

MDS Alert

Reader Questions: Continue to Report Data with In-House Testing Device

Question: Our facility has been chosen to receive a device to test for COVID-19 infection. Since we'll be able to do the tests in-house now, are we still required to report the data?

Illinois Subscriber

Answer: Yes, you must report the test results. "All laboratories must have a CLIA Certificate and report the results of the COVID-19 tests that they conduct to the appropriate federal, state, or local public health agencies. Laboratories must report data for all testing completed, for each individual tested. This data must be reported within 24 hours of test completion, on a daily basis, to the appropriate state or local public health department, based on the individual's residence. Testing sites must report all diagnostic test data in accordance with the HHS Lab Data Reporting Guidance for COVID-19 issued June 4, 2020 and meet these reporting requirements by August 1, including providing your facility name and CLIA number when reporting results," CMS says in a Frequently Asked Questions document for skilled nursing facilities.



However, note that the location of your facility may matter. Washington and New York are both exempt from the Clinical Laboratory Improvement Amendments (CLIA) certification.

"Although Washington State's Medical Test Site program and New York State's Clinical Laboratory Evaluation Program are exempt from CLIA, they do authorize a SNF/NF to have certificates that are equivalent to CLIA certificates, including the CLIA Certificate of Waiver. Nursing homes in Washington State are issued a CLIA Certificate of Waiver in addition to a Washington State License and those in New York State are issued a Limited Service Laboratory Registration. Nursing homes in these states will also be included in the HHS distribution program," CMS says.

New York facilities can find more information at

<https://protect2.fireeye.com/url?k=5dee6edc-01ba77a0-5dee5fe3-0cc47adc5fa2-d45645ac8b1d5c6a&u=https://www.wadsworth.org/regulatory/clep/limited-service-lab-certs>, and facilities in Washington state, can find more information at www.doh.wa.gov/LicensesPermitsandCertificates/FacilitiesNewReneworUpdate/LaboratoryQuality Assurance.