FebriDx®

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INTENDED USE

FebriDx® is a rapid immunoassay for the visual, qualitative, in vitro detection of elevated levels of both MxA and CRP directly from fingerstick whole blood to aid in differentiation of bacterial from viral infection. This assay aids in the evaluation of infection by identifying and differentiating a clinically significant immune response to a suspected viral and/or bacterial infection in patients 1 year of age or older that present within 3 days of an acute onset fever (exhibited or reported) and within 7 days of new onset respiratory symptoms consistent with a community-acquired acute respiratory infection.

FebriDx® is not intended to diagnose any specific bacteria or virus, including SARS-CoV-2.

The test is intended for professional use and should be used in conjunction with other clinical evidence including laboratory, radiographic, and epidemiological information.

Negative results do not preclude respiratory infection and should not be used as the sole basis for diagnosis, treatment, or other clinical and patient management decisions. In addition to utilizing radiography and clinical presentation to aid in diagnosis, additional laboratory testing (e.g. bacterial and viral culture, immunofluorescence, and polymerase chain reaction [PCR]) may be used to confirm the presence of a specific respiratory pathogen.

SUMMARY & EXPLANATION:

Acute respiratory infections (ARIs) including sinusitis, pharyngitis, bronchitis, influenza affect 20% of the population annually. The significant overlap in symptoms and signs makes it challenging for physicians to differentiate viral from bacterial infection and to identify which patients require antibiotic therapy. The vast majority of ARIs are caused by viruses, for which antibiotics provide no clinical benefit, however 30-80% receive antibiotics.[1] The over prescription of antibiotics for ARI is a leading contributor to the global antimicrobial resistance (AMR) crisis which currently causes 700K deaths annually.[2] FebriDx® utilizes dual biomarker technology to aid in the differentiation of a viral from bacterial ARI.

BIOMARKERS

MxA (Myxovirus resistance protein A)

MxA becomes elevated in the presence of acute viral infection. MxA has a low basal concentration of less than 15 ng/mL, a fast induction time of 1-2 hours, and a long half-life of 2.3 days, making it an ideal marker for viral infection.[5] Numerous clinical studies demonstrate that MxA protein expression in peripheral blood has been shown to be a sensitive and specific marker for acute viral infection.[5-10]

CRP (C-reactive protein)

CRP is a nonspecific, acute-phase protein that increases during an inflammatory process, especially following severe infection. Bacterial infection is a potent stimulus of marked CRP elevation, which occurs within 4-6 hours of infection and peaks after 36 hours.[11,12] Some viral infections, including Influenza, Adenovirus and SARS-CoV-2 may cause CRP to elevate.[3,9,13,20]

Multiplexed Pattern of Results

In isolation, neither MxA nor CRP alone is sensitive or specific enough to differentiate viral from bacterial infection. At low levels, CRP is very sensitive but non-specific at confirming a bacterial infection. At high levels, CRP becomes very specific for bacterial infection but has low sensitivity. MxA is specific for viral infection only and is insensitive for the presence of a bacterial infection. The FebriDx® test produces a multiplexed pattern of results by simultaneously detecting elevated levels of MxA and CRP together to help identify patients suffering from clinically significant ARI as well as differentiate viral from bacterial infectious etiology.[4,14-16]

PRINCIPLES OF THE TEST

The FebriDx® test is a 10-minute lateral flow immunoassay within a plastic housing that incorporates a built-in retractable lancet, blood collection and transfer tube, and buffer release mechanism. FebriDx® utilizes monoclonal anti-MxA and anti-CRP antibodies to simultaneously detect MxA at the medical decision point of approximately 40 ng/mL and CRP of approximately 20 mg/L serum equivalent.

If the fingerstick blood samples contain elevated levels of MxA or CRP at or above their respective cut-off levels, the appropriate test line will appear in the Result Window. FebriDx® cut-off values lie within the C5-C95 Interval such that observed results concentrations outside this interval are consistently negative (< C5) or consistently positive (> C95). FebriDx® also contains a control line to indicate correct sample flow and valid results.

