February 6, 2018

Mesa Biotech, Inc.
Barbara Stevens
Regulatory Affairs Consultant
6190 Cornerstone Court, Suite 220
San Diego, California 92121

Re: K171641
Trade/Device Name: Accula Flu A/Flu B Test
Regulation Number: 21 CFR 866.3980
Regulation Name: Respiratory viral panel multiplex nucleic acid assay
Regulatory Class: Class II
Product Code: OCC, OZE
Dated: June 1, 2017
Received: June 2, 2017

Dear Barbara Stevens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR

Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Steven R. Gitterman -S for

Uwe Scherf, Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171641

Device Name
Accula Flu A/Flu B Test

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5. 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: ____K171641____

1. Sponsor/Applicant Name and Address

Company Name:	Mesa Biotech, Inc.
Address:	6190 Cornerstone Court, Suite 220
	San Diego, CA 92121
Telephone:	858-800-4929
Contact Person:	Barbara Stevens
	Regulatory Consultant
Date Summary Prepared:	06/01/2017

2. Device Name and Classification

Trade Name:	Accula Flu A/Flu B Test
Classification of Device:	21 CFR 866.3980, Respiratory viral panel multiplex nucleic acid assay
Product Code	OZE, OCC

3. Predicate Device

K141520, Alere i Influenza A&B Assay

4. Device Description

Operating Principle

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, a novel Mesa Biotech PCR nucleic acid amplification technology named OscAR™, 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.

Flu A/Flu B Kit Contents

The Accula Flu A/Flu B Test Kit contains all the materials needed to run a test, except for the Accula Dock, which is provided separately. The Accula Flu A/Flu B Test Kit contains the following components.

- Puritan Rayon Swabs for nasal swab collection (25)
- Accula Nasal Swab Buffer (25)
- Accula Transfer Pipettes (25)
- Accula Flu A/Flu B Test Cassettes (25)
- Control Swab (1): Flu A+; Flu B-
- Control Swab (1): Flu B+; Flu A-
- Package Insert
- Quick Reference Instructions

Accula Dock

The Accula Dock is an electronic module which executes *in vitro* diagnostic tests on compatible Mesa Biotech Test Cassettes. It consists of an electro-mechanical interface to a single Test Cassette. The Dock contains all electrical systems, controls and logic necessary to orchestrate *in vitro* diagnostic tests within the inserted Test Cassette.

Upon insertion of a Test Cassette, the Dock will detect and identify the Cassette type. After the user transfers a clinical test sample into the Cassette and closes the Dock lid, embedded firmware in the Dock will control fluid flow of the sample into the various chambers of the Cassette, apply controlled voltage signals to the various Cassette heaters (monitored by sensors within the Dock), and provide visual status to the user with critical information such as estimated time to read, and various error states, should they be encountered.

5. Indications for Use

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 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 Accula Flu A/Flu B Test to the predicate device, the Alere i Influenza A&B Test.

Item	510(k) Device: Mesa Biotech Accula Flu A/Flu B Test	Predicate Device: Alere i Influenza A&B (K141520)
Indications for Use	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.	The Alere™ i Influenza A&B assay performed on the Alere i instrument is a rapid molecular *in vitro* 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. 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. 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. If infection with a novel influenza A virus is suspected

	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.	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 cultures should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.
Assay Targets	Influenza A virus, influenza B virus	Influenza A virus, influenza B virus;
Sample Type	Nasal swab	Nasal swab
Assay Results	Qualitative	Qualitative
Intended Users and Use Locations	Clinical lab and point of care	Clinical lab and point of care
Nucleic Acid Purification	No	No
Influenza A Target	PB2 subunit gene	PB2 gene segment
Influenza B Target	Matrix Gene	PA gene segment
Internal Control	Yes	Yes
Positive and Negative Control Swabs	Yes	Yes
Assay Technology	PCR amplification and visual identification of amplification products by hybridization to a test strip.	Isothermal nucleic acid amplification and detection of specific amplification products using molecular beacon probes

Detection	Multiplex assay using dyed microparticle conjugates to specifically detect and identify amplification reaction products. Visual interpretation of the presence or the absence of colored lines on a test strip.	Multiplex assay using fluorescently-labeled molecular beacons to specifically identify each of the amplified RNA targets. Optical detection of fluorescence
Instrument	Amplification controlled by the Accula Dock. No detection by the instrument.	Amplification and detection performed on the Alere i instrument

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 flu season and from location to location.

