March 24, 2026

Lumos Diagnostics, Inc.
Susan Hibbeln
Vice President, Regulatory Affairs
2724 Loker Ave. W.
Carlsbad, California 92010

Re: K260787
Trade/Device Name: FebriDx Bacterial / Non-bacterial Assay
Regulation Number: 21 CFR 866.3230
Regulation Name: Device To Detect And Measure Non-Microbial Analytes To Aid In The Detection And Identification Of Localized Human Infections
Regulatory Class: Class II
Product Code: QXA
Dated: March 10, 2026
Received: March 10, 2026

Dear Susan Hibbeln:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

BRYAN M. GRABIAS -S
2026.03.24 12:03:11 -04'00'

Bryan Grabias, Ph.D.
Acting Branch Chief
Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260787

Device Name
FebriDx Bacterial / Non-bacterial Assay

Indications for Use *(Describe)*
The FebriDx Bacterial/Non-bacterial Assay is a qualitative visually read rapid immunoassay for the detection of human host response proteins, Myxovirus resistance protein A (MxA) and C-reactive protein (CRP) directly from fingerstick blood. FebriDx is indicated for use in patients aged 12-64 for evaluation of acute respiratory infection who have had symptoms for less than 7 days and within 3 days of fever onset.

FebriDx test results are intended to be used in conjunction with other clinical and diagnostic findings as an aid in the diagnosis of bacterial acute respiratory infection and differentiation from non-bacterial etiology. The assessment of whether a bacterial infection is present should always be based on consideration of all available information, and not based solely on the FebridDx test results. FebriDx test results are not intended to identify a specific pathogen or the severity of infection.

FebriDx External Controls:
FebriDx External Controls are used in the FebriDx Test as assayed quality control samples to assess the performance and reliability of the FebriDx Test.

Special conditions for use statement(s):
• For in vitro diagnostic use
• For prescription use only

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.

510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

A. 510(k) Number: K260787

B. Applicant:

Lumos Diagnostics, Inc.
2724 Loker Avenue W
Carlsbad, CA 92010

Contact: Sue Hibbeln, MS, RAC
Telephone: 855.586.6739
Email: Sue.Hibbeln@LumosDiagnostics.com

Date Prepared: March 10, 2026

C. Proprietary and Established Names: FebriDx® Bacterial / Non-bacterial Assay

D. Purpose for Submission: To obtain 510(k) clearance for the FebriDx® device.

E. Measurand: Dual biomarkers: Myxovirus resistance protein A (MxA) and C-reactive protein (CRP)

F. Type of Test: Lateral flow qualitative immunoassay

G. Regulatory Information:

1. **Regulation section:** 21 CFR 866.3230
2. **Classification:** Class II
3. **Product code(s):** QXA
4. **Panel:** MI – Microbiology

H. Intended Use / Indications for Use:

The FebriDx Bacterial/Non-Bacterial Assay is a qualitative visually read rapid immunoassay for the detection of human host response proteins, Myxovirus resistance protein A (MxA) and C-reactive protein (CRP) directly from fingerstick blood. FebriDx is indicated for use in patients aged 12-64 for evaluation of acute respiratory infection who have had symptoms for less than 7 days and within 3 days of fever onset.

FebriDx test results are intended to be used in conjunction with other clinical and diagnostic findings as an aid in the diagnosis of bacterial acute respiratory infection and differentiation from non-bacterial etiology. The assessment of whether a bacterial infection is present should always be based on consideration of all available information and not based solely on the FebriDx test results. FebriDx test results are not intended to identify a specific pathogen or the severity of infection

FebriDx External Controls:
FebriDx External Controls are used in the FebriDx Test as assayed quality control samples to assess the performance and reliability of the FebriDx Test.

