QUICK REFERENCE INSTRUCTIONS

For use with Sofia, Sofia 2, and Sofia Q only

Quidel | **Sofia®** SARS Antigen FIA

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

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

℞ 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, Sofia 2, and Sofia Q 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, and Sofia Q is set to the desired Mode: **WALK AWAY** or **READ NOW**. See the "Using Sofia, Sofia 2, and Sofia Q" 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
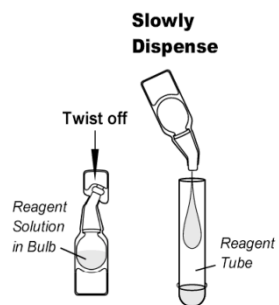
3
Place the patient swab sample into the Reagent Tube. Roll the swab at least 3 times while pressing the head against the bottom and side of the Reagent Tube.

3x

Leave the Swab in the Reagent Tube for 1 minute.

1
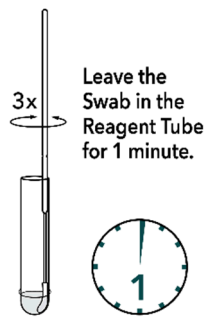
4
Roll the Swab head against the inside of the Reagent Tube as you remove it. Dispose of the used Swab in your biohazard waste.
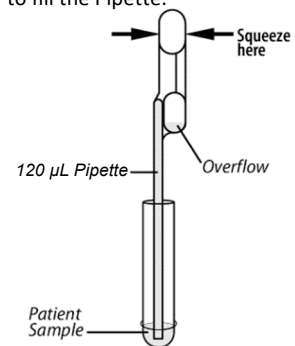

3x

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
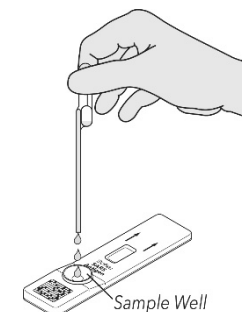
7
Proceed to the "Using Sofia, Sofia 2, Sofia Q" section to complete the test.

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.
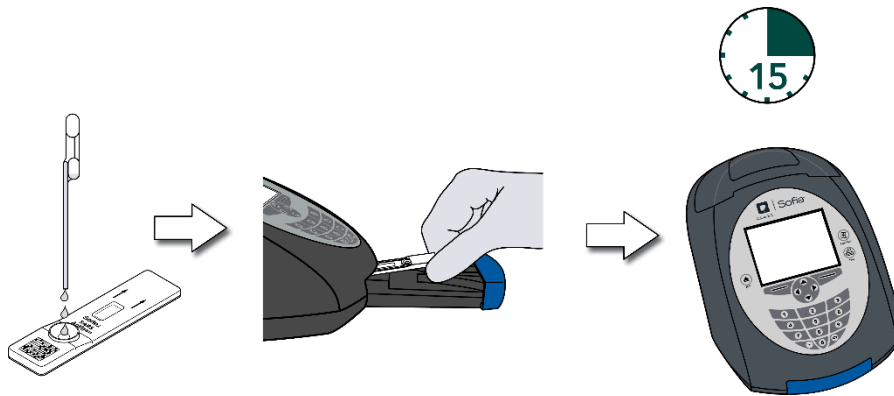
READ NOW Mode

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.**
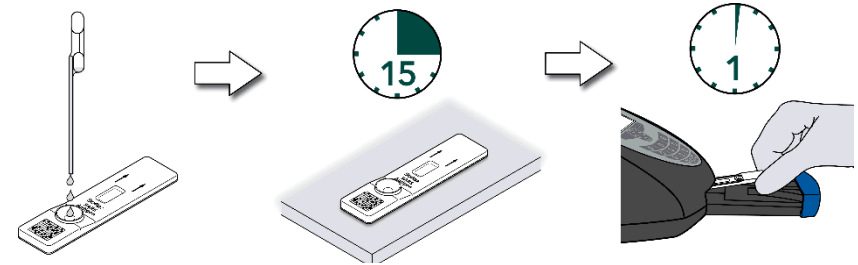
RUN TEST

1. Input the User ID with the barcode scanner or enter the data using the 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.
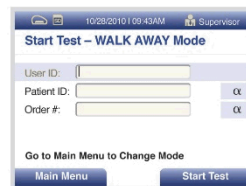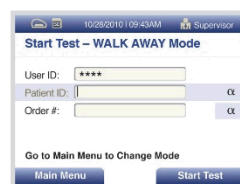
   - Press Start Test and the Sofia drawer will open.

