

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

A. 510(k) Number:

k121633

B. Purpose for Submission:

New device

C. Measurand:

Respiratory syncytial virus antigen in nasopharyngeal (NP) wash/aspirate and NP swab samples in transport media

D. Type of Test:

Qualitative chromatographic immunoassay

E. Applicant:

Becton Dickinson and Company

F. Proprietary and Established Names:

BD Veritor™ System for Rapid Detection of RSV

G. Regulatory Information:

1. Regulation section:

21 CFR § 866.3480, Respiratory syncytial virus Serological Reagents

2. Classification:

Class I

3. Product code:

GQG

4. Panel:

Microbiology (83)

H. Intended Use:

1. Intended use(s):

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 fusion protein from nasopharyngeal washes/aspirates and nasopharyngeal swabs in transport media from patients suspected of having a viral respiratory infection. This test is intended for *in vitro* 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.

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 RSV test is a chromatographic assay to qualitatively detect RSV fusion protein in samples processed from respiratory specimens. 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 RSV viral antigens bind to anti-RSV antibodies conjugated to detector particles on the RSV 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 RSV 10 test

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

k101918

3. Comparison with predicate:

The BD Veritor™ System for Rapid Detection of Flu A+B was compared to the Quidel QuickVue RSV 10 test (k101918).

Product Feature	BD Veritor™ System for RSV	Quidel QuickView RSV 10 (k101918)
Intended Use	<p>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 fusion protein 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.</p>	<p>The QuickVue RSV 10 test is an immunoassay that allows for the rapid, qualitative detection of respiratory syncytial virus (RSV) antigen directly from nasopharyngeal swab and nasopharyngeal aspirate/wash specimens for symptomatic pediatric patients (less than six years old). The test is intended for use as an aid in the rapid diagnosis of acute RSV infection. 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 cell culture. The test is intended for professional and laboratory use.</p>
Specimen Types	Nasopharyngeal swab in transport media, nasopharyngeal wash/aspirate	Nasopharyngeal swab, nasopharyngeal 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 RSV antigen.
Qualitative	Yes	Yes
Total Assay Time	Approximately 10 minutes	10 minutes
Control format	<ul style="list-style-type: none"> • Kit RSV positive and RSV negative dry swab procedural control • Internal positive control • Internal negative control 	<ul style="list-style-type: none"> • Kit RSV positive control swab • Kit RSV negative control swab • Internal control lines

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

Not Applicable

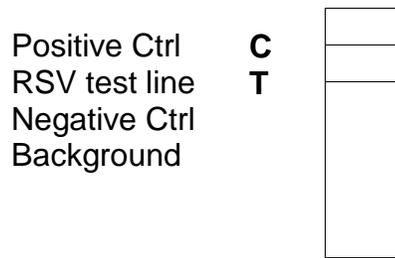
L. Test Principle:

The BD Veritor™ System RSV test is a chromatographic assay to qualitatively detect RSV viral fusion protein in respiratory specimens. 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 Veritor™ System RSV test device.

The specimen is mixed and added to the test device where RSV antigens bind to anti-respiratory syncytial antibodies conjugated to detector particles on the BD Veritor™ System RSV 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 RSV viral antigens.

The BD Veritor™ System RSV test devices are designed with four spatially-distinct zones including positive and negative control line positions, test line for the target analyte, and a background zone. The test line for the target analyte is labeled on the test device as ‘T’ for test position. The onboard positive control ensures the sample has flowed correctly and is indicated on the test device as ‘C’. Two of the four 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 Veritor™ System RSV 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 the test line. 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:
 - a. *Precision/Reproducibility:*

A study was conducted over a period of 12 days with two different operators in order to evaluate the precision of the BD RSV test. Each day, each operator tested a group of 20 swab samples that were blinded and randomized and included negatives and positives (~5% positive, ~95% positive and 100% positive). These specimens were prepared by dipping the swabs into various dilutions of virus and then letting them dry. All positive and negative swab specimens were masked and randomized prior to testing with the BD RSV test. The procedure in the package insert for the swab control was followed. To extract the viral material from the swab the sample was inserted into a unitized tube and plunged up and down for 15 seconds. The swab was then removed while squeezing the tube to expel the excess liquid and the attached filter tip was snapped in place. The processed sample was mixed and three drops were added to the sample well of the BD RSV device. After 10 minutes at room temperature the device was inserted into the BD Veritor™ System Reader for interpretation.

