



CORONAVIRUS
DISEASE 2019

(COVID-19)

WEEKLY UPDATE

LONG-TERM CARE AND RESIDENTIAL CARE FACILITIES

Tuesday, December 22, 2020

Greetings Long-Term Care and Residential Care Facilities of San Diego County,

Please find information below regarding the latest guidance and resources from county, state, and federal organizations, including **new updates**:

- CDPH **Health Alert**: SARS-CoV-2 virus variant identified in the United Kingdom, December 22, 2020
- All Facilities Letter (AFL) notifying hospice providers of the suspension of regulatory enforcement of hospice requirements (**AFL 20-47.1**)
- Notes from the California Department of Public Health conference call for Skilled Nursing Facilities to provide updates on COVID-19 (December 16 – 17, 2020)
- Provider Information Notice (PIN) notifying all licensed Adult and Senior Care Facilities on **hotel rooms** available for COVID-19 positive or exposed licensee staff (**PIN 20-45-ASC**)
- PIN to all Community Care Licensed Providers announcing a new **provider infection prevention helpline** to obtain information on infection prevention and control best practices (**PIN 20-29-CCLD**)
- County of San Diego **BinaxNOW Distribution Program**; how to request testing kits
- **Potential Safety Power Shutoff** may impact San Diego on December 23 – 24, 2020
- New County of San Diego **COVID-19 vaccine webpage**
- County **COVID-19 testing sites** operating over the holidays

- **Save-the-Date:** Long-Term Care and Residential Care Facilities telebriefings will now be held on the 2nd and 4th Thursdays of the month, 2:00 – 3:00 pm beginning January 2021; next one will be Thursday, January 14, 2021.

As a reminder, if you have a positive COVID-19 case at your facility, please report it by calling the County Epidemiology Unit phone line at (619) 692-8499 or (858) 565-5255 for after-hours or on the weekend. The County as well as your State licensing departments are here to support you.

For additional information, please see our website www.coronavirus-sd.com/LTC. Please email us at moc.logs.hhsa@sdcounty.ca.gov if you need personal protective equipment.

Thank you for your continued efforts and partnership with the County of San Diego. We wish you and your families a safe and healthy holiday season!



Announcements and News



California Department of Public Health

CDPH publishes news and All Facilities Letters (AFLs) regularly. If you would like to receive email notifications of AFLs, please submit your request to LNCPolicy@cdph.ca.gov.

NEW! CDPH **Health Alert:** SARS-CoV-2 virus variant identified in the United Kingdom – December 22, 2020

This Health Alert describes what is currently known about the SARS-CoV-2 virus variant identified in the United Kingdom and outlines how health care providers can help collect specimens for genetic sequencing to monitor for this and other variant virus strains.

Please see attached PDF titled “CAHAN_SARSCoV2_variant_+12.22.20”

NEW! Letter to All Facilities: **AFL 20-47.1** – December 21, 2020

This All Facilities Letter, which supersedes AFL 20-47, notifies hospice providers of a temporary waiver of specified regulatory requirements due to the state of emergency related to the COVID-19 outbreak. This revision rescinds prior authorization to begin operations based solely on submission of an application and clarifies that a hospice provider seeking initial licensure must receive approval before providing care.

[Click here to read AFL 20-47.1](#)

NEW! Notes from the California Department of Public Health conference call for Skilled Nursing Facilities to provide updates on COVID-19 (December 16 and 17, 2020). **Please see attached PDF** titled “AFC-SNF+IP+Call+Notes+12_16&17_2020”

Letter to All Facilities: **AFL 20-48.3** – December 16, 2020

This AFL supersedes AFL 20-48.2 and provides information on state-run alternate care sites and guidance for the transfer of COVID-19 positive patients to alleviate strain on hospitals and skilled nursing facilities and ensure patient safety. This AFL also addresses transfers to congregate living health facilities licensed by the California Department of Social Services. This guidance has been updated to revise the admission criteria and to provide additional information regarding effectuating a transfer between the alternate care site and health facility. [Click here to read AFL 20-48.3](#)

CDPH **Quarantine Guidance** – December 14, 2020

CDPH updated quarantine guidance for those that were in close contact to a COVID-19 positive person. [Click here to read the Guidance.](#)

[Click here to see a full list of recent AFLs](#)



California Department of Social Services

The Community Care Licensing Division (CCLD) of the California Department of Social Services (CDSS) publishes Provider Information Notices (PINs) to communicate important license related information to CCLD-licensed providers. The local San Diego Adult and Senior Care Regional Office can be reached at (619) 767-2300 or CCLASCPSanDiegoRO@dss.ca.gov.

NEW! All Community Care Licensed Providers – December 21, 2020

PIN 20-29-CCLD announces a new helpline resource for providers to obtain information on infection prevention and control best practices. A CCLD clinician will be available M-F (excluding holidays) from 8:00 am – 5:00 pm to answer questions related to infection prevention and control. A voicemail system will be available to leave a message after business hours, on weekends, and on holidays. [Click here to read PIN 20-29-CCLD.](#)

NEW! All Licensed Adult and Senior Care Facilities – December 18, 2020

PIN 20-45-ASC informs CCLD licensed facilities that their staff may be eligible for a program that makes hotel rooms available if they are exposed to COVID-19 or test positive for COVID-19. Qualified facilities are Residential Care Facilities for the Elderly

and Adult Residential Care Facilities. Please note, due to the high demand from facilities, delays may occur in processing requests. Thank you for your patience.

[Click here to read PIN 20-45-ASC.](#)

All Residential Care Facilities for the Elderly- Continuing Care Contracts – December 1, 2020

PIN 20-43-ASC-CCR shares the recent Adult and Senior Care PIN 20-42-ASC which provides guidance on COVID-19 infection control recommendations for celebrations and outings for licensees and staff, residents, friends, and families. This PIN includes guidance for private gatherings, resident cohorting after returning to the facility, and group activities in facilities. Pages five and six include Continuing Care Retirement Community-specific information. [Click here to read PIN 20-43-ASC-CCR](#)

[Click here to browse the full list of recent PINs](#)



BinaxNOW Distribution Program

NEW! Access to the **Abbott BinaxNOW POC antigen tests** is being coordinated by the federal government and State through our local Medical Health Operational Area Coordinator program within the County of San Diego Medical Operations Center. Kits are now available in San Diego County for long-term care facilities. These point-of-care (POC) antigen diagnostic tests detect the presence of the SARS-CoV-2 virus and can provide results in less than 20 minutes. Antigen tests have been added to the COVID-19 testing arena to meet the growing demand to identify COVID-19 positive individuals.

If you are interested in receiving these test kits, note a few of the **following requirements** which are listed in the attachment in further detail:

- Obtain a Clinical Laboratory Improvement Amendments (CLIA) waiver
- Report test results to the County of San Diego
- Ensure adequate staffing and Personal Protective Equipment to administer tests

For more information on the BinaxNOW Distribution Program, **please see the attached PDF** titled “BinaxNOW Distribution Program 12 19 20 Final.2”

You may **request BinaxNOW kits** by emailing logs.testing.hhsa@sdcounty.ca.gov



Potential Safety Power Shutoff in San Diego County

NEW! The California State Warning Center received notification from San Diego Gas & Electric (SDGE) of a Potential Safety Power Shutoff (PSPS). **The proposed date and time for de-energization is 12/23/30 at 1200 hours (12:00 PM) to 12/24/20 1800 hours (6:00 PM).**

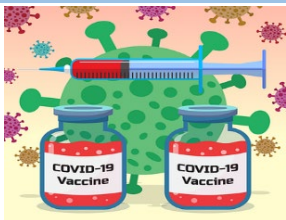
Extreme weather conditions that may cause or intensify a fire will lead to execution of a PSPS. Due to the possibility of an extended power shutoff to your facility, check generator fuel supplies, and/or plans for obtaining more fuel or evacuating if necessary.

