# COVID-19 Antigen Testing K-12 Schools Playbook

# Contents

# 1. Introduction

School closures have been part of the public health response to SARS-COVID-19 virus 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 a number of interventions to reduce COVID-19 transmission including physical distancing, face masks, enhanced hand hygiene, smaller class sizes and staggered class times. Testing asymptomatic students and staff for COVID-19 can also be an additional strategy used 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. This playbook provides information about setting up an antigen testing program in K-12 schools. Information on other testing platforms can be found at https://schools.covid19.ca.gov/ (this is also an excellent resource for many school-related COVID-19 issues).

Symptomatic staff and students should be encouraged to stay home when ill. If they do come to school or develop symptoms while at school they should be tested, if testing is available. If antigen testing is used, the ill 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 students and staff can help prevent and mitigate outbreaks in schools. Testing programs in schools are primarily designed to test asymptomatic students and staff and detect cases that might not otherwise be identified.

Molecular (e.g., PCR) testing is a common method used to diagnose COVID-19. Molecular testing is highly sensitive (unlikely to be falsely negative, i.e., a negative test result in an infected individual) and specific (unlikely to be falsely positive, i.e., a positive test result in a person who is not infected). Molecular testing is primarily conducted at high-level laboratories and the time from specimen collection to when patients receive their results may be a few days. Conversely, the BinaxNOW antigen test can be performed in a nonclinical setting such as a school and results are available within minutes.

Antigen tests were originally designed to test symptomatic people and they are more likely to be falsely negative in asymptomatic individuals (individuals without symptoms) than molecular tests. (*insert info about asymptomatic testing here-tbd*) However, positive results are likely to be truly positive and to detect those who are the most infectious. Because antigen testing may not identify asymptomatic people at the beginning of their infection if their viral load is low, it is most effective when performed more frequently than molecular testing.

## Goal, Strategy, Objectives

**Goal**: To implement screening testing of asymptomatic students and staff with the antigen BinaxNOW antigen test in K-12 schools.

**Strategy**: to simplify CLIA certification process for schools, suggest software platform options to help with consent and reporting of results to individuals, key school administrators and public health authorities and to train schools on how to perform testing.

**Objective**:

- To create a system to register schools and distribute BinaxNOW Tests.
- To train schools in multiple competencies around self-collection of nasal swabs for staff and students, testing procedures and managing the flow of testing
- To partner with software platform to help report results to the local DPH (this is optional)

# 2. Considerations in Choice of Testing

## Which Testing Type is Best for My School?

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 it is not a "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 while PCR test results are generally not available for at least 1-2 days. One of the disadvantages of an antigen testing program is that it requires training of staff at the start of the program and on-going availability of these staff for testing. Additionally, antigen testing has a lower sensitivity, thus more frequent testing is generally recommended.

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 may provide important insights. ( *consider adding list of schools doing antigen testing in appendix*).

**Advantages and Disadvantages of SARS-CoV-2 Test Types**

| Test type | Advantages | Disadvantages |
|---|---|---|
| **PCR Individual Test** (e.g. PCR) | • Ease of initiation testing program<br>• Familiarity with this testing type | • More costly than antigen-based or pooled molecular<br>• Turn-around-time variable (48 + hours) and in rural settings, turn-around-time likely longer |
| **Pooled PCR Test** (e.g., specimens from all children in one pod or classroom are combined and tested as a single test) | • Costs are less than individual based assays<br>• If test is negative, it is reassuring that all children in classroom are negative<br>• Logistically easier to collect specimens from a cohort than PCR 1:1 or antigen, since individual bar codes are not required for each student<br>• Likely best paired with PCR 1:1 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. Hence, if in-school rates of COVID-19 are high, then the pooled approach becomes less cost efficient<br>• Turn-around-time variable (48 + hours) and in rural settings, turn-around-time likely longer |
| **Antigen Test** with reflex to PCR as needed | • Cost for the test itself less than PCR test itself<br>• Almost immediate test results (within 30 minutes of collection) | • Since testing done on school site, this approach requires additional resources compared with PCR testing:<br>– Trained personnel required to perform testing and entry of test result<br>– CLIA waiver needed see https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/SchoolsGuidance.aspx.<br>• Twice per week testing recommended<br>• Follow-up molecular testing may be needed on subset of individuals (e.g. if unexpected result such as positive results in asymptomatic individual without contact or negative result in symptomatic individual) |

