QUIDEL

Sofia® Influenza A+B FIA

QUICK REFERENCE INSTRUCTIONS

For use with Sofia only.

CLIA Complexity: Waived

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

Test Procedure

Note: The procedures for testing swab samples versus apirate/wash or samples in viral transport media are different. Read carefully.
All clinical samples, including samples in VTM, 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.*

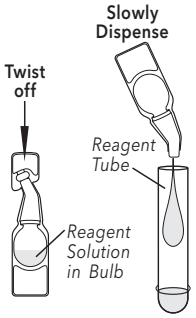
Swab Test Procedure (Nasal/Nasopharyngeal)

1

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

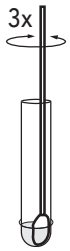
2

Dispense all of the Reagent Solution into the Reagent Tube. **Swirl the Reagent Tube to dissolve its contents.**



3

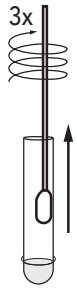
Place the patient swab sample into the Reagent Tube. Roll the Swab at least 3 times while pressing the head against the bottom and side of the Reagent Tube.



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

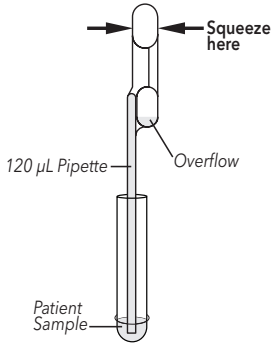
Fill the provided **Small, Clear 120 µL Fixed Volume Pipette** with patient sample from the Reagent Tube.

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 patient sample.

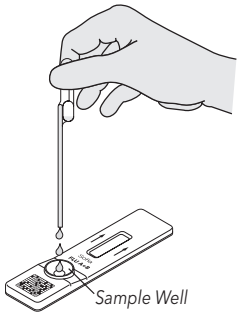
c) With the Pipette tip still in the patient sample, slowly release pressure on bulb to fill the Pipette.



6

Firmly squeeze the top bulb to empty the contents of the **Small, Clear 120 µL Fixed Volume Pipette** into the Cassette sample well. Extra liquid left over in the overflow bulb should be left behind.

NOTE: The Fixed Volume Pipettes are designed to collect and dispense the correct amount of liquid sample. Discard the Pipette in your biohazard waste.



7

Promptly proceed to the next section, "Using Sofia," to complete the test.

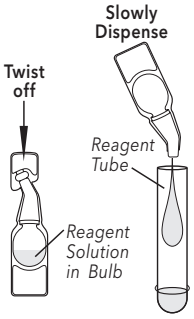
Nasopharyngeal Aspirate/Wash or Samples in Viral Transport Media Test Procedure

1

Verify that Sofia is set to the desired mode: **WALK AWAY** or **READ NOW.** See the "Using Sofia" section for more information. Also ensure that the liquid sample is at **room temperature** before proceeding.

2

Dispense all of the Reagent Solution into the Reagent Tube. **Swirl the Reagent Tube to dissolve its contents.**



3

Fill the provided **Large, Pink 250 µL Fixed Volume Pipette** with patient sample from the collection cup or test tube.

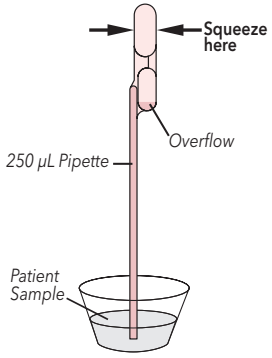
To fill the Fixed Volume Pipette with the sample:

a) FIRMLY squeeze the top bulb.

b) Still squeezing, place the Pipette tip into the patient sample.

c) With the Pipette tip still in the patient sample, slowly release pressure on the bulb to fill the Pipette.

Note: To obtain accurate results, avoid mucoid substances when filling the **Large, Pink Fixed Volume Pipette** with patient sample from the collection cup.

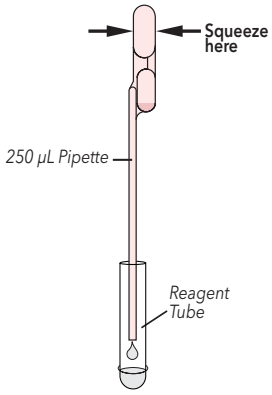


4

Firmly squeeze the top bulb to empty the contents of the **Large, Pink 250 µL Fixed Volume Pipette** into the Reagent Tube. Extra liquid left over in the overflow bulb should be left behind.

