



Sofia² SARS-CoV-2 Antibody IgG FIA

QUICK REFERENCE INSTRUCTIONS

For use with Sofia 2.



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-CoV-2 Antibody IgG FIA and may differ from other Sofia and Sofia 2 FIA procedures.

Test Procedure

DO NOT open the foil pouch containing the Test Cassette until ready to test the sample. Place the Test Cassette on a clean and level surface.

All specimens must be at room temperature before testing.

Expiration Date: Check expiration on each individual test package or outer box before using. Do not use any test past the expiration date on the label.

Fingerstick Whole Blood

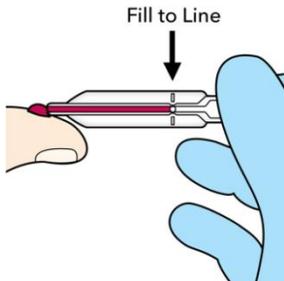
1

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

Follow Package Insert for Specimen Collection.

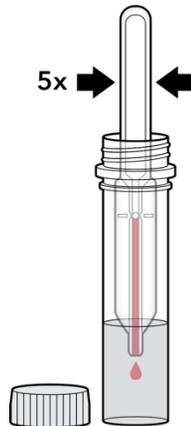
2

Hold the provided **25 µL** capillary tube **horizontally** and touch the tip to the patient blood sample. Blood will automatically draw into the capillary tube – **Do not squeeze the bulb**. Fill to the black line.



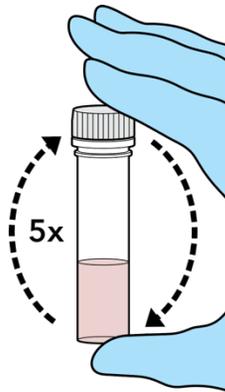
3

Submerge capillary in buffer and **squeeze** bulb on the end of the capillary tube to add patient sample to the Reagent Vial. **While submerged**, quickly squeeze bulb 5 times to mix.



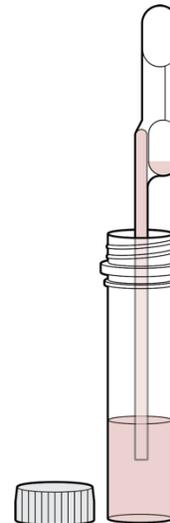
4

Screw cap on Reagent Vial and **invert** 5 times.



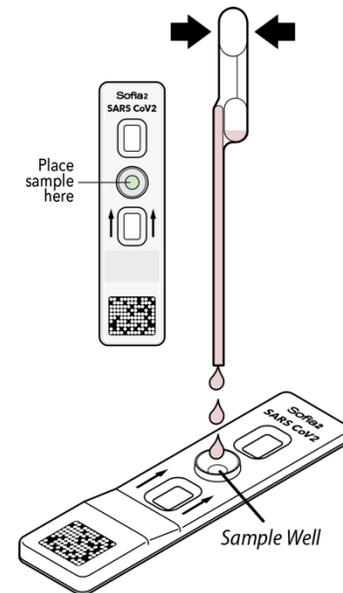
5

Fill the **100 µL** pipette with diluted sample from the Reagent Vial. Sample may go into overflow bulb.



6

Align the tip of the pipette with the round Test Cassette sample well and empty its contents.



7

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

Venous Whole Blood

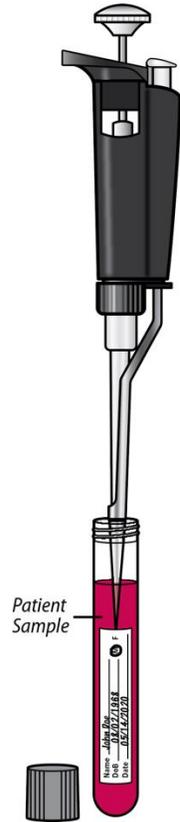
1

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

Follow Package Insert for Specimen Collection.

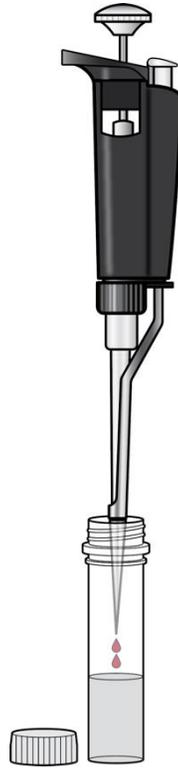
2

Fill a calibrated micropipette with **25 μL** of the patient venous whole blood sample.



