

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

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

K091235

**B. Purpose for Submission:**

New device.

**C. Measurand:**

Respiratory Syncytial Virus (RSV) F-protein antigen

**D. Type of Test:**

Qualitative immunochromatographic test

**E. Applicant:**

Response Biomedical Corporation

**F. Proprietary and Established Names:**

RAMP<sup>®</sup> RSV Assay

**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 RAMP RSV Assay is a qualitative immunochromatographic test for the detection of Respiratory Syncytial Virus (RSV) F-protein antigens in nasal wash/aspirate, nasopharyngeal aspirate and nasopharyngeal swab samples. It is an *in vitro* diagnostic assay that aids in the rapid diagnosis of RSV infections in symptomatic patients 21 years of age and younger. A negative test is presumptive and it is recommended that all negative results be confirmed by cell culture or direct specimen fluorescence assay (DSFA). Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or other management decisions. The test is intended for professional use.

2. Indication(s) for use:

Same as Intended Use

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

To be used only with the RAMP<sup>®</sup> 200 Reader

**I. Device Description:**

The RAMP RSV Assay consists of the following components:

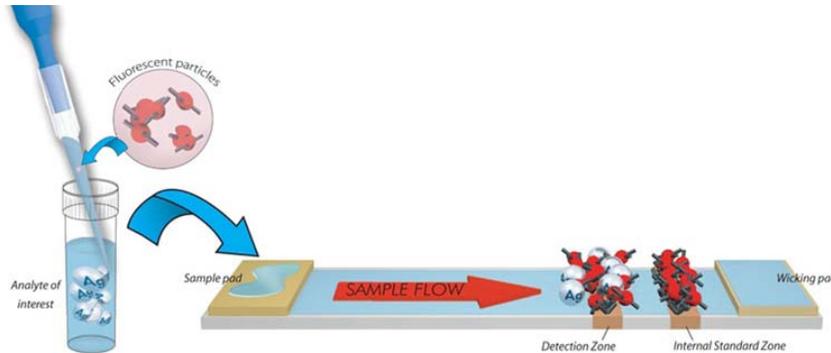
RAMP RSV test cartridges, RAMP RSV Assay tips, RAMP RSV sample buffer vials, disposable droppers, transfer device, RSV positive control swab, RSV negative control swab, lot card, package insert, and procedure card.

The device requires the following components which are not provided as part of the assay:

RAMP 200 reader, Transport Media and Specimen collection materials

The RAMP Assay Tip contains test-specific reagents. The supplied fixed volume transfer device and the RAMP Assay Tip are used to mix the test-specific reagents with the respiratory sample. Using the same transfer device and tip, an aliquot of the prepared sample is introduced to the sample well of the RAMP Test Cartridge. The RAMP Test Cartridge is a single-use; disposable, plastic housing that encloses an analyte-specific immunochromatographic assay strip. Sample is metered onto the assay strip by a pad at the bottom of the sample well. The assay strip is a Mylar-backed nitrocellulose membrane, near the terminal end of which are two closely spaced capture antibody zones, one of which is analyte-specific and the other of

which is an internal standard. An absorbent pad at the terminal end of the assay strip soaks up excess sample. A section of the bottom of the Test Cartridge is open so the Reader can scan the test strip



**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Quidel QuickVue RSV Assay

2. Predicate K number(s):

K070747

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	The RAMP RSV Assay is a qualitative immunochromatographic test for the detection of Respiratory Syncytial Virus (RSV) F-protein antigens in nasal wash/aspirate, nasopharyngeal aspirate and nasopharyngeal swab samples. It is an in vitro diagnostic assay that aids in the rapid diagnosis of RSV infections in symptomatic patients 21 years of age and younger. A negative test is presumptive and it is recommended that all negative results be confirmed by cell culture or direct specimen fluorescence assay (DSFA). Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or other management decisions. The test is intended for professional use.	The QuickVue RSV test is a dipstick immunoassay, which allows for the rapid, qualitative detection of Respiratory Syncytial virus (RSV) antigen (viral fusion protein) directly from nasopharyngeal swab, nasopharyngeal aspirate, or nasal/nasopharyngeal wash specimens for symptomatic pediatric patients (Eighteen years of age and younger). The test is intended for use as an aid in the diagnosis of acute Respiratory Syncytial viral infections. It is recommended that negative test results be confirmed by cell culture. Negative results do not preclude RSV infection and it is recommended that they not be used as the sole basis for treatment or other management decisions. The test is intended for professional and laboratory use.