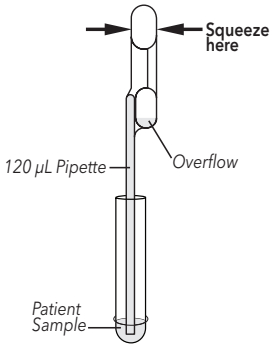
Note: Once the sample is added to the Reagent Tube, vigorously mix prior to adding the sample to the test Cassette.

NOTE: The Fixed Volume Pipettes are designed to collect and dispense the correct amount of liquid sample. Discard the Pipette in your biohazard waste.



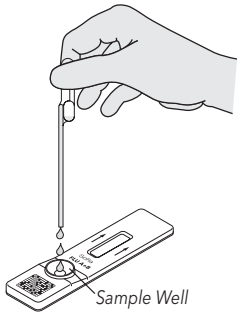
5

Fill the provided **Small, Clear 120 µL Fixed Volume Pipette** with patient sample from the Reagent Tube, by slowly releasing pressure on the bulb.



6

Firmly squeeze the top bulb to empty the contents of the **Small, Clear Fixed Volume Pipette** into the Cassette sample well.
Note: Extra liquid left over in the overflow bulb should be left behind. Discard the Pipette in your biohazard waste.



7

Promptly proceed to the next section, "Using Sofia," to complete the test.

Using Sofia

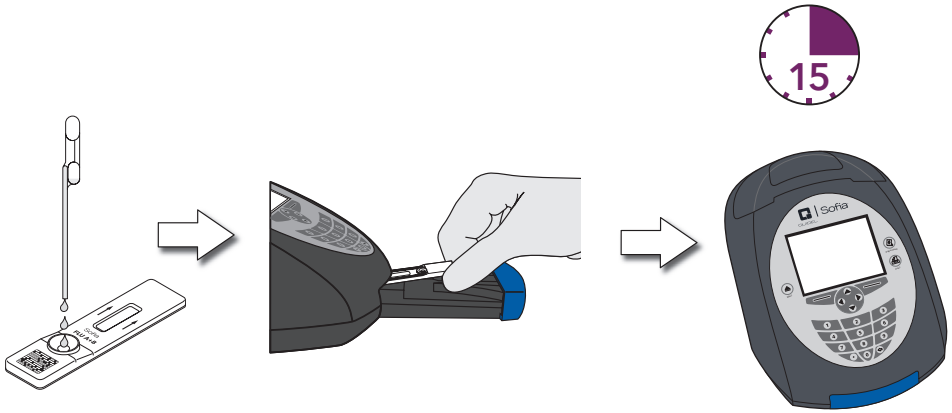
WALK AWAY/READ NOW Modes

Refer to the Sofia User Manual for operating instructions.

Sofia may be set to two different modes (WALK AWAY and READ NOW). The procedures for each mode are described below.

WALK AWAY MODE

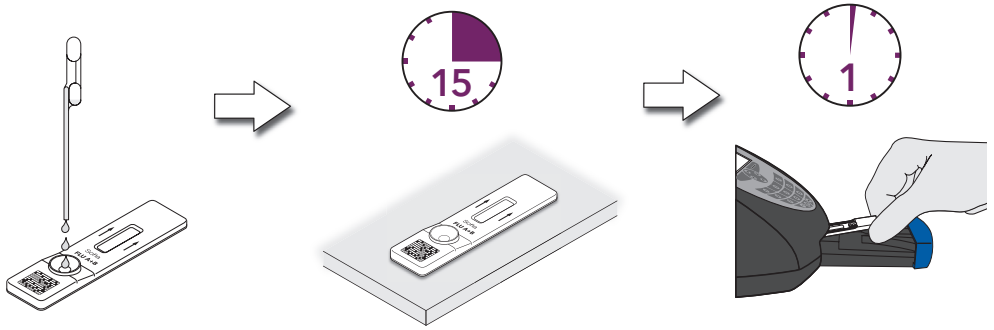
In WALK AWAY Mode, the user **immediately** inserts the Cassette into Sofia. The user then returns after 15 minutes to get the test result. In this mode, Sofia will automatically time the test development before scanning and displaying the test result.



READ NOW MODE

Critically important: Allow the test to develop for the full 15 minutes BEFORE placing it into Sofia.

The user must first place the Cassette onto the counter or bench top for 15 minutes (outside of Sofia) and manually time this development step. Then, the user inserts the Cassette into Sofia. In READ NOW Mode, Sofia 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.