From: https://schools.covid19.ca.gov/

# 3. Steps to Implement Testing

## Overview Checklist

- □ Discuss plan with local public health department
- □ Identify medical partners (physician partners, community health organizations, school nurses) to serve as liaisons and communicators
- □ Complete CDPH enrollment process (Appendix A)
- □ Choose software platform company to help register, consent, track and report results (to staff or parents, select school administrators and public health) and create dashboard for school (e.g. Primary or Color) (Appendix B)

- □ Identify MD to order tests
- □ Identify appropriate personnel who can perform testing (pages 8,9)
- □ Train personnel on BinaxNOW testing through either on-site or remote training (pages 11,12)
- □ Review guidelines for student self-swabbing (Appendix C)
- □ Acquire personal protective equipment (mask, gloves, face shields) (pages 11, 17)
- □ Develop contingency plans for confirmatory PCR testing (pages 20-22)
- □ Request Antigen Tests to be shipped to School District (page 11)
- □ Develop consent forms with necessary translation, may need input school legal team (page 10 and Appendix D)
- □ Communicate with Staff/Parents about testing program (sample language to be developed)
- □ Feedback to CDPH on the pros and cons, ways for improvement

## Enrollment

### Applying to the CDPH Program

The BinaxNOW is a "waived test" meaning that it is a low complexity, but due to federal regulations, must be performed in a "laboratory". Thus, any facility performing BinaxNOW tests is acting as a laboratory. Because of this, each school district must have a CLIA waiver. Public and private K-12 districts/schools that wish to participate in California's antigen screening program can use our State CDPH K-12 school CLIA waiver license but must complete necessary requirements. This can be done through enrollment process found below as well as (Appendix A):

- Phase I – Use this link to start enrollment process
- https://forms.office.com/Pages/ResponsePage.aspx?id=URsxH9n2U0GbrFXg75ZBuIH02axXNqRKmpoKrfn-QMZUNkhLRExaQlVXUjFaQUU5QUdEVDkwRjNFMS4u
- Phase II – use this link to complete enrollment process
- https://forms.office.com/Pages/ResponsePage.aspx?id=URsxH9n2U0GbrFXg75ZBuIH02axXNqRKmpoKrfn-QMZUMFZBVTBKWkJJV005MVVRQlI4U09RVUVPVy4u
- Competency quiz:
- https://forms.office.com/Pages/ResponsePage.aspx?id=URsxH9n2U0GbrFXg75ZBuIH02axXNqRKmpoKrfn-QMZUQVpBNVBVNzFRQjUzMTdRTjA2VUpTUk5PSC4u
- More information on the below topics found in (Appendix A):
    - Who can perform the test?
    - Who can collect the specimens?

## Preparing Your School Community

### Assembling your team

First, identify roles and responsibilities of staff facilitating the process. Sites must have trained staff on site to oversee all test administration. Staff requirements at the site will vary based on size and organization but there are multiple roles that personnel need to fill with different requirements. For example, in small schools two staff members are likely sufficient while larger schools will need more staff.

Roles:

- Guiding staff and students and managing traffic flow.
- Checking-in staff and students, locating their registration or assisting them with self-registration.
- Collecting samples (monitoring self-collection)
- Running the BinaxNOW test and reading the results.
- Preparing samples for shipping to the lab if confirmatory PCR is needed.

