Testing Task Force Update

New tests reported: 173,591

Average test positivity past 7 days : 2.3%

Unchanged from last week

Cases are rising in Europe and in the US as anticipated for the winter season which usually precedes a rise in cases in California.

Average Test Turnaround time 1 days

Turnaround time < 2 days: 97%

Turnaround time < 1 day: 75%

Reported December 15, 2021 with data as of Dec 14, 2021. <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>



Omicron

- 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>
- Currently they have identified three molecular tests that will give false negative results.
 - 1. Tide Laboratories DTPM COVID19 PCR test with a single gene target results in false negative tests to Omicron
 - 2. Meridian Bioscience, Inc, single genetic target, not currently in use.
 - 3. Linea COVID-19 Assay Kit Two viral targets
- PCR tests in general have multiple primers targeting different regions of the viral genome. There are a number of 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 a few 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.
- Antigen tests bind to the nucleocapsid protein which has been largely unchanged with Omicron. Most of the mutations
 in Omicron occurred at the spike protein. Antigen test companies are working to show that their tests work against
 Omicron. Abbott has made a statement that they think their antigen tests should work against Omicron.

Expired COVID tests

Per CMS, **if unexpired COVID-19 tests cannot be obtained**, testing programs are **allowed to use expired COVID-19 tests** if the lab director establishes a written policy for this use.

Policies and procedures must be in place to ensure the reagents are performing as expected by ensuring that any expired supplies pass quality control tests

CDPH is requiring users of expired tests supplied or overseen by CDPH, to perform controls on each lot at least once every month that the expired tests are used.

CDC guidance: <u>https://www.cdc.gov/csels/dls/locs/2020/cms_guidance_for_the_use_of_expired_sars-cov-</u> 2_tests.html CMS guidance: <u>Frequently Asked Questions (FAQs), CLIA Guidance During the COVID-19 Emergency (cms.gov)</u>

This emergency expiration date guidance currently does not have an end date. However, it is expected that the emergency guidance will not last indefinitely. This emergency guidance only applies when in-date supplies are . Organizations are encouraged to use the expired tests as quickly as possible. If CDPH sends notification that the emergency guidance has ended, organizations must immediately cease using the expired tests.

This extended expiration does not apply to the over the counter tests.

CDC international travel guidance arrival testing



ALL Travelers

RECOMMENDED

- Get tested with a COVID-19 viral test 3-5 days after travel.
 - Find a <u>U.S. COVID-19 testing location near you.</u>
- Self-monitor for <u>COVID-19 symptoms</u>; isolate and get tested if you develop symptoms.
- Follow all state and local recommendations or requirements after travel.



If You Are NOT Fully Vaccinated

RECOMMENDED

In addition to the testing recommendations above

- Stay home and self-quarantine for a full 7 days after travel, even if you test negative at 3-5 days.
- If you don't get tested, stay home and self-quarantine for 10 days after travel.