510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K162911

B. Purpose for Submission:

To demonstrate equivalent performance of the Sofia® RSV FIA on the Sofia and Sofia 2 analyzer using an assay migration study approach.

C. Measurand:

Respiratory syncytial virus (RSV) A and B nucleoprotein

D. Type of Test:

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(s):

   GQG
   KHO

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. 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 viral culture or an FDA-cleared RSV molecular assay.

   The Sofia RSV FIA may be used with the Sofia or Sofia 2.

2. Indication(s) for Use:

   Same as intended use

3. Special Conditions for Use Statement(s):

   For prescription use only

4. Special Instrument Requirements:

   Sofia or Sofia 2

I. Device Description:

1. Overview

   The Sofia RSV FIA is a rapid lateral flow immunoassay for the qualitative detection of RSV A and RSV B nucleoprotein from nasopharyngeal (NP) swab and nasopharyngeal aspirate/wash (NA/W) specimens collected from pediatric patients with signs and symptoms of respiratory infection. The Sofia RSV FIA has four main components: (1) a sample pad for receiving the specimen; (2) a label pad containing dried, fluorescently dyed microparticles coated with RSV-specific monoclonal antibodies; (3) a nitrocellulose test strip for the capture of RSV analyte; and (4) an absorbent pad to drive capillary flow. A more detailed description of the lateral flow device is available in submission K130398, under which the Sofia RSV FIA was cleared for use with the original Sofia analyzer.

   The purpose of this submission is to obtain 510(k) clearance for the Sofia RSV FIA for use with the newly developed Sofia 2 analyzer. The Sofia and Sofia 2 analyzer are similar in function and design. Both systems utilize the same fail-safes and failure alert mechanisms, the same calibration and assay-specific cartridges, and the same ultraviolet

light-emitting diodes (UV LEDs) to excite the fluorophore. The primary difference between the original Sofia and Sofia 2 analyzer is the design of the optical detection system. Sofia uses a motorized optics unit to collect fluorescent signal data as it performs a series of scans across the longitudinal axis of the Sofia RSV FIA test strip, whereas Sofia 2 captures a still image of the entire test strip window using a complimentary color-oxide semiconductor (CMOS) camera. To emulate Sofia, the Sofia 2 analyzer converts pixels captured by the CMOS camera to fluorescent signal data, after which the resulting data is analyzed in an equivalent manner to Sofia to yield qualitative test results. Other minor adjustments to the Sofia 2 analyzer affect mainly the user interface and include the addition of a touchscreen display and an integrated barcode scanner for sample identification.

2. Materials Provided

- Individually packaged cassettes (25)
- Reagent tubes containing lyophilized buffer (25)
- Vials containing salt solution (25)
- Sterile nasopharyngeal swabs (25)
- Large, pink fixed volume pipettes (25)
- Small, clear fixed volume pipettes (25)
- RSV positive control swab (1)
- Negative control swab (1)
- QC card (1)
- Printer paper

3. Materials Not Provided

- Sterile saline for collection of nasopharyngeal aspirate or wash specimens
- Equipment for collection of nasopharyngeal aspirate or wash specimens
- Sofia or Sofia 2 instrument
- Calibration cassette

4. Quality Control

The Sofia RSV FIA test strip has several chemically built-in controls to ensure that each test is performed properly. These include the negative control line, reference line, and the procedural control zone.

Negative Control Line

The negative control line is the first line that the extracted specimen encounters as it migrates across the length of the nitrocellulose test strip. The purpose of the negative control line is to enable the measurement of non-specific binding of the microparticle conjugates to the patient specimen. The fluorescent signal generated at this line is used to calculate background signal and to help ensure that high non-specific binding at the analyte-specific test line does not lead to false positive results. If the reference fluorescent

units (RFUs) for the negative control line exceed the maximum specifications, the analyzer will report that the result is "invalid."

Reference Line

The reference line is the last line on the test strip that the extracted specimen encounters before it enters the absorbent pad. The reference line is used to verify adequate sample flow through the nitrocellulose test strip and also serves as a marker to direct the Sofia analyzer to the location of each of the other test lines. If the RFUs for the reference line fall below the minimum specifications, the analyzer will report that the result is "invalid."

Procedural Control Zone

The procedural control zone is the area of the nitrocellulose test strip that is located between the negative control line and the analyte-specific test line. The RFU signal that is emitted from the procedural control zone provides additional confirmation that adequate flow of the sample has occurred. If the RFU signal falls outside of the minimum and maximum specifications allotted for this zone, the analyzer will report the result as "invalid."