**Who can perform BinaxNOW test? (Business and Professions Code 1206.5)**

Healthcare personnel who are providing direct patient care can perform the test. This includes school personnel who are caring for students under their responsibility. The lab director is responsible for ensuring that these personnel received training in the use of personal protective equipment (PPE), state and federal requirements, including privacy laws, and perform the specific test they are using.

- Appendix A
- https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/COVID-19FAQ.aspx#TestingandCollectionSites

**Who can observe self-collection of nasal swabs?**

The observation of self-collection is not listed in the scope of practice for any California licensed healthcare professionals and is not regulated under current law. However, CDC has published Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19. (Appendix A)

Any trained staff member, preferably a healthcare professional, can supervise the self-collection.

Because testing needs to occur within an hour of the nasal swab self-collection should be done on site.

### Informing your community

Create a plan to inform staff, parents and families about the purpose of the program, information on the testing platform (antigen vs. PCR), nasal swab self-collection, and how test results will be communicated. We recommend early and clear communication from leadership and recommend preparing town halls for question and answer sessions with a medical professional that is trusted by the community. Sample FAQs for parents are included below (Appendix E).

Special care should be taken in communicating with students. They should be shown the video so they understand what the sample collection will mean for them. For younger children, parents should be encouraged to have their child practice self-collection at home (with a soft cotton swab/Q-tip) (watch the video (https://youtu.be/hl8216ReYKI).

## Consent

Ideally, the consent will be for the duration of the pandemic (i.e., for multiple times over the next several months). Consent should include permission for staff and student to self-collect nasal swab (under supervision), the testing itself (antigen testing) and sharing of results with limited school administrators. Consent should also include permission for follow-up confirmatory PCR testing when needed. A consent example can be found in Appendix but should be reviewed and adapted by your legal counsel (Appendix D). In instances where children who are unable to perform self-collection, another consent may be needed for appropriate personnel to collect the specimen.

Because SARS-CoV2 is recognized as a communicable disease, which is required to be reported, California state law provides that minors 13 years and older can consent to diagnosis and treatment of COVID-19. Students ages 13-17 may consent on their own and receive results through their own contact information or through their parent's contact information. For students under the age of 13, the parent or legal guardian must provide consent, and use their email/phone to obtain results.

Additional information on school-centered testing, including the CDPH Playbook for implementation, can be found : 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 for 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 and staff test results, both positive and negative, shall be kept confidential. Student test results may be shared with the student and their legal guardian. Test results will also be reported to public health and key school administrators.

Schools must train staff on confidentiality requirements under family education rights and Privacy Act (FERPA), Health insurance Privacy Accountability Act (HIPAA), and local policy regarding student and staff health information, including a COVID-19 diagnosis.

## Obtain your materials

**BinaxNOW Tests**

To calculate the number of tests needed for 1-month supply, please use the formula below. It is best to order in increments of 640 (one case). See section under Testing with BinaxNOW for storage information and shelf life.

- Number of people (all staff and students) to be tested, multiple by 8 (for twice weekly testing and 4 weeks of testing). Then round up to the nearest increment of 640.

Request your tests by contacting Robert Nakamura at Robert.Nakamura@cdph.ca.gov (*this is temporary, will need different system as programs grows*). Please allow 10-14 days to receive the tests. Please include in the subject line: BinaxNOW Test Request, INCLUDE YOUR SCHOOL NAME AND DISTRICT

- School Name and School District Name:
- Quantity of tests requested:
- Address for delivery:
- Delivery information (is there a loading dock, hours of operation):
- Contact person to received delivery:
- Cell phone number of contact person:
- Email for contact person:
- Backup contact and cell phone:

**Protective Equipment (PPE) for observation of self-collection**

Personnel will need gloves, masks and optional, but strongly recommended, face shields or goggles.

**Trash bags**

Obtain biohazard bags for positive tests and black normal trash bags for negative tests and used gloves.

**Technology**

Obtain necessary technologic devices to run software (iPad/tablets/laptops with webcams)

## Train Personnel

The district should assure that all staff involved in testing receive required trainings. These trainings will include:

1. Specimen collection
    a. Train personnel how to guide staff and students in self-swabbing. (Appendix C)
    b. For the rare circumstance's individuals are not able to self-collect, see Troubleshooting section.

