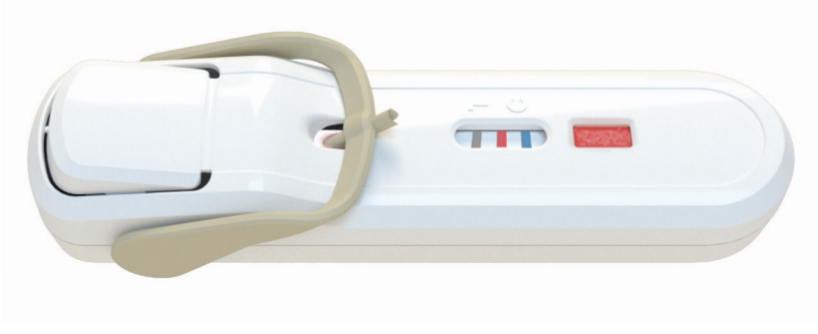
REF CP0014

FebriDx®



FebriDx®

Instructions for Use

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

For in vitro diagnostic use. Rx only.
Please read this package insert carefully prior to use and strictly follow the instructions.

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 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.

SUMMARY & EXPLANATION

Acute respiratory infections (ARIs) including sinusitis, pharyngitis, bronchitis, and influenza are the most common reason for physician office visits and antibiotic prescriptions worldwide.[1-3] The significant overlap in symptoms and signs makes it challenging for physicians to differentiate bacterial infections from non- bacterial etiology to identify which patients require antibiotic therapy. The vast majority of ARIs are caused by non-bacterial etiology, for which antibiotics provide no clinical benefit, however 30-80% receive antibiotics. The over prescription of antibiotics for ARI is a leading contributor to the global antimicrobial resistance (AMR) crisis which currently causes 700K deaths annually.[4] FebriDx® utilizes dual biomarker technology to deliver high sensitivity and specificity to differentiate a bacterial infection from non-bacterial etiology.[5]

BIOMARKERS

MxA (Myxovirus resistance protein A)
MxA is an innate host response biomarker that elevates in the presence of acute viral infection but is not specific to a particular type of virus. 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.[6] Numerous clinical studies demonstrate that MxA protein expression in peripheral blood has been shown to be a sensitive and specific marker for viral infection.[7-10] MxA is specific for viral infection only and is not elevated in the presence of a bacterial infection.[7,8]

CRP (C-reactive protein)
CRP is a nonspecific, acute-phase protein that is upregulated during the presence of acute inflammation, including response to infection. CRP is predominately produced by the liver in response to inflammatory cytokines such as IL-6 and assists in pathogen recognition and phagocytosis by macrophages.[11] Infection is a potent stimulus of CRP elevation, which occurs within 4-6 hours of infection, doubles every 8 hours and peaks after 36 hours.[12] At low levels CRP is sensitive but non-specific for bacterial infection.[13]

Multiplexed Pattern of Results

Neither MxA nor CRP alone is sensitive or specific enough to differentiate bacterial infection from non-bacterial etiology in symptomatic patients being evaluated for acute respiratory infection.[7,13-15] However, when both host response biomarkers are used together in the FebriDx® test, bacterial infection can be differentiated from non-bacterial etiologies.[5,16]

PRINCIPLES OF THE TEST

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.

MATERIALS PROVIDED

- 25 Single Use Test Devices
- 1 Package Insert
- 1 Quick Reference Instruction (QRI)

MATERIALS NOT PROVIDED

- Timer
- Gauze
- Alcohol
- Sterile Dressing
- External Controls

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use.
2. Do not remove the FebriDx® test from the foil pouch until ready to 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. Proper handling and disposal methods should be established according to local, state, and federal regulations.
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. After testing, remove gloves, clean hands, and wear a new pair of clean gloves before testing each patient.
7. The protective cap on the lancet is a single sterile barrier system. Do not use the lancet if the protective tab has been previously removed from the device.
8. The FebriDx® test is a single-use item with no reusable components. Do not use on more than one patient. The test is not intended for more than one use.
9. The FebriDx® test is designed to proceed in sequential order and locking mechanisms exist to prevent skipping the prior step.
10. Incomplete filling of the blood collection tube could lead to erroneous test results.
11. Interpretation of FebriDx® test results involves visual assessment of colored result lines. Users with color-impaired vision should not interpret the test.
12. A brightly lit environment is recommended for interpreting the test results.

