STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

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TO: **Health Care Providers**

FROM: **Matthew L. Cartter, MD, MPH, State Epidemiologist**

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SUBJECT: **Changes to requirements for SARS-CoV-2 test reporting**

DATE: **March 28, 2022**

The Coronavirus Aid, Relief, and Economic Security (CARES) Act as outlined in the guidance released by the Department of Health and Human Services (HHS) on June 4, 2020, requires every CLIA certified COVID-19 testing site to report every diagnostic and screening test result (both positive and negative results) performed to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (e.g., molecular, antigen, antibody) to the appropriate state or local public health department, based on the individual's residence. Under this guidance, 'laboratory' was defined to include point of care providers (POC) and other non-traditional laboratory locations testing for SARS-CoV-2 on-site under a CLIA certificate of waiver issued by DPH. In Connecticut, these reports are sent to the Department of Public Health (DPH).

On March 8, 2022, HHS released updated guidance https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html#who-must-report (see Table 1 in the attachment) that makes optional the reporting of SARS-CoV-2 negative test results for POC and other locations testing using a rapid antigen or rapid PCR test. DPH is adopting this change in reporting, effective **April 4, 2022**.

The changes are summarized below:

Table 1. Changes to Reporting Requirements by Type of Test and Test Location

Type of Test	Positive Results	Negative & Inconclusive Results	Location
NAAT-testing conducted in a facility CLIA certified to perform moderate- or high-complexity tests	Required	Required	For example, hospital, commercial, public health and other labs
Other testing for SARS-CoV-2 antigen or rapid PCR testing (e.g., using the Abbott ID NOW)	Required	• **No longer required to report.**	• Testing conducted in a setting operating under a CLIA certificate of waiver. • Laboratories performing non-NAAT tests
Antibody testing	**No longer required to report**	**No longer required to report**	Tests used to determine previous infection with SARS-CoV-2 in any setting

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Reports still need to include all of the required data fields as defined by DPH. The Infectious Disease Informatics Program staff will communicate about these reporting changes and any impact on reporting POC results to DPH. For further questions or information please email DPH.InformaticsLab@ct.gov.

Providers or other locations who wish to start using any SARS-CoV-2 rapid test as authorized under FDA Emergency Use Authorization[1] must ensure they have obtained a CLIA certificate of waiver to perform such tests or add a new test type to their existing CLIA certificate of waiver by contacting the DPH Facility Licensing and Inspections Section (FLIS) at DPH.FLISlab@ct.gov. Tests cannot be performed until the certificate of waiver has been issued.

Providers should note that if a patient has been found with a positive PCR/NAAT or positive Antigen test result, they are still obligated to complete the COVID-19 provider case report form using the web form found at https://dphsubmissions.ct.gov/Covid/InitiateCovidReport.

[1] https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas