



Sofia[®]

RSV FIA

QUICK REFERENCE INSTRUCTIONS

For use with Sofia and Sofia 2.
Rx only



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

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

CLIA Complexity: Moderate for pediatric patients 7 to less than 19 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 specimens versus aspirate/wash or specimens in viral transport media are different. Read carefully.

All specimens must be at room temperature before testing.

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.

Nasopharyngeal Swab Test Procedure

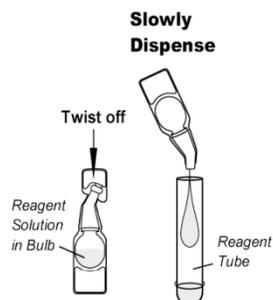
1

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

2

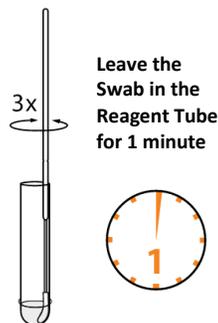
Prepare Reagent:

- 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 3 times while pressing the head against the bottom and side of the Reagent Tube.



4

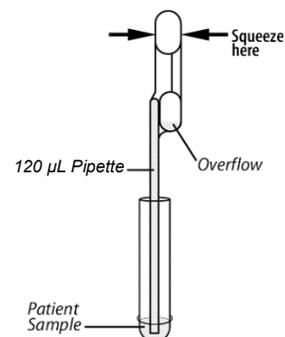
Roll the Swab head against the inside of the Reagent Tube as you remove it. Dispose of the used Swab in your biohazard waste.



5

Fill the provided **Small, Clear 120 µL 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 sample.
- With the Pipette tip still in the sample, release pressure on bulb to fill the Pipette.



6

Firmly squeeze the top bulb to empty the contents of the **Small, Clear 120 µL 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.

NOTE: Do not pour sample from the Reagent Tube. Use the provided Small, Clear 120µl Fixed Volume Pipette.



7

Proceed to the “Using Sofia” or “Using Sofia 2” section to complete the test.

Liquid Specimens Test Procedure

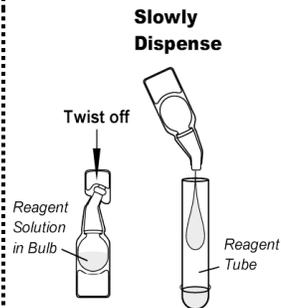
1

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



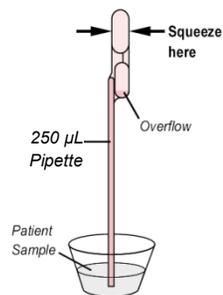
3

Fill the provided **Large, Pink 250 μ L Fixed Volume Pipette** with patient sample from the collection cup.

To fill the Fixed Volume Pipette with the 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, release pressure on bulb to fill the Pipette.

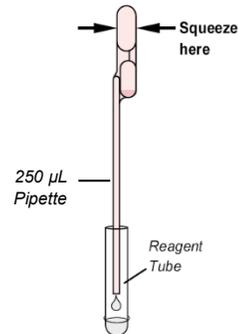
NOTE: To obtain accurate results, avoid mucoid substances when filling the Large, Pink 250 μ L Fixed Volume Pipette with patient sample from the collection cup.



4

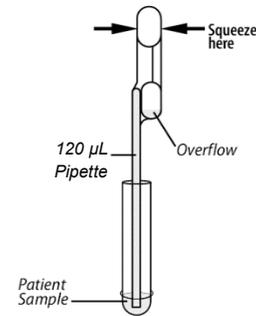
Firmly squeeze the top bulb to empty the contents of the **Large, Pink 250 μ L Fixed Volume Pipette** into the Reagent Tube. Extra liquid in the overflow bulb is OK. **Gently swirl the Reagent Tube to mix.**

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

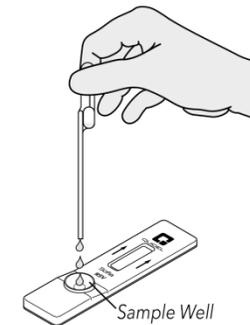
Fill the provided **Small, Clear 120 μ L Fixed Volume Pipette** with patient sample from the Reagent Tube.



6

Firmly squeeze the top bulb to empty the contents of the **Small, Clear 120 μ L Fixed Volume Pipette** into the Test Cassette sample well. Extra liquid in the overflow bulb is OK. Discard the Pipette in your biohazard waste.

NOTE: Do not pour sample from the Reagent Tube. Use the provided Small, Clear 120 μ L Fixed Volume Pipette.



7

Proceed to the “Using Sofia” or “Using Sofia 2” section to complete the test.

