510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K260787

B Applicant

Lumos Diagnostics, Inc.

C Proprietary and Established Names

FebriDx Bacterial / Non-Bacterial Assay

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QXA	Class II	21 CFR 866.3230 - Device To Detect And Measure Non-Microbial Analytes To Aid In The Detection And Identification Of Localized Human Infections	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

A Dual Submission to obtain a substantial equivalence determination for that the FebriDx Bacterial / Non-Bacterial Assay (FebriDx test).

B Measurand:

Myxovirus resistance protein A (MxA) and C-reactive protein (CRP

C Type of Test:

Lateral flow immunochromatography

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) 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.

For in vitro diagnostic use

For prescription use only

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

D Special Instrument Requirements:
None.

IV Device/System Characteristics:

A Device Description:

FebriDx is a 10-minute lateral flow assay that detects Myxovirus resistance protein A (MxA) and C-reactive protein (CRP) in patient fingerstick samples to aid in the evaluation of an infection in patients presenting with acute respiratory symptoms.

The single-use disposable FebriDx test includes a lateral flow test strip, a built-in retractable safety lancet, blood collection and transfer tube, and buffer delivery system

B Principle of Operation:

The FebriDx test includes a built-in sample collection and transfer tube detects the presence of MxA and CRP in fingerstick blood specimens using lateral flow technology. A sample 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 reduce potential 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 sample flowed properly across the device. In the presence of a valid blue control line, the FebriDx test result may be interpreted as one of two different outcomes: the presence of a single black line in the result window indicates a positive bacterial infection result whereas a red line in the result window or the absence of any line in the result window indicates a non-bacterial etiology

V Substantial Equivalence Information:

A Predicate Device Name(s):

FebriDx Bacterial / Non-Bacterial Point-of-Care Assay

B Predicate 510(k) Number(s):

K230917

C Comparison with Predicate(s):

Device & Predicate Device(s):	K260787	K230917
Device Trade Name	Same	FebriDx Bacterial / Non-Bacterial Point-of-Care Assay
General Device Characteristic Similarities		
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	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 days and within 3 days of fever onset.

	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. For in vitro diagnostic use For prescription use only	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. For in vitro diagnostic use For prescription use only
Measurand	Same	MxA/CRP
Test Type	Same	Lateral Flow Immunochromatographic Assay
Components	Same	All-in-one cassette with lateral flow test strip, safety lancet, blood collection and transfer tube, and buffer delivery system.
External Controls	Same	External positive and negative controls available
Measurement	Same	Qualitative
Device Format	Same	Single-use disposable
Sample Type	Same	Fingerstick blood
Sample Volume	Same	5 µL
Equipment	Same	Visually read
Result Time	Same	Minimum of 10 minutes, up to 1 hour

VI Standards/Guidance Documents Referenced:

Not applicable.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   Reproducibility of the FebriDx test was established previously. The device is unchanged from the predicate and additional studies were not required. Please refer to the public decision summary for K230917.

2. Linearity:

   Not applicable.

3. Analytical Specificity/Interference:

   Interference from endogenous and exogenous sources was established previously. The device is unchanged from the predicate and additional studies were not required. Refer to the public decision summary for K230917.

4. Detection Limit and Assay Reportable Range:

   The limit of detection for analytes detected by the FebriDx test were established previously. The device is unchanged from the predicate and additional studies were not required. Refer to the public decision summary for K230917.

   Assay reportable range is not applicable.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   External controls and reagent stability were evaluated previously. The device is unchanged from the predicate and additional studies were not required. Refer to the public decision summary for K230917.

6. Assay Cut-Off:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Please refer to section VII.C (Clinical Studies) below for the clinical validation regarding the method comparison studies.

2. Matrix Comparison:

   Not applicable.

C Clinical Studies:

1. FebriDx performance with trained users:

   The FebriDx test was previously cleared (K230917) based on results from a prospective, multi-center, blinded clinical study. The clinical performance of the FebriDx test was determined in patients presenting to a primary care provider, urgent care clinic, or the Emergency Department with signs/symptoms of acute respiratory infection and a recent fever. FebriDx clinical performance was evaluated against results of a clinical reference algorithm in conjunction with adjudication by two independent expert reviewers.

2. FebriDx performance with untrained users:

   To support use in CLIA waived settings, a user comparison study was conducted to show that FebriDx has comparable performance in the hands of untrained operators in waived settings. The clinical performance of the FebriDx test in waived settings was evaluated in a multi-center, prospective clinical study between December 2024 and July 2025. Nine clinical sites in geographically distinct regions of the U.S. (Southeast, Midwest, and West) representative of CLIA-waived intended use sites, including physician offices, primary care/outpatient clinics, and urgent care centers participated in the study. At each site, both trained and untrained operators collected a paired fingerstick sample from the same subject, with operators blinded to each other's results. FebriDx performance in the hands of untrained operators was compared to device performance with trained operator results and Positive Percent Agreement (PPA), Negative Percent Agreement (NPA) and confidence intervals were calculated.

   a. Operators:

