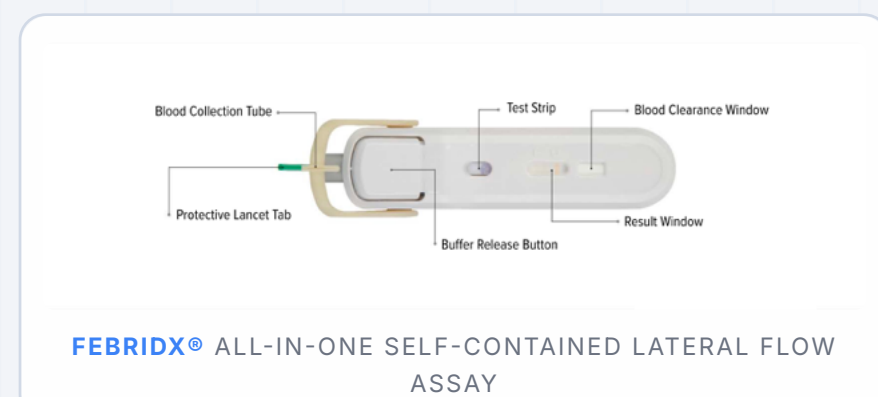


FebriDx®

The first rapid point-of-care test to differentiate bacterial from non-bacterial acute respiratory infections — in 10 minutes.



FEBRIDx® ALL-IN-ONE SELF-CONTAINED LATERAL FLOW ASSAY

98.7% **Negative Predictive Value¹**
Confidence to withhold antibiotics when bacterial infection is unlikely

93.2% **Sensitivity¹**
PPA for bacterial infection across 20-site U.S. trial, 520 participants

2.8M **AMR Infections Annually²**
Antibiotic-resistant infections in the U.S. each year — 35,000+ deaths

• FDA 510(K) CLEARED • CLIA WAIVED • CE MARK

Scan to Learn More About FebriDx®



Call 1-888-235-1400 to speak to a Representative



CLINICAL PERFORMANCE

- ✓ **98% negative predictive value to rule out bacterial infections¹**
- ✓ **Instrument-free**
- ✓ **Results in 10 minutes from a fingerstick**
- ✓ **FDA cleared, easy-to-use procedure**

DUAL BIOMARKER TECHNOLOGY

MxA

Myxovirus Resistance Protein A
↑ VIRAL / NON-BACTERIAL SIGNAL

CRP

C-Reactive Protein
↑ BACTERIAL SIGNAL

PRODUCT AT A GLANCE

SPECIMEN Fingerstick	RESULT TIME 10 min	PATIENT AGE ≥ 2 yrs
EQUIPMENT None	STORAGE 2–30°C	REGULATORY FDA-CE-HC

ANTIMICROBIAL RESISTANCE CRISIS

\$4.6B

Annual U.S. cost of treating **multidrug-resistant infections**. Up to 80% of acute respiratory infections receive unnecessary antibiotics.^{2,3}

How FebriDx Works Simple. Reliable. Actionable.

98.7%
NEGATIVE PREDICTIVE VALUE¹

AMR CRISIS Why This Test Matters

700K
Global deaths from **drug-resistant infections** — projected 10M/year by 2050⁴

30–80%
Of ARI visits receive antibiotics — **most infections are viral** and need none³

41%
Reduction in antibiotic prescribing intent with **FebriDx-guided testing⁵**

STEP-BY-STEP PROCEDURE

Review the full FebriDx® Package Insert before performing the test. Use standard precautions for collecting and handling a fingerstick blood sample.

