QUIDEL

Sofia 2 C. difficile FIA

QUICK REFERENCE INSTRUCTIONS

For use with Sofia 2.

For export only – Not for sale in the U.S.

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 C. difficile 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.

Disposable gloves and safety glasses are recommended when running this test. Wash hands thoroughly after handling any patient sample.

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

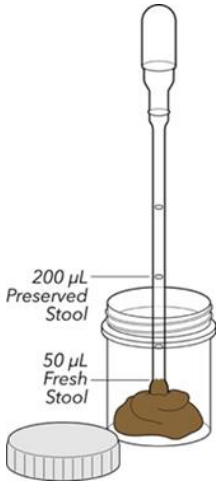
Verify that Sofia 2 is set to the desired mode: **WALK AWAY** or **READ NOW**. See the "Using Sofia 2" section for more information.

Follow Package Insert for Specimen Collection.

2

Collect 50 µL (top of flared tip) of Specimen using the Multi-Volume Pipette provided in the kit.

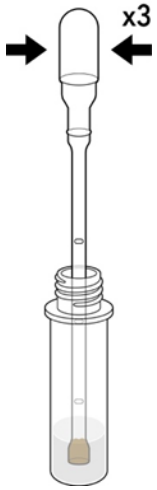
Note: For Specimens in Transport Media (preserved), collect 200 µL (2nd Graduation) using the Multi-Volume Pipette provided in the kit



3

Transfer the Specimen to the Specimen Diluent Tube and mix the solution by squeezing and releasing the top bulb of the Multi-Volume Pipette 3 times.

Remove the Multi-Volume Pipette from the Specimen Diluent Tube.

