



Sofia[®] SARS Antigen FIA

QUICK REFERENCE INSTRUCTIONS

For use with Sofia and Sofia 2 only



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

For use under the Emergency Use Authorization (EUA) only
For *in vitro* diagnostic use

R_x ONLY

IMPORTANT! Read instructions carefully before beginning. The test procedure below is unique to the Sofia SARS Antigen FIA and may differ from other Sofia and Sofia 2 FIA procedures.

Test Procedure

All specimens must be at room temperature before testing. For use with direct anterior nasal swab samples.

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.

Disposable gloves and safety glasses are recommended when running this test. Wash hands thoroughly after handling any patient sample.

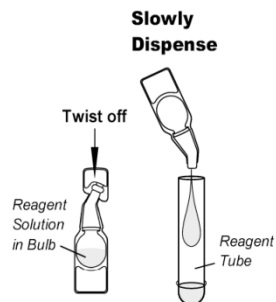
Swab Test Procedure (Direct Anterior Nasal)

1

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

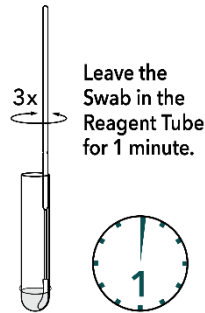
2

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.

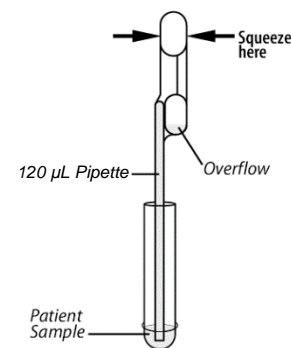


5

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

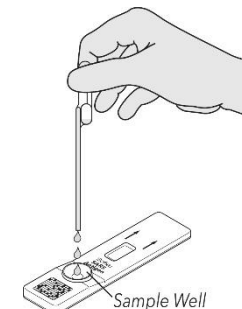


6

Firmly squeeze the top bulb to empty the contents of the **Small, Clear 120 μ L 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 μ L Fixed Volume Pipette**.



7

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

Using Sofia

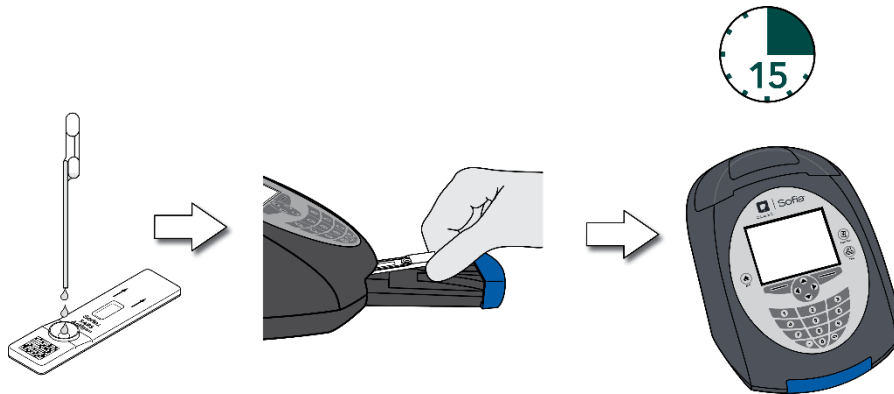
WALK AWAY/READ NOW Modes

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.

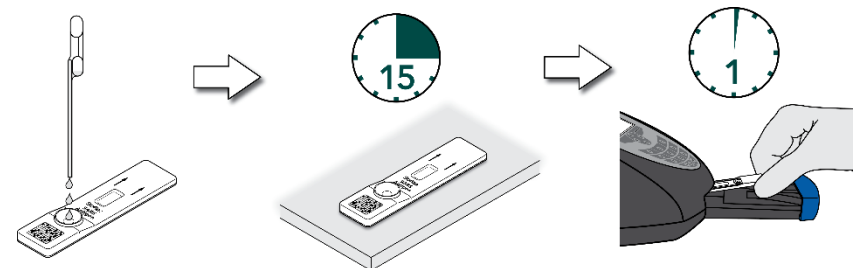


READ NOW Mode

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.

