



Sofia by Quidel



How does the assay work?

The test employs immunofluorescence technology used with Sofia to detect antigen.

The patient sample is placed in the Reagent Tube, during which time the pathogenic antigen particles in the sample are extracted.

After extraction, the sample is dispensed into the Test Cassette sample well.

From the sample well, the sample migrates through a test strip containing various unique chemical environments. If antigen is present, they will be trapped in a specific location captured by the antibodies in the test strip.

Product specifications



Sample type Nasal swab, nasopharyngeal swab, nasopharyngeal aspirate/wash

Time to results Sofia: 15 minutes

Kit storage conditions: Room temperature (15°C to 30°C/59°F to 86°F)

Controls Positive and negative

Nasal swab sensitivity* A: 90%, B: 89%

Nasopharyngeal swab sensitivity* A: 97%, B: 90%

Nasopharyngeal aspirate/wash sensitivity* A: 99%, B: 88%

Nasal swab specificity* A: 95%, B: 96%

Nasopharyngeal swab specificity* A: 95%, B: 97%

Nasopharyngeal aspirate/wash specificity* A: 96%, B: 96%

Shelf life 24 months from date of manufacture

Transport Media Compatibility Copan Universal Transport Media, Hank's Balanced Salt Solution, M4, M4-RT, M5, M6, Modified Liquid Stuarts, Saline, Starplex Multitrans

CLIA complexity Waived

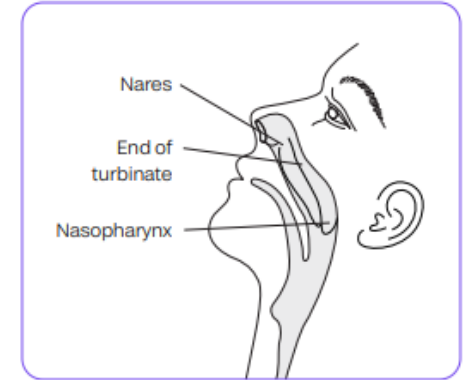
*Refer to Package Insert for additional performance claims.

Specimen collection

Obtain a nasal/nasopharyngeal specimen¹

In each case, collect samples by standard clinical methods.

Tip the patient's head back and check to see which nostril has more mucus (head should be inclined from vertical as shown for proper specimen collection). It is important to obtain as much secretion as possible.



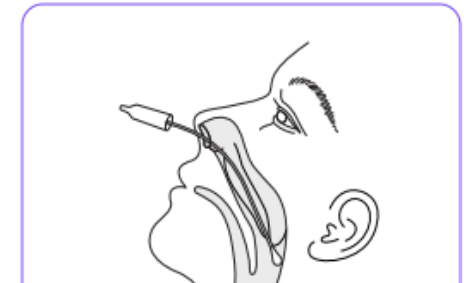
Nasal swab

1. Gently insert the sterile swab until resistance is met at the level of the turbinates (less than one inch into the nostril).
2. Rotate the swab a few times against the nasal wall and remove from nostril.
3. Sample should be tested as soon as possible.



Nasopharyngeal swab

1. Gently insert the sterile swab.
2. Keep the swab near the septum floor of the nose while gently pushing the swab into the posterior nasopharynx.
3. Rotate the swab several times and remove from nostril.
4. Sample should be tested as soon as possible.





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.

DU

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.

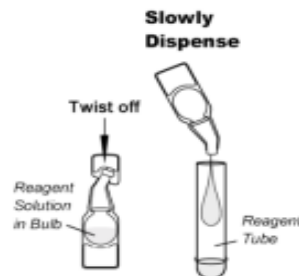
Swab Test Procedure (Nasal/Nasopharyngeal)

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.

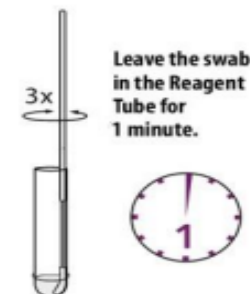
2

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



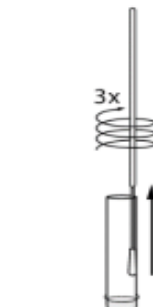
3

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.

