

Sofia 2 SARS Antigen+ FIA

Quick Reference Instructions



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

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

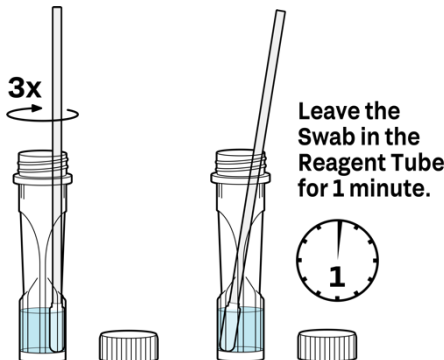
Refer to the instructions of the swab manufacturer to collect a nasal swab specimen from the patient. All specimens must be at room temperature before testing.
Expiration date: Check expiration date on each individual test package or outer box before using. Do not use any test past the expiration date on the label. Do not use cartridges that have dropped on the floor or have visible damage.
 Disposable gloves and safety glasses are recommended when running this test. Wash hands thoroughly after handling any patient sample.
 External Controls may be used to demonstrate that the reagents and assay procedure perform properly. Refer to Sofia 2 External Quality Control Section in this Instructions.

Test Procedure

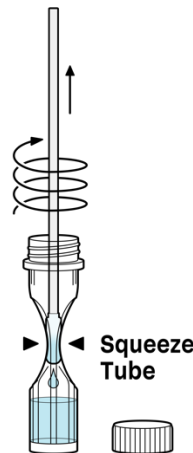
Step 1
 Verify that Sofia 2 is set to the desired Mode: WALK AWAY or READ NOW. See the "Using Sofia 2" section for more information.



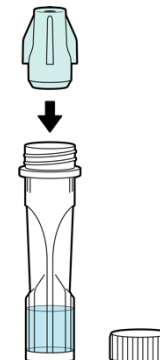
Step 2
 Open and remove the cap of the Reagent tube. Insert the swab into the Reagent tube. Roll the swab at least 3 times while pressing the head against the bottom and side of the Reagent tube. **Leave the swab in the Reagent tube for 1 minute.**



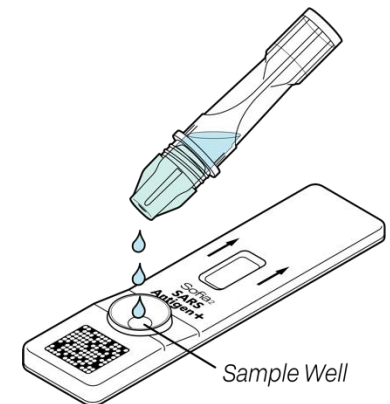
Step 3
 Express as much liquid as possible from the swab by squeezing the sides of the Tube as the swab is withdrawn in a complete twisting motion.
 Discard the Swab in accordance with your biohazard waste disposal protocol.



Step 4
 Press the dropper tip firmly into the Reagent Tube to seal the samples



Step 5
 Add **Three (3)** drops into the Test Cassette sample well.



Using Sofia 2

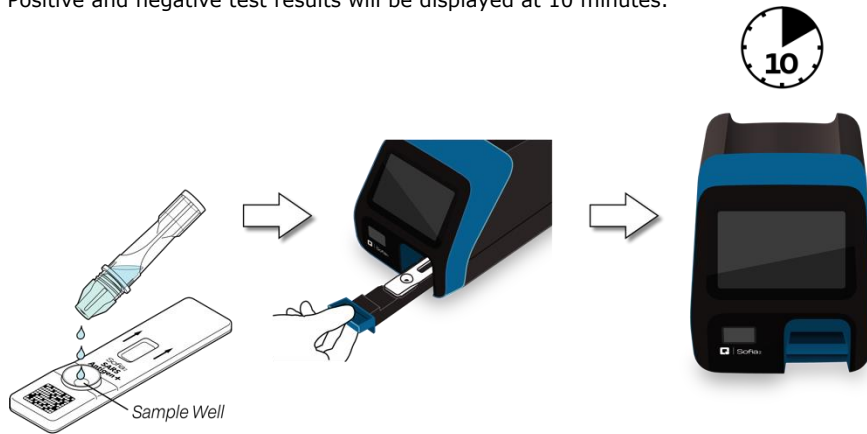
WALK AWAY/READ NOW Modes

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 10 minutes.