If the PSPS program is in effect and causes the power to go out in your facility, this triggers an “unusual event” as defined in the Public Health and Medical Emergency Operations Manual and response protocol.

Report any outages related to the PSPS to the L&C District Office and to the local Medical and Health Operational Area Coordinator (MHOAC).

AFL 20-59 - Public Safety Power Shutoff Power Outage Reporting, reminds facilities that licensing regulations require facilities to report the unusual occurrence of a PSPS event to the California Department of Public Health, Center for Health Care Quality Licensing and Certification Program. AFL 20-59: <https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-20-59.aspx>

To register for updates to this PSPS event or for future events please contact **San Diego Gas & Electric-** <https://www.sdge.com/our-commitment-wildfire-safety> or call 1-800-411-7343



COVID-19 Testing and Vaccination Information

NEW! County of San Diego COVID-19 Vaccination Webpage

Stay informed about COVID-19 vaccination information by bookmarking the [County COVID-19 webpage](#). Information regarding how the COVID-19 vaccine works, the safety of the vaccine, the phases in which the vaccine will be administered, and much more can be found on this webpage.

NEW! County of San Diego COVID-19 Testing Sites

Free COVID-19 testing will continue to be offered by the County of San Diego throughout the holidays. [Click here for details regarding the holiday schedule](#). There will be fewer locations and shorter hours on certain days. For information on testing locations, or to make an appointment at a drive-up location, visit the [Testing in San Diego County webpage](#).

If your facility serves vulnerable residents with special needs, such as individuals with dementia, developmental disabilities, or residents who are non-ambulatory, a potential resource is to utilize mobile physician services for on-site COVID-19 testing.

You can also email us at COVID-LTC@sdcounty.ca.gov for other potential resources.

CDC Pharmacy Partnership for Long-Term Care Program

The Centers for Disease Control and Prevention's Pharmacy Partnership for Long-Term Care Program partners with **CVS and Walgreens pharmacies** to provide on-site no-cost COVID-19 vaccinations.

The California Department of Public Health is activating Part A of the CDC Pharmacy Partnership, in which teams from many local CVS and Walgreens pharmacies plan to immunize thousands of California's Skilled Nursing Facilities that are registered to participate. Immunization is scheduled to begin in the week of December 28 - January 3.

We do not have information on the schedule of immunization at specific facilities. Please watch your email for information from CVS or Walgreens with further information in scheduling your facility.

Part B of this program will address immunization at registered assisted living facilities and is anticipated to be activated in the near future.

For more information, please see the Pharmacy Partnership for Long-Term Care Program for COVID-19 Vaccination [FAQs](#). For specific questions, please contact eocevent494@cdc.gov.

More COVID-19 Vaccination Information:

For information from the CDC about **COVID-19 Vaccination Planning**, [click here](#).

To view the CDC PowerPoint "What Clinicians Need to Know About the Pfizer-BioNTech COVID-19 Vaccine", [click here](#).

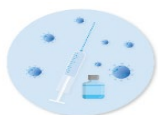


Free On-Site Flu Clinics
Champions for Health

Champions for Health, a County of San Diego mass vaccination flu provider, is looking for senior nursing facilities, adult residential facilities, single living occupancies, and more to **provide free flu shots on site**. They bring all the materials, vaccine, and San Diego Immunization Registry staff to enter vaccination data in real time. They can also provide medical volunteers to support in case your medical staff can't help with vaccinations. Preference will be given to locations in COVID-19 hot spots and if you serve a population that is high-risk for COVID-19.

Please contact Andrew.Gonzalez@ChampionsFH.org or text 213-550-9429.

You can also complete the clinic interest form [here](#). Please see attached flu clinic flyers.



Flu Vaccine Information

The influenza vaccine is available at doctors' offices and pharmacies throughout San Diego County and is covered by medical insurance. For **Flu Season 2020-2021 information**, check out the County of San Diego Immunization Program [influenza webpage](#) and find information on [Flu Vaccine Locations](#). For additional information, [click here](#) for the Centers for Disease Control and Prevention ways to protect your health this season.



COVID-19 Holiday Guidance Steps to Stay Healthy

To minimize the spread of COVID-19 and keep families safe during the upcoming holidays, the County of San Diego has issued guidance that outlines recommendations, what's not recommended, what's not allowed, and safer alternatives for traditional activities that can be high-risk for spreading viruses.

- **Celebrating Winter Holidays Guidance** ([PDF](#))

For more information on steps to stay safe during the entire holiday season. The holiday guidance is available in **8 languages**; visit the County of San Diego's Holidays and COVID-19 webpage [here](#).



Case Rates by Zip Code

The County of San Diego is working closely with federal and state agencies and the local healthcare community to monitor and test for the spread of COVID-19 virus in the region. To view an interactive COVID-19 case rates by ZIP code map, click [here](#).



Regional Stay at Home Order and Public Health Order

The Southern California intensive care unit bed capacity has dropped below 15%, requiring San Diego County to implement a [Regional Stay At Home Order](#) that prohibits gatherings of any size and closes operations in multiple sectors, including restaurants, bars, wineries and personal services. For additional information, visit the [County News Center](#).

The San Diego County **Public Health Order** has been updated, effective December 10, 2020.

[Read the latest order.](#)



REMINDER to check the County Triggers Dashboard for the Testing Positivity Rate

The frequency of routine testing of skilled nursing facility staff depends on the San Diego County Positivity Rate. Please click the link below to access the **COVID-19 Testing Positivity Rate**.

[View the current Positivity Rate here](#) (Item #10: Testing Positivity).



Upcoming Telebriefings



Thursday, January 14
at 2:00 pm

Telebriefing for Long-Term Care and Residential Care Facilities

WHEN: Beginning January 2021, the telebriefings will be held on the **2nd and 4th Thursdays** of the month from 2:00 – 3:00 PM.

More details coming soon. Please stay tuned.



To be determined

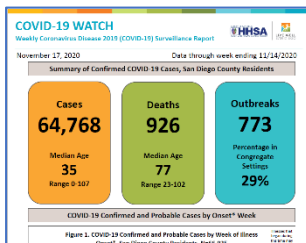
Telebriefing for Older Adult and Disability Service Providers

WHEN: January date and time to be determined

Click [here](#) to learn more about the telebriefing, [submit questions](#) before each telebriefing, and visit the **Older Adult and Disability Service Providers** sector support [webpage](#).



Ongoing Programs, Services, and Resources

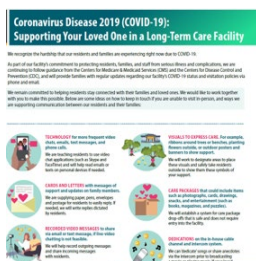


County of San Diego COVID-19 Dashboard and Weekly “COVID-19 Watch” Report

The County of San Diego publishes a weekly surveillance report on the coronavirus-sd.com website called “COVID-19 Watch”.

