

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 by September 2020. Nursing facilities received one of two testing devices:

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

In addition, HHS is actively distributing Abbott BinaxNOW™ test kits to skilled nursing facilities and assisted living communities across the country.

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

1. Review Guidance for Limitations and Cautions of these Devices

CDC has published 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.

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

It's also important to note that 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.

2. Prepare to Meet Reporting Requirements

Per the June 4th, [HHS memo](#) on laboratory data reporting, all laboratories or other sites performing rapid point of care (POC) antigen tests under a CLIA certificate report the results to the appropriate state or local public health department.

Additionally, the memo has been updated to also require CMS-certified long term care facilities to submit this data to CDC's National Healthcare Safety Network (NHSN). More information on reporting through NHSN is [here](#).

Providers should contact their state/local health department to determine if reporting POC data through NHSN meets state reporting requirements, or if any additional reporting is required.

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](#)
- [BD Veritor™ System](#)
- [Abbott BinaxNOW](#)

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:

- [How to get started with the CMS Testing Mandate](#)
- [FAQ's: Testing in Long Term Care](#)