SPECIAL 510(k)
Device Modification Decision Summary

To: BD Diagnostics **RE:** K132256

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 Clinical kit

   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) is the inclusion of the H7N9 influenza A virus strain below, to the analytical sensitivity information. The submitter tested the ability of the BD Veritor System Flu A+B test to detect the H7N9 influenza A virus. The virus used (A/Anhui/1/2013) was inactivated viral material in clarified allontoic fluid from chicken eggs obtained from the WHO Collaborating Centre for Surveillance, Epidemiology and Control of Influenza, US Centers for Disease Control and Prevention. Analytical sensitivity testing was done at10 fold dilutions from the stock received from CDC and was tested in triplicate using the BD Veritor System Flu A+B test to establish the approximate level for the LOD:

   - 7.94×10^8 $CEID_{50}$/mL
   - 7.94×10^7 $CEID_{50}$/mL
   - 7.94×10^6 $CEID_{50}$/mL
   - 3.97×10^6 $CEID_{50}$/mL
   - 1.99×10^6 $CEID_{50}$/mL
   - 7.94×10^5 $CEID_{50}$/mL
   - 7.94×10^4 $CEID_{50}$/mL

   ($CEID_{50}$/mL= 50% Chicken Egg Infectious Dose)

   A final dilution was prepared and tested in replicates of 60:

   - 5.42×10^6 $CEID_{50}$/mL

   The limit of detection of the BD Veritor System Flu A+B test with A/Anhui/1/2013 H7N9 was 5.42×10^6 $CEID_{50}$/mL with a positivity of 98.3% (59/60).

   The BD Veritor System Flu A+B Clinical kit package insert has been updated to include the additional analytical sensitivity information.

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

Device Characteristics	Predicate Device: BD Veritor System Flu A+B assay (K120049, K121797)	New Device: BD Veritor System Flu A+B assay Clinical kit (K132256)
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 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	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.	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.
Specimen Types	Liquid nasopharyngeal wash, aspirate and swab in transport media	Liquid nasopharyngeal wash, aspirate and swab in transport media
Assay Technology	Immunochromotographic	Immunochromotographic
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.	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.
Qualitative	Yes	Yes
Total Assay Time	Approximately 10 minutes	Approximately 10 minutes
Control format	• Kit Flu A+/B- dry swab procedural control • Kit Flu B+/A- dry swab procedural control • Internal positive control	• Kit Flu A+/B- dry swab procedural control • Kit Flu B+/A- dry swab procedural control • Internal positive control

	• Internal negative control	• Internal negative control
Detection of Flu A and B viruses	Differentiated influenza A and influenza B	Differentiated influenza A and influenza B

Differences

The package insert has been updated to include detection of the following H7N9 virus in the analytical sensitivity information section and strain reactivity tables:

A/Anhui/1/2013 H7N9

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."

6. **Design Control Activities Summary**:

Analytical Sensitivity Testing was conducted as described in section 7, "Summary of Studies".

Declaration of Conformity to Design Control
A "Declaration of Conformity" statement was submitted for the manufacturing facility and validation activities and signed by the Director, Regulatory Affairs and Quality Systems. The statements indicate that;

1. The verification activities, as required by the risk analysis, for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.
2. The manufacturing facility, BD Rapid Diagnostics Co Ltd, is in conformance with the design control requirements as specified in 21 CFR 820. 30 and the records are available for review.

In conclusion, based on both the results of the analytical sensitivity testing and the risk management report, 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.