

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

**A. 510(k) Number:**

K132456

**B. Purpose for Submission:**

This is a traditional 510(k) submission requesting market clearance for the BD Veritor™ System for Rapid Detection of RSV (Respiratory Syncytial Virus) directly from nasopharyngeal swabs collected from children with symptoms of respiratory infection.

**C. Measurand:**

The BD Veritor™ System for Rapid Detection of RSV qualitatively detects the fusion (F) protein located in the envelope of the virus.

**D. Type of Test:**

The BD Veritor™ System for Rapid Detection of RSV (also referred to as BD Veritor System RSV and BD Veritor RSV) is a chromatographic lateral flow immunoassay utilizing an optical reflectance reader for qualitative detection of RSV antigen.

**E. Applicant:**

Becton, Dickinson and Company, BD Diagnostics

**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 a direct nasopharyngeal swab 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 6 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):

For prescription use.

4. Special instrument requirements:

The BD Veritor™ System Reader

**I. Device Description:**

The BD Veritor™ System RSV test is a chromatographic immunoassay with an instrumented read for the qualitative detection of Respiratory Syncytial Virus antigen (RSV fusion protein) directly from a nasopharyngeal swab. It utilizes lateral flow technology and a simple optical reflectance reader. The device utilizes monoclonal antibodies for detection and capture of the RSV antigen. Each 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. When specimens are processed and added to the test device, RSV antigen

in the specimen binds to anti-RSV antibodies conjugated to detector particles in the RSV test strip. The antigen-conjugate complex migrates across the test strip to the reaction area and is captured by the line of RSV antibody on the membrane. A positive result for RSV is determined by the BD Veritor System Reader (purchased separately) when antigen-conjugate is deposited at the Test "T" position and the Control "C" position on the BD Veritor System RSV assay device. 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 total assay time is approximately 10 minutes with reactivity determined by the optical reflectance reader.

The BD Veritor™ System for Detection of RSV kit consists of (a) 30 pouched devices, each containing one test strip, (b) 30 tubes, each containing 400 µL of RV Reagent D (a detergent solution), 30 flexible mini tip flocked swabs and one each of positive and negative external controls.

The test procedure instructs the user on proper collection of a nasopharyngeal swab. The patient specimen (a nasopharyngeal swab) is inserted and mixed in a prefilled unitized tube containing RV Reagent D (an extraction reagent) and added to the test device. RV Reagent D contains mucolytic agents that function to break down mucus in a patient specimen thereby exposing viral antigens and enhancing detection in the assay device. The swab is then removed and 3 drops of the tube contents are dispensed into the sample well of the device.



The test is allowed to stand at room temperature for 10 minutes after which time it is inserted into the reader.



The System Reader provides results on the screen. The following 3 results may be obtained.

Reader Display	Interpretation
RSV: +	Positive Test for RSV (RSV antigen present)
RSV: -	Negative Test for RSV (no antigen detected)
CONTROL INVALID	Control line error

An invalid test must be repeated.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Quidel QuickVue® RSV 10

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

K101918

3. Comparison with predicate:

Item	BD Veritor™ System for RSV	Quidel QuickVue® RSV 10
	<b>Similarities</b>	
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 fusion protein from direct nasopharyngeal swabs 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 6 years. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or for other	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

<b>Item</b>	<b>BD Veritor™ System for RSV</b>	<b>Quidel QuickVue® RSV 10</b>
	<b>Similarities</b>	
	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.	test results be confirmed by cell culture. The test is intended for professional and laboratory use.
Specimen Types	Nasopharyngeal swabs	Nasopharyngeal swabs
Technology	Immunochromatographic (EIA)	Immunochromatographic (EIA)
Type of Test	Qualitative	Qualitative
Total Assay Time	10 minutes	10 minutes
	<b>Differences</b>	
Instrument	BD Veritor System Reader	None
Detection	Electronic readout	Visual readout

**K. Standard/Guidance Document Referenced (if applicable):**

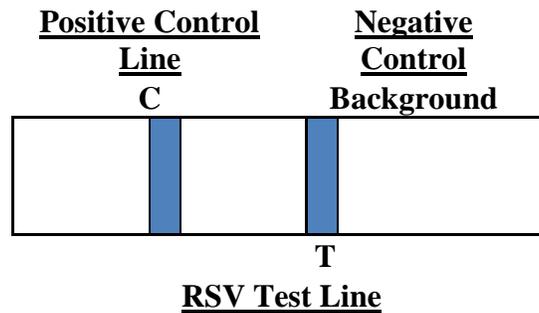
Not Applicable.

