FebriDx® FAQs

Test to treat at the point of care.

Frequently Asked Questions[1,2,3]

What patients can be tested with FebriDx?
Patients aged 12 to 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.

What patient samples can be used with the FebriDx test?
Fresh capillary blood (fingerstick) must be used on the FebriDx test. Venous blood, serum and/or plasma cannot be used.

What reimbursement codes can be applied to the FebriDx test?
PLA0442U: This FebriDx Proprietary Laboratory Assessment (PLA) code is published on the Clinical Lab Fee Schedule, effective January 1, 2025.

When can the FebriDx test results be interpreted?
Do not read results after 1 hour or before ten minutes. Reading results before the blood has cleared the Result Window or without blood in the Blood Clearance Window may lead to erroneous test results.

What is the negative predictive value (NPV) of the FebriDx test?
FebriDx has a 99% NPV to rule out bacterial infection.
Refer to the instructions for use (PM-127) for the complete performance data.

What biomarkers are used with the FebriDx test?
FebriDx utilizes proprietary dual biomarker technology: C-Reactive Protein (CRP) and Myxovirus resistance protein A (MxA).

What are the threshold limits of detection for CRP and MxA?

- CRP: 20 µg/mL
- MxA: 40 ng/mL

What are the storage conditions for the FebriDx test?
FebriDx tests can be stored at room temperature (39-77°F or 4-25°C).

What is the shelf life for the FebriDx test?
Unopened FebriDx tests are stable up to 24 months from the date of manufacture when stored at a temperature between 39-77°F (4-25°C).

How many FebriDx tests are in a kit box? In a case?
FebriDx is packaged in a kit box containing 25 tests. There are 100 FebriDx tests (4 kit boxes) per case.

Is the FebriDx test qualitative or quantitative?
The FebriDx test is a qualitative visually read rapid immunoassay.

The result line(s) is visible, but the control line is absent. Can I still report the results?
No. A blue control line must appear in the result window for the test to be valid. The absence of the blue control line indicates an invalid test, and the patient must be retested with a new FebriDx test.

The result line is faint. Does this affect the interpretation of results?
No. 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 present.

My patient has Acute Respiratory Infection (ARI) symptoms, but neither the red nor black result line appears; is the test valid?
Yes. Any test with a red result line (MxA) or no result line and a blue control line is interpreted as a non-bacterial etiology. A blue control line shows that the test is valid. The absence of the blue control line indicates an invalid test.

Are External Controls available for the FebriDx test?
Yes. Contact PHASE Scientific at 657-233-5880 to order FebriDx External Controls (P0212).

Does FebriDx support Antimicrobial Stewardship?
Yes. FebriDx aids in the diagnosis of bacterial acute respiratory infection and differentiation from non-bacterial etiology and has the potential to improve diagnostic certainty and support clinical and therapeutic management decisions.

1. FebriDx Bacterial / Non-Bacterial Point-of-Care Assay; Lumos Diagnostics Instructions for Use (PM-127); FDA 510(k)K230917
2. Shapiro NI, Filbin MR, Hou PC, Kurz MC, Han JH, Aufderheide TP, Ward MA, Pulia MS, Birkhahn RH, Diaz JL, Hughes TL, Harsch MR, Bell A, Suarez-Cuervo C, Sambursky R. Diagnostic Accuracy of a Bacterial and ViralBiomarker Point-of-Care Test in the Outpatient Setting. JAMA Netw Open. 2022 Oct 3;5(10):e2234588. doi:10.1001/jamanetworkopen.2022.34588. PMID: 36255727; PMCID: PMC9579916.
3. American Hospital Association: https://www.aapc.com/codes/cpt-codes/0442U

MKT-MC-0047 v.1.1