California K-12 School Antigen Testing Program Playbook

4/21/2021

Version 1.0

CDPH California Department of PublicHealth

Contents

1. Introduction

School closures have been an important part of the public health response to the SARS-CoV-2 pandemic. Unfortunately, school closures have adversely impacted children and their families with academic, psychological, and economic consequences. In some areas, schools have re-opened using interventions to reduce COVID-19 transmission, such as physical distancing, face masks, enhanced hand hygiene, smaller class sizes, and staggered class times. Testing asymptomatic (without symptoms) students and staff for COVID-19 can be an additional strategy for safe school re-opening. It is important to note that testing should be used in addition to other interventions; it does not take their place. The California Department of Public Health (CDPH) Testing Task Force has developed a program for antigen testing in California K-12 schools. The goal of this playbook is to describe this program and provide guidance for K-12 schools that wish to implement a testing program using the BinaxNOW antigen test.

Symptomatic staff and students should be encouraged to stay home when ill. If they come to school or develop symptoms while at school, they should be tested if testing is available. If antigen testing is used, a symptomatic individual should be advised to go home regardless of their test result. However, one of the challenges of controlling COVID-19 is that asymptomatic and pre-symptomatic individuals can spread the infection. An estimated 30-60% of infected individuals are "silent spreaders" (contagious without realizing they have the virus). Identifying asymptomatic and pre-symptomatic COVID-19 infections in staff and students can help prevent and mitigate outbreaks in schools. This antigen testing program in schools is primarily designed to test asymptomatic students and staff and detect cases that might not otherwise be identified. Testing for this program is reserved for students and staff of the schools.

Which Testing Type is Best for My School?

Molecular (PCR) testing is a common method used to diagnose COVID-19. Molecular testing is highly sensitive (unlikely to be falsely negative) and specific (unlikely to be falsely positive). Molecular testing needs to be performed in specialized laboratories and results are generally available in 1-2 days.

Antigen tests are less sensitive than molecular tests and may not detect infections in asymptomatic individuals. However, antigen tests are likely to detect those who are the most infectious. Importantly, the BinaxNOW antigen test are performed at a school and the results are available within minutes. For antigen testing to be most effective, testing should occur more frequently than molecular testing. The faster turnaround time of the BinaxNOW antigen test can

help limit transmission by more rapidly identifying infectious persons for isolation, particularly when used as a component of serial testing strategies (https://www.cdc.gov/mmwr/volumes/70/wr/mm7003e3.htm).

The various testing methods for COVID-19 include a) individual PCR tests; b) pooled PCR tests; and c) antigen tests. There are several considerations in choosing the testing method for your school as there is no "one size fits all" model. As outlined in the table below, the main advantage of an antigen testing program is that results are available within minutes. One of the disadvantages of an antigen testing program is that it requires training of staff to perform testing and on-going availability staff for testing. The decision about which testing method is best for your school should be made in consultation with your local health department as well as with district education leadership and staff. If possible, it may be helpful to reach out to school districts that have already started a testing program, as they may provide important insights.

Information on other testing platforms for schools can be found at https://schools.covid19.ca.gov/ and at https://testing.covid19.ca.gov/school-testing/.

Advantages and Disadvantages of SARS-CoV-2 Test Types

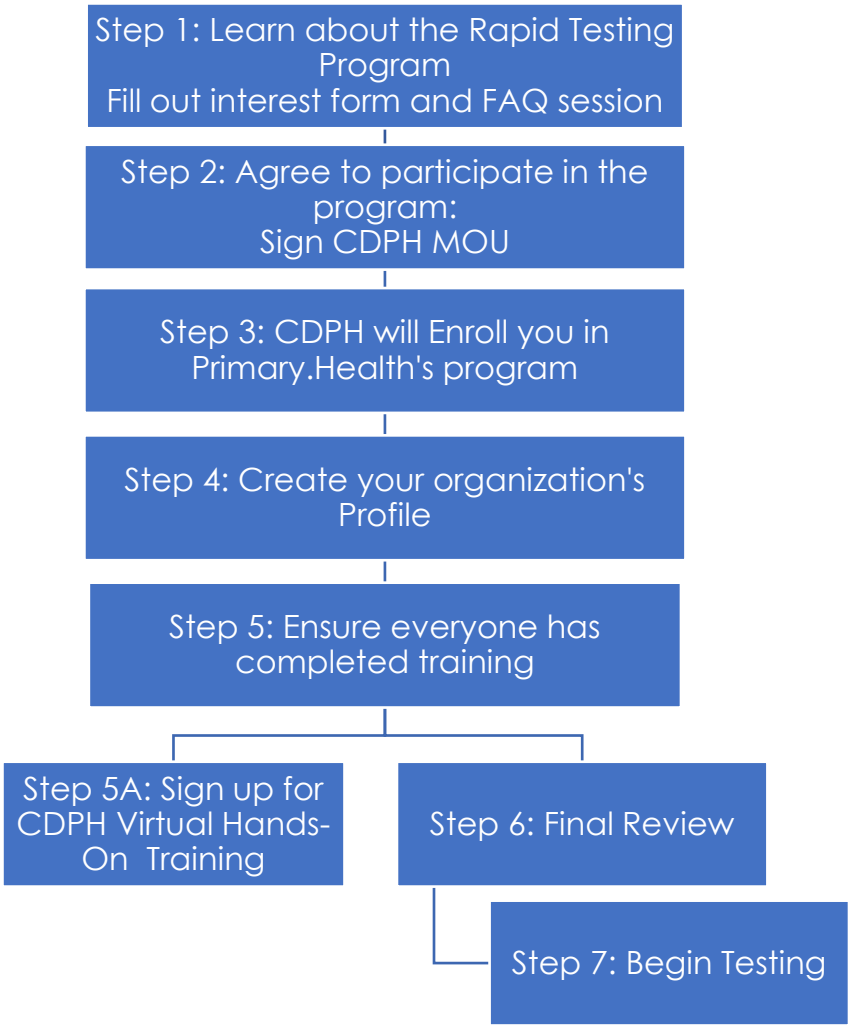
Test Type	Advantages	Disadvantages
Individual PCR Test	• Ease of initiating a testing program • Familiarity with this testing type	• More costly than antigen-based or pooled molecular • Turn-around-time variable (24-48 + hours)
Pooled PCR Test (e.g., specimens from all children in one pod or classroom are combined and tested as a single test)	• Costs are lower than individual PCR assays • If test is negative, it is reassuring that all children in classroom are negative • Likely best paired with individualized testing in staff	• If the cohort test is positive, an individual student cannot be identified specifically as infected. This would require subsequent 1:1 testing for a positive cohort. If in-school rates of COVID-19 are high, then the pooled approach becomes less cost efficient. • Turn-around-time variable (24-48 + hours)
Antigen Test (with reflex to PCR as needed)	• Almost immediate test results (within 15-20 minutes of collection) • Onsite testing • Cost for the test itself lower than PCR test	• Since testing done on school site, this approach requires additional resources compared with PCR testing: - Testing space and materials - Trained personnel to perform testing and entry of test result

		• Because of lower sensitivity than PCR, a higher frequency of testing is recommended • Follow-up molecular testing may be needed on subset of individuals (e.g. if unexpected results such as positive results in asymptomatic individual or negative result in symptomatic individual)

2. Steps to Implement Testing

Overview Checklist

K-12 School Antigen Testing Program Onboarding Flow and Checklist



Step 1: Learn about the K-12 School Antigen Testing Program.

- ☐ View materials on the California Testing Task Force Website
- ☐ Read the California K-12 School Antigen Testing Program Playbook
- ☐ Fill out the Interest Form
  After filling it out, CDPH will reach out to you to schedule FAQ session and will include the following: the playbook, 1 pager and this checklist
- ☐ Attend FAQ session
  After FAQ session, CDPH will reach out with welcome email that contains: CDPH MOU, information on the process to use the testing software through Primary.Health, BinaxNOW binder, consent form

Step 2: Agree to participate in the K-12 School Antigen Testing Program

- ☐ Sign CDPH MOU. Once MOU is signed, please return to schoolbinax@cdph.ca.gov
- ☐ Identify team members to be trained
- ☐ If you are school district, identify a Binax Lead at each school. If you are school, you are the Binax Lead (see binax lead roles and responsibilities below)
- ☐ Order the training test kits here. Order at least 40 tests per staff that needs to be trained

While you are in the process of signing the CDPH MOU:

- ☐ Ask the team members who will be trained to read the training materials and watch the videos (see playbook/see below)
- ☐ Ensure that all team members who will be trained have done the HIPAA training
- ☐ Start formatting your staff and student rosters in the format Primary.Health is requesting for .CSV upload (see attachment on the Welcome email)
- ☐ Identify which team members will have administrative access in Primary.Health software and have access to protected health information and test results
- ☐ Create Binax Binder (see attachment on the Welcome email)
- ☐ Reach out to local health department to help create a plan for a potential positive test
- ☐ Acquire materials needed to start testing (see Testing Site Supplies and Materials Checklist below)
- ☐ Identify temperature stable location to store BinaxNOW tests once received
- ☐ Develop communication plan to educated staff and parents of availability of testing

- □ Select site for testing (Outdoors is ideal with a second backup site in case of inclement weather. If inside, pick large room like gym or auditorium with adequate ventilation.)
- □ Determine testing frequency and schedule

Step 3: CDPH will enroll you in Primary.Health's program

CDPH will create a new account on Primary.Health for your school/district. Each district will have a designated Organization Lead. If you are the designated lead, you will receive an email inviting you to create an account with Primary.Health.

Step 4: Create your school/district's profile (in Primary.Health software)

- □ Set up your school/district's account
- □ Configure the profile settings for the testing program:
    - Set up your locations by entering specific address information
    - Add your logo
    - Upload staff/student rosters
    - Provide login access to your testing staff (including who can see PHI and who cannot and attesting that each person has completed confidentiality training)
    - Customize your registration pages and email/text messages
    - Configure the type of testing offered at your locations (Binax only, Binax + PCR)
    - Develop plan for positive case notification (case reports)
    - Complete training attestations confirming all testing site staff will comply with confidentiality training
- □ You and your team members should attend the virtual training and office hour sessions provided by Primary.Health. Primary.Health offers daily trainings.

Step 5: Sign up for the CDPH Virtual Hands-On Training with CDPH

- □ Ensure you have received testing kits that you ordered in Step 2
- □ Ensure staff has watched all videos and reading materials as outlined in playbook prior to hands-on training
- □ Schedule the 1 hour "hands-on" training with a CDPH trainer either through the Primary.Health website, via the schoolbinax@cdph.ca.gov email or through your local health department (in select participating counties)
- □ Prepare for your training (see hosting a hands-on training checklist below)

- ☐ Once training is complete, all staff must pass the CDPH quiz and receive a 100% score
- ☐ Please confirm that all staff have completed readings and videos, participated in hands-on training, finished the quiz and it is documented on Primary.Health's platform

Step 6: Final Review

- ☐ Once all training have been completed and the account has been configured (completion of steps 4 and 5), the Binax Lead should click the box that says "I am ready to begin testing".
  This will trigger a final review from Primary.Health.

