

SPECIAL 510(k): Device Modification Decision Summary

To: Becton, Dickinson and Company

RE: K133140

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 RSV assay

510(k) number: k121633

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 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 RSV (CAT# 256042) and INFLUENZA A+B (CAT# 256041) FROM A SINGLE NP WASH, ASPIRATE OR SWAB SPECIMEN IN TRANSPORT MEDIA

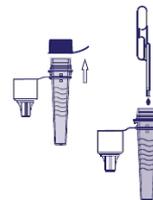
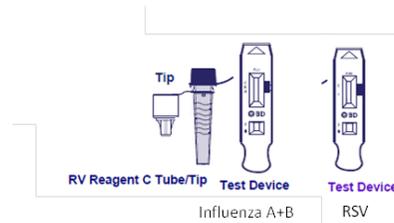
USE THIS PROCEDURE IF BOTH RSV AND INFLUENZA ARE TO BE TESTED FROM A SINGLE PATIENT

IMPORTANT NOTE: THE SAMPLE MAY BE TESTED UP TO 15 MINUTES AFTER PROCESSING.

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 Flu A+B (CAT #256041) 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 RSV device and one **BD Veritor** System Flu A+B 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).

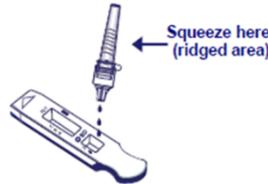


NOTE: Do not use tips from any other product, including other products from BD or other manufacturers.

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 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.

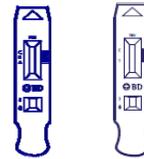


NOTE: Squeezing the tube too close to the tip may cause leakage.

10. Continue to test for Flu A+B. 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.

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 RSV 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.)



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

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

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14. 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	Proposed Device	Proposed Device
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Features	BD Veritor™ System Flu A+B assay	BD Veritor™ System Flu A+B assay
Intended Use	The BD Veritor™ System for Rapid Detection of Respiratory Syncytial Virus (RSV) is a chromatographic immunoassay with an instrumented read for the direct and qualitative detection of RSV antigen from nasopharyngeal washes/aspirates and nasopharyngeal swabs in transport media from patients suspected of having a viral respiratory infection. This test is intended for <i>in vitro</i> diagnostic use to aid in the diagnosis of RSV infections in infants and pediatric patients under the age of 20 years. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or for other management decisions. A negative test is presumptive. It is recommended that negative test results be confirmed by viral cell culture or an alternative method, such as a FDA-cleared molecular assay. The test is intended for professional and laboratory use. It is to be used in conjunction with the BD Veritor™ System Reader.	Same.
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 Flu A+B assay in addition to the RSV 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.