510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K182001

1. Sponsor/Applicant Name and Address

Company Name: Sekisui Diagnostics, LLC

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Date Summary Prepared: 11/08/2018

2. Device Name and Classification

Trade Name: Acucy™ Influenza A&B Test with the Acucy™ System

Classification of Device: 21 CFR 866.3328, Influenza virus antigen detection test system

Product Code: PSZ

3. Predicate Device

K112177, K131606, K153012: Quidel Sofia® Analyzer and Influenza A+B FIA

4. Device Description

Operating Principle

The Acucy™ Influenza A&B Test is a lateral flow immunochromatographic assay in the sandwich immunoassay format. The Acucy Influenza A&B Test consists of a Test Cassette that detects and differentiates influenza A and influenza B viral antigens from a patient sample. The test sample, a nasal swab or nasopharyngeal swab, is processed to extract nucleoproteins by mixing the swab in Acucy Influenza A&B Extraction Buffer. The mixture is then added to the sample well of the Test Cassette. From there, the sample migrates along the membrane surface. If influenza A or B viral antigens are present, they form a complex with mouse monoclonal antibodies to influenza A and/or B nucleoproteins conjugated to colloidal gold. The complex is then bound by a rat anti-influenza A and/or mouse anti-influenza B antibody coated on the nitrocellulose membrane.

The Acucy Reader is an optoelectronic instrument that uses a reflectance-based measurement method to evaluate the line signal intensities in the results window of the Test Cassette. The Reader scans the Test Cassette and measures the absorbance intensity by processing the results using method-specific algorithms. The Acucy Reader displays the test results POS (+), NEG (-), or INVALID on the screen. The results can also be automatically printed on the Acucy Printer if this option is selected.

Acucy™ Influenza A&B Test Kit Contents

The Acucy Influenza A&B Test Kit contains all the materials needed to run a test, except for the Acucy Reader, which is provided separately. The Acucy Influenza Test Kit contains the following components:

- 25 Acucy Influenza A&B Test Cassettes (+ 2 for external quality control testing)
- 25 Sterile Nasal Swabs
- 25 Acucy Influenza A&B Extraction Buffer Vials (+ 2 for external quality control testing)
- 25 Extraction Buffer Vial Dropper Tips (+ 2 for external quality control testing)
- 1 Influenza A Positive Control Swab
- 1 Influenza B Positive Control Swab
- 1 Instructions for Use (IFU)
- 1 Quick Reference Guide (READ NOW and WALK AWAY/NORMAL Modes)
- 1 External Quality Control (QC) Quick Reference Guide
- 1 Acucy System Calibration Procedure Quick Reference Guide
- 1 Workstation

The Acucy Reader is provided with an Acucy Printer, power cords and adapters, paper roll, Acucy Calibration Device with case, USB Memory Drive, and System Manual.

5. Indications for Use

The Acucy™ Influenza A&B Test for the rapid qualitative detection of influenza A and B is composed of a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral nucleoprotein antigens from nasal and nasopharyngeal swabs of symptomatic patients that is automatically analyzed on the Acucy Reader. The Acucy Influenza A&B Test is a differentiated test, such that influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single Test Cassette. The test is intended for use with the Acucy System as an aid in the diagnosis of influenza A and B viral infections. The test is not intended for the detection of influenza C viruses. Negative test results are presumptive and should be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions.

Performance characteristics for influenza A were established during the 2017-2018 influenza season when influenza A/H3N2 and A/H1N1pdm09 were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.

If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

6. Comparison to Predicate Device

The following table provides a comparison of the characteristics of the Acucy Influenza A&B Test with the Acucy System to the predicate device, the Quidel Sofia Analyzer and Influenza A+B FIA: K112177, K1131606, and K153012.