The Mesa Biotech clinical study was conducted during the 2016-2017 influenza season. The following tables show the prevalence of influenza A and influenza B observed in three subject age categories in that clinical study.

	Prospective Clinical Study during the 2016/2017 Influenza Season		
Age Group	**Number of Nasal Swab Specimens**	**Number of Influenza A Positives**	**Influenza A Positivity Rate**
≤ 5 Years of Age	488	97	19.9%
6 to 21 Years of Age	601	172	28.6%
≥ 22 Years of Age	169	20	11.8%
Total	1258	289	23.0%

	Prospective Clinical Study during the 2016/2017 Influenza Season		
Age Group	**Number of Nasal Swab Specimens**	**Number of Influenza B Positives**	**Influenza B Positivity Rate**
≤ 5 Years of Age	488	27	5.5%
6 to 21 Years of Age	601	91	15.1%
≥ 22 Years of Age	169	8	4.7%
Total	1258	126	10.0%

Accula™ Flu A/Flu B Test vs. a FDA-Cleared Molecular Influenza Assay: Prospective Clinical Study

Clinical performance characteristics of the Accula Flu A/Flu B Test were evaluated in a multi-site prospective study during the 2016-2017 flu season in the U.S. A total of sixteen investigational sites participated in the study. To be enrolled in the study, patients had to be presenting at the participating study centers with flu-like symptoms. Two nasal swabs were collected from one nostril from each subject using standard collection methods. One nasal swab was eluted in 5-mL of Accula Nasal Swab Buffer and tested with the Accula Flu A/Flu B Test according to product instructions. The other nasal swab was eluted in a 3-mL of viral transport media (VTM) and transported to one of two central laboratories for testing using the comparator method. All discrepant results were analyzed using an alternative FDA-cleared molecular assay at the reference laboratory.

A total of 1331 subjects were enrolled in this study. Of those, 73 specimens are unevaluable (i.e., failed to meet inclusion/exclusion criteria, were not transported to a Reference Laboratory per the conditions required by the clinical protocol, had invalid result for the comparator assay or had two invalid results on the Accula Flu A/Flu B Test. A total of 1258 specimens were considered evaluable. The performance of the Accula Flu A/Flu B test for influenza A and influenza B as compared to a FDA-cleared molecular comparator are presented in the tables below.

Accula Flu A/Flu B Test Flu A Performance against the Comparator Method

Accula Flu A/Flu B - **Flu A**	Comparator		
	Positive	Negative	Total
Positive	289	60[a]	349
Negative	9[b]	900	909
Total	298	960	1258
Sensitivity:	97% (95% CI: 94.1% - 98.5%)		
Specificity:	94% (95% CI: 92.0% - 95.2%)		

[a] FLU A was detected in 47/60 False Positives specimens using an alternative FDA-cleared molecular Influenza A+B Assay
[b] FLU A was not detected in 3/9 False Negative specimens using an alternative FDA-cleared molecular Influenza A+B Assay

Accula Flu A/Flu B Test Flu B Performance against the Comparator Method

Accula Flu A/Flu B - **Flu B**	Alere™ i Influenza A & B Assay		
	Positive	Negative	Total
Positive	126	14[a]	140
Negative	8[b]	1110	1118
Total	134	1124	1258
Sensitivity:	94% (95% CI: 88.2% - 97.2%)		
Specificity:	99% (95% CI: 97.9% - 99.3%)		

[a] FLU B was detected in 9/14 False Positives specimens using an alternative FDA-cleared molecular Influenza A+B Assay
[b] FLU B was not detected in 5/8 False Negative specimens using an alternative FDA-cleared molecular Influenza A+B Assay

Reproducibility Studies

The Reproducibility study was performed to demonstrate the reproducibility of the Accula Flu A/Flu B Test with 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.

The test panel consisted of five samples at virus concentration near the respective LoD (i.e., Flu A and B Negative, Flu A Low Positive, Flu A Moderate Positive, Flu B Low Positive and Flu B Moderate Positive). Each sample was prepared using the Flu A and B strains spiked into clinical matrix. The Flu A strain used in this study was Flu A/California/07/2009 and the Flu B strain used in this study was Flu B/Massachusetts/2/2012. The targeted concentrations for the Moderate Positive samples were approximately 3 X the respective LoD, the targeted concentrations for the Low Positive samples were approximately 1 X the respective LoD (C95 concentration), and the Flu A and B Negative samples contained no Flu virus.