Materials Provided

- 25 single use FebriDx® tests
- 1 Package Insert
- 1 Quick Reference Instructions

Materials Not Provided

- Timer
- Gauze
- Alcohol
- Sterile dressing

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. Keep the FebriDx® test in the sealed foil pouch until just before use. If the foil pouch is damaged do not use the test.
3. Do not use the FebriDx® test past the expiration date.
4. Use standard precautions for collecting and handling a blood sample.
5. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
6. Wash hands before and after performing the test and wear disposable gloves while handling specimens.
7. The lancet is sterile until the protective tab is removed. Do not use the lancet if the protective tab is not secured in place.
8. The FebriDx® test is designed to proceed in sequential order and locking mechanisms exist to prevent skipping the prior step.
9. The FebriDx® test is a single-use item with no reusable components. Proper handling and disposal methods should be established according to local, state, and federal regulations.
10. The FebriDx® test requires a visual readout. Do not interpret the test result if you have color-impaired vision.
11. A brightly lit environment is recommended for interpreting the test results.

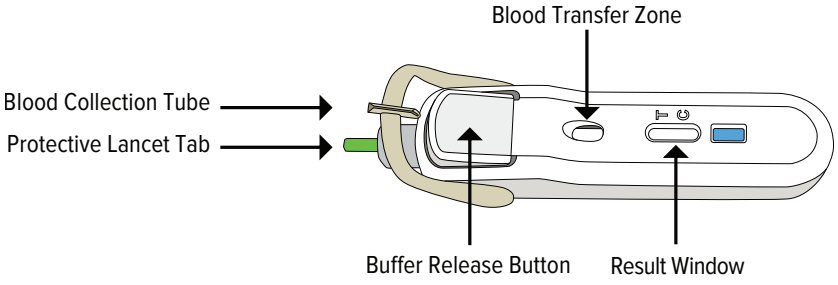
STORAGE AND STABILITY

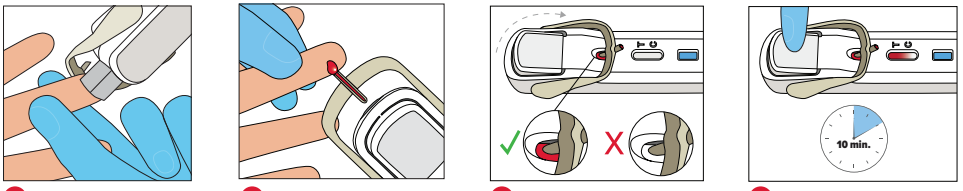
Store the FebriDx® test between 4-25°C (39-77°F). Unopened, the FebriDx® tests are stable until the expiration dates printed on their packaging.

ALTITUDE AND RELATIVE HUMIDITY (RH)

The FebriDx® test performed acceptably at altitudes between 0-2000 meters and 5-85% RH when tested immediately after removal from the foil pouch.

TEST COMPONENTS





1 Lance Finger | 2 Collect Blood | 3 Deliver Blood | 4 Deliver Buffer

TEST PROCEDURE - *Check the expiration date on all packaging.*

1. Tear open the foil pouch at the indicated perforation and remove the test just prior to testing.

Collecting and Transferring the Fingerstick Blood Sample

Note: *Use standard precautions for collecting and handling a blood sample.*

2. Cleanse the fingertip per standard practice and allow to air dry.

3. Locate the lancet and remove the **Protective Lancet Tab**. Firmly press the lancet to puncture the skin. Wipe away the first drop of blood with gauze and gently massage from the base of the finger towards the puncture site to encourage blood flow.

4. Place the **Blood Collection Tube** at approximately a 45° angle below the drop of blood and avoid touching the finger with the collection tube. Fill the **Blood Collection Tube** in its entirety by touching the blood to the tip of the **Blood Collection Tube**. If the **Blood Collection Tube** is not full, gently squeeze the finger and add more blood.

