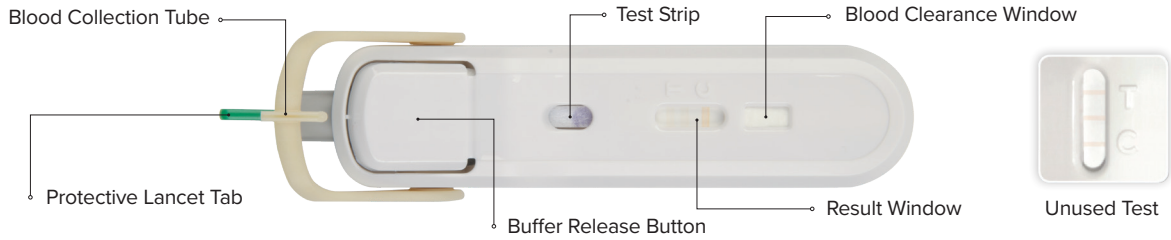


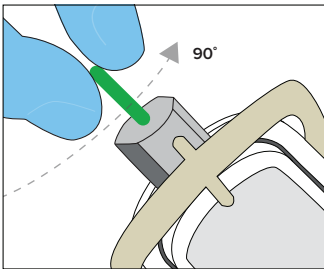
FebriDx®



Review the full FebriDx® Package Insert before performing the test. This is not a complete Package Insert. Check the expiration date on all packaging. Remove test from foil pouch. **Follow all test steps in order.**

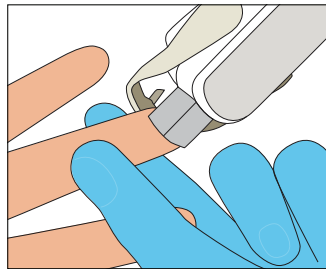
TEST PROCEDURE

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



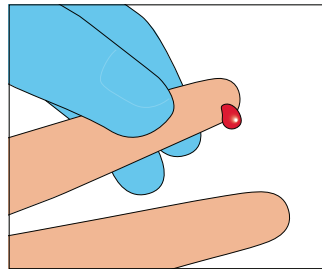
1 Prepare Lancet

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



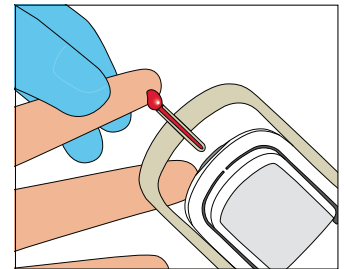
2 Lance Finger

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



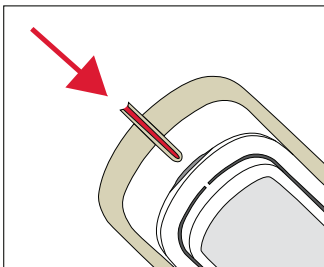
3 Massage Finger

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



4 Collect Blood

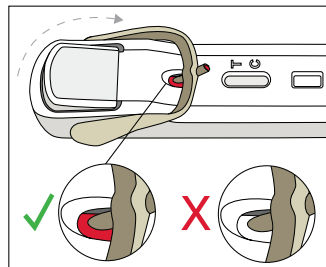
Place the Blood Collection Tube below the finger, and ensure it only touches the hanging drop of blood and not the finger.



5 Verify Tube Is Full

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

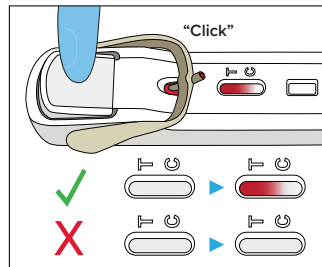
WARNING: Incomplete filling of the Blood Collection Tube could lead to erroneous test results.



6 Transfer Blood

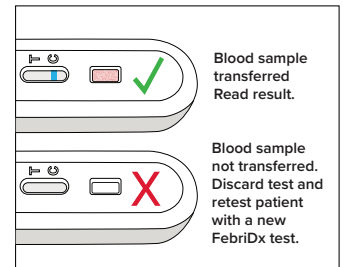
Lay the test on a flat surface.

