

SPECIAL 510(k): Device Modification Decision Summary

To: Becton, Dickinson and Company

RE: K133138

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class I 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, k132256

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 **adding a procedure for using the obtained clinical specimen to run the BD Veritor™ System RSV assay in addition to the Flu A+B assay**, both assays will be performed separately, but using a single specimen, nasopharyngeal aspirate/wash or nasopharyngeal swab in transport media. The following text and accompanying diagrams were added to the package insert:

ALTERNATIVE TEST PROCEDURE

USE OF BD VERITOR SYSTEM FOR RAPID DETECTION OF INFLUENZA A+B (CAT# 256041) AND BD VERITOR SYSTEM FOR RAPID DETECTION OF RSV (CAT# 256042) FROM A SINGLE NP WASH, ASPIRATE OR SWAB SPECIMEN IN TRANSPORT MEDIA

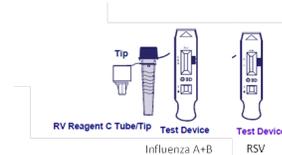
USE THIS PROCEDURE IF BOTH INFLUENZA A+B AND RSV ARE TO BE TESTED FROM A SINGLE PATIENT

IMPORTANT NOTE: THE SAMPLE TO BE TESTED IN THE RSV KIT MUST BE FROM A PATIENT LESS THAN 20 YEARS OF AGE AS INDICATED IN THE BD VERITOR RSV CLINICAL KIT PACKAGE INSERT. THE PROCESSED SAMPLE SHOULD BE TESTED WITHIN 15 MINUTES.

NOTES: Reagents, specimens and devices must be at room temperature (15–30°C) for testing. Thoroughly mix all specimens prior to removal of an aliquot for processing. Do not centrifuge specimens.

Note: The BD Veritor System for Rapid Detection of RSV (CAT #256042) is required for this procedure.

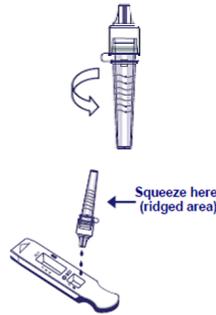
1. For each patient specimen and control swab, remove one RV Reagent C tube/tip and one BD Veritor System Flu A+B device and one BD Veritor System RSV from its foil pouch immediately before testing.
2. Label the BD Veritor System devices and one RV Reagent C tube for each specimen and control to be tested.
3. Place the labeled RV Reagent C tube(s) in the designated area of the tube rack.
4. Vortex or thoroughly mix specimen. Do not centrifuge.
5. 2. Remove and discard the cap from the RV Reagent C tube corresponding to the sample to be tested.



6. Using the transfer pipette, transfer 300 µL of specimen into the RV Reagent C tube. Discard pipette after use.
7. Press the attached tip firmly onto the RV Reagent C tube containing the processed specimen or control (threading/twisting not required).

NOTE: Do not use tips from any other product, including other products from BD or other manufacturers.

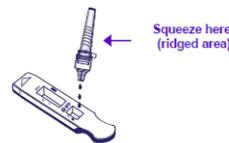
8. Vortex or mix thoroughly.



9. Invert the RV Reagent C tube and hold the tube vertically (approximately one inch above the BD Veritor System Flu A+B device sample well). Holding the tube at the ridged area, squeeze gently allowing three (3) drops of the processed sample to be dispensed into the sample well of the appropriately labeled BD Veritor System Flu A+B device.

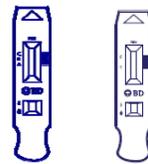
NOTE: Squeezing the tube too close to the tip may cause leakage.

10. Immediately continue to test for RSV. Invert the RV Reagent C tube and hold the tube vertically (approximately one inch above the BD Veritor System RSV device sample well). Holding the tube at the ridged area, squeeze gently allowing three (3) drops of the processed sample to be dispensed into the sample well of the appropriately labeled BD Veritor System RSV device.



NOTE: Squeezing the tube too close to the tip may cause leakage.

11. After adding the sample, allow the tests to run for 10 minutes before inserting into the reader.



12. When the test is ready, insert the BD Veritor System Flu A+B device into the BD Veritor System Reader. (The BD Veritor System Reader should be powered-on prior to use and will indicate when it is ready for insertion of the BD Veritor System device.)



Follow the reader on-screen prompts to complete the procedure and obtain the test result

13. Immediately after the Flu A+B result is obtained and recorded, insert the BD Veritor System RSV device into the BD Veritor System Reader.

Follow the reader on-screen prompts to complete the procedure and obtain the test result



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

Item Features	Proposed Device BD Veritor™ System Flu A+B assay	Proposed Device BD Veritor™ System Flu A+B assay
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 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.</p> <p>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 <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>	Same.

	<p>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 <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>	
Read Results	BD Veritor™ System Reader	BD Veritor™ System Reader
Specimen Types	nasopharyngeal swab in transport media, nasal aspirate, and nasal wash	nasopharyngeal swab in transport media, nasal aspirate, and nasal wash
Read Result Time	10 minutes	10 minutes
External Controls	Test kit contains Positive and Negative Control swabs	Test kit contains Positive and Negative Control swabs

Differences

The package insert has been updated to include an additional procedure for using the obtained clinical specimen to run the BD Veritor™ System RSV assay in addition to the Flu A+B assay. Both assays will be performed separately, but using a single nasopharyngeal aspirate/wash or nasopharyngeal swab in transport media.

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.