



Study the Package Insert and User Manual thoroughly before using Quick Reference Instructions. This is not a complete Package Insert.

IMPORTANT! Read instructions carefully before beginning. The test procedure below is unique to the Sofia Legionella FIA and may differ from other Sofia and Sofia 2 FIA procedures.

Test Procedure

DO NOT open the foil pouch containing the Test Cassette until ready to test the sample. Place the Test Cassette on a clean and level surface.

All specimens must be at room temperature before testing.

Expiration Date: Check expiration on each individual test package or outer box before using. *Do not use any test past the expiration date on the label.*

1

Verify that Sofia is set to the desired mode: **WALK AWAY** or **READ NOW**. See the "Using Sofia" section for more information.

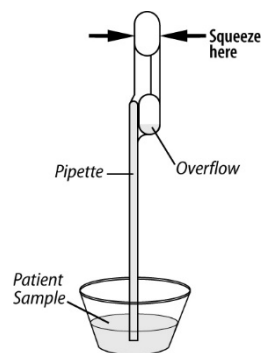
Follow Package Insert for Specimen Collection.

2

Fill the provided Small, Clear 120 μ L Fixed Volume Pipette with the patient sample.

To fill the Fixed Volume Pipette with the patient sample:

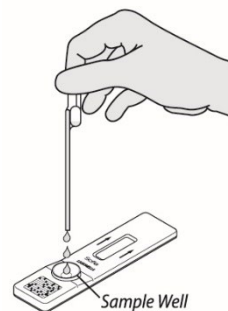
- FIRMLY squeeze the top bulb.
- Still squeezing, place the Pipette tip into the sample.
- With the Pipette tip still in the liquid sample, release pressure on bulb to fill the Pipette.



3

Firmly squeeze the top bulb to empty the contents of the Fixed Volume Pipette into the Test Cassette sample well. Extra liquid in the overflow bulb is OK.

NOTE: The Fixed Volume Pipette is designed to collect and dispense the correct amount of liquid sample. Discard the pipette in your biohazard waste.



4

Proceed to the next section, "Using Sofia," to complete the test.

Using Sofia

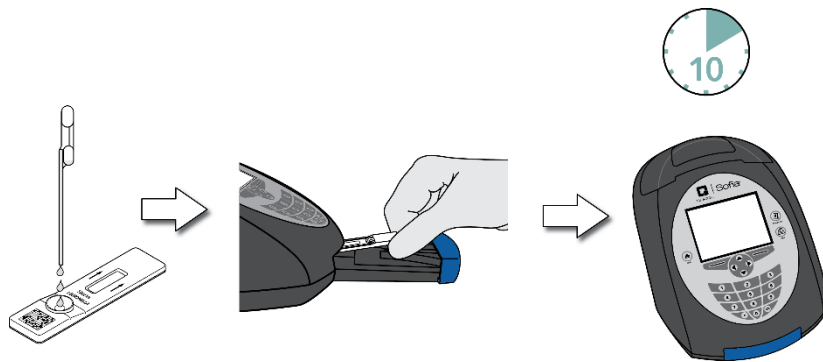
WALK AWAY/READ NOW Modes

Refer to the *Sofia User Manual*.

Sofia may be set to two different modes (WALK AWAY and READ NOW). The procedures for each mode are described below.

WALK AWAY MODE

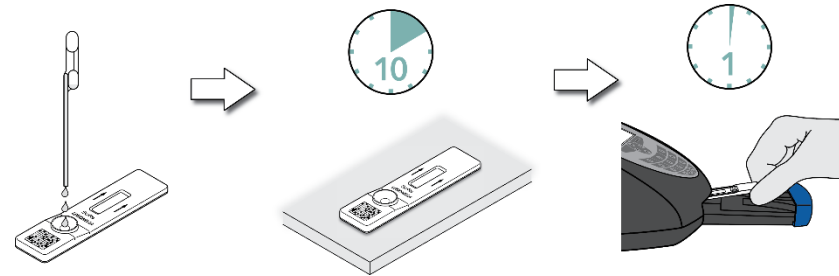
In WALK AWAY Mode, the user **immediately** inserts the Cassette into Sofia. The user then returns after 10 minutes to get the test result. In this mode, Sofia will automatically time the test development before scanning and displaying the test result.



READ NOW MODE

Allow the test to develop for the FULL 10 minutes BEFORE placing it into Sofia.

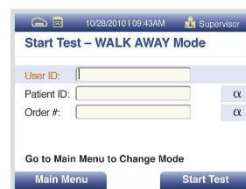
The user must first place the Cassette onto the counter or bench top for 10 minutes (outside of Sofia) and manually time this development step. Then, the user inserts the Cassette into Sofia. In READ NOW Mode, Sofia will scan and display the test result within 1 minute. **Note:** Results will remain stable for an additional 10 minutes after the recommended development time of 10 minutes.



