

Point-of-Care Antigen Test Devices

On July 14, Centers for Medicare and Medicaid (CMS) announced an initiative to distribute rapid point-of-care (POC) antigen COVID-19 testing devices to nursing homes across the country. Nursing facilities will receive one of two testing devices:

- [Quidel Sofia 2 SARS Antigen FIA](#)
- [BD Veritor System for Rapid Detection of SARS-CoV-2](#)

CMS has published the list of all nursing homes that will receive the instrument by the end of September, along with frequently asked questions, on the [CMS NHSN data site](#). HHS issued [guidance](#) to allow the use of antigen tests for off-label person (e.g. use with asymptomatic individuals), to override any state restrictions and extended the PREP act for liability to providers who use these devices.

Here are the key steps providers **must take before** using these testing devices.

1. Review CDC Guidance for Limitations and Cautions of these Devices

CDC has published two sets of guidance, linked below, on the use of antigen testing devices in nursing homes. It is important that providers review this information to understand these devices and limitations and cautions on their use in nursing homes.

- [Interim Guidance for Rapid Antigen Testing for SARS-CoV-2](#)
- [Considerations for use of SARS-CoV-2 Antigen Testing in Nursing Homes](#)

2. Contact your State/Local Health Department for Guidance on Meeting CARES Act Reporting Requirements

The CARES Act requires all laboratories with a Clinical Laboratory Improvement Amendments (CLIA) certificate to report the results of every COVID-19 tests that they conduct (positives and negatives) to the appropriate state or local public health department. This applies to nursing homes and assisted living communities who are performing point of care testing under their CLIA waiver. This is in addition to the reporting completed through the CDC NHSN website.

Providers can also review the [HHS laboratory reporting guidance](#) and related [FAQ's](#) for more information, including what specific information must be submitted. The [CDC laboratory reporting website](#) also provides information.

3. Complete Manufacturer Training

The FDA and CLIA requires that facilities performing waived tests follow the manufacturer's instructions. An individual at the facility **must** have proper knowledge and training to utilize the device, and should also have proof of completing the training.

One day prior to receiving the device, providers should receive an email from the company with links to training information. Training information can also be accessed on each company's website below:

Quidel Sofia 2 <https://togetheragain.quidel.com/>

This website is the source for all information regarding the Sofia 2 SARS Antigen FIA test.

You can access:

- Training – both online and live virtual training resources
- Kit reordering instructions
- Technical support
- FAQ's

BD Veritor™ System <https://www.bdveritor.com/>

This website provides access to all training and information long term care providers need to get started with the BD Veritor. Providers must log into the BD website to access training resources. If you need to establish an account, please complete the registration form by clicking on “Register yourself!”

4. Determine Additional Equipment and Supplies Needed

You will have the opportunity to speak to a representative from the device manufacturer regarding additional test kits and any additional supplies needed. You may need to purchase a printer for your device to print the results of each test performed. You will also need to have adequate PPE to conduct the tests (which included N-95s) as OSHA considers test collection a high-risk activity.

5. Incorporate into your Infection Prevention & Control Program and Facility Assessment.

Facilities should be sure to incorporate these new elements (point of care testing onsite, training & competency, reporting requirements, plans for interpreting results) into existing facility infection prevention and control program, as well as into their facility assessment. Engage your Medical Director and other key personnel in this process as you will likely want to get standing orders to use the POC testing devices.

6. Develop a Method to Document Testing

CMS requires documentation and tracking of all test results for residents and staff, including all contractors, consultants and volunteers. More information can be found in the links below.

7. Refer to CMS Testing Requirements for Additional Information

CMS has issued an [interim final rule](#) with requirements for routine COVID-19 testing in nursing homes and a [QSO memo 20-38](#) describing how they plan to operationalize and inspect compliance with this new regulation. The interim final rule goes into effect on September 2, 2020. Members should refer to the following resources for more information:

- [AHCA Summary of CMS' Testing Requirements](#)
- [AHCA Guidance on How to Get Started with Testing](#)