<b>Similarities</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Specimen Type	Nasal wash, nasopharyngeal aspirate, and nasopharyngeal swab specimens	Nasal/ Nasopharyngeal wash, nasopharyngeal aspirate, and nasopharyngeal swab specimens
Target Antigen	RSV-F antigen	RSV-F antigen
Antibodies	Two mouse monoclonal antibodies recognizing the F- protein of RSV	Mouse monoclonal antibodies recognizing the F- protein
Test Time	15 minutes	15 minutes
Reagent Stability	In sealed pouch: Up to the stated expiration date stored at 15-30°C. Do not remove from pouch until ready to use. Do not freeze.	Store the kit at room temperature, 15–30°C, out of direct sunlight. Kit contents are stable until the expiration date printed on the outer box. Do not freeze

<b>Differences</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Instrument	RAMP 200 Reader	None
Automated Processing	Instrument transport of test cartridge within reader is the only moving step. No internal liquid handling.	Visual results appear on the test strip, no automation
Automated Analysis	Yes	No
Quality Controls	Provided in every Test Cartridge. Built in performance controls for routine QC requirements. A comparison of the internal standard and the assay result indicates that sufficient properly mixed sample was applied to the test device and that unbound fluorescent label washed sufficiently from the detection zone, and the device was inserted and read properly by the instrument. Background fluorescence measurement serves as a negative control. Reader controls also prevent a used or expired cartridge from being read by the reader. Antibody quality, system function and assay timing are checked on each assay run. An unacceptable result from the control displays a warning message without a test result on the instrument indicating that the test should be repeated.	Provided on every test strip. The two-color result format provides a simple interpretation for positive and negative results. The appearance of a blue procedural Control Line provides several forms of positive control by demonstrating sufficient flow has occurred and the functional integrity of the Test Strip was maintained. If the blue procedural Control Line does not develop within 15 minutes, the test result is considered invalid. A built-in negative control is provided by the clearing of red background color, verifying that the test has been performed correctly. Within 15 minutes, the result area should be white to light pink and allow the clear interpretation of the test result. If background color remains and interferes with interpretation of the test result, the result is considered invalid
System Quality Controls	A built-in Internal Quality Control (IQC) function performs an automated test of all Reader analytical systems on a scheduled or operator determined basis to provide a record of proper Reader functionality. For complete quality control of the system refer to the Operator's Manual	NA
Calibrator	Lot card contains calibration and expiration information and is supplied with every kit. System will not process	NA

Differences		
Item	Device	Predicate
	cartridge if lot card information is not stored in instrument.	
Method Comparison	vs. Viral culture and DSFA	vs. Viral Culture

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

Not Applicable

**L. Test Principle:**

The RAMP<sup>®</sup> RSV Assay is a qualitative immunochromatographic test that utilizes the RAMP<sup>®</sup> 200 Reader for the identification of the presence of RSV F-protein antigens in nasal wash/aspirate, nasopharyngeal aspirate (NP aspirate) and nasopharyngeal swab (NP swab) samples.

A wash/aspirate or swab sample is added to the Sample Buffer. This sample is then mixed with the Assay Tip containing fluorescent-dyed particles conjugated to RSV specific antibodies and applied into the sample well of the Test Cartridge. The sample migrates along the strip.

Fluorescent-dyed particles coated with anti-RSV antibodies bind to RSV F-protein antigens, if present in the sample. As the sample migrates along the strip, RSV-bound particles are captured at the detection zone which is coated with monoclonal antibodies anti RSV-F. Excess fluorescent-dyed particles are captured at the internal standard zone which is coated with goat anti-mouse IgG.

