

Guidelines for Using Point-of-Care SARS-CoV-2 Antigen Tests in Long-Term Care Facilities

Background

In August 2020, the Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC) began distributing point-of-care (POC) antigen testing machines directly to some long-term care facilities (LTCFs) in Utah to test for the SARS-CoV-2 virus. This guidance addresses questions on safe and appropriate use of the tests, understanding results, and reporting requirements to the Utah Department of Health (UDOH).

What is an antigen test and how does it differ from the PCR test?

The antigen test detects an antigen on the surface of the SARS-CoV-2 virus while the PCR test detects viral RNA. The POC antigen tests distributed by CMS/CDC are less sensitive than PCR for detecting COVID-19 infections. Therefore, false negative results can occur. Specificity, however, for the antigen test is >99%, so false positive results are unlikely.

What are the available tests and the CLIA requirements for using the test?

The Food and Drug Administration (FDA) has granted Emergency Use Authorization (EUA) for two POC antigen tests: 1) Quidel Sofia SARS Antigen FIA, and 2) Becton Dickinson (BD) Veritor System. The instructions provided in this document are for the Quidel Sofia 2 machine. These tests may be performed in facilities with a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver. Most facilities have obtained this certificate. For those that have not, instructions and an application for the certificate of waiver can be found at <https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/howobtaincertificateofwaiver.pdf>.

Under a CLIA waiver, diagnostic testing of patients who are symptomatic or suspected of having COVID-19 due to an exposure

Healthcare workers (HCWs) who are exposed to COVID-19 and could put patients at risk may also be tested under the CLIA waiver. However, the tests are not validated for screening of all patients and HCWs in a facility. This should be done by scheduling a point prevalence survey with the UDOH Healthcare-Associated Infections (HAI) team (email: HAI@utah.gov).

When to use the antigen test and interpreting results

The POC antigen test is most useful for testing a symptomatic patient or HCW. Since test results can be returned in as little as 15 minutes, a positive result can be used by the facility to quickly decide the type of care necessary for the patient or HCW to prevent transmission to others in the facility. If a patient or HCW is known to have been exposed to a positive COVID-19 case, then s/he may be tested to determine

if transmission occurred. However, false negatives may occur, so negative tests need to be followed up with a standard PCR test. When there is concern of a possible outbreak in the facility, contact the UDOH HAI team (email: HAI@utah.gov) for assistance with further testing. **Do not attempt to use the antigen test to screen all asymptomatic HCWs and patients in the facility since the test is not validated for this purpose.**

How to report a positive result to the Utah Department of Health

All tests performed for COVID-19 reportable to the UDOH within 24 hours of test performance (<http://health.utah.gov/epi/reporting/>). Please email notifications of new positive cases to edx@utah.gov. A UDOH person will work with the facility to assist with on-boarding for electronic case reporting.

- All test results (positive, negative, equivocal, indeterminate) for all test types (PCR, antigen, serology) are reportable.
- Test results must be reported within 24 hours of test finalization.
- Test results must be reported to UDOH for all persons who live in Utah or whose specimen was collected by a Utah facility.

How to collect a specimen safely

The antigen test does not require a nasopharyngeal (NP) specimen, although this can be used. The specimen collection kit accompanying the test contains a nasal swab for the anterior nares or mid-turbinate collection. For the anterior nares and mid-turbinate collection, the HCW should be wearing, at minimum, a surgical mask, face shield, gown and gloves. A fit-tested N-95 or PAPR is not needed since this procedure should not result in the patient coughing or sneezing; however, if this equipment is available, it can be used for extra protection of the specimen collector.

- Insert the swab in both nares to increase sensitivity. Using the dry swab without transport media is the preferred method since transport media requires extra steps for test processing and may lower the sensitivity of the test due to dilution.

NOTE: Assuming that most facilities will be conducting testing to obtain rapid results for their residents and HCWs, transport media should not be needed. If for some reason, transporting of specimens is necessary, specific transport media must be used and additional processing steps are required that are not addressed in this document.

- Insert the dry swab directly into the Reagent Tube which contains the Reagent Solution (see Preparing the reagent tube and specimen for testing).

What is supplied in the Sophia-2 kit?

- **Reagents and materials supplied**
 - Individually Packaged Test Cassettes (25): Monoclonal anti-SARS antibodies
 - Reagent Tubes (25): Lyophilized buffer with detergents and reducing agents
 - Reagent Solution (25): Ampoules with salt solution
 - Sterile Nasal Swabs (25)
 - Small, Clear 120 µL Fixed Volume Pipettes

- SARS Positive Control Swab
- Negative Control Swab
- QC Card (located on kit box)
- **Materials not supplied (except for the timer or watch and Calibration Cassette, these materials are not needed as long as specimens are not transported)**
 - Timer or watch
 - Vortex
 - 1.0-mL Calibrated Micropipette with Pipette Tips
 - Polyester Wound Swab or Nylon Flocked Nasopharyngeal Swab
 - Copan UTM or CDC VTM
 - Calibration Cassette

Quality control procedures

Perform quality control procedures before beginning testing.

