FebriDx
an RPS diagnostic solution

QUICK REFERENCE GUIDE

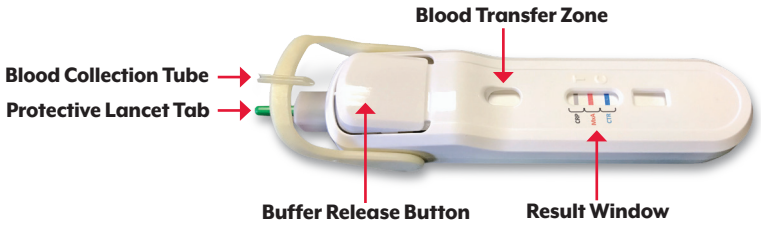
INTENDED USE

FebriDx is a rapid immunoassay for the visual, qualitative, in vitro detection of elevated levels of both MxA and CRP directly from fingerstick whole blood. The test measures a clinically significant immune response to a suspected invasive viral and/or bacterial infection in patients older than 2 years that present within 3 days of an acute onset fever (exhibited or reported) and within 7 days of new onset respiratory symptoms consistent with a community-acquired upper respiratory infection.

The FebriDx test aids in the clinical identification of patients with an underlying invasive viral infection from either Influenza A/B, Adenovirus, Respiratory Syncytial Virus, Metapneumovirus, Parainfluenza Virus, or Epstein-Barr Virus; and/or patients with a clinically significant immune response consistent with an underlying bacterial infection.

The test is intended for professional use in an outpatient setting and should be used in conjunction with other clinical evidence including laboratory, radiographic, and epidemiological information.

Negative results do not preclude respiratory infection (e.g. rhinovirus, coronavirus) and should not be used as the sole basis for diagnosis, treatment, or other clinical and patient management decisions. In addition to utilizing radiography and clinical presentation to aid in diagnosis, additional laboratory testing (e.g. bacterial and viral culture, immunofluorescence, and polymerase chain reaction [PCR]) may be used to confirm whether a specific respiratory pathogen exists.



TEST PROCEDURE

Check the expiration date on all packaging.

1. Tear open the foil pouch at the perforation and remove the test.

Collecting and Transferring the Fingerstick Blood Sample

NOTE: *Use standard precautions for collecting and handling a blood sample.*

2. Cleanse the fingertip with an alcohol pad and allow it to air dry.

3. Locate the lancet and remove the **Protective Lancet Tab**. Firmly press the lancet to puncture the skin. Wipe away the first drop of blood with gauze and gently massage towards the puncture site to encourage blood flow.

4. Place the **Blood Collection Tube** at approximately a 45 degrees angle below the finger blood sample as contact is made. Fill the **Blood Collection Tube** in its entirety by touching the blood to the tip of the **Blood Collection Tube**. If the **Blood Collection Tube** is not full, gently squeeze the finger and add more blood.

   NOTE: *Capillary action will automatically draw the blood sample into the* ***Blood Collection Tube*** *in the required amount (5 µl).*

5. Once the **Blood Collection Tube** is filled with blood, rotate it over the **Blood Transfer Zone** to deliver it to the test. The **Blood Collection Tube** will lock into position. Wait for **most of the blood to be transferred** to test strip (~5-10 seconds) before proceding to step #6 and activating the test.

   NOTE: *If the blood does not immediately begin to transfer the blood onto the test strip, reverse the* ***Blood Collection Tube's*** *rotation back to its original position. This will occur against some resistance. Add additional fingerstick blood to the the Blood Collection Tube to ensure the tube is completely filled before rotating back onto the test strip.*

6. Activate the test by firmly and fully pressing the **Buffer Release Button** to deliver the buffer. The **Buffer Release Button** should be pressed within 2 minutes of transferring the blood sample. If no fluid is visible within 25 -30 seconds, firmly re-press the **Buffer Release Button**.

7. Lay the test on a flat surface and wait for 10 minutes. Results will appear in the **Result Window**.

TEST RESULTS

Results should be interpreted at the 10-minute mark. If the majority of the background has not cleared after 10 minutes, allow an additional 5-10 minutes of running time prior to interpretation. Do not read the test results after 3 hours.

An unused test, or test that has not yet been activated by pressing the **Buffer Release Button**, will show three faint **orange** lines in the **Result Window**.

A **blue** control line must appear in the **Result Window** for the test to be valid.

POSITIVE RESULT

The positive result lines appear as **red** or **black** lines in the **Result Window**. An uneven or incomplete result line is due to an uneven sample distribution on the test strip. Even if the result line is faint in color, incomplete over the width of the test strip, or uneven in color, it should be interpreted as positive. A positive result indicates the presence of elevated MxA and/or CRP proteins.

NEGATIVE RESULT

If only a **blue** control line is visible in the **Result Window**, the test is deemed negative. A negative result indicates a lack of elevated MxA and CRP proteins.

INVALID RESULT

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

If an invalid result occurs, the test must be discarded and the patient retested using a new FebriDx test. Choose an alternative puncture site on a different finger when retesting the patient.

NOTES:

- A blood fluid wave will migrate up the Result Window and gradually disappear as the test develops.
- Faint blood streaks may be visible along the sides of the Result Window and are acceptable for reading purposes.
- If the background of the Result Window has not cleared sufficiently for interpretation of results after 30 minutes, discard the test and retest the patient with a new FebriDx test.
- FebriDx test results are stable for up to three (3) hours. Do not interpret the test results after this period of time.

Note: *The complete FebriDx package insert can be found on the downloads page at: FebriDx.com*

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RPS diagnostics

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