Sample	Clinical Kit							
	Operator 1				Operator 2			
	Positive/total tested swabs	% of positivity	Lower bound	Upper bound	Positive/total tested swabs	% of positivity	Lower bound	Upper bound
Negative Swab	0/24	0%	0.0%	14.2%	0/24	0%	0%	14.2%
5% Positive Swab	2/24	8.3%	1.0%	27.0%	7/24	29.2%	12.6%	51.1%
95% Positive Swab	18/24	75%	53.3%	90.2%	24/24	100%	85.8%	100%
Moderate Positive Swab	24/24	100%	85.8%	100%	24/24	100%	86%	100%

The reproducibility of the BD Veritor™ System for Rapid Detection of RSV test was evaluated at three clinical laboratory sites. The reproducibility panel was composed of 12 simulated RSV samples that were prepared in the same manner as for the precision study. The panel included moderate positive samples, low positive samples, high negative samples and negative samples. The panels were masked and randomized by BD prior to shipment to the clinical trial sites. Each site had two operators and each operator tested each panel for five consecutive days, resulting in a total of 60 samples tested per operator and 120 samples per site.

BD Veritor™ RSV Reproducibility (% RSV positive results)				
Sample	Site 1	Site 2	Site 3	Total
High negative RSV	0% (0/30) (95% CI: 0%, 11.3%)	3.3% (1/30) (95% CI: 0.6%, 16.7%)	3.3% (1/30) (95% CI: 0.6%, 16.7%)	2.2% (2/90) (95% CI: 0.6%, 7.7%)
Low positive RSV	93.3% (28/30) (95% CI: 78.7%, 98.2%)	76.7% (23/30) (95% CI: 59.1%, 88.2%)	93.3% (28/30) (95% CI: 78.7%, 98.2%)	87.8% (79/90) (95% CI: 79.4%, 93%)
Moderate positive RSV	100% (30/30) (95% CI: 88.6%, 100%)	100% (30/30) (95% CI: 88.6%, 100%)	100% (30/30) (95% CI: 88.6%, 100%)	100% (90/90) (95% CI: 95.9%, 100%)
Negative	0% (0/30) (95% CI: 0%, 11.3%)	0% (0/30) (95% CI: 0%, 11.3%)	0% (0/30) (95% CI: 0%, 11.3%)	0% (0/90) (95% CI: 0%, 4.1%)

b. *Linearity/assay reportable range:*

Not Applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Not Applicable

d. *Detection limit:*

Initially serial 10-fold dilutions of RSV virus stocks were made to determine the lowest detectable analyte level. Further characterization was performed using more closely spaced dilutions. The LOD was then determined as the concentration producing a 95% positivity rate. This concentration was tested using 60 to 80

replicates to define the LOD.

Viral Strain	Calculated LOD (TCID ₅₀ /mL)	No. Positive / Total	% Positive
VR-26 (Long Subgroup A)	1.43X10 ⁵	57/60	95.0
VR-955 (9320 subgroup B)	3.98X10 ⁴	57/60	95.0
VR-1540 (A-2)	1.94X10 ³	59/60	98.3
VR-1580 (Washington subgroup B)	1.08X10 ⁴	58/60	96.7
VR-1400 (Wild Type subgroup B)	2.96X10 ³	76/80	95.0

TCID₅₀/mL = 50% Tissue Culture Infectious Dose

e. Analytical specificity:

A total of 55 microorganisms (including 40 bacteria, one yeast and 14 viruses) were tested for potential cross reactivity. Bacteria and yeast were tested at a target concentration of 5 X 10⁶ CFU/mL with the exception of *Fusobacterium nucleatum* which was tested at 1.5 X 10⁵ CFU/mL. The 14 viruses were evaluated at concentrations of 10³ TCID₅₀/mL or higher.

All bacteria, yeast and viral frozen stock cultures were thawed and brought to room temperature prior to preparing target concentrations for testing. 300 µL of each organism suspension were added to the unitized tube of RV Reagent C and the attached filter tip was snapped in place. The sample was mixed and three drops of the suspension were added to the test well of a BD Veritor™ system RSV device. After 10 minutes at room temperature, the device was inserted into the BD Veritor™ System Reader for interpretation. All determinations were performed in triplicate with no cross reactivity observed for any of the tested organisms.