      Sixteen untrained operators (1-3 per site) and 16 trained operators (1-2 per site) collected paired fingerstick samples from the same study subject. To avoid bias, the trained and untrained operators performed the FebriDx testing and result interpretation during the same visit but in separate spaces where they could not see the other operator. The untrained operators were representative of the CLIA-waived intended user population. The education level of the untrained operators included high school diploma, associate degree, or university education, and included clinical and administrative staff who performed various tasks in the CLIA waived setting (medical and research assistants, nurses, and phlebotomists). Information on the operators' current job title, education level and any laboratory or relevant work experience was provided. The untrained operators did not receive any training on the use of the FebriDx test and had no hands-on experience with conducting diagnostic testing in a clinical laboratory. Trained operators met the qualifications to perform CLIA moderate to high complexity testing. FebriDx performance in the hands of untrained operators was compared to performance of the trained operators.

   b. Subjects:

A total of 610 subjects were enrolled initially, of which 595 met the inclusion criteria summarized below:

Inclusion Criteria:
- Subject is willing to provide written informed consent.
- Subject is 12-64 years of age.
- Subject exhibits or reports a new onset measured temperature (oral or tympanic) of greater than or equal to 100.5°F/38°C within 3 days (72 hours) of enrollment or at the visit.
- Subject has clinical suspicion for Acute Respiratory Infection and presents with at least one (1) of the following new onset symptoms beginning ≤ 7 days of enrollment - runny nose, nasal congestion, sore throat, cough, hoarse voice or shortness of breath.

Exclusion Criteria:
- Subject is unable or unwilling to provide signed informed consent.
- Subject is less than 12 years old or over 64 years old.
- Subject has a fever that started more than 3 days prior to enrollment.
- Subject has symptoms of Acute Respiratory Infection that started > 7 days of enrollment.
- Subject is receiving interferon therapy in the last 30 days.
- Subject is in an immunocompromised state or taking immunosuppressive or chemotherapeutic medications in the last 30 days.
- Subject has taken antibiotics or antiviral therapy in the last 14 days.
- Subject received a live viral immunization in the last 14 days.
- Subject has significant trauma or burns (> 5% total body surface area or full thickness (3rd°)) in the last 30 days.
- Subject has had major surgery in the last 30 days.
- Subject has a history of a myocardial infarction or stroke in the last 30 days.

The clinical study protocol included an enriched enrollment phase if the minimum number of positive samples were not obtained during all-comer enrollment. Sites that participated in enriched enrollment screened patients for all-comer inclusion/exclusion criteria as well as the enriched criteria: fever of 100.5ºF (either within the last 72 hours or at the study visit) and a bacterial-positive test result, or a negative respiratory viral test result, or antibiotics prescribed to the subject on the day of enrollment by the treating clinician at the standard of care visit, or a bacterial positive FebriDx test interpreted by a trained operator. To mitigate potential interpretation bias and maintain operator blinding, every third subject with a negative FebriDx test result was asked to participate in the enrichment phase.

The demographic summary of the clinical subjects is shown in Table 4 below.

Table 4: Demographic Information for Study Subjects

Study Participants (N = 554)
Gender

Female	326 (58.4%)
Male	228 (41.2%)
Age Group (Years)	
12-17 years	16 (2.9%)
18-25 years	66 (11.9%)
26-45 years	242 (43.7%)
46-64 years	230 (41.5%)
Race	
Asian	7 (1.3%)
Black/African American	69 (12.5%)
White	462 (83.4%)
Other	16 (2.89%)
Ethnicity	
Hispanic	263 (47.5%)
Non-Hispanic	2912.5%)

c. *Results:*

i. Of the 610 subjects initially enrolled, 595 met the inclusion criteria. There were 41 patients re-enrolled for the enrichment phase, yielding 554 unique subjects. A total of 1216 FebriDx tests were performed (608 tests from untrained users and 608 tests from trained users). There was a total of 26 (2.1%, 95% CI 1.5-3.1%) invalid test results (13 (50%) from untrained users and 13 (50%) from trained users). All operators correctly identified the invalid test and re-ran the test as per the instructions in the QRI. Upon re-testing, all 26 tests were valid, resulting in a final invalid rate of 0% (0/1216) with 95% CI (0-0.3%).

ii. The clinical performance of the FebriDx test with fingerstick specimens, when used by untrained operators in CLIA-waived settings, is shown in Table 5 and presented as positive and negative percent agreement compared to the trained operator. The results from the user comparison study support acceptable FebriDx test performance in the hands of untrained users in CLIA-waived environments and an insignificant risk of erroneous results.

Table 5. FebriDx Clinical Performance with Untrained Users

	FebriDx Test Result (Trained Operator)		
FebriDx Test Result (Untrained Operator)	**Bacterial**	**Non-Bacterial**	**Total**
Bacterial	106	8	114
Non-Bacterial	1	480	481
Total	107	488	595
Positive Percent Agreement	99.1% (95% CI 94.4% - 99.8%)		
Negative Percent Agreement	98.4% (95% CI 96.8% - 99.2%)		

1. Clinical Cut-Off:

Not applicable.

D Expected Values/Reference Range:

Expected values/reference range for the FebriDx test were established previously. The device is unchanged from the predicate and additional studies were not required. Refer to the public decision summary for K230917.

VIII Proposed Labeling:

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

IX Conclusion:

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