[Click here to review the report.](#)

Visualize and track data real time on the interactive web-based dashboard developed by the County of San Diego Epidemiology and Immunization Services Branch. [See the dashboard here.](#)



Supporting Your Loved One in a Long-Term Care Facility

Nursing homes and long-term care facilities can communicate actions the facility is taking to protect them and/or their loved ones, any visitor restrictions that are in place, and actions residents and families should take to protect themselves in the facility, emphasizing the importance of hand hygiene and source control. [Please click here to access this document.](#)



- [COVID-19 in Nursing Homes and Long-Term Care Facilities](#)
- [Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes](#)
- [Printable Algorithm](#) for considerations for testing asymptomatic and symptomatic residents or HCP.
- [Guidelines on Masks, How to Select, Wear, and Clean Your Mask](#)
- [Guidelines for Group Homes for Individuals with Disabilities](#)
- [Guidelines for Direct Service Providers of Individuals with Disabilities](#)
- [Considerations When Preparing for COVID-19 in Assisted Living Facilities](#)
- [Considerations for Memory Care Units in Long-term Care Facilities](#)

For general information about COVID-19 from the CDC, please visit www.cdc.gov/coronavirus.



211 San Diego

For health or testing related questions, contact your healthcare provider. For general questions about COVID-19, information about community

resources, or if you are uninsured, call **2-1-1 San Diego**. [Click here](#) for free COVID-19 testing information.



General COVID-19 Information from Federal and State Organizations

- [Centers for Disease Control and Prevention – COVID-19](#)
- [California Department of Public Health, Immunization Branch – COVID-19](#)
- [California Department of Social Services – COVID 19](#)



Recent Long-Term Care and Residential Care Sector Email Updates

- [December 16, 2020 Update](#)
- [December 10, 2020 Update](#)
- [December 3, 2020 Update](#)

[Click here to browse all past email updates.](#)



Stay Connected



For questions related to long-term care and residential care facilities, please email: COVID-LTC@sdcounty.ca.gov.



Get the latest information about what's happening across the county with COVID-19.



Text **COSD COVID-19** to **468-311**

to get text alert updates from the County of San Diego.



Health Alert

SARS-CoV-2 virus variant identified in the United Kingdom

December 22, 2020

Recently, a variant SARS-CoV-2 virus with multiple mutations in the spike protein (S) coding region has been identified in the United Kingdom and several European countries. The spike protein is responsible for viral adhesion to cells and this variant appears to bind more effectively to human ACE2 receptor, which could make it more infectious (i.e., better able to cause infection when it reaches a human host). The spike protein is also a major antigenic region for the human immune response. Information about this variant virus is available here:

<https://www.cdc.gov/coronavirus/2019-ncov/more/scientific-brief-emerging-variant.html>.

Information about the clinical and epidemiologic impacts of the mutations in this variant virus is very limited. At this time, there is no evidence that this variant is associated with increased disease severity or that COVID-19 vaccines will offer less protection against this variant. Studies are currently ongoing in the United Kingdom to assess the ability of antibody from vaccinated persons to neutralize the variant virus and results are expected soon.

Currently, this variant virus has not been identified in California or the United States. However, the California Department of Public Health (CDPH) requests that health care providers take several steps to help collect specimens for genetic sequencing to monitor for this and other variant virus strains.

Please collect and submit specimens for sequencing from individuals with COVID-19 who meet at least one the following criteria:

- Recent travel to the United Kingdom or Europe;
- Exposure to persons with recent travel to the United Kingdom or Europe;
- Marked differences in real-time RT-PCR viral target(s) cycle threshold (Ct) values (e.g., ORF1ab target Ct=27, N target Ct=26, and S target NOT DETECTED); or
- Possible re-infection (i.e. recurrence of symptoms with positive molecular testing or positive molecular testing 90 days or more after initial infection¹).

Specimens can be submitted to the CDPH Viral and Rickettsial Disease Laboratory (VRDL) for whole genome sequencing and analysis. Please email NovelVirus@cdph.ca.gov for assistance in both evaluation and specimen submission.

¹ For more information, see: <https://www.cdc.gov/coronavirus/2019-ncov/php/reinfection.html>



**California Department of Public Health
Center for Health Care Quality
AFC Skilled Nursing Facilities Infection Prevention Call
December 16 & 17, 2020**

The webinar recording, handouts and notes can be found at the Health Services Advisory Group (HSAG) registration website <https://www.hsag.com/cdph-ip-webinars> and the CDPH Skilled Nursing Facility Infection Prevention Education website: <https://www.cdph.ca.gov/Programs/CHCQ/Pages/SNFeducation.aspx>

The Wednesday & Thursday CDPH SNF IP calls are cancelled during the last two weeks of December. These calls will resume January 6 & 7, 2021. Please register at: <https://www.hsag.com/cdph-ip-webinars>

Please join the CDPH weekly Tuesday All Facilities Calls on December 22 & 29. Call in: 844.721.7239; Access code: 7993227. For questions over the holidays, please contact the CDPH HAI team at HAIPprogram@cdph.ca.gov.

The December 16th webinar presentation covered the following updates:

- Testing Taskforce Update
- COVID-19 Vaccine Update [CDPH Vaccine slides](#)

Testing Taskforce (TTF) Update

As of December 15, 2020, with data as of December 14, 2020:

- Number of new tests reported: **293,027** for a cumulative total of **27,845,066** of PCR tests
- 7-day positivity: **11.1%**
- 14-day positivity: **10.6% increase of 3.8% from prior 14 days**

<https://covid19.ca.gov/state-dashboard/>

<https://testing.covid19.ca.gov/>

Average test turnaround time (TAT) last week was 1.4 days with 87% < 2 days and 58% < 1 day

Given that testing volumes are going up across the state and country we wanted to let you know that California currently has the following in inventory, and it can be accessed through the MHOAC system through their LHJ

- Swabs 15.0 million
- Transport media 10.4 million
- BinaxNow Antigen test 2.1 million

In regard to the Valencia Branch Lab for access for testing processing, the TTF has developed a submission request form that will be available through the TTF website if you are interested in setting up a community site at your facility. Visit this website <https://testing.covid19.ca.gov> and click on the Valencia Branch Laboratory link.

Wednesday, December 16th Questions & Answers

Q: What is CDPH's position on the CDC 10-day and 7-day with a negative test for returning to work for Skilled Nursing Facility employees?

A: This is only for healthcare personnel during critical staffing shortages. We acknowledge that facilities may use crisis strategies for mitigating staffing shortages. CDPH recommends persons that reside in

congregate settings, continue to quarantine for 14 days in the absence of staffing shortages. We anticipate that this guidance will be put into more context for hospitals and nursing facilities in an AFL.

Q: Can family members bring in food, to the Yellow or Green zone, when the Facility has an exposure?

A: Gifts and food are acceptable. Visiting hasn't changed. The red and yellow restrictions still apply, but they can accept food and gifts.

Q: Can you please address how we dispose of vaccines in the unlikely event it is not useable?

A: The pharmacies coming in will take away any unused product. For LA County nursing homes, they will be trained from start to finish on vaccination handling.

Q: Can the 2 doses be administered >21 days apart?

A: CDC shared guidance on this. Vaccination on the second dose is recommended for Pfizer for 21 days. You can cut it short + or - 4 day window. There is no maximum number of days where you would need to start all over with vaccinations. Get the second dose as soon as they can. One dose is somewhat protective but second is the recommendation.

