

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

A. 510(k) Number:

K171641

B. Purpose for Submission:

This is a new 510(k) application for the determination of Substantial Equivalence for the Mesa Biotech Accula Flu A/Flu B Test and associated instrument. Mesa Biotech, Inc. has submitted a combined 510(k) and CLIA waiver package for dual review.

C. Measurand:

Influenza A PB2 RNA
Influenza B Matrix RNA

D. Type of Test:

RT-PCR amplification followed by hybridization and colorimetric visualization of amplified products on a test strip

E. Applicant:

Mesa Biotech, Inc.

F. Proprietary and Established Names:

Accula Flu A/Flu B Test

G. Regulatory Information:

1. Regulation section:

21 CFR 866.3980, Respiratory viral panel multiplex nucleic acid assay

2. Classification:

Class II

3. Product code:

OZE - Influenza A and Influenza B Multiplex Nucleic Acid Assay

4. Panel:

Microbiology (83)

H. Intended Use:

1. Intended use(s):

The Accula Flu A/Flu B Test performed on the Accula Dock is a molecular *in vitro* diagnostic test utilizing polymerase chain reaction (PCR) and lateral flow technologies for the qualitative, visual detection and differentiation of influenza A and influenza B viral RNA. The Accula Flu A/Flu B Test uses a nasal swab specimen collected from patients with signs and symptoms of respiratory infection. The Accula Flu A/Flu B assay is intended as an aid in the diagnosis of influenza infection in conjunction with clinical and epidemiological risk factors. The assay is not intended to detect the presence of influenza C virus.

Negative results do not preclude influenza virus 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 2016-2017 influenza season. 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 public 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.

2. Indication(s) for use:

Same as Intended Use.

3. Special conditions for use statement(s):

For Prescription Use

4. Special instrument requirements:

To be used only with the Accula Dock Instrument

I. Device Description:

The Accula Flu A/Flu B Test is a semi-automated, colorimetric, multiplex reverse-

transcription polymerase chain reaction (RT-PCR) nucleic acid amplification test to qualitatively detect influenza A and B viral RNA from unprocessed nasal swabs that have not undergone prior nucleic acid extraction. The system integrates nucleic acid extraction, reverse transcription, amplification using a novel Mesa Biotech technology, and hybridization-based visual detection into a completely self-contained and automated system. The Accula Flu A/Flu B system consists of a small reusable Dock to drive the automated testing process and a single-use disposable test cassette that contains all the enzymes and reagents.

Upon insertion of a Test Cassette, the Dock will detect and identify the cassette type. After the user transfers a clinical sample into the cassette and closes the dock lid, the embedded firmware will control fluid flow of the sample into the various chambers of the cassette.

Amplicon detection requires the hybridization of two internal probes to generate a signal on the Accula Flu A/Flu B detection strip. Dyed polystyrene microspheres are conjugated to oligonucleotide probes to form an amplicon-microsphere complex by hybridization to an internal region of the amplicon. The complex migrates through the pores of the detection strip membrane and across capture zones which contain oligonucleotides complementary to an amplicon region distinct from the detection probe binding site. Hybridization of the amplicon-microsphere complex to a capture zone probe retards the flow of the specific amplicon and results in the generation of a visible signal in the form of a colored line.

Interpretation of results:

Results are interpreted visually by the operator after the test has completed. A colored line of any intensity at the “Flu A” and/or “Flu B” location indicates a positive result for that influenza virus type if the test is valid. A Negative Control line at the end of the test strip controls for non-specific binding or amplification and must be absent for a valid test. A control line at the beginning of the strip displays amplification effectiveness and is necessary to interpret a test as “negative” for influenza A and influenza B.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Alere i Influenza A&B

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

K141520

3. Comparison with predicate:

Table 1: Similarities Between Accula Flu A/Flu B and Predicate Device

Similarities		
Item	Mesa Biotech Accula Flu A/Flu B Test	Alere i Influenza A&B Test
Assay Targets	Influenza A and Influenza B virus	Same
Sample Type	Nasal Swab	Same
Assay Results	Qualitative	Same
Intended Users and Locations	Clinical Lab and Point of Care	Same
Nucleic Acid Purification	No	Same
Influenza A Target	PB2 Gene	Same
Internal Control	Yes	Same
Positive and Negative Control Swabs	Yes	Same

