



CORONAVIRUS
DISEASE 2019

(COVID-19)

WEEKLY UPDATE

LONG-TERM CARE AND RESIDENTIAL CARE FACILITIES

Wednesday, December 30, 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**:

- California Health Alert Network San Diego, **Health Advisory Update #20**: SARS-CoV-2 Virus Variant Identified in the United Kingdom; Providers are requested to *immediately* contact the County of San Diego Public Health Epidemiology Unit at (619) 692-8499 or (858) 565-5255 during afterhours, weekends, or holidays) about any individuals with confirmed COVID-19 who meet certain criteria (December 28, 2020)
- All Facilities Letter (AFL) regarding California Crisis Care Continuum Guidelines: Implementing During the Surge of COVID-19 Cases (**AFL 20-91**)
- Provider Information Notice (PIN) to all Adult and Senior Care licensees regarding a COVID-19 Mitigation Plan Report and training (**PIN 20-48-ASC**)
- PIN announcing a notice of staffing opportunities on the Employment Development Departments' CalJOBS Website (**PIN 20-30-CCLD**)
- PIN regarding updated guidance related to Community Care Licensing Division's oversight role and enforcement of COVID-19 health and safety guidelines in Adult and Senior Care facilities (**PIN 20-46-ASC**)
- PIN providing guidance on preventing social isolation while practicing physical distancing (**PIN 20-47-ASC**)
- Updated information on the **BinaxNOW Point-of-Care Testing Kits ordering process**
- Updated County of San Diego **Quarantine and Isolation** Public Health Orders

- Updated extended **Regional Stay-at-Home Order**
- Updated County of San Diego **COVID-19 vaccine webpage and CDC resources**
- **Reminder: Save-the-Date** for the next Long-Term Care and Residential Care Facilities telebriefing on Thursday, January 14, 2021, 2:00 – 3:00 pm. These telebriefings will now be held on the 2nd and 4th Thursdays of the month, 2:00 – 3:00 pm beginning January 2021.

As a reminder, if you have a positive COVID-19 case at your facility, please report it by calling the County of San Diego Public Health Epidemiology Unit 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 new year!



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! Notice to General Acute Care Hospitals: **AFL 20-91** – December 28, 2020

This AFL reminds facilities of the need to develop and implement Crisis Care Continuum Guidelines, as needed, in response to the current surge in COVID-19 cases. This document provides resources to assist in implementing the continuum of crisis care, including CDPH's [California Crisis Care Continuum Guidelines](#) and [Crisis Care Guidelines Pre-Implementation Checklist](#). This document also outlines new expectations for facilities regarding the crisis care continuum during this surge. [Click here to read AFL 20-91.](#)

NEW! **CAHAN San Diego Health Advisory #20:** SARS-CoV-2 Virus Variant Identified in the United Kingdom – December 28, 2020

This CAHAN San Diego Health Advisory includes information from the California Department of Public Health regarding a new SARS-CoV-2 virus variant identified in the United Kingdom (CDPH Health Alert, December 22, 2020). **Providers are requested to**

immediately contact the County of San Diego Public Health Epidemiology Unit at (619) 692-8499 or (858) 565-5255 during afterhours, weekends, or holidays) about any individuals with confirmed COVID-19 who meet 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 infection).

County Epidemiology and the Public Health Laboratory will work with the provider to have patient specimens collected from the patient and appropriate forms submitted for whole genome sequencing and analysis.

Please see attached PDF titled “CAHAN_SanDiego_12.28.2020”

[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 Adult and Senior Care Program Licensees – December 24, 2020

PIN 20-48-ASC announces a requirement for licensees of Adult and Senior Care facilities to submit a plan for Epidemic Outbreaks, specific to COVID-19 (“**Mitigation Plan Report**”) by **January 24, 2021**. This PIN also indicates the required components for a COVID-19 Mitigation Plan Report; a COVID-19 Mitigation Plan Report template; training resources; and outlines enforcement actions. [Click here to read PIN 20-48-ASC.](#)

NEW! All Adult and Senior Care Program Licensees, Adult and Senior Care Certified Administrators, Child Care Licensees and Providers, Children’s Residential Program Licensees and Providers, and Home Care Organization Licensees and Home Care Aides – December 23, 2020

