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November 9, 2020

TO: Community Clinics

Hospitals Laboratories Pharmacies

FROM: Wilma J. Wooten, M.D., M.P.H.

Public Health Officer and Director

Public Health Services

RE: MANDATED REPORTING OF SARS-COV-2

As united partners for laboratory testing, San Diego County (County) requests your urgent action to ensure timely reporting of **all** SARS-CoV-2 testing efforts. Laboratories testing California specimens for the novel coronavirus are required to report test results to the California Department of Public Health (CDPH) or the County of San Diego Public Health Services. This requirement applies to entities that conduct Clinical Laboratory Improvement Amendments (CLIA)-waived point-of-care (POC) tests for SARS-CoV-2, including those operating at drive-through, walk-in, or mobile sites; acute care hospitals and ambulatory centers; physician offices; pharmacies; airports, and other locations. Laboratories associated with these facilities must ensure that all SARS-CoV-2 test results (i.e., positive, non-positive tests) from molecular, antigen, and antibody/serology tests that are reported within 8 hours from the time the laboratory notifies the health provider or other person authorized to receive the report. This reporting requirement is also outlined in the Health Officer Order and in the October 16, 2020, California Health Alert Notification (CAHAN).

As stated in the CAHAN, laboratories must report results electronically to the CalREDIE Electronic Lab Reporting (ELR) system or directly to the County of San Diego. Requirements include:

- Laboratories shall establish electronic lab reporting interfaces with the CalREDIE ELR system or directly to the County of San Diego through the San Diego Health Connect Health Information Exchange (HIE).
- Laboratories and pharmacies not yet registered or otherwise unable to report via ELR should contact CalREDIE to arrange for reporting through alternative methods, such as a .CSV file reporting mechanism.
- For those labs that will be submitting .CSV files, the County of San Diego requests a copy of the .CSV file to be sent to the County, as well.

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To inquire about reporting SARS-CoV-2 test results to the County of San Diego, send an email to <u>Epi-CDReporting.HHSA@sdcounty.ca.gov</u>. CalREDIE has established a special team to assist labs with questions about reporting SARS-CoV-2 results to CDPH, which may be contacted at <u>CalREDIEHelp@cdph.ca.gov</u>.

In addition, local health jurisdictions (LHJs) may establish their own reporting requirements as outlined in the State's <u>guidance</u>. Please note the following additional requirements:

- Laboratories shall report Research Use Only (RUO) test results to the CalREDIE ELR system or directly to the County of San Diego.
- While in the process of onboarding to the ELR system, labs will continue to submit .CSV files until the County of San Diego Public Health Services provides a notification to cease.
- Out-of-County Labs performing tests on patients who reside or otherwise have a primary address in San Diego County shall report those results to the CalREDIE ELR system or directly to the County of San Diego.
- Laboratories must ensure that they have reported all tests and test results starting from the date tests were first performed. Any lab that has not yet reported historical tests, such as those unable to report prior to onboarding, or for any other reason, must report those tests.

Lastly, CDPH is asking all LHJs to improve the collection of race and ethnicity data associated with testing and cases. To date, CDPH reports that approximately a third of cases and up to half of test results reported to the state do not have the required race/ethnicity data. Please help to ensure more accurate collection of this vital information.

Please keep in mind that the County will notify the State's <u>Lab Field Services</u> regarding any laboratory that fails to report SARS-CoV-2 test results. This notification will initiate progressive enforcement, which could possibly include warning letters, imposition of sanctions, and penalties.

Since the beginning of the pandemic, and with your support and partnership, the County has been a leader in aggressively combating COVID-19. This has been done in collaboration with federal, state, and local partners. We look forward to continuing our partnership with your laboratory regarding COVID-19 testing efforts. If you have any questions, please contact Sebastian Razo via email at Sebastian.Razo@sdcounty.ca.gov.

Sincerely,

Wilma L. Wooten, M.D., M.P.H.

Public Health Officer and Director of Public Health Services County of San Diego, Health and Human Services Agency

cc: Helen Robbins-Meyer, Chief Administrative Officer
Nick Macchione, Agency Director, Health and Human Services Agency