   - 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.
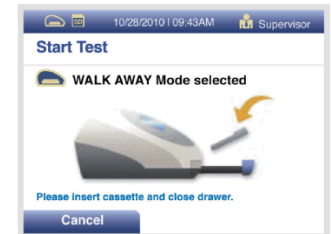
2. Input the Patient ID or Order # with the barcode scanner or enter the data using the key pad.

   - 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.
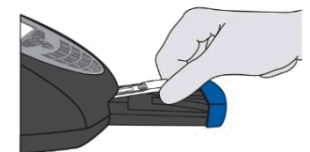
Sofia Interpretation of Results

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.

*Repeat testing does not need to be performed if patients have a positive result at any time.

**To increase the chance that the negative result for COVID-19 is accurate, you should:
- **Test again in 48 hours if the individual has symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.**

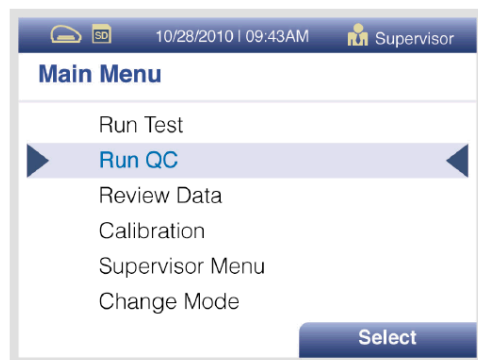| Reader Display	
SARS: Positive Procedural Control: Valid	*Positive Test SARS (SARS Antigen present)
SARS: Negative Procedural Control: Valid	**Negative Test for SARS (no SARS antigen detected)
SARS: Procedural Control: Invalid	Result Invalid

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results. Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Status on first day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

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."

NOTE: Do not perform patient tests or report patient test results if either of the QC test results fail. Repeat the test or contact Quidel Technical Support before testing patient samples. **Refer to the Package Insert for additional instructions.**
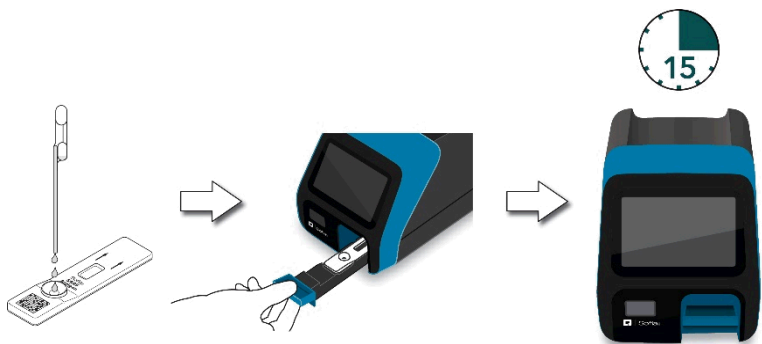
Using Sofia 2

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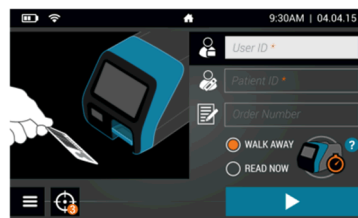
2. Input the Patient ID and Order # (if applicable) with the integrated barcode scanner or manually enter the data using the key pad.
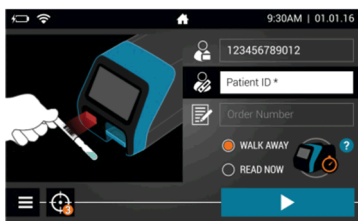
3. Verify that the correct mode (WALK AWAY or READ NOW) has been selected. Press ▶ and open the Sofia 2 drawer.
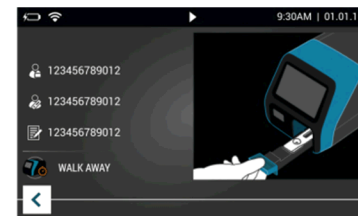
4. Insert the Test Cassette into the drawer. Then gently close the drawer.

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.

*Repeat testing does not need to be performed if patients have a positive result at any time.