PIN 20-30-CCLD provides guidance and assistance to CCL providers and caregivers seeking additional **staffing or caregiving employment opportunities**. Due to an

increase in staffing needs, CDSS encourages and invites all CCL facilities and organizations to register and create an account to view available job seekers with EDD CalJOBS. [Click here to read PIN 20-30-CCLD.](#)

NEW! All Adult and Senior Care Program Licensees – December 23, 2020

PIN 20-46-ASC provides updated guidance to Adult and Senior Care licensees related to the CDSS Community Care Licensing Division's **oversight role and enforcement** of COVID-19 health and safety guidelines. [Click here to read PIN 20-46-ASC.](#)

NEW! All Adult and Senior Care Program Residential Licensees – December 22, 2020

PIN 20-47-ASC provides guidance to Adult and Senior Care licensees on **preventing social isolation** and the importance of keeping residents socially engaged, even when following COVID-19 physical distancing guidelines. [Click here to read PIN 20-47-ASC.](#)

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.](#)

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

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



County of San Diego COVID-19 Diagnostic Antigen Test BinaxNOW Distribution Program

Updated! 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 local program within the County of San Diego Medical Operations Center. Kits are now available

in San Diego County for approved health care partners. 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 (and attach) a Clinical Laboratory Improvement Amendments (CLIA) waiver
- Read and acknowledge responsibilities in the attached BinaxNOW Distribution Program
- Complete and sign the Appendix A – Organizational Checklist and Attestation and Staffing List for the BinaxNOW Antigen Test Kits
 - Email completed and signed PDF Checklist, Attestation AND CLIA Waiver to: LOGS.TESTING.HHSA@sdcounty.ca.gov
 - Incomplete forms will delay your delivery
 - Please allow for a minimum of 48 hours for process and 2-3 days for delivery

Please direct program questions to the relevant point of contact below:

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)

For more information on the BinaxNOW Distribution Program, **please see the attached PDFs** titled “BinaxNOW Distribution Program 12 19 20 Final.2” and “BinaxNOW-Attestation and Trained Staff Table REQUIRED”



County of San Diego Updated Orders of the Health Officer Isolation and Quarantine

Updated! County of San Diego Order of the Health Officer (**Isolation of All Persons with or Likely to have COVID-19**), 12/24/2020. Click [here](#) to read more.

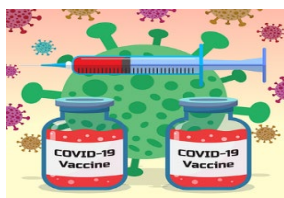
Updated! County of San Diego Order of the Health Officer (**Quarantine of Persons Exposed to COVID-19**), 12/24/2020. Click [here](#) to read more.

The **San Diego County Public Health Order**, effective December 10, 2020, can be found [here](#).



Extended Regional Stay-at-Home Order for San Diego County

Updated! Given the low availability of intensive care unit beds, the [Regional Stay At Home Order](#) for the Southern California region, including San Diego County, has been extended until further notice. For additional information, visit the [County News Center](#).



COVID-19 Vaccine Resources for Long-Term Care Facilities

Vaccination Toolkit for Long-term Care Facilities — We are pleased to let you know that the [Vaccination Toolkit for Long-term Care Facilities](#) is now live on CDC's website. For the LTC Vaccination Toolkit and all COVID-19 vaccination toolkits visit: [COVID-19 Vaccination Toolkits | CDC](#)

Updated! Importance of COVID-19 Vaccination for Residents of Long-term Care Facilities — This guidance has been updated to include long-term care consent information for COVID-19 vaccination. To learn more, please visit, [Vaccinating Long-Term Care Facility Residents](#).

Post Vaccine Considerations for Residents — While [this guidance](#) is intended for long-term care facilities, it could also be applied to patients in other healthcare settings. These considerations are based on the current understanding of signs and symptoms following COVID-19 vaccination, including timing and duration, and might change as experience with the vaccine accumulates.