Special conditions for use statement(s):

- For *in vitro* diagnostic use
- For prescription use only

I. Device Description:

FebriDx Test:
FebriDx is a rapid lateral flow immunoassay for the visual, qualitative, in vitro detection of elevated levels of host response proteins, Myxovirus resistance protein A (MxA) and C-reactive protein (CRP), directly from fingerstick blood to aid in the evaluation of acute respiratory infections. The single-use, disposable FebriDx test is an all-in-one integrated platform that includes a lateral flow test strip, a built-in retractable safety lancet, blood collection and transfer tube and buffer delivery system. The FebriDx test produces a visual-read qualitative result. Operators interpret the test and can visually see whether the infection may be due to a bacterial infection or other non-bacterial etiology.

FebriDx External Controls:

FebriDx External Controls to monitor performance and reliability of the FebriDx test are sold separately. FebriDx External Controls are a two-vial set with one negative buffer and one positive control containing recombinant CRP and MxA.

J. Test Principle:

Myxovirus resistance protein A (MxA) and C-reactive protein (CRP) are non-microbial proteins produced by the innate host response (e.g., interferons, interleukins, and the Complement System) in response to infection. The FebriDx test includes a built-in sample collection and transfer tube and detects the presence of MxA and CRP in fingerstick blood specimens using lateral flow technology. A sample of the fingerstick blood is added to the lateral flow test device; followed by a running buffer that provides sufficient volume to activate the test. The running buffer contains leukocyte membrane lysing agents that release intracellular MxA to allow subsequent detection. The first pad in the device filters out the cellular material as well as intact red-blood cells. The filtered sample then contacts a pad that contains the reagents to adjust pH and prevent non-specific binding. Prior to reaching the test strip, free MxA and CRP migrate through a dried formulation of latex beads that have been further conjugated to antibodies specific for binding a particular analyte (MxA or CRP). As the Analyte-Antibody-Bead complex continues to migrate across a porous nitrocellulose membrane, it can interact with one of three capture antibodies that are immobilized on the surface at distinct line positions, including the control line to verify that the device flowed properly. A black line present in the result window indicates a positive result (bacterial) and a red line in the result window or the absence of a line in the result window indicates a non-bacterial etiology, i.e., negative for bacterial infection. FebriDx® simultaneously detects MxA at the medical decision point of approximately 40 ng/mL and CRP of approximately 20 mg/L serum equivalent.

K. Substantial Equivalence Information:

1. **Predicate Device Name:**
   FebriDx Bacterial / Non-bacterial Point-of-Care Assay

2. **Predicate Number:**
   K230917

3. Comparison with Predicate:

	K230917 FebriDx® Bacterial/Non-Bacterial Point-of-Care Assay	**K260787** FebriDx® Bacterial/Non-Bacterial Assay
Manufacturer	**Lumos Diagnostics, Inc.**	Same as predicate
Intended Use	The FebriDx® Bacterial/Non-bacterial Point-of-Care Assay is a qualitative visually read rapid immunoassay for the detection of human host response proteins, Myxovirus resistance protein A (MxA) and C-reactive protein (CRP) directly from fingerstick blood. FebriDx is indicated for use in patients aged 12-64 who present to urgent care or emergency care settings for evaluation of acute respiratory infection who have had symptoms for less than 7 and within 3 days of fever onset. FebriDx test results are intended to be used in conjunction with other clinical and diagnostic findings as an aid in the diagnosis of bacterial	The FebriDx® Bacterial/Non-bacterial Assay is a qualitative visually read rapid immunoassay for the detection of human host response proteins, Myxovirus resistance protein A (MxA) and C-reactive protein (CRP) directly from fingerstick blood. FebriDx is indicated for use in patients aged 12-64 for evaluation of acute respiratory infection who have had symptoms for less than 7 and within 3 days of fever onset. FebriDx test results are intended to be used in conjunction with other clinical and diagnostic findings as an aid in the diagnosis of bacterial acute respiratory infection and differentiation from non-

