# RSV

## I. PRINCIPLE

The Sofia RSV employs immunofluorescence technology that is used with the Sofia analyzer (Sofia) to detect RSV antigens

## II. CLINICAL SIGNIFICANCE

UnityPoint Health Pekin Laboratory personnel will utilize Sofia RSV for the detection of RSV in symptomatic patient from nasal/nasopharyngeal swab.

## III. SPECIMEN

A. Patient ≤ 7 years of age nasopharyngeal swab
B. Patient ≥ 8 years of age will ~~be referred to UPH Methodist~~have a respiratory viral panel (RESPAT) done and sample will be sent to OSF. Refer to Send out procedure "Special Send Out Request" for further instructions.
C. Visibly bloody samples will be rejected.

## IV. REAGENT

A. Quidel Sofia Test Kit
B. **Kit storage and stability:** Store the kit at room temperature, 59°F to 86°F (15°C to 30°C), out of direct sunlight. Kit contents are stable until the expiration date printed on the outer box. Do not freeze.

## V. INSTRUMENTATION/EQUIPMENT

A. Timer
B. Sofia analyzer
C. Calibration Cassette (supplied with Sofia)

## VI. QUALITY CONTROL

***There are three types of Quality Control for Sofia and Cassette: Sofia Calibration Check procedure, built-in procedural control features, and External Controls.***

A. Sofia Calibration Check Procedure

**Note:** This is a "Calibration Check" procedure.

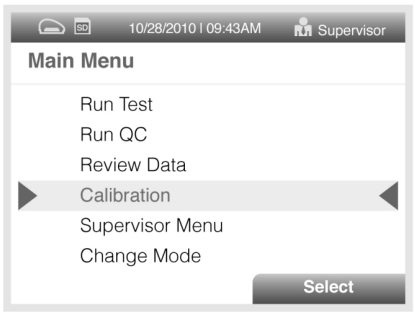
The Calibration Check Procedure is performed every 30 days. Sofia has been set to remind the user to complete the Calibration Check Procedure.

The Calibration Check is a required function that checks Sofia optics and calculation systems using a specific Calibration Cassette.

**Important:** Ensure that the Calibration Cassette is stored in the provided storage pouch between uses to protect from exposure to light.

**QUALITY CONTROL PROCEDURE:**

To check the calibration of Sofia, Select "Calibration" from the Main Menu.




Following the prompts, insert the Calibration Cassette into Sofia and close the drawer. Sofia performs the Calibration Check automatically with no user input required.


Sofia indicates when the Calibration Check is completed. Select **OK** to return to the Main Menu.

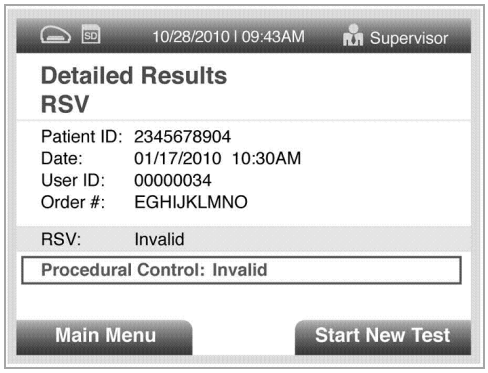
**NOTE:** If the Calibration Check does not pass, notify the on-site Supervisor or contact Quidel Technical Support for assistance from 7:00 a.m. to 5:00 p.m. Pacific Time at 800.874.1517 (in the U.S.); 858.552.1100 (outside the U.S.); Fax: 858.455.4960; custserv@quidel.com (Customer Service); technicalsupport@quidel.com (Technical Support).

B. Built-in Procedural Controls:

The Sofia RSV contains a built-in procedural control feature. Each time a test is run in Sofia, the procedural control zone is scanned by Sofia and the result is displayed on the Sofia screen.

A valid result obtained from the procedural control demonstrates that the test flowed correctly and the functional integrity of the Cassette was maintained. **The**

**procedural control is interpreted by Sofia after the Cassette has developed for 15 minutes. If the test does not flow correctly, the Sofia will indicate that the result is invalid.** Should this occur, review the procedure and repeat the test with a new patient sample and a new test Cassette.




***For example: This result shows that an invalid result had occurred.***

C. External Quality Control

External Controls are used to demonstrate that the reagents and assay procedure perform properly.