2. Antigen BinaxNOW
    a. Video of Susan Coffin overview of the BinaxNOW test: https://www.youtube.com/watch?v=rRZLDwEHkgY&feature=youtu.be
    b. Review the package insert https://www.fda.gov/media/141570/download

c. 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
   Note: Modules 5 and 6 relate to the NAVICA smartphone app. At this time the NAVICA smartphone app is not recommended (therefore, no need to view modules 5 and 6). Training videos should be watched prior to performing BinaxNOW test collection.
d. The following directions are highlights on performing the BinaxNOW test collection and processing. Detailed directions can be found in the BinaxNOW EUA available here: https://www.fda.gov/media/141570/download
e. UCSF brief video on interpreting BinaxNOW results: https://unitedinhealth.org/binax-training
f. At least one individual from your team needs to review and become familiar with the Standard operating Procedure (SOP) for BinaxNOW test (This will be provided outside of the playbook).

3. In addition to all steps above, schools will be required to have in-person training (from public health department, school personnel from another school or other entity trained in testing or visit a school where testing take place) OR virtual training with CDPH training group or is required. This training helps to coalesce all the trainings above.

4. Personal Protective Equipment (PPE)
    a. Donning (i.e., putting on the PPE)

## MASK OR RESPIRATOR

Secure ties or elastic bands at middle of head and neck

Fit flexible band to nose bridge

Fit snug to face and below chin

Fit-check respirator

## GOGGLES OR FACE SHIELD

Place over face and eyes and adjust to fit

## GLOVES

Extend to cover wrist of isolation gown

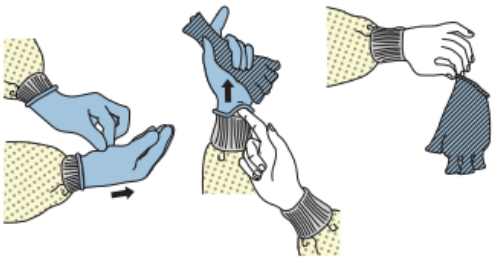
b. Doffing (i.e. removing the PPE)

## HOW TO SAFELY REMOVE PERSONAL PROTECTIVE EQUIPMENT (PPE) EXAMPLE 1

There are a variety of ways to safely remove PPE without contaminating your clothing, skin, or mucous membranes with potentially infectious materials. Here is one example. **Remove all PPE before exiting the patient room** except a respirator, if worn. Remove the respirator **after** leaving the patient room and closing the door. Remove PPE in the following sequence:

### 1. GLOVES

- Outside of gloves are contaminated!
- If your hands get contaminated during glove removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Using a gloved hand, grasp the palm area of the other gloved hand and peel off first glove
- Hold removed glove in gloved hand
- Slide fingers of ungloved hand under remaining glove at wrist and peel off second glove over first glove
- Discard gloves in a waste container

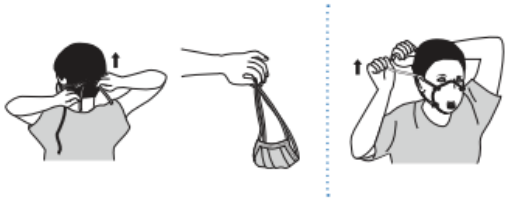


## 2. GOGGLES OR FACE SHIELD

- Outside of goggles or face shield are contaminated!
- If your hands get contaminated during goggle or face shield removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Remove goggles or face shield from the back by lifting head band and without touching the front of the goggles or face shield
- If the item is reusable, place in designated receptacle for reprocessing. Otherwise, discard in a waste container

## 3. MASK OR RESPIRATOR

- Front of mask/respirator is contaminated — DO NOT TOUCH!
- If your hands get contaminated during mask/respirator removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Grasp bottom ties or elastics of the mask/respirator, then the ones at the top, and remove without touching the front
- Discard in a waste container



5. HIPAA Training
    a. For those who do not have a HIPAA certificate, there are various online course Example found here: https://www.accountablehq.com/free-hipaa-training/privacy-rule

6. Software platform training
    a. We recommend using a software partner to help with registration, consent, test result management, and mandated electronic reporting. They will provide all training related to use of their software. Contact information located in Appendix B.

