510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

k130398

B. Purpose for Submission:

The purpose of this submission is to show that the Sofia® RSV FIA test is substantially equivalent to the BD Veritor™ System for Rapid Detection of RSV. Both assays measure the RSV viral nucleoprotein.

C. Measurand:

The Sofia® RSV FIA test measures the RSV viral nucleoprotein and is an antigen detection test. The test measures RSV nucleoprotein using fluorescently tagged monoclonal antibodies against RSV A and RSV B nucleoproteins.

D. Type of Test:

The Sofia® RSV FIA test is a qualitative antigen detection based lateral flow immunoassay.

E. Applicant:

Quidel Corporation

F. Proprietary and Established Names:

Sofia® RSV FIA

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 Sofia RSV FIA employs immunofluorescence for detection of respiratory syncytial virus (RSV) nucleoprotein antigen in nasopharyngeal swab and nasopharyngeal aspirate/wash specimens taken directly from symptomatic patients. This qualitative test is intended for use as an aid in the rapid diagnosis of acute RSV infections in pediatric patients less than 19 years of age. 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 result is presumptive, and it is recommended these results be confirmed by virus culture or an FDA-cleared RSV molecular assay.

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:

   The test cassette must be read on the Sofia Analyzer manufactured by the Quidel Corporation.

I. Device Description:

The Sofia® RSV FIA test is an antigen detection based lateral flow assay. The clinical specimen is collected and placed in the reagent tube for viral particle disruption which will expose the nucleoprotein. The sample is then placed in the cassette sample well and flows through the device via capillary action through the nitrocellulose strip, coming into contact with the fluorescently labeled monoclonal antibodies. Capture antibodies on the nitrocellulose strip will bind the fluorescent labeled antibody-antigen complex and immobilize the complex on the nitrocellulose. The Sofia Analyzer will then read the cassette and determine if there is a fluorescent signal in the RSV A or RSV B location on the nitrocellulose strip.

The relative fluorescent units (RFU) are measured at the test line for RSV A and RSV B, the negative control line (NC line), and the reference line. The background fluorescence is measured at the negative control line (signal cutoff) and the antigen

specific fluorescence is measured at the test line for RSV A and RSV B (signal). Each lot has a negative control line specific threshold. A test signal RFU greater than the lot specific threshold (when NC line is lower than the threshold) or the corrected signal cutoff (when the NC line is higher than the lot specific threshold) is considered to be a positive result. A result of "Positive for RSV", "negative" or "invalid" is then displayed on the Sofia Analyzer for the test operator to record.

Note: Depending upon the user's choice, the cassette is either placed inside of the Sofia Analyzer for automatically timed development (Walk Away Mode) or placed on the counter or bench top for a manually timed development and then placed into the Sofia Analyzer to be scanned (Read Now Mode).

J. Substantial Equivalence Information:

1. Predicate device name(s):
   BD Veritor™ System for Rapid Detection of RSV,

2. Predicate 510(k) number(s):
   K121633

3. Comparison with predicate:

Item	Proposed Device	Predicate Device
Features	**Sofia RSV FIA**	**BD Veritor™ System for Rapid Detection of RSV, K121633**
Intended Use	The Sofia RSV FIA employs immunofluorescence for detection of respiratory syncytial virus (RSV) nucleoprotein antigen in nasopharyngeal swab and nasopharyngeal aspirate/wash specimens taken directly from symptomatic patients. This qualitative test is intended for use as an aid in the rapid diagnosis of acute RSV infections in pediatric patients less than 19 years of age. 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 result is presumptive, and it is recommended these results be confirmed by virus culture or an FDA-cleared RSV molecular assay.	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 samples 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.
Read Results	Read results on instrument screen or print with optional printer	Read results on instrument screen
Instrument	Sofia Analyzer	BD Veritor
Calibrator	Yes; a Calibration Cassette and QC Card are provided	No calibrator; a verification device is provided to monitor device
Specimen Types	Nasopharyngeal swab and nasopharyngeal aspirate/wash specimens; all specimens can be tested fresh or after transport in media	Nasopharyngeal swab in transport media and nasopharyngeal aspirate/wash specimens
Read Result Time	15 Minutes	Approximately 10 Minutes
External Controls	RSV positive swab RSV negative swab	RSV positive swab RSV negative swab