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). 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 as percent agreement: actual result/expected result x 100. Results were evaluated by site, by operator and by day. Agreement was 100% across all sites, operators and days. Two

samples did not produce results because re-tests of invalid results were invalid on re-test. Results are shown below by site.

Site to Site Reproducibility: Percent Agreement

Sample Category	Site								Overall % and 95% CI
	Site 1		Site 2		Site 3		Site 4		
	%	Count	%	Count	%	Count	%	Count	
Low Pos Flu A	100%	30/30	100%	30/30	100%	29/29*	100%	30/30	100% (119/119) (96.9%, 100%)
Mod Pos Flu A	100%	29/29*	100%	30/30	100%	30/30	100%	30/30	100% (119/119) (96.9%, 100%)
Low Pos Flu B	100%	30/30	100%	30/30	100%	30/30	100%	30/30	100% (120/120) 96.9%, 100%)
Mod Pos Flu B	100%	30/30	100%	30/30	100%	30/30	100%	30/30	100% (120/120) (96.9%, 100%)
True Neg	100%	30/30	100%	30/30	100%	30/30	100%	30/30	100% (120/120) (96.9%, 100%)
*re-run of second test resulted in an invalid									

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

Limit of Detection

Multiple analyte levels were tested in 20 replicates until the LoD was determined (the level at which at least 19/20 results are positive). 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. Virus was serially diluted into Pooled Negative Clinical Matrix and spiked onto a swab to create the contrived sample for each technical replicate in LoD determination.

Limit of Detection: Observed/Expected

Volume Spiked Swab	Final Concentration (TCID50/mL)	Observed/ Expected Positives
10 µL	A/CA 300 TCID50/mL	20/20
10 µL	***A/CA 300 TCID50/mL***	***20/20***
10 µL	A Texas 2400 TCID50/mL	20/20
10 µL	***A Texas 1200 TCID50/mL***	***20/20***

10 µL	B Nevada 675 CEID50/mL	18/20
10 µL	***B Nevada 1350 CEID50/mL***	***20/20***
10 µL	B/MA 300 TCID50/mL	17/18
10 µL	***B/MA 400 TCID50/mL***	***20/20***

The limit of detection (LoD) for the Accula Flu A/Flu B Test for both Flu A and Flu B were determined with ≥ 95% detection at:

A/California/07/2009 (H1N1): 300 TCID50/mL

A/Texas/50/2012 (H3N2): 1200 TCID50/mL

B/Nevada/3/2011 (Victoria): 1350 CEID50/mL

B/Massachusetts/2/2012 (Yamagata): 400 TCID50/mL

Analytical Reactivity

Inclusivity verification was evaluated for the Accula Flu A/Flu B test at Mesa Biotech. The panel consisted of 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. At least ten (10) Influenza A strains and five (5) Influenza B strains were included, and emphasis was placed on contemporary strains. Virus was diluted into a Pooled clinical matrix and spiked onto a swab to create contrived swab samples. Each strain was tested in triplicate, at final concentration of about 2x LoD of each Influenza subtype. The following test results were obtained.

Inclusivity Verification: Influenza A and Influenza B Strains, Target Concentrations and Test Results

Influenza Strain	Subtype/ Lineage	Viral Titer TCID50/mL[a]	Flu A Test Result (# of FluA Positive /3)	Flu B Test Result (# of FluB Positive /3)
A/Beijing/262/1995	H1N1	6.00E+02	3/3	0/3
A/Brisbane/59/2007	H1N1	6.00E+02	3/3	0/3
A/Brisbane/10/2007	H3N2	2.40E+03	3/3	0/3
A/England/42/1972	H3N2	2.40E+03	3/3	0/3
A/Fort Monmouth/1/1947	H1N1	6.00E+02	3/3	0/3
A/New Caledonia/20/1999	H1N1	6.00E+02	3/3	0/3
A/Perth/16/2009	H3N2-like	2.40E+03	3/3	0/3
A/Port Chalmers/1/1973	H3N2	2.40E+03	3/3	0/3
A/Puerto Rico/8/1934	H1N1	6.00E+02	3/3	0/3
A/Solomon Islands/3/2006	H1N1	6.00E+02	3/3	0/3
A/Switzerland/9715293/2013	H3N2-like	2.40E+03	3/3	0/3
A/Sydney/5/1997	H3N2	2.40E+03	3/3	0/3
A/Victoria/3/1975	H3N2	2.40E+03	3/3	0/3
A/Victoria/361/2011	H3N2	2.40E+03	3/3	0/3

