Sutter Health Sacramento Sierra Region
We Plus You

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| **Owner:** | *Mary Cabral: Mgr, Laboratory* |
| **Policy Area:** | *Lab - Serology* |
| **References:** | *Non-Analytic* |
| **Applicability:** | *Sac Sierra Region* |

# Running and Evaluating Controls on the Quidel Sofia Analyzer, IM.NON02.01-/-SS.xx



**Background**

This procedure describes how to run and evaluate quality control specimens on the Quidel Sofia analyzer.

Three types of quality checks are performed.

- Calibration check procedure: Refer to *Performing the Calibration Check on the Quidel Sofia Analyzer*
- External controls: Positive and negative external control swabs are provided in each test kit.
- Procedural (internal) controls: These are built into each Sofia FIA assay cassette and will run each time a sample is tested. The procedural control is interpreted by the analyzer and must be valid in order to report patient test results.

The CLIA complexity of the test method determines the required frequency of external control testing and will be defined by each site.

| Test | If | Then CLIA Complexity |
|---|---|---|
| Influenza A+B FIA | Used according to package insert instructions.<br>AND<br>Sample= direct nasal swab, nasopharyngeal (NP) swab, and NP aspirate/wash specimens. | Waived |
| Influenza A+B FIA | Used according to package insert instructions.<br>AND<br>Sample= specimens eluted in transport media. | Moderate |
| RSV FIA | Used according to package insert instructions.<br>AND<br>Samples are from patients <7years old | Waived |
| Strep A+ | Used according to package insert instructions. | Waived |

**Policy**

Patient test results will not be reported if procedural or external control results are not acceptable or calibration check is not successful.

Procedural and external controls will be performed and documented for each Sofia analyzer separately if more

than one analyzer is available at a site

The CLIA complexity of the test method determines the required frequency of external control testing.

- Waived:
  - Once for each new shipment of kits and/or lot number.
  - Once for each new operator during initial training.
- Moderate:
  - Once for each new shipment of kits and/or lot number.
  - Once for each new operator during initial training.
  - At least every 31 days.
  - Lot crossover testing for each new reagent lot number using at least one negative and one positive sample of known reactivity is required. Acceptable material include:
    - Positive and negative patient samples tested on a previous reagent lot.
    - Previously tested proficiency testing samples (after survey submission date has passed.)
    - External QC samples tested a previous lot.

**Equipment/Reagents/Supplies**

Quidel Sofia analyzer

Timer

Quidel Sofia FIA kit (refer to individual procedures for further information.)

Fixed volume transfer pipettes (included in kit)

Printer paper



**Preparing External Control Samples – Influenza A+B and RSV FIA tests**

| Step | Action |
|---|---|
| 1. | Label reagent tubes for positive and negative QC. Place in rack or holder. |
| 2. | Prepare reagent:<br>• Flick or shake the reagent solution vial down to that all the fluid is in the bulb.<br>• Twist off the vial tab.<br>• Slowly dispense all of the reagent solution into the reagent tube.<br>• Gently swirl the reagent tube to dissolve its contents. |
| 3. | Place the appropriate control swab into the corresponding labeled reagent tube.<br>• Roll the swab at least 3 times while pressing the swab head against the bottom and side of the reagent tube. |
| 4. | **Leave the swab in the reagent tube for 1 minute.** |
| 5. | Roll the swab head against the inside of the reagent tube as it is removed. Discard the swab in a biohazard waste container.<br>**Note**: After extraction, the tube may be recapped and left at room temperature without loss of activity before testing for up to 4 hours for RSV and up to 12 hours for Influenza A+B. |
| 6. | Remove test cassette from pouch and place control ID on cassette.<br>Do not open the foil pouch containing the cassette until ready for immediate use. |
| 7.. | Fill the provided small, clear 120 µL fixed volume pipette with the control sample from the |

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| | reagent tube. |
| 8. | Empty the contents of the pipette into the cassette well by firmly squeezing the top bulb.<br>• Extra fluid in the overflow bulb should be left behind.<br>• Discard the pipette in a biohazard waste container. |

**Preparing External Control Samples – Strep A+ test**

| Step | Action |
|---|---|
| 1. | Label reagent tubes for positive and negative QC. Place in rack or holder. |
| 2. | Squeeze once to break glass ampule inside the reagent solution bottle.<br>• If the solution color is green before breaking the ampule, do not use the reagent solution. |
| 3. | Vigorously shake the reagent solution bottle 5 times to mix the solutions.<br>• The solution should turn green.<br>• If color does not turn green, do not use the reagent solution for testing. |
| 4. | Flick or shake the reagent solution bottle so that all the fluid is in the bottom. |
| 5. | Twist off tab and slowly dispense the reagent solution into the reagent tube **up to the fill line**. Do not overfill the reagent tube. |
| 6. | Add the control swab into corresponding labeled reagent tube.<br>• Vigorously mix the solution by plunging the swab 5 times up and down. |
| 7. | **Leave the swab in the reagent tube for 1 minute.** |
| 8. | Vigorously mix the solution by plunging the swab 5 times up and down again. |
| 9. | Express as much liquid as possible by squeezing the sides of the tube while withdrawing the swab in a complete twisting motion. Discard the swab in a biohazard waste container. |
| 10. | Remove test cassette from pouch and place control ID on cassette.<br>Do not open the foil pouch containing the cassette until ready for immediate use. |
| 11. | Fill the provided small, clear 120 µL fixed volume pipette with the control sample from the reagent tube. |
| 12. | Empty the contents of the pipette into the cassette well by firmly squeezing the top bulb. Discard the pipette in a biohazard waste container.<br>• Extra fluid in the overflow bulb should be left behind. |

