**Test Procedure**

**NOTE:** The procedures for testing Swab specimens versus aspirate/wash or specimens in viral transport media are different. Read carefully.

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.

All specimens must be at room temperature before testing.

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**Nasopharyngeal Swab Test Procedure**

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

2. **Prepare Reagent:**
   - a) Flick or shake the Reagent Solution vial down so that all fluid is in the bulb.
   - b) Twist off the tab.
   - c) Slowly dispense all of the Reagent Solution into the Reagent Tube.
   - d) Gently 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.**

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 \( \mu \text{L} \) Fixed Volume Pipette with patient sample from the Reagent Tube.**
   - 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 \( \mu \text{L} \) 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\( \mu \text{L} \) Fixed Volume Pipette.

7. **Proceed to the “Using Sofia” or “Using Sofia 2” section to complete the test.**
**Liquid Specimens Test Procedure**

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

2. **Prepare Reagent:**
   a) Flick or shake the Reagent Solution vial down so that all fluid is in the bulb.
   b) Twist off the tab.
   c) Slowly dispense all of the Reagent Solution into the Reagent Tube.
   d) Gently 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. 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, release pressure on bulb to fill the Pipette.

   **NOTE:** To obtain accurate results, avoid mucoid substances when filling the Large, Pink 250 µL 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 in the overflow bulb is OK. Gently swirl the Reagent Tube to mix.
   **NOTE:** The Fixed Volume Pipette is designed to collect and dispense the correct amount of patient 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.

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. 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” or “Using Sofia 2” 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. 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

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

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#### RUN TEST

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

   **NOTE:** If you mistakenly 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.

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

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

4. 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.

5. 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.

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**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.

<table>
<thead>
<tr>
<th>Reader Display</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>RSV: Positive</td>
<td>Positive Test for RSV (RSV antigen present)</td>
</tr>
<tr>
<td>Procedural Control: Valid</td>
<td></td>
</tr>
<tr>
<td>RSV: Negative</td>
<td>Negative Test for RSV (no antigen detected)</td>
</tr>
<tr>
<td>Procedural Control: Valid</td>
<td></td>
</tr>
<tr>
<td>RSV: Invalid</td>
<td>Result Invalid</td>
</tr>
<tr>
<td>Procedural Control: Invalid</td>
<td></td>
</tr>
</tbody>
</table>

**Sofia 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 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:** Quidel recommends that Positive and Negative External Controls be run once for each untrained operator, once for each new shipment of kits – provided that each different lot received in the shipment is tested and as deemed additionally necessary by your internal quality control procedures, and in accordance with Local, State and Federal regulations or accreditation requirements.

**NOTE:** The Calibration Check Procedure should be performed every 30 days. To calibrate Sofia, select “Calibration” from the menu and, following the prompts, insert the Calibration Cassette into Sofia and close the drawer. Sofia performs the Calibration Check automatically within two minutes with no user input required.

**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. Sofia 2 scans the Test Cassette periodically during the test development time. Positive test results will be displayed between 3 and 15 minutes. 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. **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 using 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 and simply rescan using the correct barcode. The previous one will be overwritten with the right barcode.

2. Input the Patient ID and Order # (if applicable) using 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 between 3 and 15 minutes. In READ NOW Mode, the test results will be displayed within 1 minute. See Sofia 2 Interpretation of Results section.
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.

<table>
<thead>
<tr>
<th>Reader Display</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>RSV: ☑️</td>
<td>Positive Test for RSV</td>
</tr>
<tr>
<td>Procedural Control: ☑️</td>
<td>(RSV antigen present)</td>
</tr>
<tr>
<td>RSV: ☒️</td>
<td>Negative Test for RSV</td>
</tr>
<tr>
<td>Procedural Control: ☑️</td>
<td>(no antigen detected)</td>
</tr>
<tr>
<td>RSV: ☒️</td>
<td>Result Invalid</td>
</tr>
<tr>
<td>Procedural Control: ☒️</td>
<td></td>
</tr>
</tbody>
</table>

**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).
4. Run the External Control Swabs.
5. Follow the Swab Test procedure of this Quick Reference Instructions. First test the Positive Swab followed by the Negative Swab.
6. After both the Positive and Negative Swabs have been run, the results will be displayed as ☑️ or ☒️.

**NOTE:** Quidel recommends that Positive and Negative External Controls be run once for each untrained operator, once for each new shipment of kits – provided that each different lot received in the shipment is tested and as deemed additionally necessary by your internal quality control procedures, and in accordance with Local, State and Federal regulations or accreditation requirements.

**NOTE:** The Calibration Check Procedure should be performed every 30 days. To calibrate Sofia 2, select “Run Calibration” from the main menu and, following the prompts, insert the Calibration Cassette into Sofia 2 and close the drawer. Sofia 2 performs the Calibration Check automatically within one minute with no user input required.

**INTENDED USE**
The Sofia RSV FIA employs immunofluorescence for detection of respiratory syncytial virus (RSV) nucleoprotein antigen in 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 diagnosis of acute RSV infections in pediatric patients. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or for other management decisions. A negative result is presumptive, and it is recommended these results be confirmed by viral culture or an FDA-cleared RSV molecular assay. The Sofia RSV FIA may be used with Sofia or Sofia 2.

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

**ASSISTANCE**
If Sofia, Sofia 2 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.