Testing Task Force Update

New tests reported: **598,445**

Average test positivity past 7 days: 23.1%

Cases are rising exponentially across the US and in California Average Test Turnaround time last week: 1.2 day Turnaround time < 2 days: 92% Turnaround time < 1 day: 65%



Reported January 12, 2022 with data as of January 11, 2022. <u>https://covid19.ca.gov/state-dashboard/__https://testing.covid19.ca.gov/</u> <u>COVID-19 Cases Dashboard v2.0 - CA OpeNn Data | Tableau Public</u>

Test Supplies

- Please contact your local MHOAC to request testing supplies.
- There have been some supply chain difficulties over the last few weeks and tests that were supposed to arrive did not due to weather, international shipping delays and high testing demand
- If you reached out to the local MHOAC, and have an urgent need for supplies, contact the MHOAC every 1-2 weeks for an update. If they are unable to help obtain needed supplies, contact the testing task force @ testing.taskforce@cdph.ca.gov. Please specify the county and your order details.

Omicron and PCR testing

- FDA is investigating to see if any COVID-19 tests will be affected by Omicron.
- <u>SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests | FDA</u>
- No new updates to tests that may not work against Omicron
- Currently they have identified two molecular tests that will not detect omicron
 - 1. Meridian Bioscience, Inc, single genetic target, not currently in use.
 - 2. Applied DNA Science Linea COVID-19 Assay Kit
- PCR tests in general have multiple primers targeting different regions of the viral genome. There are 26 tests will have a S gene or Spike gene drop out due to the mutation in Omicron at the spike region of the genome. This means that the Spike primer will not bind to the spike region of the genome due to mutation of the virus and will show up as not detected. If this is occurring, labs should contact their local health department and work to send the specimen for sequencing.
- There are 4 tests will have a N gene or nucleocapsid gene drop out due to the mutation in Omicron at the nucleocapsid region of the genome. This means that the N primer will not bind to the N region of the genome due to mutation of the virus and will show up as not detected. If this is occurring, labs should contact their local health department and work to send the specimen for sequencing.

Omicron and Antigen Testing

- The FDA and the NIH recently performed preliminary studies evaluating the performance of some antigen tests using patient samples containing live virus, which represents the best way to evaluate true test performance in the short-term. Early data suggests that antigen tests do detect the omicron variant but may have reduced sensitivity. The FDA has not published their data on how less sensitive these tests may be.
- In a pre-print study where 296 people tested positive for COVID-19 with 97% of positive results Omicron at a site in San Francisco, they calculated sensitivity of BinaxNOW at different viral thresholds using cycle threshold time abbreviated with CT. A high cycle threshold time indicates low levels of virus detected; a low cycle threshold time indicates high levels of virus detected.
 - BinaxNOW had a sensitivity of 95% for Ct threshold of < 30,
 - BinaxNOW had a sensitivity of 82% for CT < 35 and overall sensitivity of 65%
 - The overall specificity was 99.3%.
- These results are similar to prior performance of Abbott BinaxNOW against other COVID-19 variants.
- Antigen tests are generally less sensitive and less likely to pick up very early infections compared to
 molecular tests. In following the FDA's long-standing rapid test recommendations, if a person tests negative
 with an antigen test but is suspected of having COVID-19, follow-up molecular testing is important for
 determining a COVID-19 infection.
- As a part of a pilot project CDPH has had success in detecting Omicron with BinaxNOW tests.
- We are not recommending a change in testing strategy as a result of the FDA's findings at this time.

Who Can Perform Swabbing for COVID-19 Tests?

 More information can be found in the COVID-19 for Laboratories FAQ under Laboratory Personnel <u>https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/COVID-19FAQ.aspx#Laboratory%20Questions</u>

Licensed Personnel	Observe Self Swabbing	Anterior Nasal	Nasopharyngeal, Oropharyngeal
Medical Assistants	Yes	Yes	No
Physicians	Yes	Yes	Yes
Physicians Assistants	Yes	Yes	Yes
EMTs	Yes	Yes	Yes
Registered Nurses	Yes	Yes	Yes
LVNs	Yes	Yes	Yes
Psychiatric Technicians	Yes	Yes	Yes
CNAs, Home Health Aides, Certified Hemodialysis Technicians	Yes	No	No
Respiratory care practitioners	Yes	Yes	Yes
Pharmacists	Yes	Yes	Yes
Pharmacy Technicians	Yes	Yes	Yes
For questions about other licensed personnel, contact appropriate licensing board for information on scope of practice			