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

Not applicable

L. Test Principle:

Viral particles in the clinical sample are exposed through chemical disruption of the virion. The sample is then placed in the cassette sample well and flows through the device via capillary action through the nitrocellulose strip, coming into contact with the fluorescently labeled monoclonal antibodies. Capture antibodies on the nitrocellulose strip will bind the fluorescent labeled antibody-antigen complex and immobilize the complex on the nitrocellulose. If RSV nucleoprotein is present a fluorescent line will form where the fluorescently tagged nucleoprotein has bound the capture antibodies on the nitrocellulose strip. The Sofia Analyzer will then read the cassette and determine if there is a fluorescent signal in the RSV A or RSV B location on the nitrocellulose strip. This will be compared to a background fluorescence reading based on the negative control line and result will be reported on the Sofia Analyzer display screen.

M. Performance Characteristics:

1. Analytical performance:

a. Precision/Reproducibility:

Test samples were prepared using negative nasal swab matrix spiked with RSV A (Long VR-26) in order to prepare the following panel members: (1) high negative C_5, (2) low positive C_{95}, and (3) moderate positive 3x LoD. The low negative specimen consisted of the negative matrix containing no spiked virus.

All samples were coded and used to prepare randomized panels. Blinding was achieved by giving each user a panel that was randomized differently. The samples were frozen at -20°C and shipped on dry ice.

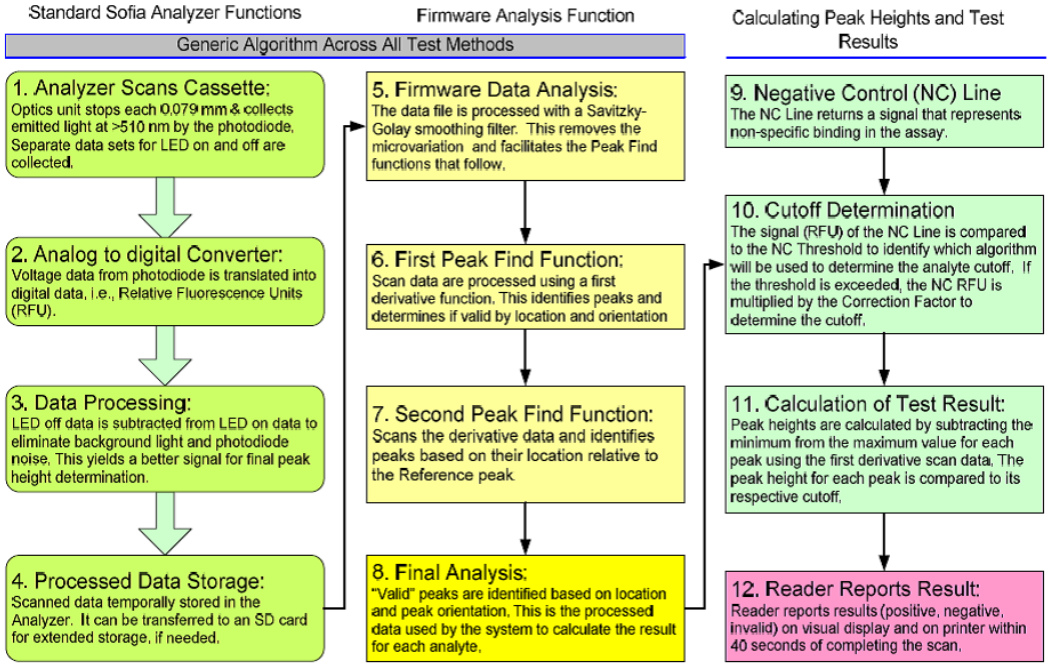
Study sites were instructed to follow the Sofia RSV FIA draft package insert and to adhere faithfully to the reproducibility study protocol. Each of the two operators at each site tested 60 coded samples in 5 panels of 12 samples each over 5 different days in a two-week period. Studies were done in the Read Now mode. The operators were instructed to test the Positive and Negative Control swabs prior to testing the panel members at the beginning of each day's run.