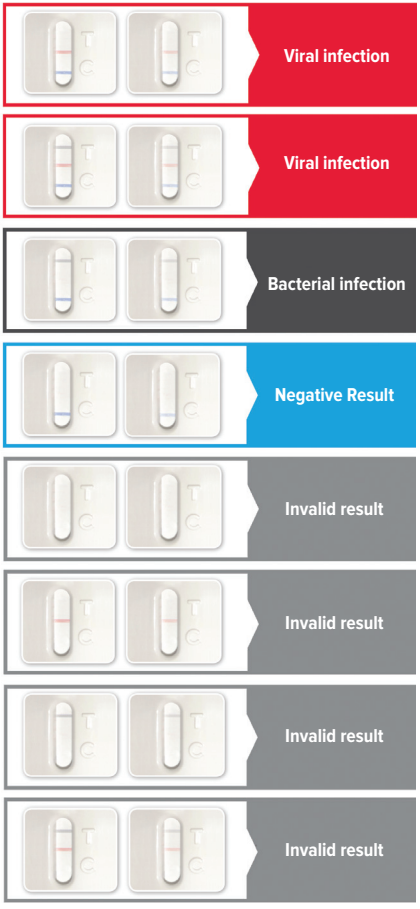
Note: *Capillary action will automatically draw the blood sample into the* ***Blood Collection Tube*** *in the required amount (5 µl).*

5. Once the **Blood Collection Tube** is filled with blood, rotate it over the **Blood Transfer Zone** to deliver it to the test. The **Blood Collection Tube** will lock into position. Wait for most of the blood to be transferred to test strip (~5-10 seconds) before proceeding to step #6 and activating the test.

Note: *Once full, the* ***Blood Collection Tube*** *should be rotated over immediately. If the blood does not immediately begin to transfer the blood onto the test strip, reverse the* ***Blood Collection Tube's*** *rotation back to its original position. This will occur against some resistance. Add additional fingerstick blood to the* ***Blood Collection Tube*** *to ensure the tube is completely filled before rotating back onto the test strip.*

6. Lay the test on a flat surface. Activate the test by firmly and fully pressing the **Buffer Release Button** to deliver the buffer. The **Buffer Release Button** should be pressed within 1 minute of transferring the blood sample. If no fluid is visible within 25-30 seconds, firmly re-press the **Buffer Release Button**. Wait for 10 minutes. Results will appear in the **Result Window**.

7. Dispose of test in the proper biohazard receptacle. After testing, remove gloves, clean hands, and wear a new pair of clean gloves before testing each patient.



TEST RESULTS

Results should be interpreted at the 10-minute mark. Do not read the test results after 1 hour.

An unused test, or test that has not yet been activated by pressing the **Buffer Release Button**, will show three faint **orange** lines in the **Result Window**.

A **blue** control line must appear in the **Result Window** for the test to be valid.

Positive Result

The positive result lines should appear as **red** or **black** lines in the **Result Window**. An uneven or incomplete result line is due to an uneven sample distribution on the test strip. Even if the result line is faint in color, incomplete over the width of the test strip, or uneven in color, it should be interpreted as positive. A positive result indicates the presence of elevated MxA and/or CRP proteins.

Negative Result

If only a **blue** control line is visible in the **Result Window**, the test is deemed negative. A negative result indicates a lack of elevated MxA and CRP proteins.

Invalid Result

The absence of the **blue** control line indicates an invalid result. If an invalid result occurs, the test must be discarded and the patient retested using a new FebriDx® test. Choose an alternative puncture site on a different finger when retesting the patient.

Notes:

- A blood fluid wave will migrate up the **Result Window** and gradually disappear as the test develops.
- Faint blood streaks may be visible along the sides of the **Result Window** and are acceptable for reading purposes.
- If the background of the **Result Window** has not cleared sufficiently for interpretation of results after 30 minutes, discard the test and retest the patient with a new FebriDx® test.
- FebriDx® test results are stable for up to one (1) hour. Do not interpret the test results after this period of time.

