



Sofia[®] Strep A+ FIA

QUICK REFERENCE INSTRUCTIONS

For use with Sofia and Sofia 2.

R_x ONLY



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

CLIA Complexity: WAIVED

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

Test Procedure

- All clinical samples and test materials must be at room temperature (15°C to 30°C) before beginning the test.
- Do not use the Reagent Solution if it is green prior to breaking the glass ampoule or if it does not turn green after breaking the glass ampoule.
- **Expiration date:** Check expiration date on each individual test package or outer box before using. *Do not use any test past the expiration date on the label.*

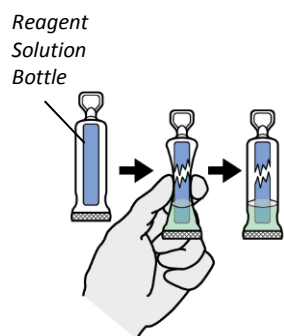
1

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

2

Squeeze **ONCE** to break the glass ampoule inside the Reagent Solution Bottle prior to running the assay.

Squeeze to break glass ampoule.



3

Vigorously shake the Reagent Solution Bottle **5 times** to mix the solutions. Solution should turn green after the ampoule is broken.

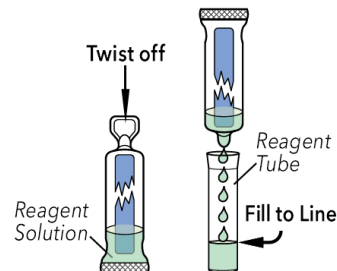
Shake 5x



4

Add Reagent:

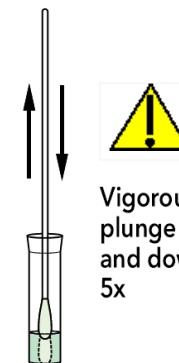
- Flick or shake the Reagent Solution Bottle so that all fluid is in the bottom.
- Twist off the tab.
- Slowly** dispense the Reagent Solution into the Reagent Tube **up to the Fill Line**.



5

Add the patient Swab sample to the Reagent Tube.

Vigorously mix the solution by plunging the Swab **5 times** in an up and down motion in the Tube.



6

Leave the Swab in the Reagent Tube for **1 minute**. Continue to Step 7 on the next page.



Test Procedure (cont.)

7

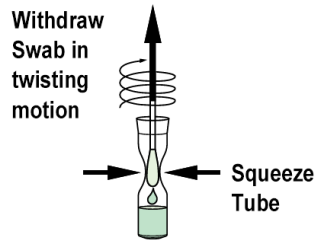
Vigorously mix the solution again by plunging the Swab 5 times in an up and down motion in the Tube.



8

Express as much liquid as possible from the Swab by **squeezing** the sides of the Tube as the Swab is withdrawn in a complete **twisting** motion.

Discard the Swab in accordance with your biohazard waste disposal protocol.

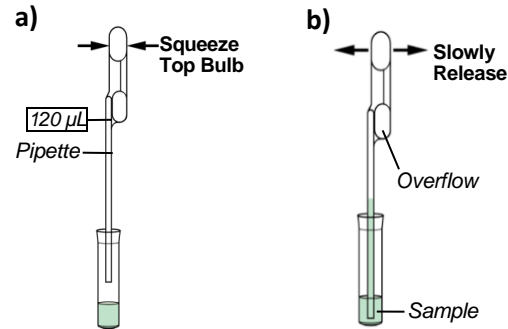


9

Fill the provided **Clear 120 μ L Fixed Volume Pipette** with the sample:

To fill the Fixed Volume Pipette with the sample:

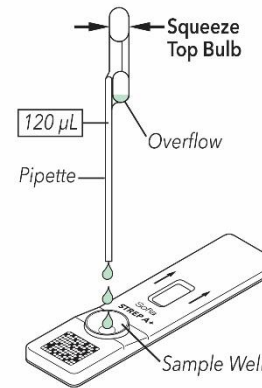
- FIRMLY squeeze the top bulb and place the Pipette tip into the sample.
- With the Pipette tip still in the sample, slowly release pressure on the top bulb to fill the Pipette.



