QUIDEL® SOFIA® SARS ANTIGEN FLUORESCENT IMMUNOASSAY (FIA) AND QUIDEL® SOFIA2® FLU + SARS ANTIGEN FIA HELPFUL TESTING TIPS

Sofia® & Sofia®2

This document is a supplement to the manufacturer's instructions and is intended to provide helpful testing tips when using the Quidel® Sofia® Antigen Immunoassays. This document has been developed specifically for the Quidel® Sofia® point-of-care (POC) tests. To ensure accurate performance of these tests, please refer to the package insert or Instructions for Use. Additional instructions can be found at www.fda.gov/media/137885/download.

For information on the Quidel® Sofia® POC tests, please view the manufacturer's website at www.quidel.com.*

* Use of trade names and commercial sources is for identification only and does not imply endorsement by the Centers for Disease Control and Prevention, the Public Health Service, or the U.S. Department of Health and Human Services.

Before the Test

Acceptable specimens include nasal swabs and nasopharyngeal swabs. Nasal swab specimens can only be collected with the nasal swab supplied with the kit. Nasopharyngeal swab specimens can be collected with the nasopharyngeal swabs supplied with the kit or a nylon flocked nasopharyngeal swab. Specimens should be tested as soon as possible and must be tested within 48 hours after collection.

If a specimen is not tested immediately, the nasal or nasopharyngeal swabs can be stored for up to 48 hours at room temperature (15–30 °C or 59–86°F) or 2°–8°C (35.6–46.4°F) in a clean, dry transport tube. All specimens must be at room temperature before beginning the assay.

Label specimens correctly to avoid recordkeeping issues.

Perform instrument calibration check every 30 days.

Transport specimens carefully from the collection area to the testing area. Time from sample collection to testing should be minimized, and the temperature of the specimen during this time must be controlled.

Do not use:

- Viral transport media or buffers. Only dry swab specimens are to be used in these assays.
- Expired reagents
- Damaged test cassettes

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.**

Do not remove the test cassette from foil pouch until ready to dispense the specimen. Exposing the cassette to room temperature before this time may compromise test performance.

Be sure that 'Transmit Patient ID' and 'Transmit Order Number' are set to the 'OFF' position in the Virena settings menu.

If USB data storage is being used, ensure 'Save Patient Data to USB' in the Sofia settings is set to ON, and connect the USB storage device to the instrument BEFORE performing the tests. Tests results cannot be retroactively saved to a USB device.

Always test in an environment within the temperature and humidity specifications in the analyzer User Manual.

During the Test

Gloves should be changed before collecting, handling, and processing a new specimen. Discard used gloves in a biohazardous waste container. If handling multiple specimens (batch testing), change gloves after collecting specimen and placing the swab in sample tube for each individual. It is not necessary to change gloves between pipetting steps for multiple cassettes when batch testing.

Closely monitor 1-minute swab processing in Reagent Tube using a timer, as directed in the manufacturer's instructions.

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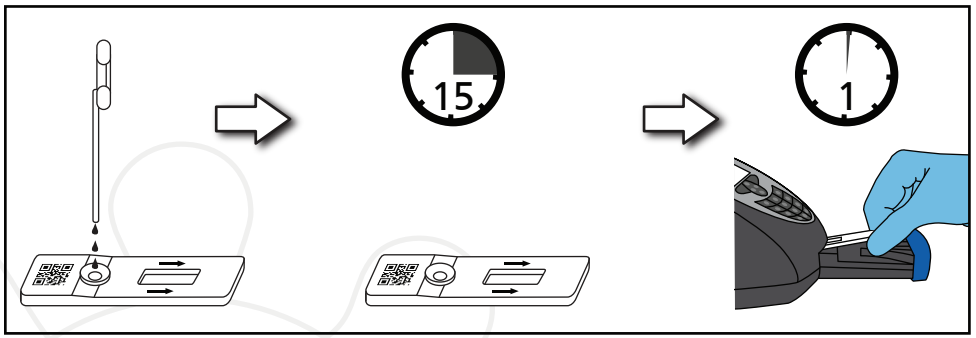

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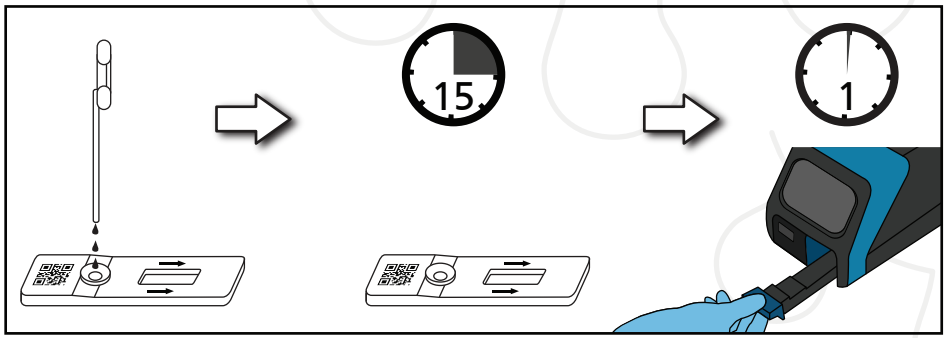

Add the correct amount of specimen to the test device as indicated on the pipette. Incorrect pipette technique such as bubbles in the pipette may lead to insufficient specimen volume.

Keep the cassette on a flat surface at all times after the specimen has been added.

Check to ensure the instrument is in the correct mode (i.e., READ NOW mode). When operating the analyzer in READ NOW mode, allow the test to develop for the full 15 minutes prior to placing the cassette into the analyzer. Results are displayed within 1 minute of cassette insertion into the instrument.

When operating the analyzer in WALK AWAY mode, the user should place the cassette in the instrument immediately after the specimen has been dispensed. Results are displayed within 15 minutes.

In all cases, do not test the cassette if more than 30 minutes have passed after specimen has been added.

When processing many specimens for batch testing, users should closely monitor incubation times for individual test cassettes. Take extra care to remove cassettes from the foil puch only when ready to use.

After the Test

To avoid cross contamination, CDC recommends decontamination of the instrument and workspace between specimen processing. If handling multiple specimens, cleaning and disinfection may be performed after batch testing has been completed. Follow the manufacturer's recommendations for using an approved disinfectant, including proper dilution, contact time, and safe handling.

Multiple sequential specimens with unexpected results inconsistent with clinical indications may indicate errors have occurred and the individuals should be retested. Disinfect the area, change gloves, rerun controls, and then retest those specimens.

Contact Technical Support should you note an increase in the number of invalid or positive results that are inconsistent with clinical indications.