QUALITY CONTROL

Procedural Controls

The FebriDx® test contains the following built-in procedural controls. For daily quality control, Lumos Diagnostics recommends documenting that these internal procedural controls are checked for the first sample tested each day.

Unused test

An unused FebriDx® test has faint **orange** lines in the **Result Window**, indicating the potential appearance of control and result lines.

Fluid wave

A blood fluid wave will migrate up the **Result Window** and gradually disappear as the test develops. Faint blood streaks may be visible along the sides of the **Result Window** and are acceptable for reading purposes.

Control line

A **blue** control line must appear in the **Result Window** for the test to be valid. The absence of a **blue** control line indicates an invalid result.

External Controls

External controls may be used to demonstrate that the reagents and assay perform properly. FebriDx® external controls are available directly through Lumos Diagnostics and consist of one (1) positive control and one (1) negative control. Refer to the FebriDx® external controls package insert for instructions on how to use. If the FebriDx external controls do not perform as expected, please repeat the test. If external controls fail on repeat testing do not perform patient testing and contact Lumos Diagnostics Technical Support.

For ordering external controls, refer to the Ordering and Contact Information section of this package insert. Refer to the FebriDx® external controls package insert for instructions on how to run the external controls. External controls will have an individual expiration date printed on each package. Discontinue use if external controls are expired.

LIMITATIONS

1. The FebriDx® test is best used within three (3) days from onset of a new fever and seven (7) days from onset of new respiratory symptoms.
2. Only fresh capillary blood (fingerstick) must be used on the FebriDx® test. Venous blood CANNOT be used.
3. The blood collection tube must be filled completely and applied to the test strip in order for the test to run properly. An erroneous result may occur if an insufficient blood sample is applied to the test.
4. The following conditions may lead to erroneous results:
   - Current immunosuppressive state or use of immunosuppressive drugs
   - Current use of oral anti-infective drugs
   - Current use of interferon therapy (e.g. for multiple sclerosis, HIV, hepatitis B/C)
   - Live viral immunization within the last 30 days
   - Major trauma, major surgical intervention, and severe burns within the preceding 30 days
   - Chronic fevers lasting more than 7 days that are not suspected to be associated with SARS-CoV-2
5. FebriDx® will not identify bacterial colonization, localized infections, or periodic viral shedding without an associated systemic host response.
6. Rheumatoid Factor (RF) ≥ 100 IU/mL (normal RF: 15 IU/mL) can produce a test line in very rare cases.
7. Reading results before 10 minutes or after 1 hour may produce erroneous results.

ARI PREVALENCE

The prevalence of ARI varies during the year and from region to region, with outbreaks typically occurring during fall and winter. ARIs are the leading cause of morbidity, accounting for 20% of medical consultations, 30% of absenteeism, and 75% of all antibiotic prescriptions.[15]

Approximately 24-62% of patients presenting to the outpatient setting with respiratory symptoms do not have infection.[14,15,21] A negative FebriDx® test in a symptomatic patient can be indicative of an illness other than an acute respiratory infection e.g., environmental trigger of respiratory illness, allergic rhinitis, autoimmune, subclinical, or past infection.

CLINICAL EVIDENCE

FebriDx® has been evaluated in prospective, multicenter, blinded clinical trials, Self, (Jan-Nov 2014) and Shapiro (Nov 2015-Jul 2016) with untrained operators to determine the diagnostic performance characteristics of the FebriDx® test to identify a host immune response and differentiate viral or bacterial community-acquired febrile ARI as compared to the reference standard (standardized microbiologic and laboratory testing adjudicated by clinical experts).[10,14,15] Participants 1 year of age and older who presented to primary care, urgent care, or an emergency department (ED) within 3 days of an acute onset fever and within 7 days of new onset respiratory symptoms consistent with a community-acquired ARI were eligible for inclusion. Two studies were conducted. The first study enrolled patients in 2014 using the dual-strip FebriDx® test (RPS-FDX-CA).[15] The second study enrolled patients between 2015-2016 using the single strip FebriDx® test (CP0004).[14]

