

Date: November 10, 2020
To: Medical Care Providers, Healthcare and other Facilities
From: Thea Papasozomenos, MD, MPH, Assistant Health Officer

Please distribute to all providers and relevant staff in your facility.

Health Alert

Point-of-Care (POC) COVID Antigen Testing

Several point-of-care (POC) antigen tests are available under emergency use authorizations (EUAs) from the FDA as diagnostic tests to detect current infection with SARS-CoV-2. Antigen tests directly detect fragments of SARS-CoV-2 viral protein as opposed to viral RNA detected by nucleic acid amplification tests (NAAT, i.e. RT-PCR). The main advantages of antigen tests include fast turnaround time, simple POC use, and lower cost. However, their reliability depends on the circumstances in which they are used, including exposure history and clinical presentation of the individual tested.

POC antigen tests are most reliable when used on symptomatic individuals. Therefore, the FDA EUAs for their use extends only to symptomatic individuals. Confirmation of POC antigen test results with non-POC NAAT, such as RT-PCR, run by a lab, may be necessary depending on the testing scenario.

Guidance for Stanislaus County Facilities and Providers:

POC COVID-19 rapid antigen testing

- Antigen tests are appropriate for diagnostic testing in individuals who present *during the period following symptom onset* as allowed under their respective FDA EUAs.
- If antigen tests are used outside the EUA recommended window from symptom onset or to test asymptomatic individuals, false positive test results may occur.
- For symptomatic individuals:
 - Consider positive antigen test results as true positives: no need to confirm results
 - Consider negative antigen test results as presumptive: confirm results with non-POC NAAT testing, such as RT-PCR, and recommend isolation until non-POC NAAT results available

Report POC COVID-19 test results

- Facilities/providers are required to submit a Covid-19 Confidential Morbidity Report (CMR) form for all positive results to Public Health (PH). Submit CMRs through the CalREDIE Provider Portal.
- Facilities/providers *performing* COVID-19 testing act as the lab entity and must conform to mandatory lab reporting requirements.
 - Report all COVID-19 lab/test results through either the CalREDIE Electronic Laboratory Reporting system (ELR) or CalREDIE Manual Laboratory Reporting Module (MLRM)
 - Report positive results within 8 hours and non-positive results at least daily to PH of the county where the patient resides.
- Facilities/providers that only *collect* specimens that are processed by an outside lab need only submit CMR of positive results.

How to Report Labs:

- Transmission of lab reports through the ELR system:
<https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/CalREDIE-ELR.aspx>
- Reporting COVID-19 test results through the CalREDIE MLRM:
 - Complete the CalREDIE Manual Reporting Account Authorization Form:
https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/MLR_Account_Re

[quest Form.pdf](#)

- Applications for access to this system should be sent to calrediehelp@cdph.ca.gov
- CalREDIE Manual Lab Reporting Quick Start Guide:
https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/MLR_Quickstart_Guide.pdf
- Reporting CMRs through the CalREDIE Provider Portal:
 - Complete the CalREDIE Reporter/Provider Account Request Form:
<https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/CalREDIE-Reporter-Provider-Account-Request-Form.pdf>
 - Applications for access to this system should be sent Stanislaus County PH:
CovidHealthcareFacilities@schsa.org
- COVID-19 CMR: <http://schsa.org/PublicHealth/pages/corona-virus/pdf/stan-cmr-covid.pdf>
- For questions or assistance, contact Stanislaus County PH: CovidHealthcareFacilities@schsa.org

Additional Information:

- CDC: [Overview of Testing for SARS-CoV-2](#)
- CDC: Interim guidance for rapid antigen testing for SARS-CoV-2: <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html#:~:text=CDC%20recommends%20confirming%20negative%20antigen,confirmed%20to%20have%20COVID%2D19.>
- CDPH: Antigen testing guidance (updated September 12):
<https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/CDPH-Guidance-on-the-Use-of-Antigen-Tests-for-Diagnosis-of-Acute-COVID-19.aspx>
- Stanislaus County Health Services Agency (HSA): <http://schsa.org/PublicHealth/pages/corona-virus/>

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