Step 7: Begin Testing

- ☐ You will receive a notification that testing can begin from Primary.Health once review is complete

Step 8: Adding new users

If you train additional staff for testing:

- ☐ Add the users to the organization's account on Primary.Health. They will only be able to view their practice group and training materials. Once they have completed their trainings, the Binax Lead can check them off. They can access their testing group and begin assisting with testing.
- ☐ Schedule a CDPH Virtual Hands-On Training for the new users via Primary.Health or contact CDPH via schoolbinax@cdph.ca.gov
- ☐ Complete Primary.Health's virtual training

Testing Site Supplies and Materials Checklist:

Materials needed:

- ☐ Obtain BinaxNOW tests (plan to use initial tests for training to pilot your program, request here)
- ☐ Table space to lay the necessary number of cards flat during the 15-30 minutes when the tests will be running and read
- ☐ Paper towels or table covering like butcher paper to lay tests on
- ☐ Hand sanitizer to clean hands/gloves
- ☐ Trash cans with bags and biohazard bags
- ☐ Personal protective equipment (at minimum gloves and disposal surgical masks, optional face shields, gowns).
- ☐ Permanent markers like Sharpies (to mark the BinaxNOW cards)

- ☐ Large digital clock to write down time the tests were performed on the cards
- ☐ Optional Timers (to time the BinaxNOW tests)
- ☐ Laminated reading materials: Reader Guide and Interpretation Tree, Test Time Calculator (Appendix A) and BinaxNOW Binder
- ☐ Appropriate technology devices (iPads/tablets/laptops with USB compatible webcams, Kindle Fires do not work) to use software to manage check-in and report results. Minimum of 2 devices per testing site.
- ☐ Internet access
- ☐ Paper consent forms in case of emergency (most consent forms will be submitted electronically via Primary.Health, which is the preferred option). Consent forms can be downloaded and printed directly from your Primary.Health account.
- ☐ BinaxNOW Binder
- ☐ Optional tape to tape down cards in case of windy conditions.

CDPH School BinaxNOW Testing Program Training Checklist

Reading Materials:
☐ COVID-19 Antigen Testing K-12 Schools Playbook
☐ Abbott BinaxNOW IFU https://www.fda.gov/media/141569/download
Videos:
☐ Abbott BinaxNOW training modules:
https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html
The following modules must be completed:

Module 1: Getting Started
Module 2: Quality Control
Module 3: Specimen Collection and Handling
Module 4: Patient (Individual) Test

☐ Preparing for & Running the BinaxNOW Rapid Test
https://www.youtube.com/watch?v=rRZLDwEHkgY&feature=youtu.be
☐ Reading the BinaxNOW Covid-19 Ag card Test
https://youtu.be/pXIzMxOasQs
☐ CDPH COVID-19 Demonstration of Children Self-Swabbing
https://www.youtube.com/watch?v=DU_G-D_sL3I
☐ Confidentiality training (HIPAA), watch this 5-minute video (certification is not required). https://www.accountablehq.com/free-hipaa-training/privacy-rule
☐ CDPH Virtual Hands-On Training

☐ Pass the California K-12 Antigen Testing Program Competency Quiz with 100% score.
☐ Sign the Training Log Attestation Form and place in the BinaxNOW Binder (Appendix A of the CDPH playbook)

Preparing for CDPH Virtual Hands-On Training

If staff are participating in the virtual training on individual computers, we recommend that they have video capabilities on their computers so we can observe them doing the tests. Some schools do choose to train their staff together in the same room.

- ☐ Ensure that each staff training member has a box of BinaxNOW Tests (containing 40 tests, 40 swabs, one positive control foil packet and one reagent bottle)
- ☐ Gloves for each person participating in training
- ☐ Paper towel or table covering
- ☐ Sharpie
- ☐ Access to a clock/timer
- ☐ Hand sanitizer
- ☐ Sign-in sheet to keep track of who has been trained.

Responsibilities of the BinaxLead

Pre-training:

- ☐ Identify team members for your site
- ☐ Identify level of access that each member will have for Primary.Health (access to protected health information)
- ☐ Review and print the Binax Binder PDF

Training:

- ☐ Ensure that team member completes training materials (readings and videos) for both CDPH and primary
- ☐ Ensure that team member has completed the confidentiality training (HIPAA video)
- ☐ Ensure that team members complete the CDPH Virtual Hands-On training
- ☐ Ensure that team members have completed the post-training quiz
- ☐ Ensure trainees sign training attestation form in Primary.Health

Ongoing responsibilities:

- ☐ Complete quality control procedures with each new lot in a shipment
- ☐ Maintain Quality Control Log

- ☐ Maintain Adverse Event and Product Deviation Log
- ☐ Schedule and coordinate trainings of new team members
- ☐ Update and maintain Binax Binder
- ☐ Submit electronic copies of the site training documents, Quality Control Log, test deviation reports or adverse event reports to CDPH via email to antigenlabdirector-reporting@cdph.ca.gov

Interest and Enrollment Forms

Enrolling in the California K-12 School Antigen Testing Program

The Abbott BinaxNOW test is a waived test, meaning that it is a simple test with low risk for erroneous results, but federal and state law require that, as a clinical lab test, it must be performed in a laboratory. Because of this, any facility performing BinaxNOW testing must have a CLIA Certificate of Waiver and a California clinical laboratory registration. If you choose to work with a 3rd party contractor to help you run the tests, CDPH is unable to provide training support, BinaxNOW tests, Primary.Health software platform or allow for use of the statewide CLIA waiver and health care provider's order. The contracted 3rd party will need to provide their own CLIA waiver, health care provider's order, and training support for your school, in addition to helping the school obtain BinaxNOW tests.

Public and private K-12 districts/schools that wish to participate in California K-12 School Antigen Testing Program can use the State's CDPH K-12 school CLIA Certificate of Waiver and California clinical laboratory registration if they meet the necessary requirements.

The forms for the State's CDPH K-12 Antigen Testing Program can be found at the following links as well as Appendix B:

- **Interest Form** – Use this link to request follow up information: https://forms.office.com/Pages/ResponsePage.aspx?id=URsxH9n2U0GbrFXg75ZBuIH02axXNqRKmpoKrfn-QMZUNkhLRExaQlVXUjFaQUU5QUdEVDkwRjNFMS4u

If you have questions, please email SchoolBinax@cdph.ca.gov.

Preparing Your School Community

Assembling your team

The BinaxNOW tests can be performed by school personnel who are trained to perform the test. Sites should identify one or two persons to be the "Binax Lead," who will be responsible for ensuring that all personnel have met the training requirements and have signed the training attestation. The Binax Lead will maintain a binder that holds the printed training material, training records, the

quality control records, Instructions for Use (IFU) and product inserts, and other material. A PDF version of this binder will be provided to all Binax Leads by CDPH. The Binax Lead is responsible for performing quality control checks (see QC procedure) and for sharing updates to their team from the CDPH School Antigen team.

Additional information about the qualifications of personnel performing BinaxNOW tests can be found at https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/SchoolsGuidance.aspx (Appendix C).

The Centers for Disease Control and Prevention (CDC) has published Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19. Any trained staff member, preferably a healthcare professional, can supervise the self-collection. Because testing needs to be performed soon after swabbing, nasal swab self-collection should be done on site.

Testing involves five different roles. Staff requirements will vary based on size and organization, and one person can perform multiple roles if necessary.

Roles:

- Check-in: Performs check-in and associates the BinaxNOW card with the staff member or student.
- Swab Supervisor: Monitors self-collection.
- Tester: Performs the BinaxNOW test.
- Reader: Tracks the time of the test. Reads the results.
- Data Entry: Enters the data into the software platform.

Informing your community

Create a plan to inform staff, parents, and families about the purpose of the program, information on the testing platform (antigen), nasal swab self-collection, and how test results will be communicated. We recommend early and clear communication from leadership and recommend conducting town halls for question and answer sessions with a medical professional who is trusted by the community. An information sheet for parents (Appendix D) should be distributed to all parents along with the consent form (Appendix E). Additional FAQs for the school community are included in Appendix F.

Special care should be taken in communicating with students, particularly about self-collection of nasal swabs. A video, available at https://youtu.be/DU_G-D_sL3I should be shown to students so they understand what the sample collection will mean for them. For younger children, parents

should be encouraged to watch the video with their children and have their children practice self-collection at home (with a soft cotton swab/Q-tip).

Consent

A consent form will be provided by Primary.Health. Children who are 13 and older can provide consent and administer the tests themselves. If they do so, results will only be delivered to them, and not to a parent/guardian. If a parent/guardian registers for a child age 13-17, the parent/guardian can consent and can provide their contact details in the registration process to receive the results on behalf of the child. Children who are under 13 must have parental or guardian consent during the registration process. Following testing, the parent or guardian that registered and consented on behalf of the child will receive the results.

Additional information on school-centered testing, including the CDPH Playbook for implementation, can be found at https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/COVID-19/K12_School_Testing_Considerations_Information.pdf.

Below is a table that outlines the testing consent requirements by age group.

Age Range	**Consent**	**Results Reporting**
< 13	Parental consent required	Parent only
13-17	Parental consent possible, but not necessary	Student by default, parent can be added
>=18	No parental consent required	Student only

Liability

Schools should contact their own legal counsel, but schools and school personnel are likely to be entitled to immunity from claims of loss resulting from performing COVID-19 testing under the Public Readiness and Emergency Preparedness (PREP) Act, except for acts of willful misconduct. For additional information about the PREP Act, visit https://sharedsystems.dhsoha.state.or.us/DHSForms/Served/le3529.pdf and https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx.

Privacy

Student test results must be shared with the student and/or their legal guardian in a manner compliant with the federal Health Insurance Privacy Accountability

Act (HIPAA) and family education rights and Privacy Act (FERPA). Test results will also be reported to public health and key school administrators.

Train Personnel

There are multiple training requirements for personnel performing the BinaxNOW tests. Training must be completed prior to starting testing. The training includes watching ~30 minutes of educational videos, performing hands-on training with a CDPH-approved trainer, and passing a short quiz. Please see the BinaxNOW Training Guide in (Appendix A) for more detailed instructions regarding training requirements.

In addition to training on the BinaxNOW, personnel need to be trained on health privacy with a HIPAA training.

- We require all participants to attest they have viewed this 5-minute video (certification is not required). https://www.accountablehq.com/free-hipaa-training/privacy-rule.

Software Platform Training

CDPH requires using Primary.Health to help with registration, consent forms, test result management, and mandated electronic reporting. Primary.Health will provide training related to use of their software. For more information please see Appendix G.

Testing Day:

Step 1: Register and consent prior to testing day

- Staff and students/parents register electronically through Primary.Health ahead of time.

Step 2: Check- in

- Identify staff and students in Primary.Health and confirm their identity and information.
- Use the QR code on a newly opened BinaxNOW card to associate the test with the person.
- After check-in, open a test kit and mark it with participant's name or initials.

Step 3: Self-Swabbing

- Teach staff and students how to self-collect their sample.
- Once swabbing is complete, staff or students give the swabs to the personnel assigned to perform and read the tests.

Step 4: Performing the Tests

- Testing personnel applies reagent to BinaxNOW card, then accepts swab and inserts swab into card, twists swab 3 times, and seals the card.
- Testing personnel then records the time the swab was inserted into card and starts the timer.

Step 5: Reading the Tests and Communicating Results

- BinaxNOW cards should be read after 15 minutes, and before 30 minutes. Once read, each result must be recorded on the Primary.Health software data platform.
- Ideally two individuals independently read the results and take a photograph of the results.
- Negative results are communicated electronically to staff and parents of students tested. The results will also be shared with a limited number of previously designated administrative staff.
- Positive results can be communicated electronically, but in the event of a positive or ambiguous test result, we recommend a confidential phone call or in-person discussion of the result in a private area.
- All results must be logged into Primary.Health and include a picture of the test for quality control purposes.

Select Your Location

When selecting your testing site location, consider the number of participants you will be testing. Outdoor locations are ideal to reduce COVID-19 transmission but may not be feasible. If you choose an outdoor location, have contingency plans for inclement weather such as wind/rain, with supplies to cover electronics and paperwork and an alternative indoor location such as a gymnasium or auditorium with good ventilation and sufficient space for social distancing.

Some schools may choose to have a mobile testing cart that goes from classroom to classroom. Remember, whatever the testing location, you will need **flat areas** to lay the cards on when performing the test, such as tables or drawers in a cart.

Software Preparation

For enrollment into our California K-12 School Antigen Testing Program, schools must use the software program Primary.Health to help with mandated electronic reporting to the department of public health. Primary.Health will assist with registration, consent forms, test result management, and secure reporting to parents/participants. Primary.Health will provide training for your personnel on how to use the software. For more information please see Appendix G.