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.

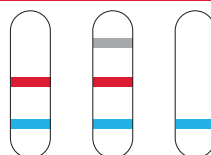
INTERPRETATION OF RESULTS

Bacterial Infection



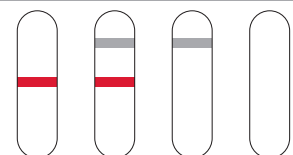
A black only result line is interpreted as bacterial infection. A blue control line shows the test is valid.

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 the test is valid.

Invalid



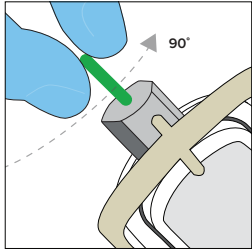
The absence of the blue control line indicates an invalid result. Discard test and retest patient with a new FebriDx® test.

Faint or incomplete result lines should still be interpreted as positive, as long as a control line is present.

Dispose in the proper biohazard receptacle. After testing, remove gloves, clean hands and wear a new pair of clean gloves before testing each patient.



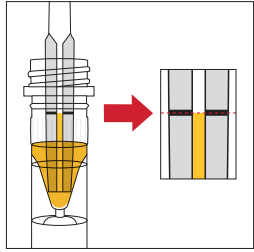
EXTERNAL CONTROL PROCEDURE



1 Deploy Lancet

Twist the Protective Lancet Tab 90 degrees and pull to remove. Firmly press the lancet on a hard surface to move past the patient sampling step.

Take care not to make skin contact with the lancet.



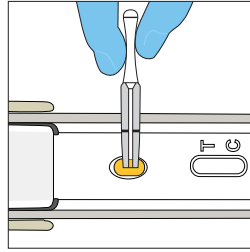
2 Collect Control Solution

Do NOT squeeze the pipette bulb in this step.



Locate either the Positive or Negative Control vial and remove the cap.

Without squeezing, hold the bulb end of the pipette and dip the other end into the control solution until the pipette is filled to the indicator line.

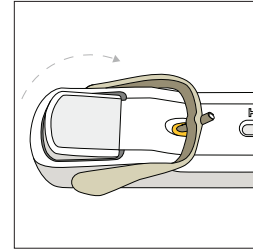


3 Dispense Control Solution

Lay the test on a flat surface.

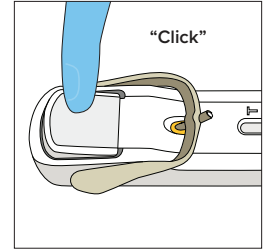
Hold the filled pipette vertically while making contact with the Test Strip and squeeze the pipette bulb to release the control fluid onto the Test Strip.

Discard pipette after one use. If more or less control solution than indicated by the indicator line is applied, discard the test and start again.



4 Rotate Blood Collection Tube

Rotate the Blood Collection Tube until it touches the Test Strip and clicks into position.



5 Deliver Buffer Solution

Firmly press the Buffer Release Button until it clicks to deliver the buffer, which will migrate across the Test Strip. If the fluid is not visible in the Result Window within 30 seconds, press the Buffer Release Button again until clicking is audible.

Wait for 10 minutes.



Results will appear in the Result Window. Do not read results after 1 hour.

INTERPRETATION OF RESULTS

A **blue** control line shows the test is valid.

Positive Control



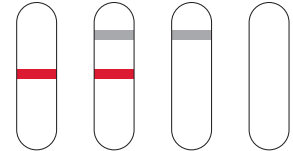
Positive Control will produce three test lines: CRP, MxA and Control (**black**, **red**, and **blue**) result lines.

Negative Control



Negative Control will only produce the **blue** control line.

Invalid



The absence of the **blue** control line indicates an invalid result.

Please scan code for the electronic FebriDx® Package Insert or go to the following webpage:

<https://lumosdiagnostics.com/febridx/PM-127>



Visit LumosDiagnostics.com for more information.

For technical assistance call 1.855.LumosDx / 1.855.586.6739 or email technical.support@lumosdiagnostics.com

Reference the Package Insert for Warnings and Precautions, Specimen Collection and Handling, and Quality Control.