Q: Resident stayed in SNF less than 28 days. Who will give the 2nd dose?

A: There is a lot of layering of systems to let providers know who has been vaccinated. If the vaccination registry has a call reminder program, that could be helpful. On discharge, hopefully there will be more options where that second dose is available. We don't have a list just yet on where that second dose could happen.

Q: What recommendations do you have for staggering vaccinations for facilities which continue to be in the pharmacy partnership program? LA County has recommended staggering vaccinations to mitigate potential staffing shortages. Those working with CVS & Walgreens appear not to have that flexibility.

A: They are only able to provide 3 clinics over the course of 3 months. Healthcare staff should be vaccinated as soon as they are eligible. If staff have other options, they are encouraged to get the vaccine that way as well. Phase 1a is about getting the most people vaccinated as possible initially, but we know it takes time to get everyone vaccinated.

Q: Walgreens has said that they cannot schedule vaccination dates until the vaccine has been 'approved' by the state of CA. Has California approved the vaccine?

A: California has approved the Pfizer vaccine.

Q: Are there guidelines for those that decline the vaccine?

A: From an infection control standpoint, all preventive measures still need to be followed whether vaccinated or not. Employers can decide on their own policies. Be educated and informed, and encourage others to accept the vaccine.

Q: How shortly after a positive COVID test can one get the vaccine? Is it the same as with the influenza vaccine, which is after they have completed isolation?

A: Yes, if someone has active COVID, they need to have resolved symptoms before getting the vaccine.

Q: CDC/NHSN survey no longer asks for suspect cases. Will the CDPH daily survey eliminate this question for staff & residents? With the symptom list very long & our ability to clear very quickly with 2 tests, it is difficult to evaluate who CDPH would want included in this count.

A: Some of the data dictionary is federally required and some is additional that we have placed in there for CDPH. We'll get new information from the federal side to see what needs to be updated.

Q: Post Vaccination, what will be the guidelines to SNFs regarding isolations (Red, Yellow, Green, etc). Are residents who have been vaccinated returned to green or PUI units?

A: Cohorting should remain the same. Receiving either one or both vaccine doses should not determine whether residents are in "Green" or "Yellow" zones. Symptoms and test results should continue to be used as determining factors for cohorting.

Q: How can I find more information about CVS & Walgreens, and can I contact them with questions?

A: Here are the email addresses and websites for CVS & Walgreens.

CVS Information:

- Website: <https://www.omnicare.com/covid-19-vaccine-resource>
- Webinar: <https://cvsh-tv.qumucloud.com/view/B6DiTH0xfjc#/>
- Email: CovidVaccineClinicsLTCF@CVSHealth.com

Walgreens Information:

- Website: <https://www.walgreens.com/covidvaccine>
- Webinar: <https://wba.qumucloud.com/view/oDAT0v8obvH#/>
- Email: immunizeltc@walgreens.com

Thursday, December 17th Questions & Answers

Q: When will COVID-19 vaccine allocations be given to medical centers to treat high risk patients? We can foresee a scenario where SNF patients get their first dose at the SNF, and then are transferred to the hospital 21 days later when they are due for their second dose? My concern is that we will not be able to fulfill the second dose timely.

A: There will be future recommendations forthcoming. Consider why they are in the hospital if for acute reasons and if they are well enough to receive the vaccine. Inpatient vaccination is not yet in the recommendation so guidance will be forthcoming. There is no maximum time period for the second dose. If longer than 21 days, vaccinate at the next time available.

Q: Is there any information about continuing vaccination after the federal partnership for tier 1a? For example, Walgreens/CVS are vaccinating in January/February...can SNFs get Moderna in March/April 2021? Our SNF needs to continue vaccination for new patients and hires in the spring and we want to be sure that we can continue after the federal partnership.

A: The state is currently working with all major pharmacies, including Walgreens and CVS, to ensure stable supplies of vaccinations. In addition, the state is also working with wholesalers as well. The federal government is contracting with other pharmacies once the supply of vaccines is much greater. We recognize there is a gap in timing for SNF settings. The systems are being discussed to get continued vaccination.

Q: What is the possibility of getting false positive results in the antigen testing for COVID when one receives the vaccine?

A: The CDC has guidance on this. In the ACIP meeting slides and on their website, after a person is vaccinated, using the PCR and or antigen test will not be affected by the vaccine. The antibody test, however, could show a false positive.

Q: Will an email affirmation by a family for a SNF resident attached to a consent be ok?

A: This will need to be checked with the person doing vaccination. CVS and Walgreens are creating their own consent processes. You should refer to CVS or Walgreens for consent processes when they connect with your facility.

Q: Is there a vaccine information sheet (VIS) available for Moderna vaccine? If so where can we access it?

A: Moderna is still being reviewed and analyzed by the FDA. Once approved, that information will be released and made readily available to the public.

Q: If residents refuse the COVID-19 vaccine, can they remain in green zone?

A: Yes, they can remain in the green zone. We don't want to place an unexposed person in the yellow or red zones where there is a risk of exposure.

Q: Since we are a 12-hour hospital/SNF, do we need to mandate our part time staff to come in on their days off to get a second test done? Example: Does a staff member that only works on Monday and Tuesday need to come in on Thursday to get a second test?

A: Yes, they would need to come in two times a week. Testing on Monday and on Tuesday would not make sense, so they would need to come in an additional day later in the week to receive their second test. This is due to the CDPH and CMS requirement for two tests a week if your county positivity rate is >10%.

Q: Is it necessary to don and doff PPE for every patient in every room? For example, for an LVN to have a 90 second or so transaction with a patient to give medications, are they required to don and doff?

A: HCP can implement extended use of a respirator/face mask and face shield between residents when working with residents in the same cohort. If HCP touch the respirator/face shield, then they need to perform hand hygiene. Gowns are trickier and more problematic. We recommend avoiding reuse/extended use of gowns unless you have a supply crisis for gowns. Extended use of gowns is only appropriate in a cohort of residents with same diagnosis and no other MDROs. One strategy is to reserve gown use for areas where there is high resident contact. Med passing could be one activity where you would not need to use a gown. There is guidance on AFL 20-74 <https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-20-74.aspx>. See table for more guidance. [CDPH HAI Program COVID-19 PPE, Resident Placement/Movement, and Staffing Considerations by Resident Category](#). Remember to contact the MHOAC if your PPE is limited.

Q: Question regarding [AFL 20.74](#): New guidance came out recently that seems to contradict this AFL. Can the reduced quarantined period be applied in a SNF?

A: No, we don't recommend that for SNF residents. There is a consideration in the guidance that says per persons that reside or work in high risk settings such as a SNF that they should still quarantine for 14 days. HCP in SNF who have high risk exposure outside the facility, would generally observe a 14-day quarantine unless there is a staffing shortage that would cause a 7-day quarantine with a negative PCR test.

Q: As we vaccinate our residents, are there any recommendations on vaccinating short term residents? Any liability on the SNF side?

A: For the second dose, this will be available through clinics that will be receiving supply. For individuals going to the hospital, it is important to determine why they are going to the hospital and if giving a vaccine is appropriate. We will also follow up with additional information on this situation.

Q: What's the process for SNF residents to get Monoclonal Antibodies for Treatment of COVID-19?

A: We unfortunately don't have the right person on this call to answer this specific question. We did cover this information on our Tuesday call. We are still working on finalizing these testing resources and treatments and will continue to provide further updates going forward.