5. Results Interpretation

Upon completion of the test, the results are reported as text on the display screen of the Sofia or Sofia 2 analyzer. There are three possible test results for the Sofia RSV FIA: RSV positive, RSV negative, or invalid. If an invalid test result is reported, the Sofia RSV FIA should be repeated with a new patient sample and a new test cassette.

Note: The Sofia and Sofia 2 analyzers may be set to one of two operating modes: Walk Away or Read Now. Time to results for the Sofia and Sofia 2 analyzer are described below.

- In Walk Away Mode, the user inserts the test cassette into the analyzer immediately following addition of the specimen to the Sofia RSV FIA sample port. The Sofia analyzer automatically times the test development and provides positive or negative test results after 15 minutes. The Sofia 2 analyzer images the test cassette at 3, 5, 8, 10, and 15 minutes and reports a positive test result at the time RSV is detected. If the test is negative, the result will be displayed after 15 minutes.

- In the Read Now Mode, the user incubates the test cassette on the benchtop for 15 minutes before inserting the cassette into the Sofia or Sofia 2 analyzer. Positive and negative test results are displayed within 1 minute.

J. Substantial Equivalence Information:

1. Predicate Device Name(s):

   Sofia RSV FIA performed on the Sofia analyzer

2. Predicate 510(k) Number:

   K130398

3. Comparison with Predicate:

Table 1: Comparison with the Predicate Device

	Similarities and Differences	
	Device	**Predicate device**
Item	**Sofia RSV FIA on Sofia 2**	**Sofia RSV FIA on Sofia**
510(k) number	K162911	K130398
Regulation	866.3480	Same
Product code	GQG	Same
Device class	I	Same
Technology principle of operation	Lateral flow immunoassay	Same
Assay targets	RSV A and B nucleoprotein	Same
Assay results	Qualitative	Same
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. 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 viral culture or an FDA-cleared RSV molecular assay. The Sofia RSV FIA may be used with the Sofia or Sofia 2.	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. 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 viral culture or an FDA-cleared RSV molecular assay.

	Similarities and Differences	
	Device	**Predicate device**
Item	**Sofia RSV FIA on Sofia 2**	**Sofia RSV FIA on Sofia**
Indications for Use	Pediatric patients with signs of respiratory infection in conjunction with clinical and epidemiological risk factors	Same
Specimen types	NP swab and NA/W specimens	Same
Internal assay controls	Negative control line, procedural control zone and reference line	Same
External assay controls	RSV positive and negative control swab	Same
Instrument	Sofia 2	Sofia
Dimensions	19.7 cm x 11.4 cm x 12.7cm	24 cm x 16 cm x 10 cm
Weight	2.5 lbs	3 lbs
Power supply	100-240 VAC, self-switching, or with rechargeable lithium polymer battery	100-240 VAC, self-switching, or with 4 AA batteries
Printer	External	Integrated
Assay/instrument interface	Drawer	Same
User interface	4 inch color LCD touchscreen display	3.5 inch diagonal color LCD display and numeric keypad with function specific buttons touchscreen display
User types	User and supervisor level plus a Quidel only service level	Same
Sample ID	Integrated barcode scanner	External hand-held barcode scanner
Cassette ID	Integrated barcode scanner with custom 0.3MP camera	Integrated barcode scanner
Optics	CMOS camera converts signal data to RFUs	Scanning optics collects signal data expressed in RFUs
Development Modes	Two assay development modes: Walk Away and Read Now	Same
Time to obtain results	Potential for early read in Walk-Away Mode. Sofia 2 will image cassette at 3, 5, 8, 10, and 15 minutes until a positive result is obtained.	15 minutes

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

1. Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures. EP17-A2: Approved Guideline-Second Edition 2012.
2. Medical Devices – Application of Risk Management to Medical Devices. ISO 14971:2007/EN ISO 14971:2012.
3. Medical Device Software – Software Life Cycle Process. IEC 62304:2006.