Similarities		
Item	510(k) Device: Acucy™ Influenza A&B Test with the Acucy™ System	Predicate Device: Sofia® Analyzer and Influenza A+B FIA K112177
Indications for Use	The Acucy™ Influenza A&B Test for the rapid qualitative detection of influenza A and B is composed of a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral nucleoprotein antigens from nasal and nasopharyngeal swabs of symptomatic patients that is automatically analyzed on the Acucy Reader. The Acucy Influenza A&B Test is a differentiated test, such that influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single device. The test is intended for use with the Acucy System as an aid in the diagnosis of influenza A and B viral infections. The test is not intended for the detection of influenza C viruses.	The Sofia Influenza A+B FIA employs immunofluorescence to detect influenza A and influenza B viral nucleoprotein antigens in nasal swab, 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 differential diagnosis of acute influenza A and influenza B viral infections. The test is not intended to detect influenza C antigens. A negative test is presumptive and it is recommended these results be confirmed by virus culture or an FDA-cleared influenza A and B molecular assay. Negative results do not preclude influenza virus infections and should not be used as the sole basis for treatment or other management

	Negative test results are presumptive and should be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions. Performance characteristics for influenza A were established during the 2017-2018 influenza season when influenza A/H3N2 and A/H1N1pdm09 were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary. If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.	decisions. The test is intended for professional and laboratory use. Performance characteristics for influenza A and B were established during February through March 2011 when influenza viruses A/California/7//2009 (2009 H1N1), A/Perth/16/2009 (H3N2), and B/Brisbane/60/2008 (Victoria-Like) were the predominant influenza viruses in circulation according to the Morbidity and Mortality Weekly Report from the CDC entitled "Update: Influenza Activity – United States, 2010-2011 Season, and Composition of the 201102012 Influenza Vaccine". Performance characteristics may vary against other emerging influenza viruses. If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Virus culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.
Assay Results	Qualitative	Same
Assay Targets	Influenza A and B antigens	Same
Assay Format	Lateral flow test cassette	Same

Sample Types	Nasal swab; nasopharyngeal swab	Nasal swab, nasopharyngeal swab; nasopharyngeal aspirate/wash
Assay Antibodies	Monoclonal antibodies to influenza A and B nucleoproteins	Same
Sample Transfer Method	Dropper tip applied to extraction tube to transfer extracted sample	Fixed volume pipet used to transfer extracted sample
Reporting of Results	Reader displays results on screen; or may be printed	Same
Time to Result	15 minutes	Same
Instrument Modes	Read Now or Walk Away/Normal	Same
Intended Users and Use Locations	Clinical laboratory and point of care	Same
Calibrator	Yes – QC verification cassette provided	Yes – Calibration cassette and QC card provided
Storage Temperature	Room Temperature	Same
Assay Controls	Internal procedural control	Same
Instrument Quality Control Features	• Scanning procedural control zone for adequate flow • Reader prevents use of used cassettes • Reader prevents use of expired cassettes • Prevents improper cassette insertion	Same
Test Principle	Immunochromatographic device	Immunofluorescence device
Instrument Detection Method	Absorbance	Fluorescence
External Controls	• Influenza A Positive/B Negative Control • Influenza B Positive/A Negative Control	• Positive Influenza A/Influenza B Control • Negative Control

7. Performance Summary

Expected Values

The prevalence of influenza varies from year to year, with outbreaks occurring during the fall and winter months. The influenza positivity rate is dependent upon many factors, including specimen collection, test method, and geographic location. Prevalence varies throughout the influenza season and from location to location.

The Sekisui Diagnostics prospective clinical study was conducted during the 2017-2018 influenza season. The following tables show the positivity rates of influenza A and influenza B as determined by the Acucy Influenza A&B Test in three subject age categories in that clinical study. The overall positivity rate observed during the 2017-2018 U.S. clinical study, based on 1003 evaluable nasal or nasopharyngeal swab samples, was 24.6% for influenza A and 14.6% for influenza B.

Flu A Positives by the Acucy™ Influenza A&B Test by Age Group

	Flu A Positivity Rate for Nasal & Nasopharyngeal Swab Samples		
Age Group	**Number of Specimens**	**Number of Flu A Positives**	**Flu A Positivity Rate**
≤ 5 Years of Age	326	84	25.8%
6 to 21 Years of Age	406	130	32.0%
≥ 22 Years of Age	271	33	12.2%
Total	1003	247	24.6%

Flu B Positives by the Acucy™ Influenza A&B Test by Age Group

	Flu B Positivity Rate for Nasal & Nasopharyngeal Swab Samples		
Age Group	**Number of Specimens**	**Number of Flu B Positives**	**Flu B Positivity Rate**
≤ 5 Years of Age	326	36	11.0%
6 to 21 Years of Age	406	76	18.7%
≥ 22 Years of Age	271	34	12.5%
Total	1003	146	14.6%