	acute respiratory infection and differentiation from non-bacterial etiology. The assessment of whether a bacterial infection is present should always be based on consideration of all available information, and not based solely on the FebriDx test results. FebriDx test results are not intended to identify a specific pathogen or the severity of infection.	bacterial etiology. The assessment of whether a bacterial infection is present should always be based on consideration of all available information, and not based solely on the FebriDx test results. FebriDx test results are not intended to identify a specific pathogen or the severity of infection.
Intended Use External Controls	FebriDx External Controls are used in the FebriDx Test as assayed quality control samples to assess the performance and reliability of the FebriDx Test.	Same as predicate
Intended User	Professional Use	Same as predicate
Equipment	Visually read	Same as predicate
Measurement	Qualitative	Same as predicate
Device Format	Single use disposable	Same as predicate
Analyte	One or more non-microbial analytes	Same as predicate
Measurand	MxA/CRP	Same as predicate
Test Type	Lateral Flow immunochromatographic assay	Same as predicate
Components	All-in-one cassette with lateral flow test strip, safety	Same as predicate

	lancet, blood collection and transfer tube, and buffer delivery system.	
Sample Type	Fingerstick blood	Same as predicate
Sterility	Test not provided sterile/sterile lancet included	Same as predicate
Sample Volume	5 µl	Same as predicate
External Controls	External positive and negative controls available	Same as predicate
Result time	Minimum of 10 minutes (do not read after 1 hour)	Do not read results after 1 hour or before 10 minutes

L. Standards/Guidance Documents Referenced:

1. ISO 10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
2. ISO 15223-1 Fourth Edition 2021-07 Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements
3. CLSI EP07, Third Edition, Interference Testing in Clinical Chemistry
4. CLSI EP12-A2, User Protocol for Evaluation of Qualitative Test Performance
5. CLSI EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures
6. CLSI EP18-A2, Risk Management Techniques to Identify and Control Laboratory Error Sources
7. CLSI EP25-A, Evaluation of Stability of In Vitro Diagnostic Reagents

M. Performance Characteristics:

1. **Analytical Performance:**
   a. Precision/Reproducibility

The Precision & Reproducibility study was run at three (3) sites over five (5) days with two (2) medical professionals at each site who were representative of intended users, three (3) test kit lots and eighteen (18) blinded samples per run consisting of 3 blinded replicates of each sample. The evaluated panel members included C5 and C95 concentrations of both MxA and CRP as described below.

Table 1. Panels and Sample Description

Sample	Sample Description
P1	C5 CRP / C95 MxA
P2	C95 CRP / C5 MxA
P3	C95 CRP/ C95 MxA
P4	C95 CRP / high (120 ng/mL) MxA
P5	High (150 ug/mL) CRP/ C95 MxA
P6	Negative (0 CRP/ 0 MxA)

The results demonstrate that the test is reproducible across the expected range of variability that would be encountered during normal expected use in the intended use setting. Results are summarized in the following table:

Table 2. Reproducibility Study Results Final Interpretation – By Site

Sample	% Agreement with Expected Results				
	Site 1	**Site 2**	**Site 3**	**Overall**	**95% CI**
P1	80% (24/30)	70% (21/30)	76.7% (23/30)	75.6% (68/90)	65.8-83.3%
P2	100% (30/30)	90% (27/30)	73.3% (22/30)	87.8% (79/90)	79.4-93.0%
P3	100% (30/30)	90% (27/30)	100% (30/30)	96.7% (87/90)	90.7-98.9%
P4	100%	100%	100%	100%	95.9-100%

Sample	% Agreement with Expected Results				
	Site 1	Site 2	Site 3	Overall	95% CI
	(30/30)	(30/30)	(30/30)	(90/90)	
P5	100% (30/30)	90% (27/30)	93.3% (28/30)	94.4% (85/90)	87.7-97.6%
P6	100% (30/30)	90% (27/30)	100% (30/30)	96.7% (87/90)	90.7-98.9%