L. Test Principle:

The Sofia RSV FIA is an immunofluorescence-based lateral flow assay that uses a sandwich design for the detection of RSV A and B nucleoprotein antigen. The FDA-cleared Sofia RSV FIA (K130398) has not been modified; it is compatible with the newly developed Sofia 2 analyzer. The Sofia 2 analyzer is a microprocessor-controlled device equipped with UV LEDs for excitation of the fluorophore, a complimentary color-oxide semiconductor (CMOS) camera for image capture, and a multicolor display screen for reporting results. Following illumination of the Sofia RSV FIA cassette by the UV LEDs, the CMOS camera images the entire length of the nitrocellulose test strip window, which includes a negative control line, RSV test line, procedural control zone and reference line. To process the data, Sofia 2 utilizes an analog-to-digital converter to convert the pixels at the test line, negative control line and reference line into a digital value which is in turn converted to an RFU value. The resulting data is analyzed in a similar manner as Sofia to yield a qualitative result.

M. Performance Characteristics

Limited studies were conducted to demonstrate equivalent performance of the Sofia RSV FIA on the Sofia and Sofia 2 analyzer. These studies included limit of detection, reproducibility, assay precision, and method comparison. Results from each of these studies are described below. Additional analytical and clinical performance data for the Sofia RSV FIA is available under K130398.

1. <u>Analytical Performance</u>

   a. Limit of Detection

   The limit of detection (LoD) of the Sofia RSV FIA was established on both the Sofia and Sofia 2 analyzers. The study included two RSV A and two RSV B strains spiked into negative clinical nasal swab matrix, and was designed to follow the classical approach outlined in CLSI document EP17-A, entitled "Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures."

   Briefly, an initial range finding study was conducted in which each of the four RSV strains were prepared at three different concentrations and tested in replicates of five with two reagent lots on both the Sofia and Sofia 2 instrument platforms. For each strain, the lowest dilution yielding all five positive results was then used to prepare 10 replicates of

four additional two-fold virus dilutions that were similarly tested with both of the reagent lots and instrument platforms. From this study, the lowest dilution yielding all 10 positive results was defined as the preliminary LoD.

Additional low level testing was performed with a minimum of 60 replicates of each virus strain at the preliminary LoD using a single Sofia RSV FIA reagent lot. Testing spanned three days with at least 20 replicates run per day for each strain, lot and instrument combination. Using these data, the mean signal-to-cutoff ratios (S/CO) and standard deviations were calculated, and the LoD was determined using the parametric analysis equation, with the limit of blank set to n = 1.

The results of the LoD study are shown in the Table 1 below. The LoD values that were initially established for the Sofia RSV FIA on the Sofia analyzer (Sofia*) at the time of product release (K130398) are included in Table 1. The slight variation in LoD values for the Sofia analyzer between studies suggests minimal drift has occurred.

Table 1: Sofia RSV FIA LoD Study results on the Sofia and Sofia 2 analyzers

Viral Strain	Platform	LoD (S/CO)	LoD ($TCID_{50}$/mL)
RSV A Long	Sofia*	1.58	372
	Sofia	1.42	471
	Sofia 2	1.45	467
RSV A-2	Sofia*	1.75	3,153
	Sofia	1.43	5,511
	Sofia 2	1.24	5,950
RSV B CH93-18(18)	Sofia*	1.63	476
	Sofia	1.26	585
	Sofia 2	1.35	620
RSV B Washington/18537/62	Sofia*	1.19	32.3
	Sofia	1.45	78.6
	Sofia 2	1.47	91.1

The newly established LoDs for the Sofia RSV FIA on the Sofia and Sofia 2 analyzer differ by less than two-fold, indicating that the instrument platforms are performing equivalently.

b. Reproducibility

A blinded, multi-center study was conducted to demonstrate that the performance of the Sofia RSV FIA is highly reproducible when tested on the Sofia 2 analyzer. For comparison, testing was also performed on the original Sofia analyzer.

Two operators at three study sites tested a nine-member reproducibility panel on both the Sofia and Sofia 2 analyzers once per day on five different days (2 operators x 3 sites x 9 panel members x 1 run x 5 days) for a total of 270 runs per instrument platform. The study was conducted in the Read Now mode with a single Sofia RSV FIA reagent lot.

The reproducibility specimen panel consisted of one RSV A (Long) strain prepared in triplicate at two concentration levels: a "low positive" sample with an analyte concentration approximately 1X the LoD and a "moderate positive" sample with an analyte concentration 2- 3X the LoD. The reproducibility panel was prepared in pooled negative clinical nasal swab matrix and included three additional samples consisting of clinical nasal swab matrix only.

The percent agreement between the expected results and the reproducibility study results for the Sofia and Sofia 2 analyzer for each analyte concentration tested is shown in Tables 2 and 3, respectively.