Allow time (at least 2 business days) so that each of your staff members and parents of students can register their individual accounts and sign consent forms, which allow them to access the system. Registration information can be preloaded into the software platform using the CSV format. At minimum, the CSV must include participant name and email or phone number. Additional elements can be included to help streamline the registration process; however, it is not required. Through this process, participants can include additional information needed for reporting and consent to testing.

Paper forms can be printed as a back-up in case of internet problems. If paper forms are used, all information collected must be entered in the online platform once internet is available as consent is required for logging results. As patient data is collected on these paper forms, the school site is responsible for securely shredding these documents. This is necessary because the data is considered protected health information (PHI), which is protected by HIPAA.

Crowd Management

Certain measures must be used when testing large groups of people to avoid people congregating in the same area:

- Develop signage that directs staff and students where to check-in and where they should line up.
- Place markers on the ground to help people maintain distance when waiting in line and at the different stations.
- Consider placing educational materials where people are waiting to prepare them for the testing set up and teach them how to do self-swabbing (e.g. show continuous video https://youtu.be/DU_G-D_sL3I, also found in Appendix H)
- Consider using an appointment model or having assigned times for participants to avoid crowding.

3.Testing with BinaxNOW

Test Storage

Designate a secure place to store the BinaxNOW tests where temperature does not fall below 36 degrees Fahrenheit or above 86 degrees Fahrenheit.

BinaxNOW tests have a shelf life between 6-9 months. The expiration date can be found on the outside of the boxes near the lot number. Abbott recently announced a 3-month extension to most of these kits. Please contact the manufacturer if you have questions about the extension of the expiration date. Abbott recently extended the shelf-life by two months for most kits, please refer to the expiry letter in BinaxNOW binder.

Quality Control (QC)

Specific details on how to run and document quality control can be found in BinaxNOW Lead binder.

Quality control is important for the reliability of test results as well as accuracy of test results. The BinaxNOW test has two quality control measures:

1. The first is an internal procedural control on every test card. This is the line at the "control" position that starts blue and when the test is run successfully (reagents work, test flows) turns a pink/purple color.

2. The second is a positive control swab included in the box. A positive control is a test that, when run, will always result in a positive test. A negative control is a test (an unused swab) that, when run, will always result in a negative test.

To maintain good quality control practices (QC), QC (a positive and negative control) must be run:

- On every shipment received at your facility
    - If the shipment contains multiple lots, QC must be performed on each lot
    - If a new shipment contains a lot that QC has previously been run on, the QFC must be performed again
- For each new user being trained
- If there is any concern that the tests being run are abnormal

For more information: BinaxNOW COVID-19 Ag CARD Instructions for Use (IFU) https://www.fda.gov/media/141569/download

Personal Protective Equipment (PPE)

Type	Personnel requirement	PPE requirement/recommendations	Comments
OBSERVATION of self-collection of anterior nares swabs	Personnel who are observing individuals performing self-collection should be trained on proper technique: https://www.cdc.gov/coronavirus/2019-ncov/downloads/community/COVID-19-anterior-self-swab-testing-center.pdf	Facemask and gloves required, eye protection (googles or face shield) also recommended since children may sneeze when they swab.	Most children can self-collect. (View video at https://youtu.be/DU_G-D_sL3I) Since students will have to remove their masks, recommend that when possible testing be done in a well-ventilated outdoor setting and that when the masks are removed, all staff and students remain at least 6 feet apart.
COLLECTION of anterior nares swab	Trained health care providers: Physician Assistant, Registered Nurse, Licensed Vocational Nurse, Medical Assistant, Psychiatric Technician.	N95 or higher-level respirator that has been FIT tested (or facemask if a respirator is not available), eye protection, gloves, and a gown, when collecting specimens.	

Specimen testing/Running the test

- Always keep the card flat.
- Add 6 drops of reagent to the well.
- Accept and insert the swab so the top of the swab is in the well and rotate the swab clockwise 3 times.
- Remove adhesive liner and close the test card.
- Record the time on the card.
- Read the results after 15 minutes have passed. Do not read after 30 minutes.
- The test should be read by two independent readers whenever possible. If you have any concerns about the test results, photograph the card and consider repeating the test.

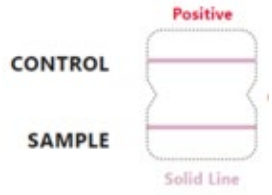
To avoid false results:

- Do not delay inserting the swab after applying the reagent.
- Collected nasal swabs should not be placed back in original swab packaging.
- The swab should not touch anything after specimen collection.
- Test cards must remain FLAT for the duration of the 15 minutes. If the card needs to be moved, keep flat and move minimally.
- The sample nasal swab should be tested immediately after collection for best results.
- Tests read before 15 minutes or after 30 minutes are invalid and must be repeated.

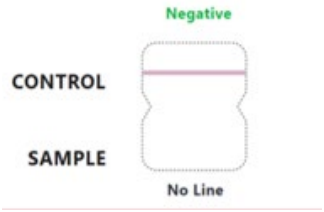
More information in the manufacturer's instructions for use
https://www.fda.gov/media/141569/download

How to read results:

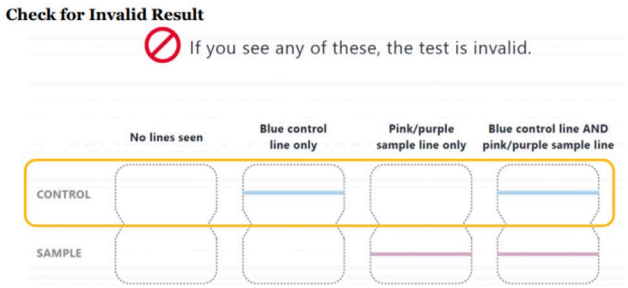
Positive: A positive test has two pink lines.



Negative: A negative test has just one pink line at the control.



Invalid: The test is invalid if the control band remains blue or if the control band is absent.



Should there appear a very faint line in the control or sample window:

See Troubleshooting Section

Reported Deviations of Test Performance

The Binax Leads at each site are asked to report suspected occurrences of false positive (testing positive on antigen test and confirmatory PCR is negative) or false negative (symptomatic individual tests negative and the PCR comes back positive) results and significant deviations of test performance to antigenlabdirector-reporting@cdph.ca.gov to facilitate the laboratory's reporting to FDA and to the manufacturer.

Example deviations may include test kits not performing correctly, controls not working, blue control line missing in untested test kits, etc. Deviations can be recorded in the Adverse Event and Product Deviation Log (Provided in your Binax Lead Binder

Send site records to CDPH Laboratory Director

The Binax Leads are also asked to submit electronic copies of the site training documents, Quality Control documentation, and any test deviation reports, adverse events or issues to the CDPH Laboratory Director. The Laboratory Director can be contacted at antigenlabdirector-reporting@cdph.ca.gov.

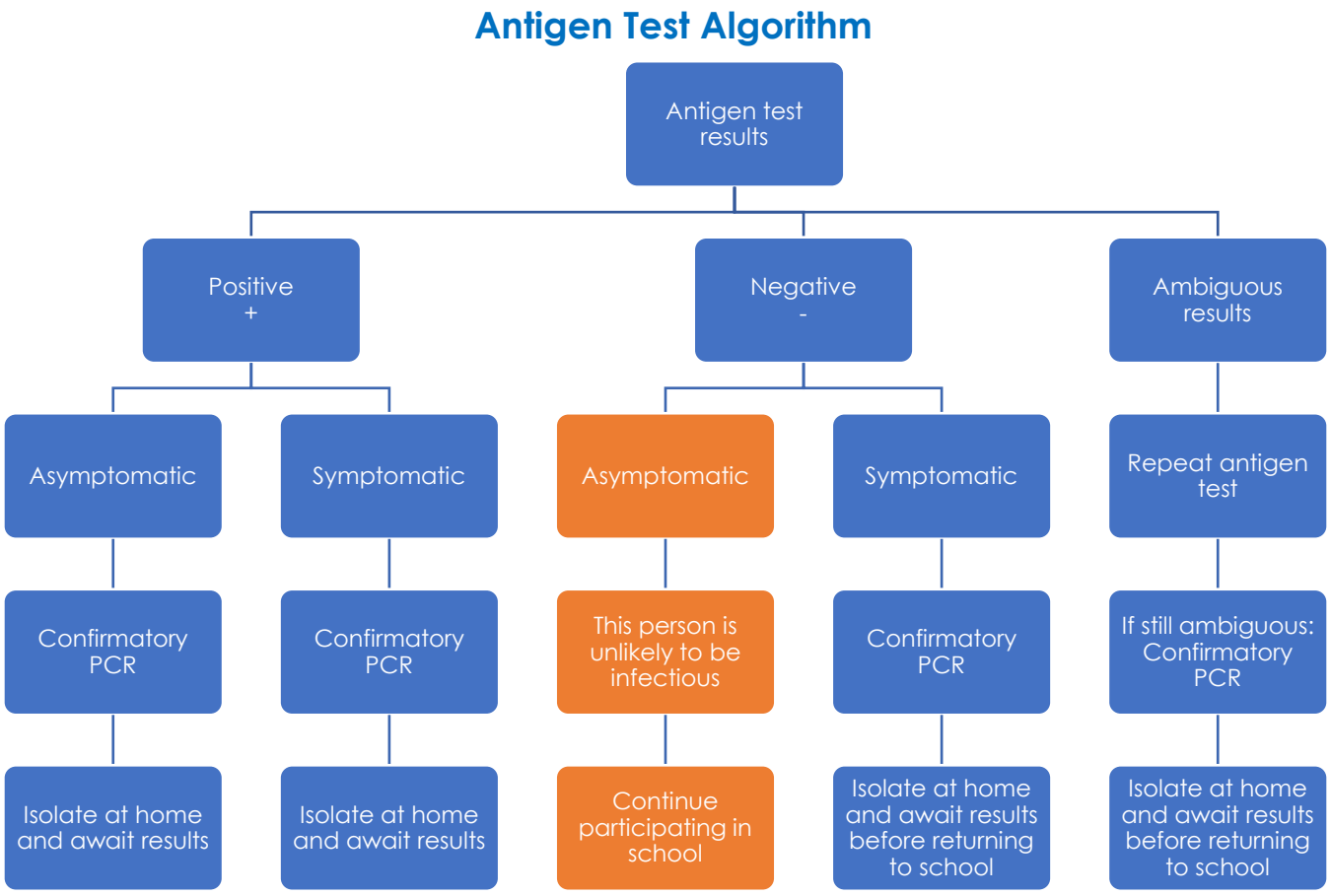
Disposal of Cards

Disposal of BinaxNOW Cards – once result is finalized and recorded, disposal of BinaxNOW cards is determined based on negative or positive result.

Per CDPH Novel Coronavirus Disease 2019 (COVID-19) Medical Waste Management - Interim Guidelines, waste from COVID-19 positive patients must be handled as standard regulated medical waste (RMW). Guidelines for handling COVID-19 materials, including used swabs and test components, are as follows:

- If the test is negative, test components can be placed in a regular trash bag.
- If the test is positive, these items must be placed in a red biohazard container that is certified to meet the ASTM D1709 dart drop test and kept in a properly marked biohazard container with a lid.
    - All biohazard bags/container must also be labeled with the generator name, address, and phone number. If the integrity of the primary bag is compromised in any way (leaks, tears, etc.), 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.
- Check local enforcement guidance on medical waste management, which can be found at: https://www.cdph.ca.gov/Programs/CEH/DRSEM/Pages/EMB/MedicalWaste/Local-Enforcement-Agencies.aspx

4. Understanding Test Results



Positive Results in a symptomatic person

A symptomatic individual who has a positive BinaxNOW test result should have confirmatory PCR testing sent within 24 hours. Symptoms of COVID-19 include any of the following per CDC:

- Fever or chills
- Cough
- Shortness of breath or difficulty breathing
- Fatigue
- Muscle or body aches
- Headache
- New loss of taste or smell
- Sore throat
- Congestion or runny nose
- Nausea or vomiting
- Diarrhea

The tested individual should go home to isolate per CDC guidance and close contacts* should be tested and quarantined per CDC guidance.