The Positive and Negative External Controls are run:

1. at the time of training
2. once for each new shipment of kits and each new lot number
3. Every 30 days
4. Log on Serology Monthly Log Sheet (UPPK SER-0583.01)

To test External Controls, the user must first select Run QC on the Sofia Main Menu. Then, when prompted, scan the QC Card (located on kit box). This card provides information specific to the kit lot, including lot number and expiration date. Sofia will prompt the user to select the desired mode (Walk Away or Read Now) and then to run the External Control swabs.

External Positive and Negative Control swabs are supplied in the kit and should be tested using the Swab Test Procedure provided in this Package Insert or in the Quick Reference Instructions**. The Positive Control test must be run prior to the Negative Control test.** When the QC run is complete, each result will be displayed as “Passed” or “Failed” for the Positive Control and the Negative Control.

Do not perform patient tests or report patient test results if either of the QC test results fail. Repeat the test or contact Quidel Technical Support before testing patient samples.

Additional External Control swabs may be obtained separately by contacting Quidel's Customer Support Services at 800.874.1517 (toll-free in the U.S.) or 858.552.1100.

## VII. TEST PROCEDURE

**All clinical specimens must be at room temperature before beginning the assay.**

**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.*

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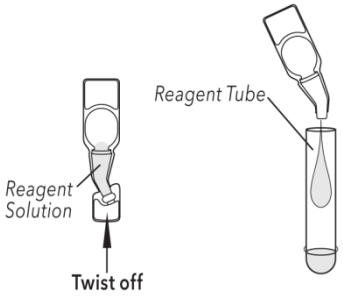
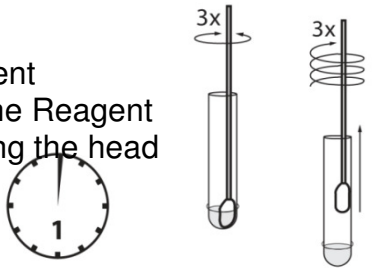
**A.** Swab Test Procedure (Nasal / Nasopharyngeal Swab)




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

1. Dispense all of the Reagent Solution into the Reagent Tube. Gently swirl the Reagent Tube to dissolve its contents.

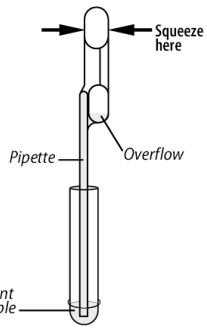



2. Label the reagent tube with the small label from the patient test request label. Place the patient swab sample into the Reagent Tube. Roll the swab at least three (3) times while pressing the head against the bottom and side of the Reagent Tube.

3. **Leave the swab in the Reagent Tube for 1 minute.**

4. Open foil pouch and remove the test cassette. Label with the small sticker from the patient test request label.

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




6. Fill the provided **small, clear** Fixed Volume Pipette with the pati
the Reagent Tube.

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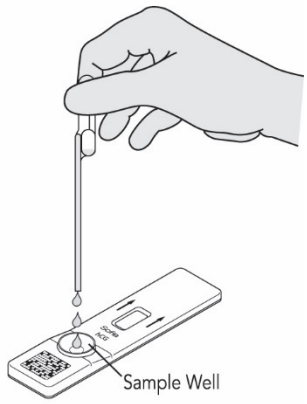
**To fill the Fixed Volume Pipette with the patient sample:**

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, release pressure on bulb to fill the Pipette.




7. Firmly squeeze the top bulb to empty the contents of the Fixed Volume Pipette into the 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 liquid sample. Discard the pipette in your biohazard waste.

8. Proceed to the next section, "Using Sofia," to complete the test.

## VII. 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

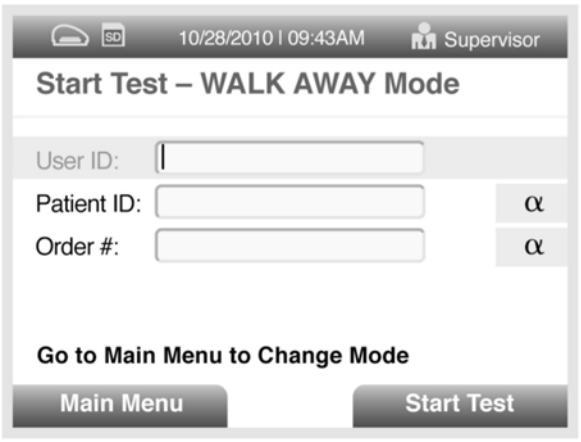
In WALK AWAY Mode, the user **immediately** inserts the Cassette into Sofia. The user then returns after 15 minutes to get the test result. In this mode, Sofia will automatically time the test development before scanning and displaying the test result.