Table 2: Qualitative Reproducibility Study Results Using the Sofia analyzer

Site	Operator	RSV Negative	RSV Low Positive (1X LoD)	RSV Moderate Positive (2-3X LoD)
1	1	15/15	15/15	15/15
	2	15/15	14/15	15/15
2	1	15/15	15/15	15/15
	2	15/15	15/15	15/15
3	1	15/15	15/15	15/15
	2	15/15	15/15	15/15
Combined Total		90/90	89/90	90/90
Percent Agreement		100%	98.9%	100%

Table 3: Qualitative Reproducibility Study Results Using the Sofia 2 analyzer

Site	Operator	RSV Negative	RSV Low Positive (1X LoD)	RSV Moderate Positive (2-3X LoD)
1	1	15/15	15/15	15/15
	2	15/15	15/15	15/15
2	1	15/15	15/15	15/15
	2	15/15	15/15	15/15
3	1	15/15	15/15	15/15
	2	15/15	15/15	15/15
Combined Total		90/90	90/90	90/90
Percent Agreement		100%	98.9%	100%

For each of the RSV analyte concentration levels listed above, the mean relative fluorescence units (RFU), standard deviation (SD), and percent coefficient of variation (% CV) were calculated. Results for samples tested using the Sofia and Sofia 2 analyzers are shown in Tables 4 and 5 below. Also shown below (Table 6) are the corresponding reproducibility standard deviation ratios of the two analyzers, along with the 95% confidence intervals (CI).

Table 4: Semi-Quantitative Reproducibility Results Using the Sofia Analyzer

Sample Type	Site	Mean RFU	SD	% CV
Negative	1	1,257	220	17.5
	2	1,246	211	16.9
	3	1,173	176	15.0
	Average	1,225	204	16.7
RSV Low Positive (1X LoD)	1	5,584	1,707	30.6
	2	4,491	488	10.9
	3	4,905	567	11.6
	Average	4,993	1,156	23.2
RSV Moderate Positive (2-3X LoD)	1	13,048	2,693	20.6
	2	11,495	1,065	9.3
	3	12,378	1,209	9.8
	Average	12,307	1,902	15.5

Table 5: Semi-Quantitative Reproducibility Results Using the Sofia 2 Analyzer

Sample Type	Site	Mean RFU	SD	% CV
Negative	1	1,236	284	23.0
	2	1,092	244	22.3
	3	1,016	225	22.1
	Average	1,115	266	23.8
RSV Low Positive (1X LoD)	1	5,452	1,180	21.6
	2	4,569	532	11.6
	3	4,891	642	13.1
	Average	4,970	903	18.2
RSV Moderate Positive (2-3X LoD)	1	12,919	1,890	14.6
	2	11,589	1,330	11.5
	3	12,850	1,924	15.0
	Average	12,453	1,823	14.6

Table 6: Reproducibility Standard Deviation Ratios (Sofia2/Sofia)

Site	Analyte Concentration	SD Ratio	Lower 95% CI	Upper 95% CI
1	Negative	1.29	0.89	1.87
2	Negative	1.15	0.80	1.67
3	Negative	1.28	0.88	1.85
1	RSV Low Positive	0.69	0.48	1.00
2	RSV Low Positive	1.09	0.75	1.58
3	RSV Low Positive	1.13	0.78	1.64
1	RSV Moderate Positive	0.70	0.48	1.02
2	RSV Moderate Positive	1.25	0.86	1.81
3	RSV Moderate Positive	1.59	1.10	2.31

Based on this analysis, the numerical output (RFU) and the level of variance that is observed for the Sofia 2 analyzer are comparable to the original Sofia analyzer for each of the RSV analyte concentrations tested.

c. Assay Precision

To supplement the reproducibility study, within-laboratory precision of the Sofia and Sofia 2 analyzers was evaluated. One strain of RSV A (Long) spiked into negative clinical nasal swab matrix was tested at two different analyte concentrations: a "low positive" sample with an analyte concentration approximately 1X the LoD and a "moderate positive" sample with an analyte concentration 2- 3X the LoD. Negative samples consisting of clinical nasal swab matrix only were also included in the testing.

One aliquot of each sample type (negative, low positive and moderate positive) was tested on three Sofia RSV FIA reagent lots, by two operators on 12 different days (1 aliquots x 3 reagent lots x 2 operators x 12 days) totaling 72 replicates per sample per instrument. One Sofia analyzer and one Sofia 2 analyzer were used in this study, both of which were calibrated prior to use on the first day of testing and again after approximately 30 days to ensure that testing was performed over multiple calibration cycles.

