Testing Task Force Update

New tests reported: 268,385

Average test positivity past 7 days : 2.9%

down 0.4% from last week and down from 7.2% from early August

Average test turnaround time last week: 1.3 days

- < 2 days: 90%
- < 1 day: 70%



Reported Sept 22, 2021 with data as of Sept 21, 2021.

https://covid19.ca.gov/state-dashboard/_https://testing.covid19.ca.gov/ COVID-19 Cases Dashboard v2.0 - CA OpeNn Data | Tableau Public

Carestart Antigen tests

• Approved for use in individuals within 5 days for symptom onset.

	Sensitivity	Specificity
BinaxNOW	84.60%	98.50%
Carestart	87%	100%

(Data from EUA)

• In field use, there was slightly lower sensitivity and specificity in one study compared to BinaxNOW and similar performance to BinaxNOW in another study. Overall their field use is limited.

Our experience is that BinaxNOW and Carestart have high specificity, meaning that if you don't have COVID-19 you will likely test negative in comparison to Binaxnow.

- With frequent use for screening of staff, these tests should work to identify cases and prevent outbreaks. With training and practice, people should be able to perform the tests. Please read the IFU carefully prior to their use and feel comfortable performing the tests.
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- BinaxNOW supplies may be limited for some time. ٠
- EUA CareStart COVID-19 Antigen test Instructions for Use (fda.gov) ٠

Process for starting testing with Carestart

• Requested through MHOAC

• If a facility already has a CLIA certificate of waiver and state registration but wants to start using a new POC antigen test, the facility must notify CMS and LFS of the new test by submitting a new <u>CMS 116</u> form to <u>LFSCLIA@cdph.ca.gov</u>. The facility must also report the new testing information through the <u>COVID-19 Testing Notification</u> link. The facility may begin using the new test as soon as it has submitted this information.

• As the temporary allowance letter states, <u>Temporary Allowance for Waived SARS-CoV-2</u> <u>Antigen Testing (ca.gov)</u>, the facility can begin testing with the new test as soon as it has submitted the CMS form and changed the information on the TTF testing notification page. It doesn't need to wait for a response or approval.