RUN TEST

1. Input the User ID with the barcode scanner or enter the data using the key pad.

NOTE: If you scan the wrong barcode, use the Arrow Keys on Sofia to re-highlight the field and simply rescan using the correct barcode. The previous one will be overwritten with the right barcode.



2. Input the Patient ID or Order # with the barcode scanner or enter the data using the key pad.

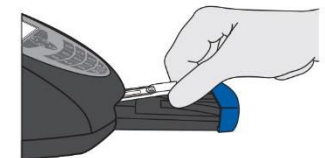


3. Press Start Test and the Sofia drawer will automatically open.



4. Verify that the correct mode (WALK AWAY or READ NOW) has been selected. Insert the Test Cassette into the drawer. Then gently close the drawer.

5. Sofia will start automatically and display the progress. In WALK AWAY Mode, the test results will be displayed on the screen within 10 minutes. In READ NOW Mode, the test results will be displayed on the screen within 1 minute. See Interpretation of Results section.



Interpretation of Results

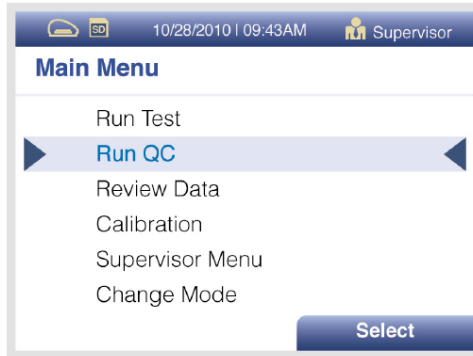
When the test is complete, the results will be displayed on the Sofia screen. The results can be automatically printed on the integrated printer if this option is selected. Test Lines, which are fluorescent, will never be visible to the naked eye.

Results: The Sofia screen will display results for the procedural control as being “valid or invalid” and will provide positive or negative result for the detection of *Legionella pneumophila* serogroup 1. If the procedural controls are “invalid,” retest the patient’s sample with a new Test Cassette.

Reader Display	Interpretation
Legionella: Positive Procedural Control: Valid	Positive test for <i>Legionella pneumophila</i> serogroup 1. (Legionella antigen present)
Legionella: Negative Procedural Control: Valid	Negative test for <i>Legionella pneumophila</i> serogroup 1. (no antigen present)
Legionella: Invalid Procedural Control: Invalid	Result Invalid

External Quality Control

- 1 From the main menu, select Run QC.



- 2 Following the prompt on the screen, scan the QC Card (located on the kit box).
- 3 Sofia will prompt the user to select the desired mode (WALK AWAY or READ NOW) and then to run the External Controls.
- 4 Follow the External Quality Control Test Procedure in the Package Insert to test each control, first the Positive Control followed by the Negative control.
- 5 After both the Positive and Negative Controls have been run, the results will be displayed as “Passed” or “Failed.”

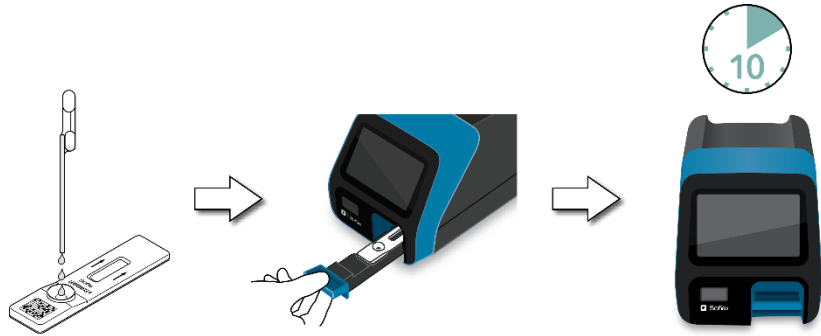
WALK AWAY/READ NOW Modes

Refer to the Sofia 2 User Manual.

Sofia 2 may be set to two different modes (WALK AWAY and READ NOW). The procedures for each mode are described below.

WALK AWAY MODE

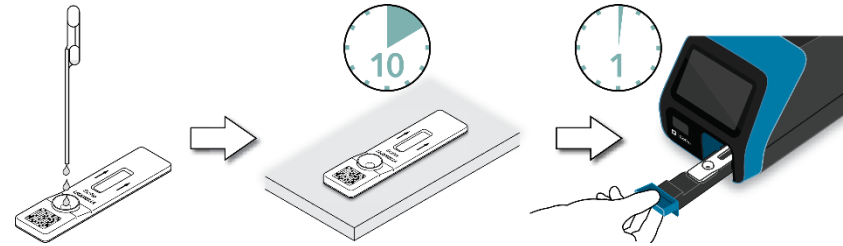
In WALK AWAY Mode, the user **immediately** inserts the Cassette into Sofia 2. The user then returns after 10 minutes to get the test result. In this mode, Sofia 2 will automatically time the test development before scanning and displaying the test result.