Sample Description	Concentration Tested	Cross Reactivity with RSV (Yes or No)
Adenovirus Type 1	1.58 X 10 ⁵ TCID ₅₀ /mL	No
Adenovirus Type 7	2.81 X 10 ⁴ TCID ₅₀ /mL	No
<i>Bacteriodes fragilis</i>	5 X 10 ⁶ CFU/mL	No
<i>Bordetella pertussis</i>	5 X 10 ⁶ CFU/mL	No
<i>Candida albicans</i>	5 X 10 ⁶ CFU/mL	No
<i>Chlamydia pneumoniae</i>	2.81 X 10 ⁴ TCID ₅₀ /mL	No
<i>Corynebacterium diptherium</i>	5 X 10 ⁶ CFU/mL	No
Cytomegalovirus	1.58 X 10 ⁵ TCID ₅₀ /mL	No
Enterovirus VR-28 Human Coxsackievirus	8.89 X 10 ⁵ TCID ₅₀ /mL	No
<i>Escherichia coli</i>	5 X 10 ⁶ CFU/mL	No
<i>Fusobacterium nucleatum</i>	1.5 X 10 ⁶ CFU/mL	No
<i>Haemophilus parainfluenzae</i>	5 X 10 ⁶ CFU/mL	No

Sample Description	Concentration Tested	Cross Reactivity with RSV (Yes or No)
<i>Hemophilus influenzae</i>	5 X 10 ⁶ CFU/mL	No
Influenza A/California/7/2009 H1N1	1.0 X 10 ⁶ TCID ₅₀ /mL	No
Influenza A/Victoria/3/75 H3N2	4.11 X 10 ⁵ TCID ₅₀ /mL	No
Influenza A/Brisbane/10/2007 H3N2	7.63 X 10 ⁴ TCID ₅₀ /mL	No
Influenza B/Brisbane/60/2008	6.31 X 10 ⁵ TCID ₅₀ /mL	No
Influenza B/Florida/4/2006	2.15 X 10 ⁵ TCID ₅₀ /mL	No
Influenza B/Lee/40	4.44 X 10 ⁵ TCID ₅₀ /mL	No
HSV Type 1 (HF)	8.89 X 10 ⁵ TCID ₅₀ /mL	No
Human coronavirus	1.5 X 10 ⁴ TCID ₅₀ /mL	No
Human metapneumovirus	2.2 X 10 ⁵ TCID ₅₀ /mL	No
Human parainfluenza	6.5 X 10 ⁶ TCID ₅₀ /mL	No
<i>Kingella kingae</i>	5 X 10 ⁶ CFU/mL	No
<i>Klebsiella pneumoniae</i>	5 X 10 ⁶ CFU/mL	No
<i>Lactobacillus casei</i>	5 X 10 ⁶ CFU/mL	No
<i>Legionella pneumophila</i>	5 X 10 ⁶ CFU/mL	No
Measles	1.5 X 10 ³ TCID ₅₀ /mL	No
<i>Moraxella catarrhalis</i>	5 X 10 ⁶ CFU/mL	No
Mumps virus	1.5 X 10 ⁴ TCID ₅₀ /mL	No
<i>Mycobacterium tuberculosis</i> avirulent	5 X 10 ⁶ CFU/mL	No
<i>Mycoplasma pneumoniae</i>	5 X 10 ⁶ CFU/mL	No
<i>Neisseria gonorrhoeae</i>	5 X 10 ⁶ CFU/mL	No
<i>Neisseria meningitidis</i>	5 X 10 ⁶ CFU/mL	No
<i>Neisseria mucosa</i>	5 X 10 ⁶ CFU/mL	No
<i>Neisseria perflaus</i>	5 X 10 ⁶ CFU/mL	No
<i>Neisseria subflava</i>	5 X 10 ⁶ CFU/mL	No
<i>Peptostreptococcus anaerobius</i>	5 X 10 ⁶ CFU/mL	No
<i>Porphyromonas asaccharolyticus</i>	5 X 10 ⁶ CFU/mL	No
<i>Prevotella oralis</i>	5 X 10 ⁶ CFU/mL	No
<i>Propionibacterium acnes</i>	5 X 10 ⁶ CFU/mL	No
<i>Proteus mirabilis</i>	5 X 10 ⁶ CFU/mL	No
<i>Pseudomonas aeruginosa</i>	5 X 10 ⁶ CFU/mL	No
Rhinovirus	1.5 X 10 ³ TCID ₅₀ /mL	No
<i>Serratia marcescens</i>	5 X 10 ⁶ CFU/mL	No