Table 2: Differences Between Accula Flu A/Flu B and Predicate Device

Differences		
Item	Mesa Biotech Accula Flu A/Flu B Test	Alere i Influenza A&B Test
Intended Use	<p>The Accula Flu A/Flu B Test performed on the Accula Dock is a molecular <i>in vitro</i> diagnostic test utilizing polymerase chain reaction (PCR) and lateral flow technologies for the qualitative, visual detection and differentiation of influenza A and influenza B viral RNA. The Accula Flu A/Flu B Test uses a nasal swab specimen collected from patients with signs and symptoms of respiratory infection. The Accula Flu A/Flu B assay is intended as an aid in the diagnosis of influenza infection in conjunction with clinical and epidemiological risk factors. The assay is not intended to detect the presence of influenza C virus.</p> <p>Negative results do not preclude influenza virus infection and should not be used as the sole</p>	<p>The Alere™ i Influenza A & B assay performed on the Alere™ i Instrument is a rapid molecular <i>in vitro</i> diagnostic test utilizing an isothermal nucleic acid amplification technology for the qualitative detection and discrimination of influenza A and B viral RNA in nasal swabs from patients with signs and symptoms of respiratory infection. It is intended for use as an aid in the differential diagnosis of influenza A and B viral infections in humans in conjunction with clinical and epidemiological risk factors. The assay is not intended to detect the presence of influenza C virus.</p> <p>Negative results do not preclude influenza virus infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions.</p>

Differences		
Item	Mesa Biotech Accula Flu A/Flu B Test	Alere i Influenza A&B Test
	<p>basis for treatment or other patient management decisions.</p> <p>Performance characteristics for influenza A were established during the 2016-2017 influenza season. When other influenza A viruses are emerging, performance characteristics may vary.</p> <p>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 public 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.</p>	<p>Performance characteristics for influenza A were established during the 2012-2013 influenza season when influenza A/H3 and A/H1N1 pandemic were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.</p> <p>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.</p>
Influenza B Target	Matrix Gene	PA Gene
Assay Technology	PCR amplification and visual identification of amplified products by hybridization to a test strip	Isothermal nucleic acid amplification and detection of amplified products using molecular beacon probes
Detection	Dyed microparticle conjugates specifically detect amplified products	Fluorescently-labeled molecular beacons identify amplified RNA targets
Instrument	Amplification controlled by the Accula Dock	Amplification performed on the Alere i Instrument
Results Interpretation	Visual interpretation of colored lines on a test strip	Optical detection of fluorescence by the Alere i instrument

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

Not applicable

L. Test Principle:

Nucleic acid amplification plus hybridization to a membrane and chromatographic visual detection

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The reproducibility of the Accula Flu A/Flu B Test was tested in a study using contrived nasal swabs at three CLIA-waived sites and one moderately complex site based in the United States. The objective of this study was to test panels of contrived nasal swab samples with the Accula Flu A/Flu B Test to demonstrate reproducibility of the assay in the hands of multiple users at multiple sites over multiple non-consecutive days.

Samples were provided to testing operators in panels of 5 samples (Flu A Low Positive and Moderate Positive, Flu B Low Positive and Moderate Positive, and Negative). The targeted concentrations for the Moderate Positive samples were approximately 3X the respective LoD, the targeted concentrations for the Low Positive samples were approximately 1X the respective LoD, and the Negative samples contained no influenza virus. Samples were blinded and randomized. Each operator tested one panel per day, testing a maximum of five samples at a time. Each sample was tested in triplicate (from separate swabs) (2 operators x 1 run x 3 swabs x 5 non-consecutive days = 30 observations for each site per sample type). Results are reported for counts and percent agreement with expected results. Results were evaluated by site, by operator and by day.

Table 3: Site-to-Site Reproducibility: Percent Agreement and Total Counts

	Agreement By Site								Overall Percent Agreement and 95% CI	
	Site 1		Site 2		Site 3		Site 4			
	%	Count	%	Count	%	Count	%	Count		
LP ¹ Flu A	100%	30/30	100%	30/30	100%	29/29*	100%	30/30	100%	(96.9%, 100%)
MP ¹ Flu A	100%	29/29*	100%	30/30	100%	30/30	100%	30/30	100%	(96.9%, 100%)
LP ¹ Flu B	100%	30/30	100%	30/30	100%	30/30	100%	30/30	100%	(96.9%, 100%)
MP ¹ Flu B	100%	30/30	100%	30/30	100%	30/30	100%	30/30	100%	(96.9%, 100%)
TN ^{1,2}	100%	30/30	100%	30/30	100%	30/30	100%	30/30	100%	(96.9%, 100%)

¹ LP = Low Positive, MP = Moderate Positive; TN = True Negative

² Percent agreement is for negative results

* Test and retest resulted in an invalid test result

Agreement of actual results with expected results was 100%. There were no differences observed within run (replicates tested by one operator), between runs (five different days), between sites (four sites), or between operators (eight operators).

b. Linearity/assay reportable range:

Not Applicable; this is a qualitative assay.

