Sofia® Influenza A+B 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 direct nasal swab, nasopharyngeal swab and nasopharyngeal aspirate/wash specimens

CLIA Complexity: Moderate for nasopharyngeal swab and nasopharyngeal aspirate/wash specimens eluted in transport media

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

Test Procedure

NOTE: *The procedures for testing swab specimens versus liquid 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.*
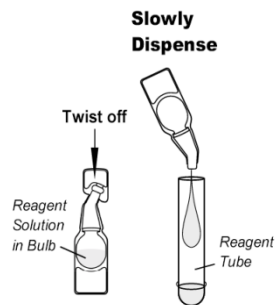

Swab Test Procedure (Nasal/Nasopharyngeal)

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 Dispense all of the Reagent Solution into the Reagent Tube. **Swirl the Reagent Tube to dissolve its contents.**

Slowly Dispense — Twist off — Reagent Solution in Bulb — Reagent Tube

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.

3x — Leave the swab in the Reagent Tube for 1 minute.
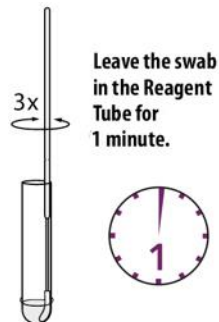
4 Roll the Swab head against the inside of the Reagent Tube as you remove it. Dispose of the used Swab in your biohazard waste.
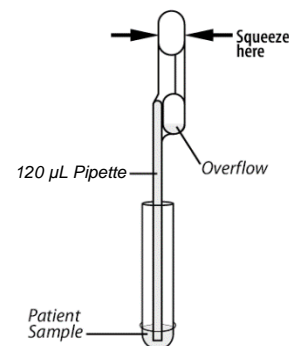

3x

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:

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

Squeeze here — 120 µL Pipette — Overflow — Patient Sample

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 120 µL Fixed Volume Pipette.

Sample Well

7 Proceed to the "Using Sofia" or "Using Sofia 2" section to complete the test.
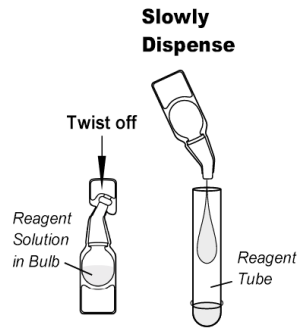
Liquid Specimens Test Procedure

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

Dispense all of the Reagent Solution into the Reagent Tube. **Swirl the Reagent Tube to dissolve its contents.**

Slowly Dispense

Twist off

Reagent Solution in Bulb

Reagent Tube

3

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

To fill the Fixed Volume Pipette with the sample:

a) FIRMLY squeeze the top bulb.
b) Still squeezing, place the Pipette tip into the patient sample.
c) 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 μL Fixed Volume Pipette** with patient sample from the collection cup.
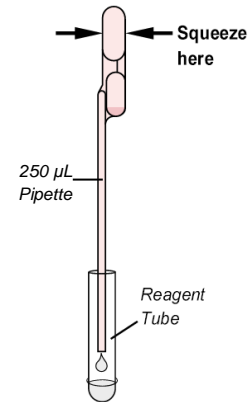
Squeeze here

250 μL Pipette

Overflow

Patient Sample
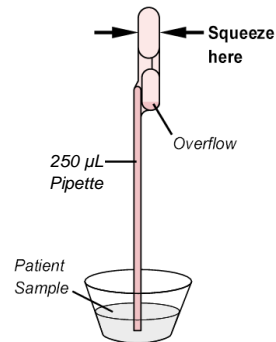
4

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

NOTE: Once the sample is added to the Reagent Tube, vigorously mix prior to adding the sample to the Test Cassette.

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

Squeeze here

250 μL Pipette

Reagent Tube

5

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

Squeeze here

120 μL Pipette

Overflow

Patient Sample

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

Sample Well

7

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

Using Sofia
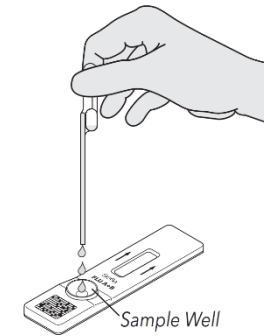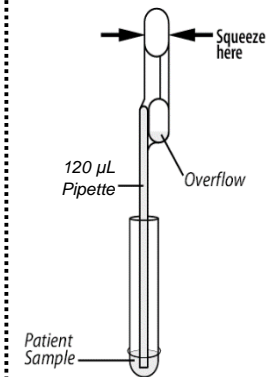
WALK AWAY/READ NOW Modes