### READ NOW Mode

**Allow the test to develop for the full 15 minutes BEFORE placing it into Sofia.**

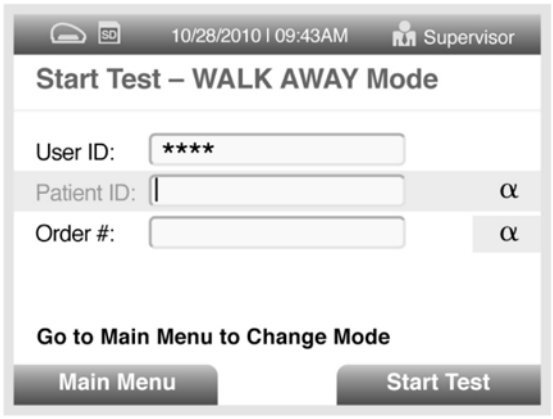
A. Run Test
   1. Input the User ID using the barcode scanner or manually enter the data using the key pad.

      ***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.*



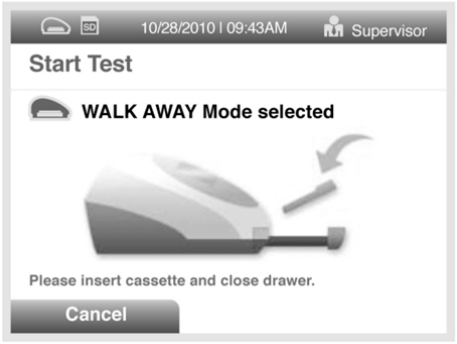


2. *Input the Patient ID or Order # using the barco*de scanner or manually enter the data using the key pad.



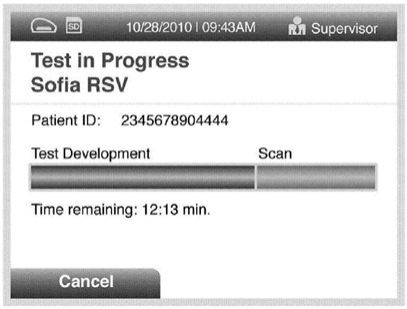


*3.* Press Start Test and Sofia drawer will automatically open



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, as shown in the example below. 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.



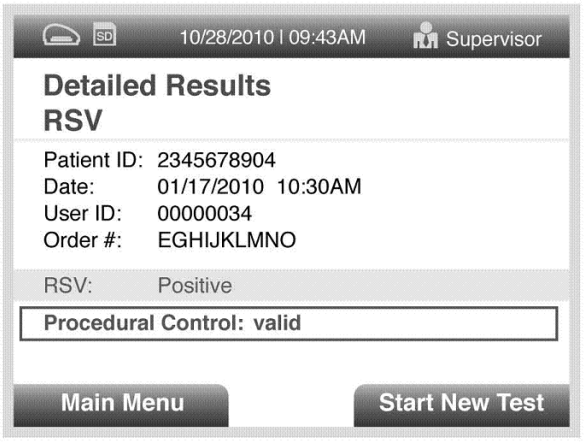

***For example: This display shows that the test in WALK AWAY mode has 12 minutes, 13 seconds remaining. Sofia will read and display the results after 15 minutes.***

