SACRAMENTO COUNTY
SACRAMENTO COUNTY PUBLIC HEALTH
Promote • Prevent • Protect

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Revised COVID-19 Laboratory Reporting Requirements
April 7, 2022

The Department of Health and Human Services (HHS) revised COVID-19 laboratory reporting requirements, effective April 4, 2022. The California Department of Public Health (CDPH) has adopted these requirements with slight modifications.

Effective April 4, 2022, the following changes will apply to SARS-CoV-2 reporting requirements in California:

Testing Conducted in Facilities Certified under CLIA to Perform Non-waived (Moderate- or High-Complexity) Testing*

- Continue to report all laboratory-based SARS-CoV-2 Nucleic Acid Amplification Tests (NAAT) results, including positive and non-positive (negative, indeterminate, etc.)
- Continue to report all antibody/serology testing results, including positive and non-positive (negative, indeterminate, etc.)
- Report SARS-CoV-2 **positive** results of non-NAAT diagnostic testing (e.g. high throughput antigen testing)

Testing Conducted in Facilities with a CLIA Certificate of Waiver*

- Report SARS-CoV-2 **positive** diagnostic results only
  - Reporting of non-positive results (negative, indeterminate, etc.) is no longer required
  - This includes rapid testing conducted for screening or diagnostic purposes at schools, correctional facilities, employee testing programs, long-term care facilities, and rapid tests performed in pharmacies, medical providers offices, and drive-thru and pop-up testing sites

Over-the-Counter (OTC) Self-Tests

- Tests approved for OTC use, when performed without CLIA oversight, are not required to be reported. Individuals should report according to the instructions provided by the test if not automatically reported.
- If performed in a setting regulated under CLIA, positive results form self-tests are required to be reported

** Laboratories must continue to follow all State and CLIA requirements for recording and maintaining all laboratory results*

Resources:

1. Letter to Entities Performing SARS-CoV-2/COVID-19 Testing (CDPH): https://files.constantcontact.com/296dc3ca601/b78740fd-d50b-45c6-bd47-61cc416654b5.pdf
2. COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115 (HHS): https://www.cdc.gov/coronavirus/2019-ncov/downloads/lab/HHS-Laboratory-Reporting-Guidance-508.pdf

Sincerely,

Olivia Kasirye MD

Olivia Kasirye, MD, MS
Public Health Officer

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Table 1. Reporting Requirements by Entity and Type of Testing

	Reporting Required?		Examples
	Positive Results	**Negative & Inconclusive Results**	
NAAT-testing conducted in a facility certified under CLIA to perform moderate or high-complexity tests	**Required**	**Required**	• Laboratory-based Nucleic Acid Amplification Test (NAAT) testing, including RT-PCR, TMA, LAMP, and SDA tests (https://www.cdc.gov/coronavirus/2019-ncov/lab/naats.html)
Antibody testing conducted in a facility certified under CLIA to perform moderate or high-complexity tests	**Required**	**Required**	• Tests used to determine previous infection with SARS-CoV-2 in any setting
All other testing (except over-the-counter performed without CLIA oversight)	**Required**	Optional	• Testing conducted in a setting operating under a CLIA certificate of waiver such as rapid tests (e.g., screening testing at schools, correctional facilities, workplaces, long-term care facilities, and point-of-care testing performed in pharmacies, medical provider offices, drive-thru and pop-up testing sites) • Non-NAAT diagnostic testing (e.g., high throughput antigen) testing conducted in a facility certified under CLIA to perform moderate or high-complexity tests
Over-the-counter self-tests performed without CLIA oversight	Not required	Not required	• Over-the-counter self-tests that are purchased without a prescription and specimens are collected and completely processed by an individual anywhere outside of a healthcare or lab setting without the supervision of a trained professional