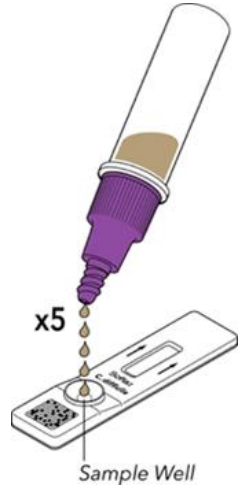


4

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

5

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



6

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

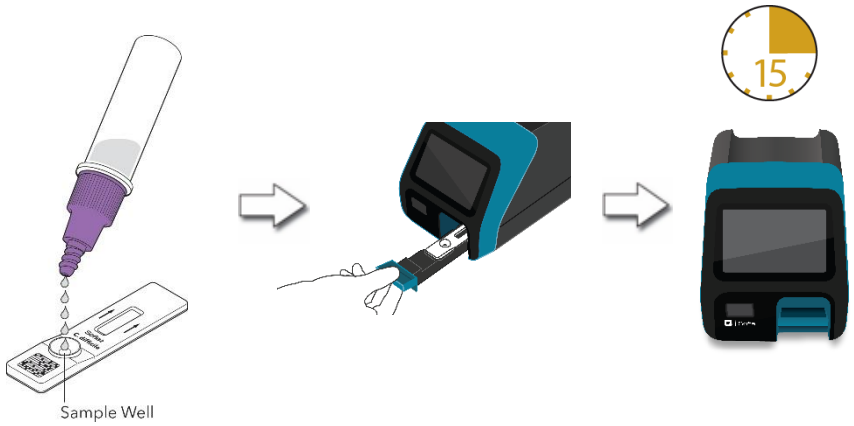
WALK AWAY/READ NOW Modes

***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

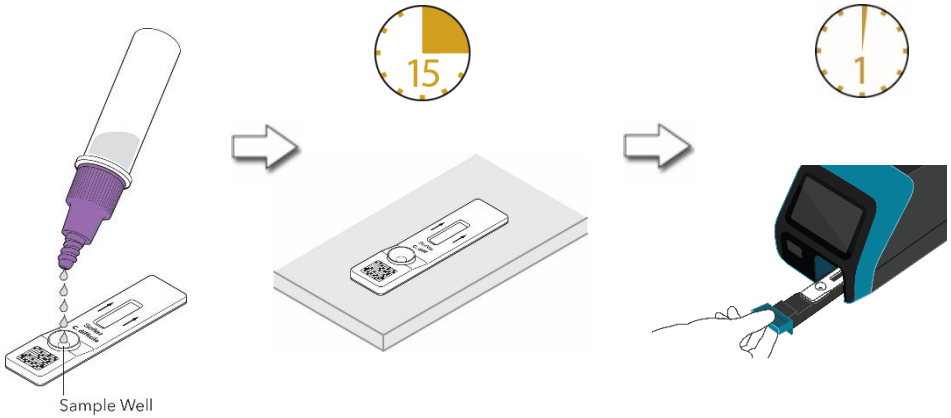
In WALK AWAY Mode, the user **immediately** inserts the Test Cassette into Sofia 2. Sofia 2 will automatically time the test development, and the results will be displayed in 15 minutes.



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

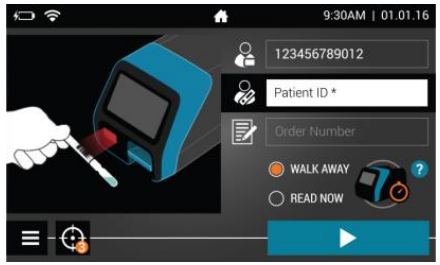
1. Input the User ID with the integrated barcode scanner or enter the data using the touchscreen.

   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.*

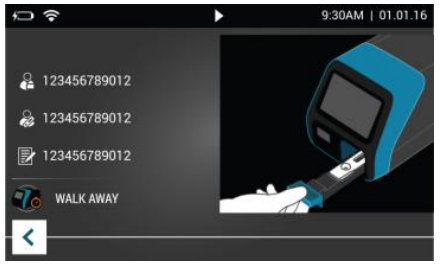
2. Input the Patient ID and/or Order # (if applicable) using the integrated barcode scanner or enter the data using the touchscreen.

3. Verify that the correct mode (WALK AWAY or READ NOW) has been selected. Press ▶ and 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 in 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.

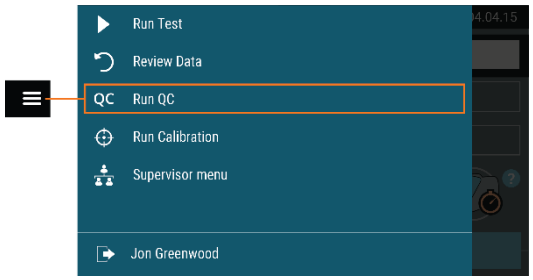
Results: The Sofia 2 screen will display results for the procedural control as being ✓ or ✗. If the control is ✗, retest starting with Step 1 and a new Test Cassette.

Reader Display	Interpretation
GDH ⊕ Toxin ⊖ Control ✓	Positive Test for *C. difficile* GDH antigen
GDH ⊖ Toxin ⊕ Control ✓	Positive Test for *C. difficile* Toxins A/B
GDH ⊕ Toxin ⊕ Control ✓	Positive Test for *C. difficile* GDH antigen and Toxins A/B
GDH ⊖ Toxin ⊖ Control ✓	Negative Test for *C. difficile* GDH antigen and Toxins A/B

GDH Toxin 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). 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 ✓ 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

The Sofia 2 C. difficile FIA employs immunofluorescence for the qualitative detection of *Clostridiodes difficile* glutamate dehydrogenase (GDH) antigen and Toxins A /B. The test detects *C. difficile* antigen, glutamate dehydrogenase, as a screen for the presence of *C. difficile* and confirms the presence of toxigenic *C. difficile* by detecting Toxins A/B in human fecal specimens from persons suspected of having *C. difficile* disease. The test can be used with unpreserved fecal specimens and fecal specimens preserved in transport media. Test results should be taken into consideration by the physician in conjunction with patient history and symptoms.

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

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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