Q: [AFL 20-48](#) - Where can we find more information on alternative care sites?

A: We have Sleep Train in Sacramento, Fairview in Orange county and Porterville in Central Valley. There is one in Imperial, but this one is just for Imperial county individuals. In addition, each county may also be setting up and operating their own alternative care sites. Continue to work with your local public health to see what the surge plan is and what potential alternative sites might be available.

COVID-19 Diagnostic Antigen Test Distribution Program BinaxNOW™: Point-of-Care Test Kits

December 17, 2020



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COVID-19 Diagnostic Antigen Test Distribution Program

BinaxNOW: Point-of-Care Test Kits

Executive Summary

December 17, 2020

I. INTRODUCTION

COVID-19 Antigen Tests

COVID-19 antigen tests are point-of-care diagnostic tests that detect the presence of certain proteins on the surface of SARS-CoV-2 virus and can provide results within 15 minutes. Antigen tests have recently been added to the COVID-19 testing arena to meet the growing demand to quickly identify and isolate COVID-19 positive individuals and quarantine close contacts.

Although antigen tests tend to have lower sensitivity than current polymerase chain reaction (PCR) testing, when antigen tests are performed on symptomatic individuals within the FDA-authorized period for a given test, a positive antigen test closely correlates with a positive PCR test and likely represents evidence of COVID-19 disease. Data are emerging to show they can be effectively used for screening as well, particularly when used on a frequent basis.

These tests have been approved as Clinical Laboratory Improvement Amendments (CLIA) waived, point-of-care (POC) tests. Currently there are fewer than ten of these tests on the market with approval to use under Emergency Use Authorization (EUA) while others are working their way through the EUA process. Please see [here](#) for additional information and guidance on antigen testing for SARS-CoV-2 from Centers for Disease Control and Prevention (CDC).

Distributions of the Abbott BinaxNOW™ Antigen Test Kits

Access to the Abbott BinaxNOW™ antigen tests is currently being coordinated by the federal government. On September 28, 2020, the federal government announced the upcoming distribution of rapid BinaxNOW™ POC tests to states to expand testing capacity through the end of December 2020. The federal government has started distributing rapid BinaxNOW™ POC tests directly to facilities that manage high-risk populations such as Skilled Nursing facilities.

In order to ensure equitable distribution and testing access for all Californians, the initial allocation of the BinaxNOW™ POC tests from the federal government will be dispersed through the California Department of Public Health (CDPH) to counties throughout the state. Distribution to San Diego County will be via request to the [County's Medical and Health Operational Area Coordinator \(MHOAC\)](#) using the established Multi-Agency Coordination (MAC) process.

The County of San Diego (CoSD) has developed a distribution plan with input from internal and external partners, including the Laboratory Testing Task Force Antigen Testing Workgroup (Workgroup), and incorporates *current* California Testing Task Force guidance for distribution of these testing kits. The following packet includes instructions, checklists, and materials that will need to be completed to receive kits allotted to our County.

II. BINAXNOW™ POINT-OF-CARE TESTING PROGRAM: REQUIREMENTS AND ATTESTATION

Implementation for any eligible facility includes consideration of the following topics:

- Indications for use,
- Test site obligations,
- Testing requirements,
- Clinical laboratory improvement amendment (CLIA) certificate of waiver or other CLIA certification,
- Test inventory and personal protective equipment (PPE),
- Training requirements,
- Use of BinaxNow™ tests and consent,
- Evaluating the results of testing and possible confirmatory testing; disposal of testing materials, and
- Documentation and reporting of test results.

III. SETTINGS RECOMMENDED FOR BINAXNOW ANTIGEN TESTING

CDPH and the California Laboratory Testing Task Force initially recommended use of these test kits in symptomatic individuals in the following settings, including:

- Hospital emergency departments, prioritizing public safety net hospitals that provide healthcare to individuals regardless of insurance or ability to pay such as county hospitals which predominantly care for those disproportionately impacted by COVID-19 and/or have limited access due geographic or socioeconomic barriers.
- Urgent care clinics associated with federally qualified health centers (FQHCs), Community Health Centers, Tribal Clinics, Migrant Health Centers, Health Care for the Homeless, Health Centers for Residents of Public Housing, and Rural Health Clinics.
- Locations associated with COVID-19 outbreaks.
- Congregate settings (e.g., correctional facilities, homeless shelters, SNFs/ALFs).
- Facilities with frontline healthcare workers and first responders with inadequate time (<48 hours) between weekly shifts to await PCR test results.

As per the California Laboratory Testing Task Force, above uses for antigen testing may be liberalized when PCR testing is limited. *Please note that since the initial recommendation, [updated CDC guidelines](#) also discuss the use of antigen tests for screening in high-risk congregate as well as high, moderate, and low pretest probability settings.* Additionally, CDPH will reassess and update the recommended uses as more data becomes available in the future.

The San Diego County Laboratory Testing Task Force Antigen Testing Workgroup assessed the local utility of the BinaxNOW™ test kit. In addition to the settings recommended by CDPH above, it determined that using these kits for testing **asymptomatic** individuals in the above settings, as well as for asymptomatic individuals in school settings, were appropriate uses of these tests.¹

Locally, the County has engaged many of the entities recommended by the State to utilize the BinaxNOW™ testing kit. Such entities include federally qualified health centers, hospital healthcare systems, school, and Substance Use Disorder Treatment facilities. This BinaxNOW™ point-of-care testing program requirements and attestation document will be pushed out to all sectors currently engaged with COVID-19 pandemic response. Testing kits will be available from the CDPH at least spring 2021.

IV. SUMMARY

Antigen testing is another tool to use as part of a comprehensive approach to prevent, identify, and mitigate the impact of COVID-19. Organizations that can meet the standards set by CDPH and the CA state testing taskforce, including reporting positive and non-positive results, may request BinaxNOW™ testing kits.

¹ COVID-19 Antigen Testing Workgroup White Paper: Antigen Testing in Schools

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San Diego County
COVID-19 Diagnostic Antigen Test Distribution Program
BinaxNOW™: Point-of-Care Test Kits
Updated December 17, 2020

I. INTRODUCTION

A. Testing for Coronavirus

[Testing for SARS-CoV-2](#) is one component of a comprehensive COVID-19 response strategy. It also includes promoting personal behaviors that reduce spread, such as social distancing, hand hygiene, and use of facial coverings; conducting symptom screening and exposure checks; performing case investigations and contact tracing; adhering to isolation and quarantine guidelines; utilizing current treatment modalities; and, when available, obtaining COVID-19 vaccination.

Since the beginning of the COVID-19 pandemic, diagnosis has used the molecular, real time reverse transcription–polymerase chain reaction (RT-PCR) tests that detect the virus’s genetic material. More recently, another diagnostic test has become available – antigen tests that detect specific proteins from the virus.

B. COVID-19 Antigen Tests

COVID-19 antigen tests are point-of-care diagnostic tests that detect the presence of certain proteins on the surface of SARS-CoV-2 virus and can provide results in less than 20 minutes. Antigen tests have recently been added to the COVID-19 testing arena to meet the growing demand to quickly identify and isolate COVID-19 positive individuals and quarantine close contacts.