Frequently Asked Questions about COVID-19 Vaccination in Long-Term Care Facilities (LTCF) — Making sure LTCF residents can receive COVID-19 vaccination as soon as vaccine is available will help save the lives of those who are most at risk of dying from COVID-19. CDC updates [frequently asked questions](#) for Healthcare Infection Prevention and Control and Healthcare Professionals regularly based on feedback from professionals on the ground.

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.

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.

Additional 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](#).



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.



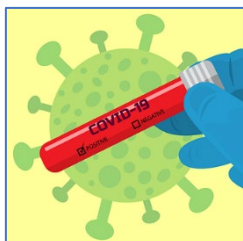
Free On-Site Flu Clinics

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.



Community	San Diego County	San Diego County	San Diego County
San Diego County	6.7%	72%	3.6%
San Diego County	20%	2%	97%
San Diego County	1%	36%	95%
San Diego County	0.3%	53%	38%
San Diego County		87%	

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](#).

County of San Diego Testing Information & Resources

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](#). 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.

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**

Updated! WHEN: Beginning January 2021, the telebriefings will be held on the 2nd and 4th Thursdays of the month, 2:00 – 3:00 pm. We look forward to seeing you on Thursday, January 14, 2:00 pm.



To be determined

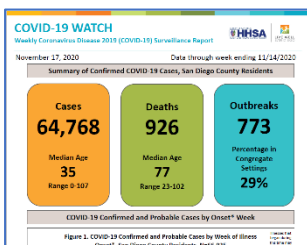
Telebriefing for **Older Adult and Disability Service Providers**

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](#)

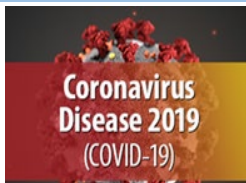
- [Considerations When Preparing for COVID-19 in Assisted Living Facilities](#)
- [Considerations for Memory Care Units in Long-term Care Facilities](#)

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 22, 2020 Update](#)
- [December 16, 2020 Update](#)
- [December 10, 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.





To: CAHAN San Diego Participants
Date: December 28, 2020
From: Public Health Services

Health Advisory Update #20: SARS-CoV-2 Virus Variant Identified in the United Kingdom

Key Messages

- Please see attached information from the California Department of Public Health (CDPH) regarding a new SARS-CoV-2 variant identified in the United Kingdom. **Providers are requested to immediately contact the County of San Diego Public Health Epidemiology at (619) 692-8499 (or (858) 565-5255 during afterhours, weekends, or holidays) about any individuals with confirmed COVID-19 who meet 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 infection).
- County Epidemiology and the Public Health Laboratory will work with the provider to have patient specimens collected from the patient and appropriate [forms](#) submitted for whole genome sequencing and analysis.

General public inquiries about COVID-19 should be directed to [2-1-1 San Diego](#) or to the [County COVID-19 website](#). Thank you for your participation.

CAHAN San Diego

County of San Diego Health & Human Services Agency
Epidemiology and Immunization Services Branch
Phone: (619) 692-8499; Fax: (858) 715-6458
Urgent Phone for pm/weekends/holidays: (858) 565-5255
E-mail: cahan@sdcounty.ca.gov
Secure Website: <https://member.everbridge.net/892807736722952/login>
Public Website: <http://www.cahansandiego.com>



State of California—Health and Human Services Agency
California Department of Public Health



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>

CDPH Director's Office, MS 0500 • P.O. Box 997377 • Sacramento, CA 95899-7377
(916) 558-1700 • (916) 558-1762 FAX
Internet Address: www.cdph.ca.gov



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)

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

- ✓ Date:
- ✓ Organization name:
- ✓ Primary point of contact - name:
phone number:
email:
- ✓ Secondary point of contact - name:
phone number:
email:
- ✓ Number of tests desired in multiples of 40 (40 tests per box):
- ✓ Testing address(s), including clinic and building name(s):
Clinic/building name:
Address:
City: , CA Zip code:
- ✓ Shipping address for receiving the test kits:
Organization:
Address:
City: , CA Zip code:
- ✓ 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): /week
- ✓ **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). Yes No
- ✓ 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). Yes No
- ✓ **Established** reporting process with [Epidemiology Data Reporting Unit](#). Yes No
- ✓ 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). Yes No

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