**L. Test Principle:**

The BD Veritor™ System RSV test is a chromatographic immunoassay where RSV viral antigens in the patient sample bind to anti-RSV antibodies conjugated to detector particles on the test strip. The antigen-conjugate complex migrates across the test strip to the reaction area and is captured by an antibody line imbedded 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 test devices are designed with four spatially-distinct zones including positive and negative control lines, a 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 (not labeled on the test device) addresses non-specific signal generation. 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. 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 also evaluated as the reflectance is compared to that of the control and test zones. The instrument analyzes the reflectance data to provide the proper interpretation.

The schematic of the test strip is shown below:



**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. *Precision/Reproducibility:*

An analytical study was conducted over a period of 12 days to evaluate repeatability of the BD Veritor RSV test when used by two different operators. The test samples were prepared in a stabilizing liquid buffer at target concentrations of RSV to generate positive observation rates of approximately 5% (high negative), 95% (low positive) and 100% (moderate positive). The reproducibility samples were prepared by drying the liquid viral samples onto swabs. A negative swab sample was also included. Each day, each operator tested a group of 8 swab samples that were blinded and randomized and included negatives and positives (~5% positive, ~95% positive and 100% positive). The following table summarizes the results.

Sample	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%	4/24	16.7%	4.7%	37.4%
95% Positive Swab	20/24	83.3%	62.6%	95.3%	20/24	83.3%	62.6%	95.3%
Moderate Positive Swab	24/24	100%	85.8%	100%	24/24	100%	85.8%	100%

Another study was conducted over a period of 5 days to evaluate reproducibility of the BD Veritor RSV test across 3 testing sites; one site was a clinical laboratory while the other two were point-of-care sites. The samples were prepared in the same manner as above for the precision study. Two operators at each site tested a panel of 12 samples each day. The panel consisted of 3 replicates of each nominal concentration. The panels were masked and randomized. The percent of positive samples with the 95% confidence intervals (CI) for each panel member are shown below.

Sample	Site 1	Site 2	Site 3	Total
High negative RSV	6.7% (2/30) (1.8%, 21.3%)	6.7% (2/30) (1.8%, 21.3%)	13.3% (4/30) (5.3%, 29.7%)	8.9% (8/90) (4.6%, 16.6%)
Low positive RSV	90.0% (27/30) (74.4%, 96.5%)	76.7% (23/30) (59.1%, 88.2%)	80.0% (24/30) (62.7%, 90.5%)	82.2% (74/90) (73.1%, 88.8%)
Moderate positive RSV	100% (30/30) (88.6%, 100%)	100% (30/30) (88.6%, 100%)	100% (30/30) (88.6%, 100%)	100% (90/90) (95.9%, 100%)
Negative	0% (0/30) (0%, 11.3%)	0% (0/30) (0%, 11.3%)	0% (0/30) (0%, 11.3%)	0% (0/90) (0%, 4.1%)

*b. Linearity/assay reportable range:*

Not applicable.

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

Not applicable.

*d. Detection limit:*

The limit of detection for the BD Veritor™ RSV test was determined for five RSV strains. Initially 10-fold serial dilutions of RSV in saline were prepared and each was tested in triplicate to find the lowest level detectable by three readers. Further characterization was performed using closely spaced dilutions. The final LoD, a concentration producing 95% positivity, was confirmed by testing 60 replicates.

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

To demonstrate that the LoD findings were not influenced by matrix effects, the sponsor conducted a matrix equivalence study by testing two RSV strains in dilutions near the established LoD, using (1) saline, (2) BD Universal Transport Media (UTM), and (3) negative clinical wash/aspirate sample matrix. There were 20 replicates of each dilution tested with the BD Veritor RSV test.