Although antigen tests tend to have lower sensitivity than current RT-PCR testing, when antigen tests are performed on symptomatic individuals within the FDA-authorized period for a given test, a positive antigen test closely correlates with a positive PCR test and likely represents evidence of COVID-19 disease. Data are emerging to show that the antigen test can be effectively used for screening, as well, particularly when used on a frequent basis.

These tests have been classified as Clinical Laboratory Improvement Amendments (CLIA) waived, point-of-care tests. Currently fewer than ten of these tests on the market have received Food and Drug Administration (FDA) Emergency Use Authorization (EUA), while others are working their way through the EUA process.

The federal government has distributed Abbott BinaxNOW SARS-CoV-2 antigen test kits to states. These kits can be requested from the California Department of Public Health (CDPH) by healthcare and other organizations via their local [County Medical Health Operational Area Commander \(MHOAC\) process](#).

C. Distribution of the Abbott BinaxNOW™ Antigen Test Kits

Access to the Abbott BinaxNOW™ antigen tests is currently being coordinated by the federal government. On September 28, 2020, the federal government announced the upcoming distribution of rapid BinaxNOW™ POC tests to states to expand testing capacity through the end of December 2020. The federal government has started distributing rapid BinaxNOW™ POC tests directly to facilities that manage high-risk populations such as Skilled Nursing facilities here in San Diego County.

In order to ensure equitable distribution and testing access for all Californians, the initial allocation of the BinaxNOW™ POC tests from the federal government will be dispersed through the California Department of Public Health (CDPH) to counties throughout the state. Distribution to San Diego County will be via request to the County's Medical and Health Operational Area Coordinator (MHOAC) using the established Multi-Agency Coordination (MAC) process.

The CoSD has developed a distribution plan with input from internal and external partners, including the Laboratory Testing Task Force Antigen Testing Workgroup, and incorporates *current* California Testing Task Force guidance for distribution of these testing kits. The following packet includes instructions, checklists, and materials that will need to be completed to receive kits allotted to our County.

D. Purpose of This Document

This document provides information about the Abbott BinaxNOW™ antigen test kits and requirements organizations must meet and attest to when requesting kits from the County. *Please note that requirements may change as the state requirements are updated.* Additional information about antigen testing is provided by the [Centers for Disease Control and Prevention \(CDC\)](https://www.cdc.gov).

II. BINAXNOW™ POINT-OF-CARE TESTING PROGRAM: REQUIREMENTS AND ATTESTATION

A. Indications for Use

The [Abbott](#) BinaxNOW™ [rapid antigen test](#) is a minimally invasive, anterior nasal swab test intended for use in Point-of-Care settings for qualitative detection of protein antigen from SARS CoV-2 in individuals suspected of COVID-19 within the first seven days of symptom onset. This U.S. Food and Drug Administration (FDA) [authorized](#) diagnostic test consists of a swab, test card, and reagent, does not require other instrumentation, and yields a result in 15 minutes for the presence of SARS-CoV-2 in the sample. The test must be ordered by a medical provider and be administered by a trained individual. BinaxNOW™ antigen tests are currently authorized for use in **symptomatic** individuals within 1 week of symptom onset. For technical usage questions about the BinaxNOW™ test, please contact Abbott technical support directly at ts.scr@abbott.com or 1-800-257-9525.

CDPH and the California Laboratory Testing Task Force currently recommend use of these test kits in

symptomatic individuals in the following settings that include:

- Hospital emergency departments, prioritizing public safety net hospitals that provide healthcare to individuals regardless of insurance or ability to pay such as county hospitals which predominantly care for those disproportionately impacted by COVID-19 and/or have limited access due to geographic or socioeconomic barriers.
- Urgent care clinics associated with FQHCs, Community Health Centers, Tribal Clinics, Migrant Health Centers, Health Care for the Homeless, Health Centers for Residents of Public Housing, and Rural Health Clinics.
- Locations associated with COVID-19 outbreaks.
- Congregate settings (e.g., correctional facilities, homeless shelters, SNFs/ALFs).
- Facilities with frontline healthcare workers and first responders with inadequate time (<48 hours) between weekly shifts to await PCR test results.

As per the California Laboratory Testing Task Force, above uses for antigen testing may be liberalized when PCR testing is limited. *Please note that since the initial recommendation, [updated CDC guidelines](#) also discuss the use of antigen tests for screening in high-risk congregate as well as high, moderate, and low pretest probability settings.* Additionally, CDPH will reassess and update the recommended uses as more data becomes available in the future.

The San Diego County Laboratory Testing Task Force Antigen Testing Workgroup assessed the local utility of the BinaxNOW™ test kit. In addition to the settings recommended by CDPH above, it determined that using these kits for testing **asymptomatic** individuals in the above settings, as well as for asymptomatic individuals in school settings, were appropriate uses of these tests.²

B. Test Site Obligations

Health care and other facilities that wish to receive BinaxNOW tests to administer at their Point-of-Care site must first complete and submit an attached application (*See **Appendix A - Organization Checklist and Attestation for BinaxNOW™ Antigen Test Kits and Appendix B for Quick Reference Resources***).

The application and attestation require the following information:

- Organization name
- Primary and secondary points of contact
- Testing address(s), including clinic and building name(s)
- Number of staff members and number of patients/guests/residents per week
- Number of tests desired in multiples of 40 (40 tests per box)
- Shipping address for receiving the test kits
- Clinical Laboratory Improvement Amendments (CLIA) Number of Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation (Note that the facility can also work

² COVID-19 Antigen Testing Workgroup White Paper: Antigen Testing in Schools

with a laboratory or medical institution that has an existing CLIA certificate)

- First and last names of all trained individuals administering the tests and their titles/roles (prior to receiving kits, training includes watching the training videos and understanding facility policy and procedures/protocol).
- Policy and Procedures or protocols in place that details antigen testing protocols (can be a separate procedure or incorporated into existing testing procedures). Details should include quality assurance measures, storage, proper disposal, training, organizational points of contact, confirmatory PCR/NAAT testing plan/process for those symptomatic who test negative, process for reporting all results to Public Health Services in a timely manner, and next steps for individuals who test positive (i.e., if symptomatic, treat as probable case and isolate and if asymptomatic, have plan for confirmatory testing with PCR).

The CoSD will notify the facility when their application is approved. **For questions about the online application process, please email LOGS.TESTING.HHSA@sdcounty.ca.gov.**

C. Testing Requirements

To participate, all facilities must agree to meet the following conditions:

1. *PRIOR to Using BinaxNOW™ Tests*

- The facility has or [obtains](#) a CLIA registration that applies to these POC tests. Facilities may also partner with labs that currently has a CLIA certificate. Facilities need to visit the [CDPH Laboratory Field Services page](#) to apply for CLIA registration. Questions should be directed towards CDPH by calling 510-620-3800 or emailing LFSCC@cdph.ca.gov.
- Testing personnel will complete the required training as outlined in this guidance document prior to administering any BinaxNOW™ tests.
- The facility can receive the tests in one central location and potentially store the maximum number of tests requested until their expiration date.
- Facilities not already reporting other test results to epidemiology must establish a secure test results reporting process with the County Public Health Services Epidemiology Data Reporting Unit.
- The facility has a process in-place for disposal of medical waste created through the testing process.
- The facility develops a policy and procedure or protocol (or incorporate into existing protocols). Details should at the least quality assurance measures, cover storage, training, organizational points of contact, confirmatory PCR/NAAT testing plan/process for those symptomatic who test negative, process for reporting all results to Public Health Services in a timely manner, and next steps for individuals who test positive (i.e., if symptomatic, treat as probable case and isolate and if asymptomatic, have plan for confirmatory testing with

PCR).