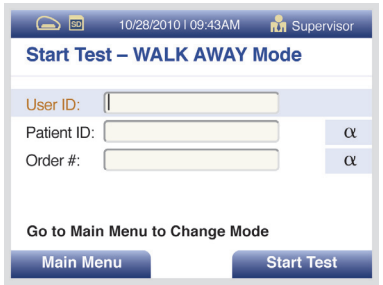


Using Sofia *(cont.)*

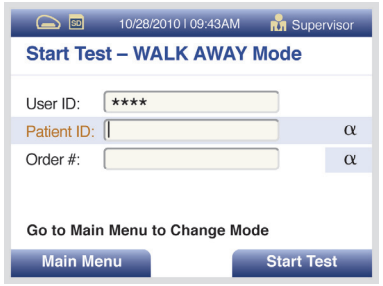
RUN TEST

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

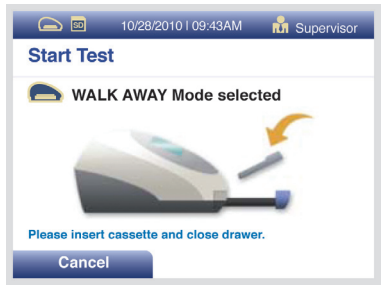
   NOTE: *If you mistakenly scan the incorrect barcode, use the Arrow Buttons on the Sofia key pad to re-highlight the field. Then simply rescan using the correct barcode, and the previous one will be overwritten with the correct barcode.*



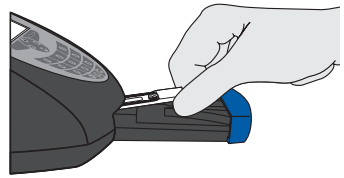
2. Input the Patient ID or Order # using the barcode scanner or manually enter the data using the key pad.



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



4. Verify that the correct development mode, WALK AWAY or READ NOW, has been selected. Insert the prepared patient test Cassette into the drawer of Sofia and close the drawer.



5. Sofia will start automatically and display the progress. In WALK AWAY Mode, the test results will be displayed on the screen in approximately 15 minutes. In READ NOW Mode, the test results will be displayed on the screen within 1 minute. See Interpretation of Results section.

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, which are fluorescent, cannot be seen with the naked eye.

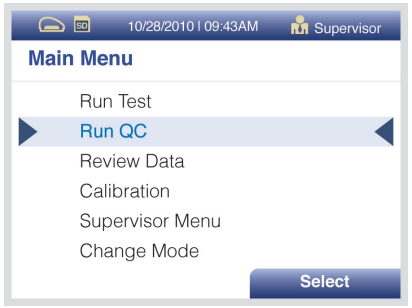
The Sofia screen will display results for the procedural control being "valid or invalid," and will individually provide a positive or negative result for both influenza A and influenza B. If the procedural control is "invalid," retest with a new patient sample and a new Cassette.

Reader Display	Interpretation
Flu A: Positive Flu B: Negative	Positive Test for Flu A (influenza A antigen present)
Flu A: Negative Flu B: Positive	Positive Test for Flu B (influenza B antigen present)
Flu A: Positive Flu B: Positive	Positive Test for both Flu A and Flu B* (influenza A and B antigen present)
Flu A: Negative Flu B: Negative	Negative Test for Flu A and Flu B (no antigen detected)
Flu A: Invalid Flu B: Invalid Procedural Control: Invalid	Result Invalid

*Co-infection with influenza A and B is rare. Sofia Influenza A+B FIA "dual positive" clinical specimens (influenza A and influenza B positive) should be re-tested with a new patient sample and a new test Cassette. Repeatable influenza A and B "dual positive" results should be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay before reporting results.

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

1 From the main menu, select Run QC.



2 Following the prompt on the screen, scan the QC Card (located on the kit box).

3 Sofia will prompt the user to select the desired mode (WALK AWAY or READ NOW) and then to run the External Control Swabs.

4 Follow the Swab Test procedure of this Quick Reference Instructions to test each Control Swab, **first the Positive Control followed by the Negative Control**.

5 After both the Positive and Negative Swabs have been run, the results will be displayed as "Passed" or "Failed."

INTENDED USE

The Sofia Influenza A+B FIA employs immunofluorescence to detect influenza A and influenza B viral nucleoprotein antigens in nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash specimens taken directly from symptomatic patients. This qualitative test is intended for use as an aid in the rapid differential diagnosis of acute influenza A and influenza B viral infections. The test is not intended to detect influenza C antigens. A negative test is presumptive and it is recommended these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative results do not preclude influenza virus infections and should not be used as the sole basis for treatment or other patient management decisions.

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, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture samples.

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

CUSTOMER SERVICE

If Sofia 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

2741ID1014D (10/14)