## Day(s) of Testing

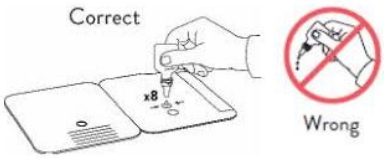
## Testing Day: Step by step

Step 1: Register and consent prior to testing day.

Step 2: Check-in

Step 3: Self-Swabbing

Step 4: Running tests




Step 5: Reading tests and communicating results

Primary color

**Step 1: Register and consent prior to testing day**

- Staff and students/parents register electronically ahead of time. Depending on the software company used, there may be the ability to do same day registration and consent.

**Step 2: Check- in**

- Staff and students identified in the software platform system and their identity and information is confirmed.
- After check-in, a test kit is opened and marked with participant's name or initials
- Associate the person with QR code on a newly opened BinaxNOW card

**Step 3: Self-Swabbing**

- Staff and students proceed to be taught on how to self-collect their sample (ideally would have been shown https://youtu.be/hI8216ReYKI) before as well)
- Once swabbing is complete, the swab is then given to the personnel assigned to run and read the tests.

**Step 4: Running the Tests**

- Testing personnel applies reagent to BinaxNOW card, 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 at 15 minutes, no longer than 30 minutes. Once read, each result must be recorded on the software data platform
- Ideally two independents individuals read the results and/or a photograph is taken of the results
- The negative results are communicated electronically to children's parents and staff tested. The results will also be shared with a limited number of previously designated administrative staff.
- The positive results can be communicated electronically, but in the event of a positive or ambiguous test result we recommend a confidential over the phone or in-person discussion of the result in a private area.

## 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 transmission but may not be feasible. If you choose an outdoor location having contingency plans for inclement weather such as wind/rain, have supplies to cover electronics and paperwork and an alternative indoor location such as a gymnasium.

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

## Software Preparation

Your software company (Appendix B) will walk you through the preparations necessary and provide training for your personnel on how to use the software.

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.

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 patient data is collected on these paper forms, the site is responsible for securely shredding these documents. This is necessary because the data is considered personal health information (PHI) which is protected by HIPAA.

## Crowd Management

Certain measures need to 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
- Acquire or develop markers on the ground to help people maintain distance when waiting in line and when at the different stations
- Consider placing educational materials where people are waiting so that they are prepared for the testing set up and how to do self-swabbing (e.g. show continuous video https://youtu.be/hl8216ReYKI )
- Consider using an appointment model or to have assigned times for participants avoid spread out testing

## Ensure Supplies

Before testing begins, ensure that you have the following materials in preparation for your testing event:

- Personal protective equipment (gloves and disposal surgical masks)
- Trash cans with bags and biohazard bags
- Pens (to mark the BinaxNOW cards)
- Timers (to time the BinaxNOW tests)
- Appropriate technologic devices: iPad/tablets/laptops with cameras available to use software to manage check-in and reporting results
- Clocks available to write down time the tests were performed on the cards.
- Table space to lay the volume of cards you need flat during the 15-30 minutes when the tests will be running and read
- Paper version of consent in case of emergency (most consents will be done electronically via the platform which is the preferred option).

# 4. 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. Tests currently available in CA will expire April – June 2021.

## Quality Control (QC)

Personnel should record in the data system the required quality control documentation below.

QUALITY CONTROL BinaxNOW COVID-19 Antigen Card has built-in procedural controls.

The pink-to-purple line at the "Control" position is an internal procedural control. If the test flows and the reagents work, this line will always appear.