READ NOW MODE

Allow the test to develop for the FULL 10 minutes BEFORE placing it into Sofia 2.

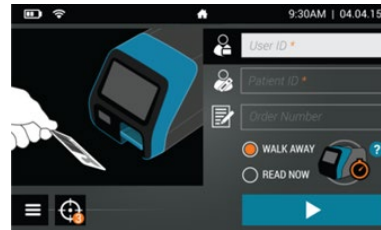
The user must first place the Cassette onto the counter or bench top for 10 minutes (outside of Sofia 2) and manually time this development step. Then, the user inserts the Cassette into Sofia 2. In READ NOW Mode, Sofia 2 will scan and display the test result within 1 minute. **Note:** Results will remain stable for an additional 10 minutes after the recommended development time of 10 minutes.



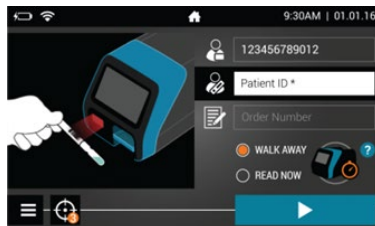
RUN TEST

1. Input the User ID with the integrated barcode scanner or enter the data using the on-screen key pad.

NOTE: If you scan the incorrect barcode, select the field again to re-highlight it. Then simply rescan using the correct barcode, and the previous one will be overwritten with the correct barcode.

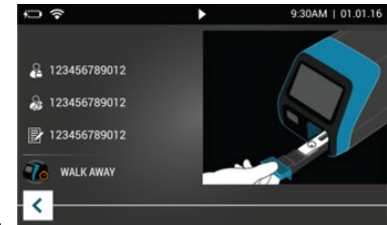


2. Input the Patient ID and/or Order # (if applicable) using the integrated barcode scanner or enter the data using the on-screen key pad.



3. Verify that the correct mode (WALK AWAY or READ NOW) has been selected. Press ► and open the Sofia 2 drawer.

4. Insert the Test Cassette into the drawer. Then gently close the drawer.



5. Sofia 2 will start automatically and display the progress. In WALK AWAY Mode, the test results will be displayed on the screen in 10 minutes. In READ NOW Mode, the test results will be displayed on the screen within 1 minute. See Interpretation of Results section.

Interpretation of Results

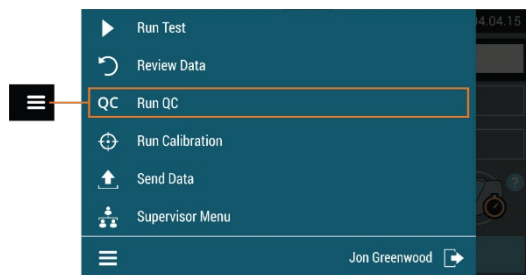
When the test is complete, the results will be displayed on the Sofia 2 screen. Test Lines will not be visible to the naked eye.

Results: The Sofia 2 screen will display results for the procedural control as being or and will provide positive or negative result for the detection of *Legionella pneumophila* serogroup 1. If the control is , retest starting with Step 1 and a new Test Cassette.

Reader Display	Interpretation
Legionella: Control:	Positive test for <i>Legionella pneumophila</i> serogroup 1. (Legionella antigen present)
Legionella: Control:	Negative test for <i>Legionella pneumophila</i> serogroup 1. (no antigen present)
Legionella: Control:	Result Invalid

External Quality Control

- From the main menu, select Run QC.



- Follow the prompt on the screen. Scan the QC Card (located on the assay kit box).
- Sofia 2 prompts the user to select the desired mode (WALK AWAY or READ NOW). Run the External Controls.
- Follow the External Quality Control Test Procedure in the Package Insert to test each Control, first the Positive Control followed by the Negative Control.
- After both the Positive and Negative Controls have been run, the results will be displayed as or .

INTENDED USE

The Sofia Legionella FIA employs immunofluorescence for qualitative detection of *Legionella pneumophila* serogroup 1 antigen in human urine specimens. It is designed to test specimens from patients with symptoms of pneumonia. Test results are to be used as an aid in diagnosis of Legionella pneumophila serogroup 1 infection. A negative result does not preclude infection with Legionella pneumophila serogroup 1. Test results are to be used in conjunction with information obtained from the patient's clinical evaluation and other diagnostic procedures.

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

ASSISTANCE

If Sofia or the assay do not perform as expected, contact Quidel Technical Support 800.874.1517 (in the U.S.), 858.552.1100 (outside the U.S.), technicalsupport@quidel.com, or your local Quidel distributor.



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