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

Quality Control:

Each test cassette contains two internal process controls: an internal positive control and a negative control. The positive control is a non-infectious RNA molecule of the MS2 bacteriophage. The negative control is a non-influenza nucleic acid target intended to check for non-specific binding. Each test kit also contains separate control swabs with inactivated virus for influenza A or influenza B. The manufacturer recommends positive controls be run for each new lot or shipment of kits received, and for each new operator performing the test. Additional positive control swabs are available for purchase from the manufacturer.

Specimen Stability

Contrived samples of Influenza A (A/CA/07/2009; 300 TCID₅₀/mL) and Influenza B (B/Massachusetts/02/2012; 400 TCID₅₀/mL) were tested in triplicate on the Accula Flu A/Flu B assay. Samples were prepared in pooled negative matrix containing the Accula Flu A/Flu B nasal swab buffer solution and stored at various conditions. For freeze/thaw cycles, samples were frozen for at least 3 hours before thaw. Test

conditions and the results of the testing are summarized in the table below:

Table 4: Specimen Stability After Elution in Sample Buffer

Test Sample	Storage Condition	Duration	Pos. Flu A / Expected	Pos. Flu B / Expected	Pass/Fail
Flu A	Null	N/A	3/3*	0 / 0	PASS
Flu A	15-30°C	1 Hour	3/3	0 / 0	PASS
Flu A	15-30°C	4 Hours	3/3	0 / 0	PASS
Flu A	15-30°C	24 Hours	3/3	0 / 0	PASS
Flu A	2-8°C	72 Hours	2/3	0 / 0	FAIL
Flu A	-20°C	72 Hours	3/3	0 / 0	PASS
Flu A	-20°C	1 Week	3/3	0 / 0	PASS
Flu A	-80°C	72 Hours	3/3	0 / 0	PASS
Flu A	-80°C	2 Weeks	3/3	0 / 0	PASS
Flu A	-20°C	1 Freeze/thaw	3/3	0 / 0	PASS
Flu A	-20°C	2 Freeze/thaw	3/3	0 / 0	PASS
Flu A	-20°C	3 Freeze/thaw	3/3	0 / 0	PASS
Flu B	Null	N/A	0 / 0	3/3	PASS
Flu B	15-30°C	1 Hour	0 / 0	3/3	PASS
Flu B	15-30°C	4 Hours	0 / 0	3/3	PASS
Flu B	15-30°C	24 Hours	0 / 0	3/3	PASS
Flu B	2-8°C	72 Hours	0 / 0	2/3	PASS
Flu B	-20°C	72 Hours	0 / 0	3/3	PASS
Flu B	-20°C	1 Week	0 / 0	3/3	PASS
Flu B	-80°C	72 Hours	0 / 0	3/3	PASS
Flu B	-80°C	2 Weeks	0 / 0	3/3	PASS
Flu B	-20°C	1 Freeze/thaw	0 / 0	3/3	PASS
Flu B	-20°C	2 Freeze/thaw	0 / 0	3/3	PASS
Flu B	-20°C	3 Freeze/thaw	0 / 0	3/3	PASS

* Initial testing resulted in 2 out of 3 positive for Flu A. New samples were prepared and tested 3/3 positive for Flu A.

Mesa Biotech has indicated that specimens should be transferred to the nasal swab buffer sample tube immediately after collection and stored for no longer than one hour at room temperature.

Shelf Life

Accula Flu A/Flu B test kits are being tested for shelf life by storage at 30°C for different lengths of time. At each time interval (day 0, 1 week, 2 weeks, 1 month, and 1 month intervals beyond) stored test kits are used to test control swabs and simulated influenza A and influenza B samples prepared in clinical matrix. Contrived specimens are prepared in clinical matrix at approximately 3X LoD. Negative samples and control swabs are tested as one replicate. Acceptance criteria for shelf life studies are as follows: all positive samples and controls must yield a 100% positive rate and all negative samples and controls must yield a 100% negative rate. Tests were

considered stable as long as they continued to produce positive results for positive samples and negative results for negative samples. Data generated so far demonstrates that two lots are stable for three months and a third lot is stable for at least two months. Kit storage conditions for the Accula Flu A/Flu B test are being labeled as stable at 15-30°C for at least two months. Expiration dating will be extended as the study continues provided that correct results are obtained for all three test lots during the testing period.