For proper QC, a positive and negative control must be run on each lot that is shipped to your facility. In each 40-test BinaxNOW box there is one external positive control (packaged separately). An unused swab can be used for a negative control. For quality control, test one positive and one negative control from one box out of the entire order to ensure that test reagents are working. If your shipment has tests from more than one lot, you must perform QC on each lot that was received.

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For more information: BinaxNOW COVID-19 Ag CARD EUA
https://www.fda.gov/media/141570/download

## Who can collect specimen?

## Personal Protective Equipment (PPE)

| Type | Personnel requirement | PPE requirement/recommendations | Comments |
|---|---|---|---|
| | | | |
| OBSERVATION of Self-Collection 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 below) https://youtu.be/hl8216ReYKI<br><br>Since students will have to remove their masks, recommend that when possible testing be done in an outdoor, well ventilated 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 Assistants; Psychiatric Technician. | N95 or higher-level respirator (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
- Insert the swab so the top of the swab is in the well and rotate the swab clockwise 3 times
- Remove adhesive 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 any concerns about the test results, please photograph

To avoid false results:

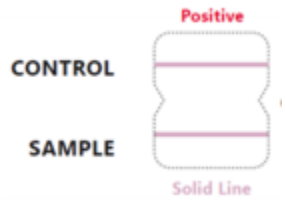
- Do not delay inserting the swab after applying the reagent
- Collected nasal swabs should not be placed back in original swab packaging
- The swab should not touch anything after specimen collection
- Test cards must remain FLAT for the duration of the 15 minutes. If the card needs to be moved, keep flat and move minimally

- The sample should be tested immediately after collection for best results
- Tests read before 15 minutes or after 30 minutes are invalid and must be repeated

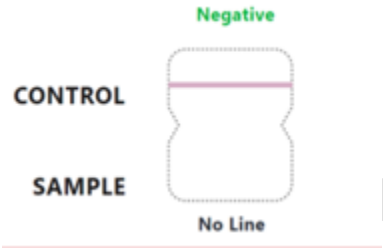
More information in the package insert https://www.fda.gov/media/141570/download

## How to read results:

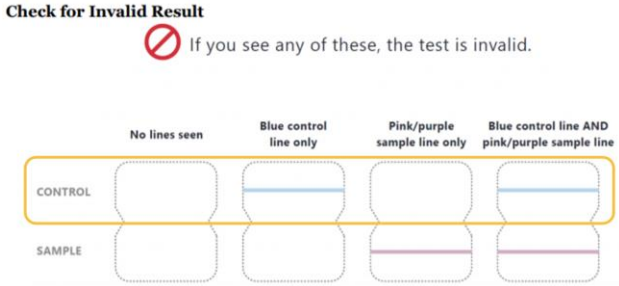
Positive:




Negative:




Ambiguous:



Should there appear a faint line: See troubleshooting section


## 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). This includes used swabs and test components.

- If the test is negative, these 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 certified to meet the ASTM D1709 dart drop test and kept in a properly marked biohazard container with a lid.
    - Per local ordinance, 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 and can be found: https://www.cdph.ca.gov/Programs/CEH/DRSEM/Pages/EMB/MedicalWaste/Local-Enforcement-Agencies.aspx

