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

CLIA Complexity: WAIVED

R_x Only

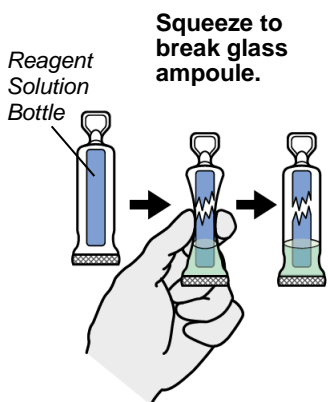
IMPORTANT! Read instructions carefully before beginning. The test procedure below is unique to the Sofia Strep A+ FIA and may differ from other Sofia FIA procedures.

Test Procedure

- All clinical samples and test materials must be at room temperature 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.
 - Do not allow the Cassette to develop on the bench or counter top prior to placing the Cassette into Sofia.
- NOTE:** The Sofia Strep A+ FIA will automatically be run in the WALK AWAY Mode in Sofia once a prepared Test Cassette is inserted.
- **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

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



2

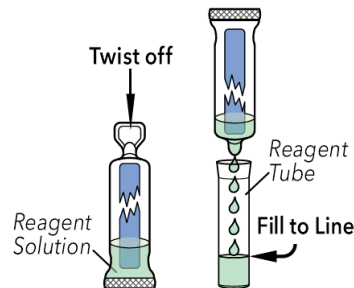
Vigorously shake the Reagent Solution Bottle **5 times** to mix the solutions. Solution should turn green after the ampoule is broken.



3

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**.



4

Add the patient Swab sample to the Reagent Tube.

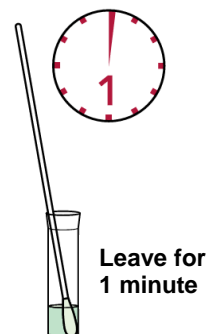
Vigorously mix the solution by plunging the Swab **5 times** in an up and down motion in the Tube.

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



5

Leave the Swab in the Reagent Tube for 1 minute.



6

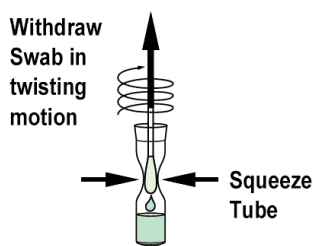
Vigorously mix the solution again by plunging the Swab **5 times** in an up and down motion in the Tube.



7

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.

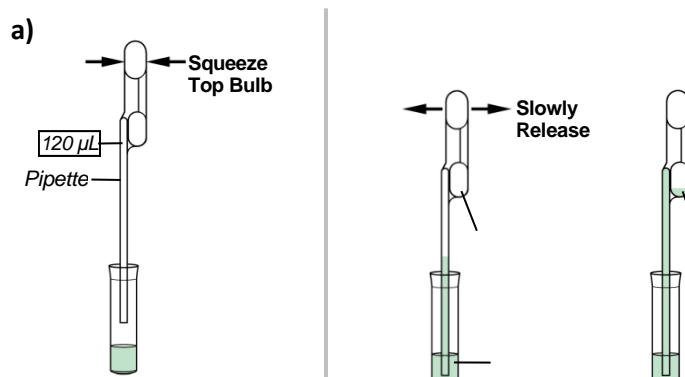


8

Fill the provided **clear 120 µL Fixed Volume Pipette** with the sample:

To fill the Fixed Volume Pipette with the sample:

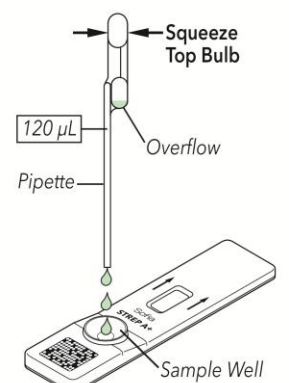
- FIRMLY** squeeze the top bulb and place the Pipette tip into the sample.
- With the Pipette tip still in the sample, **slowly** release pressure on the top bulb to fill the Pipette.



9

Empty the contents of the Pipette into the 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. Extra liquid left over in the overflow bulb should be left behind. Discard the Pipette in your biohazard waste.



Using Sofia

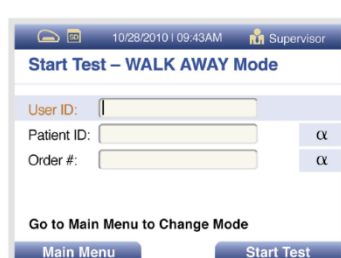
10

Select "Run Test" from the Main Menu on Sofia.

11

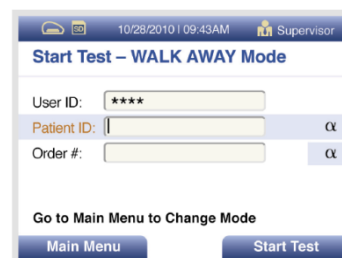
Input the User ID using the handheld barcode scanner or manually enter the data using the key pad.

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



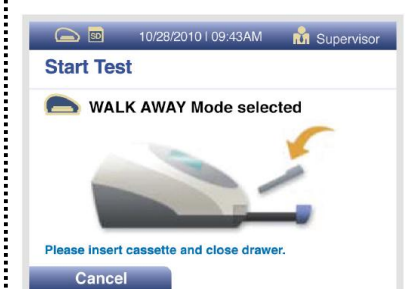
12

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



13

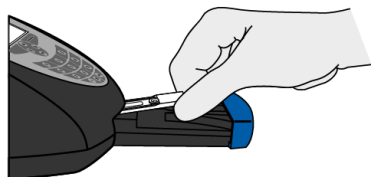
Press Start Test and the Sofia drawer will automatically open.



NOTE: Regardless of the current selected Mode, the Sofia Strep A+ FIA will automatically be forced into the WALK AWAY Mode once the Test Cassette is inserted and the drawer is closed.

14

Insert the prepared patient Test Cassette into the drawer and gently close the drawer.



15

Sofia will start automatically in WALK AWAY Mode and display the progress as shown in the example. The test results will be displayed on the screen in approximately 5 minutes. 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.

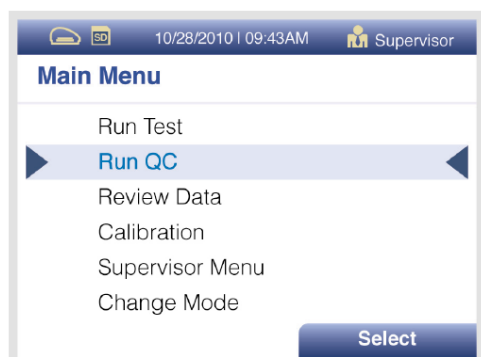
Results: The Sofia screen will display results for the procedural control as being “valid” or “invalid.” If the control is “invalid,” retest with a new patient sample and new Test Cassette.

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 Procedural Control: 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 to test each Control Swab.

NOTE: Always run the Positive Control Swab before the Negative.

5

After both the Positive and Negative Swabs have been run, the results will be displayed as “Passed” or “Failed.”

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 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.



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



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