Influenza Strain	Subtype/ Lineage	Viral Titer TCID50/mL[a]	Flu A Test Result (# of FluA Positive /3)	Flu B Test Result (# of FluB Positive /3)
A/Wisconsin/67/2005	H3N2-like	2.40E+03	3/3	0/3
B/Brisbane/60/2008	Victoria	2.70E+03	0/3	3/3
B/Florida/4/2006	Yamagata	8.00E+02	0/3	3/3
B/Lee/1940	Victoria	2.70E+03	0/3	3/3
B/Malaysia/2506/2004	Victoria	2.70E+03	0/3	3/3
B/Maryland/1/1959	Yamagata	8.00E+02	0/3	3/3
B/Phuket/3073/2013	Yamagata	8.00E+02	0/3	3/3
B/Russia/1969	Yamagata	8.00E+02	0/3	3/3
B/Wisconsin/1/2010	Yamagata	8.00E+02	0/3	3/3
[a] *Concentration of contrived sample after 10uL of virus dilution Spiked onto Swab and Swirled in 5mL assuming 100% viral elution recovery.*				

All twenty-three (23) strains of Influenza were detected with the Mesa Biotech FluA/FluB Test at concentration of about 2x LoD.

The Analytical Specificity (Cross- Reactivity)

The analytical specificity was evaluated with a panel of common organisms when tested on the Accula Flu A/Flu B assay internally at Mesa Biotech. Thirty-three (33) organisms were obtained from Zeptometrix Corporation excepted for *Chlamydia pneumonia* and *Corynebacterium glycinophilum* (were obtained from ATCC). These potentially cross-reacting non-influenza organisms were tested in replicates of three (3) in this study. The organisms were diluted into a Pooled Negative Nasal Sample (PNNS) matrix to create samples at the concentration in the table below for testing.

Analytical Exclusivity – Organisms Tested, Concentrations and Test Results

Organism Key #	Organism Name	Stock Concentration	Test Level	FluA Result (# Positive / 3)	FluB Result (# Positive / 3)
1	Adenovirus Type 1	1.02E+08 TCID50/mL	5.10E+05 TCID50/mL	0/3	0/3
2	Adenovirus Type 7	6.61E+06 TCID50/mL	3.31E+04 TCID50/mL	0/3	0/3
3	Human herpesvirus 5 (Cytomegalovirus)	2.19E+06 TCID50/mL	1.10E+04 TCID50/mL	0/3	0/3
4	Human coronavirus 229E	2.19E+06 TCID50/mL	1.10E+04 TCID50/mL	0/3	0/3
5	Human coronavirus OC43	5.89E+07 TCID50/mL	2.95E+05 TCID50/mL	0/3	0/3
6	Human Enterovirus 71 (HEV-71)	4.17E+05 TCID50/mL	1.04E+04 TCID50/mL	0/3	0/3
7	Epstein-Barr virus	7.95E+09 cp/mL	3.98E+07 cp/mL	0/3	0/3
8	Human parainfluenza virus 1	1.26E+06 TCID50/mL	1.26E+04 TCID50/mL	0/3	0/3
9	Human parainfluenza virus 2	2.19E+06 TCID50/mL	1.10E+04 TCID50/mL	0/3	0/3