10

Empty the contents of the Pipette into the Test Cassette sample well by firmly squeezing the top bulb.

NOTE: The Fixed Volume Pipette is designed to collect and dispense the correct amount of patient sample. Do not pour sample from the Reagent Tube. Use the provided Small, Clear 120 μ L Fixed Volume Pipette. Extra liquid left over in the overflow bulb should be left behind. Discard the Pipette in your biohazard waste.



11

Proceed to the "Using Sofia" or "Using Sofia 2" section to complete the test.

Using Sofia

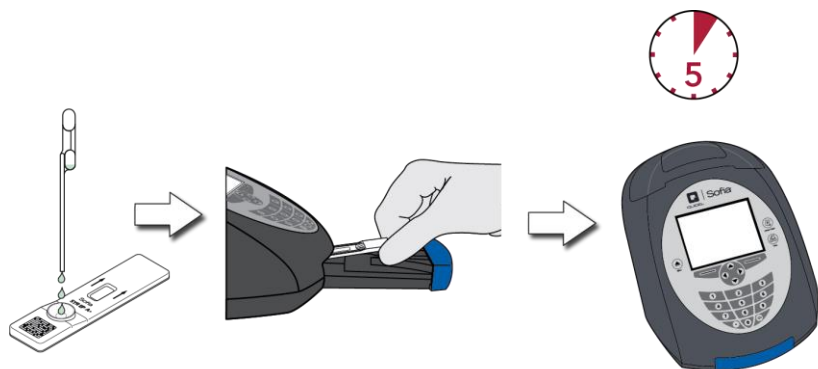
WALK AWAY/READ NOW Modes

Refer to the Sofia User Manual for operating instructions.

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

WALK AWAY Mode

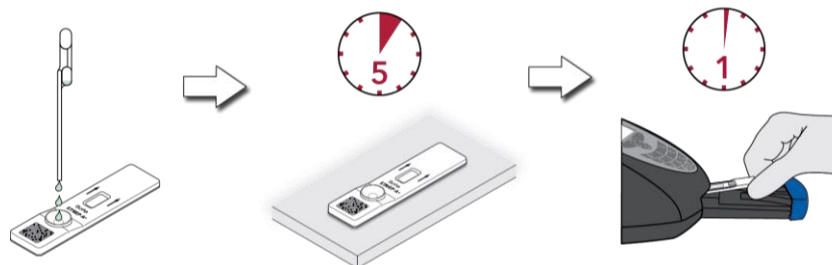
In WALK AWAY Mode, the user **immediately** inserts the Test Cassette into Sofia. The user then returns after 5 minutes to get the test result. In this mode, Sofia will automatically time the test development before scanning and displaying the test result.



READ NOW Mode

Allow the test to develop for the FULL 5 minutes BEFORE placing it into Sofia.

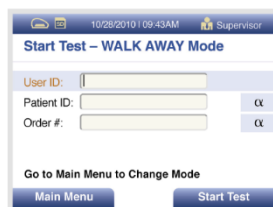
The user must first place the Test Cassette onto the counter or bench top for 5 minutes (outside of Sofia) and manually time this development step. The Test Cassette **MUST** remain on the benchtop 5 minutes to get an accurate result. Then, the user inserts the Test Cassette into Sofia. In READ NOW Mode, Sofia will scan and display the test result within 1 minute. **Note:** Results will remain stable for an additional 5 minutes after the recommended development time of 5 minutes.



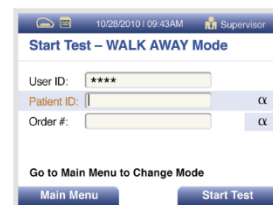
RUN TEST

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

NOTE: If you mistakenly 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 # using the handheld barcode scanner or manually 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 in approximately 5 minutes. In READ NOW Mode, the test results will be displayed on the screen within 1 minute. See Sofia Interpretation of Results section.