Table. 3 Reproducibility Study Results Final Interpretation – By *Lot*

Sample	% Agreement with Expected Results		
	Lot 1	Lot 2	Lot 3
P1	75% (27/36)	80.5% (29/36)	66.7% (12/18)
P2	83.3% (30/36)	91.7% (33/36)	88.9% (16/18)
P3	100% (36/36)	100% (36/36)	83.3% (15/18)
P4	100% (36/36)	100% (36/36)	100% (18/18)
P5	91.7% (33/36)	94.4% (34/36)	100% (18/18)
P6	100% (36/36)	100% (36/36)	83.3% (15/18)

b. Analytical Specificity

i. Cross-reactivity

Not applicable.

ii. Interfering Substances

The analytical specificity of the FebriDx test was determined by evaluating a series of samples that included MxA and CRP at the C95 concentration and negative levels in whole blood, spiked with interfering substances.

The following substances were evaluated on the FebriDx test and found to not interfere at the listed test concentrations:

Table 4. Concentrations of substances found to not interfere on FebriDx

Test Substance	Concentration
Acetaminophen	15.6 mg/dL
Acetylsalicylic acid	3 mg/dL
Alcohol	789 mg/dL
Azithromycin	1.11 mg/dL
Biotin	3500 ng/mL
Caffeine	10 mg/dL
Celecoxib	0.879 mg/dL
Cetirizine HCl	0.435 mg/dL
Conjugated Bilirubin	40 mg/dL
Dextromethorphan	1.56 ug/dL
Doxycycline	1.8 mg/dL
Furosemide	1.59 mg/dL
HAMA	524.6 ng/mL
Hemoglobin	1000 mg/dL
Ibuprofen	21.9 mg/dL
Imipenem	18 mg/dL
Levofloxacin	3.6 mg/dL
Loratadine	0.5 mg/dL
Nicotine	0.097 mg/dL
Oxymetazoline HCl	0.09 mg/dL
Phenylephrine	0.003 mg/dL
Prednisolone	0.120 mg/dL
Protein (total)	9 g/dL
Rheumatoid Factor (RF)	50 IU/mL
Salmeterol	6.03 ug/dL
Tiotropium	4.80 ng/dL
Triglycerides	1500 mg/dL

Unconjugated Bilirubin	40 mg/dL
Vancomycin	12 mg/dL

The results of the FebriDx Interfering Substances Verification Study showed that the test substances did not interfere with the FebriDx test at the listed concentrations and acceptance criteria were met. Of note (*), Rheumatoid Factor levels of up to 1000 IU/mL were evaluated and false negative/false positive results were identified. The interference effect disappeared at concentrations less than or equal to 50 IU/mL.

c. Detection Limit

The Limits of Detection (LoD) for the CRP and MxA assays on the FebriDx test were determined on two (2) lots of tests. A series of whole blood samples spiked with MxA and CRP analytes at concentrations spanning the assay range were blinded to test operators, tested, and read to determine the Limit of Detection (LoD) concentration (C95) and the C5:

Table 5. Limit of Detection (LoD) Concentrations

	MxA (ng/mL)		CRP (ug/mL)	
Lot	**C5**	**C95 (LoD)**	**C5**	**C95 (LoD)**
1	19	38	9	17
2	19	38	9	16

Based on the study results, the LoD (C95) was conservatively established as 40 ng/mL for the MxA assay and as 20 ug/mL for the CRP assay.

d. High Dose Hook Effect

The Hook Effect study assessed whether a hook effect exists on either the CRP and/or the MxA assays on the FebriDx test. MxA and CRP analytes were spiked into blood at the high concentrations shown in the table below and tested in replicates of ten (10) for each sample.