10	Human parainfluenza virus 3	5.89E+05 TCID50/mL	1.18E+04 TCID50/mL	0/3	0/3
11	Measles virus	5.89E+07 TCID50/mL	2.95E+05 TCID50/mL	0/3	0/3
12	Human metapneumovirus	3.55E+05 TCID50/mL	1.01E+04 TCID50/mL	0/3	0/3
13	Mumps virus	1.95E+07 TCID50/mL	9.75E+04 TCID50/mL	0/3	0/3
14	Respiratory syncytial virus	3.16E+06 TCID50/mL	1.58E+04 TCID50/mL	0/3	0/3
15	Human rhinovirus 17	6.61E+06 TCID50/mL	3.31E+04 TCID50/mL	0/3	0/3
16	*Bordetella pertussis*	8.43E+08 cfu/mL	4.22E+06 cfu/mL	0/3	0/3
17	*Chlamydia pneumoniae*	≥ 5E+03 IFU/mL*	≥ 1.67E+04 IFU/mL	0/3	0/3
18	*Corynebacterium glycinophilum*	≥ 5.56E+07 IFU/mL**	≥ 1.59E+06 IFU/mL	0/3	0/3
19	*Escherichia coli*	3.83E+09 cfu/mL	1.92E+07 cfu/mL	0/3	0/3
20	*Haemophilus influenzae*	2.40E+08 cfu/mL	1.20E+06 cfu/mL	0/3	0/3
21	*Lactobacillus sp.*	6.00E+08 cfu/mL	3.00E+06 cfu/mL	0/3	0/3
22	*Legionella longbeachae*	1.93E+09 cfu/mL	9.65E+06 cfu/mL	0/3	0/3
23	*Moraxella catarrhalis*	3.97E+07 cfu/ml	1.99E+05 cfu/ml	0/3	0/3
24	*Mycobacterium tuberculosis*	7.23E+08 cfu/mL	3.62E+06 cfu/mL	0/3	0/3
25	*Mycoplasma pneumoniae*	5.62E+07 CCU/mL	2.81E+05 CCU/mL	0/3	0/3
26	*Neisseria meningitidis*	2.55E+08 cfu/mL	1.28E+06 cfu/mL	0/3	0/3
27	*Neisseria subflava*	1.46E+09 cfu/mL	7.30E+06 cfu/mL	0/3	0/3
28	*Pseudomonas aeruginosa*	1.21E+08 cfu/mL	6.05E+05 cfu/mL	0/3	0/3
29	*Staphylococcus aureus*	1.39E+10 cfu/mL	6.95E+07 cfu/mL	0/3	0/3
30	*Staphylococcus epidermidis*	6.47E+09 cfu/mL	3.24E+07 cfu/mL	0/3	0/3
31	*Streptococcus pneumonia*	4.17E+08 cfu/mL	2.09E+06 cfu/mL	0/3	0/3
32	*Streptococcus pyogenes*	5.43E+09 cfu/mL	2.72E+07 cfu/mL	0/3	0/3
33	*Streptococcus salivarius*	4.63E+08 cfu/mL	2.32E+06 cfu/mL	0/3	0/3

All 33 exclusivity organisms were negative at the concentrations tested. Exclusivity is verified for the strains tested.

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. Additionally, each strain was tested without the interfering substance as a control.

The results are shown in the table. The Accula Flu A/Flu B test performance is not negatively affected by the potentially interfering substances under "worst case" concentration conditions.

Interfering Substances: Agreement of Observed/Expected

Interferent Description, Concentration	Target	% Agreement with Expected Results
Mucin, 20 µg Mucin/mL	Negative	100% (3/3)
	FluA/Cali	100% (3/3)
	FluA/Texas	100% (3/3)
	FluB/Nevada	100% (3/3)
	FluB/Mass	100% (3/3)
Blood (Human) 1% (v/v)	Negative	100% (3/3)
	FluA/Cali	100% (3/3)
	FluA/Texas	100% (3/3)
	FluB/Nevada	100% (3/3)
	FluB/Mass	100% (3/3)
Neo-Synephrine (phenylephrine nasal spray)	Negative	100% (3/3)
	FluA/Cali	100% (3/3)
	FluA/Texas	100% (3/3)
	FluB/Nevada	100% (3/3)
	FluB/Mass	100% (3/3)
Afrin (Oxymetazoline nasal spray)	Negative	100% (3/3)
	FluA/Cali	100% (3/3)
	FluA/Texas	100% (3/3)
	FluB/Nevada	100% (3/3)
	FluB/Mass	100% (3/3)
Nasacort (Triamcinolone, nasal corticosteroid)	Negative	100% (3/3)
	FluA/Cali	100% (3/3)
	FluA/Texas	100% (3/3)
	FluB/Nevada	100% (3/3)
	FluB/Mass	100% (3/3)
No Interferent	Negative	100% (3/3)
	FluA/Cali	100% (3/3)
	FluA/Texas	100% (3/3)

