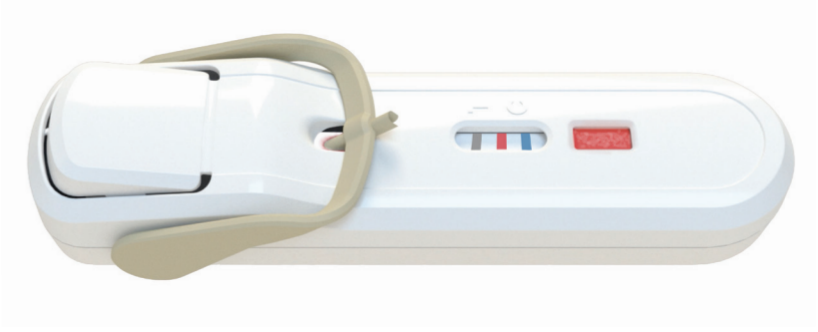
FebriDx®



FebriDx®

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. The test measures a clinically significant immune response to a suspected viral and/or bacterial infection in patients older than 1 year of age that present within 7 days of new onset respiratory symptoms consistent with a community-acquired acute respiratory infection (ARI).

The FebriDx® test aids in the clinical identification of patients with an underlying viral infection, including Influenza A/B, Adenovirus, Respiratory Syncytial Virus (RSV), Metapneumovirus, Parainfluenza Virus, Epstein-Barr Virus (EBV), Cytomegalovirus (CMV), and Herpes Simplex Virus (HSV), or patients with a clinically significant immune response consistent with an underlying bacterial infection.

The FebriDx® test is intended for use as a point-of-care test in a professional healthcare setting for and not for home or self-testing 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:

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 deliver high sensitivity and specificity to differentiate 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.[3] Numerous clinical studies demonstrate that MxA protein expression in peripheral blood has been shown to be a sensitive and specific marker for viral infection.[3-8]

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.[9,10] Some viral infections, including Influenza, and Adenovirus may cause CRP to elevate.[11,12]

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 acute respiratory infection as well as differentiate viral from bacterial infectious etiology.[13-15]

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 above their respective cut-off levels, the appropriate test line will appear in the Result Window. FebriDx® also contains a control line to indicate correct sample flow and valid results.

Materials Provided

- 25 single use tests
- 1 package insert

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.

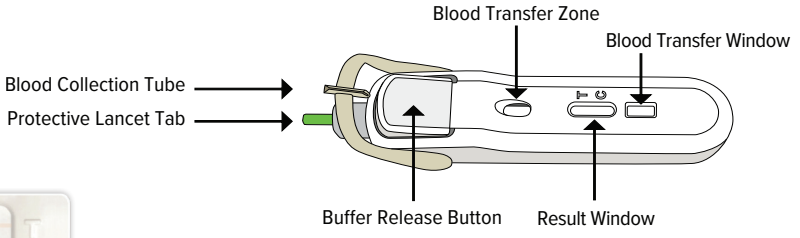
STORAGE AND STABILITY

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

The FebriDx® test performed acceptably when tested at altitudes between 0 – 2000 meters.

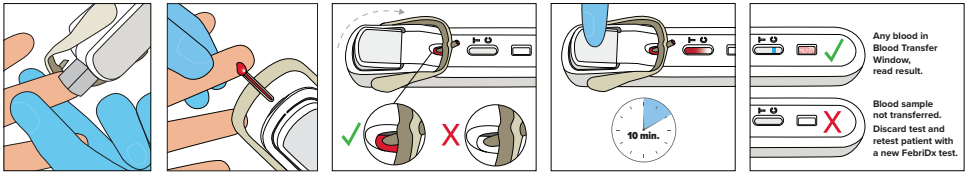
TEST COMPONENTS



Unused Test

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.

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



1 Lance Finger 2 Collect Blood 3 Deliver Blood 4 Deliver Buffer 5 Check Blood Transfer

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.

