.0%, 94.3%)			

Invalid rates for the BD Flu A+B clinical assay while running patient specimens were calculated. Invalid rates were calculated as the number of invalid results from the first compliant run divided by the total number of compliant results. The following table reports the invalid rates for five Japan and six U.S. investigational sites. Invalid rate for BD Veritor System for Rapid Detection of Flu A+B assay for the U.S. and Japan sites combined was 0.6% (2/308, 0.2%-2.3%).

Invalid Rates- Japan (J) and U.S. (S) sites		
Investigational Sites	Invalid Rate	95% CI of Invalid Rate
J1	0.0% (0/7)	(0.0%, 35.4%)
J2	0.0% (0/30)	(0.0%, 11.3%)
J3	0.0% (0/16)	(0.0%, 19.4%)
J4	0.0% (0/19)	(0.0%, 16.8%)
J5	0.0% (0/21)	(0.0%, 15.5%)
S1	1.7% (1/60)	(0.3%, 8.9%)
S2	0.0% (0/31)	(0.0%, 11.0%)
S3	0.0% (0/34)	(0.0%, 10.1%)
S4	0.0% (0/6)	(0.0%, 39.0%)
S5	1.3% (1/80)	(0.2%, 6.7%)
S6	0.0% (0/4)	(0.0%, 49.0%)
Overall	0.6% (2/308)	(0.2%, 2.3%)

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The overall prevalence observed with an FDA-cleared influenza A and B molecular assay in the U.S. during the 2010-2011 clinical study was 23.9% for influenza A and 7.5% for influenza B. At the clinical site located in Hong Kong, the prevalence observed with the same FDA-cleared influenza A and B molecular assay was 7.2% for influenza A and 3.4% for influenza B.

The prevalence from the six participating U.S. sites during the 2011-2012 clinical study with an FDA-cleared influenza A and B molecular assay was 31.7% for influenza A and 4.5% for influenza B. At the five 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.

N. Instrument Name:

BD Veritor System Reader

O. System Descriptions:

1. Modes of Operation:

The Veritor System Reader is a small, battery powered, bench top instrument that is used to read the Veritor lateral flow test cassette. After the extracted patient sample has been added to the test cassette, the test is developed at room temperature for 10 minutes. The cassette is then placed into the reader where it is scanned. The cassette is divided into distinct zones where the analyzer reads the negative background, positive control, and the Influenza A and B specific zones. The reader applies an algorithm to determine the background of the test as well as the specific signal from the A or B test zones. The reader has a finite number of reads and will prompt the end-user as the total number of reads approaches the lifetime of the unit.

2. Software:

The Veritor System Reader is the identical instrument that has been reviewed and cleared with the 510(k) BD influenza A and B assay k112277. FDA has reviewed applicant's instrument Hazard Analysis and software development processes for this instrument and for this analyte. Please refer to decision summary for k112277.

Yes X or No

3. Specimen Identification:

Not Applicable

4. Specimen Sampling and Handling:

Not Applicable

5. Calibration:

The Veritor Reader is not configurable by the end user and is designed to have a finite lifetime based on number of tests performed or shelf life from date of manufacture. Device calibration is not required, however, a verification device is provided with the reader to monitor the device function.

6. Quality Control:

Each BD Flu A+B test strip is designed with spatially-distinct zones containing a positive and negative internal controls. The positive control zone ensures that the sample has flowed correctly, and the negative control zone serves to monitor non-specific signal generation. The BD Veritor™ System Reader determines the line intensity at each of the spatially-defined control zones and utilizes specific algorithms to determine the presence or absence of any target analyte. The BD Veritor™ System Reader must be used to read the BD Flu A+B test devices, as these devices cannot be interpreted visually by the user.

In addition to the two internal controls, each BD Flu A+B kit contains the following external controls:

1. Control A+/B- is a dry swab control that contains inactivated recombinant influenza A nucleoprotein antigen and is tested in a similar manner as patient specimens and is used as an external control. A positive flu A test result and a negative flu B test result on the reader LCD display confirm that the operator performed the test correctly.

2. Control B+/A- is a dry swab control that contains inactivated recombinant influenza B nucleoprotein antigen and is tested in a similar manner as patient specimens and is used as an external control. A positive flu B test result and a negative flu A test result on the reader LCD display confirm that the operator performed the test correctly.

The BD Flu A+B device is to be read only by the instrument and cannot be read manually. At a minimum, the external dry swab controls should be run as a quality control procedure for each new lot and new shipment received. Controls should be tested in accordance with local, state and/or federal regulations or accreditation requirements and the standard Quality Control procedures. If desired, appropriate reagent performance and proper testing technique may also be determined by using specimens qualified as positive or negative for the influenza A or B virus. The user is instructed not to use the BD Flu A+B test results if control A+/B- and control B+/A- do not yield appropriate results.

P. Other Supportive Instrument Performance Characteristics Data Not Covered in the “Performance Characteristics” Section above:

Not Applicable

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

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