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. Sofia will automatically time the test development, and the results will be displayed in 15 minutes.
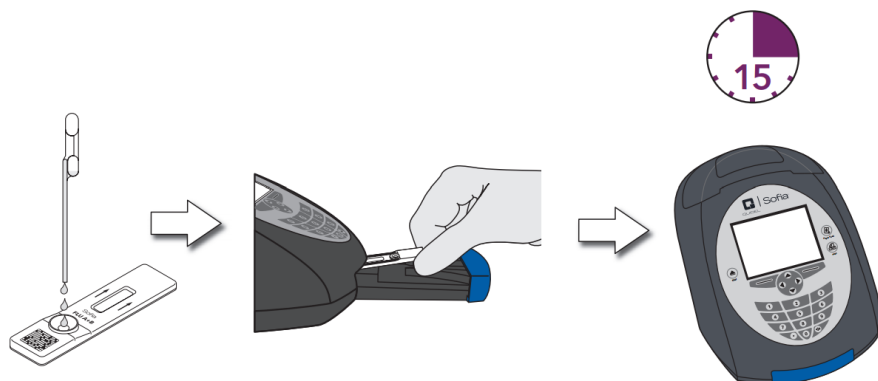
READ NOW Mode

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.
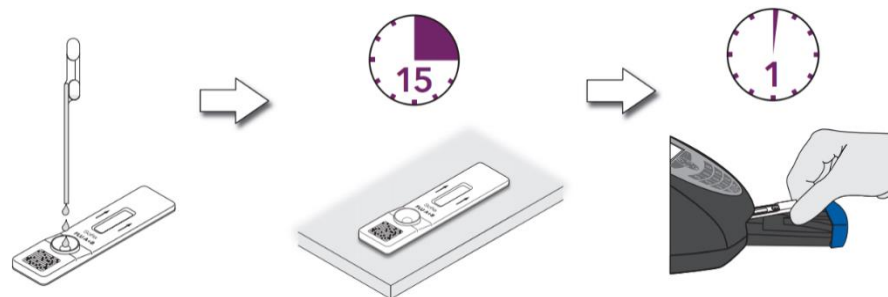
RUN TEST

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

   NOTE: If you 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 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.
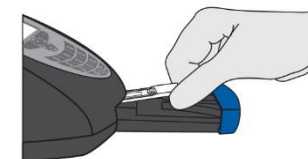
Sofia Interpretation of Results

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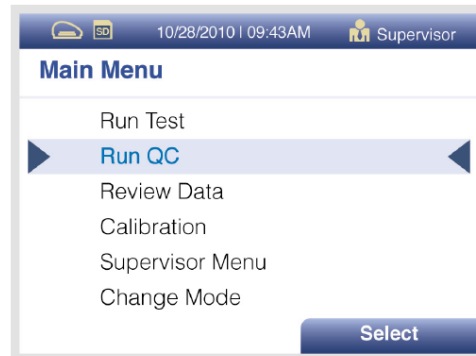
Results: The Sofia screen will display results for the procedural control as being "valid or invalid." If the control is "invalid," retest with a new patient sample and new Test Cassette.

Reader Display	Interpretation
Flu A: Positive Flu B: Negative Procedural Control: Valid	Positive Test for Flu A (influenza A antigen present)
Flu A: Negative Flu B: Positive Procedural Control: Valid	Positive Test for Flu B (influenza B antigen present)
Flu A: Positive Flu B: Positive Procedural Control: Valid	Positive Test for both Flu A and Flu B (influenza A and B antigen present)
Flu A: Negative Flu B: Negative Procedural Control: Valid	Negative Test for Flu A and Flu B (no antigen detected)
Flu A: Invalid Flu B: 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.

```
🖥 SD   10/28/2010 | 09:43AM   👥 Supervisor
Main Menu
    Run Test
▶   Run QC              ◀
    Review Data
    Calibration
    Supervisor Menu
    Change Mode
                    Select
```

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."