2. Use standard precautions for collecting and handling a fingerstick blood sample.

3. Twist and pull to remove the Protective Lancet Tab. Firmly press the lancet to puncture the skin. Wipe away the first drop of blood with gauze. Gently massage finger to encourage blood flow to obtain a drop of blood that hangs from the finger.

4. Place Blood Collection Tube at a 45 degree angle below the finger, making contact with the hanging drop of blood. Avoid direct contact with the patient's finger. **ENSURE BLOOD COLLECTION TUBE IS COMPLETELY FULL.**

Note: *Capillary action will automatically draw the blood sample into the Blood Collection Tube.*

5. Once the Blood Collection Tube is completely filled with blood, rotate it over the Blood Transfer Zone. **ENSURE THAT BLOOD IS TRANSFERRED TO THE TEST STRIP.** Wait for ~5-10 seconds before proceeding to step #6.

Note: **If the blood does not immediately transfer onto the test strip, reverse the Blood Collection Tube's rotation back to its original position and add additional blood to fill the tube.** There will be some resistance. Once the Blood Collection Tube is completely filled, rotate it over the Blood Transfer Zone. **ENSURE THAT BLOOD IS TRANSFERRED TO THE TEST STRIP.** Wait for ~5-10 seconds before proceeding to step #6.

6. Lay the test on a flat surface. **Blood must be visible on the test strip before releasing buffer.** 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.

Note: If no fluid is visible within 25-30 seconds, firmly re-press the Buffer Release Button.

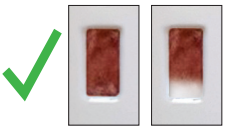
7. Read results at the 10-minute mark. If the blood has not cleared at 10 minutes, wait for the background to clear before reading the test results. Do not read the test results after 1 hour. Dispose of test in the proper biohazard receptacle.

BLOOD TRANSFER CHECK

Confirm the **Blood Transfer Confirmation Window** changed from **white** to pink/red to indicate the correct transfer of the blood sample.

If the **Blood Transfer Confirmation Window** does not change to a pink/red color, then the sample was not transferred correctly and the test needs repeating.

Blood Transfer Confirmation Window



Any blood in Blood Transfer Confirmation Window, read result.

Blood sample not transferred. Discard test and retest patient with a new FebriDx test.

TEST RESULTS

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

Viral infection

Bacterial infection

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.

* Cannot preclude co-infection. The incidence of co-infection is low and varies on severity of illness and setting.

Negative result

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

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.

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.

QUALITY CONTROL

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.

Blood Transfer Confirmation Window

Confirm the **Blood Transfer Confirmation Window** changed from white to pink/red to indicate the correct transfer of the blood sample.

If the **Blood Transfer Confirmation Window** does not change to a pink/red color, then the sample was not transferred correctly and the test needs repeating.

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.

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
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 MxA line in very rare cases.
7. Reading results before 10 minutes or after 1 hour may produce erroneous results.

PERFORMANCE CHARACTERISTICS

FebriDx® has been evaluated in multiple prospective, multicenter, blinded clinical trials 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 ARIs as compared to the reference standard (standardized microbiologic and laboratory testing adjudicated by clinical experts).[8,13,14] Subjects 1 year of age and older who presented to primary care, urgent care, or an emergency department 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.

Viral testing:

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

Bacterial testing:

- FilmArray® PCR for atypical bacteria: *Chlamydophila pneumoniae, Mycoplasma pneumoniae, Bordetella pertussis, Fusobacterium necrophorum, Neisseria gonorrhoeae*.
- 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 6 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, CMV, HSV; (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. gonorrhoeae, C. diphtheria, 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 association with 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. Otherwise, the patients were characterized as a viral infection.