Positive Results in an Asymptomatic Person

An asymptomatic individual who has a positive BinaxNOW test result should be considered COVID-19 positive.

- If the individual is truly asymptomatic, confirmatory PCR testing should be performed within 24 hours of the positive antigen test, the tested individual should go home to isolate. Close contacts* should go home to quarantine and test per CDC guidelines.
    - If the PCR test result is positive, the tested individual should remain isolated and close contacts* should remain quarantined per CDC guidelines.
    - If the PCR test result is negative, and the person remains asymptomatic the positive antigen test was falsely positive and the tested individual and close contacts* may return to school.
- When an asymptomatic individual has a positive antigen test result, it may be helpful to interview them, since it is possible that the individual thought that very mild symptoms were due to allergies or other causes and did not mention them.

Negative Results in an Asymptomatic Person

Negative results in an asymptomatic individual mean that the tested person is likely not infectious and can remain at school. This is likely to be the largest group of tested individuals. They should continue to observe non-pharmacological

interventions to prevent the spread of COVID-19 including wearing a mask that covers the nose and mouth, physical distancing, and frequent handwashing. Asymptomatic testing should continue at the recommended frequency.

Negative Results in a Symptomatic Person

Negative antigen test results in a symptomatic individual require confirmatory PCR testing but may suggest that the individual likely does not have active COVID-19 infection. Symptoms of COVID-19 include any of the symptoms listed on the CDC symptoms list. However, because antigen tests can be falsely negative (negative when an individual is actually infectious), negative results should be confirmed by PCR within 24 hours and the tested individual should be considered infected until PCR results are available.

- The symptomatic person should go home to isolate until the PCR test result is back, but close contacts* may remain in school.
- If the PCR test result is positive, the symptomatic individual should be considered infected and continue to be isolated, and close contacts* should go home to quarantine.
- If the PCR test result is negative, the symptomatic individual can return to school per school policy.

***A close contact is defined by CDPH and CDC as a person who is <6 feet from a case for >15 cumulative minutes in a 24-hour period. In some school situations, it may be difficult to determine whether individuals have met this criterion and an entire stable cohort, classroom, or other group may need to be considered exposed, particularly if the group has spent time together indoors for an extended period. Some local health departments have an expanded definition of close contacts in schools (e.g., those participating on the same sports team or entire elementary school cohorts). Schools should work closely with their local health departments to ensure the appropriate definition is used.**

Ambiguous Tests

The test is invalid if the control band remains blue or if the control band is absent (see examples). If the test is invalid, a repeat BinaxNOW test is required.

- If there is any doubt about the absence or presence of a line in the sample window, the BinaxNOW test should be repeated (this will be uncommon).
- If the repeat test is still ambiguous, consider direct consultation with the school's Binax Lead for the next steps. In most cases, a confirmatory PCR test should be performed, and the tested individual should go home to isolate.

    - If the PCR test result is positive, the tested individual should be considered infected and continue to be isolated, and close contacts* should go home to quarantine.
    - If the PCR test result is negative, the tested individual may return to school if asymptomatic or return to school per school policy if symptomatic.
- If there is a faint line in the sample window and it extends edge-to-edge on the sample window, this is a positive result (see several examples and note how faint the line can be and still be considered positive).
- If there is a faint line in the sample window but it **does not extend edge-to-edge**, the test result is most likely negative.
- Other resources for reading the BinaxNOW test results are available at https://unitedinhealth.org/binax-training.
- **Whenever possible, antigen test results should be read by two independent readers.**

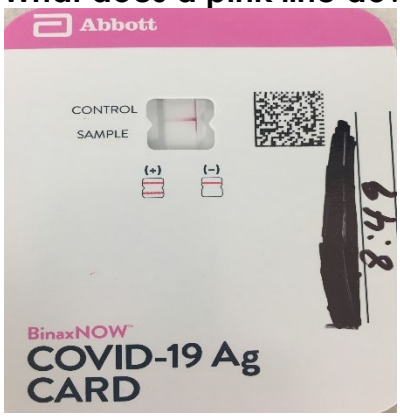
How to Manage a Positive Result

A positive result needs to be managed in coordination with your local health department.

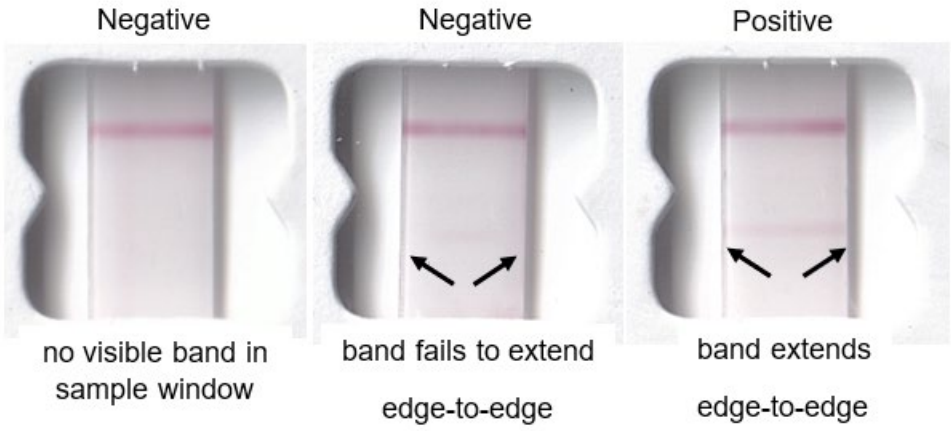
5. Troubleshooting

Test Questions

What does a pink line down the side of the test mean?

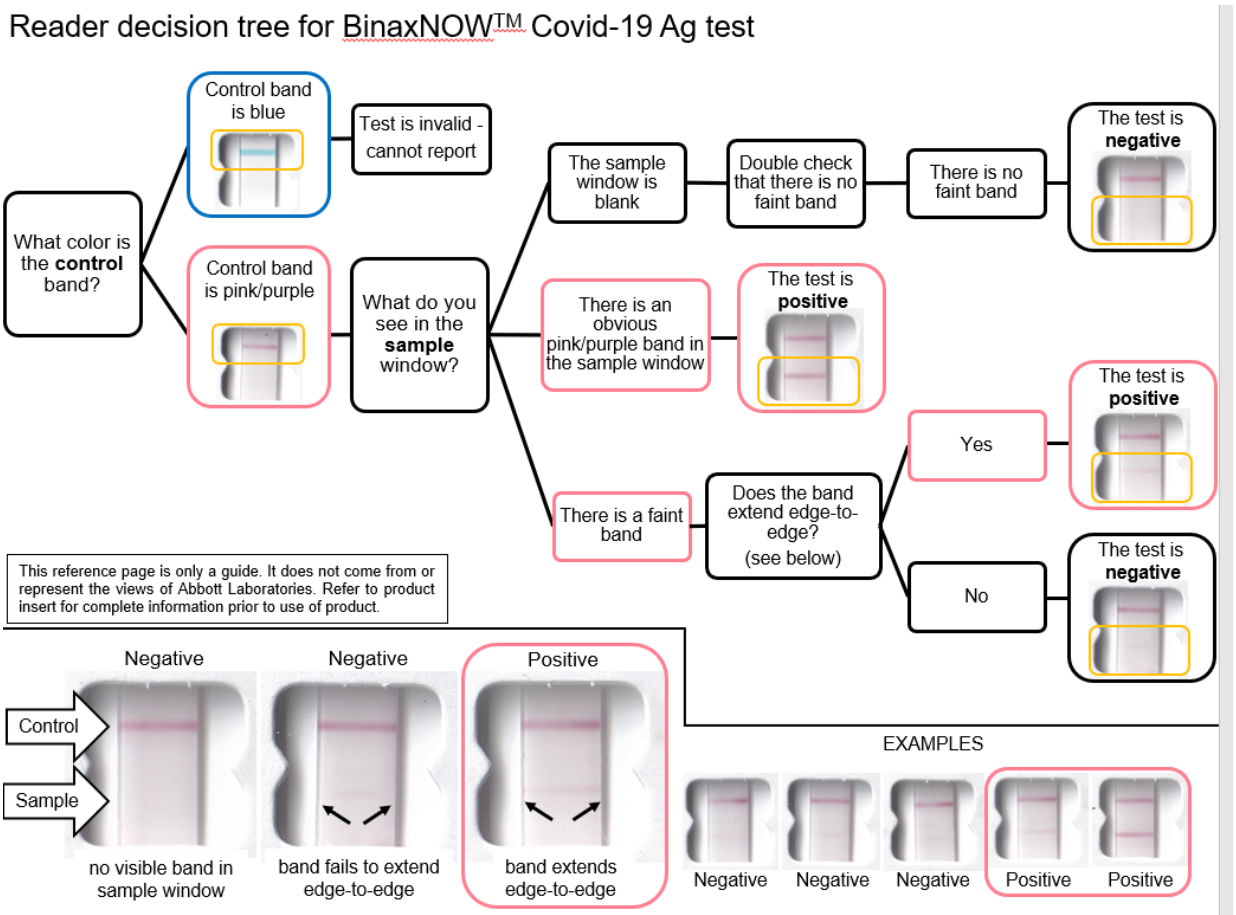


A pink line down the side of the test is normal. As long as the control line appears pink and extends edge to edge the test is valid.



What should I do if a faint band appears in the sample window?

- Photograph the test and ask your Binax Lead or the health care personnel working with your school (nurse or physician) to review the test.
- Repeat test collection and BinaxNOW test with a new card.
- If on the repeat test, the band extends edge to edge, count it as a positive test.
- If on the repeat test, the band does not extend edge-to-edge, count it as a negative test and reflex to a PCR test.
- If on the repeat test, there is no faint line, count it as negative.



What do I do if the control line is not a solid line?
If the control line does not extend edge to edge, repeat the test.

What happens if I drop the swab or the swab accidently touches something before, I insert it in the card?
Repeat swabbing.

What happens if I forgot to twirl the swab in the test?
Repeat the test.

What should I do if my hand was shaky and one drop of reagent missed the well?
Add one additional drop to the well. If a drop does not go in the well, do not count it towards the 6 drops of reagent.

What if a card was not flat while it was running?
Repeat the test.

What should I do if the test was read after 30 minutes?
Repeat the test.

What should I do if I don't know when the test card was closed?
Repeat the test.

What if an adverse event occurs during testing?
Adverse events can occur, such as a bloody nose. If this occurs, please inform your Binax Lead. This event will need to be reported to CDPH via the Adverse Event and Product Deviation Log and via email to antigenlabdirector-reporting@cdph.ca.gov.

What should I do if I am testing in extreme weather conditions?
The BinaxNOW tests perform ideally at their storage temperatures between 36 degrees Fahrenheit and 86 degrees Fahrenheit. However, tests have been performed outside of these temperature parameters and that has not affected functioning of the tests. If it is raining, we recommend ensuring that the cards are kept in a dry location.

Self-Swabbing Questions

What if a student refuses to self-swab?
If a student refuses to self-swab, then they cannot be tested. You may refer them to a testing center where appropriate medical personnel who have been trained in specimen collection can collect a specimen.

6. Reporting

Legal Requirements

California Code of Regulations, Title 17, Section 2505 requires laboratories to report laboratory test results for reportable diseases, including SARS-CoV-2. Schools using the State's CDPH K-12 school CLIA Certificate of Waiver and California clinical laboratory registration are acting as laboratories, and therefore must agree to report test results to the local public health department (via CALREDIE in most counties).

CalREDIE

In order to report to CalREDIE you will need a CLIA number. Primary.Health will grant your school use of the CDPH School Antigen Testing Program's CLIA number once you have completed all training requirements within the Primary.Health platform. Primary.Health will facilitate with reporting all logged results to the public health department.

7. Appendices

Appendix A: BinaxNOW Training Guide (Standard Operating Procedures)

Training Requirements for Performing the Abbott BinaxNOWTM COVID-19 Ag Card Test for Schools

Purpose

The purpose of this document is to provide training requirements for personnel that will perform testing using the Abbott BinaxNOWTM COVID-19 Ag Card Test at school sites.