Viral testing:

- FilmArray® PCR: Influenza A/B, Adenovirus, RSV, Parainfluenza virus 1-4, Metapneumovirus, non-SARS-CoV-2 Coronavirus, and Rhinovirus
- Supplemental real-time reverse transcriptase PCR for EBV, HSV, and CMV
- EBV IgM Serology

Bacterial testing:

- FilmArray® PCR for atypical bacteria: *Chlamydophila pneumoniae, Mycoplasma pneumoniae, Bordetella pertussis, Fusobacterium necrophorum, Neisseria gonorrhoeaea.*
- Oropharyngeal cultures (blood, chocolate, and MacConkey plates)

Laboratory testing:

- Procalcitonin (PCT) and white blood cell count (WBC), lymphocytes and percentage of immature WBC (bands)

A composite reference-testing algorithm adjudicated by an expert physician panel served as the reference standard from which FebriDx® was compared. Each patient underwent the following reference tests: (1) throat swab bacterial culture; (2) combined nasopharyngeal and oropharyngeal (NP/OP) swabs for multiplex PCR using the FilmArray® Respiratory Panel (Biomerieux, Inc.; Marcy-L'Etoile, France); (3) combined NP/OP swabs for real-time reverse transcriptase PCR for EBV, HSV, and CMV; (4) EBV IgM serum antibody with the Immunosimplicity® IS-EBV-VCA IgM test kit (Diamedix Co; Miami Lakes, FL, USA); (5) serum PCT concentration measurement using the BRAHMS PCT Kryptor™ (ThermoFisher Scientific; Waltham, MA, USA); (6) WBC with band differential, and (7) MxA protein ELISA and CRP enzyme immunoassay (Biocheck; Foster City, CA, USA). Reference testing was completed at a central laboratory and blinded to patients, treating clinicians, and study personnel who performed FebriDx® testing.

The reference testing algorithm classified patients as having a bacterial infection if any of the following 5 criteria were met: (1) throat culture positive for a bacteria that commonly causes pharyngitis (group A and C ß-hemolytic Streptococci, *N. gonorrhoeaea, C. diphtheriae, A. haemolyticum*) plus PCT ≥0.1 ng/mL; (2) throat culture positive for any other bacteria plus PCT ≥0.15 ng/mL; (3) NP/OP sample PCR positive for atypical bacteria (*M. pneumoniae, C. pneumoniae, B. pertussis*) plus PCT ≥0.1 ng/mL; (4) PCT ≥0.25 ng/mL plus no identified pathogen; (5) PCT ≥0.15 ng/mL plus WBC ≥15,000 cells/mcl or presence of WBC bands plus no identified pathogen.

Pharyngeal bacterial colonization was differentiated from true systemic bacterial infection if cell culture growth occurred in the absence of an elevated PCT level (measure of host immune response). Patients with a negative FebriDx® result without an identified pathogen and a normal PCT (absent host immune response) were considered negative for infection.

The reference testing algorithm classified patients as having a viral infection if any of the following 3 criteria were met: (1) NP/OP sample PCR positive for Influenza A or B, Adenovirus, RSV, Human Metapneumovirus, Parainfluenza viruses 1-4, CMV, and HSV; (2) NP/OP sample PCR positive for EBV plus serum IgM positive for EBV; (3) PCT between 0.15 ng/mL and 0.25 ng/mL plus WBC <15,000 cells/mcl plus no WBC bands plus no identified pathogen.

Patients who did not meet the criteria for bacterial or viral infection were classified as negative by the reference testing algorithm.