Site	Operator	Low Negative (no virus)	RSV High Negative (C_5)	RSV Low Positive (C_{95})	Moderate Positive (3x LoD)	Overall Accuracy
1	1	15/15	14/15	15/15	15/15	59/60
	2	15/15	14/15	15/15	15/15	59/60
	Total	**30/30**	**28/30**	**30/30**	**30/30**	**118/120**
2	1	15/15	15/15	13/15	15/15	58/60
	2	15/15	15/15	15/15	15/15	60/60
	Total	**30/30**	**30/30**	**28/30**	**30/30**	**118/120**
3	1	15/15	15/15	15/15	15/15	60/60
	2	15/15	15/15	15/15	15/15	60/60
	Total	**30/30**	**30/30**	**30/30**	**30/30**	**120/120**
Total ALL:		**90/90**	**88/90**	**88/90**	**90/90**	**356/360**

The reproducibility for this device is acceptable. The instances where the expected result differed from the actual result are within what is reasonable for C_5 and C_{95} samples.

b. Linearity/assay reportable range:

There is not a reportable range for this device since the result is based on the reading of multiple spots on the nitrocellulose inside the cassette. Below is a schematic of how the test result is determined. Please also see the device description.



c. Sample stability:
Sample stability was evaluated using collected nasopharyngeal swab samples from asymptomatic donors in Saline, PBS and 8 different viral transport media (M4, M4-RT, M6, HBSS, UTM, Multitrans, Stuart's, Copan E-Swab (Amies)). All tested media showed no false positive results when evaluated at 2°C, 8°C, and 25°C from zero to 72 hours.

Positive samples were generated by spiking negative nasopharyngeal swab samples in media with 1-1.5 x LoD of RSV type A Long train (VR-26). All samples tested positive at 4, 8, 24, 48, and 72 hours stored at either 2-8°C or 25°C. At time zero 1/20 M4 samples and 1/40 M4-RT samples gave a false negative result. This false negative result was deemed to have been due to testing at virus concentrations close to the LoD. The sample stability study is acceptable in all tested media at both 2-8°C and 25°C for 72 hours. The package insert recommends storage in the indicated solutions and viral transport media for up to 24 hours.

d. Kit stability:
Kit stability studies were performed at room temperature. Current real time studies show stability up to 6 months and real-time studies are on-going to continue for 24 months.

Reagent stability studies were conducted to determine the stability of reconstituted extraction reagent supplied with the Sofia RSV FIA test. The rehydrated extraction reagent was stable when stored at room temperature up to 12 hours.

e. Expected values (controls, calibrators, or methods):
Negative and positive control swabs are included in the Sofia RSV FIA kit. Three lots of positive and negative control swabs were tested on two different lots of test cassettes. Ten replicates of each swab lot were tested on two lots of test cassettes. Testing was performed as described in the package insert. The correct results were obtained for all replicates in all lots. Therefore, the positive and negative control swabs are acceptable.

f. Limit of detection:
The LoD is the lowest concentration of the analyte that yields a positive signal in the assay 95% of the time. The LoD concentration of analyte is also referred to as the C_{95}. The general approach undertaken in this study was to first determine the test line signal response in relative fluorescence units (RFUs) associated with this C_{95} concentration according to the methods detailed in the CLSI document EP17-A, entitled "Protocols for Determination of Limits of Detection and Limits of Quantitation". Once this signal value was determined, dose-response curves were generated using two RSV type A and two RSV type B virus strains. The C_{95} concentration for each strain was interpolated from its respective dose- response curve. Finally, the LoD was verified for each strain by

testing 80 replicates at the calculated LoD and verifying that the 95% confidence interval of the proportion of positive results bracketed 95% positive results, as recommended in the CLSI document. The final LoD is listed in the table below.