d. Detection limit:

The objective of the Analytical Sensitivity Study was to identify the limit of detection (LoD) of the Accula Flu A/Flu B assay using characterized strains of Influenza A and Influenza B. Four (4) influenza strains were run in replicates of twenty (20) for each concentration. The influenza strains selected for testing included a 2009-like seasonal H1N1 influenza A strain, an H3N2 influenza A strain, and two influenza B strains representing Victoria and Yamagata lineages. Clinical matrix was used as dilution material for all LoD determination/confirmation experiments.

To determine the limit of detection, a range-finding study was first conducted to establish the lower limit of analytical sensitivity using virus dilutions tested in replicates of n=5. Following identification of the lower end of the detectable concentrations in the range finding study, virus concentrations ranging from 1.3-fold to 2-fold more concentrated were prepared for each virus based on experimental design and viral stock available. Virus concentration was increased until at least 19/20 independent positives were found reproducibly (i.e., in two similar confirmations) during testing. The final concentrations whereby at least 95% of results ($\geq 19/20$) were positive for the target virus are shown in the table below:

Table 5: Accula Flu A/Flu B Limits of Detection

Influenza Strain Tested	Concentration	Detected (Observed / Expected)
A/California/07/2009 (H1N1)	300 TCID ₅₀ /mL	20/20
A/Texas/50/2012 (H3N2)	1200 TCID ₅₀ /mL	20/20
B/Nevada/3/2011	1350 CEID ₅₀ /mL	20/20
B/Massachusetts/2/2012	400 TCID ₅₀ /mL	20/20

e. Analytical reactivity:

Inclusivity verification was evaluated for the Accula Flu A/Flu B test using 23 influenza strains. The chosen strains represented subtypes in the population, including A: H1N1, A: H3N2, A: H1N1 (2009), B Victoria lineage strains, and B Yamagata lineage strains. Virus was diluted into a pooled clinical matrix to create contrived samples at a 1.5X LOD concentration. Each strain was tested in triplicate. The influenza A and influenza B strains, test concentrations, and results are shown below:

Table 6: Accula Flu A/Flu B Reactivity

Virus Tested	Subtype / Lineage	Concentration Tested (TCID₅₀/mL)	Flu A Positive Results / Expected	Flu B Positive Results / Expected
A/Beijing/262/1995	H1N1	600	3/3	0/3
A/Brisbane/59/2007	H1N1	600	3/3*	0/3
A/Brisbane/10/2007	H3N2	2400	3/3	0/3
A/England/42/1972	H3N2	2400	3/3	0/3
A/Fort Monmouth/1/1947	H1N1	600	3/3	0/3
A/New Caledonia/20/1999	H1N1	600	3/3	0/3
A/Perth/16/2009	H3N2-like	2400	3/3	0/3
A/Port Chalmers/1/1973	H3N2	2400	3/3	0/3
A/Puerto Rico/8/1934	H1N1	600	3/3	0/3
A/Solomon Islands/3/2006	H1N1	600	3/3	0/3
A/Switzerland/9715293/2013	H3N2-like	2400	3/3	0/3
A/Sydney/5/1997	H3N2	2400	3/3*	0/3
A/Victoria/3/1975	H3N2	2400	3/3	0/3
A/Victoria/361/2011	H3N2	2400	3/3	0/3
A/Wisconsin/67/2005	H3N2-like	2400	3/3	0/3
B/Brisbane/60/2008	Victoria	2700	0/3	3/3
B/Florida/4/2006	Yamagata	800	0/3	3/3
B/Lee/1940	Victoria	2700	0/3	3/3*
B/Malaysia/2506/2004	Victoria	2700	0/3	3/3
B/Maryland/1/1959	Yamagata	800	0/3	3/3
B/Phuket/3073/2013	Yamagata	800	0/3	3/3*
B/Russia/1969	Yamagata	800	0/3	3/3
B/Wisconsin/01/2010	Yamagata	800	0/3	3/3

* Replicate repeated due to an invalid result.

f. Analytical specificity:

To determine the analytical specificity of the Accula Flu A/Flu B assay, 40 commensal and pathogenic microorganisms (15 viruses, 18 bacteria) that may be present in the nasal cavity or nasopharynx were tested. No cross-reactivity was observed for any of the microorganisms tested. Details are shown in the table below:

Table 7: Accula Flu A/Flu B Specificity/Cross-Reactivity

Organism Tested	^{1,2}Concentration Tested	Flu A Positive Results / Expected	Flu B Positive Results / Expected
Adenovirus Type 1	5.10E+05	0/3*	0/3*
Adenovirus Type 7	3.31E+04	0/3	0/3
Human Cytomegalovirus	1.10E+04	0/3	0/3
Human Coronavirus 229E	1.10E+04	0/3	0/3
Human Coronavirus OC43	2.95E+05	0/3	0/3
Human Enterovirus 71	1.04E+04	0/3*	0/3*
Epstein-Barr virus	3.98E+07 cp/mL	0/3	0/3
Parainfluenza 1	1.26E+04	0/3	0/3
Parainfluenza 2	1.10E+04	0/3	0/3
Parainfluenza 3	1.18E+04	0/3	0/3
Measles virus	2.95E+05	0/3	0/3
Human Metapneumovirus	1.01E+04	0/3	0/3
Mumps virus	9.75E+04	0/3	0/3
Respiratory Syncytial virus	1.58E+04	0/3	0/3
Human rhinovirus 17	3.31E+04	0/3*	0/3*
<i>Bordetella pertussis</i>	4.22E+06	0/3	0/3
<i>Chlamydia pneumoniae</i>	≥ 1.67E+04	0/3	0/3
<i>Corynebacterium glycinophilum</i>	≥ 1.59E+06	0/3	0/3
<i>Escherichia coli</i>	1.92E+07	0/3	0/3
<i>Haemophilus influenzae</i>	1.20E+06	0/3	0/3
<i>Lactobacillus sp.</i>	3.00E+06	0/3	0/3
<i>Legionella longbeachae</i>	9.65E+06	0/3	0/3
<i>Moraxella catarrhalis</i>	1.99E+05	0/3	0/3
<i>Mycobacterium tuberculosis</i>	3.62E+06	0/3	0/3
³ <i>Mycoplasma pneumoniae</i>	2.81E+05	0/3	0/3
<i>Neisseria meningitidis</i>	1.28E+06	0/3	0/3
<i>Neisseria subflava</i>	7.30E+06	0/3	0/3
<i>Pseudomonas aeruginosa</i>	6.05E+05	0/3	0/3
<i>Staphylococcus aureus</i>	6.95E+07	0/3	0/3
<i>Staphylococcus epidermidis</i>	3.24E+07	0/3	0/3
<i>Streptococcus pneumoniae</i>	2.09E+06	0/3*	0/3*
<i>Streptococcus pyogenes</i>	2.72E+07	0/3	0/3
<i>Streptococcus salivarius</i>	2.32E+06	0/3*	0/3*

* Replicate repeated due to an invalid result.

¹ Virus concentrations in TCID₅₀/mL; bacteria concentrations in CFU/mL.

² *Chlamydia pneumoniae* and *Corynebacterium glycinophilum* concentration in IFU/mL.

³ *Mycoplasma pneumoniae* concentration in CCU/mL.

g. Interfering Substances:

To assess substances with the potential to interfere with the performance of the Accula Flu A/ Flu B test, four (4) influenza strains were tested in replicates of three (3) with each interfering substance at the “worst case” concentration. The influenza strains selected for testing include a 2009 pandemic swine-like H1N1 influenza A strain, an H3N2 influenza A strain, and two influenza B strains representing Victoria and Yamagata lineages. Virus was serially diluted into a pooled clinical matrix to achieve a 1.5X LoD concentration.

Each influenza strain was tested with the “worst case” interferent concentration, representing the highest concentration likely to be found in a respiratory sample.

Table 8: Interfering Substances Tested

Substance	Concentration
Mucin	0.0625%
Whole Blood	1%
NeoSynephrine Cold and Sinus Extra Strength Spray	0.05%
Afrin (Oxymetazoline Hydrochloride)	0.05%
Nasacort (nasal corticosteroid)	0.31mg/mL
Zicam Allergy Relief	n/a
Cepacol (Benzocaine)	3 mg/mL
Zanamivir (Relenza)	10 mg/mL
Tobramycin	2.43 mg/mL
Mupircoin	12 mg/mL

No interference was observed for any of the substances tested above at the concentrations listed.

h. Assay cut-off:

Not applicable; the detection signal is read visually.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable. Performance of the Accula Flu A/Flu B Test was evaluated against the comparator method in a prospective clinical study.

b. Matrix comparison:

Not applicable.