2. *ONGOING BinaxNOW Testing Program Requirements*

- Testing personnel will adhere to the written Instructions for Use (IFU) provided by the manufacturer in the test package insert.
- The facility will ensure that CoSD Public Health has up-to-date information on personnel administering tests and testing locations.
- The facility will abide by the medical waste disposal criteria.
- The facility will have all individuals being tested, or his/her parent/guardian, sign an authorization for testing
- Test sites must submit all required data elements to CoSD Public Health in a timely manner as required.
- Test sites must retain documentation related to this testing program for period needed by organization's retention policies.

D. Waiver to Perform Laboratory Testing

The BinaxNOW Emergency Use Authorization (EUA) supports testing in point-of-care settings operating under a Clinical Laboratory Improvement Amendment (CLIA) Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation. Any site that performs laboratory testing must follow applicable regulatory requirements including federal, state, and local mandates for testing, as well as requirements for the safety and confidentiality of personal information. Use of this authorized test is limited to CLIA-certified laboratories. Questions about CLIA and applying for a CLIA certificate should be directed towards [CDPH Laboratory Field Services](#).

E. Test Inventory

1. *Test Inventory*

The CoSD's Emergency Medical Services/Public Health Preparedness and Response Medical Operations Center (MOC) is receiving incremental shipments of the BinaxNOW test kits through the MHOAC process. Facilities that choose to participate in the testing program will receive shipments of tests as requested through the application process if they so choose. The FACILITY must select a centralized location for receipt of the test kits. Test kits, packed 40 in a box, must be stored at 35.6° to 86°F and used by the expiration date listed on the packaging. Facilities must have the capacity to store the maximum number of tests requested.

F. Training Requirements

It is very important that testing staff administer the test correctly, to assure the highest confidence in the test results. The [BinaxNOW test training videos](#), produced by the manufacturer, provides a

detailed step-by-step guide to the test process. All testing staff must watch the overview video and modules one through four before performing tests on individuals. Training should be documented, and test kits will not be sent until confirmation of training completion is provided.

G. Use of BinaxNOW Tests and Consent

The Emergency Use Authorization for the Abbott BinaxNOW antigen test is for testing of [symptomatic](#) individuals within seven days of symptom onset. However, the test has been used “off-label” to screen asymptomatic individuals.

1. Point-of-Care Requirements

When individuals are suspected to have COVID- 19, they should be isolated from others. Trained individuals should administer this test in a space which should:

- Have facilities and/or products for proper hand hygiene (e.g., alcohol-based hand cleanser).
- Have appropriate waste disposal within arm’s length from the patient.

2. Materials Needed

Test administration requires the following resources:

- PPE for the health professional using contact and droplet precautions. Recommended PPE include gown, surgical mask, protective eyewear, and gloves, as well as hand hygiene products. Facilities can request the PPE necessary to administer these tests safely from the MOC.
- BinaxNOW Ag test kit.
- Copy of consent (parental or staff).
- [Patient educational materials to provide information about the test and interpreting results.](#)
- Waste bags for discarding used testing materials and PPE.

3. Consent for Testing

Test administrators should obtain written consent for anyone they test. For those under age 12, a parent or guardian should provide written consent.

4. Records Retention Policy

Participating Facilities should maintain record of signed consent forms as long as their policies require. For questions obtaining consent, the FACILITY should consult their legal counsel.

H. Evaluating the Results of Rapid Antigen Testing

1. Test Results

Health professionals administering the BinaxNOW™ tests should consult the [BinaxNOW](#)

[COVID-19 Ag Care Procedure Card](#) for determining the test results. Rapid antigen tests perform best when the person is tested in the early stages of infection with SARS-CoV-2 when viral load is generally highest. A positive test is considered probable and is diagnostic for COVID-19 in a symptomatic individual. In an asymptomatic individual, a positive result needs confirmatory PCR testing.

2. Actions Taken in Response to Test Results

Positive Test Result

People testing positive shall be instructed on [isolation requirements](#).

Those positive by antigen tests are classified as probable cases. Symptomatic individuals undergoing diagnostic testing who test positive do not need follow up or confirmatory testing. Asymptomatic individuals undergoing testing for screening purposes who test positive will need confirmatory or follow up PCR testing as soon as possible and preferably within 48 hours.

Negative Test Results

- Symptomatic individuals with negative test results, but who are showing possible COVID-19 symptoms, should be encouraged to follow-up with their health care provider to consider other diagnosis options as well as confirmatory PCR testing.
- Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.
- Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.
- Currently CDPH [states](#) that negative results may need to be confirmed with PCR.

For technical usage questions about the BinaxNOW™ test, contact Abbott directly at ts.scr@abbott.com or 1-800-257-9525.

I. Disposal of Testing Materials

1. MEDICAL SOLID WASTE

Per [CDPH guidance](#), test packaging and PPE that is not contaminated with COVID-19 may be considered “solid waste” and disposed to municipal trash. San Diego County Code defines “medical solid waste” as solid waste of obvious medical origin. Although it is not regulated medical waste; it could be perceived to be so by the general public. Some examples of medical solid waste are empty specimen containers, bandages, dressings containing non-liquid blood, surgical gloves, decontaminated medical waste, etc.

Out of an abundance of caution, these items should be placed in a lined container. Prior to disposal, the bag should be tightly closed off before being placed in the solid waste bin for pickup. In San Diego

County, medical solid waste must be stored in an area secured as to deny access to unauthorized persons, animals, wind, rain, insects, and rodents prior to disposal. If medical solid waste is placed in a trash receptacle or compactor which is accessible to unauthorized persons, it must be locked to prevent access to the contents by anyone other than authorized persons or refuse collection personnel. More stringent security requirements were established because waste of obvious medical origin is perceived as high risk and therefore a cause for concern by the general public.

If it is not possible to arrange for a lockable trash dumpster at the facility, It is recommended that medical solid waste be disposed of in black or opaque trash bags and kept in a locked room, closet, or cabinet inside the building until just before pick up to limit the amount of time that an unauthorized person has access to this waste.

Practice proper hygiene by thoroughly cleaning your hands with soap and water for 20 seconds (preferred) or alcohol-based hand sanitizer immediately after handling these items.

2. MEDICAL WASTE - BIOHAZARDOUS

Per [CDPH Novel Coronavirus Disease 2019 \(COVID-19\) Medical Waste Management - Interim Guidelines](#), waste from COVID-19 or potential COVID-19 patients (i.e., test kits from individuals who have positive antigen testing results) must be handled as standard regulated medical waste (RMW). This includes used swabs and used test components. These items must be placed in a red biohazard bag that certified to meet the ASTM D1709 dart drop test and kept in a properly marked biohazard container with a lid. Per San Diego County Code, all biohazard bags must also be labeled with the generator name, address, and phone number. If the integrity of the primary bag is compromised in any way (e.g., punctures, leaks, tears), a compliant secondary bag must be used.

When the biohazard bag is ready for transport offsite, it must be tied off and placed into a USDOT-approved container lined with a biohazard bag that is ASTM D1709 and ASTM D1922 certified. Refer to Hazardous Materials Division's guidance document for [regulated storage time limits and requirements](#). Generally, facilities generating more than 20 pounds of biohazardous waste per month are required to dispose of biohazardous waste within 7 days, or within 90 days if frozen. Refer to the [Medical Waste Management Act](#) for additional California statutes.