RSV Type	Strain	Limit of Detection $TCID_{50}$/mL
A	A-2	3153
A	Long	372
B	CH9318(18)	476
B	Wash/18537/62	32.3

g. Analytical sensitivity:
Two additional strains of RSV B were tested as described above in the LoD study. The LoD for those additional strains is listed in the table below.

RSV Type	RSV Strain	Estimated LoD ($TCID_{50}$/mL)
B	B 9320	8.7
B	B WV/14617/85	163

h. Analytical specificity:
Two studies were conducted to determine if organisms commonly found in respiratory samples would cross-react in the assay and result in false positive or false negative results. The first study tested common respiratory flora alone and the second study tested the same organisms in the presence of RSV A and RSV B, separately.

Direct Testing of the Potential Cross-Reactants: The organisms listed below were suspended in saline at the concentrations indicated; 330 µL was added to the extraction reagent. This rehydrated the extraction reagent. Then 250 µL of UTM containing no virus was added to the extraction tube and gently mixed. The extracted sample was incubated for one minute and then 120 µL of the extracted sample, containing the potential cross-reactant, was transferred to the test cassette. The assay proceeded as described in the draft package insert for testing liquid specimens in the Read Now mode. Five replicates of each organism were tested.

None of the Bacteria, Yeast, or Viruses evaluated in this study showed cross- reactivity in the Sofia RSV FIA.

Testing the RSV-Spiked Sample in Presence of the Potential Cross-Reactant (Interference Testing): The potential cross-reactants were suspended in saline at

the concentrations indicated; 330 µL was added to the extraction reagent. Then 250 µL of UTM containing RSV A or B at a concentration near the LoD was added to the extraction tube and gently mixed. The extracted sample was incubated for one minute and then 120 µL of the extracted sample, containing the potential cross-reactant and RSV, was transferred to the test cassette. The assay proceeded as described in the package insert for testing liquid specimens in the Read Now mode. Five replicates of each organism were tested.

No interference was observed at concentrations of 2.32E+06 CFU/mL or higher with the yeast and bacteria listed below with the exception of *Mycoplasma pneumonia*. Interference was observed at concentrations higher than 1.0E+05 CFU/mL. A limitation stating that interference in the presence of *Mycoplasma pneumonia* at concentrations higher than 1.0E+05 CFU/mL, may occur has been added to the package insert.

No interference was observed at concentrations of greater than or equal to 2.32E+05 $TCID_{50}$/mL with the viruses listed below with the exception of the following viruses: Adenovirus 4 and VZV showed no interference at the highest attainable test concentration (due to low stock concentration) of 2.64E+04 and 3.55E+04 respectively. In addition one (1) false negative was obtained when testing Adenovirus 5 (RSV A Long Strain). Fifteen (15) additional replicates were tested, all of which were in 100% agreement with the expected results, confirming the false negative as atypical.

Bacteria or Yeast	Test Concentration
Acinetobacter baumannii	2.32E+06
Bacteroides fragilis	2.32E+06
Bordetella pertussis	2.32E+06
Candida albicans (yeast)	2.32E+06
Corynebacterium diptheriae	2.32E+06
Escherichia coli	2.32E+06
Haemophilus influenzae	2.32E+06
Klebsiella pneumoniae	2.32E+06
Lactobacillus plantarum	2.32E+06
Legionella pneumophila	2.32E+06
Moraxella catarrhalis	2.32E+06
Mycobacterium avium	2.32E+06
Mycobacterium intracellulare	2.32E+06
Mycobacterium tuberculosis	2.32E+06
Mycoplasma pneumoniae	1.00E+05
Neisseria meningitides	2.32E+06
Neisseria mucosa	2.32E+06