Sample Description	Concentration Tested	Cross Reactivity with RSV (Yes or No)
<i>Staphylococcus aureus</i>	5 X 10 ⁶ CFU/mL	No
<i>Staphylococcus epidermidis</i>	5 X 10 ⁶ CFU/mL	No
<i>Streptococcus mutans</i>	5 X 10 ⁶ CFU/mL	No
<i>Streptococcus pneumoniae</i>	5 X 10 ⁶ CFU/mL	No
Group A <i>Streptococcus</i>	5 X 10 ⁶ CFU/mL	No
<i>Streptococcus sp. Group C</i>	5 X 10 ⁶ CFU/mL	No
<i>Streptococcus sp. Group G</i>	5 X 10 ⁶ CFU/mL	No
<i>Streptococcus salivarius</i>	5 X 10 ⁶ CFU/mL	No
<i>Veillonella parvula</i>	5 X 10 ⁶ CFU/mL	No

f. *Interfering substances:*

An analytical study was conducted to evaluate a series of substances for potential interference with the BD Veritor™ System for Rapid Detection of RSV test at concentrations comparable to or greater than levels that may be present in patient respiratory samples. RSV positive samples were prepared at an antigen concentration corresponding to a weak positive and tested in triplicates. None of the substances listed in the table below exhibited interference with the BD Veritor™ System for Rapid Detection of RSV.

Substance	Concentration Tested	Interference with RSV Result
Whole Blood	2%	No
4-Acetamidophenol	10 mg/mL	No
Acetylsalicylic acid	20 mg/mL	No
Albuterol	0.083 mg/mL	No
Amantadine	500 ng/mL	No
Ayr Saline Nasal Gel	10 mg/mL	No
Beclomethasone	500 ng/mL	No
Budesonide	500 ng/mL	No
Chlorpheniramine maleate	5 mg/mL	No
Dextromethorphan	10 mg/mL	No
Diphenhydramine HCl	5 mg/mL	No
Dexamethasone	10 mg/mL	No
Fexofenadine	500 ng/mL	No
FluMist®	1%	No
Flunisolide	500 ng/mL	No
Fluticasone	500 ng/mL	No
Guaiacol Glyceryl Ether	20 mg/mL	No
Ibuprofen	10 mg/mL	No
Loratidine	100 ng/mL	No
Menthol Throat Lozenges	10 mg/mL	No
Mometasone	500 ng/mL	No

Mupirocin	500 ng/mL	No
Oxymetazoline	0.05 mg/mL	No
Osteltamivir	500 ng/mL	No
Phenylephrine	1 mg/mL	No
Pseudoephedrine HCl	20 mg/mL	No
Purified Mucin Protein	1 mg/mL	No
Ribavirin	500 ng/mL	No
Rimantadine	500 ng/mL	No
Tobramycin	500 ng/mL	No
Triamcinolone	500 ng/mL	No
Zanamivir	1 mg/mL	No
Synagis	4 ug/mL	No
Antiseptic Mouthwash (CVS)	5%	No
Cool Mint Listerine Antiseptic	5%	No
Scope Outlast Mouthwash	5%	No
Ibuprofen Concentrated Drops	25%	No
Pedia Care Drops for infants	25%	No
Triaminic infants drops	25%	No
Infants Advil concentrated Drops	25%	No
Nasal Spray	10%	No
Nasal Spray	10%	No
Nasal Spray	10%	No
Homeopathic Allergy Medicine	10 mg/mL	No

g. Specimen storage and stability:

Transport media listed in the Table below were evaluated for specimen storage and stability with the BD Veritor™ System for Rapid Detection of RSV test. Testing was performed using two RSV strains (Long subgroup A and 9320 subgroup B). Each transport medium was spiked with RSV virus at 4-5XLoD and used for testing on Day 1, Day 2, Day 3 and Day 4. 300µL of the spiked media were added to a unitized tube containing RV Reagent C. The attached filter tip was snapped into place, the suspension was mixed and three drops were added to the sample well of the BD Veritor™ System RSV device. After 10 minutes at room temperature the device was inserted into the BD Veritor™ System Reader for interpretation. Each transport media was tested on three different BD Veritor™ System RSV devices. The remaining volume of each spiked transport media were stored in a refrigerator (2-8°C) and tested again on Day 2, Day 3 and Day 4. No virus stability issues were noted for any of the transport medium spiked with RSV Strain Long and RSV Strain 9320 when stored for up to 3 days at 2-8°C.