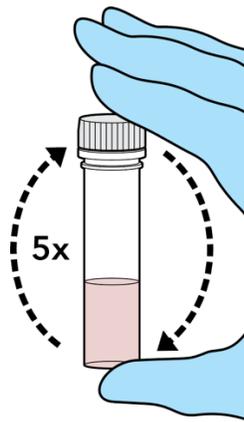
3

Add patient sample to the Reagent Vial and **gently mix**.



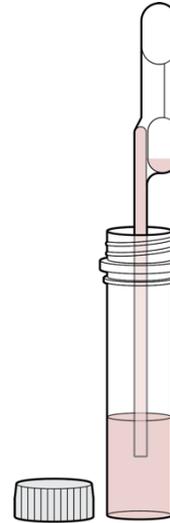
4

Screw cap on Reagent Vial and **invert 5 times**.



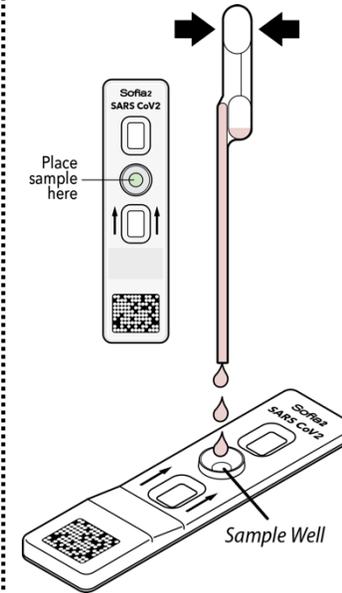
5

Fill the provided disposable pipette with **100 μL** of diluted sample from the Reagent Vial.



6

Align the tip of the pipette with the round Test Cassette sample well and empty its contents.



7

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

Serum/Plasma

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.

Follow Package Insert for Specimen Collection.

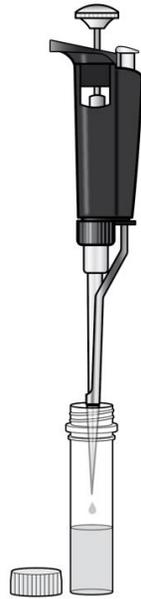
2

Fill a calibrated micropipette with **10 μ L** of the patient serum/plasma sample.



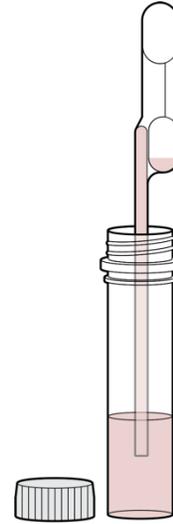
3

Add patient sample to the Reagent Vial and **gently mix**.



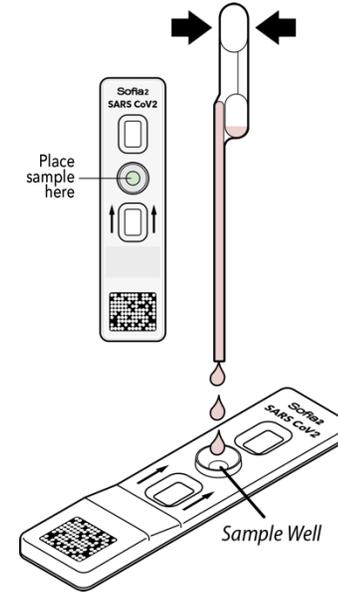
4

Fill the provided disposable pipette with **100 μ L** of diluted sample from the Reagent Vial.



5

Align the tip of the pipette with the round Test Cassette sample well and empty its contents.