Overview

From the Abbott BINAXNOW COVID-19 AG CARD (PN 195-000) – INSTRUCTIONS FOR USE: "The BinaxNOW™ COVID-19 Ag Card is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal (nares) swabs from individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high, or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation."

During the COVID-19 emergency, the State of California will allow the use of the BinaxNOW™ COVID-19 Ag Card (hereafter referred to as "BinaxNOW") on asymptomatic individuals.

The BinaxNOW is a CLIA waived test. As such, the test must be performed in a facility that holds a CLIA certificate of waiver. The State of California will allow the use of the CDPH K-12 School Laboratories license if all requirements for training and competency are met. All personnel that will participate in BinaxNOW testing at schools require training. This document describes the training requirements for personnel performing testing with the BinaxNOW.

Qualifications of personnel performing the BinaxNOW tests

The BinaxNOW tests can be performed by school personnel who are caring for students under their responsibility including, but not limited to teachers, administrators, and healthcare workers who are trained to perform the test. Sites should identify one or two persons to be the "Binax Lead," who will be responsible for ensuring that all personnel are properly trained. The Binax Lead will maintain a binder that holds the printed training material, training records,

the quality control records, Instructions for Use (IFU) and product inserts, and other material. The Binax Lead is responsible for reading updates to the CDPH School Antigen Testing Program Playbook and sharing any other updates transmitted by the CDPH School Antigen team.

A trainer is someone who has met all the qualifications of the Binax Lead (including maintaining the binder and performing QC procedures), has been trained via a CDPH trainer, has performed all 5 roles at a test site and has performed >50 tests. The trainer must also sign an attestation of these criteria before they can begin training others (found here: https://forms.office.com/Pages/ResponsePage.aspx?id=URsxH9n2U0GbrFXg75ZBulH02axXNqRKmpoKrfn-QMZUOFhVVjdKS0RSQjhNMzZFMUJOUVUzWTVSSC4u)

Training

Training is required for all personnel who will participate in BinaxNOW testing at schools. The BinaxNOW training requires reviewing the: 1) Reading Material and Training Videos, including the sections below on Quality Control (QC) Procedure, and Workflow. In addition, the trainee will: 2) perform hands-on training, and 3) pass the CDPH competency quiz. After completing these tasks, the trainee will complete the Checklist and sign the Training Log in the BinaxNOW binder. These steps are described below.

1. Reading Material and Training Videos.

Prior to in-person training, trainees are required to review the following information:

- Reading Material:
  - COVID-19 Antigen Testing K-12 Schools Playbook
  - Abbott BinaxNOW IFU: https://www.fda.gov/media/141569/download
- Videos:
  - Abbott BinaxNOW training modules: https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html
  - The following modules must be completed:
    - Module 1: Getting Started
    - Module 2: Quality Control
    - Module 3: Specimen Collection and Handling
    - Module 4: Patient (Individual) Test
  - Preparing for & Running the BinaxNOW™ Rapid Test: https://youtu.be/rRZLDwEHkgY

- Reading the BinaxNOW Covid-19 Ag card test: https://youtu.be/pXIzMxOasQs
- CDPH COVID-19 Testing: Demonstration of Self-Swabbing for Students: https://youtu.be/DU_G-D_sL3I
- Confidentiality training (HIPAA), 5 minute video (certification is not required): https://www.accountablehq.com/free-hipaa-training/privacy-rule

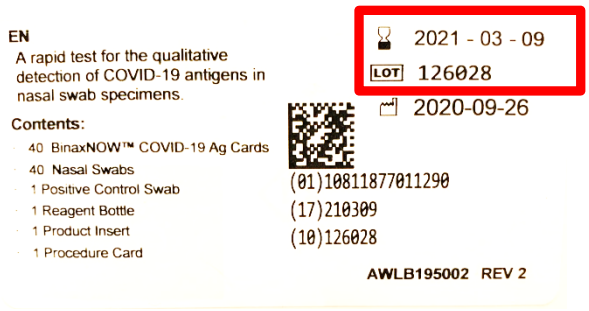
Quality Control (QC) Procedure

Schools will typically receive BinaxNOW tests monthly. For every shipment that arrives, trained personnel must inspect the shipment and record date, number of tests, the Lot Number and Expiration date for the tests in the QC log in the BinaxNOW Binder (see picture below; expiration and lot number are in the red box). If the shipment contains multiple lots of the tests, all Lot Numbers must be entered.

To maintain good quality control practices, QC must be run:

- On every shipment received at your facility
  - If the shipment contains multiple lots, QC must be performed on each lot.
  - If a new shipment contains a lot that QC has previously been run on, the QC must be performed again.
- By each new user being trained
  - If there is any concern that the tests are not performing normally

It is not necessary to perform QC on each box of 40 tests. QC involves running the positive control and negative control swabs. In each 40-test BinaxNOW box there is one, foil-wrapped, external positive control. An unused swab can be used for a negative control. After running the control swabs, record the results in the QC log and record the date and name of the person who performed the QC. The Binax Lead should periodically review the QC log. If the control swabs do not work as expected, contact Abbott technical service and CDPH for guidance.



Workflow

The protocol for performing the BinaxNOW test must follow the manufacturer's IFU and CDPH guidelines. Each school site is unique, and the workflow will be different depending upon the layout of the site, the number of testing personnel, the software platform, and other factors. Example roles for BinaxNOW school testing personnel are described below.

Check in. Participants will check in at the first station of a testing site using Primary.Health software. At registration, the check-in person "associates" the participant taking the test with a BinaxNOW test card by marking the initials of the person taking the test on the BinaxNOW test card. The card should be returned to the foil pouch.

Swab Supervisor. The swab supervisor will take the "associated" BinaxNOW test card and hand the participant a swab. The swab supervisor will observe the self-swabbing and escort the participant to the testing table where the swab supervisor drops off the test card with the tester.

Tester. Prior to being handed the swab, the tester will prepare the BinaxNOW test by adding 6 drops of the reagent to the well on the card. The participant will hand the swab to the tester who will insert it into the BinaxNOW test card, rotate 3 times clockwise, peel off the adhesive liner, and securely seal the test card. The tester will write the start time and end time of the test and lay the test on a flat surface. At this point, the tester should sanitize their gloves or change gloves if the glove has become contaminated. Gloves must be changed after sanitizing 6 times or if a Covid-19-positive swab has been handled.

Reader. 15-30 minutes later, the reader will examine the BinaxNOW test card and first determine if the test is valid by examining the control band. Next the reader will examine the sample line and determine whether the test result is positive or negative. It is highly recommended that a second person (this could be the tester) review the card to confirm the interpretation of the reader. If in agreement, the reader should mark a "+" or "- "on the card to indicate the result.

Data Entry. The data entry staff will record the BinaxNOW result as "positive," "negative," or "undetermined/invalid" in the data system. The names of the "tester" and "reader" should also be recorded. It is highly recommended to take a picture of the BinaxNOW cards with ambiguous results (Primary.Health has the capability to do this).

2. CDPH Virtual Hands-On Training

If staff are participating in the virtual training on individual computers, we recommend that they have video capabilities on their computers so we can observe them doing the tests. Some schools do choose to train their staff together in the same room.

- Ensure that all staff have a box of BinaxNOW Tests (containing 40 tests, 40 swabs, one positive control foil packet and one reagent bottle)
- Gloves for each person participating in training
- Paper towel or table covering
- Sharpie
- Access to a clock/timer
- Hand sanitizer
- Sign-in sheet to keep track of who has been trained.

Required Material. The school site should have following items available for the CDPH Virtual Hands-On training and eventual testing.

- Obtain BinaxNOW tests (plan to use initial tests for training to pilot your program, see playbook)
- Table space to lay the necessary number of cards flat during the 15-30 minutes when the tests will be running and read
- Paper towels or table covering like butcher paper to lay tests on
- Hand sanitizer to clean hands/gloves
- Trash cans with bags and biohazard bags
- Personal protective equipment (at minimum gloves and disposal surgical masks, optional face shields, gowns).
- Permanent markers like Sharpies (to mark the BinaxNOW cards)
- Large digital clock to write down time the tests were performed on the cards
- Optional Timers (to time the BinaxNOW tests)
- Laminated reading materials: Reader Guide and Interpretation Tree, Test Time Calculator and BinaxNOW Binder

- Appropriate technology devices (iPads/tablets/laptops with USB compatible webcam, Kindle Fires do not work) to use software to manage check-in and report results. Minimum of 2 devices per testing site.
- Internet Access
- Paper consent forms in case of emergency (most consent forms will be submitted electronically via the software platform, which is the preferred option).
- BinaxNOW Binder
- Optional tape to tape down cards in case of windy conditions.

Hands-on training will occur under the guidance of a CDPH certified trainer. On the day of training, all trainees should have completed sections 1-3 of this document. The requirements for trainees to complete hands-on training are listed below.

Personal Protective Equipment (PPE). PPE is required for all personnel touching any part of the test kits. The PPE required are masks and gloves. Goggles or face shields and gowns are recommended but not required. Trainees should practice putting on and removing PPE. Those in the role of testers will need to change or clean their gloves after handling a swab. The CDC has issued guidelines for cleaning gloves using alcohol-based hand sanitizer. Gloves must be changed after a tester or reader handles a positive COVID-19 BinaxNOW test. Potentially contaminated PPE should be disposed of in the biohazardous waste container.

Familiarization with the Test Kit. The trainee should examine the outside of a BinaxNOW box and note the sticker that has the expiration date and lot number of the test. The trainee should open the box and verify that it contains the test cards, nasal swabs, positive control swab, reagent bottle, product insert, and procedure card.

Performing the QC Procedures. The trainee should perform the QC procedure by running the positive and negative control swabs according to the instructions in the product insert. It is recommended that the trainee first run a negative control swab, which is an unused swab.

- Set up a clean area with a paper towel or absorbent paper, a swab, a new BinaxNOW card, and the reagent bottle.
- Partially open the swab from the bottom end.
- Open a new BinaxNOW card pack, remove the card, and write "negative control" on the card.
- Open the BinaxNOW card and lay it flat.

- Making sure to hold the reagent bottle vertically, carefully add 8 drops of the reagent to the top hole. Note that the control swabs require 8 drops of reagent while patient samples will use 6 drops.
- Insert the swab into bottom hole and rotate 3-times clockwise.
- Peel off the adhesive liner and close and securely seal the card.
- Write the start and end time on the card; leave the card on a flat surface for 15 minutes.
- After 15 minutes, read the test. Verify that the blue control line has turned pink/red.
- Read the sample line. Mark a "+" or "-"on the card to indicate the result of the test.
- Write the actual time that the test was read on the card. Note, this time could be between 15 and 30 minutes after inserting the swab.
- It is not necessary to record the results of the control into a computer system or to report results to CalREDIE.

The same procedure should be repeated for the positive control swab. After the trainee has run both the positive and negative swabs, the trainer should examine the cards and review the test results to ensure that the controls are performing as expected.

Observing and Instructing Anterior Nares (Nares) Self-Swabbing. The trainee will first observe the trainer describing the Anterior Nares self-swab procedure. From the Abbott BinaxNOWTM COVID-19 Ag Card IFU (January 2021), "Firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall 5 times or more for a total of 15 seconds, then slowly remove from the nostril. Using the same swab, repeat sample collection in the other nostril." Note the updated BinaxNOW Instructions for Use state "5 times or more for a total of 15 seconds" which is different from their training materials which have not yet been updated.

3. Quiz

After completing sections 1) through 4) of the Training section of this document, trainees will be provided with an online quiz.

A passing score of 100% is required to complete the training. The quiz can be taken as many times as necessary to receive a passing score.

BinaxNOW Training Materials – Training Attestation Form

I have read the most recently published version of the COVID-19 Antigen Testing K-12 Schools Playbook.

