



Point-of-Care Antigen Testing A to Z

A number of questions have been swirling about point-of-care antigen testing. We have created this quick reference sheet to help answer the most common questions. This reference sheet will be updated as new questions and new information surface.

HHS Point-of-Care Testing Device Initiative

HHS [announced](#) in July that they would be sending point-of-care antigen testing devices and tests to all eligible nursing homes in the country. To be eligible, the nursing home must be CMS-certified and must hold a CLIA certificate or certificate of waiver. Information on how to apply for a CLIA certified of waiver can be found [here](#). Nursing homes who currently hold certificates of waiver do not need to take additional action or make any changes to existing certificates.

When Testing Devices and Test Kits Will Be Distributed

Initially anticipated to be distributed over approximately 14 weeks, [invocation of the Defense Production Act](#) has sped up the process. HHS now anticipates completing distribution by September 30. Testing devices and test kits will be distributed in 2 waves. The first wave began July 20 and completed August 14. Nursing homes were prioritized for this wave of distribution based on community prevalence (hotspot counties) and infection rates and testing access within the nursing home as identified through the use of NHSN data. More information about distribution and prioritization is available [here](#) under “Supporting COVID-19 Testing”.

Numbers of Test Kits to Expect

In order to determine the number of testing devices and test kits that each nursing home would receive, HHS divided nursing homes into 5 categories based on several factors including the number of beds in the nursing home, average census, and average staffing. The categories and corresponding devices and test kits are as follows:

Facility Category	Testing Devices	Test Kits
Small	1	150
Small-Medium	1	240 – 250
Medium – Large	1	325 – 330
Large	1	600
Major Outliers	2	900

Purchasing Devices and Extra Tests

Additional devices and test kits can be purchased through the manufacturer. Each manufacturer has set up a “concierge” service for providers who receive these machines. Part of this concierge service includes priority re-ordering for nursing homes. To order more test kits go to the website that corresponds with the brand of the device you have received:

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

For BD Veritor machines: <https://www.bdveritor.com/long-term-care-facilities/system-overview/>

Training on the Use of Devices

Training for the use of the point-of-care devices is available online at the corresponding brand’s special nursing home concierge site:

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

For BD Veritor machines: <https://www.bdveritor.com/long-term-care-facilities/system-overview/>

Life Expectancy of a Point-of-Care Testing Device

According to the user manual, the BD Veritor testing device is good for a maximum of 3,000 tests or 22-24 months from the date of the first test with a maximum of 34 months from the date of manufacture.

We were unable to obtain this information for the Quidel Sofia and Sofia 2 testing devices, but note that the devices must be calibrated every 30 days.

Antigen Testing with Asymptomatic Individuals

Point-of-care antigen tests may be used for testing asymptomatic individuals in the nursing home as part of screening testing in response to an outbreak or as part of routine testing of staff because both scenarios involve repeated testing over a period of time. Both [CDC](#) and [FDA](#) support the use of point-of-care antigen tests in nursing homes to rapidly identify and respond to COVID-19 cases.

False Negatives

Antigen tests are slightly less sensitive than nucleic acid tests (PCR tests), which means you have a higher chance of a false negative with an antigen test than you would with a PCR test. However, antigen test are recommended for use in nursing homes when part of a repeat testing plan, like screening testing in response to an outbreak, because they generally yield a faster result than a PCR test and can help nursing homes identify and respond to COVID-19 cases faster.

Confirming Negative Antigen Test Results through Follow-Up PCR Testing

Confirming negative point-of-care antigen test results with a PCR test may be recommended under certain circumstances, but is not necessary for all circumstances. The decision to perform confirmatory PCR testing should be determined based on clinical context such as symptom presentation and disease prevalence. This means that if the individual is showing symptoms or has been exposed to someone who is COVID-positive and the antigen test result is negative, a PCR test may need to be performed. If the individual is asymptomatic and there is no known exposure, a PCR test may not be necessary.

CDC has created [this tool](#) to help guide decisions about when to conduct follow-up PCR testing.

Reporting Point-of-Care Testing

Nursing homes conducting point-of-care testing under a CLIA certificate or CLIA certificate of waiver are required to comply with CLIA requirements for reporting lab data. These requirements were [updated on June 4, 2020 specific to COVID-19 testing](#). Nursing homes must report all tests to the state/local health department within 24 hours. For specific information on how to report, contact your state/local health department.

Nursing homes that fail to report point-of-care testing according to the CLIA guidelines will be subject to Civil Money Penalties (CMPs) of \$1,000 for the first day of noncompliance and \$500 for each additional day.

Acceptance of Antigen Test Results

We have heard from members that some states are not accepting point-of-care antigen testing to satisfy state testing requirements. CMS has been in communication with many states to address concerns, but you will need to continue to comply with state requirements.

We do know that antigen test results are acceptable for the new [federal testing requirements](#), which require diagnostic testing in response to symptoms, screening testing in response to an outbreak, and routine surveillance testing of staff according to community prevalence (county positivity rates).

We also know that antigen test results are acceptable when reporting on confirmed cases through NHSN. In fact, NHSN has begun collecting data on antigen testing, including whether or not nursing homes have received antigen testing devices and have access to supplies.