Sofia Interpretation of Results

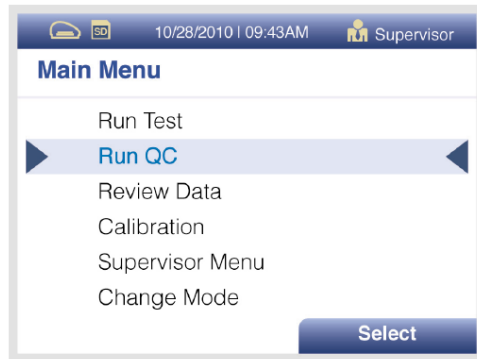
When the test is complete, the results will be displayed on the Sofia screen. The results can be automatically printed on the integrated printer if this option is selected. Test Lines, which are fluorescent, will never be visible to the naked eye.

Results: The Sofia screen will display results for the procedural control as being “Valid or Invalid.” If the control is “Invalid,” retest with a new patient sample and new Test Cassette.

Reader Display	Interpretation
Strep A: Positive Procedural Control: Valid	Positive Test for Strep A (Strep A antigen present)
Strep A: Negative Procedural Control: Valid	Negative Test for Strep A (no antigen detected)
Strep A: Invalid Procedural Control: Invalid	Result Invalid (repeat the test)

Sofia External Quality Control *(External Positive and Negative Swabs are supplied in the kit)*

- 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 Control Swabs.
- 4 Follow the Test Procedure of this Quick Reference Instructions to test each Control Swab. **NOTE:** Always run the Positive Control first 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.”

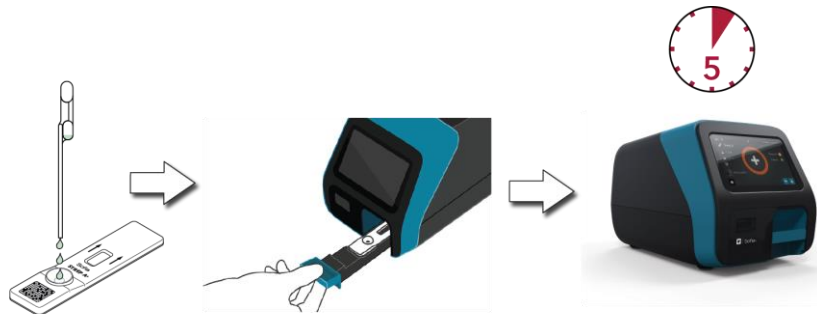
WALK AWAY/READ NOW Modes

Refer to the Sofia 2 User Manual for operating instructions.

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

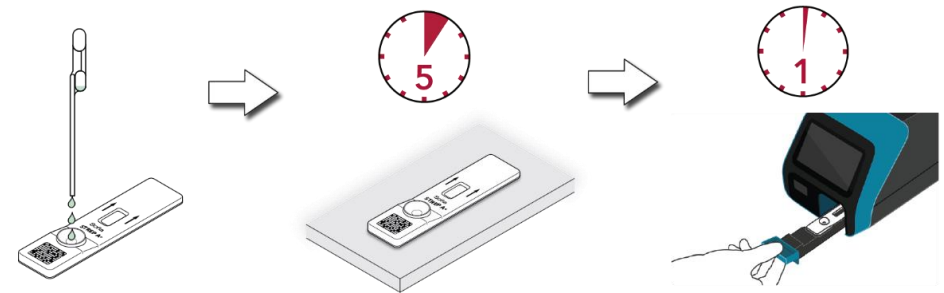
In WALK AWAY Mode, the user **immediately** inserts the Test Cassette into Sofia 2. The user then returns after 5 minutes to get the test result. In this mode, Sofia 2 will automatically time the test development before scanning and displaying the test result.