Using Sofia

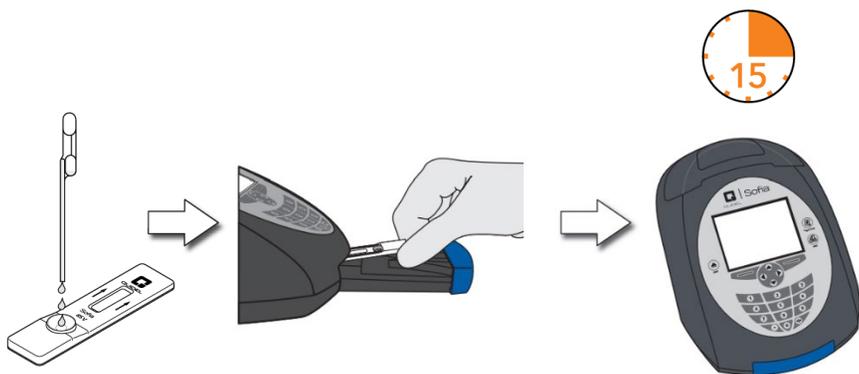
WALK AWAY/READ NOW Modes

Refer to the Sofia User Manual.

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

WALK AWAY Mode

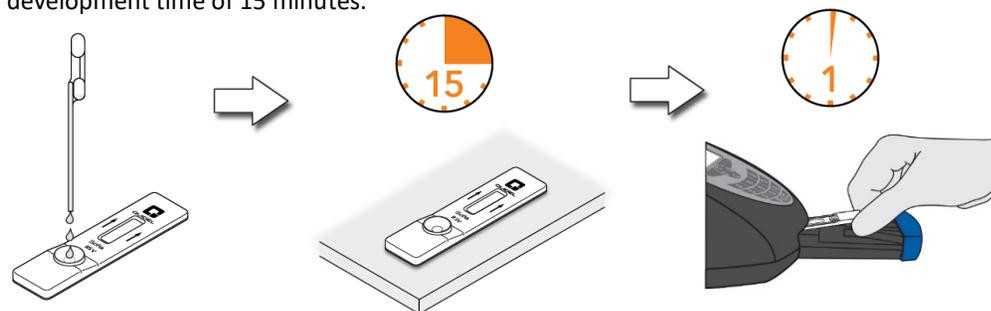
In WALK AWAY Mode, the user **immediately** inserts the Test Cassette into Sofia. The user then returns after 15 minutes to get the test result. In this mode, Sofia will automatically time the test development before scanning and displaying the test result.



READ NOW Mode

Allow the test to develop for the FULL 15 minutes BEFORE placing it into Sofia.

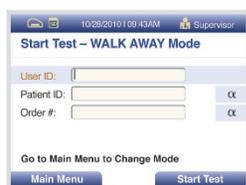
The user places the Test Cassette onto the counter or bench top for 15 minutes (outside of Sofia). The user manually times this development step. The Test Cassette **MUST** remain on the bench for 15 minutes to get an accurate result. Then, the user inserts the Test Cassette into Sofia. In READ NOW Mode, Sofia will scan and display the test result in 1 minute. **Note:** Results will remain stable for an additional 15 minutes after the recommended development time of 15 minutes.



RUN TEST

1. Input the User ID with the barcode scanner or 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 # with the barcode scanner or enter the data using the key pad.

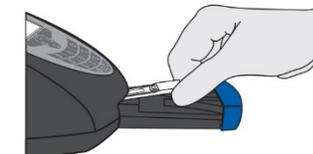


3. Press Start Test and the Sofia drawer will open.

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 in approximately 15 minutes. In READ NOW Mode, the test results will be displayed in 1 minute. See Sofia Interpretation of Results section.
- 6.



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 will not 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
RSV: Positive Procedural Control: Valid	Positive Test for RSV (RSV antigen present)
RSV: Negative Procedural Control: Valid	Negative Test for RSV (no antigen detected)
RSV: Invalid Procedural Control: Invalid	Result Invalid

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

1 From the main menu, select Run QC.



The screenshot shows the Sofia Main Menu interface. At the top, it displays the date and time (10/28/2010 | 09:43AM) and the user role (Supervisor). The menu options are: Run Test, Run QC (highlighted with a blue bar and arrow), Review Data, Calibration, Supervisor Menu, and Change Mode. A 'Select' button is located at the bottom right of the menu.

- 2** Follow the prompts on the screen. Scan the QC Card (located on the kit box).
- 3** Sofia prompts the user to select the desired mode (WALK AWAY or READ NOW). Run the External Control Swabs.
- 4** Follow the Swab Test Procedure of this Quick Reference Instructions. First test 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.”

NOTE: 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 and as deemed additionally necessary by your internal quality control procedures, and in accordance with Local, State and Federal regulations or accreditation requirements.