Table 6. Hook Effect

Sample ID	MxA (ng/mL)	CRP (µg/mL)
1	700	1000
2	600	800
3	500	600
4	400	500
5	200	250
6	100	125
7	50	62.5
8	0	0

These results indicate that there is no hook effect in the FebriDx test for the CRP assay up to a concentration of 1000 ug/mL and for the MxA assay up to a concentration of 700 ng/mL.

e. Assay cut-off

Not applicable.

f. Matrix Equivalency

Due to difficulties obtaining sufficient volumes of capillary blood, analytical studies for the FebriDx test were conducted with venous whole blood. To demonstrate equivalent analytical performance between venous whole blood and capillary fingerstick blood, a matrix equivalency study was conducted and similar LoDs for MxA and CRP were established for both matrices. This data is not intended to support a venous blood sample type.

g. Controls

i. Internal Controls

The FebriDx test has built-in procedural controls represented by a blue control line. For daily quality control, Lumos Diagnostics recommends documenting the procedural controls for the first sample tested each day.

ii. External Controls

External controls should be used to demonstrate that the reagents and assay perform properly. External controls (one positive and one negative) are optional and are not supplied with the FebriDx test kit (i.e. box of 25 devices). External controls should be used, consistent with good laboratory practices, to verify test performance. The manufacturer recommends external controls be run with every new lot, every new shipment, and with every first-time operator, but every testing site should follow their own protocols for running external controls.

h. Stability

Real time Stability Study

Real time stability was performed on three (3) production lots of the FebriDx test to support the recommended storage conditions of 4-25°C and demonstrated stability of 24 months.

Transport Stability Study

A transport stability study was performed on one (1) production lot of the FebriDx test. Results demonstrated that the FebriDx test is stable when exposed to expected conditions of transport.

In-Use Stability Study

In-use stability of one (1) lot of FebriDx tests was evaluated at various timepoints by a minimum of three (3) operators at each timepoint after being removed from the sealed packaging and being exposed to the environment (open pouch stability). The study demonstrated in-use stability of up to 45 minutes after removal from sealed packaging.

External Quality Controls Shelf-Life Testing

Real time stability was performed on three (3) production lots of the FebriDx External Quality Controls to support the recommended storage conditions of 15-25°C and demonstrated stability of 10 months.

2. Clinical Performance:

A well-controlled, prospective, multi-center blinded clinical trial was conducted in the United States (U.S.) to evaluate the clinical performance of FebriDx. The study was conducted at 20 point-of-care (POC) testing sites that were representative of the intended user and setting. Patients who presented with signs/symptoms of Acute Respiratory Infection (ARI) within 7 days and recent fever within 3 days were screened for eligibility between October 2019-April 2021. Subjects were followed at study day 7 to identify participants who were admitted to the hospital for any reason. FebriDx was compared to a composite Clinical Reference Algorithm that incorporated pathogen detection testing (bacterial culture, multiplex PCR) as well as measures of host immune response. Physician adjudicators made a final qualitative diagnosis after review of all clinical and laboratory testing data.

Comparator Method

Final diagnosis (Clinical Truth) was based on results of the Clinical Reference Algorithm (Comparator) in conjunction with adjudication by two independent expert reviewers, who were blinded to FebriDx results. Diagnostic accuracy was calculated by comparing the FebriDx result to the adjudicated Clinical Reference Algorithm. Primary analysis of diagnostic accuracy was based on positive percent agreement (PPA), negative percent agreement (NPA) and 95% confidence intervals (CI).

The following specimens were collected from each participant, on the day of FebriDx testing.

Table 7. Clinical Comparator

Comparator Testing	Visit 1
FilmArray® Respiratory Panel PCR	x
Epstein Barre Virus (EBV), Herpes Simplex Virus (HSV), Cytomegalovirus qPCR	x
Bocavirus, *Fusobacterium necrophorum*, *Neisseria gonorrhoeae* PCR	x
SARS-CoV-2 PCR	x
Bacterial Culture	x
Hematology: Complete Blood Cell Count (CBC)	x
Antibody Testing: EBV IgM	x
B.R.A.H.M.S Procalcitonin	x

Study Demographics

Participants with symptoms for acute respiratory infection and a recent fever, were eligible for enrollment in the ARI cohort and participants without signs/symptoms of acute respiratory infection were eligible for enrollment in the asymptomatic control cohort. Demographics are summarized in the following table.