**To increase the chance that the negative result for COVID-19 is accurate, you should:
- **Test again in 48 hours if the individual has symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.**
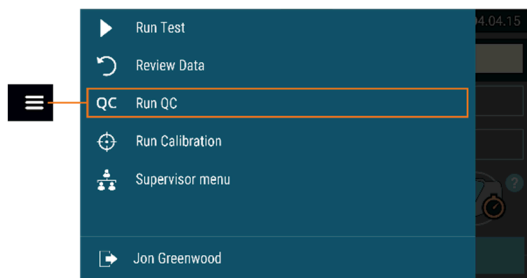
Reader Display	Interpretation
SARS: ➕ Procedural Control: ✅	*Positive Test for SARS (SARS antigen present)
SARS: ➖ Procedural Control: ✅	**Negative Test for SARS (no SARS antigen detected)
SARS: Procedural Control: ❌	Result Invalid

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results. Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Status on first day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

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

1 From the main menu, select Run QC.

▶	Run Test
↺	Review Data
QC	Run QC
⊕	Run Calibration
⊥	Supervisor menu
⇥	Jon Greenwood

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 ✅.

NOTE: Do not perform patient tests or report patient test results if either of the QC test results fail (✅). Repeat the test or contact Quidel Technical Support before testing patient samples. **Refer to the Package Insert for additional instructions.**

Using Sofia Q

Installing the Sofia Q App

In order to begin using the Sofia Q system the Sofia Q App will need to be downloaded and installed from the Apple App Store. The application is currently compatible with iOS 13 and above and iPhone 8 and above. The App can be found by searching on the Apple App Store for Sofia Q App.
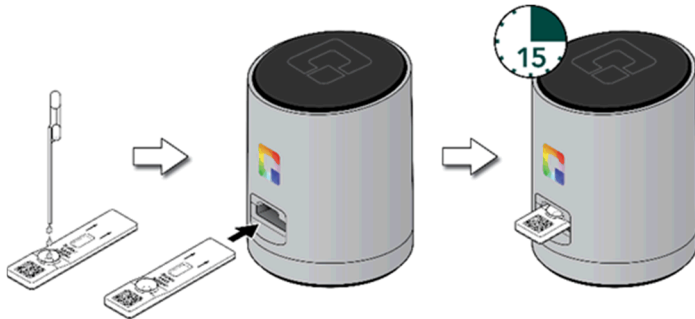
WALK AWAY/READ NOW Modes

Refer to the Sofia Q User Manual.

Sofia Q 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 Q. 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 Q.

The user first places the Test Cassette onto the counter or bench top for 15 minutes (outside of Sofia Q). 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 Q. In READ NOW Mode, Sofia Q 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.**
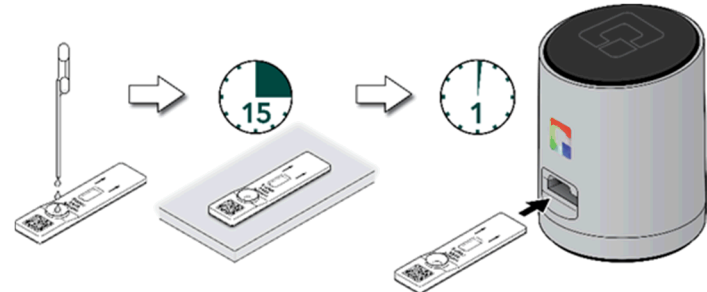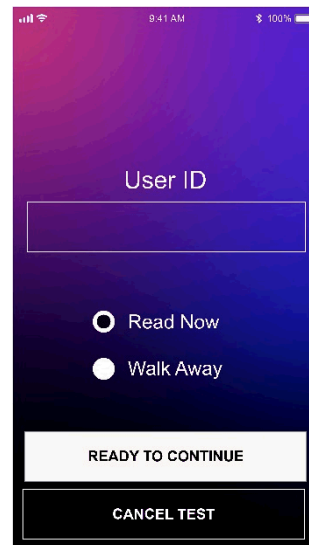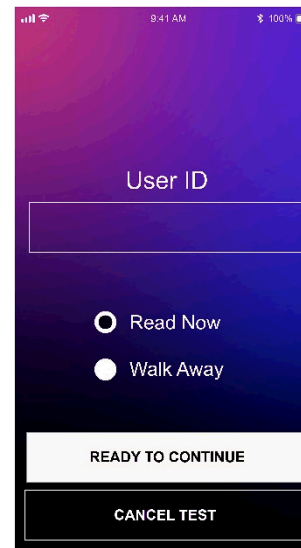
RUN TEST

