



FebriDx is now
CLIA-Waived

FebriDx

Clear Results aid in More Confident Antibiotic Decisions

FebriDx is a rapid, easy-to-use test delivering actionable results to aid clinicians wherever Acute Respiratory Infection patients are seen

- Identify a bacterial infection and initiate appropriate treatment during a patient visit
- Improve practice workflow with rapid test results
- Ensure that bacterial infections are not overlooked
- Easily implement an antimicrobial stewardship solution
- Helps clinicians make confident antibiotic use decisions in conjunction with other clinical and diagnostic information every day

- ✓ **99% negative predictive value to rule out bacterial infections¹**
- ✓ **Instrument-free**
- ✓ **Results after 10 minutes from a fingerstick**
- ✓ **Simple CLIA-Waived², FDA 510(k)-cleared³ procedure**



Instructional Video



<https://www.youtube.com/@FebriDxInstructionalVideo>

Simple Instrument-Free Test Procedure

Intended for patients with symptoms of ARI (e.g., fever, cough, shortness of breath, cold, sore throat)

FebriDx is intended to be used at sites operating with a CLIA Certificate of Waiver. CLIA complexity Waived for fingerstick blood. Follow all steps in order. This is not a complete Package Insert.

1 REMOVE DEVICE & CHECK EXPIRY

Check expiry date

Tear open foil pouch and remove device.

2 MASSAGE FINGER & CLEAN

Select finger and massage from base to tip to increase blood flow.

Cleanse the finger and wipe dry with fresh dry gauze.

3 PREPARE LANCET

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

4 LANCE FINGER & WIPE AWAY BLOOD

Firmly press the lancet against the finger to puncture the skin.

Wipe away first drop of blood with clean new gauze.

5 MASSAGE FINGER

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

6 COLLECT BLOOD

Fill the Blood Collection Tube **completely** with blood. Ensure the Blood Collection Tube only touches the hanging drop of blood and not the finger.

7 VERIFY TUBE IS FULL

If the Blood Collection Tube is still not full, massage the entire finger to obtain more fingerstick blood. If still not full, **discard test. Repeat testing with a new device and finger.**

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

8 TRANSFER BLOOD TO TEST STRIP

Once the Blood Collection Tube is **completely full**, lay the test on a flat surface. Rotate the Blood Collection Tube to touch the Test Strip.

9 VERIFY BLOOD TRANSFER TO TEST STRIP

Make sure the blood has transferred to the Test Strip.

If the blood does not immediately transfer to the Test Strip,

- Push the Blood Collection Tube down to make sure it is touching the Test Strip.
- If the blood still has not transferred, reverse the Blood Collection Tube back to its original position and repeat steps 5-8 within two (2) minutes.
- If the step above is unsuccessful, **discard test. Repeat testing with a new device and finger.**

10a DELIVER BUFFER

After blood completely transfers, firmly push the Buffer Release Button until it clicks to deliver the buffer.

Make sure Buffer Release Button is completely pushed down.

10b CHECK BLOOD IS FLOWING ACROSS THE RESULT WINDOW

If the blood is not visible in the Result Window within 30 seconds press the Buffer Release Button again until clicking is audible.

If blood is still not visible after pressing the buffer release button again, **discard test. Repeat testing with a new device and finger.**

11 VERIFY TEST IS READY FOR INTERPRETATION

- Result Window** must be **clear** of blood.

If Result Window is **not clear** after waiting up to 30 minutes, **discard test. Repeat testing with a new device and finger.**
- Blood Clearance Window** must contain **pink/red**.

If Blood Clearance Window **does not contain pink/red** after waiting up to 30 minutes, **discard test. Repeat testing with a new device and finger.**
- Do not read results **after 1 hour** or before ten minutes. Reading results before the blood has cleared the Results Window or without blood in the Blood Clearance Window may lead to erroneous test results.

*Test lines depicted are shown as an example.

12a CHECK FOR VALID TEST

- **Blue** control (CTL) line present = **Valid Test**

- Valid Test Result is ready for Interpretation

- No **blue** control (CTL) line = **Invalid Test**

Discard test. Repeat testing with a new device and finger.

12b CHECK FOR BACTERIAL INFECTION

Result is **BACTERIAL INFECTION** if:

- **Grey/black** line (CRP) + **blue** control (CTL) line

12c CHECK FOR NON-BACTERIAL ETIOLOGY

Result is **NON-BACTERIAL ETIOLOGY** if:

- No test line + **blue** control (CTL) line only, OR
- **Red** line (MxA) + **blue** control (CTL) line, OR
- **Grey/black** line (CRP) + **Red** line (MxA) + **blue** control (CTL) line

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

- 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. Oct 3 2022;5(10):e2234588. doi:10.1001/jamanetworkopen.2022.34588T
- FebriDx Bacterial / Non-Bacterial Assay; FDA 510(k) K260787
- FebriDx Bacterial / Non-Bacterial Point of Care Assay 510(k) K230917