



**Sofia**<sup>®</sup>  
RSV 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.

CLIA Complexity: Moderate for pediatric patients 7 to less than 19 years of age

CLIA Complexity: WAIVED for children less than 7 years of age

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

## Test Procedure

**NOTE:** The procedures for testing swab samples versus aspirate/wash or samples in viral transport media are different. Read carefully.

**All samples, including samples in VTM, must be at room temperature before 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.

## Nasopharyngeal Swab Test Procedure

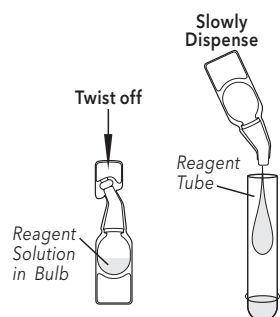
**1**

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

**2**

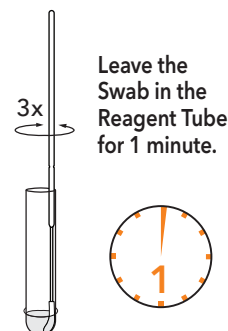
**Prepare Reagent:**

- Flick or shake the Reagent Solution vial down so that all fluid is in the bulb.
- Twist off the tab.
- Slowly dispense all of the Reagent Solution into the Reagent Tube.
- Gently swirl the Reagent Tube to dissolve its contents.



**3**

Place the patient Swab sample into the Reagent Tube. Roll the Swab at least three (3) times while pressing the head against the bottom and side of the Reagent Tube.



**4**

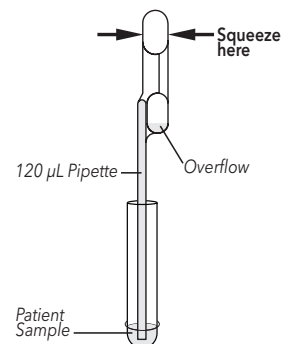
Roll the Swab head against the inside of the Reagent Tube as you remove it. Dispose of the used Swab in your biohazard waste.



**5**

Fill the provided **Small, Clear 120  $\mu$ L Fixed Volume Pipette** with patient sample from the Reagent Tube. **To fill the Fixed Volume Pipette with the patient sample:**

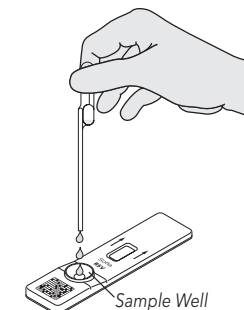
- FIRMLY** squeeze the top bulb.
- Still squeezing, place the Pipette tip into the patient sample.
- With the Pipette tip still in the sample, slowly release pressure on bulb to fill the Pipette.



**6**

Firmly squeeze the top bulb to empty the contents of the **Small, Clear 120  $\mu$ L Fixed Volume Pipette** into the Cassette sample well. Extra liquid left over in the overflow bulb should be left behind.

**NOTE:** The Fixed Volume Pipette is designed to collect and dispense the correct amount of patient sample. Discard the Pipette in your biohazard waste.



**7**

Promptly proceed to the next section, "Using Sofia," to complete the test.

## Nasopharyngeal Aspirate/Wash or Samples in Viral Transport Media Test Procedure

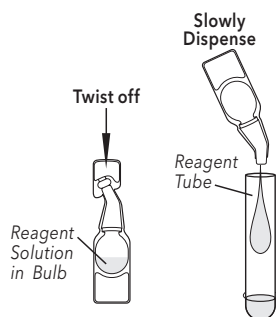
1

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

2

### Prepare Reagent:

- Flick or shake the Reagent Solution vial down so that all fluid is in the bulb.
- Twist off the tab.
- Slowly dispense all of the Reagent Solution into the Reagent Tube.
- Gently swirl the Reagent Tube to dissolve its contents.

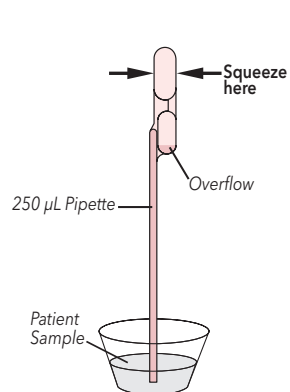


3

Fill the provided **Large, Pink 250  $\mu$ L Fixed Volume Pipette** with patient sample from the Collection Cup.

