



Sofia[®]

Strep A FIA

QUICK REFERENCE INSTRUCTIONS

For use with Sofia only.



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 Strep A FIA and may differ from other Sofia FIA procedures.

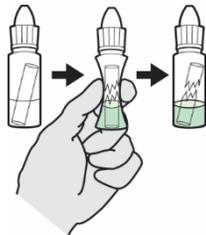
Test Procedure

1

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

2

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



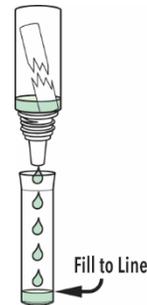
3

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



4

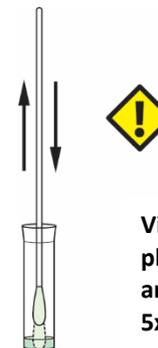
Remove the cap. Holding the Bottle vertically, fill the Reagent Tube **to the line** (approximately 6 drops).



5

- Immediately 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.

NOTE: Best results are obtained when the specimen is vigorously extracted in the solution.



**Vigorously
plunge up
and down
5x**

6

Leave the Swab in the Reagent Tube for 1 minute.



**Leave
for
1 minute**

7

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

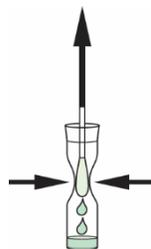


Vigorously plunge up and down 5x

8

Express as much liquid as possible from the Swab by **squeezing the sides of the Tube as the Swab is withdrawn**.

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

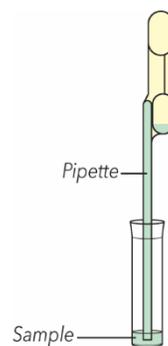


9

Fill the provided **yellow** Fixed Volume Pipette with the sample:

To fill the Fixed Volume Pipette (100 μ L) with the sample:

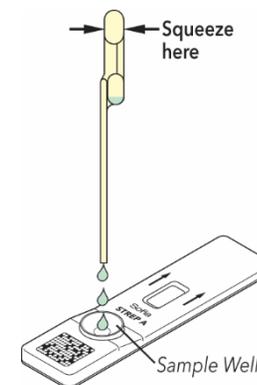
- FIRMLY squeeze the top bulb.
- Still squeezing, place the Pipette tip into the sample.
- With the Pipette tip still in the sample, release pressure on the top bulb to fill the Pipette.



10

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 patient sample. Discard the Pipette in your biohazard waste.



11

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

Using Sofia

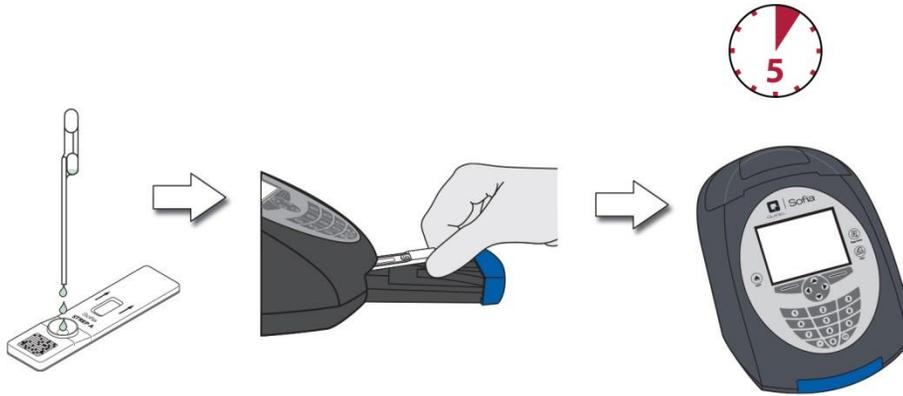
WALK AWAY / READ NOW Modes

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

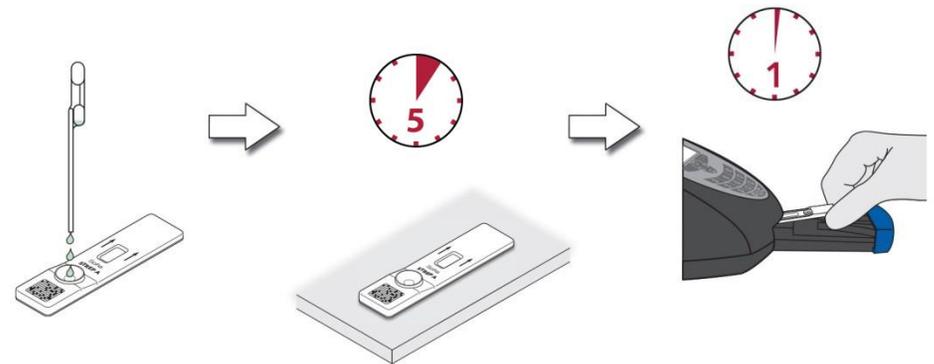
In WALK AWAY Mode, the user **immediately** inserts the Test Cassette into Sofia. The user then returns after 5 minutes to get the test result. In this mode, Sofia will automatically time the test development before scanning and displaying the test result.



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. Then, the user inserts the Test Cassette into Sofia. In READ NOW Mode, Sofia will scan and display the test result within 1 minute.



Using Sofia (cont.)

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 correct barcode.



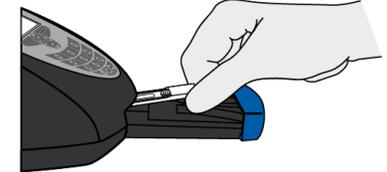
2. Input the Patient ID and/or Order # using the handheld barcode scanner or manually enter the data using the key pad.



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 door.



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 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.” If the control is “invalid,” retest with a new patient sample and new Test Cassette.

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

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 run the External Control Swabs.
- 4 Follow the Test Procedure of this Quick Reference Instructions.

INTENDED USE

The Sofia Strep A FIA employs immunofluorescence technology to detect Group A Streptococcal antigens from throat swabs of symptomatic patients. All negative test results should be confirmed by bacterial culture 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.

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 distributor.



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