

A Rapid Point-of-Care Test for Acute Respiratory Infections

FebriDx is a rapid Point-of-Care test to aid in the diagnosis of acute respiratory infection and differentiate bacterial from non-bacterial etiology.

- 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

- ✓ **99% negative predictive value to rule out bacterial infections¹**
- ✓ **Instrument-free**
- ✓ **Results after 10 minutes from a fingerstick**
- ✓ **FDA 510(k) cleared², easy-to-use procedure**



Instructional Video



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

Simple Instrument-Free Test Procedure

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

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.

Cleanse the finger.

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.

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 it only touches the hanging drop of blood and not the finger.

7 VERIFY TUBE IS FULL

If the Blood Collection Tube is not full, massage the entire finger to obtain more fingerstick blood. If not full, stop, discard, retest.

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,

1. Push the Blood Collection Tube down to make sure it is touching the Test Strip.
2. If the blood still has not transferred, reverse the Blood Collection Tube back to its original position and repeat steps 5-8.
3. If the step above is unsuccessful, **stop, discard, retest.**

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 RESULTS 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, **stop, discard, retest.**

TEST RESULTS

11 VERIFY TEST IS READY FOR INTERPRETATION

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

Result Window

If Result Window is **not clear** after waiting up to 1 hour, **stop, discard, retest.**
- 2. Blood Clearance Window** must contain **pink/red**.

Blood Clearance Window

If Blood Clearance Window **does not contain pink/red** after 1 hour, **stop, discard, retest.**
- 3. 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.

**Test lines depicted are shown as an example.*

TEST INTERPRETATION

12 INTERPRETATION OF RESULTS

Faint or incomplete test lines may still be interpreted as present.

Bacterial Infection, Valid Test

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

Non-Bacterial Etiology, Valid Test

- Red line (MxA) + blue control line

- Red line (MxA) + grey/black line + blue control line

- No test line + blue control line only

Invalid

- No blue control line

- Discard test and retest with a new FebriDx test.

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

1. 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
2. 510(k) #K230917; FebriDx Bacterial / Non-bacterial Point of Care Assay