



Sofia² Campylobacter FIA

QUICK REFERENCE INSTRUCTIONS

For use with Sofia 2.



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 2 Campylobacter 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. All specimens must be mixed prior to 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.

Precautions: Users should adhere to standard Universal Precautions when performing this Test Procedure. Precautions may include the use of nitrile gloves, safety glasses and the covering of any cuts or abrasions on the hands. Wash hands thoroughly after performing this Test Procedure.

1

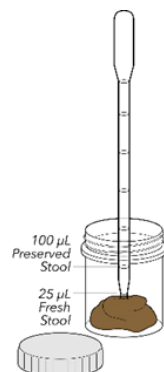
Verify that Sofia 2 is set to the desired mode: **WALK AWAY** or **READ NOW**. See the "Using Sofia 2" section for more information.

Follow Package Insert for Specimen Collection.

2

Collect **25 µL** (first Graduation) of Specimen using the Graduated Pipette provided in the kit.

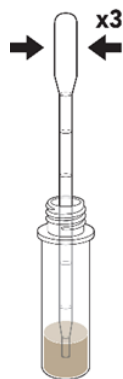
Note: For Specimens in Transport Media (preserved), collect **100 µL** (2nd Graduation) using the Graduated Pipette provided in the kit



3

Transfer the Specimen to the Specimen Diluent Tube and mix the solution by squeezing and releasing the top bulb of the Graduated Pipette **3 times**.

Remove the Graduated Pipette from the Specimen Diluent Tube.



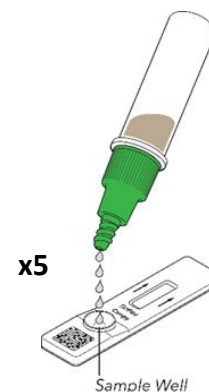
4

Screw the green Dropper Tip to Specimen Diluent Tube and mix well.



5

Remove the small clear cap, hold the Specimen Diluent Tube vertical and dispense **5 drops** into the Test Cassette sample well.



6

Proceed to the next section, "Using Sofia 2," to complete the test.

Using Sofia 2

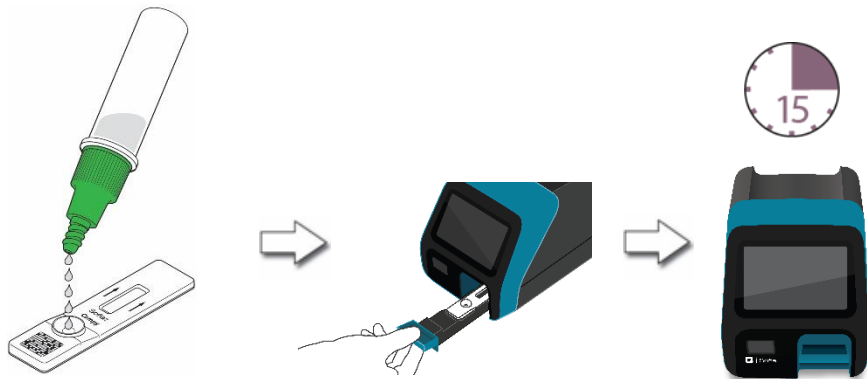
WALK AWAY/READ NOW Modes

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. **Note:** The Supervisor has the option to set the Sofia 2 to Locked WALK AWAY mode, which will prevent an operator from selecting any other mode than WALK AWAY for running a test.

WALK AWAY Mode

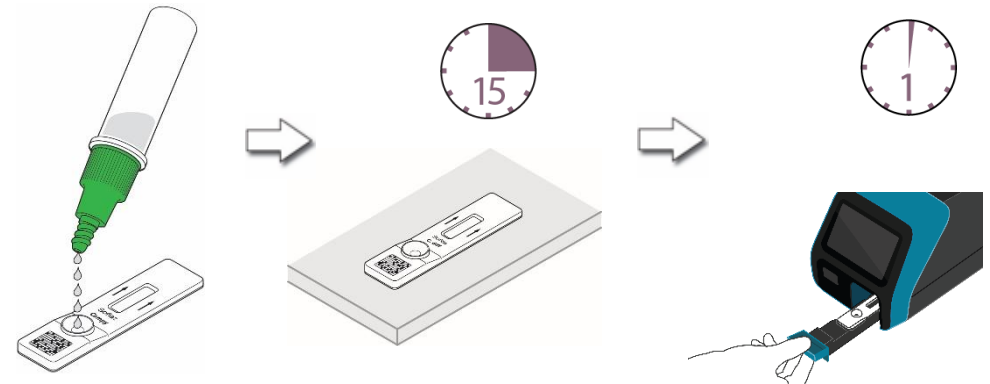
In WALK AWAY Mode, the user **immediately** inserts the Test Cassette into Sofia 2. Sofia 2 will automatically time the test development, and the results will be displayed in 15 minutes.