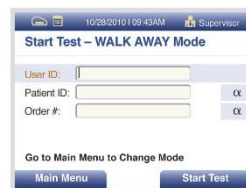
Warning: Results must not be interpreted past 30 minutes after inoculation. Using the Sofia past this time may result in false results.



RUN TEST

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

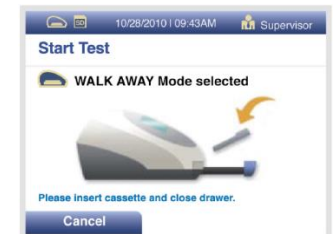
NOTE: If you scan the wrong barcode, use the Arrow Keys on Sofia to re-highlight the field and simply rescan using the correct barcode. The previous one will be overwritten with the right barcode.



2. Input the Patient ID or Order # with the barcode scanner or enter the data using the keypad.

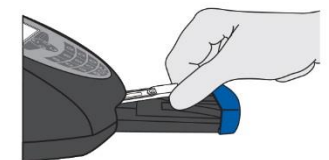


3. Press Start Test and the Sofia drawer will open.



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.

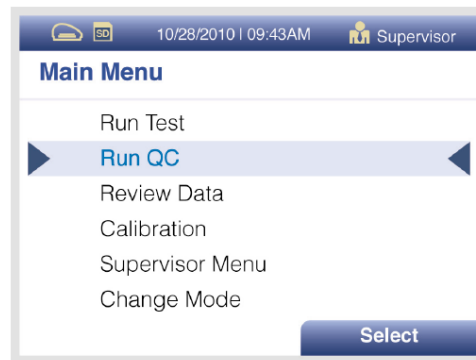
Results: The Sofia screen will display results for the procedural control as being “valid or invalid.” If the control is “invalid,” retest with a new patient sample and new Test Cassette. If used on asymptomatic individuals for serial testing, a second test should be obtained with at least 24 hours (and no more than 36 hours) between tests.

Reader Display	Interpretation
SARS: Positive Procedural Control: Valid	Positive Test SARS (SARS Antigen present)
SARS: Negative Procedural Control: Valid	Negative Test for SARS (no SARS antigen detected)
SARS: 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.



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.”

Using Sofia 2

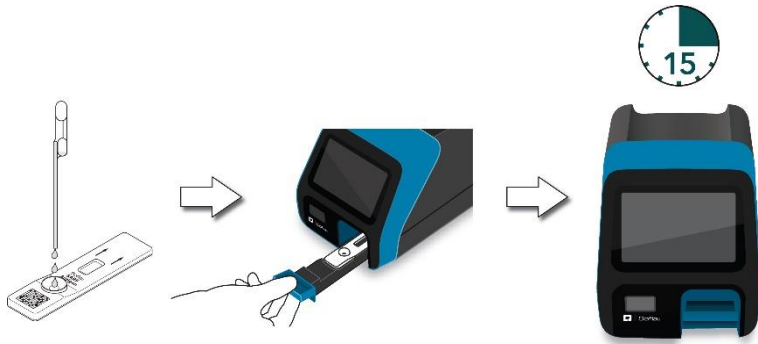
WALK AWAY/READ NOW Modes

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

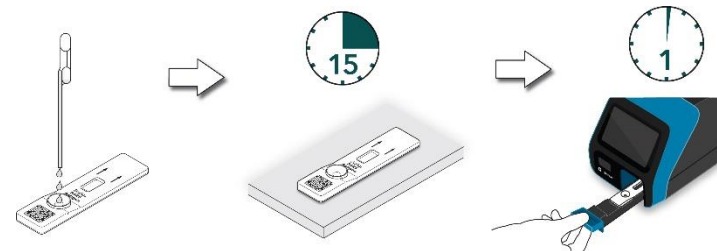
In WALK AWAY Mode, the user **immediately** inserts the Test Cassette into Sofia 2. Positive and negative test results will be displayed at 15 minutes.