The Reader then measures the amount of fluorescence emitted by the complexes at the detection zone and at the internal standard zone. The instrument calculates a ratio (RAMP<sup>®</sup> Ratio) of the detection zone fluorescence reading to the internal standard zone fluorescence reading. The Reader then compares these ratios to pre-defined threshold limits to determine a positive or negative result for RSV in the tested sample. The RAMP<sup>®</sup> 200 is a general use fluorometer that analyzes results produced by immunoassays that use a fluorophore having an excitation wavelength of 560 nm and an emission wavelength of 610 nm.

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

1. Analytical performance:

a. *Precision/Reproducibility:*

The precision and reproducibility of the RAMP RSV Assay was evaluated using a panel consisting of a high negative RSV sample, a limit of detection (LoD) RSV sample (low positive), and a 2x LoD RSV sample (moderate positive). The RSV strain used to prepare the samples was RSV A (A-2)

(ATCC VR-1540) following viral titer determinations. To evaluate reproducibility, multiple operators at multiple sites tested each of the three precision samples on 5 different days. Testing at Site 2 was performed in a point-of-care (POC) setting (pediatric clinic, under CLIA umbrella of the hospital). At one site (Site 3), to evaluate precision, operators tested each of the three precision samples an additional 7 days for a total of 12 days. There was 99.2% agreement (393/396) with the expected test results for all specimens tested, with no significant differences within run (same operator on same day) between run, operators or sites. The RAMP RSV Assay is a qualitative assay based on numerical RAMP Ratio values.

	Panel Member ID	RSV High Negative	RSV Low Positive	RSV Moderate Positive	Total Agreement All (%)
	Viral Titer (TCID <sub>50</sub> /mL)	200	1200	2400	
Site 1	Agreement	30/30	30/30	30/30	90/90 (100%)
	Mean RAMP Ratio* Value	1176	3226	5460	
	% CV	11%	11%	9%	
Site 2	Agreement	30/30	29/30	30/30	89/90 (98.9%)
	Mean RAMP Ratio Value	1209	3273	5600	
	% CV	13%	14%	18%	
Site 3	Agreement	71/72	71/72	72/72	214/216 (99.1%)
	Mean RAMP Ratio Value	1330	3615	6193	
	% CV	17%	12%	11%	
	Total Agreement	131/132 (99.2%)	130/132 (98.5%)	132/132 (100%)	393/396 (99.2%)
	95% CI	95.8 – 99.9%	94.6 – 99.6%	97.1 – 100%	97.8 – 99.7%
	Overall Mean RAMP Ratio	1268	3449	5892	
	Overall % CV	16%	13%	14%	

b. *Linearity/assay reportable range:*

Not Applicable

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

Not Applicable

d. *Detection limit:*

The RAMP RSV Assay was evaluated for analytical sensitivity and reactivity after viral titer was determined by testing 6 strains of RSV (RSV A-Long, RSV A (A-2), RSV B CH93 (18)-18, RSV B Wash/18537/62, RSV B WV/14617/85, RSV B9320) at the LoD concentration in either viral transport media (VTM) to simulate a swab sample type or saline solution to simulate a wash sample type. Although the specific RSV strains causing infection in humans can vary year to year, all contain the conserved membrane-bound F-protein antigens targeted by the RAMP RSV Assay. Analytical sensitivity (LOD) ranged from  $3.5 \times 10^2$  to  $>1.7 \times 10^5$  TCID<sub>50</sub>/mL.

RSV Sample	LoD Concentration (TCID <sub>50</sub> /mL)	RAMP Result
A-Long in Saline	$6.5 \times 10^3$	100% RSV Positive
A-Long in VTM	$2.5 \times 10^3$	100% RSV Positive
A (A-2) in Saline	$1.0 \times 10^3$	100% RSV Positive
A (A-2) in VTM	$1.2 \times 10^3$	100% RSV Positive
B CH93(18)-18 in Saline	$3.5 \times 10^2$	100% RSV Positive
B CH93(18)-18 in VTM	$3.5 \times 10^2$	100% RSV Positive
B Wash/18537/62 in Saline	$7.0 \times 10^3$	95% RSV Positive
B Wash/18537/62 in VTM	$6.0 \times 10^3$	100% RSV Positive
B WV/14617/85 in Saline	$5.0 \times 10^3$	100% RSV Positive
B WV/14617/85 in VTM	$2.5 \times 10^3$	100% RSV Positive
B9320 in ZMC matrix	$> 1.7 \times 10^5$	90% RSV Positive

e. *Analytical specificity:*

Cross Reactivity:

