

Point-of-Care Antigen Tests

Point-of-Care Antigen Tests, such as the Abbott BinaxNOW, are widely used in long term care facilities for the diagnosis of COVID-19. These tests are relatively inexpensive, easy to administer and have rapid turnaround times, making them ideal for both surveillance and outbreak testing. They can also be operated in a CLIA waived environment. Here are the key steps we recommend providers 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. It is important that providers review this information to understand these devices and limitations and cautions on their use in nursing homes.

- [CDC Guidance for Rapid Antigen Testing for SARS-CoV-2](#)
- [Guidance for SARS-CoV-2 Rapid Testing Performed in Point-of-Care Settings](#)

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

This [HHS memo](#) on laboratory data reporting outlines the requirement that 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. Alternatively, long term care facilities may report results via NHSN.

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.

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

Facilities should be sure to incorporate these elements (Point-of-Care testing onsite, training & competency, reporting requirements, plans for interpreting results) into existing facility IPC program, as well as into their facility assessment. Engage your Medical Director and other key personnel as you will likely want to get standing orders to use the POC testing devices.

5. 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 below.

6. Refer to CMS Testing Requirements for Additional Information

CMS [QSO memo 20-38](#) describes the regulatory requirements for testing.