

Visit [LumosDiagnostics.com](https://LumosDiagnostics.com) for more information.

For technical assistance call 1.855.LumosDx / 1.855.586.6739  
or email [technical.support@lumosdiagnostics.com](mailto:technical.support@lumosdiagnostics.com)

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



Lumos Diagnostics, Inc.  
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1.855.LumosDx / 1.855.586.6739 [LumosDiagnostics.com](https://LumosDiagnostics.com)

If the correct external control results are not obtained, repeat the test or  
contact Lumos Diagnostics Technical Support at 1.855.LumosDx.

PM-079.3 JUL 2025

## WARNINGS AND PRECAUTIONS

1. Refer to the FebriDx Package Insert for additional information.
2. FebriDx External Controls should be stored between 15-25°C.
3. FebriDx External Controls may be used until the expiration date noted on the outer packaging and/or label. Do not use FebriDx External Controls past their expiration date.
4. Do not dilute FebriDx External Controls.
5. Do not overfill or underfill the pipette. If control solution is not at the 5 µl indicator line, the volume is incorrect and the control solution should be re-sampled.
6. Number of uses per control vial will depend on technique.
7. FebriDx External Controls will appear yellowish orange in color.

## STORAGE AND STABILITY

FebriDx External Controls should be stored between 15-25°C until the expiration date noted on the outer packaging and/or label.

## TECHNICAL SUPPORT

Lumos Diagnostics Technical Support 1.855.LumosDx

## GLOSSARY OF SYMBOLS

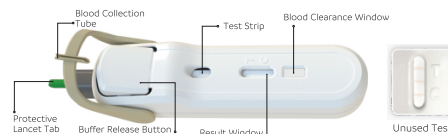
Symbol	Description
	In vitro diagnostic medical device
	Reference number (SKU)
	Lot number
	Use-by (expiration) date
	Positive Control
	Negative Control
	Caution
	Temperature limit
	Consult instructions for use
	Manufacturer

# FebriDx

## FebriDx External Controls

REF CP0007

### Instructions for Use



Instructional Video  
Access via QR or link



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

### Materials Provided:

- 1 FebriDx Positive Control Vial
- 1 FebriDx Negative Control Vial
- 44 Single-Use Pipettes
- 1 Instructions For Use

### You Will Also Need:

Two (2) FebriDx Tests (Test Kit [REF CP0014](#))



## INTENDED USE

FebriDx External Controls are used in the FebriDx test as assayed quality control samples to assess the performance and reliability of the FebriDx test.

## CONTENTS OF CONTROLS

### Positive Control (MxA/CRP)

250 µl of buffered stabilizing solution containing preservative and recombinant MxA and CRP proteins.

### Negative Control

250 µl of buffered solution containing preservative.

## POSITIVE AND NEGATIVE EXTERNAL CONTROLS

Positive and negative external controls should be used as consistent with good laboratory practice. The manufacturer recommends external controls be run with every new lot, every new shipment, and with every first-time operator, but every testing site should follow their own protocols for running external controls.

Perform a positive and negative control on two separate FebriDx tests. Follow steps in order.

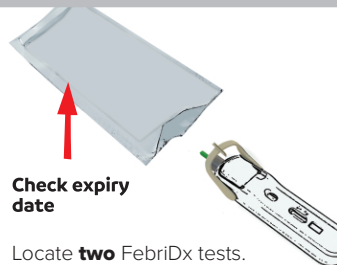
**Note:** The FebriDx test is designed to proceed in sequential order and locking mechanisms exist to prevent skipping steps. Therefore, it is essential to incorporate all the test steps in order.

## EXTERNAL CONTROL PROCEDURE

FebriDx External Controls are used to assess the performance and reliability of the FebriDx test.

**FebriDx External Controls should be performed with every new lot, every new shipment, and every first-time operator.** Read the complete test procedure and external control procedure prior to performing the FebriDx test. Wash hands and put on gloves before performing External Controls procedure. Perform a positive and negative control on two separate FebriDx tests. Follow steps in order.

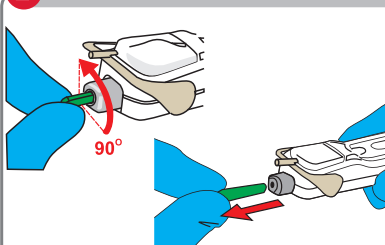
### 1 REMOVE DEVICE & CHECK EXPIRY



Check expiry date

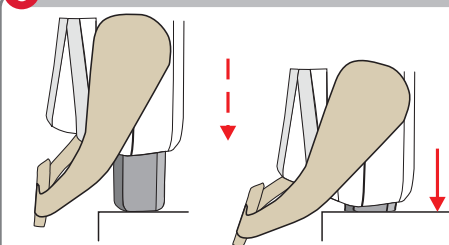
Locate **two** FebriDx tests. Tear open **one** foil pouch and remove device.