6

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

Using Sofia 2

WALK AWAY/READ NOW Modes

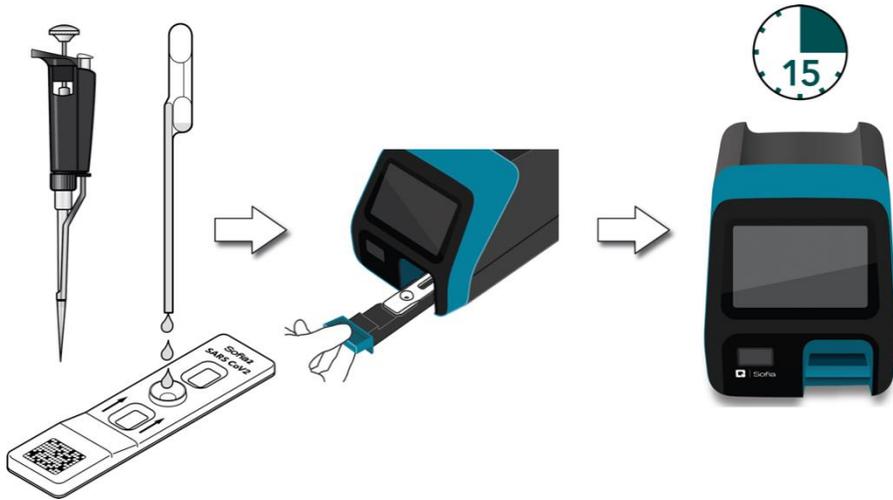
Refer to the *Sofia 2 User Manual for operating instructions.*

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. Test results will be displayed in 15 minutes.

Note: A calibrated micropipette or a disposable 100 μ L pipette may be used.

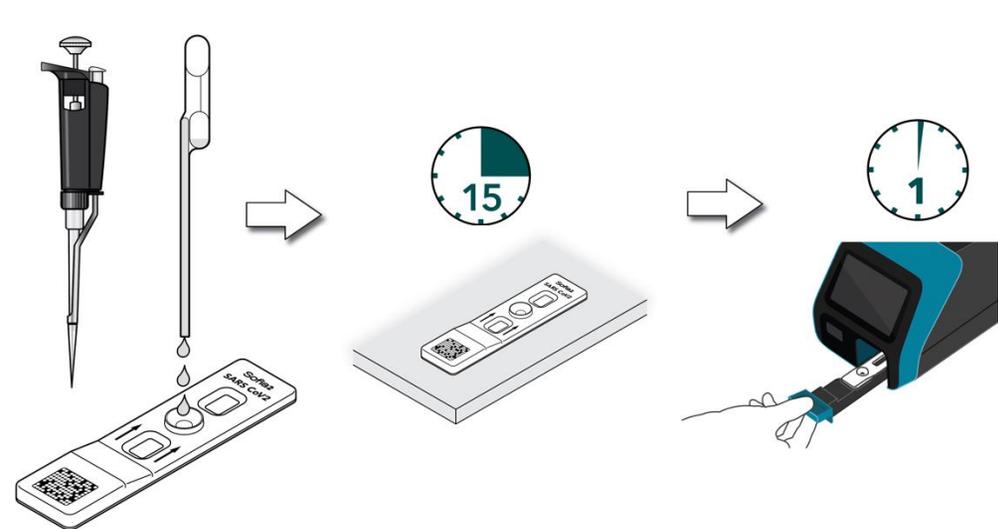


READ NOW Mode

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

The user must first place the Test Cassette onto the counter or bench top for 15 minutes (outside of Sofia 2) and manually time this development step. 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: A calibrated micropipette or a disposable 100 μ L pipette may be used.



RUN TEST

1. Input the User ID using the integrated barcode scanner or manually enter the data using the on-screen key pad.

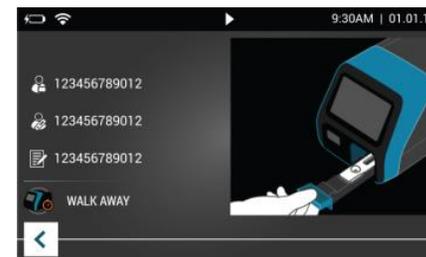
NOTE: If you mistakenly scan the incorrect barcode, select the field again to re-highlight it. Then simply rescan using the correct barcode, and the previous one will be overwritten with the correct barcode.



2. Input the Patient ID and/or Order # using the integrated barcode scanner or manually enter the data using the on-screen 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 on the screen in 15 minutes. In READ NOW Mode, the test results will be displayed on the screen within 1 minute. See 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, which are fluorescent, will never be visible to the naked eye.