STORAGE AND STABILITY

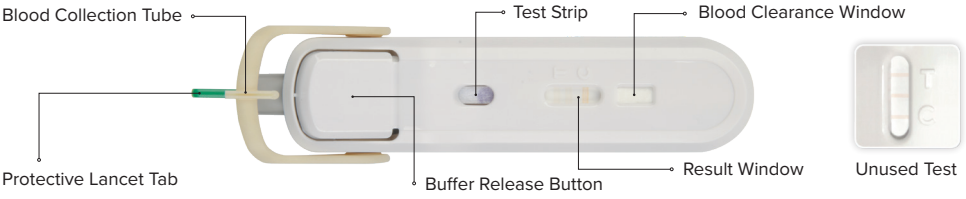
Store the FebriDx® tests unopened at a temperature between 39 - 77°F (4 - 25°C). Tests are individually packaged in sealed pouches that make them impervious to humidity differences during transport and storage. As such, unopened FebriDx® tests are stable until the expiration date printed on their packaging if stored at the listed temperatures.

OPERATING, HUMIDITY, AND ALTITUDE

The FebriDx® test performed acceptably when tested in the following environments:

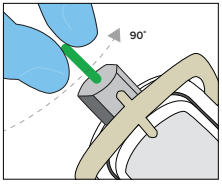
- Relative humidity between 5 – 85%
- Altitudes between 0 – 2000 meters

TEST COMPONENTS



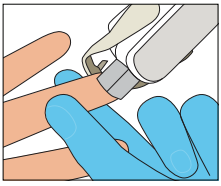
TEST PROCEDURE

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



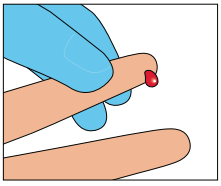
1 Prepare Lancet

Twist the Protective Lancet Tab 90 degrees and pull to remove.



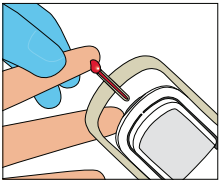
2 Lance Finger

Firmly press the lancet against the finger to puncture the skin. Wipe away the first drop of blood.



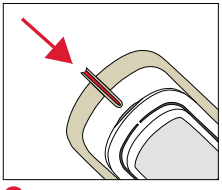
3 Massage Finger

Massage entire finger to obtain a large drop of blood that hangs from the finger.



4 Collect Blood

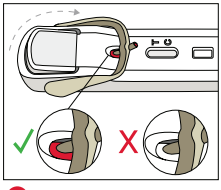
Place the Blood Collection Tube below the finger, and ensure it only touches the hanging drop of blood and not the finger.



5 Verify Tube Is Full

If the Blood Collection Tube is not full, massage the entirefinger to obtain more finger-stick blood.

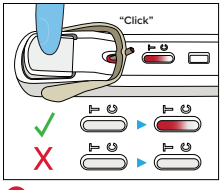
WARNING: Incomplete filling of the Blood Collection Tube could lead to erroneous test results.



6 Transfer Blood

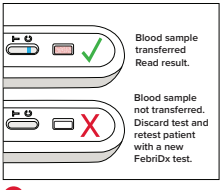
Lay the test on a flat surface.

Rotate the Blood Collection Tube to make contact with the Test Strip. If the blood does not immediately transfer, reverse the Tube back to its original position and fill with more blood. Then rotate the Tube back onto the Test Strip.



7 Deliver Buffer

Firmly press the Buffer Release Button until it clicks to deliver the buffer. If the blood is not visible in the Result Window within 30 seconds, press the Buffer Release Button again until clicking is audible.



8 Check Blood Transfer

Wait for at least 10 minutes for the blood to clear to read result lines. Reading results before the blood has cleared the Result Window may lead to erroneous test results.

If there is no blood visible in the Blood Clearance Window, discard and re-test with a new FebriDx® test.

Do not read results after 1 hour.

TEST RESULTS

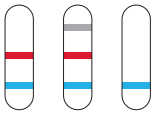
Wait for at least 10 minutes after pressing the buffer release button to read result lines. Results should not be read if blood has not cleared the result window, which may take longer than 10 minutes. Do not read the test results after 1 hour or if blood is not visible in the clearance window.

TEST INTERPRETATION

Bacterial Infection

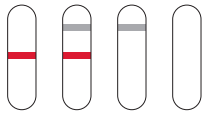
A black only result line is interpreted as bacterial infection. A **blue** control line shows that the test is valid.