# 5. Understanding Test Results

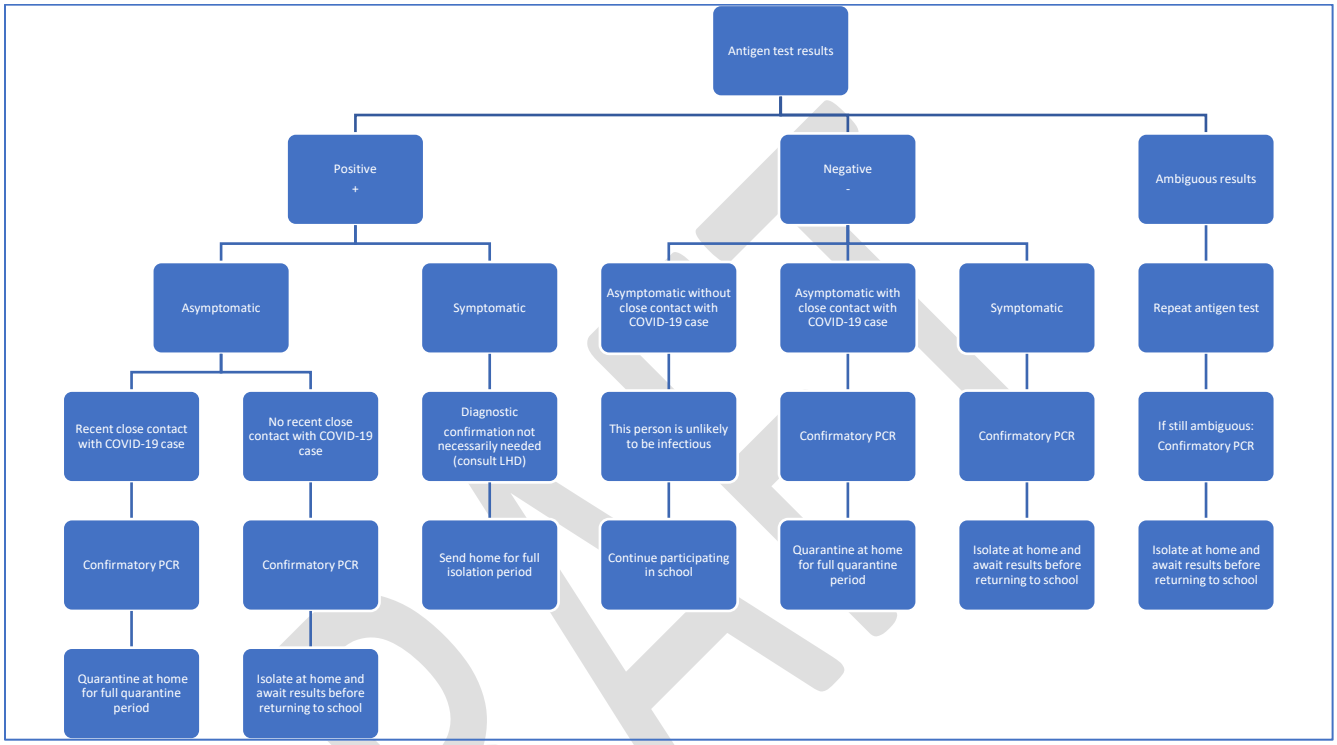
Recommendations for the interpretation of BinaxNOW test results: When to perform follow-up PCR testing in school settings

*This applies to BinaxNOW antigen testing only*

Early in the implementation of a school's rapid antigen BinaxNOW testing program, additional testing by PCR (or another molecular test) may be helpful to confirm antigen test results while test readers become proficient. Confirmatory testing with PCR for the first few weeks of a testing program builds confidence in antigen testing and it is suggested that at least 10 samples be sent during the early phase. These samples should be from a combination of positive and negative individuals. After demonstrating concordance, confirmatory testing can be stopped and then used only as needed (as described below). These are recommendations only and as issues arise, discussion with local public health department and school leadership is important.

Notably, the BinaxNOW tests are very reliable in terms of positive results, but negative results may be less reliable than those from molecular tests, thus confirmatory PCR testing should be performed in individuals with negative antigen results when high suspicion of infection as outlined below.

## Antigen Test Algorithm




### Positive Results in Asymptomatic Person

An asymptomatic individual that has a positive BINAXNOW test result in an asymptomatic individual should be considered COVID-19 positive.