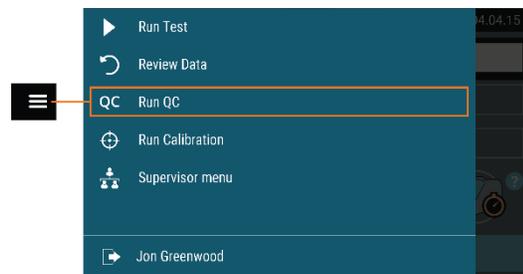
Results: The Sofia 2 screen will display results for the procedural control as being ✓ or ✗. If the control is ✗, retest starting with Step 1 and a new Test Cassette.

Reader Display	Report Result
N: + S1: - S2: - Procedural Control: ✓	Positive Test for IgG antibodies to SARS-CoV-2 N protein
N: - S1: + S2: - Procedural Control: ✓	Positive Test for IgG antibodies to SARS-CoV-2 S1 protein
N: - S1: - S2: + Procedural Control: ✓	Positive Test for IgG antibodies to SARS-CoV-2 S2 protein
N: + S1: + S2: - Procedural Control: ✓	Positive Test for IgG antibodies to SARS-CoV-2 N and S1 protein

Procedural Control: ✓	
N: + S1: - S2: + Procedural Control: ✓	Positive Test for IgG antibodies to SARS-CoV-2 N and S2 proteins
N: - S1: + S2: + Procedural Control: ✓	Positive Test for IgG antibodies to SARS-CoV-2 S1 and S2 proteins
N: + S1: + S2: + Procedural Control: ✓	Positive Test for IgG antibodies to SARS-CoV-2N, S1, and S2 proteins
N: - S1: - S2: - Procedural Control: ✓	Negative Test for IgG antibodies to SARS-CoV-2 N, S1, and S2 proteins
N: ✗ S1: ✗ S2: ✗ Procedural Control: ✗	Result Invalid

Sofia 2 External Quality Control

- 1 From the main menu, select Run QC.



- 2 Following the prompt on the screen, scan the QC Card (located on the assay kit box).
- 3 The user will select the desired mode (WALK AWAY or READ NOW) and then run the External Controls.
- 4 Follow the External Quality Control Test Procedure in the Package Insert to test each Control, first the Positive Control followed by the Negative Control.
- 5 After both the Positive and Negative Controls have been run, the results will be displayed as ✓ or ✗.

INTENDED USE

The Sofia 2 SARS-CoV-2 Antibody IgG FIA is a single-use rapid immunochromatographic test for the qualitative detection of Immunoglobulin G (IgG) antibodies to SARS-CoV-2 in fingerstick whole blood, venous whole blood, serum, or plasma (lithium or sodium heparin) samples. The Sofia 2 SARS-CoV-2 Antibody IgG FIA test is intended for use either as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection, or to determine the presence of IgG antibodies post vaccination.

Results from the Sofia 2 SARS-CoV-2 Antibody IgG FIA test should not be used as the sole basis for diagnosis of prior SARS-CoV-2 infection or immune status to the virus.

Results are for the detection of SARS-CoV-2 IgG antibodies. IgG antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although levels over the course of infection are not well characterized. Positive results for IgG antibodies could occur after infection and can be indicative of acute or recent infection. Laboratories are required to report all positive results from non-vaccinated individuals to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Results must be combined with clinical observations, patient history, and epidemiological information. IgG antibodies may not be detected in the first few days of infection; the sensitivity of the Sofia 2 SARS-CoV-2 Antibody IgG FIA test early after infection is unknown.

IgG antibodies to SARS-CoV-2 are generally detectable in blood 10 days after the first vaccination shot. The presence of IgG antibodies after the initial vaccination shot of a two-shot protocol does not indicate immunity to the virus, and the second shot should be administered.

False positive results for IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

At this time, it is unknown for how long IgG antibodies may persist following infection.

The Sofia 2 SARS-CoV-2 Antibody IgG FIA test is intended for use by trained clinical laboratory personnel and individuals proficient in performing the test in patient care settings.

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

ASSISTANCE

If Sofia 2 or the assay does not perform as expected, contact Quidel Technical Support 800.874.1517 (in 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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