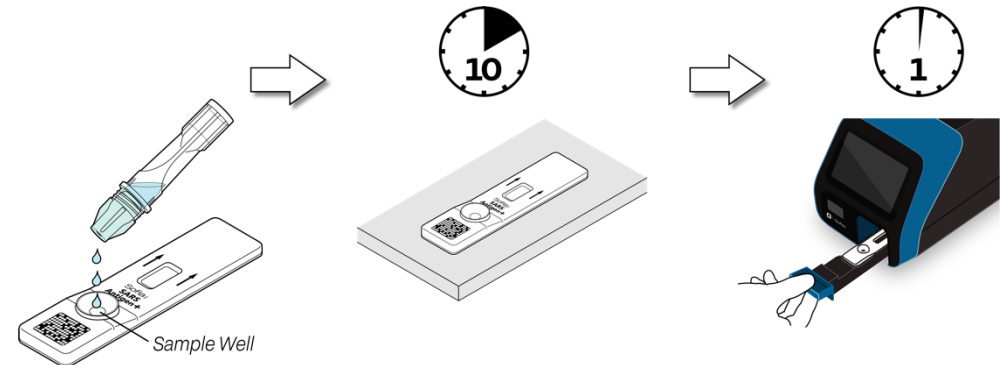


READ NOW Mode

Allow the test to develop for the FULL 10 minutes BEFORE placing it into Sofia 2.

The user first places the Test Cassette onto the counter or bench top for 10 minutes (outside of Sofia 2). The user manually times this development step. The Test Cassette **MUST** remain on the bench for 10 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.

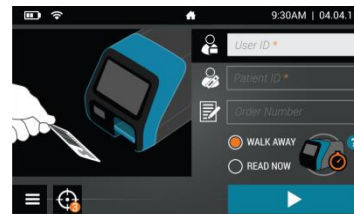
Warning: Results must not be interpreted past 20 minutes after inoculation. Using the Sofia 2 past this time may result in false results.



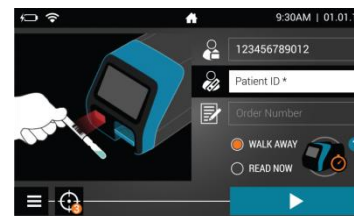
Run Test


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

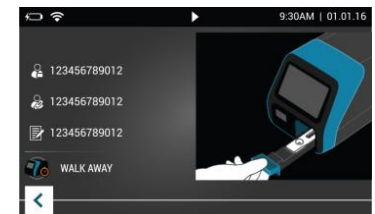
NOTE: If you scan the wrong barcode, re-highlight the field using the touchscreen on Sofia 2. The previous one will be overwritten with the right barcode.



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 10 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.

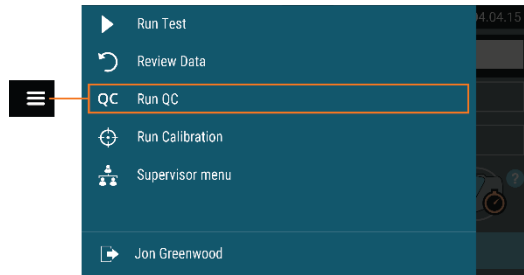
Results: The Sofia 2 screen will display results for the procedural control as being  or . If the control is , retest with a new patient sample and new Test Cassette. Test results should be reported in accordance with local, state, and federal regulations.



Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing

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)

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 .
Do not proceed with testing of clinical samples if either the Positive Control or Negative Control fails the QC check.

Intended Use

The Sofia 2 SARS Antigen+ FIA is a lateral flow immunofluorescent sandwich assay that is used with the Sofia 2 instrument for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal swab specimens from individuals with signs and symptoms of upper respiratory infection (i.e., symptomatic) when testing is started within 6 days of symptom onset. The test is intended for use as an aid in the diagnosis of SARS-CoV-2 infections (COVID-19) in symptomatic individuals when tested at least twice over three days with at least 48 hours between tests.

The test does not differentiate between SARS-CoV and SARS-CoV-2.

A negative test result is presumptive, and it is recommended these results be confirmed by a molecular SARS-CoV-2 assay. Negative results do not preclude SARS-CoV-2 infections and should not be used as the sole basis for treatment or other patient management decisions.

Positive results do not rule out co-infection with other respiratory pathogens.

Performance characteristics for SARS-CoV-2 were established during the 2021-2022 SARS-CoV-2 pandemic when SARS-CoV-2 Omicron was the predominant SARS-CoV-2 variant in circulation. When other SARS-CoV-2 virus variant are emerging, performance characteristics may vary.

This test is intended for prescription use only and can be used in Point-of-Care settings.

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

Assistance

If the Sofia 2 or the assay do not perform as expected, contact QuidelOrtho Technical Support 800.874.1517 (in the U.S.), 858.552.1100 (outside the U.S.), technicalsupport@quidelortho.com, or your local distributor.



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