SPECIAL 510(k): Device Modification
Decision Summary

To: BD Diagnostics **RE:** K132693

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II device requiring 510(k). The following items are present and acceptable

1. The name and 510(k) number of the SUBMITTER'S previously cleared device:

   Trade Name: BD Veritor™ System Flu A+B assay

   510(k) number: k120049, k121797

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling.

3. A description of the device **MODIFICATION(S).** The modification presented in this 510(k) consisted of **expanded reactivity table to include reactivity information for** the H3N2v influenza A virus and minimal concentration detected for all viruses in the reactivity table. The submitter tested the ability of the BD Veritor™ System Flu A+B assay to detect influenza A virus; 6 H3N2v strains as well as 4 H1N1 strains, 1 H3N2 strain and 12 influenza B strains. BD diagnostics re-tested the non H3N2v strains using a dilution series protocol to maintain consistent testing protocols for all viruses listed in the reactivity table. The following tables show in *italics* the viruses tested for this submission and the minimal detected concentration:

Strain	Subtype	Minimal Detected Concentration
A/Brisbane/59/2007	H1N1	3.3×10^2 $TCID_{50}$/mL
A/California/7/2009	H1N1	5.0×10^3 $TCID_{50}$/mL
A/Denver/1/57	H1N1	4.45×10^4 $CEID_{50}$/mL
A/FM/1/47	H1N1	$7.91\ 10^4$ $CEID_{50}$/mL
A/Mal/302/54	H1N1	2.22×10^5 $CEID_{50}$/mL
A/New Caledonia/20/1999	H1N1	2.5×10^3 $TCID_{50}$/mL
A/New Jersey/8/76	H1N1	1.58×10^3 $CEID_{50}$/mL
A/NWS/33	H1N1	1.58×10^4 $CEID_{50}$/mL
A/PR/8/34	H1N1	6.31×10^2 $TCID_{50}$/mL
A/Solomon Island/03/2006	H1N1	2.5×10^3 $TCID_{50}$/mL
A/Weiss/43	H1N1	7.03×10^6 $CEID_{50}$/mL
A/WS/33	H1N1	7.91×10^2 $CEID_{50}$/mL
A/Aichi/2/68	H3N2	7.91×10^3 $CEID_{50}$/mL
A/Brisbane/10/2007	H3N2	7.27×10^2 $TCID_{50}$/mL
A/Hong Kong/8/68	H3N2	$8.89\ 10^4$ $CEID_{50}$/mL
A/Moscow/10/99	H3N2	5.8×10^6 $TCID_{50}$/mL
A/Perth/16/2009	H3N2	1.0×10^6 $TCID_{50}$/mL
A/Port Chalmers/1/73	H3N2	3.95×10^4 $CEID_{50}$/mL
A/Wisconsin/67/2005	H3N2	2.5×10^5 $TCID_{50}$/mL
A/Victoria/3/75	H3N2	3.11×10^3 $CEID_{50}$/mL
A/Indiana/08/2011	H3N2v	1×10^4 $TCID_{50}$/mL
A/Indiana/10/2011	H3N2v	7.9×10^6 $CEID_{50}$/mL
A/Kansas/13/2009	H3N2v	1.0×10^3 $TCID_{50}$/mL
A/Minnesota/11/2010	H3N2v	7.9×10^5 $CEID_{50}$/mL
A/Pennsylvania/14/2010	H3N2v	1.26×10^6 $CEID_{50}$/mL
A/West Virginia/06/2011	H3N2v	7.9×10^3 $TCID_{50}$/mL
A/Anhui/1/2013	H7N9	5.42×10^6 $CEID_{50}$/mL

Strain	Minimal Detected Concentration
B/Brazil/178/96	2.32 x 10^4 $TCID_{50}$/mL
B/Brisbane/60/2008	7.42 x 10^3 $TCID_{50}$/mL
B/Brisbane/72/97	1.00 x 10^4 $TCID_{50}$/mL
B/Canada/548/99	>0.64 HA
B/Egypt/393/99	>1.28 HA
B/Florida/2/2006	1.08 x 10^5 $TCID_{50}$/mL
B/Florida/4/2006	1.30 x 10^3 $TCID_{50}$/mL
B/Fujian/93/97	3.95 x 10^5 $TCID_{50}$/mL
B/Fukushima/220/99	9.33 x 10^2 $TCID_{50}$/mL
B/GuangXi/547/98	2.32 x 10^5 $TCID_{50}$/mL
B/Hawaii/01/97	>6.4 HA
B/Hong Kong/5/72	1.11 x 10^4 $CEID_{50}$/mL
B/Hong Kong/219/98	>1 HA
B/Jiangsu/10/2003	1.16 x 10^4 $TCID_{50}$/mL
B/Johannesburg/5/99	3.95 x 10^4 $TCID_{50}$/mL
B/Lee/40	4.44 x 10^4 $CEID_{50}$/mL
B/Lisbon/03/96	>0.08 HA
B/Malaysia/2506/2004	5.0 x $10^4$$TCID_{50}$/mL
B/Maryland/1/59	3.51 x 10^2 $CEID_{50}$/mL
B/Mass/3/66	1.58 x 10^5 $CEID_{50}$/mL
B/Ohio/11/96	>0.16 HA
B/Ohio/1/05	1.34 x 10^5 $TCID_{50}$/mL
B/Puerto Mont/10427/98	0.02 HA
B/Russia/69	3.9 x 10^2 $TCID_{50}$/mL
B/Shangdong/7/97	1.58 x 10^6 $TCID_{50}$/mL
B/Shanghai/04/97	1.58 x 10^5 $TCID_{50}$/mL
B/Shenzhen/135/97	3.16 x 10^4 $TCID_{50}$/mL
B/Sichuan/116/96	0.016 HA
B/Taiwan/2/62	2.81 x 10^2 $CEID_{50}$/mL
B/Victoria/504/00	4.64 x 10^4 $TCID_{50}$/mL
B/Yamagata/16/88	9.75 x 10^3 $TCID_{50}$/mL
B/Yamanashi/166/98	4.88 x 10^4 TCID50/mL