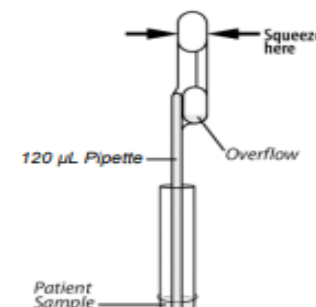


5

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 120 µL Fixed Volume Pipette**.



7

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

Run Test

Using Sofia

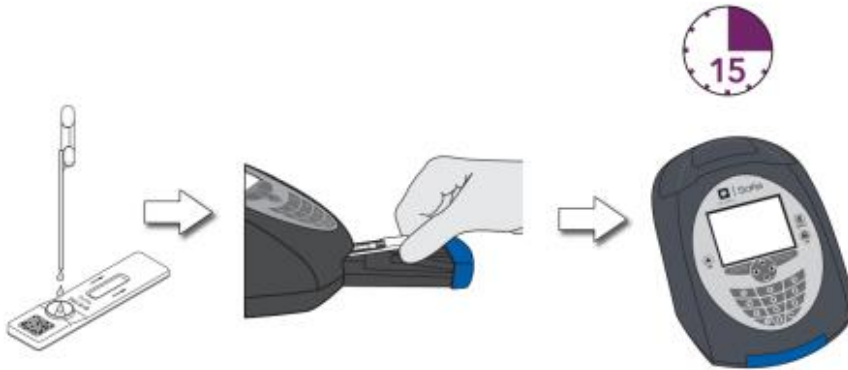
WALK AWAY/READ NOW Modes

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

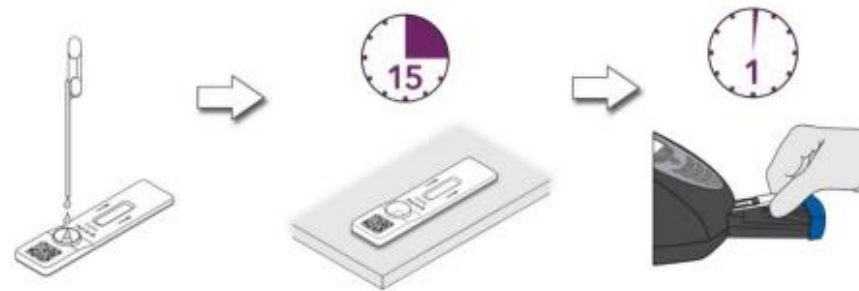
In WALK AWAY Mode, the user **immediately** inserts the Test Cassette into Sofia. Sofia will automatically time the test development, and the results will be displayed in 15 minutes.



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.



Using Sofia

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 (Flu example)

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

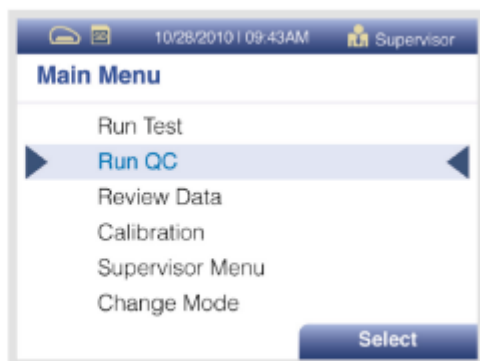
Running QC

Required on new lot, new shipment, new operator
Calibration required every 30 days

Sofia 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 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."



References

IFU Sofia Strep:

<https://static.webareacontrol.com/CommonFile/instructions-for-use-1678096459246.pdf>

SARS Antigen FIA FAQ's

<https://static.webareacontrol.com/CommonFile/instructions-for-use-1678096459246.pdf>

blob:https://techdocs.quidelortho.com/43a95bab-7e3a-43a2-bb88-dc662dd63bd5

SARS Antigen FIA Quiz

blob:https://techdocs.quidelortho.com/de1e9575-5129-490a-8512-3b47e2d4b14f

Quick reference guide:

<https://techdocs.quidelortho.com/?country=United+States&language=English&docId=16842597&isauthenticated=public>