I have completed the required reading and video training modules:
Reading Material:

- COVID-19 Antigen Testing K-12 Schools Playbook
- Abbott BinaxNOW IFU https://www.fda.gov/media/141569/download

Videos:

- Abbott BinaxNOW training modules: https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html

  The following modules must be completed:
  - Module 1: Getting Started
  - Module 2: Quality Control
  - Module 3: Specimen Collection and Handling
  - Module 4: Patient (Individual) Test
- Preparing for & Running the BinaxNOW Rapid Test: https://youtu.be/rRZLDwEHkgY
- Reading the BinaxNOW Covid-19 Ag card test:
- https://youtu.be/pXIzMxOasQs

I have completed hands-on training with a CDPH approved BinaxNow trainer and have run a negative and positive control.

I have completed the Confidentiality training (HIPAA) (certification is not required). https://www.accountablehq.com/free-hipaa-training/privacy-rule

I have successfully passed the California K-12 Antigen Testing Program Competency Quiz with 100% score and received my certificate.

I have provided proof of my competency quiz and completion of the HIPAA training to the Binax Lead.

Signature _____

Date: _____

Name: _____

Position: _____

Materials for the Testing Table

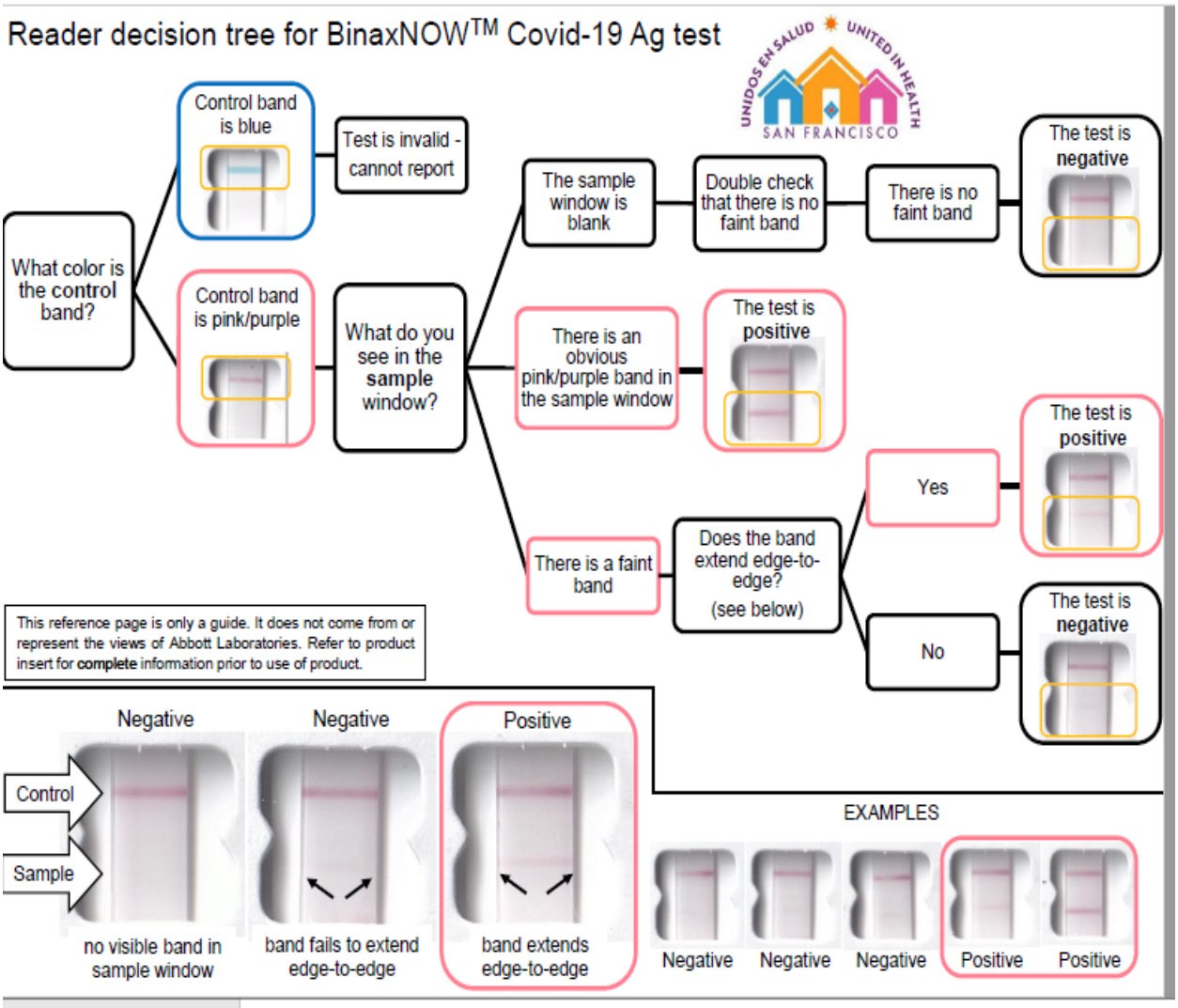
See attached Test Time Calculator and Reader Guide

Test Start Time HH:MM	Test End Time HH:MM	Test Start Time HH:MM	Test End Time HH:MM
HH:00	HH:15	HH:30	HH:45
HH:01	HH:16	HH:31	HH:46
HH:02	HH:17	HH:32	HH:47
HH:03	HH:18	HH:33	HH:48
HH:04	HH:19	HH:34	HH:49
HH:05	HH:20	HH:35	HH:50
HH:06	HH:21	HH:36	HH:51
HH:07	HH:22	HH:37	HH:52
HH:08	HH:23	HH:38	HH:53
HH:09	HH:24	HH:39	HH:54
HH:10	HH:25	HH:40	HH:55
HH:11	HH:26	HH:41	HH:56
HH:12	HH:27	HH:42	HH:57
HH:13	HH:28	HH:43	HH:58
HH:14	HH:29	HH:44	HH:59
HH:15	HH:30	HH:45	HH:00
HH:16	HH:31	HH:46	HH:01
HH:17	HH:32	HH:47	HH:02
HH:18	HH:33	HH:48	HH:03
HH:19	HH:34	HH:49	HH:04
HH:20	HH:35	HH:50	HH:05
HH:21	HH:36	HH:51	HH:06
HH:22	HH:37	HH:52	HH:07
HH:23	HH:38	HH:53	HH:08
HH:24	HH:39	HH:54	HH:09
HH:25	HH:40	HH:55	HH:10
HH:26	HH:41	HH:56	HH:11
HH:27	HH:42	HH:57	HH:12
HH:28	HH:43	HH:58	HH:13
HH:29	HH:44	HH:59	HH:14

Decision Tree

DISCLAIMER:

This guide is not sponsored by or affiliated with Abbott Laboratories. With respect to information contained in this guide, neither the University of California nor any of their respective regents, officers, board members, agents, employees, students, or volunteers makes any warranty, express or implied, including the warranties of merchantability and fitness for a particular purpose; nor assumes any legal liability or responsibility for the accuracy, completeness, or usefulness of information; nor represents that its use would not infringe privately owned rights. This guide should not be considered medical advice; anyone who believes that they may be infected with the SARS-COV-2 virus should immediately seek medical advice from their doctor or other health professionals.



Appendix B: Interest Information and Trainer Certification Information

Schools who want to participate in the CDPH K-12 School Antigen Testing program and who would like to use the CDPH K-12 Schools CLIA Certificate of Waiver should follow this process:

Interest Form to be completed upon initial interest in program: https://forms.office.com/Pages/ResponsePage.aspx?id=URsxH9n2U0GbrFXg75ZBuIH02axXNqRKmpoKrfn-QMZUNkhLRExaQlVXUjFaQUU5QUdEVDkwRjNFMS4u

Trainer Certification: If you would like to be considered an official trainer and be able to train others in the hands-on training and meet the following criteria:

- Performed the role of the Binax Lead (including maintaining the binder) at school
- You have been trained by a CDPH trainer
- Performed all 5 roles at a school test site
- Performed >50 tests in a school setting

Please email SchoolBinax@cdph.ca.gov with any questions.

Appendix C: Useful Information/Links

Who can perform testing?

- See School Testing guidance: https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/SchoolsGuidance.aspx

Antigen BinaxNOW:

- Review the package insert/BinaxNOW IFU https://www.fda.gov/media/141570/download
- Training on the use of the Abbott BinaxNOW test (See modules 1-4): https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html
- UCSF website interpreting BinaxNOW results: https://unitedinhealth.org/binax-training
- BinaxNOW safety data sheet included in the following link: https://nhfa-ems.com/wp-content/uploads/2020/11/BinaxNOW-COVID-19-Device-SDS-US-195-.pdf
- Video on Preparing and Running the BinaxNOW test: https://youtu.be/rRZLDwEHkgY

Self-Swabbing References:

- CDPH COVID-19 Testing: Demonstration of Self-Swabbing for Students: https://youtu.be/DU_G-D_sL3I
- CDC self-swabbing reference: https://www.cdc.gov/coronavirus/2019-ncov/downloads/community/COVID-19-anterior-self-swab-testing-center.pdf

Liability information:

- https://sharedsystems.dhsoha.state.or.us/DHSForms/Served/le3529.pdf
- https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx

Regulations:

Who Can Perform Waived Testing?

Personnel who are authorized under California Business and Professions Code (BPC) subsection 1206.5 (a) to perform waived COVID-19 testing at school sites include:

- A licensed **physician and surgeon** holding an M.D. or D.O degree.
- A person licensed under Chapter 3 of the BPC to engage in clinical laboratory practice or to direct a clinical laboratory. This includes **medical laboratory technicians (MLT), clinical laboratory scientists (CLS), bio analysts, and master's or doctoral degree scientists limited to a specialty.**
- A **public health microbiologist director** and **public health microbiologist** authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the HSC.
- A licensed **physician assistant** if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535 of the BPC.
- A **registered nurse** licensed under Chapter 6 (commencing with Section 2700) of the BPC.
- A **licensed vocational nurse** licensed under Chapter 6.5 (commencing with Section 2840) of the BPC.
- **Other health care personnel** providing direct patient care.

This includes school personnel who are caring for students under their responsibility. The lab director is responsible for ensuring that these personnel receive training in the use of personnel protective equipment (PPE), State and Federal requirements, including privacy laws, and performance of the specific test they are using.

http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=BPC&sectionNum=1206.5

Who can observe sell-collection of anterior nares swabs?

The observation of self-collection is not listed in the scope of practice for any California licensed healthcare professionals, to our knowledge. Observation of self-collection does not appear to be regulated under current law and is not currently a regulatory issue.

Self-collection is not regulated under federal CLIA regulations, but the CDC has published Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19.

Who can collect anterior nares specimens (for instances where individuals cannot self-collect)?

The California Department of Public Health has contacted various professional boards to collect information about practitioners who are authorized under their scope of practice to collect specimens using swabs. Current information is that specimens using swabs, including nasopharyngeal (NP) swabs, can be collected by the following healthcare personnel:

- The Medical Board of California and the Osteopathic Medical Board of California state that allopathic and osteopathic physicians can collect these specimens.
- Physician assistants can perform collection of specimens for COVID-19 testing using nasal swabs as long as they meet the current waiver requirements of DCA Waiver 02-04, in the following circumstances:
    - A physician assistant moves to a practice site or organized health care system to assist with the COVID-19 response, but does not have a practice agreement in place with any authorized physician of the site or system; or
    - As a result of the COVID-19 response, no supervising physician with whom a physician assistant has an enforceable practice agreement is available to supervise the physician assistant.
    - Please note that the waiver keeps in place the current law that all physician assistants must be supervised by licensed physicians, must be competent to perform the services they provide, and must be educated, trained, and experienced to perform services.
- According to the Dept. of Consumer Affairs medical assistant webpage, medical assistants can collect using nasal swabs, but front of the nose only. They may not collect using nasopharyngeal or oropharyngeal swabs.