The analytical specificity of the RAMP RSV Assay was determined by testing a panel consisting of 16 viruses and 17 bacteria that may be present in the nasal cavity or nasopharynx. Bacterial and viral isolates were tested at the concentrations listed after titer determination. None of the organisms tested gave a positive result in the RAMP RSV Assay. Note: RAMP RSV Assay potential cross-reactivity with *Chlamydomphila pneumoniae* has not been determined.

Strain/Isolate	Concentration	RSV result
Adenovirus, Type 1	$10^5$ TCID <sub>50</sub> /mL	Negative
Adenovirus, Type 7a	$10^5$ TCID <sub>50</sub> /mL	Negative
Human coronavirus, Strain OC43	$10^5$ TCID <sub>50</sub> /mL	Negative
Human coronavirus, Strain 229E	$10^5$ TCID <sub>50</sub> /mL	Negative

Strain/Isolate	Concentration	RSV result
Cytomegalovirus	10 <sup>5</sup> TCID <sub>50</sub> /mL	Negative
Enterovirus, Type 71	10 <sup>5</sup> TCID <sub>50</sub> /mL	Negative
Epstein Barr Virus	10 <sup>5</sup> TCID <sub>50</sub> /mL	Negative
Human Parainfluenza, Type 1	10 <sup>5</sup> TCID <sub>50</sub> /mL	Negative
Human Parainfluenza, Type 2	10 <sup>5</sup> TCID <sub>50</sub> /mL	Negative
Human Parainfluenza, Type 3	10 <sup>5</sup> TCID <sub>50</sub> /mL	Negative
Influenza A, Brisbane/10/07	10 <sup>5</sup> EID <sub>50</sub> /mL	Negative
Influenza B, Ohio/01/06	10 <sup>5</sup> TCID <sub>50</sub> /mL	Negative
Measles	10 <sup>5</sup> TCID <sub>50</sub> /mL	Negative
Human metapneumovirus	10 <sup>5</sup> TCID <sub>50</sub> /mL	Negative
Mumps virus	10 <sup>5</sup> TCID <sub>50</sub> /mL	Negative
Human Rhinovirus, Strain 1A	10 <sup>5</sup> TCID <sub>50</sub> /mL	Negative
<i>Bordetella pertussis</i>	10 <sup>6</sup> cfu/mL	Negative
<i>Corynebacterium</i> Sp.	10 <sup>6</sup> cfu/mL	Negative
<i>Escherichia coli</i>	10 <sup>6</sup> cfu/mL	Negative
<i>Haemophilus influenzae</i>	10 <sup>6</sup> cfu/mL	Negative
<i>Lactobacillus casei</i>	10 <sup>6</sup> cfu/mL	Negative
<i>Legionella pneumophila</i>	10 <sup>6</sup> cfu/mL	Negative
<i>Moraxella catarrhalis</i>	10 <sup>6</sup> cfu/mL	Negative
<i>Mycobacterium tuberculosis</i> , Avirulent	10 <sup>6</sup> cfu/mL	Negative
<i>Mycoplasma pneumoniae</i>	10 <sup>6</sup> cfu/mL	Negative
<i>Neisseria meningitidis</i>	10 <sup>6</sup> cfu/mL	Negative
<i>Neisseria sicca</i>	10 <sup>6</sup> cfu/mL	Negative
<i>Pseudomonas aeruginosa</i>	10 <sup>6</sup> cfu/mL	Negative
<i>Staphylococcus aureus</i> , Strain 176	10 <sup>6</sup> cfu/mL	Negative
<i>Staphylococcus epidermidis</i> , Strain 78	10 <sup>6</sup> cfu/mL	Negative
<i>Streptococcus pneumoniae</i>	10 <sup>6</sup> cfu/mL	Negative
<i>Streptococcus pyogenes</i>	10 <sup>6</sup> cfu/mL	Negative
<i>Streptococcus salivarius</i>	10 <sup>6</sup> cfu/mL	Negative