Sample Description	Day 0		Day 1		Day 2		Day 3	
	RSV Long	RSV 9320						
Amies Medium	Positive							
Bartel ViraTrans Medium	Positive							

BD Universal Transport	Positive							
Earle's Minimal Essential Medium	Positive							
Hanks Balanced Salt Solution	Positive							
M4	Positive							
M4-RT	Positive							
M5	Positive							
Normal Saline	Positive							
Phosphate Buffered Saline	Positive							

2. Comparison studies:

a. *Method comparison with predicate device:*

Not Applicable

b. *Matrix comparison:*

Transport media compatibility:

Various transport media commonly used for the preservation and transport of respiratory specimens were evaluated for compatibility with the BD Veritor™ System for Rapid Detection of RSV test. The effects of frozen storage of transport media samples on the stability of the antigen were also evaluated in this study. Unspiked transport media were tested to determine if any of the media displayed compatibility issues (generation of a false positive or background problems) with the BD Veritor™ System RSV test. 300µL of non-frozen media were added to a unitized tube containing RV Reagent C and the attached filter tip was snapped into place. The suspension was mixed and three drops were added to the sample well of the BD Veritor™ System RSV device. After 10 minutes at room temperature the device was inserted into the BD Veritor™ System Reader for interpretation. Additionally, each media type was subjected to one freeze/thaw cycle and then tested in triplicate to evaluate effects of overnight storage at -20 ± 5 °C. Testing was performed as described above for the non-frozen media. Similarly, the RSV positive samples were evaluated to assure no interference was caused by any of the media (generation of a false negative) in the assay. Positive samples were prepared by diluting stock concentrations of an RSV antigen suspension to a concentration correlating to a weak positive. No compatibility issues were noted for any of the media tested at room temperature with either unspiked or spiked samples.

Sample Description	Reactivity with BD RSV assay (false positive)	Interference with BD RSV assay (false negative)
Amies Medium	No	No
Bartel ViraTrans	No	No

Medium		
BD Universal Transport	No	No
Earle's Minimal Essential Medium	No	No
Hanks Balanced Salt Solution	No	No
M4	No	No
M4-RT	No	No
M5	No	No
Normal Saline	No	No
Phosphate Buffered Saline	No	No
M6	No	No

Matrix comparison:

An additional matrix comparison study was conducted to evaluate matrix effects on the assay's sensitivity. The matrix effect study was designed using two RSV strains VR-26 (Long subgroup A) and VR-955 (9320 subgroup B) which were serially diluted in BD Universal Transport Media (UTM) and in a negative pooled wash/aspirate matrix (pool of around 70 specimens). LoD was determined using a minimum of 20 replicates. The results of the study showed that there were no significant differences in the LoD between the two matrices tested, UTM and negative clinical wash/aspirate matrix.

3. Clinical studies:

Performance characteristics for the BD Veritor™ System for Rapid Detection of RSV test were established in multi-center clinical studies conducted at five U.S. trial sites during the 2011-2012 respiratory season. A total of 1174 prospectively collected specimens received in the laboratory with an order for respiratory virus testing were enrolled in the study, of which, 26 were noncompliant with the study protocol and inclusion criteria and one was noncompliant on the viral cell culture reference testing level. Removal of these specimens yields a total of 1147 specimens. One additional specimen had a final undetermined viral cell culture reference result which could not be verified. Removal of this specimen results in a total of 1146 specimens. A total of 1146 were evaluated using the BD Veritor™ System for Rapid Detection of RSV test and viral cell culture. The prospective specimens consisted of 440 Nasopharyngeal Wash /Aspirates (NPWA) and 706 nasopharyngeal swabs (NPS) in transport media from symptomatic patients. 44.3% of the samples were from females and 55.7% from males. 80% of patients were 2 years and under.

