QUICK REFERENCE GUIDE

IMPORTANT
See package insert for complete instructions for use, warnings and precautions, limitations, and study results. For questions and technical support, contact RPS at +1.941.556.1850.

INTENDED USE
FebriDx is a rapid immunoassay for the visual, qualitative, in vitro detection of elevated levels of both MxA and CRP directly from peripheral 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.

COMPONENTS
- Test card
- Accessory kit (1 lancet, 2 pipettes)
- Buffer solution

TEST PROCEDURE
Note: Use standard precautions for collecting and handling a blood sample.

1. Grasp the flap at the red arrow and lift the flap to the left to expose the sample application zone. Gently bend the flap to the left to ensure it is fully open.
2. Cleanse the fingertip with an alcohol pad and allow it to air dry.
3. Locate the lancet and remove the protective cap. 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. Hold one of the pipettes horizontally and collect 5 μl of blood (to reach black fill line) from the puncture site. Do not squeeze the pipette bulb.
5. Position the pipette over the blue strip in the sample application zone. Touch the tip of the pipette to the strip and squeeze the pipette bulb to transfer the full amount of blood.
6. Hold the second pipette horizontally and collect another 5 μl of blood (to reach black fill line) from the puncture site. Do not squeeze the pipette bulb.
7. Position the pipette over the purple strip in the sample application zone. Touch the tip of the pipette to the strip and squeeze the pipette bulb to transfer the full amount of blood.
8. Close the flap. Using two thumbs, press down on the black fingerprints to snap the pegs into place.
9. Slowly squeeze the buffer solution into the blue activation window until all of the liquid has been emptied, ensuring that none of the liquid spills onto the test card.
10. Lay the test card on a flat surface for 15 minutes.

To order, visit FebriDx.com or call +1.941.556.1850.
TEST RESULTS
A fluid wave is observed moving across the result windows while the test is running. If a fluid wave is not visible after approximately one (1) minute, locate another buffer solution tube and slowly squeeze to add more liquid (4-5 drops) into the blue activation window. Once the majority of the background in each result window has cleared (aside from minor peripheral blood streaks along the sides of each result window) and at least 15 minutes have elapsed, the test may be accurately read.

Note: If the majority of the background has not cleared after 15 minutes, allow additional development time prior to interpretation. If the majority of the background has not cleared sufficiently for interpretation of results after 30 minutes of development time, the test cannot be accurately read and must be discarded. Use a new FebriDx test card to retest the patient.

A blue control line must appear in each result window for the test to be valid.

POSITIVE RESULT
The result lines appear as red or black lines in the result windows. 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 antigens.

NEGATIVE RESULT
If only a blue control line is visible in both result windows, the test is deemed negative. A negative result indicates a lack of elevated MxA and CRP antigens.

INVALID RESULT
The absence of two blue control lines indicates an invalid result. A blue control line must appear in each result window for the test to be valid.

WARNINGS AND PRECAUTIONS
1. For in vitro diagnostic use only.
2. Keep the FebriDx test card in the sealed foil pouch until just before use.
3. Do not use the FebriDx test card or the buffer solution past the expiration date.
4. Use standard precautions for collecting and handling a blood sample.
5. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent. Proper handling and disposal methods should be established according to local, state, and federal regulations.
6. Wear disposable gloves while handling samples and wash hands after the test is complete.
7. The lancet is sterile until the protective cap is removed. Do not use lancet if protective cap is not secured in place.
8. After the two (2) blood samples are applied to the test card and it is snapped closed, buffer solution should be applied immediately into the blue activation window. The test must be run within one (1) minute after closing the flap.
9. The FebriDx test card, pipettes, lancet, and buffer solution are single use items. Do not reuse with multiple specimens.
10. The FebriDx test requires a visual readout. Do not interpret the test result if you have color-impaired vision.
11. Result interpretation requires a brightly lit environment.