- Prepare Lancing Tab**
Tear the Protective Lancing Tab 90 degrees and peel to remove.
- Massage Finger**
Firmly press the lancing tab against the finger to produce the skin flap. Wipe away the first drop of blood.
- Massage Finger**
Massage entire finger to obtain a large drop of blood that hangs from the finger.
- Collect Blood**
Place the Blood Collection Tube below the finger, and ensure a single tear of the hanging drop of blood enters the tube.
- Wipe Tube to Flat**
Lay the test on a flat surface. Use the message on the side of the tube to ensure new finger sticks blood.
- Transfer Blood**
Rotate the Blood Collection Tube to expose the test strip. If the blood does not immediately transfer, remove the Tube back to its original position, and fill with more blood. Then repeat the Tube stick onto the test strip.
- Release Buffer**
Firmly press the Buffer Release Button until it clicks to ensure the buffer fills the blood in the test strip. The Buffer Release Button will click in the audible.
- Check Blood Flow**
Wait for at least 10 seconds for the blood to reach the test strip. Reading results before the blood has cleared the Blood Strips may lead to erroneous test results. If there is no blood visible in the Blood Clearance Window, discard and retest with a new FebriDx®. Do not retest results after 1 hour.

REVIEW FULL PACKAGE INSERT BEFORE USE · DO NOT READ RESULTS AFTER 1 HOUR

INDICATION FOR USE

For use in urgent and emergency care settings in patients ≥2 years presenting with acute respiratory infection (ARI) symptoms. Use in conjunction with clinical signs, symptoms, and other laboratory findings.

SPECIFICATIONS

SPECIMEN Fingerstick blood	RESULT TIME 10 minutes
PATIENT AGE ≥ 2 years	EQUIPMENT None required
STORAGE 2–30°C	REGULATORY FDA · CE · HC

INTERPRETING RESULTS

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

Non-Bacterial Pathology
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.

BLUE CONTROL LINE CONFIRMS TEST VALIDITY · DISCARD AND RETEST IF INVALID

CLINICAL BENEFITS

- ✓ **Reduce unnecessary antibiotics** — distinguish viral from bacterial at the point of care; directly supports stewardship programs.^{5,6}
- ✓ **Combat antibiotic resistance** — FebriDx-guided testing linked to 41% reduction in prescribing intent in primary care.⁵
- ✓ **Increase diagnostic confidence** — dual MxA + CRP biomarkers outperform CRP alone for bacterial vs viral differentiation.^{1,6}
- ✓ **Improve patient outcomes** — actionable bedside results drive appropriate therapy sooner, when it matters most.
- ✓ **No capital cost** — instrument-free, portable, single-use device ideal for urgent care, ED, and primary care settings.

SUPPORTING EVIDENCE & REFERENCES

- Shapiro NI, Filbin MR, Hou PC, et al. Diagnostic accuracy of a bacterial and viral biomarker point-of-care test in the outpatient setting. *JAMA Netw Open*. 2022;5(10):e2234588. [93.2% sensitivity; 98.7% NPV]
- CDC. Measuring Outpatient Antibiotic Prescribing. Updated October 2022. [30–80% of ARI visits receive unnecessary antibiotics]
- Lewnard JA, et al. Use of FebriDx® host-response POC test may reduce antibiotic use for RTIs in primary care. *J Antimicrob Chemother*. 2024;79(6):1441–1449. [41% reduction in prescribing intent]
- Nelson RE, et al. National estimates of healthcare costs associated with MDR bacterial infections among hospitalized patients. *Clin Infect Dis*. 2021;72(S1):S17–S26. [\$4.6B annual U.S. cost]
- CDC. Antibiotic Resistance Threats in the United States, 2019. U.S. Dept. of Health and Human Services. [2.8M infections; 35,000 deaths annually]
- WHO. Antimicrobial Resistance: Global Report on Surveillance. Geneva, 2023. [700K annual deaths; 10M projection by 2050]
- Shapiro NI, Self WH, Rosen J, et al. Prospective, multicentre US clinical trial determining accuracy of FebriDx for acute upper respiratory infections. *Ann Med*. 2018;50(5):420–429.
- Harris AM, Hicks LA, Qaseem A. Appropriate antibiotic use for acute respiratory tract infection in adults. *Ann Intern Med*. 2016;164(6):425–434.



FebriDx®

aletradiagnostics.com · Precision Diagnostics for Respiratory Infections

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