The BD Veritor™ System Flu A+B assay package insert has been updated to include the additional analytical reactivity information and to list the minimal detected concentration for all viruses listed in the reactivity table.

4. The **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

5. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, and physical characteristics:

Similarities

Features	**BD Veritor™ System Flu A+B**	**BD Veritor™ System Flu A+B**
Intended Use	The **BD Veritor™** System for Rapid Detection of Flu A+B is a rapid chromatographic immunoassay for the direct and	Same

	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.	
Read Results	BD Veritor System Reader	Same
Specimen Types	Nasal swab, nasopharyngeal swab	Same
Read Result Time	10 minutes	Same
External Controls	Test kit contains Positive and Negative Control swabs	Same

Differences

The package insert has been updated to include detection of the influenza A H3N2v strains in the analytical reactivity information section and minimal detected concentration information has been listed for all viruses in the reactivity table:

Strain	Subtype	Minimal Detected Concentration
A/Brisbane/59/2007	H1N1	3.3×10^2 $TCID_{50}$/mL
A/California/7/2009	H1N1	5.0×10^3 $TCID_{50}$/mL
A/Denver/1/57	H1N1	4.45×10^4 $CEID_{50}$/mL
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A/Aichi/2/68	H3N2	7.91×10^3 $CEID_{50}$/mL
A/Brisbane/10/2007	H3N2	7.27×10^2 $TCID_{50}$/mL
A/Hong Kong/8/68	H3N2	$8.89\ 10^4$ $CEID_{50}$/mL
A/Moscow/10/99	H3N2	5.8×10^6 $TCID_{50}$/mL
A/Perth/16/2009	H3N2	1.0×10^6 $TCID_{50}$/mL
A/Port Chalmers/1/73	H3N2	3.95×10^4 $CEID_{50}$/mL
A/Wisconsin/67/2005	H3N2	2.5×10^5 $TCID_{50}$/mL
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A/Indiana/08/2011	H3N2v	1×10^4 $TCID_{50}$/mL
A/Indiana/10/2011	H3N2v	7.9×10^6 $CEID_{50}$/mL
A/Kansas/13/2009	H3N2v	1.0×10^3 $TCID_{50}$/mL
A/Minnesota/11/2010	H3N2v	7.9×10^5 $CEID_{50}$/mL
A/Pennsylvania/14/2010	H3N2v	1.26×10^6 $CEID_{50}$/mL
A/West Virginia/06/2011	H3N2v	7.9×10^3 $TCID_{50}$/mL
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B/Brisbane/72/97	1.00×10^4 $TCID_{50}$/mL
B/Canada/548/99	>0.64 HA
B/Egypt/393/99	>1.28 HA
B/Florida/2/2006	1.08×10^5 $TCID_{50}$/mL
B/Florida/4/2006	1.30×10^3 $TCID_{50}$/mL
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B/GuangXi/547/98	2.32×10^5 $TCID_{50}$/mL
B/Hawaii/01/97	>6.4 HA
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B/Maryland/1/59	3.51×10^2 $CEID_{50}$/mL
B/Mass/3/66	1.58×10^5 $CEID_{50}$/mL
B/Ohio/11/96	>0.16 HA
B/Ohio/1/05	1.34×10^5 $TCID_{50}$/mL
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B/Shangdong/7/97	1.58×10^6 $TCID_{50}$/mL
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B/Sichuan/116/96	0.016 HA
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B/Yamagata/16/88	9.75×10^3 $TCID_{50}$/mL
B/Yamanashi/166/98	4.88×10^4 TCID50/mL

Although this test has been shown to detect novel avian influenza A (H7N9) and H3N2v cultured viruses the performance characteristics of this device with clinical specimens that are positive for novel avian influenza A (H7N9) and H3N2v influenza viruses has not been established. The BD Veritor™ System Flu A+B assay can distinguish between influenza A and B viruses, but it cannot differentiate influenza A subtypes.

6. **Design Control Activities Summary**:

a) Analytical Reactivity Testing was conducted as described in section 3, Device Modifications.

b) Declaration of Conformity
A "Declaration of Conformity" statement was submitted for the manufacturing facility and validation activities and signed by the Director of Quality Assurance and the Senior Director of Technical Operations respectively. The statements indicate that:

1. The manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

2. The validation activities, as required by the risk analysis, for the modification were performed by the designated individuals and the results demonstrated that the predetermined acceptance criteria were met.

In conclusion, based on the results of the analytical reactivity testing the modified labeling is truthful and accurate. The changes do not affect the performance of the test and it is therefore substantially equivalent to the current cleared test.

7. A **Truthful and Accurate Statement**, a **510(k) Summary**, and the **Indications for Use Enclosure**.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. On this basis, I recommend the device be determined substantially equivalent to the previously cleared device.