READ NOW Mode

Allow the test to develop for the FULL 15 minutes BEFORE placing it into Sofia 2.

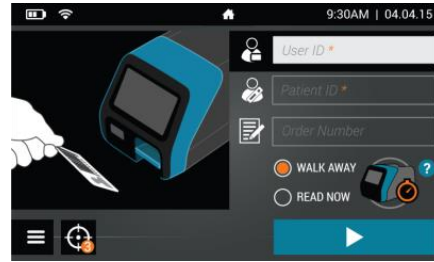
The user places the Test Cassette onto the counter or bench top for 15 minutes (outside of Sofia 2) and manually times this development step. Then, the user inserts the Test Cassette into Sofia 2. In READ NOW Mode, Sofia 2 will scan and display the test result within 1 minute. **Warning: Results must not be interpreted past 30 minutes after inoculation. Using the Sofia 2 past this time may result in false results.**



RUN TEST

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

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.



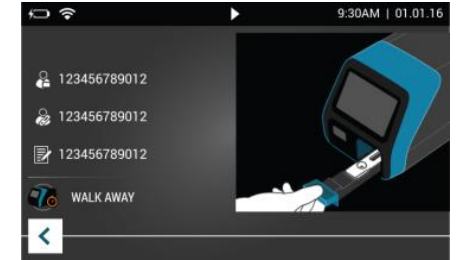
2. Input the Patient ID and/or Order # (if applicable) using the integrated barcode scanner or enter the data using the on-screen keypad.

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

NOTE: If the instrument is set in Locked Walk Away mode, users will only be able to use the “walk away” mode option for running tests. Read Now Mode will be grayed out when in Locked Walk Away Mode.



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



5. Sofia 2 will start and display the progress. In WALK AWAY Mode, the test results will be displayed after 15 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

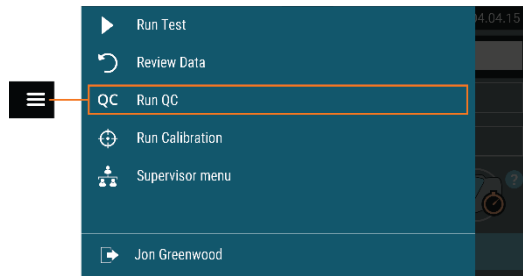
When the test is complete, the results will be displayed on the Sofia 2 screen. Test Lines will not be visible to the naked eye.



Results: The Sofia 2 screen will display results for the procedural control as being or . If the control is , retest starting with Step 1 and a new Test Cassette.

Reader Display	Interpretation
Campy Control	Positive Test for <i>Campylobacter</i>
Campy Control	Negative Test for <i>Campylobacter</i>
Campy Control	Result Invalid

External Quality Control

- 1 From the main menu, select Run QC.



- 2 Follow the prompt on the screen. Scan the QC Card (located on the assay kit box).
- 3 Sofia 2 prompts the user to select the desired mode (WALK AWAY or READ NOW).
- 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  or .

Quidel recommends that Positive and Negative External Controls be run:

- Once for each untrained operator.
- Once for each new shipment of kits – provided that each different lot received in the shipment is tested.
- As deemed additionally necessary by your internal quality control procedures, and in accordance with Local, State and Federal regulations or accreditation requirements.

Intended Use

Sofia 2 *Campylobacter* FIA employs immunofluorescence for the rapid qualitative detection of a *Campylobacter*-specific antigen in human fecal specimens. Sofia 2 *Campylobacter* FIA is designed to detect *C. jejuni*, *C. coli*, *C. lari* and *C. upsaliensis* from patients with signs and symptoms of gastroenteritis. The test is intended for use with preserved fecal specimens in transport media and unpreserved fecal specimens. Test results should be considered in conjunction with clinical findings and patient history.

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

ASSISTANCE

If you have any questions regarding the use of this product or if you want to report a test system problem, please call Quidel Technical Support 800.874.1517 (in the U.S.), 858.552.1100 (outside the U.S.), technicalsupport@quidel.com, or your local distributor.



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