1. Once the app is installed, tap the **Sofia Q App** icon to start the app. Press Run Test when ready.
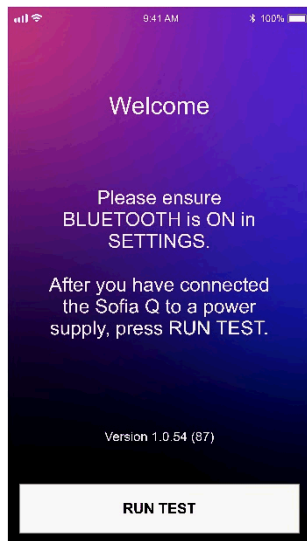

2. Input the **User ID** by tapping the field and using the onscreen keyboard. The field only accepts letters and number and no spaces.

3. Select the preferred mode, **READ NOW** or **WALK AWAY**. The selection will be retained for subsequent runs.

4. Input the **Serial Code** by tapping the camera icon and scan the barcode on the bottom of the Sofia Q. The pairing will be retained for subsequent runs.
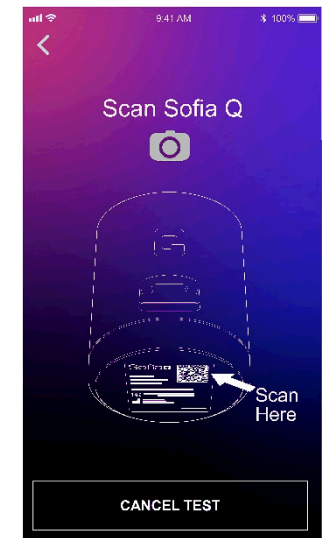
Sofia Q Interpretation of Results

When the test is complete, the results will be displayed on the phone screen. Test Lines will not be visible to the naked eye.

Results: The Sofia Q screen will display results as being ⊕ or ⊖. If the sample is deemed invalid ✓, retest with a new patient sample and new Test Cassette.

*Repeat testing does not need to be performed if patients have a positive result at any time.

**To increase the chance that the negative result for COVID-19 is accurate, you should:

- **Test again in 48 hours if the individual has symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.**

Reader Display	Interpretation
SARS: ⊕	*Positive Test for SARS (SARS antigen present)
SARS: ⊖	**Negative Test for SARS (no SARS antigen detected)
SARS: INVALID: ✗	Result Invalid

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results. Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Status on first day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

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

Perform QC using the patient Swab Test procedure of this Quick Reference Instructions. The QC card located on the kit box does not need to be scanned and QC can be performed in the same manner as a patient test. After both the Positive and Negative QC Swabs have been run, the results will be displayed as ⊕ or ⊖. Check the result displayed against the expected result of the External Control to ensure the Positive Control displays a ⊕ for a positive result and the Negative Control displays a ⊖ for a negative result. Make note of the QC results, as needed, as the result will not be stored within the Sofia Q App.

NOTE: Do not perform patient tests or report patient test results if either of the QC test generate unexpected results. Repeat the test or contact Quidel Technical Support before testing patient samples. **Refer to the Package Insert for additional instructions.**

INTENDED USE

The Sofia SARS Antigen FIA is a lateral flow immunofluorescent sandwich assay that is used with the Sofia, Sofia 2, and Sofia Q instrument intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal (NS) swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first five (5) days of symptom onset when tested at least twice over three days with at least 48 hours between tests, or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 48 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 which is generally detectable in anterior nasal swab 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 definitive cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. Negative results 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 measures such as isolating from others and wearing masks. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

The Sofia SARS Antigen FIA is intended for use by medical professionals or operators who are proficient in performing tests in a point of care setting.

The Sofia SARS Antigen FIA should be used with Sofia, Sofia 2 or Sofia Q instruments. The Sofia SARS Antigen FIA test is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

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

EMERGENCY USE AUTHORIZATION – WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.

In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use Authorization for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements 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. 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 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 authorization is revoked sooner.

Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.

If you have had symptoms longer than 5 days you should consider testing at least three times over five days with at least 48 hours between tests.

ASSISTANCE

If the Sofia, Sofia 2, Sofia Q 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
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quidel.com