Interferent Description, Concentration	Target	% Agreement with Expected Results
	FluB/Nevada	100% (3/3)
	FluB/Mass	100% (3/3)
Zicam (Nasal gel, homeopathic allergy relief medicine)	Negative	100% (3/3)
	FluA/Cali	100% (3/3)
	FluA/Texas	100% (3/3)
	FluB/Nevada	100% (3/3)
	FluB/Mass	100% (3/3)
Cepacol (throat lozenge)	Negative	100% (3/3)
	FluA/Cali	100% (3/3)
	FluA/Texas	100% (3/3)
	FluB/Nevada	100% (3/3)
	FluB/Mass	100% (3/3)
Zanamivir (anti-viral drug) 10mg/mL	Negative	100% (3/3)
	FluA/Cali	100% (3/3)
	FluA/Texas	100% (3/3)
	FluB/Nevada	100% (3/3)
	FluB/Mass	100% (3/3)
Mupirocin (antibiotic) 12 mg/mL	Negative	100% (3/3)
	FluA/Cali	100% (3/3)
	FluA/Texas	100% (3/3)
	FluB/Nevada	100% (3/3)
	FluB/Mass	100% (3/3)
Tobramycin (antibacterial) 2.43 mg /mL	Negative	100% (3/3)
	FluA/Cali	100% (3/3)
	FluA/Texas	100% (3/3)
	FluB/Nevada	100% (3/3)
	FluB/Mass	100% (3/3)

CLIA Waiver Studies

Clinical Performance by Intended Users

The performance of the Accula Flu A/Flu B Test was evaluated at sixteen intended use sites by non-laboratory personnel in a prospective clinical study during the 2016-2017 flu season in the U.S. Nasal swabs were collected from patients with flu-like symptoms and were tested with the Accula Flu A/Flu B Test and the comparator method, a FDA-cleared molcular influenza assay. All specimens generating discrepant results were investigated by testing using an alternative FDA-cleared molcular assay. The performance of the Accula Flu A/Flu B test for influenza A and influenza B compared with the comparator method are presented in the tables below.

Accula Flu A/Flu B Test Flu A performance against the Comparator Method

Accula Flu A/Flu B - **Flu A**	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 Positives specimens using an alternative FDA-cleared molecular Influenza Assay
[b] FLU A was not detected in 3/9 False Negative specimens using an alternative FDA-cleared molecular Influenza Assay

Accula Flu A/Flu B Test Flu B performance against the Comparator Method

Accula Flu A/Flu B - **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 B was detected in 9/14 False Positives 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

The study demonstrates the performance of the Accula Flu A /Flu B test in a CLIA Waived clinical setting.

Performance Near the Cut-Off

Three CLIA-waived sites that participated in the prospective clinical study participated in the Near Cut-off study. The testing was performed by three (3) untrained intended operators at each of the sites. This study was conducted to demonstrate that untrained intended users could perform the Accula Flu A/Flu B Test and consistently detect Low Positive samples at the Limit of Detection.

The test panel consisted of three contrived samples: Flu A Low Positive, Flu B Low Positive, and a True Negative. Each sample was prepared using Flu A and B strains spiked into clinical

matrix. The Flu A strain used in this study was Flu A/California/07/2009 and the Flu B strain used in this study was Flu B/Massachusetts/2/2012. The targeted concentrations for the Low Positive samples were approximately 1 X the respective LoD (C95 concentration), and the Flu A and B Negative samples contained no Flu virus. Test samples of Influenza A or Influenza B were coded and blinded to the operators. Swab specimens were presented to the intended use operators throughout the course of a normal testing day and were masked as subject samples. Testing took place over the course of two weeks on non-consecutive days, while the clinical study was in progress. Each operator tested 5 samples each testing day. Each site ultimately tested a panel of 60 samples: 20 replicates of each sample. Testing was performed with one lot of Accula Flu A/Flu B Test cassettes.

Test results are shown in the table below. This study demonstrates untrained intended use operators are able to accurately perform and interpret the Mesa Biotech Flu A/Flu B test at the level of the LoD for both Influenza A and Influenza B.

Near Cut-off Study Test Results: Agreement of Observed/Expected

Site	Swab Type		
	Low A Positive/Total	Low B Positive/Total	Negative/Total
ADP	19/20	19/20	19/19*
DCO	20/20	20/20	20/20
GVP	19/20	19/20	20/20
Total Agreement	58/60 = 97%	58/60 = 97%	59/59 = 100%
*****1 negative result resulted in an unresolved Invalid (2 invalid results on the same sample)			

8. Conclusion

The information presented in this Premarket Notification demonstrates that the performance of the Accula Flu A/Flu B Test is substantially equivalent in intended use, technological characteristics, and performance to the predicate device, thereby supporting 510(k) clearance.