## VIII. INTERPRETATION OF RESULTS:

A. 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.

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

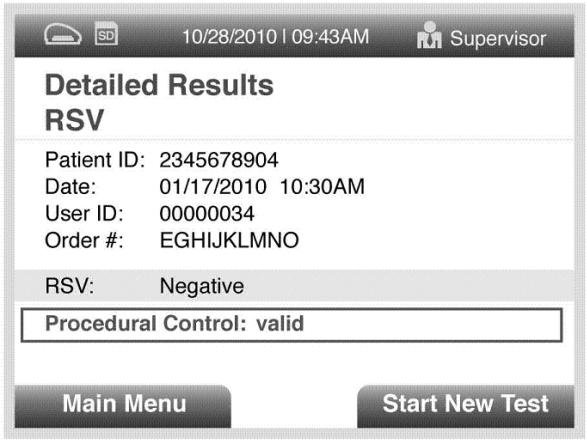
**1. Positive Results:**




***For example: This display shows a valid positive result for RSV.***

**NOTE:** A positive result does not rule out co-infections with other pathogens.

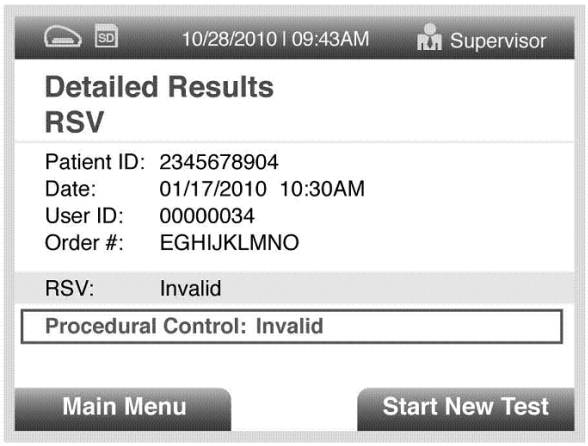
## 2. Negative Results:




***For example: This display shows a valid negative result for RSV.***

**NOTE:** A negative result does not exclude RSV viral infection. Negative results should be confirmed by viral culture.

## 3. Invalid Results:




***For example: This display shows an invalid result.***

**Invalid Result:** If the test is invalid, a new test should

be performed with a new patient sample and a new Cassette.

4. Enter patients' and control results (positive or negative) on Serology Patient Worksheet (UPPK SER-0583.02) and result in computer.

## IX. LIMITATIONS:

A. This test is waived for the pediatric population (less than 7 years of age only).
B. The contents of this kit are to be used for the qualitative detection of RSV antigen from nasopharyngeal swab and nasopharyngeal aspirate/wash samples.
C. This test detects both viable (live) and non-viable RSV. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
D. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
E. Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
F. Test results must be evaluated in conjunction with other clinical data available to the physician.
G. Positive test results do not rule out co-infections with other pathogens.
H. Negative test results are not intended to rule in other non-RSV viral or bacterial infections.
I. Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods of low RSV activity when prevalence is moderate to low.
J. Monoclonal antibodies may fail to detect, or detect with less sensitivity, RSV viruses that have undergone minor amino acid changes in the target epitope region.
K. Samples contaminated with whole blood >1% may interfere in the interpretation of the test. Visually bloody samples should not be used.
L. Mycoplasma pneumoniae at levels greater than $1x10^5$ cfu/mL may cross-react or interfere with the performance of the test.
M. The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection.

## X. EXPE CTED VALUES:

A. The rate of positivity observed in RSV testing will vary depending on the method of specimen collection, handling/transport system employed, detection method utilized, time of year, age of the patient, and disease prevalence. The prevalence observed with culture during the clinical study was 12% (211/1755).

## XI. REFERENCE:

A. Quidel Corporation, 10165 McKellar Court, San Diego, CA 92121, Manufacturer Sofia RSV instructions. 09/14

| ***POLICY CREATION :*** | | ***Date*** |
|---|---|---|
| ***Author:*** | ***Gretchen Norton, MT (ASCP)*** | ***05/18/16*** |
| ***Medical Director:*** | ***Kathryn Kramer, MD*** | ***05/18/16*** |

| ***MEDICAL DIRECTOR*** | | |
|---|---|---|
| DATE | NAME | SIGNATURE |
| January 10, 2019 | Lori Racsa, DO | L Racsa DO. |
| | | |

| **REVISION HISTORY (began tracking 2011)** | | | |
|---|---|---|---|
| Rev | Description of Change | Author | Effective Date |
| 1 | Updated referral location and referenced special send out request procedure | A. Guppy | 1/8/19 |
| | | | |
| | | | |

**Reviewed by**

| Lead | Date | Coordinator/ Manager | Date | Medical Director | Date |
|---|---|---|---|---|---|
| A. Guppy | 1/8/19 | | | L Racsa DO. | 1/10/19 |
| | | | | | |