3. MEDICAL WASTE – STORAGE, PERMITTING, AND DISPOSAL

All medical wastes requiring storage must be kept in properly marked, leak-proof, puncture-resistant containers with tightly fitted lids. The storage area should be well ventilated and be inaccessible to pests and unauthorized persons and posted with required warning signs. Any facility that generates regulated medical wastes must be [permitted or registered with the County of San Diego Hazardous Materials Division](#).

Note: Additional information on biohazardous and medical waste disposal can be found at the

Department of Environmental Health's [Medical Waste website](#). Additional questions can be directed to the Department of Environmental Health [Hazardous Materials Duty Desk](#) at (858) 505-6880 Monday through Friday, from 8 am to 5 pm.

J. Documentation and Reporting of BinaxNOW Test Results

By administering BinaxNOW tests, a facility is acting as a laboratory. Laboratories are required to submit all COVID-19 test results (positives and non-positives) for tests performed in their facility to the CoSD. The facility is also acting as the provider. Providers are required to submit case reports to CoSD Public Health.

The information to be reported must include the necessary lab result details and the details about the patient. Required data fields include facility information, patient demographics, lab results (both positive and negative) and basic information about symptoms.

A facility has a few options of how they report to the County's Epidemiology Unit. ***Facilities who do not have already established reporting processes must reach out to the Epidemiology Data Unit at Epi-CDReporting.HHSA@sdcounty.ca.gov to establish a reporting mechanism.*** This includes the following options or how to report:

1. An electronic line list through a specific formatted file format and submitted to the state's lab reporting system known as the California COVID-19 Reporting System (CCRS). This would be a comma separated value (CSV) file format and submitted via Secure File Transfer Protocol (SFTP). This option is best for higher volume facilities.
2. Manual entry into the County's web-based laboratory reporting module. This option is best for lower volume facilities.

NOTE: Please see ***Appendix B for Quick Reference Resources.***

III. SETTINGS RECOMMENDED FOR BINAXNOW ANTIGEN TESTING

CDPH and the California Laboratory Testing Task Force initially recommended use of these test kits in symptomatic individuals in the following settings:

- Hospital emergency departments, prioritizing public safety net hospitals that provide healthcare to individuals regardless of insurance or ability to pay, such as county hospitals which predominantly care for those disproportionately impacted by COVID-19 and/or have limited access due geographic or socioeconomic barriers.

- Urgent care clinics associated with FQHCs, Community Health Centers, Tribal Clinics, Migrant Health Centers, Health Care for the Homeless, Health Centers for Residents of Public Housing, and Rural Health Clinics.
- Settings associated with COVID-19 outbreaks.
- Congregate settings (e.g., correctional facilities, homeless shelters, SNFs/ALFs).
- Facilities with frontline healthcare workers and first responders with inadequate time (<48 hours) between weekly shifts to await PCR test results.

As per the California Laboratory Testing Task Force, above uses for antigen testing may be liberalized when PCR testing is limited. *Please note that since the initial recommendation, [updated CDC guidelines](#) also discuss the use of antigen tests for screening in high-risk congregate as well as high, moderate, and low pretest probability settings.* Additionally, CDPH will reassess and update the recommended uses as more data becomes available in the future.

The San Diego County Laboratory Testing Task Force Antigen Testing Workgroup assessed the local utility of the BinaxNOW™ test kit. In addition to the settings recommended by CDPH above, it determined that using these kits for testing **asymptomatic** individuals in the above settings, as well as for asymptomatic individuals in school settings, were appropriate uses of these tests.³

Locally, the County has engaged many of the entities recommended by the State to utilize the BinaxNOW™ testing kit. Such entities include:

- FQHCs,
- hospital healthcare systems,
- school, and
- substance use disorder treatment facilities.

This BinaxNOW™ point-of-care testing program requirements and attestation document will be pushed out to all sectors currently engaged with COVID-19 pandemic response. Testing kits will be available from the CDPH at least spring 2021.

IV. SUMMARY

Antigen testing is another tool to use as part of a comprehensive approach to prevent, identify, and mitigate the impact of COVID-19. Organizations that can meet the standards set by CDPH and the CA state testing taskforce and can report results can request BinaxNOW™ kits.

³ COVID-19 Antigen Testing Workgroup White Paper: Antigen Testing in Schools

V. APPENDICES

- **Appendix A – Organization Checklist and Attestation for BinaxNOW™ Antigen Test Kits**
- **Appendix B – Quick Reference Resources**

Appendix A – Organization Checklist and Attestation for BinaxNOW™ Antigen Test Kits

- ✓ Date
- ✓ Organization name:
- ✓ Primary point of contact (name, phone number, and email):
- ✓ Secondary point of contact (name, phone number, and email):
- ✓ Number of tests desired in multiples of 40 (40 tests per box):
- ✓ Testing address(s), including clinic and building name(s):
- ✓ Shipping address for receiving the test kits
- ✓ Intended audience and estimate re: numbers of intended audience:
 - Number of staff members (if an intended audience):
 - Number of patients/guests/residents per week (if an intended audience):
- ✓ **Attached** copy of current Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation (Note that the facility can also work with a laboratory that has an existing CLIA certificate).
- ✓ First and last names of all **trained** individuals who will be administering the tests and their titles/roles (prior to receiving kits, training includes watching the training videos and understanding facility policy and procedures/protocol).
- ✓ **Established** reporting process with [Epidemiology Data Reporting Unit](#).
- ✓ Policy and Procedures or protocols in place that details antigen testing protocols (can be a separate procedure or incorporated into existing testing procedures). Details should at the least cover storage, training, organizational points of contact, confirmatory PCR/NAAT testing plan/process for those symptomatic who test negative, process for reporting all results to Public Health Services in a timely manner, and next steps for individuals who test positive (i.e., isolation).

I certify, on behalf of my organization, that my organization has met the above criteria and will report all positive and non-positive results to Public Health Services.

Print Name: _____

Title: _____

Signature and Date: _____

Please return completed forms to: LOGS.TESTING.HHSA@sdcounty.ca.gov

Appendix B – Quick Reference Resources

| Topic | Name | Contact Information |
|---|--|--|
| Application, Test Allotment and Shipments | CoSD MOC | LOGS.TESTING.HHSA@sdcounty.ca.gov |
| Electronic Reporting of Test Results | CoSD PUBLIC HEALTH Electronic Reporting On-boarding Team | Epi-CDReporting.HHSA@sdcounty.ca.gov |
| CLIA related questions | CDPH Laboratory Field Services | Call 510-620-3800 or LFSCC@cdph.ca.gov |
| Infectious Waste Disposal | Department of Environmental Health | Hazardous Materials Duty Desk at (858) 505-6880 Monday through Friday, from 8 am to 5 pm. |
| Training | Abbott (Manufacturer) | ts.scr@abbott.com or call 1-800-257-9525. Training videos can be found here . |

[Helpful Documents for the BinaxNOW COVID-19 Test Kit](#)

Available materials include:

BinaxNOW COVID-19 Ag Healthcare Provider Fact Sheet (English)

BinaxNOW COVID-19 Ag Patient Fact Sheet (English and Spanish)

BinaxNOW COVID-19 Ag Procedure Card (English)

BinaxNOW COVID-19 Ag Card Package Insert (English)