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

FEBRIDX® PERFORMANCE DATA

Prospective, Multi-Center Clinical Studies (FebriDx® Diagnostic Performance: Bacterial vs. Viral ARI)

- Controls[14]
  - 165 Asymptomatic controls without signs or symptoms of infection and who were 1 year of age or older were enrolled.
  - 2 subjects had invalid test results and were excluded prior to analysis.
  - 163 subjects were included in the analysis.
  - MxA ELISA and CRP enzyme immunoassay testing were performed. Specificity (true negative rate) and the false positive rate for FebriDx® were calculated.
  - Results:

	n	% (95% CI)
Specificity (true negative rate)	161/163	99% (96-100%)
False positive rate	2/163	1.2% (0.1-4.4%)

- ARI Cohort[13,14]

  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. 425 symptomatic ARI were included in the analyses.
  - 4 subjects were excluded prior to analysis (3 had insufficient reference standard testing to determine final diagnosis and 1 had an invalid FebriDx® test)
  - Results
    - 16% (66/425) Bacterial
    - 46% (196/425) Viral
    - 38% (163/425) Negative
    - 13% (26/205) exhibited a fever at the time of enrollment[14]
    - 55% (121/220) exhibited a fever at the time of enrollment[13]

Summary of FebriDx® Diagnostic Performance (Bacterial vs. 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)[13]	*Exhibited* on Enrollment (55%)	Bacterial	95% [77-100]	94% [88-98]	76% [59-87]	99% [93-100]
Shapiro (n = 220)[13]	Reported within 3 days	Bacterial	85% [69-95]	93% [89-96]	69% [56-79]	97% [94-99]
Self (n = 205)[14]	Reported within 3 days	Bacterial	80% [59-93]	93% [90-97]	63% [45-79]	97% [94-99]

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

Study (Sample Size)	Fever (Exhibited or Reported)	Diagnosis	PPA [95% CI]	NPA [95% CI]	PPV [95% CI]	NPV [95% CI]
Shapiro (n = 121/220)[13]	*Exhibited* on Enrollment (55%)	Viral	90% [81-96]	78% [62-89]	89% [82-93]	80% [67-89]
Shapiro (n = 220)[13]	Reported within 3 days	Viral	90% [83-94]	76% [66-84]	83% [77-87]	85% [77-90]
Self (n = 205)[14]	Reported within 3 days	Viral	87% [75-95]	83% [77-89]	64% [53-75]	95% [90-98]

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

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. C95 is defined as low positive concentration whereby a positive result is yielded 95% of the time (and a negative result 5% of the time) whereas the C5 is defined as a high negative concentration whereby a positive result is yielded 5% of the time (and negative result 95% of the time). A total of 1080 determinations were performed by untrained operators at three (3) different sites over five (5) contiguous days during a two-week period. 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

Site No.	Operator No.	Operator Job/Role	Day 1	Day 2	Day 3	Day 4	Day 5
1	1	Director of Clinical Research	100%	100%	100%	100%	100%
	2	Registered nurse	91.7%	100%	83.3%	100%	91.7%
2	1	Registered nurse	100%	100%	100%	100%	100%
	2	Unit coordinator	100%	100%	100%	91.7%	100%
3	1	Registered nurse	100%	100%	91.7%	91.7%	100%
	2	Registered nurse	100%	100%	100%	91.7%	100%

Within-day reproducibility

Site No.	Day 1	Day 2	Day 3	Day 4	Day 5
1	95.8%	100%	91.7%	100%	95.8%
2	100%	100%	100%	95.8%	100%
3	100%	100%	95.8%	91.7%	100%

Within laboratory total precision

Site No.	Total Precision
1	96.7%
2	99.2%
3	97.5%

Overall reproducibility

Site No.	Overall Reproducibility
All Sites	97.8%

Results from the panel of samples prepared showed a high level of inter and intra operator and site reproducibility, ranging between 83.3 – 100%. The FebriDx® Precision and Reproducibility Study demonstrated a high level of precision - within laboratory total precision was between 96.7 – 99.2 and overall reproducibility 97.8%—and indicates the FebriDx® test has a low likelihood of producing an erroneous result.

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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