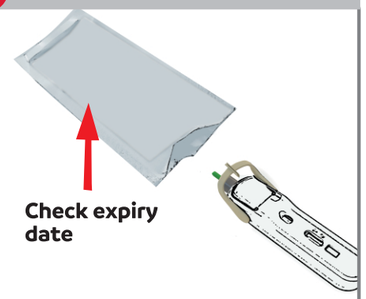
TEST PROCEDURE

Wash hands and put on gloves before testing. Users with color-impaired vision should not interpret the test.

Read the EXTERNAL CONTROL procedure and complete test procedure prior to performing the FebriDx test. CLIA complexity Waived for fingerstick blood. Follow all steps in order.

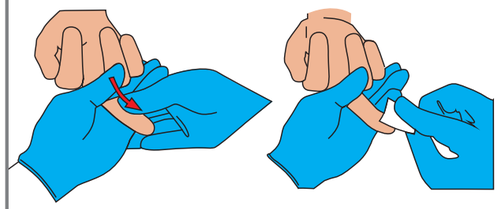
FebriDx®

1 REMOVE DEVICE & CHECK EXPIRY



Tear open foil pouch and remove device.

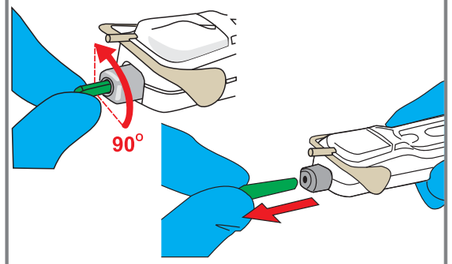
2 MASSAGE FINGER & CLEAN



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

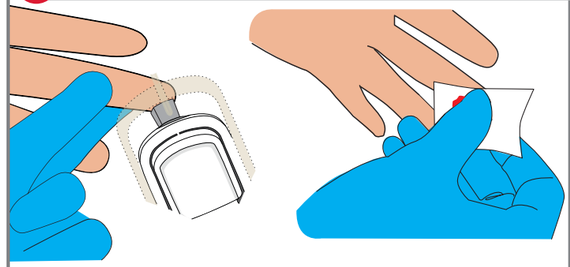
Cleanse the finger and wipe dry with fresh dry gauze.

3 PREPARE LANCET



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

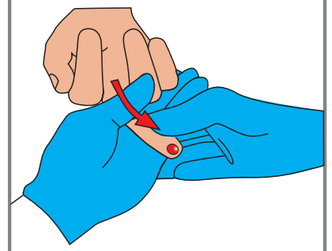
4 LANCE FINGER & WIPE AWAY BLOOD



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

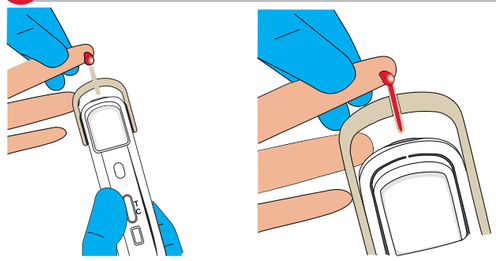
Wipe away first drop of blood with clean new gauze.

5 MASSAGE FINGER



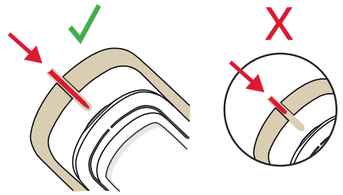
Massage entire finger from base to tip to obtain a large drop of blood that hangs from the finger.

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.

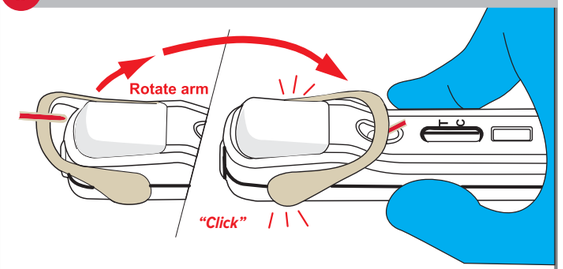
7 VERIFY TUBE IS FULL



If the Blood Collection Tube is 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.