### To fill the Fixed Volume Pipette with the patient sample:

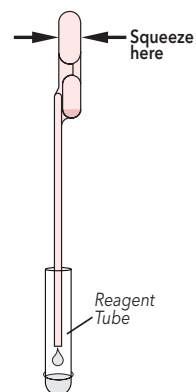
- FIRMLY squeeze the top bulb.
- Still squeezing, place the Pipette tip into the patient sample.
- With the Pipette tip still in the patient sample, slowly release pressure on bulb to fill the Pipette.



4

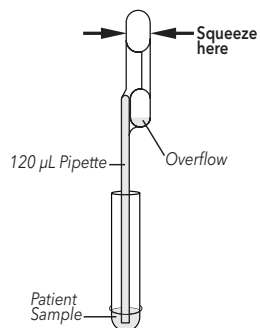
Firmly squeeze the top bulb to empty the contents of the **Large, Pink 250  $\mu$ L Fixed Volume Pipette** into the Reagent Tube. Extra liquid left over in the overflow bulb should be left behind. **Gently swirl the Reagent Tube to mix.**

**NOTE:** The Fixed Volume Pipette is designed to collect and dispense the correct amount of patient sample. Discard the Pipette in your biohazard waste.



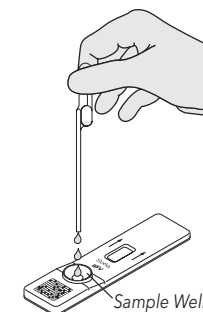
5

Fill the provided **Small, Clear 120  $\mu$ L Fixed Volume Pipette** with patient sample from the Reagent Tube, by slowly releasing pressure on the bulb.



6

Firmly squeeze the top bulb to empty the contents of the **Small, Clear 120  $\mu$ L Fixed Volume Pipette** into the Cassette sample well. Extra liquid left over in the overflow bulb should be left behind. Discard the Pipette in your biohazard waste.



7

Promptly proceed to the next section, "Using Sofia," to complete the test.