Viral Strain	Saline			Clinical Matrix			UTM		
	LOD (TCID <sub>50</sub> /mL)	No. Pos/Total	Rate of Positivity	LOD (TCID <sub>50</sub> /mL)	No. Pos/Total	Rate of Positivity	LOD (TCID <sub>50</sub> /mL)	No. Pos/Total	Rate of Positivity
VR-26 (Long Subgroup A)	1.43E+05	57/60	95%	1.52E+05	20/20	100%	1.43E+05	20/20	100%
				1.43E+05	18/20	90%	1.39E+05	18/20	90%
				1.32E+05	17/20	85%	1.35E+05	17/20	85%
VR-955 (9320 subgroup B)	3.98E+04	57/60	95%	3.71E+04	20/20	100%	4.41E+04	20/20	100%
				3.46E+04	17/20	85%	3.09E+04	19/20	95%
				3.28E+04	18/20	90%	2.63E+04	14/20	70%

The observed rate of positivity for VR-26 (Long Subgroup A) RSV strain at concentrations close to the established LoD (95% positivity rate), based on 20 replicates, ranged from 85% to 100% in both, the clinical matrix and UTM. Similarly, the observed rate of positivity for VR-955 (9320 Subgroup B) RSV strain at concentrations close to the established LoD ranged from 85% to 100% in clinical matrix and from 70% to 100% in UTM. These results suggest that there is no significant matrix effect on the assay performance at concentrations near LoD.

*e. Analytical specificity:*

The BD Veritor for RSV test was evaluated for potential cross-reactivity with other microorganisms. Various bacteria, viruses and yeast were tested at clinically relevant concentrations. All determinations were performed in triplicate with no cross reactivity observed for any of the tested organisms. The results are shown below.

Sample Description	Concentration Tested	Cross Reactivity with RSV (Yes or No)
Adenovirus Type 1	1.58 X 10 <sup>5</sup> TCID <sub>50</sub> /mL	No
Adenovirus Type 7	1.01 X 10 <sup>5</sup> TCID <sub>50</sub> /mL	No
<i>Bacteriodes fragilis</i>	5 X 10 <sup>6</sup> CFU/mL	No
<i>Bordetella pertussis</i>	5 X 10 <sup>6</sup> CFU/mL	No
<i>Candida albicans</i>	5 X 10 <sup>6</sup> CFU/mL	No
<i>Chlamydia pneumoniae</i>	1.01 X 10 <sup>5</sup> TCID <sub>50</sub> /mL	No
<i>Corynebacterium diphtherium</i>	5 X 10 <sup>6</sup> CFU/mL	No
<i>Cytomegalovirus</i>	1.58 X 10 <sup>5</sup> TCID <sub>50</sub> /mL	No
<i>Enterovirus VR-28 Human Coxsackievirus</i>	8.89 X 10 <sup>5</sup> TCID <sub>50</sub> /mL	No
<i>Escherichia coli</i>	5 X 10 <sup>6</sup> CFU/mL	No
<i>Fusobacterium nucleatum</i>	1.5 X 10 <sup>6</sup> CFU/mL	No
<i>Haemophilus influenzae</i>	5 X 10 <sup>6</sup> CFU/mL	No
<i>Haemophilus parainfluenzae</i>	5 X 10 <sup>6</sup> CFU/mL	No
HSV Type 1 (HF)	8.89 X 10 <sup>5</sup> TCID <sub>50</sub> /mL	No
Human coronavirus	1.01 X 10 <sup>5</sup> TCID <sub>50</sub> /mL	No
Human metapneumovirus	2.2 X 10 <sup>5</sup> TCID <sub>50</sub> /mL	No
Human parainfluenza	6.5 X 10 <sup>6</sup> TCID <sub>50</sub> /mL	No
Influenza A/California/7/2009 H1N1	1.0 X 10 <sup>6</sup> TCID <sub>50</sub> /mL	No
Influenza A/Brisbane/10/2007 H3N2	1.02 X 10 <sup>5</sup> TCID <sub>50</sub> /mL	No
Influenza A/Victoria/3/75 H3N2	4.11 X 10 <sup>5</sup> TCID <sub>50</sub> /mL	No
Influenza B/Brisbane/60/2008	6.31 X 10 <sup>5</sup> TCID <sub>50</sub> /mL	No
Influenza B/Florida/4/2006	2.15 X 10 <sup>5</sup> TCID <sub>50</sub> /mL	No
Influenza B/Lee/40	4.44 X 10 <sup>5</sup> TCID <sub>50</sub> /mL	No