For testing specimens with the BD Veritor™ System RSV test, sites were instructed to follow the procedural instructions outlined in the draft package insert. Briefly, NP wash/aspirate specimens and NP swab in transport media specimens were vortexed or thoroughly mixed and 300 µL of the specimen was transferred into the unitized tube

containing RV Reagent C using the disposable volumetric pipette. The attached filter tip was snapped in place, the contents were mixed by agitating the tube, and three drops of the mixture were added to the sample well of the BD Veritor™ System RSV device. After 10 minutes at room temperature the device was inserted into the BD Veritor™ System Reader for result interpretation. Visual interpretation of results was not permitted from the device.

The performance of the BD Veritor™ System for Rapid Detection of RSV test was compared to viral cell culture followed by DFA using an FDA cleared D³ Duet DFA Influenza A/ Respiratory virus screening test. The data were tabulated using the reference method results to categorize the BD RSV test results into the following categories:

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

Clinical Performance- Veritor RSV to Viral Cell Culture, By Specimen Type				
		Culture		
Specimen Type	Veritor RSV	P	N	
NPS	P	153	9*	162
	N	20	524	544
		173	533	706
Reference Method: Culture Sensitivity: 88.4% (82.8%, 92.4%) Specificity: 98.3% (96.8%, 99.1%)				
NPWA	P	152	15**	167
	N	14	259	273
		166	274	440
Reference Method: Culture Sensitivity: 91.6% (86.3%, 94.9%) Specificity: 94.5% (91.2%, 96.7%)				

*of the 9 BD Veritor RSV Positive, Viral Cell Culture negative specimens, 6 were positive by FDA cleared Prodesse Pro Flu+ molecular assay

**of the 15 BD Veritor RSV Positive, Viral Cell Culture negative specimens, 8 were positive by FDA cleared Prodesse Pro Flu+ molecular assay

Invalid rates for the BD Veritor™ System for Rapid Detection of RSV were calculated by dividing the number of invalids by the total number of compliant specimens tested. The following table reports the invalid rates for five U.S. investigational sites. Invalid rate for BD Veritor™ System for Rapid Detection of RSV assay for the U.S. sites combined was 1.5% (17/1148, 0.9%-2.4%).

<i>BD Veritor™ RSV Invalid Rate – By Specimen Type and Site</i>			
Specimen Type	Site	Invalid Rate	95% CI
NPS	S1	0.0% (0/18)	(0.0%, 17.6%)
	S2	0.0% (0/193)	(0.0%, 2.0%)
	S3	0.0% (0/165)	(0.0%, 2.3%)
	S5	2.1% (7/331)	(1.0%, 4.3%)
	Overall	1.0% (7/707)	(0.5%, 2.0%)
NPWA	S1	0.0% (0/22)	(0.0%, 14.9%)
	S2	0.0% (0/150)	(0.0%, 2.5%)
	S4	0.0% (0/19)	(0.0%, 16.8%)
	S5	4.0% (10/250)	(2.2%, 7.2%)
	Overall	2.3% (10/441)	(1.2%, 4.1%)

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The rate of positivity observed in RSV testing will vary depending on the method of specimen collection, handling/transport system employed, detection method utilized, time of year, age of the patient, geographic location and most importantly, local disease prevalence. In the 2011/2012 clinical trial, the overall prevalence of RSV as determined by viral cell culture for the NP swabs in transport media was 24.5% (range of 5.6% to 31.8%). The overall prevalence of RSV as determined by viral cell culture for the NPWA specimens was 37.7% (range of 10.5% to 49.6%).

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 BD influenza A and B assay k112277. FDA has reviewed applicant's instrument Hazard Analysis and software development processes for this instrument. Please refer to decision summary for k112277.

Yes 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 Veritor™ System RSV test strip is designed with spatially-distinct zones containing a positive and negative internal control. The positive control zone ensures that

the sample has flowed correctly, and the negative control zone serves to address 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 Veritor™ RSV test devices, as these devices cannot be interpreted visually by the user.

In addition to the two internal controls, each BD RSV kit contains the following external controls:

1. Control + is a dry swab control that may be used as an external control. A positive RSV test result on the reader LCD display confirms that the operator performed the test correctly.
2. Control – is a dry swab control that may be used as an external control. A negative RSV test result on the reader LCD display confirms that the operator performed the test correctly.

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 RSV virus. The user is instructed not to use the BD Veritor™ System RSV test if control + and control 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.