Neisseria sicca	2.32E+06
Neisseria subflava	2.32E+06
Pseudomanas aeruginosa	2.32E+06
Serratia marcescens	2.32E+06
Staphylococcus aureus	2.32E+06
Staphylococcus aureus Strain: Cowen 1	2.32E+06
Staphylococcus epidermidis	2.32E+06
Streptococcus mutans	2.32E+06
Streptococcus pneumoniae	2.32E+06
Streptococcus pyogenes Grp A	2.32E+06
Streptococcus sanguis	2.32E+06
Streptococcus sp. Grp B	2.32E+06
Streptococcus dysgalactiae Grp C	2.32E+06
Streptococcus sp. Grp F	2.32E+06
Streptococcus dysgalactiae Grp G	2.32E+06
Virus	**Test**
Adenovirus 3 strain: GB	2.32E+05
Adenovirus 4 strain: R1-67	2.64E+04
Adenovirus 5 strain: Adenoid 75	8.98E+05
Adenovirus Type 7A	2.32E+05
Adenovirus 11 strain: Slobitski	2.32E+05
Coronavirus strain: OC43	2.32E+05
Coronavirus strain: 229E	2.32E+05
Coxsackievirus Type B5 strain: Faulkner	2.32E+05
Cytomegalovirus strain: AD-169	2.32E+05
Cytomegalovirus strain: Towne	2.32E+05
Echovirus Type 3 strain: Morrisey	2.32E+05
Herpes Simplex Virus 1 strain: HF	2.32E+05
Herpes Simplex Virus 2 strain: MS	2.32E+05
Human Metapneumovirus strain: A1	2.32E+05
Human Metapneumovirus Type 20 strain: A2*IA14-2003 G gene, A2*	2.32E+05
Human Metapneumovirus strain: B1	2.32E+05
Human Metapneumovirus Type 4 strain: Peru1-2002 G gene, B2	2.32E+05
Influenza A/Mexico/4108/2009/H1N1	2.32E+05
Influenza A/Denver/1/57/H1N1	2.32E+05
Influenza A/FM/1/47/H1N1	2.32E+05
Influenza A/New Jersey/8/76/H1N1	2.32E+05

Influenza A/PR/8/34/H1N1	2.32E+05
Influenza A/Victoria/3/75/H3N2	2.32E+05
Influenza B/Hong Kong/5/72	2.32E+05
Influenza B/Panama/45/90	2.32E+07
Influenza C/Taylor/1233/47	2.32E+05
Measles strain: Edmonston	2.32E+05
Metapneumovirus strain: VR-03-00181	2.32E+05
Mumps strain: Enders	2.32E+05
Parainfluenza Virus 1 strain: C-35	2.32E+05
Parainfluenza Virus 2	2.32E+05
Parainfluenza Virus 3 strain: C243	2.32E+05
Parainfluenza Virus 4A strain: M-25	2.32E+05
ParainfluenzaVirus 4B strain: CH19503	2.32E+05
Rhinovirus 1B strain: 632	2.32E+05
Rhinovirus Type 2	2.32E+05
Rhinovirus Type 3 strain: FEB	2.32E+05
Rhinovirus Type 7	2.32E+05
Rhinovirus Type 15 strain: 1734	2.32E+05
Rhinovirus Type 18 strain: 5983-CV-17	2.32E+05
Rhinovirus Type 37	2.32E+05
VZV strain: Ellen	3.55E+04

i. Interfering Substances:
All interfering substances evaluated in this study were initially screened at or above their suggested concentrations and were then further diluted until no interference (100% agreement with the control) was achieved. Testing was conducted over several days using samples with UTM alone, with RSV A or with RSV B.