Overall percent agreement between the expected results and the precision study results for the Sofia and Sofia 2 analyzer is shown in Table 7 below.

Table 7: Qualitative Precision Study Results Summary

Sample Type	Sofia		Sofia 2	
	Overall Agreement	% Overall Agreement	Overall Agreement	% Overall Agreement
Negative	72/72	100	72/72	100
RSV Low Positive (1X LoD)	72/72	100	71/72	98.6
RSV Moderate Positive (2-3X LoD)	72/72	100	72/72	100

For each of the sample types listed above, the mean relative fluorescence units (RFU), standard deviation (SD), and percent coefficient of variation (%CV) were calculated. Results for samples tested using the Sofia and Sofia 2 analyzers are shown in Table 8. Also shown (Table 9) are the corresponding reproducibility standard deviation ratios of the Sofia and Sofia 2 analyzers, along with the 95% confidence intervals (CI).

Table 8: Semi-Qualitative Precision Study Results Summary

Platform	Sample Type	Mean RFU	SD	% CV
Sofia	Negative	1,434	225	16
	RSV Low Positive (1X LoD)	5,620	875	16
	RSV Moderate Positive (2-3X LoD)	17,983	2463	14
Sofia 2	Negative	1,110	196	18
	RSV Low Positive (1X LoD)	5,058	847	17
	RSV Moderate Positive (2-3X LoD)	16,755	1992	12

Table 9: Precision Standard Deviation Ratios (Sofia2/Sofia)

Sample Type	SD Ratio	Lower 95% CI	Upper 95% CI
Negative	0.87	0.69	1.10
RSV Low Positive (1X LoD)	0.97	0.76	1.22
RSV Moderate Positive (2-3X LoD)	0.82	0.65	1.03

Based on this analysis, the numerical output (RFU) and the level of variance that is observed for Sofia 2 analyzer are comparable to the original Sofia analyzer for each of the sample types tested.

2. Comparison Studies

a. Method Comparison

Performance of the Sofia RSV FIA on the Sofia and Sofia 2 analyzers was evaluated for equivalency in a method comparison study using clinical sample panels. The study was conducted at three study sites using identical specimen panels that consisted of 100 RSV positive and 100 RSV negative clinical samples. The RSV positive panel members were prepared by diluting RSV positive clinical samples into negative clinical matrix. Each preparation was subsequently assigned to one of four analyte concentration levels (Table 10) based on the signal-to-cutoff ratio (S/CO) that was obtained from a single replicate on the Sofia analyzer. For the RSV negative panel members, clinical samples were designated as either negative or high negative if the S/CO values during the initial screening process were <0.5 or 0.5-0.9, respectively.

Table 10: Method Comparison Panel Member Composition

Panel Member	Target S/CO	Quantity per panel
Negative	<0.5	67
High Negative	0.5-0.9	33
Low Positive (1X LoD)	1.2-2.0	30
Moderate Positive(2-3X LoD)	2.1-4.8	30
High Positive (4-5X LoD)	5.6-7.5	20
Very High Positive (>5X LoD)	7.5+	20

A total of 200 tests were performed at each of the three study sites by two operators on four different Sofia and Sofia 2 analyzers. To assess the potential for early read with Sofia 2, data was collected in Walk Away Mode. In this mode, Sofia 2 captures images of

the Sofia RSV FIA test cassette at 3, 5, 8 and 15 minutes. The overall study results obtained after the full 15 minutes are shown in Table 11 below. Agreement between the results obtained on the Sofia and Sofia 2 analzyer for each of the individual analyte levels tested is shown in Table 12.

Table 11: Method Comparison Study Results for the Sofia and Sofia 2 Analyzer

	Sofia Positive	**Sofia Negative**
Sofia 2 Positive	314	10*
Sofia 2 Negative	9*	267

Table 13: Agreement by Analyte Level

Analyte Level	**Qualitative Method Comparison Results**		
		Sofia Positive	Sofia Negative
Negative	Sofia 2 Positive	3*	0
	Sofia 2 Negative	0	198
High Negative	Sofia 2 Positive	14	8
	Sofia 2 Negative	8	69
Low Positive (1X LoD)	Sofia 2 Positive	88	1
	Sofia 2 Negative	1	0
Moderate Positive (2-3X LoD)	Sofia 2 Positive	89	1
	Sofia 2 Negative	0	0
High Positive (4-5X LoD)	Sofia 2 Positive	60	0
	Sofia 2 Negative	0	0
Strong Positive (>5X LoD)	Sofia 2 Positive	60	0
	Sofia 2 Negative	0	0

*Specimens were clearly positive on both the Sofia and Sofia 2 analyzers, and were likely contaminated, misclassified or mixed at the site.