## Using Sofia

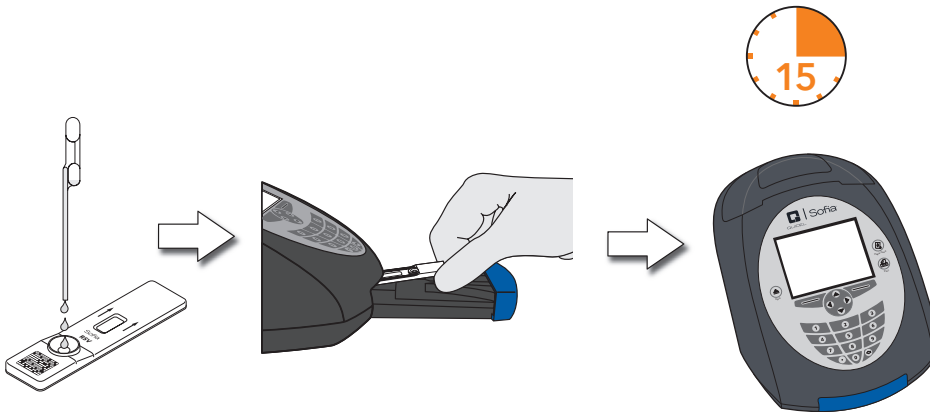
### WALK AWAY/READ NOW MODES

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

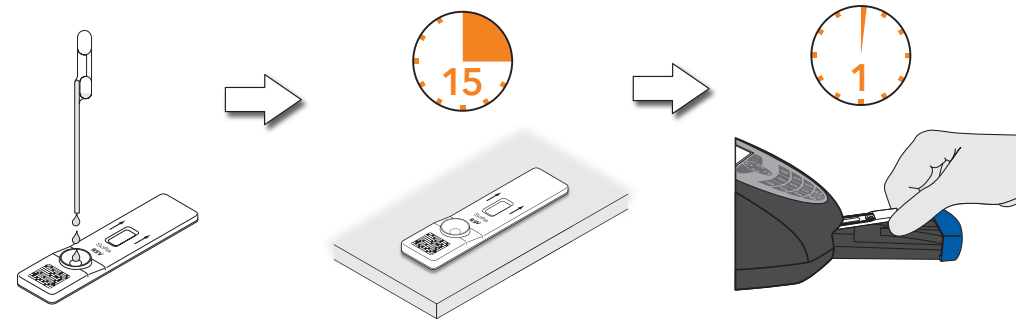
In WALK AWAY Mode, the user **immediately** inserts the Cassette into Sofia. The user then returns after 15 minutes to get the test result. In this mode, Sofia will automatically time the test development before scanning and displaying the test result.



#### READ NOW MODE

**Critically important: Allow the test to develop for the FULL 15 minutes BEFORE placing it into Sofia.**

The user must first place the Cassette onto the counter or bench top for 15 minutes (outside of Sofia) and manually time this development step. The Cassette **MUST** stand 15 minutes to get an accurate result. Then, the user inserts the 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 15 minutes after the recommended development time of 15 minutes.



## 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 the Sofia key pad to re-highlight the field. Then simply rescan using the correct barcode, and the previous one will be overwritten with the correct barcode.

10/28/2010 1 09:43AM Supervisor

**Start Test – WALK AWAY Mode**

User ID:

Patient ID:  α

Order #:  α

Go to Main Menu to Change Mode

Main Menu Start Test



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

10/28/2010 1 09:43AM Supervisor

**Start Test – WALK AWAY Mode**

User ID: \*\*\*\*

Patient ID:  α

Order #:  α

Go to Main Menu to Change Mode

Main Menu Start Test



3. Press Start Test and the Sofia drawer will automatically open.

10/28/2010 1 09:43AM Supervisor

**Start Test**

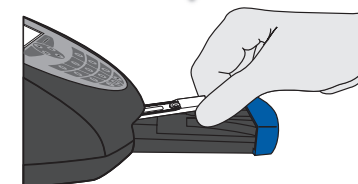
WALK AWAY Mode selected

Please insert cassette and close drawer.

Cancel



4. Verify that the correct mode, WALK AWAY or READ NOW, has been selected. Insert the prepared patient 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 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 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.

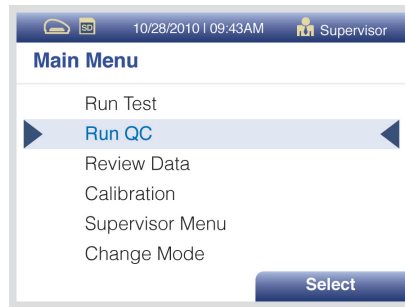
**Results:** The Sofia screen will display results for the procedural control being “valid or invalid.” If the control is “invalid,” retest with a new patient sample and new test Cassette.

Reader Display	Interpretation
RSV: Positive	Positive Test for RSV (RSV antigen present)
RSV: Negative	Negative Test for RSV (no antigen detected)
RSV: Invalid Procedural Control: Invalid	Result Invalid

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

- 1 From the main menu, select Run QC.

**NOTE:** The Positive Control Swab must be tested before the Negative Control Swab.



- 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 Nasopharyngeal Swab Test procedure of this Quick Reference Instructions to test each control swab, **first the Positive swab followed by the Negative swab.**
- 5 After both the Positive and Negative swabs have been run, the results will be displayed as "Passed" or "Failed."


### INTENDED USE

The Sofia RSV FIA employs immunofluorescence for detection of respiratory syncytial virus (RSV) nucleoprotein antigen in nasopharyngeal swab and nasopharyngeal aspirate/wash specimens taken directly from symptomatic patients. This qualitative test is intended for use as an aid in the rapid diagnosis of acute RSV infections in pediatric patients. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or for other management decisions. A negative result is presumptive, and it is recommended these results be confirmed by virus culture or an FDA-cleared RSV molecular assay.

**Reference the Package Insert for Warnings and Precautions, Sample 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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