Clinical Performance

A prospective, multi-center study was conducted to evaluate the performance of the Acucy Influenza A&B Test for the detection of influenza A and influenza B in nasopharyngeal and nasal swabs from patients with signs and symptoms of influenza. The study was conducted during the 2017-2018 influenza season at sixteen investigational sites across the U.S. The study was performed in point-of-care (POC) locations, such as physician office laboratories, urgent care, and outpatient clinics. The Acucy Influenza A&B Test was compared to a Composite Reference, consisting of two FDA cleared molecular influenza A&B assays and cell culture. A sample was considered positive for influenza A or influenza B by the Composite Reference if two or three of the comparative reference methods gave a positive result. A sample was considered negative for influenza A or influenza B by the composite reference if two or three of the comparative reference methods gave a negative result. A total of 1053 subjects were enrolled in the study, and of those, 1003 were considered evaluable. Comparison with the Composite Reference method is summarized in the following tables. Sensitivity, specificity and 95% confidence intervals are reported. Results are shown for nasal swabs, nasopharyngeal swabs, and both swab types combined.

Acucy™ Influenza A&B Test Influenza A Performance Against the Composite Reference Nasal and Nasopharyngeal Swabs

Acucy™ Influenza A&B Test Flu A	Composite Reference		
	Positive	**Negative**	**Total**
Positive	216	31	247
Negative	8	748	756
Total	224	779	1003
Sensitivity	96.4% (95% CI: 93.1% - 98.2%)		
Specificity	96.0% (95% CI: 94.4% - 97.2%)		

Acucy™ Influenza A&B Test Influenza B Performance Against the Composite Reference Nasal and Nasopharyngeal Swabs

Acucy™ Influenza A&B Test Flu B	Composite Reference		
	Positive	**Negative**	**Total**
Positive	130	16	146
Negative	28	829	857
Total	158	845	1003
Sensitivity	82.3% (95% CI: 75.6% - 87.4%)		
Specificity	98.1% (95% CI: 96.9% - 98.8%)		

Acucy™ Influenza A&B Test Influenza A Performance Against the Composite Reference Nasal Swabs

Acucy™ Influenza A&B Test Flu A	Composite Reference		
	Positive	**Negative**	**Total**
Positive	96	16	112
Negative	4	379	383
Total	100	395	495
Sensitivity	96.0% (95% CI: 90.2% - 98.4%)		
Specificity	95.9% (95% CI: 93.5% - 97.5%)		

Acucy™ Influenza A&B Test Influenza B Performance Against the Composite Reference Nasal Swabs

Acucy™ Influenza A&B Test Flu B	Composite Reference		
	Positive	**Negative**	**Total**
Positive	61	9	70
Negative	14	411	425
Total	75	420	495
Sensitivity	81.3% (95% CI: 71.1% - 88.5%)		
Specificity	97.9% (95% CI: 96.0% - 98.9%)		

Acucy™ Influenza A&B Test Influenza A Performance Against the Composite Reference Nasopharyngeal Swabs

Acucy™ Influenza A&B Test Flu A	Composite Reference		
	Positive	**Negative**	**Total**
Positive	120	15	135
Negative	4	369	373
Total	124	384	508
Sensitivity	96.8% (95% CI: 92.0% - 98.7%)		
Specificity	96.1% (95% CI: 93.7% - 97.6%)		

Acucy™ Influenza A&B Test Influenza B Performance Against the Composite Reference Nasopharyngeal Swabs

Acucy™ Influenza A&B Test Flu B	Composite Reference		
	Positive	**Negative**	**Total**
Positive	69	7	76
Negative	14	418	432
Total	83	425	508
Sensitivity	83.1% (95% CI: 73.7% - 89.7%)		
Specificity	98.4% (95% CI: 96.6% - 99.2%)		

Reproducibility Studies

The reproducibility of the Acucy Influenza A&B Test was evaluated in testing performed at three point of care (POC) sites. A panel of swabs including true negative (no virus), high negative (below the limit of detection), low positive (at or near the limit of detection) and moderate positive (at or near 2x the limit of detection) for influenza A (H3N2) and B were coded, randomized, and masked to the operators. The study was conducted with two operators per site over five non-consecutive days. As seen in the table below, the Acucy Influenza A&B Test produces reproducible results when tested by multiple intended users, at multiple sites, over multiple days.