### 2 PREPARE LANCET



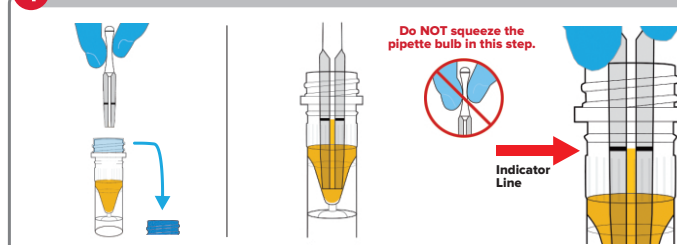
Twist Protective Lancet Tab **90 degrees** and pull to remove.

### 3 PRESS LANCET ON HARD SURFACE



Firmly press the lancet on a hard surface to move past the patient sampling step. Take care not to puncture skin with lancet.

### 4 COLLECT NEGATIVE CONTROL SOLUTION

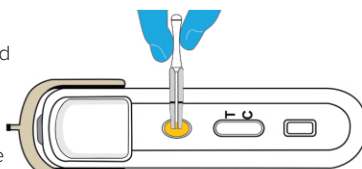


Locate the **Negative Control** vial and remove the cap. **Without squeezing**, hold the bulb end of the pipette and dip the other end into the control solution until the pipette is filled to the indicator line.

### 5 DISPENSE CONTROL SOLUTION

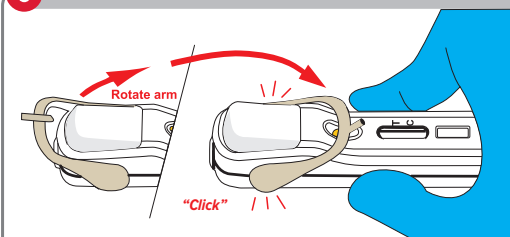
Lay the test on a flat surface.

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.



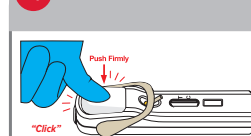
Discard pipette after one use. If more or less control solution than indicated by the indicator line is applied, **discard the test and start again.**

### 6 ROTATE BLOOD COLLECTION TUBE



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

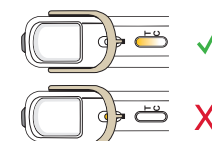
### 7a DELIVER BUFFER



Firmly press the Buffer Release Button until it clicks to deliver the buffer.

Make sure Buffer Release Button is completely pushed down.

### 7b CHECK FLUID IS FLOWING ACROSS THE RESULT WINDOW



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

If fluid is still not visible after pressing the buffer release button again, **discard the test and start again.**

### 8 VERIFY TEST IS READY FOR INTERPRETATION

**1. Result Window** must be **clear** of fluid.



Result Window

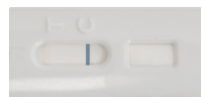


If Result Window is **not clear**, wait up to 1 hour until the Result Window is clear.

**2. Blood Clearance Window** must contain **yellow/orange**.



Blood Clearance Window



If Blood Clearance Window **does not contain yellow/orange** after 1 hour, **stop, discard, retest.**

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

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

### 9 INTERPRETATION OF RESULTS

**The FebriDx Positive Control is formulated to be a weak positive result around the cut-off of the assay. Lines should be expected to appear faint.**

Positive Control, Valid Test



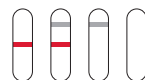
- Grey/black line (CRP) + red Line (MxA) + blue control line

Negative Control, Valid Test



- No test line + blue control line only

Invalid

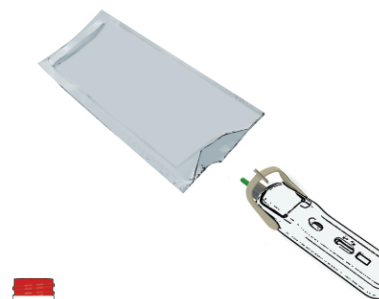


- No blue control line

- Discard test and retest with a new FebriDx test.

### 10 COLLECT POSITIVE CONTROL SOLUTION

Repeat all steps with the second FebriDx test and the **Positive Control** vial.



FebriDx Positive Control vial

Dispose the used FebriDx tests and pipettes when testing is complete.