3. Clinical studies:

Clinical performance was evaluated in a multi-site study in the U.S. during the 2016-2017 influenza season. Accula Flu A/Flu B was used to evaluate fresh, prospectively collected nasal swab specimens from children and adults with suspected respiratory infection and meeting the inclusion/exclusion criteria. Samples were tested with the Accula Flu A/Flu B within one hour of sample collection. At all sites, one swab specimen was tested directly on the Accula Flu A/Flu B according to product instructions. The other swab was eluted in VTM and shipped to a reference laboratory for testing with a high performance, FDA-cleared molecular influenza assay. Elution and shipping of the reference swab sample was performed according to the kit instructions.

A total of 1331 nasal swab specimens were enrolled in the study. Of those, 73 specimens were unevaluable: four did not meet eligibility criteria, 53 samples were rejected due to protocol deviations, and 16 samples returned invalid results after repeat testing. A total of 1258 nasal swab specimens were considered evaluable. Patient age and gender distribution for the evaluable specimens is presented in the table below:

Table 9: Prospective Clinical Study Age and Gender Distribution

Age Group (Years)	Female	Male	Total
<5	230	258	488
6-21	279	322	601
22-59	78	49	127
≥60	26	16	42
Total	613	645	1258

During the prospective clinical study, the initial invalid rate for nasal swab samples (before repeat testing per the product instructions) was 9.1% (116/1272). After repeat testing per the product instructions, the invalid rate was 1.1% (14/1272). Performance of the Accula Flu A/Flu B assay compared to an FDA-cleared molecular assay for nasal swab samples is presented below.

Table 10: Accula Flu A/Flu B Influenza A Performance Compared to FDA-cleared Molecular Comparator.

Accula Flu A/Flu B	Comparator		
	Positive	Negative	Total
Positive	289	60 ^a	349
Negative	9 ^b	900	909
Total	298	960	1258
Sensitivity:	97% (95% CI: 94.4-98.4%)		
Specificity:	94% (95% CI: 92.0-95.1%)		

^a Flu A was detected in 47/60 false positive specimens using an alternative FDA-cleared molecular influenza assay.

^b Flu B was not detected in 3/9 false negative specimens using an alternative FDA-cleared molecular influenza assay.

Table 11: Accula Flu A/Flu B Influenza B Performance Compared to FDA-cleared Molecular Comparator.

Accula Flu A/Flu B	Comparator		
	Positive	Negative	Total
Positive	126	14 ^a	140
Negative	8 ^b	1110	1118
Total	134	1124	1258
Sensitivity:	94% (95% CI: 88.7-97.0%)		
Specificity:	99% (95% CI: 97.9-99.3%)		

^a Flu A was detected in 9/14 false positive specimens using an alternative FDA-cleared molecular influenza assay.

^b Flu B was not detected in 5/8 false negative specimens using an alternative FDA-cleared molecular influenza assay.

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

In the Accula Flu A/Flu B clinical study (described in the “Clinical Studies” section above), a total of 1258 nasal swab specimens were evaluable by the Accula Flu A/Flu B assay. The number and percentage of influenza A and influenza B positive cases per specified age group, as determined by the Accula Flu A/Flu B assay, are presented in the tables below:

Table 12: Influenza A Expected Values

Age Group (Years)	Number of Specimens	Number of Influenza A Positives	Influenza A Positivity Rate
<5	488	97	19.9%
6-21	601	172	28.6%
≥22	169	20	11.8%
Total	1258	289	23.0%

Table 13: Influenza B Expected Values

Age Group (Years)	Number of Specimens	Number of Influenza B Positives	Influenza B Positivity Rate
<5	488	27	5.5%
6-21	601	91	15.1%
≥22	169	8	4.7%
Total	1258	126	10.0%

N. Instrument Name:

Accula Dock

O. System Descriptions:

1. Modes of Operation:

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

Yes _____ or No X_____

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

Yes _____ or No X_____

2. Software:

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

Yes X_____ or No _____

3. Specimen Identification:

Specimen ID is entered by hand directly onto the test cassette.

4. Specimen Sampling and Handling:

Not applicable. The specimens are manually inserted into the test cassette in the instrument.

5. Calibration:

The Accula Dock is factory calibrated and does not require any further calibration at the user site.

6. Quality Control:

Quality control is addressed for each specific FDA-cleared assay to be run on the instrument (separately cleared).

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The “Performance Characteristics” Section above:

N/A

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable.

R. Conclusion:

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