<i>Kingella kingae</i>	5 X 10 <sup>6</sup> CFU/mL	No
<i>Klebsiella pneumoniae</i>	5 X 10 <sup>6</sup> CFU/mL	No
<i>Lactobacillus casei</i>	5 X 10 <sup>6</sup> CFU/mL	No
<i>Legionella pneumophila</i>	5 X 10 <sup>6</sup> CFU/mL	No
Measles	1.58 X 10 <sup>4</sup> TCID <sub>50</sub> /mL	No
<i>Moraxella catarrhalis</i>	5 X 10 <sup>6</sup> CFU/mL	No
Mumps virus	1.05 X 10 <sup>5</sup> TCID <sub>50</sub> /mL	No
<i>Mycobacterium tuberculosis</i> avirulent	5 X 10 <sup>6</sup> CFU/mL	No
<i>Mycoplasma pneumoniae</i>	5 X 10 <sup>6</sup> CFU/mL	No
<i>Neisseria gonorrhoeae</i>	5 X 10 <sup>6</sup> CFU/mL	No
<i>Neisseria meningitidis</i>	5 X 10 <sup>6</sup> CFU/mL	No
<i>Neisseria mucosa</i>	5 X 10 <sup>6</sup> CFU/mL	No
<i>Neisseria perflava</i>	5 X 10 <sup>6</sup> CFU/mL	No
<i>Neisseria subflava</i>	5 X 10 <sup>6</sup> CFU/mL	No
<i>Peptostreptococcus anaerobius</i>	5 X 10 <sup>6</sup> CFU/mL	No
<i>Porphyromonas asaccharolyticus</i>	5 X 10 <sup>6</sup> CFU/mL	No
<i>Prevotella oralis</i>	5 X 10 <sup>6</sup> CFU/mL	No
<i>Propionibacterium acnes</i>	5 X 10 <sup>6</sup> CFU/mL	No
<i>Proteus mirabilis</i>	5 X 10 <sup>6</sup> CFU/mL	No
<i>Pseudomonas aeruginosa</i>	5 X 10 <sup>6</sup> CFU/mL	No
Rhinovirus	1.58 X 10 <sup>4</sup> TCID <sub>50</sub> /mL	No
<i>Serratia marcescens</i>	5 X 10 <sup>6</sup> CFU/mL	No
<i>Staphylococcus aureus</i>	5 X 10 <sup>6</sup> CFU/mL	No
<i>Staphylococcus epidermidis</i>	5 X 10 <sup>6</sup> CFU/mL	No
<i>Streptococcus mutans</i>	5 X 10 <sup>6</sup> CFU/mL	No
<i>Streptococcus pneumoniae</i>	5 X 10 <sup>6</sup> CFU/mL	No
Group A <i>Streptococcus</i>	5 X 10 <sup>6</sup> CFU/mL	No

<i>Streptococcus sp. Group C</i>	5 X 10 <sup>6</sup> CFU/mL	No
<i>Streptococcus sp. Group G</i>	5 X 10 <sup>6</sup> CFU/mL	No
<i>Streptococcus salivarius</i>	5 X 10 <sup>6</sup> CFU/mL	No
<i>Veillonella parvula</i>	5 X 10 <sup>6</sup> CFU/mL	No

*f. Interference*

Various substances were evaluated for potential interference with the BD Veritor System for RSV test at concentrations comparable to or greater than levels that may be present in patient respiratory samples. In this study RSV positive samples, prepared at an antigen concentration corresponding to a weak positive, were spiked with the substances listed below. No interference was observed at the concentrations shown.

<b>Substance</b>	<b>Concentration Tested</b>	<b>Interference with RSV Result</b>
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
Dexamethasone	10 mg/mL	No
Dextromethorphan	10 mg/mL	No
Diphenhydramine HCl	5 mg/mL	No
Fexofenadine	500 ng/mL	No
FluMist <sup>®</sup>	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
Oseltamivir	500 ng/mL	No
Oxymetazoline	0.05 mg/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
Synagis	4 ug/mL	No
Tobramycin	500 ng/mL	No
Triamcinolone	500 ng/mL	No
Zanamivir	1 mg/mL	No
Antiseptic Mouthwash (CVS)	5%	No
Cool Mint Listerine Antiseptic	5%	No
Homeopathic Allergy Medicine	10 mg/mL	No
Ibuprofen Concentrated Drops	25%	No
Infants Advil concentrated Drops	25%	No
Nasal Spray	10%	No
Nasal Spray	10%	No
Nasal Spray	10%	No
Pedia Care Drops for infants	25%	No
Scope Outlast Mouthwash	5%	No
Triaminic infants drops	25%	No

