QUIDEL

Sofia 2 Flu+SARS Antigen FIA

QUICK REFERENCE INSTRUCTIONS

For use with Sofia 2.
Rx only

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 2 Flu + 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.

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.*

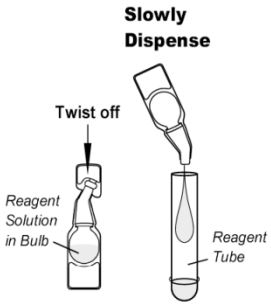
Swab Test Procedure (Nasal/Nasopharyngeal)

1

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

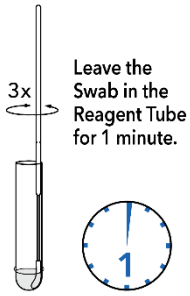
2

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. Leave the Swab in the Reagent Tube for 1 minute.



4

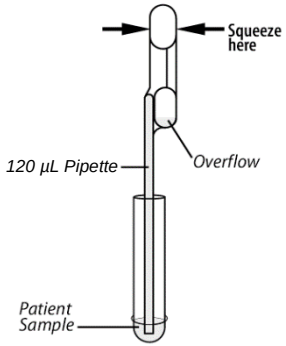
Roll the Swab head against the inside of the Reagent Tube as you remove it. Dispose of the used Swab in your biohazard waste.

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:

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.

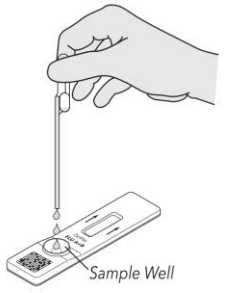


6

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 2" section to complete the test.

Using Sofia 2

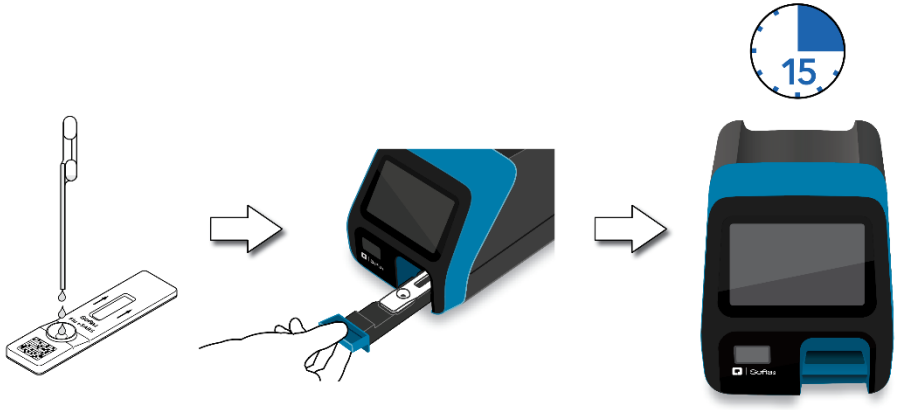
WALK AWAY/READ NOW Modes

***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

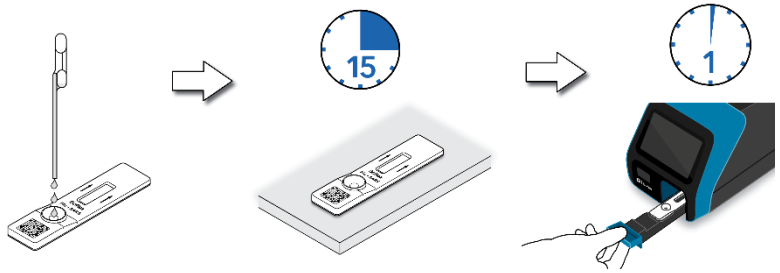
In WALK AWAY Mode, the user **immediately** inserts the Test Cassette into Sofia 2. Results will be displayed at 15 minutes.



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. **Note:** Results will remain stable for an additional 15 minutes after the recommended development time of 15 minutes.



RUN TEST

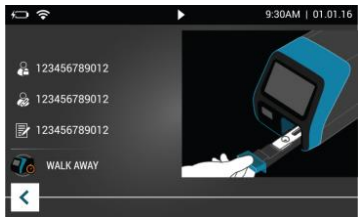
1. Input the User ID with the integrated barcode scanner or manually enter the data using the key pad.

   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.