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.
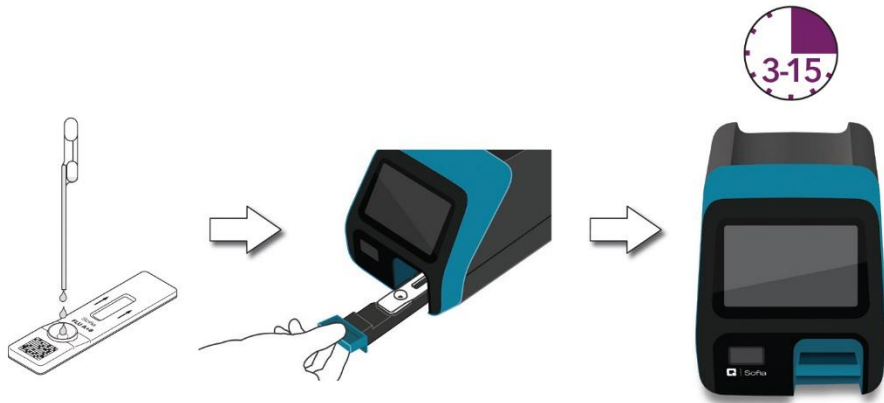
READ NOW Mode

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.
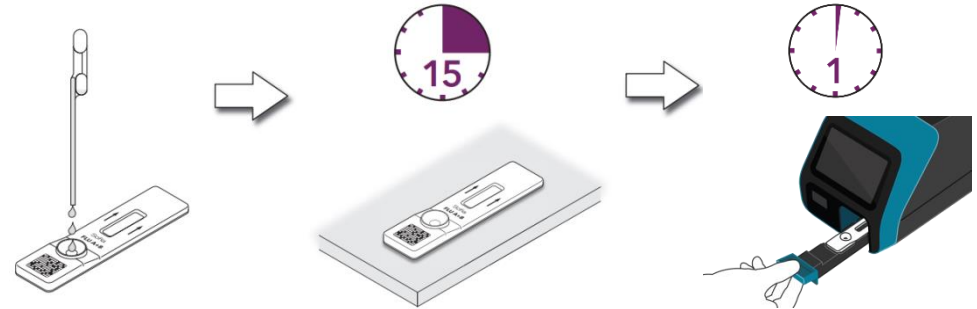
RUN TEST

1. Input the User ID with 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. The previous one will be overwritten with the right barcode.

2. Input the Patient ID and Order # (if applicable) with the integrated barcode scanner or manually enter the data using the key pad.
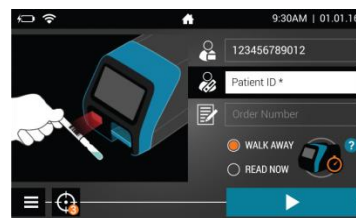
3. Verify that the correct mode (WALK AWAY or READ NOW) has been selected. Press ▶ and open the Sofia 2 drawer.
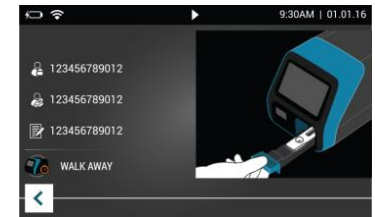
4. Insert the Test Cassette into the drawer. Then gently close the drawer.

5. Sofia 2 will start automatically and display the progress. In WALK AWAY Mode, the test results will be displayed in approximately 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
Flu A: ➕ Flu B: ➖ Procedural Control: ✅	Positive Test for Flu A (influenza A antigen present)
Flu A: ➖ Flu B: ➕ Procedural Control: ✅	Positive Test for Flu B (influenza B antigen present)
Flu A: ➕ Flu B: ➕ Procedural Control: ✅	Positive Test for both Flu A and Flu B (influenza A and B antigen present)
Flu A: ➖ Flu B: ➖ Procedural Control: ✅	Negative Test for Flu A and Flu B (no antigen detected)
Flu A: Flu B: Procedural Control: ❌	Result Invalid

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

1 From the main menu, select Run QC.
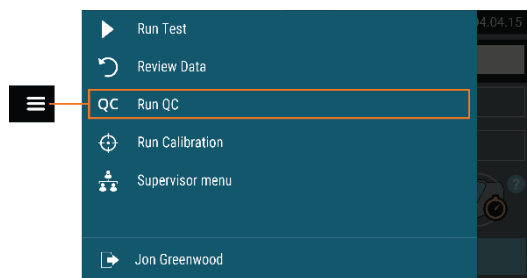
2 Follow the prompts on the screen. Scan the QC Card (located on the kit box).

3 Sofia 2 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 ✅ or ❌.

INTENDED USE

The Sofia Influenza A+B FIA employs immunofluorescence to detect influenza A and influenza B viral nucleoprotein antigens in direct nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash specimens and nasopharyngeal swab and nasopharyngeal aspirate/wash specimen in transport media from symptomatic patients. This qualitative test is intended for use as an aid in the rapid differential diagnosis of acute influenza A and influenza B viral infections. The test is not intended to detect influenza C antigens. A negative test is presumptive and it is recommended these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative results do not preclude influenza virus infections and should not be used as the sole basis for treatment or other patient management decisions. The Sofia Influenza A+B 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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