Studies in UTM (alone): Four rounds of testing were performed with potential interfering substances in UTM alone (RSV negative). All of the listed potential interfering substances were evaluated and none of the interferents caused false positive results.

Studies in the Presence of RSV A or RSV B CH9318(18) strain: T esting potential interferents at the highest concentrations, in the presence of RSV A or RSV B, resulted in interference for several substances. For this reason, repeat testing was performed of the substances alone in UTM (as well as with the viruses) at lower concentrations until the concentration was found at which there were no false positives obtained with UTM alone or in the presence of RSV A and RSV B. The RSV A and RSV B were tested at virus titers near the assay's

LoD for that virus. The results obtained with the RSV B strain were similar to those obtained with RSV A. The highest overall concentration that yielded passing results (i.e. no false positive results in the presence of RSV A and RSV B) is reported in the table below. No limitations were included in the labeling as the concentrations listed below are well above the relevant clinical concentrations of these substances likely to be present in the nasal mucosa.

Item #	Substance	Concentration
1	OTC Mouthwash #1 (Listerine)	58.0%
2	OTC Mouthwash #2 (Crest Pro-Health)	58.0%
3	OTC Mouthwash #3 (Scope)	58.0%
4	OTC Cough Drop #1 (CVS)	19.8%
5	OTC Cough Drop #2 (Ricola)	15.8%
6	OTC Cough Drop #3 (Halls)	34.8%
7	Nasal Spray #1 (Vick's)	23.2%
8	Nasal Spray #2 (4-Way)	23.2%
9	Nasal Spray #3 (Equate)	23.2%
10	Blood	1.0 %
11	Acetamidophenol	23.2 mg/mL
12	Acetylsalicylic acid	23.2 mg/mL
13	Chlorpheniramine	4.0 mg/mL
14	Dextromethorphan	4.0 mg/mL
15	Diphenhydramine	3.3 mg/mL
16	Mucin	9.2 mg/mL
17	Guaiacol	46.5 mg/mL
18	Phenylephrine	11.6 mg/mL
19	Rimantadine	116 µg/mL
20	Albuterol	26.4 mg/mL

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Transport media comparison was performed in the following media; M4, M4-RT, M6, HBSS, UTM, Multitrans, Stuart's, Copan E-Swab (Amies). All media tested was determined to be appropriate for testing with the Sofia RSV FIA. See section 1c, "Analytical performance: sample stability" for matrix comparison procedure.

3. Clinical studies:

a. Clinical Sensitivity and Specificity:

This clinical study used two specimen types: nasopharyngeal swab (NPS) and nasopharyngeal aspirate/wash (NPA/W). The study was conducted over two seasonal outbreaks of RSV, including February through April of 2012 and October through December of 2012. Two NPS specimens were collected from each patient, one was tested directly with the Sofia RSV FIA and the other was placed in VTM for transport to one of the two reference laboratories for re-testing in the Sofia RSV FIA and for culture. Usually only one sample was collected from patients providing an aspirate or wash. An aliquot was tested directly in the Sofia RSV FIA and the remaining specimen was suspended in an approximately equal volume of VTM and transported to the reference laboratory for testing. External Controls on each Analyzer were run each day before clinical testing was started.

Viral culture was performed at either of two reference laboratories following the procedures consistent with the guideline, CLSI M41-A. Male and female patients of less than nineteen (<19) years of age, presenting with upper and/or lower respiratory tract infection suggestive of respiratory syncytial virus (RSV) illness, were eligible for participation in this study. The subjects were excluded if they were nineteen years of age or older were; the parent or legal guardian was unable to understand and consent to participation and/or they were treated during this infection with anti-RSV Synagis®.

A total of 1817 subjects were enrolled in this study. Subsequently, results from sixty-two patients were excluded, leaving 1755 patient results for the performance analyses. The demographics of the subjects enrolled in the study and included in the analyses are shown in the table below.