Reproducibility Results by Site - Influenza A: Counts and Percent Agreement				
Sample	**Site 1**	**Site 2**	**Site 3**	**Overall Percent Agreement and 95% CI**
Influenza A High Negative	100% (30/30)	100% (30/30)	96.7% (29/30)	98.9% (94.0%-99.8%)
Influenza A Low Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (95.9%-100%)
Influenza A Moderate Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (95.9%-100%)
True Negative	100% (30/30)	100% (30/30)	100% (30/30)	100% (95.9%-100%)

Reproducibility Results by Site - Influenza B: Counts and Percent Agreement				
Sample	**Site 1**	**Site 2**	**Site 3**	**Overall Percent Agreement and 95% CI**
Influenza B High Negative	100% (30/30)	100% (30/30)	100% (30/30)	100% (95.9%-100%)
Influenza B Low Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (95.9%-100%)
Influenza B Moderate Positive	100% (30/30)	100% (30/30)	96.7% (29/30)	98.9% (94.0-99.8)
True Negative	100% (30/30)	100% (30/30)	100% (30/30)	100% (95.9%-100%)

Analytical Sensitivity: Limit of Detection

The limit of detection (LoD) for the Acucy Influenza A&B Test was established in dilution studies performed with two influenza A strains and two influenza B strains on two lots of the Acucy Influenza A&B Test. The LoD represents the concentration of influenza virus that produces consistently positive results >95% of the time. The approximate LoD concentrations identified for each strain tested are listed in the table below.

Limit of Detection			
Strain	**Type**	**Subtype**	**LoD $TCID_{50}$/mL**
A/California/07/09 pdm	A	H1N1pdm09	$1.41x10^1$
A/Hong Kong/4801/14	A	H3N2	$7.06x10^1$
B/Brisbane/60/08	B	Victoria	$2.35x10^1$
B/Phuket/3073/13	B	Yamagata	$3.40x10^1$

Analytical Reactivity

A total of 28 influenza A and B strains were tested with the Acucy Influenza A&B Test, at levels at or near the assay LoD. All influenza A virus isolates gave positive A and negative B results. All influenza B virus isolates gave negative A and positive B results**.**

Analytical Reactivity				
Strain	**Concentration $TCID_{50}$/mL**	**Type**	**Subtype**	**Test Result**
A/NY/02/09	$1.06x10^2$	A	H1N1pdm09	Detected
A/Mexico/4108/09	$1.06x10^2$	A	H1N1pdm09	Detected
A/PR/8/34	$1.06x10^2$	A	H1N1	Detected
A/Singapore/63/04	$2.04x10^3$	A	H1N1	Detected
A/Taiwan/42/06	$1.02x10^3$	A	H1N1	Detected
A/Canada/6294/09	$2.12x10^3$	A	H1N1pdm09	Detected
A/New Cal/20/99	$1.06x10^2$	A	H1N1	Detected
A/Solomon Islands/03/06	$1.06x10^2$	A	H1N1	Detected
A/NY/01/09	$1.06x10^2$	A	H1N1pdm09	Detected
A/NY/03/09	$1.06x10^2$	A	H1N1pdm09	Detected
A/Brisbane/59/07	$1.06x10^2$	A	H1N1	Detected
A/Brisbane/10/07	$1.06x10^2$	A	H3N2	Detected
A/Victoria/361/11	$1.06x10^2$	A	H3N2	Detected
A/HK/8/68	$1.06x10^2$	A	H3N2	Detected
A/Perth/16/09	$1.06x10^2$	A	H3N2	Detected
A/Wisconsin/67/05	$1.06x10^2$	A	H3N2	Detected
A/Rhode Island/01/2010	$5.00x10^5$	A	H3N2	Detected
A/New York/55/2004	$2.00x10^5$	A	H3N2	Detected
A/Florida/2/2006	$3.30x10^5$	A	H3N2	Detected
A/Texas/50/2012	$1.06x10^2$	A	H3N2	Detected
A/Texas/71/2007	$4.08x10^3$	A	H3N2	Detected
A/Indiana/08/2011	$5.30x10^2$	A	H3N2v	Detected
B/Malaysia/2506/04	$5.10x10^1$	B	B	Detected
B/Massachusetts/2/12	$5.10x10^2$	B	B	Detected
B/Wisconsin/1/10	$5.10x10^1$	B	B	Detected
B/Texas/6/11	$7.24x10^2$	B	B	Detected
B/Florida/07/04	$2.55x10^2$	B	B	Detected
A/Anhui/1/2013	$1.00x10^8$	A	A (Avian)	Detected