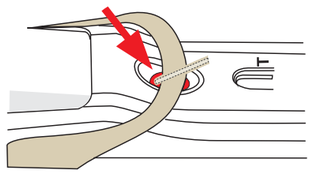
8 TRANSFER BLOOD TO TEST STRIP

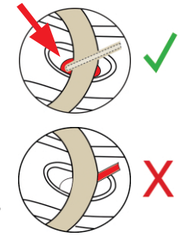


Once the Blood Collection Tube is **completely full**, lay the test on a flat surface. Rotate the Blood Collection Tube to touch the Test Strip.

9 VERIFY BLOOD TRANSFER TO TEST STRIP

Make sure the blood has transferred to the Test Strip.

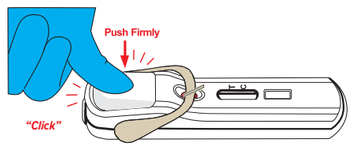




If the blood does not immediately transfer to the Test Strip,

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

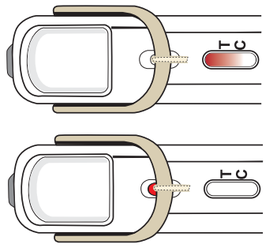
10a DELIVER BUFFER



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 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.

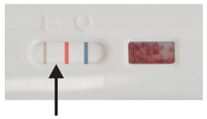
If blood is still not visible after pressing the buffer release button again, **discard test. Repeat testing with a new device and finger.**

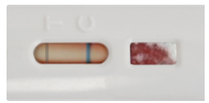
TEST DISPOSAL

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

11 VERIFY TEST IS READY FOR INTERPRETATION

1. 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.**

2. 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.**

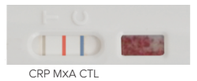
3. Do not read results **after 1 hour** or before ten minutes.

Reading results before the blood has cleared the Result Window or without blood in the Blood Clearance Window may lead to erroneous test results.

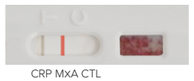
**Test lines depicted are shown as an example.*

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

12a CHECK FOR VALID TEST

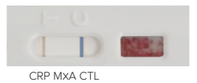


- **Blue** control (CTL) line present = **Valid Test**
- Valid Test Result is ready for Interpretation



- 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:

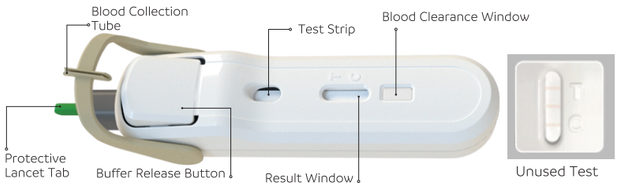
- No test line + **blue** control (CTL) line only, *OR*

- **Red** line (MxA) + **blue** control (CTL) line, *OR*

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

QUICK REFERENCE INSTRUCTIONS

FebriDx®



Instructional Video

Access via QR or link

You will need these items:

- Timer
- Gauze
- Alcohol
- Gloves
- Bandage

Materials Provided:

- 25 Single Use Test Devices
- 1 Package Insert
- 1 QRI

For In Vitro Diagnostic Use Only. For Prescription Use Only.
The FebriDx Bacterial / Non-Bacterial Assay is intended to be used at sites operating with a CLIA Certificate of Waiver. Laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the FebriDx test. Any modifications by the user(s) to the manufacturer's test procedures will result in the test no longer meeting the requirements for waived classification.
This is not a complete Package Insert.

Please scan code for the electronic FebriDx Package Insert or go to the following webpage: http://lumosdiagnostics.com/febridx/PM-127

SCAN ME

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.

IVD Σ25 4°C 25°C

Device

LUMOS DIAGNOSTICS

Lumos Diagnostics, Inc.
2724 Loker Avenue West, Carlsbad, CA 92010 USA
1.855.LumosDx / 1.855.586.6739 LumosDiagnostics.com

PM-063.5 MAR 2026