Non-Bacterial Etiology



Any test with a **red** result line (MxA) or no result line is interpreted as a non-bacterial etiology. A **blue** control line shows that the test is valid.

Invalid



The absence of the **blue** control line indicates an invalid result. Discard test and retest patient with a new FebriDx® test.

QUALITY CONTROL

Procedural Control

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.

External Controls

External controls should be used to demonstrate that the reagents and assay perform properly. External controls (one positive and one negative) 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. Please contact Lumos Diagnostics at 1.855.LumosDx to order external controls.

LIMITATIONS

1. The FebriDx® test should be used within three (3) days from onset of a fever and less than seven (7) days of new respiratory symptoms.
2. The clinical study was not adequately powered to demonstrate performance among different age groups. Clinical performance has not been established in pediatric patients younger than 12 years old or in elderly patients above 64 years old. The FebriDx® test should not be used in these patient populations.
3. The clinical study was not adequately powered to evaluate performance differences in specific races and ethnicities; therefore, results should be interpreted in conjunction with clinical assessments and other diagnostic findings.
4. The FebriDx® test is used in conjunction with clinical assessments and other laboratory findings as an aid to diagnose bacterial infection in patients presenting with symptoms of an acute respiratory infection to urgent care or emergency care settings. 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.
5. Predictive values of the FebriDx® test depend on the likelihood ratios and the prevalence of disease.
6. Fresh capillary blood (fingerstick) must be used on the FebriDx® test. Venous blood, serum and/or plasma cannot be used.
7. The blood collection tube must be filled completely and transferred to the test strip for the test to run properly. An erroneous result may occur if an insufficient blood sample is applied to the test.
8. Reading results before the blood clears the result window or after 1 hour may produce erroneous results.
9. Clinical performance has not been established in the following populations:
   - Patients who are immunosuppressed or those receiving immunosuppressive or chemotherapeutic drugs
   - Patients receiving anti-infective drugs
   - Patients receiving interferon therapy
   - Patients receiving live viral immunization within the last 30 days
   - Patients with chronic symptoms or fevers lasting more than 7 days
   - Patients without symptoms of acute respiratory infection
10. Interference testing indicated Rheumatoid Factor may contribute to false negative and false positive results at levels above 50 IU/mL.
11. The FebriDx® test is not for home or self-testing.

CLINICAL PERFORMANCE CHARACTERISTICS

A well-controlled, prospective, multi-center blinded clinical trial was conducted in the United States (U.S.) to evaluate the clinical performance of FebriDx® in patients with Acute Respiratory Infection (ARI) as well as healthy controls. The study was conducted at 20 point-of-care (POC) testing sites that were representative of the intended user and setting. Patients who presented to urgent care or emergency care settings for evaluation of acute respiratory infection (ARI) within 7 days of symptoms with symptoms for less than 7 days and within 3 days of fever onset were screened for eligibility between October 2019-April 2021. ARI 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 (e.g., 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.

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.

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	38.0	32.0	28.5	33.0
(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)

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

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.

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. There were no deaths, adverse events or unanticipated device effects that occurred during the study. FebriDx® performance characteristics for bacterial infection are summarized in the following table:

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

Positive Percent Agreement (PPA), Negative Percent Agreement (NPA), Positive Predictive Value (PPV), Negative Predictive Value (NPV), Likelihood Ratio (LR), Confidence Interval (CI)

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.

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

Positive Percent Agreement (PPA), Negative Percent Agreement (NPA), Positive Predictive Value (PPV), Negative Predictive Value (NPV), Likelihood Ratio (LR), Confidence Interval (CI)

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 with two (2) operators. 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. Based on the study results, the LoD was conservatively established as 40 ng/ml for the MxA assay and 20 ug/mL for the CRP assay.

PRECISION AND REPRODUCIBILITY STUDY

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.

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.

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% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	95.9-100%
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%

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)

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 and found to not interfere at the listed 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

*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.

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. The 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.

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.

Venous and fingerstick blood samples procured from patients with a recent clinical fever were run on the FebriDx® test and a reference ELISA method. Results of the comparisons for both MxA and CRP proteins showed agreement between the two sample matrices. This data is not intended to support a venous blood sample type.

TECHNICAL SUPPORT

Contact Lumos Diagnostics Technical Support at +1.855.LumosDx or email technical.support@lumosdiagnostics.com for assistance.

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