- **Calibration check (should be performed every 30 days)**
 - Perform the calibration check procedure every 30 days.
 - To check the calibration of Sofia 2, select “Run Calibration” on the Main Menu.
 - Following the prompts, insert the Calibration Cassette into Sofia 2 and close the drawer. Sofia 2 performs the calibration check automatically within 1 minute with no user input required.
 - Sofia 2 indicates when the calibration check is completed. Select  to return to the “Run Test” screen.

NOTE: If the calibration check does not pass, notify the on-site Supervisor or contact Quidel Technical Support for assistance Monday through Friday from 7:00 a.m. to 5:00 p.m. Pacific Time; PH: 800-874-1517 (U.S.); Fax: 858-455-4960; Email: customerservice@quidel.com (Customer Service) or technicalsupport@quidel.com (Technical Support); or contact your local distributor.

- **Built-in procedural controls**
 - The Sofia SARS Antigen FIA contains a built-in procedural control feature. Each time a test is run on Sofia 2, the procedural control zone is scanned by the Sofia 2 and the result is displayed on the screen.
 - A valid result obtained from the procedural control demonstrates that the test flowed correctly and the functional integrity of the Test Cassette was maintained.
 - The procedural control is interpreted by Sofia 2 after the Test Cassette has developed for 15 minutes. If the test does not flow correctly, Sofia 2 will indicate the result is invalid. Should this occur, review the procedure and repeat the test with a new patient sample and a new Test Cassette.
- **External quality control**
 - Quidel recommends that Positive and Negative External Controls be run once for each new shipment of kits—provided that each different lot received in the shipment is tested.

- The user must first select “Run QC” on the Main Menu of Sofia 2 and 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.
- Select the desired mode (**WALK AWAY** or **READ NOW**), then 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 the package insert or in the Quick Reference Instructions. The SARS Positive Control Swab contains SARS antigen. **The Positive Control Swab must be run first, followed by the Negative Control Swab.**
 - When the QC run is complete, each result will be displayed as  or  on Sofia 2, for the Positive 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.

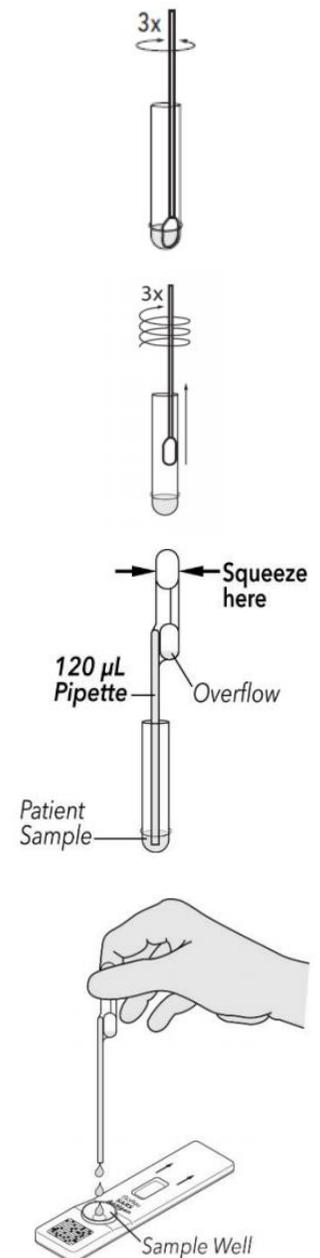
Preparing the reagent tube and specimen for testing

Swab test procedure for nasal swab

- Verify that the Sofia 2 is set to the desired mode: **WALK AWAY** or **READ NOW**. See “Using Sofia 2” for more information.
- Dispense all of the Reagent Solution into the Reagent Tube. **Swirl the Reagent Tube to dissolve its contents.**
- Place the patient swab directly into the Reagent Tube. Roll the swab at least 3 times while pressing the head against the bottom and side of the Reagent Tube.
- **Leave the swab in the Reagent Tube for 1 minute.** 
- Roll the swab head against the inside of the Reagent Tube as you remove it. Dispose of the used swab in your biohazard waste.
- Fill the provided **Small, Clear 120 µL Fixed Volume Pipette** with the patient sample from the Reagent Tube.