FEBRIDX® PERFORMANCE DATA

- ARI Cohort[14,15]
  - 429 ARI subjects symptomatic within 7 days and febrile within 3 days of presentation and who were ≥ 1 year were enrolled in the outpatient setting.
  - 4 subjects were excluded prior to analysis (3 had insufficient reference standard testing to determine final diagnosis and 1 had an invalid FebriDx® test)
  - 425 symptomatic ARI were included in the analyses (study 1: 205[15]; study 2: 220[14])
  - Results
    - 15% (66/425) Bacterial
    - 44% (189/425) Viral
    - 38% (163/425) Non-Infectious
    - 13% (26/205) exhibited a fever at the time of enrollment[15]
    - 55% (121/220) exhibited a fever at the time of enrollment[14]

Subsequently a pivotal, prospective, multi-center, blinded clinical trial was conducted in the United States (U.S.) to evaluate the clinical performance of the FebriDx test as compared to a previously published composite Clinical Reference Algorithm that incorporated extensive pathogen detection testing (bacterial culture and multiple molecular testing methods including multiplex PCR and TEM PCR) as well as measures of host immune response. The study was performed between October 2019-April 2021 and enrolled participants 1 year of age or older who presented with symptoms of acute respiratory infection and a recent fever who presented to primary care, urgent care or an emergency department (ED). All participants were

tested using the FebriDx all-in-one device (CP0003). The final analysis included a total of 520 participants enrolled from 20 clinical sites with testing performed by 72 untrained operators. The participant cohort was comprised of 44% male and 56% female participants of diverse racial and ethnic backgrounds. Additionally, the cohort was comprised of 21% children/adolescents, 71% adults, and 8% elderly with a mean age of 35 years and a range of 1 to 95 years of age.

The performance data for the 3 prospective studies is summarized in the following tables.

Summary of FebriDx® Performance (Bacterial ARI)

Study (Sample Size)	Fever (Exhibited or Reported)	Diagnosis	PPA [95% CI]	NPA [95% CI]	PPV [95% CI]	NPV [95% CI]
Shapiro (N = 121/220)[14] *Study performed with FebriDx single-strip device CP0004*	*Exhibited* on Enrollment (55%)	Bacterial	95% [77-100]	94% [88-98]	76% [59-87]	99% [93-100]
Shapiro (N = 220)[14] *Study performed with FebriDx single-strip device CP0004*	Reported within 3 days	Bacterial	85% [69-95]	93% [89-96]	69% [56-79]	97% [94-99]
Self (N = 205)[15] *Study performed with FebriDx dual-strip device RPS-FDX-CA*	Reported within 3 days	Bacterial	80% [59-93]	93% [90-97]	63% [45-79]	97% [94-99]
DISRUPT Study (N = 520)[21] *Study performed with FebriDx all-in-one device CP003*	Reported within 3 days	Bacterial	93% [85-97]	88% [85-91]	58% [49-67]	99% [97-99]

PPA, Positive Percent Agreement; NPA, Negative Percent Agreement; PPV, Positive Predictive Value; NPV, Negative Predictive Value; CI, Confidence Interval

Summary of FebriDx® Performance (Viral ARI)

Study (Sample Size)	Fever (Exhibited or Reported)	Diagnosis	PPA [95% CI]	NPA [95% CI]	PPV [95% CI]	NPV [95% CI]
Shapiro (N = 121/220)[14] *Study performed with FebriDx single-strip device CP0004*	*Exhibited* on Enrollment (55%)	Viral	90% [81-96]	78% [62-89]	89% [82-93]	80% [67-89]
Shapiro (N = 220)[14] *Study performed with FebriDx single-strip device CP0004*	Reported within 3 days	Viral	90% [83-94]	76% [66-84]	83% [77-87]	85% [77-90]
Self (N = 205)[15] *Study performed with FebriDx dual-strip device RPS-FDX-CA*	Reported within 3 days	Viral	87% [75-95]	83% [77-89]	64% [53-75]	95% [90-98]
DISRUPT Study (N = 520)[21] *Study performed with FebriDx all-in-one device CP003*	Reported within 3 days	Viral	70% [65-75]	88% [83-92]	90% [85-93]	67% [61-72]

PPA, Positive Percent Agreement; NPA, Negative Percent Agreement; PPV, Positive Predictive Value; NPV, Negative Predictive Value; CI, Confidence Interval