The positive and negative percent agreement between the Sofia and Sofia 2 analyzers was 97.2% (314/323; 95% CI: 94.7-98.6) and 96.4% (267/277; 95% CI: 93.4-98.1), respectively. These study results demonstrate that the performance of the Sofia RSV FIA on the Sofia 2 is similar to the predicate device. Furthermore, the number of discordant samples that tested positive on Sofia and negative on Sofia 2 (n =9) was approximately equivalent to the number of discordant samples that tested positive on Sofia 2 and negative on Sofia (n = 10). Thus, no evidence of significant instrument bias was observed.

A summary of the results that were obtained at the earlier read times on the Sofia 2 analyzers is shown in Table 14 below. For RSV specimens at ≥4X LoD, at least 70% of the specimens yielded positive results by 8 minutes, and at least 25% by 5 minutes. For levels of RSV that were not highly positive, early read times generally did not give positive results.

Table 14: Summary of Early Read Time Results on the Sofia 2 analyzer

		Sofia 2 Results			
Analyte Level	**Number of Replicates**	**3 min**	**5 min**	**8 min**	**15 min**
Negative	198	NEG	NEG	NEG	NEG
	3*	NEG	NEG	NEG	POS
High Negative	77	NEG	NEG	NEG	NEG
	22	NEG	NEG	NEG	POS
Low Positive	1	NEG	NEG	NEG	NEG
	88	NEG	NEG	NEG	POS
	1*	POS	POS	POS	POS
Moderate Positive	88	NEG	NEG	NEG	POS
	1	NEG	NEG	POS	POS
	1*	POS	POS	POS	POS
High Positive	18	NEG	NEG	NEG	POS
	27	NEG	NEG	POS	POS
	10	NEG	POS	POS	POS
	5	POS	POS	POS	POS
Very High Positive	13	NEG	NEG	NEG	POS
	4	NEG	NEG	POS	POS
	3	NEG	POS	POS	POS
	40	POS	POS	POS	POS

*Replicates were clearly positive on both the Sofia and Sofia 2 analyzers, and were likely contaminated, misclassified, or mixed at the site.

N. Instrumentation/System Description

1. Instrument Name:

   Sofia and Sofia 2

2. System Description:

   The Sofia instruments are equipped with UV LED lighting and optical detection systems that are designed to collect and analyze fluorescent data emitted from the Sofia RSV FIA test cassettes. The instrument software contains embedded assay-specific algorithms that are used to convert the fluorescent signal data into a qualitative RSV test result.

3. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types.

   Yes ____X_____ or No _____

4. Level of Concern

   Moderate

5. Software Description

   The Sofia 2 Analyzer images the test strip and utilizes an embedded software algorithm to process the resulting data set into a qualitative test result. A positive test result for the analyte is determined by detection and analysis of the fluorescent signal at the test and reference lines, which are processed by the assay-specific algorithm. The algorithm employs a smoothing filter to the data and, identifies a peak maxima, minima and width, then calculates the RFU value based on peak height for the RSV test line. Results are presented on a screen and can be printed on an integrated printer.

6. Specimen Identification

   Specimens are manually loaded onto the Sofia RSV FIA test cassette by the user. Each cassette is labeled with a barcode that is detected by the Sofia 2 internal barcode reader. The 2-dimensinal barcode contains lot, expiration, and test method information. If the cassette is not in the correct orientation, the barcode cannot be read and the analyzer will display an error.

7. Calibration

   To ensure that signal drift is controlled, the Sofia 2 analyzer has a calibration algorithm that enables the operator to insert a calibration cassette specifically prepared and labeled as a Calibration Cassette at least once every 30 days. The Calibration Cassette contains a barcode with specific test information and four fluorescent simulated test lines at predefined locations on the test strip.

O. Other supportive Instrument Characteristics Data Not Covered in the "Performance Characteristics" Section Above

N/A

P. Proposed Labeling

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

Q. Conclusion

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