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

December 17, 2020

COUNTY OF SAN DIEGO
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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).

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 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.

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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)