Serial Testing (SARS)

Repeat testing is needed to improve test accuracy of the SARS test. 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	Day 0 (Test 1)	Day 2 (Test 2)
With Symptoms	COVID-19 (-) Serial testing recommended for COVID Flu A or B (-) Flu A or B result is Negative	COVID-19 (-) COVID result is Negative COVID-19 (+) COVID-19 result is Positive Flu A or B (-) Flu result is Negative Flu A or B (+) Flu result is Positive
	COVID-19 (-) Serial testing recommended for COVID Flu (+) Flu A or B result is Positive	COVID-19 (-) COVID-19 result is Negative COVID-19 (+) COVID-19 result is Positive Flu A or B (-) **Maintain Flu Positive interpretation** Flu A or B (+) Flu A or B result is Positive
	COVID-19 (+) COVID Positive Flu A or B (-) Flu A or B Negative	No serial testing recommended
	COVID-19 (+) COVID Positive Flu A or B (+) Flu A or B Positive	No serial testing recommended

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

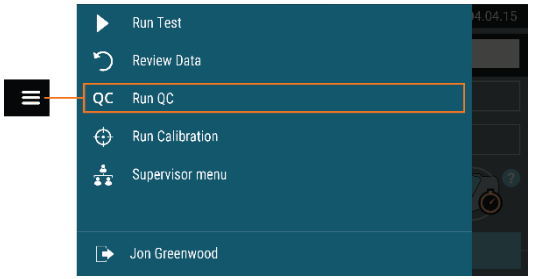
To increase the chance that a negative result for COVID-19 is accurate, you should:

- 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
Flu A: ⊕ Flu B: ⊖ SARS: ⊖ Procedural Control: ✓	Positive Test for Flu A (influenza A antigen present)
Flu A: ⊖ Flu B: ⊕ SARS: ⊖ Procedural Control: ✓	Positive Test for Flu B (influenza B antigen present)
Flu A: ⊖ Flu B: ⊖ SARS: ⊕ Procedural Control: ✓	*Positive Test for SARS (SARS antigen present)
Flu A: ⊕ Flu B: ⊖ SARS: ⊕ Procedural Control: ✓	Positive Test for both Flu A and SARS (influenza A and SARS antigen present)
Flu A: ⊖ Flu B: ⊕ SARS: ⊕ Procedural Control: ✓	Positive Test for both Flu B and SARS (influenza B and SARS antigen present)
Flu A: ⊖ Flu B: ⊖ SARS: ⊖ Procedural Control: ✓	Negative Test for Flu A, Flu B, and **SARS (no antigen detected)
Flu A: Flu B: 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 ✗.

INTENDED USE

The Sofia 2 Flu + SARS Antigen FIA is a lateral flow immunofluorescent sandwich assay that is used with Sofia 2. Sofia 2 Flu + SARS Antigen FIA is intended for the simultaneous qualitative detection and differentiation of nucleocapsid protein antigen from SARS-CoV-2, influenza A, and influenza B directly from nasopharyngeal (NP) and nasal (NS) swab specimens collected from individuals who are suspected of respiratory viral infection consistent with 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. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar. 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 test is intended for use in the simultaneous rapid in vitro detection and differentiation of SARS-CoV-2, influenza A virus, and influenza B virus nucleocapsid protein antigen, but does not differentiate, between SARS-CoV and SARS-CoV-2 viruses and is not intended to detect influenza C antigens. Performance characteristics for influenza A and B were established during February through March 2011 when influenza viruses A/California/7/2009 (2009 H1N1), A/Perth/16/2009 (H3N2), and B/Brisbane/60/2008 (Victoria-Like) were the predominant influenza viruses in circulation according to the Morbidity and Mortality Weekly Report from the CDC entitled “Update: Influenza Activity--United States, 2010-2011 Season, and Composition of the 2011-2012 Influenza Vaccine.” Performance characteristics may vary against other emerging influenza viruses. If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, samples should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing.

SARS-CoV-2, influenza A, and influenza B viral antigens are 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 SARS-CoV-2 results to the appropriate public health authorities.

All negative SARS-CoV-2 results are presumptive and should be confirmed with a molecular assay, if necessary, for patient management. 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 a patient’s recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

All negative influenza A and B test results are presumptive. It is recommended these results be confirmed by an FDA-cleared influenza A and B molecular assay. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions.

The Sofia 2 Flu + SARS Antigen FIA is intended for use on the Sofia 2 only and by medical professionals or trained operators who are proficient in performing tests using the Sofia 2 Instrument. The Sofia 2 Flu + 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.

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 test has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use Authorization for use by authorized laboratories; and 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, influenza A, and influenza B, 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. You may need to purchase additional tests to perform this serial (repeat) testing. Consistent with serial testing recommendations for SARS-CoV-2, for multi-analyte tests, symptomatic individuals who test positive for influenza A or B on the initial test but test negative for SARS-CoV-2 should be tested again in 48 hours to evaluate for co-infection with SARS-CoV-2 infection.

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

ASSISTANCE

If you have any questions regarding the use of this product, please call Quidel's Technical Support Number 800.874.1517 (in the U.S.) or 858.552.1100, Monday through Friday, from 7:00 a.m. to 5:00 p.m., Pacific Time. If outside the U.S., contact your local distributor or technicalsupport@quidel.com. Test system problems may also be reported to the FDA through the MedWatch medical products reporting program (phone: 800.FDA.1088; fax: 800.FDA.0178; http://www.fda.gov/medwatch).

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

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