Table 8. Demographics

Characteristics	Asymptomatic Controls	ARI	Withdrawal After Consent	Overall
Sex				
Female	55.3% (94/170)	55.8% (290/520)	58.8% (10/17)	55.7% (394/707)
Male	44.7% (76/170)	44.2% (230/520)	41.2% (7/17)	44.3% (313/707)
Age				
N	170	520	18	708
Mean ± SD	43.5 ± 24.4	35.2 ± 17.7	31.1 ± 17.7	37.1 ± 19.8
Median	38	32	28.5	33
(IQR)	(19.0, 69.0)	(23.0, 48.0)	(24.0, 48.0)	(22.0, 50.0)
Min, Max	3, 87	1, 95	2, 66	1, 95
Age Group				
1-21 years	31.2% (53/170)	20.8% (108/520)	22.2% (4/18)	23.3% (165/708)
22-64 years	31.8% (54/170)	71.7% (373/520)	72.2% (13/18)	62.1% (440/708)
65+ years	37.1% (63/170)	7.5% (39/520)	5.6% (1/18)	14.5% (103/708)
Race				
American Indian	0	0.4% (2/520)	0	0.3% (2/708)
Asian	1.2% (2/170)	2.7% (14/520)	0	2.3% (16/708)
Black	17.1% (29/170)	21.2% (110/520)	33.3% (6/18)	20.5% (145/708)
Other	2.4% (4/170)	7.1% (37/520)	11.1% (2/18)	6.1% (43/708)
Pacific Islander	0	0.2% (1/520)	0	0.1% (1/708)
Unknown	0	0	5.6% (1/18)	0.1% (1/708)
White	79.4% (135/170)	68.5% (356/520)	50.0% (9/18)	70.6% (500/708)
Ethnicity				
Hispanic	12.4% (21/170)	18.7% (97/520)	5.6% (1/18)	16.8% (119/708)
Not Hispanic	87.6% (149/170)	80.6% (419/520)	88.9% (16/18)	82.5% (584/708)
Declined to answer	0	0.8% (4/520)	5.6% (1/18)	0.7% (5/708)

The study included 520 symptomatic participants with suspected acute respiratory infection who met inclusion and did not meet exclusion criteria. The cohort included male and female participants from each age group (pediatric, adult, elderly) with diverse ethnic backgrounds that were comparable to the 2020 U.S Census Bureau released demographic analysis.

All participants enrolled in the symptomatic cohort had multiple symptoms, with cough and sore throat being the most prevalent**.** All participants presented with a fever ≥ 100.5°F within 72 hours of enrollment, of which 31.9% were febrile at the time of enrollment.

External Controls

Positive and negative controls were performed every day of enrollment, with every new lot or shipment and with every first-time test operator. Prior to performing testing on study participants, 100% of positive and negative controls were read as positive and negative, respectively.

Analysis

Asymptomatic Controls

Of the total enrolled asymptomatic controls, FebriDx detected a bacterial infection in 3 cases where the adjudicated clinical reference algorithm classified the case as non-bacterial (NPA 98.1% (157/160), 95% CI (94.6%-99.4%)).

Acute Respiratory Infection (ARI) Cohort

Of the total enrolled participants with acute respiratory infection, 14.0% (73/520) were classified as having bacterial infection and 81.3% (423/520) were classified as having non-bacterial etiology by the comparator. FebriDx performance characteristics for bacterial infection are shown in the following table.

Table 9. FebriDx Performance Characteristics for Bacterial Infection (Overall)

Characteristic	Estimate	95% CI
PPA	93.2% (68 / 73)	84.9% - 97.0%
NPA	88.4% (374 / 423)	85.0% - 91.1%
PPV	58.1% (68 / 117)	49.1% - 66.7%
NPV	98.7% (374 / 379)	96.9% - 99.4%
LR+	8.0	6.1 - 10.5

LR-	0.08	0.03 - 0.2

FebriDx performance was analyzed as a subgroup of microbiologically confirmed infections. The performance for bacterial infection improved; PPA increased from 93.2% to 100%; NPA increased from 88.4% to 91.0%.