#### Interfering Substances:

Whole blood and a number of other potentially interfering substances (medications and over the counter (OTC) products) that may be present naturally or artificially introduced in the nasal cavity or nasopharynx were evaluated in the RAMP RSV Assay. The substances were added to a simulated negative sample (0.85% saline), an RSV LoD positive sample and an RSV 2x LoD positive sample and tested in the RAMP RSV Assay. The RSV strain used to prepare the samples was RSV A (A-2), interference was not evaluated with an RSV B strain. The following substances were found to have no effect on the test results of the RAMP RSV Assay when present in positive and negative RSV simulated respiratory samples at the concentrations indicated:

Substance Tested	Conc. Tested	Negative		RSV LoD		RSV 2x LoD	
		RAMP Results	Percent of Mean Control Ratio	RAMP Results	Percent of Mean Control Ratio	RAMP Results	Percent of Mean Control Ratio
Control Saline (0.85%) only (No interfering substance)	N/A	Neg 3/3	100%	Pos 3/3	100%	Pos 3/3	100%
Whole Blood	2% v/v	Neg 3/3	118%	Pos 2/3	89%	Pos 3/3	86%
Mucin	1% w/v	Neg 3/3	123%	Pos 3/3	96%	Pos 3/3	94%
Scope® Mouthwash	40% v/v	Neg 3/3	117%	Pos 2/3	91%	Pos 3/3	85%
Good and Kind™ Mouthwash	40% v/v	Neg 3/3	122%	Pos 3/3	93%	Pos 3/3	83%
Cepacol® Mouth Wash	40% v/v	Neg 3/3	128%	Pos 2/3	90%	Pos 3/3	78%
Cepacol® Lozenge (Benzocaine)	30% w/v	Neg 3/3	115%	Pos 3/3	93%	Pos 3/3	69%
Fisherman's Friend® Throat Drop (Menthol)	30% w/v	Neg 3/3	107%	Pos 3/3	94%	Pos 3/3	80%
Rhinocort® Nasal Spray (Budesonide)	15% v/v	Neg 3/3	125%	Pos 3/3	102%	Pos 3/3	76%
Nasacort® Nasal Spray (Triamcinolone)	15% v/v	Neg 3/3	141%	Pos 3/3	98%	Pos 3/3	85%
Flonase® Nasal Spray (Fluticasone Furoate)	30% v/v	Neg 3/3	145%	Pos 3/3	105%	Pos 3/3	85%
Nasonex® Nasal Spray (Mometasone Furoate)	15% v/v	Neg 3/3	134%	Pos 3/3	94%	Pos 3/3	79%
Tylenol® Tablets (4-Acetamidophenol)	20 mg/mL	Neg 3/3	96%	Pos 3/3	90%	Pos 3/3	81%
Aspirin® Tablets (Acetylsalicylic Acid)	30 mg/mL	Neg 3/3	127%	Pos 3/3	98%	Pos 3/3	80%
Chlor-Tripolon™ Tablets (Chlorpheniramine)	10 mg/mL	Neg 3/3	106%	Pos 3/3	110%	Pos 3/3	98%
Benadryl™ Allergy Tablet (Diphenhydramine)	5 mg/mL	Neg 3/3	136%	Pos 3/3	107%	Pos 3/3	91%
Delsym® DM Cough Syrup (Dextromethorphan)	2 mg/mL	Neg 3/3	135%	Pos 3/3	121%	Pos 3/3	105%
Robitussin® Syrup (Guaiaicol Glycerol Ether)	40 mg/mL	Neg 3/3	140%	Pos 3/3	89%	Pos 3/3	82%
Phenylpropanol-amine HCl (pure)	40 mg/mL	Neg 3/3	142%	Pos 3/3	105%	Pos 3/3	96%