**Running External Controls**

| Step | Action |
|---|---|
| 1. | On the Main menu display of the Sofia analyzer, select Run QC. |
| 2. | Enter the user ID by using the barcode scanner to scan the employee ID badge or enter manually using keypad then press OK. |
| 3. | When prompted, scan the QC card (located on the kit box) using the barcode scanner. This card provides information specific to the kit lot, including lot number and expiration date. |
| 4. | Select the desired mode (WALK AWAY or READ NOW.) |

<table>
<tr><td>5.</td><td>Proceed to the next step based on the mode selected.<ul><li>Refer to specific test procedures for development times.</li><li>The positive control test must be run prior to the negative control test, as prompted on the Sofia analyzer.</li></ul>
<table>
<tr><th>IF</th><th>THEN</th></tr>
<tr><td>WALK AWAY mode</td><td>Immediately insert the cassette into the analyzer. The analyzer will automatically time the test development before scanning and displaying the test results.</td></tr>
<tr><td>READ NOW mode</td><td>Leave the cassette on the bench top and manually time the development. All the test to develop for the FULL development time before placing it into the Sofia for scanning and resulting.</td></tr>
</table></td></tr>
<tr><td>6.</td><td>When complete, evaluate the results of each external control.</td></tr>
</table>

**Evaluating Control Results**

| If ... | Then ... |
|---|---|
| Procedural control result is valid and external control results PASS | • Record QC results on the appropriate test kit QC log<br>• Proceed to patient testing |
| Procedural control is valid and external control results FAIL | • Record QC results on the appropriate test kit QC log<br>• Do not perform patient testing<br>• Repeat external controls with new controls.<br>• If controls continue to fail, notify supervisor and/or contact Quidel Technical Support at 800 874-1517. |
| Procedural control is invalid and external control results invalid | • Record QC results on the appropriate test kit QC log<br>• Do not perform patient testing<br>• Repeat external controls with new controls.<br>• If controls continue to fail, notify supervisor and/or contact Quidel Technical Support at 800 874-1517. |
| Lot crossover samples have the same results on the new reagent lot as on a previous reagent lot (moderate complexity Sofia Influenza A+B FIA only) | • Record QC results on the test kit QC log.<br>• Proceed to patient testing |
| Lot crossover samples have different results on the new reagent lot than on the previous reagent lot (moderate complexity Sofia Influenza A+B FIA only) | • Record QC results on the test kit QC log.<br>• Do not perform patient testing.<br>• Repeat crossover testing. |

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| | • If lot crossover results are still unacceptable, notify supervisor and/or contact Quidel Technical Support at 800 874-1517. |

**Procedural Notes**

If only a single control fails, the use has the option of repeating both the positive and negative controls OR to repeat only the control that failed. The user may select "Skip" on the Sofia display in order to skip the control test that previously passed. The QC results will show a skipped control test as "unknown."

Each Sofia FIA test kit includes one set of external controls. Additional external control swabs may be obtained separately from Quidel.

Contact Quidel Technical Support at 800-874-1517 if a replacement QC card is needed.

**Related Documents**

*Operating the Quidel Sofia Analyzer*

*Performing Calibration Check on the Quidel Sofia Analyzer*

*Performing the Quidel Sofia Influenza A+B Patient Test*

*Performing the Quidel Sofia RSV Patient Test*

**References**

Quidel Sofia analyzer user manual

Quidel Sofia Influenza A+B FIA package insert

Quidel Sofia Influenza RSV FIA package insert

Quidel Sofia Strep A+ FIA package insert



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## Attachments:

No Attachments

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Lab Directors/Managers | Steven Stern: Mgr, Laboratory | 9/5/2017 |
| Lab Directors/Managers | Pamela Hill: Dir, Laboratory | 8/29/2017 |
| Lab Directors/Managers | Trudy Fidler: Dir, Lab | 8/28/2017 |
| Lab Directors/Managers | Mary Cabral: Mgr, Laboratory | 8/24/2017 |
| Lab Directors/Managers | Stephen Medland: Mgr, Clinical Lab | 8/23/2017 |
| Lab Directors/Managers | Dixie Matson: Dir, VA Fndtion Lab Operations | 8/22/2017 |
| Lab Directors/Managers | Cyndee Jones: Mgr, Lab | 8/21/2017 |

| Step Description | Approver | Date |
|---|---|---|
| Lab Medical Directors | Rowberry Ron: MD | 8/21/2017 |
| Lab Medical Directors | Hannah Wong: MD | 8/21/2017 |
| Lab Medical Directors | Marian Butcher: MD | 8/17/2017 |
| Lab Medical Directors | Andrea Ong: MD | 8/16/2017 |
| Lab Medical Directors | Kristen Vandewalker: MD | 8/15/2017 |
| Lab Medical Directors | Mary Keohane: MD | 8/15/2017 |
| Lab Medical Directors | Jamie Cassity: MD | 8/15/2017 |
| | Mary Cabral: Mgr, Laboratory | 8/15/2017 |