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State of California—Health and Human Services Agency
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GAVIN NEWSOM
Governor

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Dear Entities Performing SARS-CoV-2/COVID-19 Testing,

Thank you for your continued efforts over the last two years to report SARS-CoV-2 results to public health. The data provided by laboratories continue to be a critical component of California's pandemic response. As the pandemic continues to evolve, the California Department of Public Health (CDPH) is committed to evaluating and optimizing reporting requirements to meet the needs of monitoring the pandemic while minimizing impacts on entities performing testing. The revised reporting requirements below were adapted from revisions to [COVID-19 laboratory reporting guidance](#), announced by the Department of Health and Human Services and the Centers for Disease Control and Prevention.

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.).
 - Examples of NAAT tests includes RT-PCR, TMA, LAMP and SDA.
- Continue to report all antibody/serology testing results, including positive and non-positive (negative, indeterminate, etc.).
 - CDPH uses these data to calculate seroprevalence which has been an important pandemic trend to monitor.
- Report SARS-CoV-2 POSITIVE results of non-NAAT diagnostic testing (e.g. high throughput antigen testing).
- Laboratories must continue to follow all State and CLIA requirements for recording and maintaining all laboratory results.

Testing Conducted in Facilities With a CLIA certificate of waiver

- Report SARS-CoV-2 POSITIVE diagnostic results only.

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- 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 testing performed in pharmacies, medical providers offices, and drive-thru and pop-up testing sites.
- Testing facilities must continue to follow all State and CLIA requirements for recording and maintaining all laboratory results.

Over-the-counter (OTC) self-tests

- Tests approved for over-the-counter (OTC) use, when performed by individuals upon their own specimens without CLIA oversight are not required to be reported to public health agencies. Individuals should report their test result according to the instructions recommended by the test. Some home tests have automatic reporting, others have the option to report results through a phone application.
- If performed in a setting regulated under CLIA, positive results from self-tests are required to be reported.

Questions about these reporting changes can be directed calrediehelp@cdph.ca.gov. We sincerely appreciate the extraordinary work our testing partners have undertaken over the last two years.

Thank you,



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*At this time, the following requirements, outlined in Article 8 of Assembly Bill No. 86 applies to reporting of positive tests conducted in schools: Article 8: COVID-19 Reporting and Public Health Requirements 32090. (a) (1) Upon learning that a school employee or pupil at a public or private school campus maintaining kindergarten or any of graded 1 o 12, inclusive, in the state has tested positive for COVID-19 and was present on campus while infectious, the school administrator or other person in charge of the public or private school shall immediately, and in no case later than 24 hours after learning of the positive case, notify the local health officer or the local health officer's representative about the positive case.

Table 1. Reporting Requirements by Entity and Type of Testing

	Is Reporting Required Under this Guidance?		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 • See 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 through 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.

