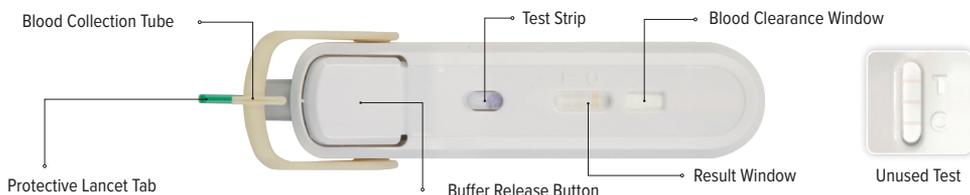


FebriDx®

FebriDx® External Controls

Instructions for Use



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.

PACKAGE COMPONENTS

- FebriDx® Positive Control
- FebriDx® Negative Control
- 44 Pipettes (2 bags x 22 pipettes)
- Instructions for Use

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.

EXTERNAL CONTROL PROCEDURE

1. Locate one (1) FebriDx® test. Check the expiration date on the packaging.
2. Tear open the foil pouch at the indicated perforation and remove the test.

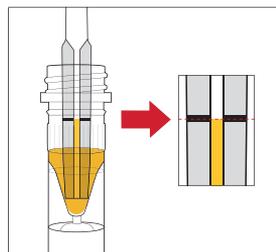
Note: The FebriDx® test is designed to proceed in sequential order and locking mechanisms exist to prevent skipping steps. Therefore, it is essential to incorporate all the test steps in order.

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

Note: Take care not to make skin contact with the lancet.

4. Locate **either** the **Positive** or **Negative** Control vial and remove the cap.
5. Without squeezing, hold the bulb end of one of the provided pipettes and dip the other end into the control solution until the pipette is filled by capillary action to the indicator line (indicator line marks 5 µl of solution).

Do NOT squeeze the pipette bulb in this step.

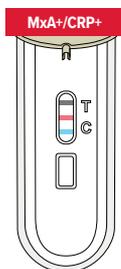


6. Hold the filled pipette vertically over the Test Strip, and, while **making contact** with the Test Strip, squeeze the pipette bulb to release the control fluid. Discard pipette after one use.

Note: If more or less control solution than indicated by the indicator line is applied, discard the test and start again.

7. Rotate the Blood Collection Tube over the Test Strip until it clicks into position.
8. Lay test on a flat surface. Activate the test by firmly and fully pressing the Buffer Release Button to deliver the buffer. If no fluid is visible within 25-30 seconds, firmly re-press the Buffer Release Button.
9. Wait for 10 minutes. Results will appear in the Result Window.

EXPECTED RESULTS

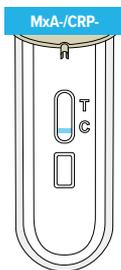


Red and Black Lines Visible

Positive Control

The presence of a blue control line, a red MxA line and a black CRP line should appear to indicate a positive result.

Note: 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.



No Result Line

Negative Control

The presence of only a blue control line should appear to indicate a Negative result.

A blue control line must appear in the result window for the test to be valid. The absence of a blue control line indicates an invalid result.

Refer to the FebriDx® Quick Reference Instructions (QRI) for information on reading and interpreting results.

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.

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

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.

MATERIALS NOT PROVIDED

- FebriDx® Test Kit (REF CP0014)
- Gloves
- Timer

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.

AVAILABILITY

FebriDx External Controls (REF CP0007)

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



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