Analytical Specificity: Cross-Reactivity and Microbial Interference

The Acucy Influenza A&B Test was evaluated with 41 organisms (bacterial, viral, fungal) and Human DNA. Bacterial isolates were tested at concentrations of approximately10^6 colony forming units per mL (cfu/mL) or color changing units per mL (CCU/mL). Viral isolates were tested at approximately 10^5 plaque forming units per mL (pfu/mL), copies/mL, or tissue culture infectious dose 50% per mL ($TCID_{50}$/mL). No cross-reactivity was observed at the concentrations tested as all of the microorganisms tested produced negative responses for influenza A and B. No interference toward the detection of influenza A analyte or influenza B analyte was observed from all microorganisms and human genomic DNA at the concentrations tested.

Potentially Cross-Reacting Bacterial and Fungal Isolates	Potentially Cross-Reacting Non-Influenza Virus Strain and Human DNA
Bordetella pertussis	Adenovirus type 1
Candida albicans	Adenovirus type 7A
Chlamydia pneumoniae	Human coronavirus
Escherichia coli	Enterovirus
Haemophilus influenzae	Coxsackie virus
Klebsiella pneumoniae	Cytomegalovirus
Lactobacillus acidophilus Z048	Epstein Barr virus (EBV)
Legionella pneumoniae	Parainfluenza type 1
Moraxella catarrhalis	Parainfluenza type 2
Mycoplasma hominis	Parainfluenza type 3
Mycobacterium tuberculosis	Measles virus
Mycoplasma pneumoniae	Human metapneumovirus 3 type B1
Neisseria meningitidis	Human metapneumovirus 9 type A1
Neisseria gonorrhoeae	Human herpes virus 6 (HHV6), Z29
Pseudomonas aeruginosa	Human herpes virus 7 (HHV7), SB
Staphylococcus aureus MRSA	Mumps virus
Staphylococcus aureus MSSA	Respiratory syncytial virus type A2
Staphylococcus epidermidis MRSE	Respiratory syncytial virus type B
Streptococcus pneumoniae	Rhinovirus
Streptococcus pyogenes	Human genomic DNA
Streptococcus salivarius	
Corynebacterium ulcerans	

Assay Cutoff

The assay cutoffs (thresholds of detection) for influenza A and influenza B were initially determined by testing contrived influenza A samples, influenza B samples, and negative samples prepared in clinical nasal matrix. Samples were tested in replicates of 60 with two lots of reagents (a total of 360 test results).

To validate the primary cutoff values, a clinical dataset comprised of 1252 prospectively and retrospectively collected samples was tested with the Acucy Influenza A&B Test, and Receiver Operator Characteristic (ROC) analysis was performed to determine the optimal values for sensitivity and specificity. The assay cutoffs were adjusted slightly based on this ROC analysis.

The Acucy Influenza A&B Test also employs a secondary cutoff in the event that one analyte (influenza A or B) is present in the sample at a very high titer. High titer samples have been shown to generate higher levels of non-specific binding at the test line for the second analyte. Use of the secondary cutoff prevents reporting of a false positive result for the second analyte. This cutoff was validated by testing high titer samples of one analyte mixed with varying concentrations of the second analyte and testing with the Acucy Influenza A&B Test. Ten different mixtures of influenza A and influenza B samples were tested in replicates of 20. The validation demonstrated the effectiveness of the secondary cutoff in preventing false positive results caused by high titer samples.

Interfering Substances

The Acucy Influenza A&B Test was evaluated with potential interferents that may be encountered in respiratory specimens. The substances were tested at the concentrations listed in the table below. No interference was observed with the test for any of the substances at the concentrations tested.