*g. Specimen stability:*

The BD Veritor for RSV test is intended to be used with nasopharyngeal samples immediately after collection. However, since a delay in testing may occur in real life situations, the sponsor conducted a sample stability study to allow for such circumstances. In this study, RSV strains Long (A) and 9320 (B) were used to spike swabs at viral loads near the LoD. The swabs were held at room temperature and were sampled at 0.5 hr intervals from 0 hours up to 2 hours after being spiked. All swabs tested as positive at all-time points for both strains and no deterioration of signal was observed. These results support the decision to allow patient testing to be conducted for up to 1 hour after collection of the NP swab.

*h. Assay cut-off:*

The output of the BD Veritor Reader is provided in arbitrary units (AU) measuring reflectance. A “zero” AU signal is assigned when reading a white surface and 100 AU is the maximum signal that the Reader can provide. The assay cutoff was initially evaluated using negative specimens (with determined zero concentration of analyte) to assess the inherent noise level of the system which was determined to be approximately 0.4-0.5 AU. Additional measurements of contrived samples with concentrations near the cutoff plus leftover clinical samples were used to estimate a preliminary assay cutoff to be 1.5 AU (3 X 0.5 AU). Following an ROC analysis of the results, the final assay cutoff was determined to achieve optimal balance between maximal sensitivity without compromising the specificity. The selected assay cutoff was ultimately validated with clinical positive and negative samples in the clinical study. The results provided to the user are qualitative for any valid result, either positive or negative.

2. Comparison studies:

a. *Method comparison with predicate device:*

See clinical studies below.

b. *Matrix comparison:*

Not applicable.

3. Clinical studies:

Performance characteristics of the BD Veritor System for Rapid Detection of RSV test were evaluated in a multi-center prospective study across eight geographically diverse testing sites using nasopharyngeal (NP) swabs collected from patients with signs and symptoms consistent with respiratory tract infection. The study was conducted between November 2012 and June 2013. A total of 540 patients were enrolled in the clinical study of which 17 were excluded due to protocol deviations, leaving 523 specimens to be included in the calculations of estimates of assay performance. All specimens were collected from patients < 6 years of age. Of those, 58.3% (305) were from subjects < 2 years old and 41.7% (218) were from patients 2-5 years of age. There were 223 (42.6%) females and 300 (57.4%) males. Informed consent was obtained for all patients prior to testing. Two NP swabs were collected sequentially, one swab from each nostril, from each subject. One swab was placed into transport media for reference testing. The other swab was either placed in an empty tube until ready for testing, or tested immediately on the BD Veritor™ System. The order of swabs used for reference testing vs. the direct testing with the device was randomized. The direct testing with the BD Veritor device was intended to be completed immediately. If the sample could not be tested immediately, it was held at room temperature (20-25°C) for no longer than one hour prior to testing. The reference testing consisted of RSV viral culture and PCR testing (using the remaining specimen) with an FDA cleared molecular test for RSV.

Clinical Performance

The performance of the BD Veritor System for Rapid Detection of RSV test with NP swabs was estimated based on the comparison with results from viral cell culture (sensitivity and specificity) as well as in comparison with the results obtained by a PCR comparator method (positive percent agreement (PPA) and negative percent agreement (NPA)).

BD Veritor RSV test performance with NP swabs versus viral culture, based on 523 specimens:

BD VERITOR RSV	CULTURE	
	POSITIVE	NEGATIVE
POSITIVE	123	26*
NEGATIVE	11	363
TOTAL	134	389

**SENSITIVITY:** 91.8% (95% CI: 85.9%, 95.4%)

**SPECIFICITY:** 93.3% (95% CI: 90.4%, 95.4%)

\*Of the 26 BD Veritor RSV Positive, Viral Cell Culture negative specimens, 23 were positive by an FDA cleared molecular assay.