Substance Tested	Conc. Tested	Negative		RSV LoD		RSV 2x LoD	
		RAMP Results	Percent of Mean Control Ratio	RAMP Results	Percent of Mean Control Ratio	RAMP Results	Percent of Mean Control Ratio
Afrin® Nasal Spray (Oxymetazoline HCl)	0.05% v/v	Neg 3/3	103%	Pos 3/3	86%	Pos 3/3	76%
Neo-Synephrine® Nasal Spray (Phenylephrine HCl)	20 mg/mL	Neg 3/3	121%	Pos 3/3	87%	Pos 3/3	84%
Otrivin® Saline (NaCl w/preservatives)	1.4% w/v	Neg 3/3	122%	Pos 3/3	91%	Pos 3/3	94%
Rebetol® (Ribavirin)	100 ng/mL	Neg 3/3	116%	Pos 2/3	92%	Pos 3/3	82%
Relenza® (Zanamivir)	20 mg/mL	Neg 3/3	105%	Pos 3/3	89%	Pos 3/3	76%
Rimantadine HCl	500 ng/mL	Neg 3/3	118%	Pos 3/3	87%	Pos 3/3	85%
Tamiflu® (Oseltamivir Phosphate)	50 mg/mL	Neg 3/3	146%	Pos 3/3	127%	Pos 3/3	108%

*f. Assay cut-off:*

The kit lot threshold is determined by applying a standard factor to the difference in the mean RAMP Ratios between the negative and the QC standard. This estimated range of the factor was determined through pre-clinical testing with retrospective positive and negative clinical samples. The value of the factor was found to be optimized at 0.7 and validated by Receiver Operator Curve (ROC) analysis. This lot-specific threshold is then programmed into the lot cards and must be uploaded to the reader when a new kit lot is opened in order to run a test. This factor was then applied to the clinical trial lots to determine the clinical results and will be the standard factor used to generate the lot-specific Ratio Threshold for all manufacturing lots.

2. Comparison studies:

*a. Method comparison with reference method:*

*Not Applicable*

*b. Matrix comparison:*

**Sample Collection Swab Compatibility:**

Four swab materials (see below) were evaluated for compatibility in the RAMP RSV Assay by testing a negative sample (swab alone with no virus

present), an RSV LoD positive sample and an RSV 2x LoD positive sample in the RSV test. The RSV strain used to prepare the samples was RSV A (A-2) following titer determination. Each swab was dosed with the appropriate sample and extracted into Copan Universal Transport Media prior to testing in the RAMP RSV Assay. The RAMP RSV Assay is a qualitative assay based on numerical RAMP Ratio values. The %CVs were calculated for the RAMP Ratios. The negative sample (swab alone) tested negative and all 2x LoD samples tested positive. None of the swabs tested interfered with the performance of the RAMP RSV Assay. Note: In general, calcium alginate swabs are not recommended because they may be cytotoxic to cells and cause viral culture assay inhibition.

Swab Material Tested	RAMP Results		
	Negative	RSV LoD	RSV 2x LoD
<b>Foam</b>	100% Neg	100% Pos	100% Pos
<b>Polyester</b>	100% Neg	67% Pos	100% Pos
<b>Rayon</b>	100% Neg	67% Pos	100% Pos
<b>Nylon</b>	100% Neg	100% Pos	100% Pos
<b>Average RAMP Ratio % CV</b>	9%	21%	21%

**Transport Media Compatibility :**

Multiple lots of each of seven commercially available transport media (see below) were evaluated for compatibility in the RAMP RSV Assay by testing a negative sample (transport media only), an RSV LoD positive sample and an RSV 2x LoD positive sample. The RSV strain used to prepare the samples was RSV A (A-2) following titer determination. The RAMP RSV Assay is a qualitative assay based on numerical RAMP Ratio values. The %CVs were calculated for the RAMP Ratios. None of the tested transport media interfered with the performance of the RAMP RSV Assay.