READ NOW Mode

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

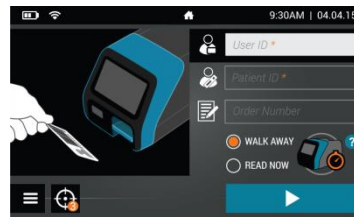
The user first places the Test Cassette onto the counter or bench top for 15 minutes (outside of Sofia 2). The user manually times this development step. The Test Cassette **MUST** remain on the bench for 15 minutes to get an accurate result. Then, the user inserts the Test Cassette into Sofia 2. In READ NOW Mode, Sofia 2 will scan and display the test result within 1 minute. **Warning: Results must not be interpreted past 30 minutes after inoculation. Using the Sofia past this time may result in false results.**



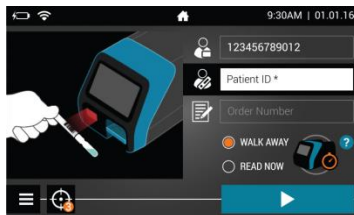
RUN TEST

1. Input the User ID with the integrated barcode scanner or manually enter the data using the keypad.

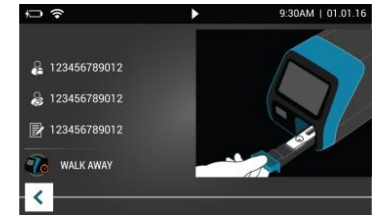
NOTE: If you scan the wrong barcode, re-highlight the field using the touchscreen on Sofia 2. The previous one will be overwritten with the right barcode.



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






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.

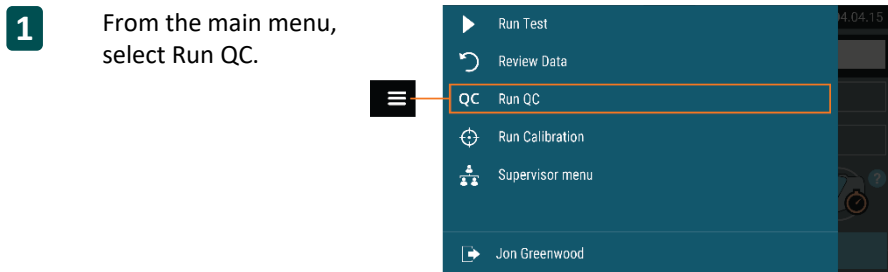
Sofia 2 Interpretation of Results



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. If used on asymptomatic individuals for serial testing, a second test should be obtained with at least 24 hours (and no more than 36 hours) between tests.

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

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



- 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 SARS Antigen FIA is a lateral flow immunofluorescent sandwich assay that is used with the Sofia, Sofia instrument intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal (NS) swab specimens from individuals who are either suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms, or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 36 hours between tests. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

The Sofia SARS Antigen FIA does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results should be treated as presumptive, do not rule out SARS-CoV-2 infection, and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary, for patient management. For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with as a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection..

The Sofia SARS Antigen FIA is intended for use by trained clinical laboratory personnel and individuals trained in point of care settings, and proficient in performing tests using the Sofia, Sofia 2 and Sofia Q instruments. The Sofia SARS Antigen FIA is only for use under the Food and Drug Administration's Emergency Use Authorization.

The Sofia SARS Antigen FIA should be used with Sofia, Sofia 2.

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform to perform moderate, high or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and, In the USA, - the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the authorization is revoked sooner

Reference the Package Insert for *Warnings and Precautions, Limitations, Specimen Collection and Handling, and Quality Control.*

ASSISTANCE

If the 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.



Quidel Corporation
San Diego, CA 92121 USA
quidel.com

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