Substance	Potential Interferent	Concentration
No substance control	Dry swab	N/A
Control	Viral transport media (VTM)	N/A
Mucus (Bovine)	Mucin protein	19 mg/mL
Whole blood	Whole blood with EDTA	5% v/v
Tylenol	Acetaminophen	0.1 mg/mL
NSAIDs	Aspirin	16.2 mg/mL
	Ibuprofen	40 mg/mL
	Naproxen	110 mg/mL
Nasal Corticosteroids	Dexamethasone (injection)	3 mg/mL
	Dexamethasone (oral)	0.5 mg/mL
	Fluticasone	50 µg/mL
	Mometasone furoate	2.5 µg/mL
	Budesonide	25 µg/mL
	Flunisolide	68.75 µg/mL
	Triamcinolone acetonide	5.5 µg/mL
	Beclomethasone	16 µg/mL
Nasal Sprays	Oxymetazoline	0.025% v/v
	Phenylephrine	0.5% v/v
	Sodium chloride	0.325% v/v
Nasal Gel	Galphima glauca, Luffa operculate	4x,4x
Antiviral	Oseltamivir	5 mg/mL
Antibacterial, systemic	Tobramycin	40.0 µg/mL
Throat Lozenges	Benzocaine	2.5% soln.
Antibiotic Nasal Ointment	Mupirocin	0.15 mg/mL
Allergy Medicine	Histaminum hydrochloricum	1% solution

CLIA Waiver Studies

Clinical Performance by Intended Users

The performance of the Acucy Influenza A&B Test was evaluated at 16 intended use sites by non-laboratory personnel in a prospective clinical study during the 2017-2018 influenza season in the U.S. Nasal or nasopharyngeal swabs were collected from patients with flu-like symptoms and were tested with the Acucy Influenza A&B Test and the reference methods. Results were compared to a compostite reference, which was calculated from the results of three reference methods: two molecular methods and cell culture. Results for nasal and nasopharyngeal swabs combined are shown in the following tables.

Acucy™ Influenza A&B Test Influenza A Performance Against the Composite Reference Nasal and Nasopharyngeal Swabs

Acucy™ Influenza A&B Test Flu A	Composite Reference		
	Positive	**Negative**	**Total**
Positive	216	31	247
Negative	8	748	756
Total	224	779	1003
Sensitivity	96.4% (95% CI: 93.1% - 98.2%)		
Specificity	96.0% (95% CI: 94.4% - 97.2%)		

Acucy™ Influenza A&B Test Influenza B Performance Against the Composite Reference Nasal and Nasopharyngeal Swabs

Acucy™ Influenza A&B Test Flu B	Composite Reference		
	Positive	**Negative**	**Total**
Positive	130	16	146
Negative	28	829	857
Total	158	845	1003
Sensitivity	82.3% (95% CI: 75.6% - 87.4%)		
Specificity	98.1% (95% CI: 96.9% - 98.8%)		

Performance Near the Cutoff

Three CLIA-waived sites that participated in the prospective clinical study participtated in the Near Cutoff Study. The testing was performed by three untrained intended operators at each of the sites. This study was conducted to demonstrate that untrained intended users could perform the Acucy Influenza A&B Test and consistently detect samples at the limit of detection (LoD).

The test panel consisted of four contrived samples applied to nasal swabs: a low positve influenza A sample at 1x LoD, a high negative influenza A sample at 0.1 x LoD, a low positive influenza B sample at 1x LoD, and a high negative influenza B sample at 0.25 LoD. low positive samples are expected to give a positive result, and high negative samples are expected to give a negative result.

Samples were masked as subject samples and were presented to the intended use operators for testing throughout the course of a normal testing day. Testing took place over the course of two weeks on non-consecutive days. Each operator tested seven samples each testing day. Each site ultimately tested a panel of 84 samples.

The test results are summarized in the table below. The study demonstrates that untrained intended use operators are able to accurately perform and interpret the Acucy Influenza A&B Test at and below the level of the LoD for both influenza A and influenza B.

Near Cutoff Study Test Results: Percent Agreement of Observed/Expected Values

Site	Sample Type			
	Low Positive A	Low Positive B	High Negative A	High Negative B
1	21/21	20/21	21/21	20/21
2	21/21	20/21	21/21	21/21
3	21/21	21/21	21/21	21/21
Total	63/63	61/63	63/63	62/63
Agreement	100%	96.83%	100%	98.41%

8. Conclusion

The information presented in this Premarket Notification demonstrates that the performance of the Acucy Influenza A&B Test with the Acucy System is substantially equivalent in intended use, technological characteristics, and performance to the predicate device.