Transport Media Tested	RAMP Results		
	Negative	RSV LoD	RSV 2x LoD
<b>Copan: Universal Transport Media (UTM)</b>	100% Neg	100% Pos	100% Pos
<b>Remel: M4 Media</b>	100% Neg	100% Pos	100% Pos

Transport Media Tested	RAMP Results		
	Negative	RSV LoD	RSV 2x LoD
Remel: M4-RT Media	100% Neg	100% Pos	100% Pos
Remel: M5 Media	100% Neg	100% Pos	100% Pos
Starplex Transport Media	100% Neg	100% Pos	100% Pos
0.85% Saline Solution	100% Neg	93% Pos	100% Pos
Phosphate Buffered Saline (PBS) Solution	100% Neg	93% Pos	100% Pos
Average RAMP Ratio: % CV	12%	16%	14%

3. Clinical studies:

a. *Clinical Sensitivity:*

Not Applicable

b. *Clinical specificity:*

Not Applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Prospective Clinical Studies:

The performance of the RAMP RSV Assay was compared to cell culture and DSFA in a prospective study conducted as part of a multi-center trial during the 2008-2009 RSV season. Eight (8) independent laboratories located in distinct geographical regions across the United States (NY, MO(2), MD, OH(2), MA, AR) evaluated the RAMP RSV Assay in parallel with cell culture / DSFA. Testing staff included both laboratory and non-laboratory personnel, and two sites (MO, AR) also performed testing in point-of-care settings (near patient). The sites included an Emergency Department and Pediatric Testing Unit (both under CLIA umbrella of the individual hospital). One thousand, two hundred and seventy nine (1279) fresh specimens were collected from pediatric patients 21 years of age and younger. Of these specimens, valid results were obtained from 1140, with an approximately equal mix of male and female patients. During the clinical study, if either the cell culture or DSFA result was positive for a patient sample, it was determined to be a positive reference result. A reference result was deemed negative only if both, culture and DSFA, were negative

**Results with Prospective Nasopharyngeal Swab Samples**

NP Swab			
Culture / DSFA	RAMP RSV		
	Positive	Negative	Total
Positive	112	15	127
Negative	7*	257	264
Total	119	272	391
			<b>95% CI</b>
Sensitivity	88.2%		81.4 – 92.7
Specificity		97.4%	94.6 – 98.7

\* 1 was positive by the RAMP RSV Assay and by the Prodesse ProFlu RT-PCR analysis.

**Results with Prospective Nasopharyngeal Aspirate Samples**

NP Aspirate			
Culture / DSFA	RAMP RSV		
	Positive	Negative	Total
Positive	168	29*	197
Negative	15**	291	306
Total	183	320	503
			<b>95% CI</b>
Sensitivity	85.3%		79.7 – 89.6
Specificity		95.1%	92.1 – 97.0

\* 8 were negative by the RAMP RSV Assay and by an investigational RT-PCR.

\*\* 3 were positive by the RAMP RSV Assay and by an investigational RT-PCR.

**Results with Prospective Nasal Wash / Aspirate Samples**

Nasal Wash / Aspirate			
Culture / DSFA	RAMP RSV		
	Positive	Negative	Total
Positive	98	11*	109
Negative	9**	128	137
Total	107	139	246
			<b>95% CI</b>
Sensitivity	89.9%		82.8 – 94.3
Specificity		93.4%	88.0 – 96.5

\* 1 was negative by the RAMP RSV Assay and by an investigational RT-PCR.

\*\* 1 was positive by the RAMP RSV Assay and by an investigational RT-PCR

4. Clinical cut-off:

Not Applicable

5. Expected values/Reference range:

The prevalence of RSV varies each year with epidemics occurring during the fall and winter months in the US. Variables that affect the rate of positivity observed in respiratory testing include: the efficiency and timing of specimen collection, handling and transport of the specimen, the time of year, age of the patient, and local disease prevalence.

The prevalence observed with culture and DSFA during the clinical study (November 2008 – February 2009) was 33.9% (443/1306). During the previous U.S. respiratory season (October 2007 – March 2008), the prevalence of RSV was 15.9%<sup>8</sup>.

**N. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**O. Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.