READ NOW Mode

Allow the test to develop for the FULL 5 minutes BEFORE placing it into Sofia 2.

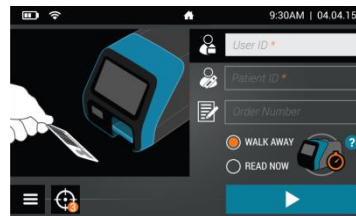
The user must first place the Cassette onto the counter or bench top for 5 minutes (outside of Sofia 2) and manually time this development step. The Test Cassette **MUST** remain on the benchtop 5 minutes to get an accurate result. Then, the user inserts the Test Cassette into Sofia 2. In READ NOW Mode, Sofia 2 will scan and display the test result within 1 minute. **Note:** Results will remain stable for an additional 5 minutes after the recommended development time of 5 minutes.



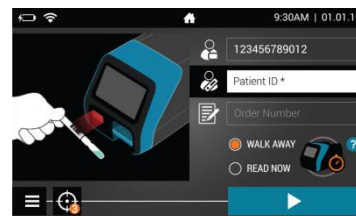
RUN TEST

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

NOTE: If you mistakenly scan the wrong barcode, re-highlight the field using the touchscreen on Sofia 2 and simply rescan using the correct barcode. The previous one will be overwritten with the right barcode.

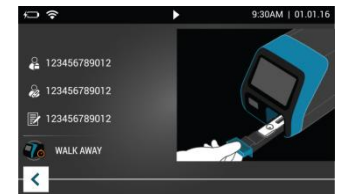


2. Input the Patient ID or Order # using the integrated barcode scanner or manually enter the data using the key pad.



3. Press Start Test and open the Sofia 2 drawer.




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

Sofia 2 Interpretation of Results

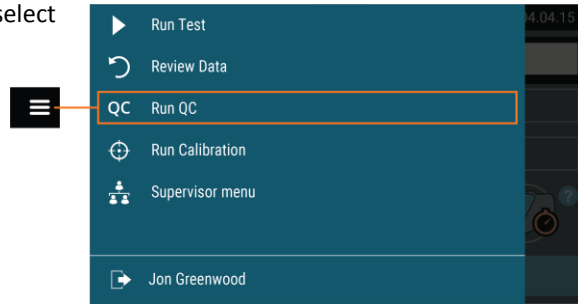
When the test is complete, the results will be displayed on the Sofia 2 screen. Test Lines, which are fluorescent, will never be visible to the naked eye.



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

Reader Display	Interpretation
Strep A:  Procedural Control: 	Positive Test for Strep A (Strep A antigen present)
Strep A:  Procedural Control: 	Negative Test for Strep A (no antigen detected)
Strep A: Procedural Control: 	Result Invalid (repeat the test)

Sofia 2 External Quality Control *(External Positive and Negative Swabs are supplied in the kit)*

- 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 2 will prompt the user to select the desired mode (WALK AWAY or READ NOW) and then to run the External Control Swabs.
- 4 Follow the Test Procedure of this Quick Reference Instructions to test each Control Swab. **NOTE:** Always run the Positive Control first followed by the Negative Control.
- 5 After both the Positive and Negative Controls have been run, the results will be displayed as  or .

INTENDED USE


The Sofia Strep A+ FIA detects Group A Streptococcal antigens from throat swabs from patients with signs and symptoms of pharyngitis, such as sore throat. All negative test results should be confirmed by either bacterial culture or an FDA-cleared molecular assay because negative results do not preclude Group A Strep infection and should not be used as the sole basis for treatment. The test is intended for professional and laboratory use as an aid in the diagnosis of Group A Streptococcal infection.


The Sofia Strep A+ FIA may be used with Sofia or Sofia 2.

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

ASSISTANCE

If Sofia, Sofia 2 or the assay do not perform as expected, contact Quidel Technical Support 800.874.1517 (in the U.S.), technicalsupport@quidel.com, or your local distributor.

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

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