- EMTs and paramedics are authorized by the Director of the California Emergency Medical Services Authority to collect nasopharyngeal swabs only for COVID-19 testing and only for the duration of the COVID-19 emergency.
- Registered nurses can collect specimens using nasopharyngeal or oropharyngeal swabs.
- Nasopharyngeal or oropharyngeal swab collection is within the scope of practice for a licensed vocational nurse (LVN) and psychiatric technician (PT) if the LVN or PT:
    - Receives specialized instruction in the proper procedure from a registered nurse or licensed physician.
    - Demonstrates the requisite knowledge, skills, and ability prior to performance of the procedure; and
    - Performs the procedure in accordance with a licensed physician's order.
    - Respiratory care practitioners are authorized under their scope of practice to collect specimens using swabs, including NP and OP swabs.

Is the BinaxNOW test FDA Approved?

The federal Food and Drug Administration (FDA) has authorized this test for use under an Emergency Use Authorization (EUA) for testing of symptomatic patients. The federal Centers for Medicare & Medicaid Services (CMS) state the following in their document entitled "Updated CLIA SARS-CoV-2 Molecular and Antigen Point of Care Test Enforcement Discretion": "CMS will temporarily exercise enforcement discretion under CLIA for the duration of the COVID-19 public health emergency for the use of authorized SARS-CoV-2 molecular and antigen POC tests on asymptomatic individuals outside of the test's authorization. Specifically, CMS will not cite facilities with a CLIA Certificate of Waiver when authorized SARS-CoV-2 molecular or antigen POC tests are performed on asymptomatic individuals outside of the test's authorization, when done so considering the information in FDA's FAQ."
https://www.cms.gov/files/document/clia-sars-cov-2-point-care-test-enforcement-discretion.pdf

The FDA states in their FAQ on Testing for SARS-CoV-2:

"Q: Does the FDA have recommendations for health care providers using SARS-CoV-2 diagnostic tests for screening asymptomatic individuals for COVID-19?

"A: Although the current available literature suggests that symptomatic individuals with COVID-19 and asymptomatic individuals without known

exposure may have similar levels of viral genetic material, there is limited data on the distribution of viral loads in individuals with and without symptoms across demographics, different settings, and specimen types. Therefore, when screening asymptomatic individuals, health care providers should consider using a highly sensitive test, especially if rapid turnaround times are available. If highly sensitive tests are not feasible, or if turnaround times are prolonged, health care providers may consider use of less sensitive point-of-care tests, even if they are not specifically authorized for this indication (commonly referred to as 'off-label'). If less sensitive tests, such as some rapid point-of-care tests, are used, health care providers should be aware of the performance of the tests and may want to consider different testing approaches, such as serial testing. 'Negative' results should be considered as 'presumptive negative,' and health care providers should consider them in the context of clinical observations, patient history, and epidemiological information. Thus, if there is a significant new outbreak in a congregate care facility or high clinical suspicion of an infection in an individual resident, a negative point-of-care test should be confirmed with a highly sensitive molecular test (refer to CDC guidelines). It is not necessary to perform confirmatory high-sensitivity molecular tests on individuals with negative antigen test or other point-of-care test results if they are obtained during routine screening or surveillance." https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-test-uses-faqs-testing-sars-cov-2

Appendix D: Information for Parents for the Abbot BinaxNOW Antigen Test in Schools

Please distribute this information sheet to all parents/guardians.

You are being given this information sheet because your school is participating in an antigen testing program. This is a voluntary program. This information sheet contains information to help you understand the risks and benefits of this testing program. This program is testing for the SARS CoV-2 virus that causes COVID-19. Symptoms of COVID-19 can range from no symptoms to severe respiratory illness. Symptoms can include fever, chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, diarrhea. For more information see the CDC Symptoms of Coronavirus.

The Abbott BinaxNOW is a rapid antigen test designed to test for the SARS CoV-2 virus with results available in 15-30 minutes. The sample will be collected by your child by inserting a soft swab ½ an inch inside the nose and slowly rotating the swab for 15 seconds and then repeating on the second nostril. Even children in kindergarten can self-swab their own noses. Most people describe a ticklish sensation or feeling the need to sneeze.

The benefits of taking the test:

- The results of this test can help keep your school community healthy, along with mask wearing, social distancing, and frequent handwashing.
- This test can help limit the spread of COVID-19 to your family and your community.
- Results are available in 15-30 minutes.

The risks of taking the test:

- Possible discomfort or other complications that can arise from sample collection.
- Possible incorrect test result.

The antigen test is not as sensitive as PCR testing. PCR is a high complexity test that needs to be run in a specialized laboratory and results are not available for 24-48 hours. Because of the lower sensitivity of antigen tests, more frequent testing is recommended. Although this test was originally designed to test symptomatic people it can be a good tool for screening individuals without illness, particularly because of the quick turnaround time and lower costs.

If a participant tests positive, they are likely infected with the SARS CoV-2 virus. The school will immediately contact you and inform you to take your child

home. A confirmatory PCR test will likely be needed. You should contact your child's medical provider to let them know about the positive result. Your child should isolate at home and all close contacts, such as family members, should follow CDC quarantine guidelines. The school will work with you and local health officials to determine the best course of action for a safe return to school.

For more information regarding COVID-19 and rapid testing from CDC, please visit: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

Fact Sheet for Patients for BinaxNOW Rapid Antigen Test:
https://www.fda.gov/media/141569/download

Appendix E: Letter of Consent

California Rapid Antigen Testing Program

School-based Testing

Standard Consent

Please carefully read and sign the following Informed COVID 19 Screening Test Consent and Authorization for the Release of Information and Test Results:

For non-minors, all sections that reference "my child" refer to the individual signing

To help make our California schools safer and reduce the risk of COVID-19 being transmitted at school, the California Department of Public Health in partnership with your school is implementing a COVID-19 testing program. Students and staff who are studying or working at the school will be tested one to two times a week for COVID-19 free of charge. Rapid tests results will generally be available within one hour. If additional laboratory-based testing is needed, you will be notified. You will receive a message when the test result is available for both negative and positive cases. This document provides consent for participation in the school-based testing program:

- I authorize on behalf of myself, or my child COVID-19 testing by self-collection of a nasal swab. Most children and adults will swab the first inch or so of their nose themselves.

- I represent that I am the parent or guardian authorized to sign this document for my child.

- I acknowledge that a positive test result is an indication that I or my child must isolate at home, follow state and county isolation procedures, and wear amask or face covering as directed in an effort to avoid infecting others.

Primary.Health Standard Consent

School-based Testing

I authorize that my or my child's test results be disclosed to the district, county and state health department, or to any other governmental entity as may be required by law.

- I authorize Primary Diagnostics, Inc. ("Primary") and each of the parties listed below to release personal information for me or my child (including name, gender, date of birth, and, to the extent applicable, dependent and/or guardianship information), contact information (including, to the extentapplicable, my telephone number, email address, and physical or mailing address), appointment information, transaction identification number, SARS-CoV-2 ("COVID-19") test information and results to the following Primary Diagnostics, Inc. partners, in order to facilitate testing for the COVID-19 infection and for the purpose of making such further disclosures as set forth in the Primary Privacy Policy, available at https://primary.health:

    - The ordering provider for your COVID-19 test
    - The ordering provider for your child's COVID-19 test
    - The California Department of Public Health, as required by law, and local public health agencies, as required by law
    - Any laboratory partner providing confirmation RT-PCR tests and/or providing mandatory reporting to the state health department
    - Primary Diagnostics, Inc. to collect the test information and share it with me, **designated school personnel** and other Primary partners, as necessary and determined by Primary Diagnostics, Inc.

Primary.Health Standard Consent

School-based Testing

- I understand that this testing site does not act as a medical provider and the testing does not replace treatment by a medical provider. I assume complete and full responsibility to take appropriate action with regards to the test results. I agree I will seek medical advice, care, and treatment from a medical provider, as applicable, if I have questions or concerns, or if conditions worsen.

- I understand that, as with any medical test, there is the potential for a false positive or false negative COVID-19 test result. I have been informed about the test purpose, procedures, possible benefits, and risks, and, if requested, have received a copy of this Informed Consent for participation in the COVID-19 test. I have been given the opportunity to ask questions before I sign, and throughout the entire testing procedure.

- I understand that the information used or disclosed pursuant to this authorization may be subject to re-disclosure by the school and may no longer be protected by federal regulations that protect the privacy and security of an individual's health information under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") or personally identifiable information contained in student education records as defined by the Family Educational Rights and Privacy Act ("FERPA"). Notwithstanding the foregoing, this consent serves as my permission to release the information used or disclosed as a result of my child's participation, provided that such release is in accordance with the terms of this consent.

- I understand that I may revoke my authorization for consent at any time by notifying Primary.Health in writing at Primary Diagnostics, Inc. at 595 Pacific Ave FL4, San Francisco, CA 94133 or support@primary.health of my desire to revoke it. In addition to notifying Primary Diagnostics, I must also provide written notice to the designated school. I understand that any action already taken in reliance on this authorization prior to my revocation cannot be reversed.

- Unless revoked earlier, this authorization expires 12 months from the date of this authorization.

- I understand the school may also request and conduct molecular (such as PCR)tests as an additional precautionary measure for certain individuals tested through the COVID antigen rapid test screener. For example, individuals with a positive result will be re-swabbed to confirm the positive antigen test. If and when this happens, the school is authorized to use my insurance information to ensure that there is no cost to me for this service. If my insurance does not cover this service, the school will work to ensure that there is not out of pocket cost.

- **Warning of Risks & Assumption of Risks:** Participating in COVID-19 screening involves inherent health risks. There is a risk of exposure to COVID-19 when leaving one's home. There is a risk that upper respiratory tract swabbing may cause discomfort, sneezing, a gag reflex, or nosebleed. By consenting to participate, I acknowledge that I understand that the risk of my or my child's participation is low risk and I voluntarily accept any health risks.

- **Waiver, Release, and Indemnification:** I understand that participating in this screening is an activity that may be a potentially hazardous activity for some individuals. I hereby assume full and complete responsibility for any injury, illness, or accident which may occur during my or my child's participation. I hereby release, waive, hold harmless and covenant not to bring a suit against the administrators, sponsors, organizers, volunteers, employees, agents or any affiliated individuals or entities associated with this screening from any and all losses, damages, liabilities or other claims and causes of action that may arise out of my participation.

- To the extent permitted by applicable law, in the event of a conflict between the English and another language version of this Informed Consent, the English language version shall control.

Note: Electronic Consent will be collected through the Primary.Health platform. If written or verbal consent is needed, the electronic consent may be exported to a printable format with the appropriate signature lines and information.

Name of Participant:_____

Date:_____

Signature of Participant:

_____

AND/OR

Name of Parent/Guardian:_____

Date:_____

Signature of Parent/Guardian:

_____

Appendix F: FAQs for the School Community

How will the sample be collected?

To collect the specimen, the participant will insert a soft swab about ½ an inch inside the nose and slowly rotate the swab at least 5 times for a total of 15 seconds and then repeat the same steps on the second nostril.

What is self-swabbing?

Self-swabbing means you collect the sample yourself. A study done at UCSF found that even young children could self-swab their own noses without difficulty. (Cooch et al, mdRxiv 2020)

What will the test feel like for my child?

Most participants describe a ticklish sensation or feeling the need to sneeze.

Why was I (or my child) tested?

You (or your child) was tested as part of routine screening at school to detect cases of COVID-19 to help avoid spread of the virus. This screening program does not replace the other important safety measures that help keep the school community safe, such as mask-wearing, social distancing, frequent handwashing and increasing ventilation.

What if I or my child refuses to self-swab?

Your school will inform you what alternatives there are for children who refuse or who are unable to self-swab.

What does it mean if a staff or student has a positive test result?

If the person currently has any symptoms of COVID-19 that began less than 7 days ago and test positive using BinaxNOW, then is the person has confirmed COVID-19 and they should isolate per CDC guidelines and get a confirmatory PCR test within 24 hours. If the person does not have any symptoms, it is highly likely that they have COVID-19 and should isolate per CDC guidelines. Because antigen tests are slightly less specific than PCR tests, there is a small chance that the test was falsely positive. For that reason, a PCR test should be obtained within 24 hours to confirm the result. If the confirmatory PCR test within 24 hours was negative and the person still does not have symptoms, the antigen test was falsely positive, and isolation can be ended. The participant or the parent/guardians of a minor will be notified if there is a positive test. Please also inform your primary care doctor and let them know about your/your child's test results. The school and the department of public health will also be notified.