To fill the Fixed Volume Pipette with the patient sample:

- FIRMLY squeeze the top bulb.
 - Still squeezing, place the Pipette Tip into the patient sample.
 - With the Pipette Tip still in the patient sample, slowly release pressure on the bulb to fill the Pipette.
- 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 left over in the overflow bulb should be left behind.



NOTE: The Fixed Volume Pipettes are designed to collect and dispense the correct amount of liquid sample. Discard the Pipette in your biohazard waste.

Do not pour sample from the Reagent Tube. Use the provided Small, Clear 120 µL Fixed Volume Pipette.

- Promptly proceed to the next section, “Using Sofia 2,” to complete the test.

Using Sofia 2

WALK AWAY Mode

- In WALK AWAY Mode, the user **immediately** inserts the Test Cassette into Sofia 2. The Sofia 2 scans the Test Cassette periodically during the test development time. Positive and negative test results will be displayed in 15 minutes.

READ NOW Mode

Critically Important: Allow the test to develop for the FULL 15 minutes BEFORE placing it into Sofia 2.

- The user must first place the Test Cassette onto the counter or bench top for 15 minutes (outside of Sofia 2) and manually time this development step. Then, insert the Test Cassette into Sofia 2. In READ NOW Mode, Sofia 2 will scan and display the test result within 1 minute.
- **WARNING: Results must not be interpreted past 30 minutes after inoculation. Using the Sofia 2 past this time may result in false results.**

Running the Test with Sofia 2

- Input the User ID (1234) using the integrated barcode scanner or manually enter the data using the on-screen keypad.

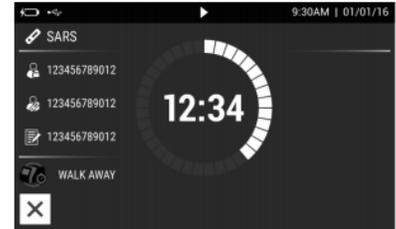


NOTE: If you mistakenly scan the incorrect barcode, select the field again to re-highlight it. Then simply rescan using the correct barcode, and the previous one will be overwritten with the correct barcode.

- Input the Patient ID (or Accession Number) using the barcode scanner or manually enter the data using the on-screen keypad.
- Verify that the correct development mode, WALK AWAY or READ NOW, has been selected. Press ▶ and open the Sofia 2 drawer.
- Insert the prepared Test Cassette into the drawer of Sofia 2 and close the drawer.



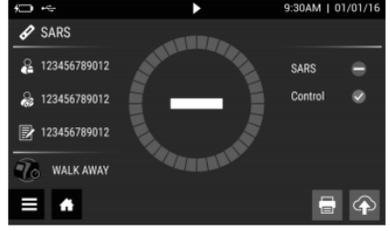
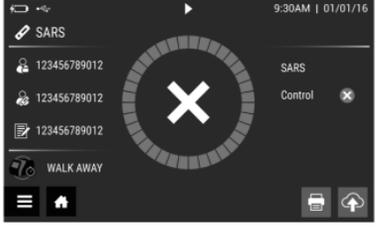
- Sofia 2 will start automatically and display the progress, as shown in the example below. In WALK AWAY Mode, the test results will be displayed on the screen in 15 minutes. In READ NOW Mode, the test results will be displayed on the screen within 1 minute. See “Reading results on the Sofia 2.”



- **Additional Precautions**
 - NEVER open the foil pouch of the Test Cassette exposing it to the ambient environment until the Test Cassette is ready for immediate use.
 - To obtain accurate results, an opened and exposed Test Cassette should not be used inside a laminar flow hood or in a heavily ventilated area.
 - To obtain accurate results, do not use visually bloody or overly viscous samples.

Reading results on the Sofia 2

- When the test is complete, the results will be displayed on the Sofia 2 screen. Test lines, which are fluorescent, cannot be seen with the naked eye.
- The Sofia 2 screen will display results for the procedural control as being or , and will individually provide a positive or negative result for SARS. If the procedural control is , retest with a new patient sample and a new Test Cassette. If a printer is connected, the results can be printed manually by selecting the print icon while the test results are displayed on the screen.

| Positive Results | Negative Results | Invalid Results |
|--|--|---|
|  |  |  |
| <p>NOTE: A positive result does not rule out coinfections with other pathogens.</p> | <p>NOTE: Negative results from patients with symptom onset beyond 5 days should be treated as presumptive and confirmed with a molecular assay.</p> | <p>Invalid Result: If the test is invalid, a new test should be performed with a new patient sample and a new Test Cassette.</p> |

Acknowledgement

Much of the text for the detailed laboratory procedures was prepared by Dr. Bert Lopansri, Director, Infectious Disease Laboratory, Intermountain Healthcare. UDOH HAI Team appreciates his contribution.