ADDITIONAL PROSPECTIVE CLINICAL STUDIES FEBRIDX® PERFORMANCE:

Viral infection in patients during COVID-19 pandemic

Multiple real-world studies evaluating FebriDx® in hospitalized subjects with suspected COVID-19 were performed during the first wave (March-April 2020) of the COVID-19 pandemic.[3,4]

FebriDx® aids in the identification and differentiation of patients with viral or bacterial acute respiratory infection and is not intended to diagnose any specific bacteria or virus, including SARS-CoV-2. FebriDx® demonstrated a 92 to 99% negative predictive value (NPV) for COVID-19, during high to low prevalence.

PRECISION AND REPRODUCIBILITY STUDY

Samples were prepared in fresh EDTA whole blood with recombinant MxA and CRP proteins. Six (6) samples, consisting of a combination of no analyte, C5 and C95 concentrations of MxA and CRP were tested.[19] A total of 1080 determinations were performed by untrained operators at three (3) different sites over five (5) days. The study demonstrates overall reproducibility among three (3) lots of material, among three (3) separate sites, and among six (6) separate users.

Within Run Reproducibility

	Day 1		Day 2		Day 3		Day 4		Day 5	
	Observed	Percentage	Observed	Percentage	Observed	Percentage	Observed	Percentage	Observed	Percentage
Site 1										
Operator 1	36/36	100.00%	36/36	100.00%	36/36	100.00%	36/36	100.00%	36/36	100.00%
Operator 2	33/36	91.70%	36/36	100.00%	30/36	83.30%	36/36	100.00%	33/36	91.70%
Site 2										
Operator 1	36/36	100.00%	36/36	100.00%	36/36	100.00%	36/36	100.00%	36/36	100.00%
Operator 2	36/36	100.00%	36/36	100.00%	36/36	100.00%	33/36	91.70%	36/36	100.00%
Site 3										
Operator 1	36/36	100.00%	36/36	100.00%	33/36	91.70%	33/36	91.70%	36/36	100.00%
Operator 2	36/36	100.00%	36/36	100.00%	36/36	100.00%	33/36	91.70%	36/36	100.00%

Within Day Reproducibility

	Day 1		Day 2		Day 3		Day 4		Day 5	
	Observed	Percentage	Observed	Percentage	Observed	Percentage	Observed	Percentage	Observed	Percentage
Site 1	69/72	95.80%	72/72	100.00%	66/72	91.70%	72/72	100.00%	69/72	95.80%
Site 2	72/72	100.00%	72/72	100.00%	72/72	100.00%	69/72	95.80%	72/72	100.00%
Site 3	72/72	100.00%	72/72	100.00%	69/72	95.80%	66/72	91.70%	72/72	100.00%

Within Site Total Precision

	Observed	Expected	Percentage
Site 1	348	360	96.70%
Site 2	357	360	99.20%
Site 3	351	360	97.50%

INTERFERING SUBSTANCES

The Interfering Substances Verification Study assessed the impact of substances that might be found in samples on the analytical specificity and analytical sensitivity of the FebriDx® test. This assessment was performed by evaluating three replicates each of a series of samples that included MxA and CRP at the C95 concentration (i.e. low positive) and negative levels in whole blood, spiked with interfering substances. Positive and negative interference with the potentially interfering substances was evaluated by three independent researchers blinded to the sample composition.

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

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

Test Substance	Concentration
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

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REF CP0003: FebriDx® 25 Test Kit

REF CP0008: FebriDx® External Controls

GLOSSARY OF SYMBOLS

Manufacturer	Contains sufficient for 25 tests	Catalog number
Caution	Consult instructions for use	Batch code
Temperature limit	Sterilized using irradiation	Authorized representative in the European Community
Do not re-use	Do not use if package is damaged	CE conformity marking
Use-by date	in vitro diagnostic medical device	
Contains sufficient for 1 test		

LUMOS DIAGNOSTICS

Manufacturer and United States Representative /
Fabricant et mandataire pour les États-Unis

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