Collecting Patient Sample

1. Put on appropriate personal protective equipment (PPE) including full gown, gloves, face mask and eye protection.

2. Prepare clean dry transport tubes labeled with unique patient identification.

3. Instruct the patient to blow their nose (to clear out excess mucus).

4. Open the nasal swab provided in the test kit, taking care to hold by the shaft and not to touch the swab tip.

5. Carefully insert the foam swab tip approximately 1” into the nostril. While in the nostril, rotate the swab several times against the nasal wall, then remove it from the nostril.

6. Place each swab tip downwards into individual clean, dry transport tube labeled with unique patient identification. The swabs must be tested within 48 hours.

Preparing Patient Sample

1. Write the patient ID on the glass reagent tube from the test kit to match the patient ID on the dry tube, and place tube in the provided tube holder. Remove gray cap from tube.

2. Pick up the clear bulb (reagent solution) by the narrow tip. Snap your wrist down until all the liquid is in the larger bottom bulb. Twist off the tab from bulb to open it.

3. Dispense all of the liquid from the clear bulb (reagent solution) into the glass reagent tube. Swirl the liquid in the tube to dissolve the dry contents.

4. Remove the swab from the labeled transport tube and place it into the liquid. Gently roll the swab at least 3 times while pressing the foam tip against the bottom and side of the glass reagent tube.

5. Leave the swab for 1 minute in the glass reagent tube. Set timer for 1 minute. This step is very important.

6. Open one test cassette by tearing the foil at the notched mark. Never open test cassettes until just before you are ready to run the tests. To label the cassette, turn the cassette over and write the patient ID on the back of the cassette prior to dispensing the sample into the cassette. Place the cassette on a clean, flat surface.

7. Roll the foam tip against the inside of the glass reagent tube as you remove it (this helps to remove remaining liquid from the swab). Throw away the used swab in biohazard waste.

8. Use the provided clear pipette to draw up the liquid from the glass reagent tube. Do not touch the shaft of the pipette. Hold it only by the top bulb. FIRMLY squeeze the top bulb before you insert the pipette all the way into the liquid to the bottom of the glass reagent tube while still holding the bulb. Once submerged in the liquid, slowly release the bulb so the liquid flows into the pipette. Note: You may see fluid go into the overflow bulb. This is normal. Make sure there are no bubbles in the pipetted sample. Remove the pipette from the tube.

9. Add the liquid from the pipette into the cassette sample well by squeezing the pipette bulb as the pipette is positioned over the sample well.

10. Leave the cassette on the flat surface and set a timer for 15 minutes. This is very important.

11. When your first patient timer is set, you may move onto preparing the second sample. Follow steps 1 through 10 and set the second timer for 15 minutes. When the timers are complete, you are ready to process in the Sofia 2.

Warning: Results must not be interpreted past 30 minutes after completing step 9. Using the Sofia or Sofia 2 past this time may result in false results.
Running the Test Using the Sofia 2

1. Enter the User ID and Patient ID (if applicable) on the Sofia 2. And make sure the unit is in READ NOW mode and press run.

2. Insert the cassette into the drawer with the sample well of the cassette closest to you. Shut the Sofia 2 drawer.

3. The test will begin running and provide a result in less than 1 minute.

4. After the test provides a result, open the Sofia 2 drawer, remove the cassette and discard the cassette in biohazard waste.


The Sofia SARS Antigen FIA and Sofia 2 Flu + SARS Antigen FIA have not been FDA cleared or approved, but have been authorized by the FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories for the detection of proteins from SARS-CoV-2, and influenza, not for any other viruses or pathogens. These assays are 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. § 360bb-3(b)(1), unless authorization is terminated or revoked sooner.