NOTE: The Calibration Check Procedure should be performed every 30 days. To calibrate Sofia, select “Calibration” from the menu and, following the prompts, insert the Calibration Cassette into Sofia and close the drawer. Sofia performs the Calibration Check automatically within two minutes with no user input required.

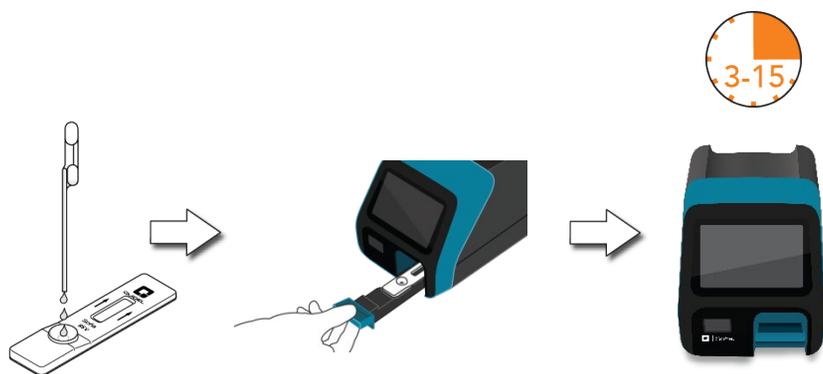
Using Sofia 2

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.

WALK AWAY Mode

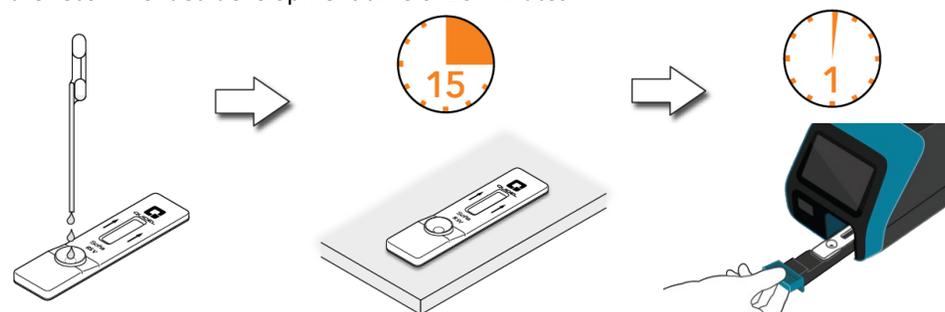
In WALK AWAY Mode, the user **immediately** inserts the Test Cassette into Sofia 2. Sofia 2 scans the Test Cassette periodically during the test development time. Positive test results will be displayed between 3 and 15 minutes. Negative test results will be displayed at 15 minutes.



READ NOW Mode

Allow the test to develop for the FULL 15 minutes BEFORE placing it into Sofia 2.

The user first places the Test Cassette onto the counter or bench top for 15 minutes (outside of Sofia 2). The user manually times this development step. The Test Cassette **MUST** remain on the bench for 15 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 15 minutes after the recommended development time of 15 minutes.



RUN TEST

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

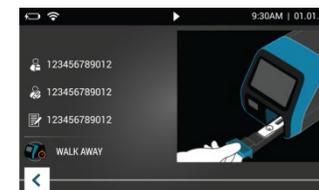
NOTE: If you scan the wrong barcode, re-highlight the field using the touchscreen on Sofia 2 and simply rescan using the correct barcode. The previous one will be overwritten with the right barcode.



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



3. Verify that the correct mode (WALK AWAY or READ NOW) has been selected. Press ▶ and open the Sofia 2 drawer.
4. 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 between 3 and 15 minutes. In READ NOW Mode, the test results will be displayed 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 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 with a new patient sample and new Test Cassette.

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

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

- From the main menu, select Run QC.



- Follow the prompts on the screen. Scan the QC Card (located on the kit box).
- Sofia 2 prompts the user to select the desired mode (WALK AWAY or READ NOW).
- Run the External Control Swabs.
- Follow the Swab Test procedure of this Quick Reference Instructions. First test the Positive Swab followed by the Negative Swab.
- After both the Positive and Negative Swabs have been run, the results will be displayed as  or .

NOTE: 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 and as deemed additionally necessary by your internal quality control procedures, and in accordance with Local, State and Federal regulations or accreditation requirements.

NOTE: The Calibration Check Procedure should be performed every 30 days. To calibrate Sofia 2, select “Run Calibration” from the main menu and, following the prompts, insert the Calibration Cassette into Sofia 2 and close the drawer. Sofia 2 performs the Calibration Check automatically within one minute with no user input required.

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 viral culture or an FDA-cleared RSV molecular assay. The Sofia RSV 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.), 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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