What does it mean to have a negative test result?

A negative test means a person most likely does not have the virus that causes COVID-19, unless they have symptoms of COVID 19. If they have symptoms of COVID 19 and test negative, then a confirmatory PCR test should be performed.

It is possible, though unlikely, for this test to give a negative result that is incorrect (a false negative) in some people with COVID-19. This means a person could still possibly have COVID-19 even though the test results are negative. This is why individuals who test negative must still observe safety measures including mask wearing, physical distancing and handwashing and the test will be repeated on a regular basis.

How does the Abbot BinaxNOW test compare to other types of tests?

The Abbot BinaxNOW test is a rapid antigen test. It works by identifying SARS-CoV-2, the virus that causes COVID-19 disease in 15-30 minutes. This test is different from a PCR test. A PCR test is a high complexity test and needs to be run in a specialized laboratory and results are not available for 24-48 hours. A PCR test, like an antigen test, identifies an active infection with SARS-CoV-2. It is also different from an antibody test, which is a blood test that checks whether or not you have had a SARS-CoV-2 infection in the past.

What does self-isolate mean?

People who are in isolation should stay home until it's safe for them to be around others. In the home, anyone sick or infected should separate themselves from others by staying in a specific "sick room" or area and using a separate bathroom. Don't share personal household items, like cups, towels, and utensils. Members of the household should wear masks when around other people, if possible. Isolation lasts for at least 10 days from the positive test unless otherwise instructed by your primary care doctor or public health department. (More information from the CDC on self-isolation and caring for others with COVID-19)

If I get the COVID-19 vaccine, will I test positive?

No, getting the COVID-19 vaccine will not affect the result of the antigen test.

Is this test FDA approved?

The FDA has authorized this test for use under an Emergency Use Authorization (EUA) for testing of symptomatic patients. The FDA states: "If highly sensitive tests are not feasible, or if turnaround times are prolonged, health care providers may consider use of less sensitive point-of-care tests, even if they are not specifically authorized for this indication (commonly referred to as 'off-label'). If less sensitive

tests, such as some rapid point-of-care tests, are used, health care providers should be aware of the performance of the tests and may want to consider different testing approaches, such as serial testing." (https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-test-uses-faqs-testing-sars-cov-2)

What is the sensitivity and specificity of this test?

Positive agreement of the BinaxNOW compared a PCR assay was "99/117, 84.6% (95% CI: 76.8% - 90.6%)." Negative agreement of the BinaxNOW compared to a PCR assay was "338/343, 98.5% (95% CI: 96.6% - 99.5%)." For more information about the sensitivity and specificity of the test, please see the Abbott Instructions for Use for the COVID-19 Ag Card Rev. 2 2020/12 (https://www.fda.gov/media/141569/download).

If my child is sick, can I send him/her to school so he/she can be tested?

No, please keep your child at home and seek testing at a local COVID-19 testing center. Please seek care with your child's primary care provider.

Does a deviated septum affect the test?

No, a deviated septum does not affect the test.

How long after testing positive for COVID-19 should someone wait before being retested?

Follow CDC guidelines as when retesting can occur following a previous positive test.

Appendix G: Information on software platform Primary.Health

Primary

School-Based Rapid COVID-19 Testing

Who We Are

Primary.Health is the engine behind your COVID-19 testing and vaccination programs. Our web-based platform helps schools conduct affordable, convenient, and efficient rapid COVID-19 testing for teachers, students, and staff to promote a safer in-person learning environment.

Why Choose Primary

- User-friendly interface
- Web-based portal works with any browser
- Works on any smartphone, tablet, or computer
- Phone support for those without Internet access
- Supports 15 languages
- No need to install apps or create logins
- Fully HIPAA-compliant

School-Based Rapid Testing Using Abbott BinaxNOW™

Primary provides a comprehensive solution to help you run safe and effective COVID-19 rapid testing programs for students, faculty, and staff. We can also arrange for onsite nasal or saliva-based PCR testing. Our team assists with staff/student roster uploads, parental consents, capacity planning and site logistics, onsite workflows, automated state reporting, and result notification.

Our dashboards and data analytics help schools track cases, identify outbreaks early, and quickly isolate positives to stem viral spread.

"Parents and students are eager for schools to reopen in San Diego. Primary.Health's automated technology is giving us the tools we need to register, streamline and organize testing so that we can get life back to normal for our kids, while ensuring teachers and parents feel healthy and safe."

Donnie Salamanca, Deputy Superintendent, Coronado Unified School District

"Primary.Health got our BinaxNOW™ program up and running in less than 24 hours. Their platform helped us create a safer in-person learning environment for all of our staff especially our teachers and students."

Roy Mendiola, Ed.D., Superintendent, McSwain Union Elementary School District, Merced CA

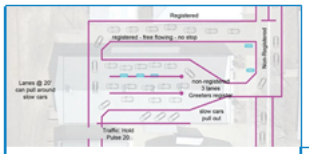
For more information, visit Primary.Health

595 Pacific Ave, San Francisco, CA 94133 | 1-855-970-0077

Primary

School-Based Rapid COVID-19 Testing

How It Works



Site Logistics & Capacity Planning

We design a program that meets the needs of your locations, populations, and program goals.

Participant Registration & Digital Consent Forms

Participants can easily register, sign consents, and view results.

On-Site Workflow Management

We help you test students and staff quickly and efficiently to minimize classroom disruptions.

Automated Reporting

Eliminate paperwork and reduce errors by automating state reporting and participant notifications. We provide digital proof of test result/vaccination.

Data Analytics & Dashboards

Monitor program metrics to identify outbreaks quickly and track cases over time at a district level.

The Platform

Key Features

- Easy staff/student roster uploads
- On-demand scheduling and self-check-out features
- Digital participant/parental consent
- Faster on-site check-in and check-out
- Automated result notification
- Automated state reporting
- Register household members
- Collect insurance information (optional)

Our Platform Supports

- PCR testing
- Saliva Direct
- Abbott BinaxNOW™
- Rapid antigen
- LAMP
- Emerging technologies
- Flu vaccine
- COVID-19 vaccine

COVID-19 Vaccine Features

- Unique access codes
- Health equity tools
- Multi-dose scheduling management
- Appointment reminders
- Proper dosing intervals
- Pre-screening questions
- Automated follow-up symptom questionnaire

For more information, visit Primary.Health

595 Pacific Ave, San Francisco, CA 94133 | 1-855-970-0077

Appendix H: Guidelines for student self-swabbing.

This is a guide to teaching students and staff how to self-swab.

Steps for Self-Swabbing (images below)

1. Take the participant or a small group of participants outside to the testing site.
2. Have the participants space out at least 6 feet apart or guide them individually.
3. Have the participants wash their hands or use hand sanitizer prior to testing.
4. Open the swabs and hand out swabs to the participants and let participants know not to touch the soft end of the swab.
5. Have the participants slide their masks below their noses, keeping the mask over their mouths (while maintaining a 6-foot distance from them).
6. Have the participants place their swabs about a half an inch (about the depth of 2 pencil erasers or the length of the soft part of the swab) into one of their nostrils and twist the swab and circle around, rubbing the inside surface of the nose at least 5 times slowly for 15 seconds*, then have the participants place the swab in the second nostril and twist the swab around at least 5 times slowly for 15 seconds*.
7. Have the participant pull their masks back above their noses and carefully take the swabs back from the participants.
8. Perform the test according to manufacturer's instructions.

For a video demonstration: CDPH COVID-19 Testing: Demonstration of Self-Swabbing for Students:

https://youtu.be/DU_G-D_sL3I

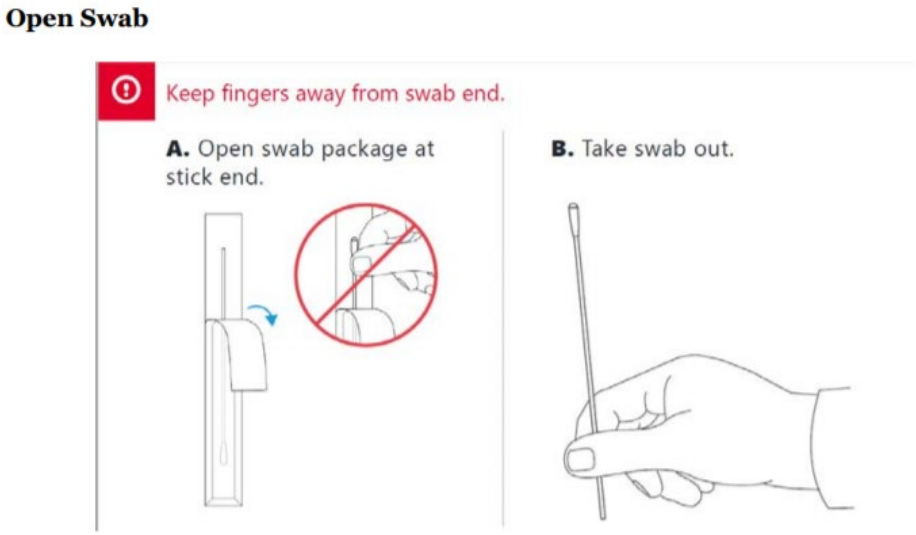
Language considerations for children: When guiding staff and students in self-swabbing, be aware of the language you are using.

- Children may not know typical references such as "half an inch." Consider using a different reference such as "put the swab in just the front part your nose, about 2 pencil erasers in depth, like you are picking your nose."
- Use comforting terms, as children might be anxious about this new experience, especially if they have previously been tested by someone else. Using phrases like "this test might tickle a little bit or cause you to sneeze" can be comforting. Avoid negative phrases such as "this may feel uncomfortable" or "this won't hurt."

Prepare children for the test: Preparing students for testing beforehand will make the testing process smoother.

- Encourage parents to watch the video with their children and have the children practice with soft cotton swabs (Q-tips) at home.
- Talk about the testing in class to prepare the children in the days prior to the first test and prepare them for how often testing will occur.
- Consider showing the video to children in class on the day of testing.
- Consider showing students the images below or using a model of a nose (or a paper image of a nose), to demonstrate how far the swab is inserted in the nose.
- Place posters of how to do the test in the area where students will be waiting for their turn.

*Note that the CDC Guidelines for Anterior Nasal Swab Sample Collection states "at least 4 times for a total of 15 seconds", the updated BinaxNOW Instructions for Use state "5 times or more for a total of 15 seconds"



HOW TO COLLECT YOUR ANTERIOR NASAL SWAB SAMPLE FOR COVID-19 TESTING

Follow the instructions included with your sample kit. Use **only** materials provided in your kit to collect and store your sample, unless the kit says to do otherwise. Use **only** an approved sample collection kit given to you by your healthcare provider or personnel at the testing center.

Initial set-up

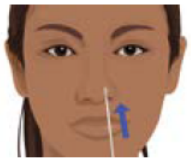
1. Open the sampling kit.

2. Apply hand sanitizer with at least 60% alcohol. Cover all surfaces of your hands and rub them together until they feel dry.

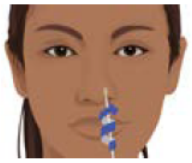
Sample collection

3. Remove the swab from the container, being careful not to touch the soft end, which is the absorbent tip.

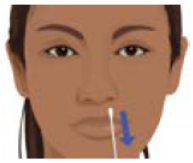
4. Insert the entire absorbent tip of the swab into your nostril, but do not insert the swab more than ¾ of an inch (1.5 cm) into your nose.



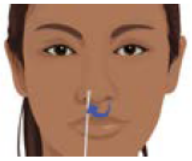
5. Slowly rotate the swab in a circular path against the inside of your nostril at least 4 times for a total of 15 seconds. Be sure to collect any nasal drainage that may be present on the swab.



6. Gently remove the swab.



7. Using the same swab, repeat steps 4-6 in your other nostril.



CS 317702-C 11/13/2020

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