Table 10. FebriDx Performance Characteristics Bacterial Infection (Microbiologically Confirmed)

Characteristic	Microbiologically Confirmed	Overall Performance
PPA (95% CI)	100% (33/33) (89%, 100%)	93.2% (68 / 73) (84.9%, 97.0%)
NPA (95% CI)	91.0% (263/289) (87%, 94%)	88.4% (374/ 423) (85.0%, 91.1%)
PPV (95% CI)	55.9% (33/59) (47%, 65%)	58.1% (68 / 117) (49.1%, 66.7%)
NPV (95% CI)	100% (263/263) (98.6%, 100%)	98.7% (374/ 379) (96.9%, 99.4%)
LR+ (95% CI)	11.1 (7.7, 16.0)	8.0 (6.1, 10.5)
LR- (95% CI)	0.0	0.08 (0.03, 0.2)

FebriDx performance was analyzed for different age groups (1-21 years, 22-64 years, 65+ years). A Fisher's exact test was performed to evaluate the potential differences in age groups. The analysis showed there are no significant differences between the age groups for PPA. The DISRUPT study was not adequately powered to evaluate differences in performance among different age or demographic groups

Table 11. FebriDx Performance Characteristics (By Age)

Characteristic	Estimate	95% CI
1-21 years		
PPA	100.0% (13 / 13)	77.2%, 100.0%
NPA	95.7% (88 / 92)	89.3%, 98.3%
LR+	23.0	8.8, 60.0
LR-	0.0	NA
22-64 years		
PPA	92.3% (48 / 52)	81.8%, 97.0%
NPA	86.7% (260 / 300)	82.4%, 90.1%
LR+	6.9	5.1, 9.3
LR-	0.1	0.03, 0.2
65+ years		
PPA	87.5% (7 / 8)	52.9%, 97.8%
NPA	83.9% (26 / 31)	67.4%, 92.9%
LR+	5.4	2.3, 12.6
LR-	0.1	0.02, 0.9

Participants were contacted on study day 7 to identify participants who were admitted to the hospital for any reason. By study day seven, 0.96% (5/520) of participants were admitted to the hospital (i.e., discharged home and returned to the hospital, requiring an overnight stay). Participants classified as 'non-bacterial' by the comparator at the initial study visit, and subsequently required hospitalization for pneumonia with objective evidence of a bacterial infection had the final classification changed to 'bacterial'. None of the admitted patients met criteria for reclassification and there were no deaths, adverse events or unanticipated device effects that occurred during the study.

N. Other Supportive Information

Flex studies were conducted to evaluate the robustness of the FebriDx Bacterial/Non-bacterial Assay given the variations in workflow and operating environment that may be reasonably expected to occur with untrained operators in the intended use CLIA Waived setting, including conditions outside of those recommended in the IFU. The following flex studies were conducted with contrived samples generated by diluting CRP and MxA at levels near the

cut-off into a whole blood matrix to appropriately stress the FebriDx Test:

- Operational Temperature and Humidity flex study
- Direct Sunlight
- Sub-optimal Lighting
- Altitude
- Contamination During Handling
- Drop Testing
- Effect of Vibration
- Operator Timings
- Incorrect Blood Delivery
- Read Time
- Surface Slope
- Vertical Movement
- Intermittent Sampling

The results of the flex studies demonstrated that the FebriDx test is robust and that false results can be expected to be reasonably mitigated through labeling.

O. Proposed Labeling:

The labeling supports the determination of substantial equivalence for this device.

P. Conclusions:

The evidence provided in this Premarket Notification is sufficient to support a determination that the subject device is substantially equivalent to the legally marketed predicate device based on intended use, technology, performance, as well as the scientific rationale.