Characteristics of the Subject Population
Providing Specimens that were Tested Directly

Gender Distribution			
Gender:	**Female**	**Male**	**Total**
Total	784 (45%)	971 (55%)	1755
Age Distribution			
Gender:	**Female**	**Male**	**Total**
< 1 years	293 (37%)	361 (37%)	654 (37%)
1-<2 years	174 (22%)	238 (25%)	412 (23%)
2-<6 years	269 (34%)	324 (33%)	593 (34%)
6 -<19 years	48 (6%)	48 (5%)	96 (5%)

Characteristics of the Subject Population that Provided Specimens for Transport in VTM to the Laboratory

Gender Distribution			
Gender:	**Female**	**Male**	**Total**
Total	787 (45%)	977 (55%)	1764
Age Distribution			
Gender:	**Female**	**Male**	**Total**
< 1 years	294 (37%)	365 (37%)	659 (37%)
1-<2 years	174 (22%)	239 (24%)	413 (23%)
2-<6 years	270 (34%)	324 (33%)	594 (34%)
6 -<19 years	49 (6%)	49 (5%)	98 (6%)

Direct Testing of Specimens

A total of 1817 subjects were enrolled in the study. Data from sixty-two (62) subjects were excluded due to the following; invalid results, SD card data not available, no culture data available, specimen received warm, patient was outside of inclusion age or withdrawn consent. 1755 patient results were used for analysis. These included nine hundred seventy-six (976) subjects who provided nasopharyngeal swabs and seven hundred seventy-nine (779) who provided a nasopharyngeal aspirate/wash specimen.

Sofia RSV FIA Test Performance versus Culture for Fresh Nasopharyngeal Swab

	Culture	
	Pos	Neg
Sofia Pos	126	26
Sofia Neg	20	804
Total:	146	830

Sens. = 86% (126/146) (95% C.I=80-91%)

Spec. = 97% (804/830) (95% CI=95-98%)

PPV = 83% (126/152)

NPV = 98% (804/824)

Sofia RSV FIA Test Performance versus Culture for Fresh Nasopharyngeal Aspirate/Wash

	Culture	
	Pos	Neg
Sofia Pos	58	13
Sofia Neg	7	701
Total:	65	714

Sens. = 89% (58/65) (95% CI= 79-95%)

Spec. = 98% (701/714) (95% CI=97-99%)

PPV = 82% (58/71)

NPV = 99% (701/708)

Specimens Transport in VTM

A total of 1817 subjects were enrolled in this study. Data from fifty three (53) subjects were excluded due to the following; SD card data not available, no culture data available, specimen received warm, patient was outside of inclusion age or withdrawn consent. 1764 patient specimens were used for analysis. Among these, nine hundred seventy-one (971) subjects provided a NPS and seven hundred ninety-three (793) provided a NPA/W specimen.

Sofia RSV FIA Performance versus Culture for Nasopharyngeal Swabs Diluted and Transported in VTM

	Culture	
	Pos	Neg
Sofia Pos	125	26
Sofia Neg	18	802
Total:	143	828

Sens. = 87% (125/143) (95% CI=81-92%)

Spec. = 97% (802/828) (95% CI=95-98%)

PPV = 83% (125/151)

NPV = 98% (802/820)

Sofia RSV FIA Performance versus Culture for Nasopharyngeal Aspirate/Wash Diluted and Transported in VTM

	Culture	
	Pos	Neg
Sofia Pos	59	12
Sofia Neg	8	714
Total:	67	726

Sens. = 88% (59/67) (95% CI=78-94%)

Spec. = 98% (714/726) (95% CI=97-99%)

PPV = 83% (59/71)

NPV = 99% (714/722)

The clinical study was performed appropriately and sampled an acceptable range of ages of pediatric patients..

4. Clinical cut-off**:**

N/A

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 prevalence observed with culture during the clinical study was 12% (211/1755).

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.