



On July 14, 2020, the Department of Health and Human Services (HHS) announced a new initiative to distribute point-of-care testing devices to all CMS-certified nursing homes over the following 14 weeks. Nursing homes are prioritized if they:

1. Are located within a hotspot county, or
2. Reported any of the following through the NHSN COVID-19 module by July 5:
 - 3 or more confirmed or suspected new cases in the last week
 - At least 1 new COVID-19 case in the past week when previously there had been 0 cases
 - Inadequate access to testing in the last week
 - At least 1 new resident death due to COVID-19 in the last week
 - At least 1 new confirmed or suspected COVID-19 case among staff in the last week

In order to use these point-of-care testing devices in nursing homes, the nursing home must have a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver. In June 2020, the CARES Act created a [new requirement](#) that labs, including facilities and other locations performing testing at point-of-care, must report all COVID-19 test results to HHS. To meet this requirement, HHS has directed that labs must report all test results to state or local public health departments. This information must be reported within 24 hours of determining results.

Q: If I receive a point-of-care testing device, do I have to use it?

A: No, nursing home providers are not required to use the point-of-care testing device. However, should you choose not to use the point-of-care device, be prepared to implement other testing strategies as needed. For example, if a resident shows symptoms consistent with COVID-19 and you choose not to use the point-of-care device to which you have access, but also fail to access alternatives, this could be problematic.

Q: In reviewing the [HHS Lab Data Reporting Guidance](#), I see that there are 18 required data elements and numerous other data elements to report with each test. Do nursing homes have to report this data for every test?

A: Yes, because you are conducting these tests under your CLIA waiver, you must adhere to the [HHS Lab Data Reporting Guidance](#) that requires the reporting of all results of all COVID-19 tests conducted to be reported to HHS via the state or local health department. This guidance requires reporting data on all tests, whether results are positive, negative, or inconclusive.

Q: Is CMS mandating that all staff be tested once per week?

A: In the [reopening recommendations for state and local officials](#), CMS recommended testing of staff on a weekly basis. CMS [recently stated](#) that they will soon require testing of all staff in nursing homes located in states with a positivity rate of 5% or greater. However, this will require rulemaking. This Notice

of Proposed Rulemaking (NPRM) has not yet been released and CMS is unable to discuss any details of the requirement during the rulemaking process.

Q: Am I required to use my point-of-care testing device to test staff?

A: CMS has stated that they will not tell providers how they can or cannot use these devices. They are meant to augment other testing strategies and should be used to meet CMS/CDC testing recommendations and state testing mandates.

Q: Must I report on this testing to CMS?

A: Again, we have yet to see the rule, so we cannot speculate about a new requirement. But here's what we do know: if you are conducting a point-of-care test, you must report testing data to HHS through your state or local health department. Additionally, you must report all confirmed COVID-19 cases, including those among staff, to CDC and CMS through the National Healthcare Safety Network (NHSN) system.

Q: Does NHSN (CDC) accept antigen test results?

A: Yes, CDC has said that they will accept antigen test results for the purposes of reporting through the NHSN COVID-19 module for long-term care facilities.

Q: We've heard that FDA recommends following up a negative point-of-care antigen test result with a lab PCR test.

A: Yes, this is true. There is a 20% chance of a false negative with a point-of-care antigen test. It is recommended that a negative test be considered "presumed negative" and taken in the context of the resident's exposure and symptoms. We had heard that these tests were not recommended for use with asymptomatic individuals, but then later heard that FDA may be reconsidering that recommendation.

Q: My state does not accept antigen testing results from nursing homes. Can I use the point of care device I receive from CMS?

A: Many states do not accept test results from the antigen testing devices CMS is sending to nursing homes. You are still free to use the device and may find it helpful for quick confirmation of whether a symptomatic person has COVID19.