BD Veritor RSV test performance with NP swabs versus an FDA cleared PCR molecular assay, based on 523 specimens:

BD VERITOR RSV	PCR	
	POSITIVE	NEGATIVE
POSITIVE	146	3
NEGATIVE	33	341
TOTAL	179	344

**PPA:** 81.6% (95% CI: 75.2%, 86.6%)

**NPA:** 99.1% (95% CI: 97.5%, 99.7%)

Among the 523 tests performed with the BD Veritor RSV test, there was one invalid result. The overall invalid rate was calculated to be 0.2% (95% CI: 0.0%, 1.1%).

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, and disease prevalence. The overall prevalence of RSV infection observed during the time the BD Veritor RSV trial was 25.6% when determined by the results obtained with cell culture, or 34.2% when determined by the results obtained with PCR. The prevalence observed at each testing site during the study, depending on the reference method, is shown below.

Site	Prevalence based on Viral Cell Culture	Prevalence based on PCR
P1	32.9% (49/149)	45.6% (68/149)
P2	12.9% (12/93)	17.2% (16/93)
P3	7.7% (4/52)	15.4% (8/52)
P4	30.2% (13/43)	37.2% (16/43)
P5	26.3% (26/99)	34.3% (34/99)
P6	65.2% (15/23)	69.6% (16/23)
P7	21.1% (12/57)	31.6% (18/57)
P8	42.9% (3/7)	42.9% (3/7)
<i>Overall</i>	<i>25.6% (134/523)</i>	<i>34.2% (179/523)</i>

The positive and negative predictive values for the BD Veritor RSV assay, under hypothetical prevalence conditions, were calculated using the overall performance estimates (when compared to culture and when compared to PCR, separately).

Hypothetical Positive and Negative Predictive Values for BD Veritor RSV Test,

Based on Performance against Viral Culture:

Performance against Viral Culture	Hypothetical Prevalence	Positive Predictive Value	Negative Predictive Value
<b>Sensitivity</b> <b>91.8%</b>	5%	42.0%	99.5%
	10%	60.4%	99.0%
	20%	77.4%	97.8%
<b>Specificity</b> <b>93.3%</b>	30%	85.5%	96.4%
	40.0%	90.2%	94.5%

Hypothetical Positive and Negative Predictive Values for BD Veritor RSV Test,

Based on Performance against PCR:

Performance against PCR	Hypothetical Prevalence	Positive Predictive Value	Negative Predictive Value
<b>PPA 81.6%</b>	5%	83.1%	99.0%
	10%	91.2%	98.0%
<b>NPA 99.1%</b>	20%	95.9%	95.6%
	30%	97.6%	92.6%
	40.0%	98.4%	89.0%

**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 conducted an additional review of the applicant's instrument Hazard Analysis and software development processes associated with this specific device, the BD Veritor System for RSV.

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 cartridge is provided with the reader to perform a functional test of the reader.

### 6. Quality Control:

The Quality Control testing during the clinical trial was performed each day of testing at each site using the external Positive and Negative control swabs. A functional check of the Reader with the cartridge verification was also performed daily. The summary of QC results is shown below.

	QC POS				QC NEG				VERIFY			
	PASS		FAIL		PASS		FAIL		PASS		FAIL	
Site	N	%	N	%	N	%	N	%	N	%	N	%
<b>P1</b>	92	98.9	1	1.1	93	100	0	0.0	93	100	0	0.0
<b>P2</b>	96	99.0	1	1.0	96	98.0	2	2.0	94	100	0	0.0
<b>P3</b>	34	94.4	2	5.6	35	100	0	0.0	36	100	0	0.0
<b>P4</b>	31	100	0	0.0	31	100	0	0.0	31	100	0	0.0
<b>P5</b>	25	100	0	0.0	25	100	0	0.0	25	100	0	0.0
<b>P6</b>	18	100	0	0.0	18	100	0	0.0	17	94.4	1	5.6
<b>P7</b>	34	100	0	0.0	34	100	0	0.0	36	100	0	0.0
<b>P8</b>	9	100	0	0.0	9	100	0	0.0	9	100	0	0.0
<b>P9</b>	20	100	0	0.0	20	100	0	0.0	20	100	0	0.0
<b>Total</b>	359	98.9	4	1.1	361	99.4	2	0.6	361	99.7	1	0.3

**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.