- When such an individual has a positive antigen test result, it may be helpful to interview them since it is possible that very mild symptoms were thought to be from allergies or other causes and were not previously mentioned.
    - If during the interview, the individual describes positive signs or symptoms consistent with COVID-19, confirmatory PCR testing is not necessarily needed, and the tested individual should be considered infected.
    - The tested individual should go home to isolate and close contacts* should go home to quarantine.
- If confirmatory PCR testing is performed, the tested individual should go home to isolate, and close contacts* should go home to quarantine.
    - If PCR is positive, the tested individual should remain isolated and close contacts* should remain quarantined.
    - If PCR is negative, the tested individual and close contacts* may return to school.

## Negative Results in Asymptomatic Person

Negative results in an asymptomatic individual means that the tested person is likely not infectious and can remain at school. This will be the largest group of tested individuals.

## Negative Results in Asymptomatic Person with a COVID-19 Close Contact

- Those who have had recent close contact (<10 days) with an infected person should be quarantined and should not come to school.
- If such an individual does come to school and is tested and is antigen test negative, confirmatory PCR testing should be done.

## Negative Results in a Symptomatic Person

Negative antigen test results in symptomatic individuals suggest that the individual does not have active COVID-19 infection. However because antigen tests can be 'falsely negative' (negative when individual is actually infection) the tested individual should be considered infected until PCR results are available

Negative results in symptomatic individuals should be confirmed by PCR within 24 hours.

- The symptomatic person should go home to isolate until the 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 invalid, a repeat BinaxNOW test is required.

- If there is any doubt about the absence or presence of a line in sample window, the BinaxNOW test should be repeated (this will be an uncommon event).
- If the repeat test is still ambiguous consider direct consultation with the school's CLIA lab director and/or a physician. In most cases, a confirmatory PCR test should be performed, and the tested individual should go home to isolate. Close contacts* may remain at school.
    - If PCR test is positive, the tested individual should be considered infected and continue to be isolated, and close contacts* should go home to quarantine.

    - If PCR test 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 sample window, this is a positive result (see several examples and note how faint the line can be and still be considered positive).
- Conversely, if a faint line is observed 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.**

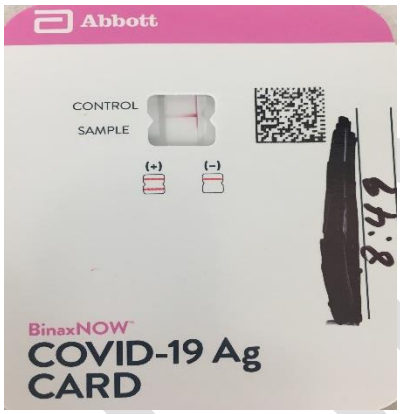
### How to Manage a Positive Result

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

## 6. Troubleshooting

### Test Questions

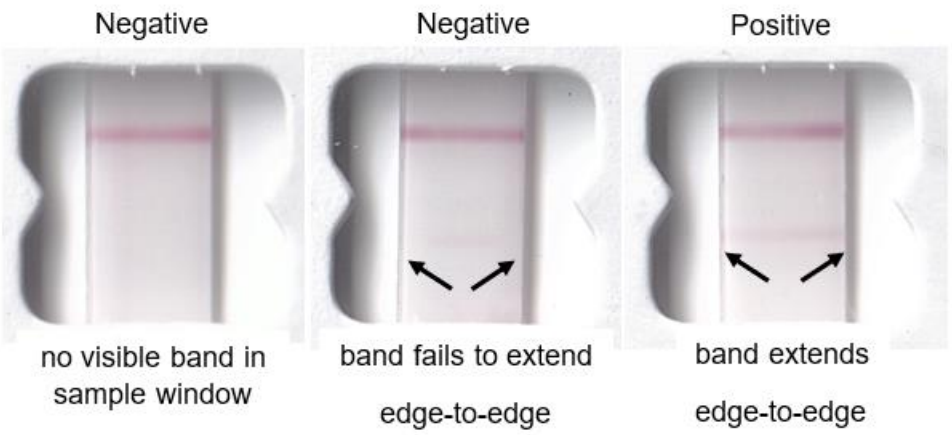
**What do I do if I see a pink line down the side of the test?**

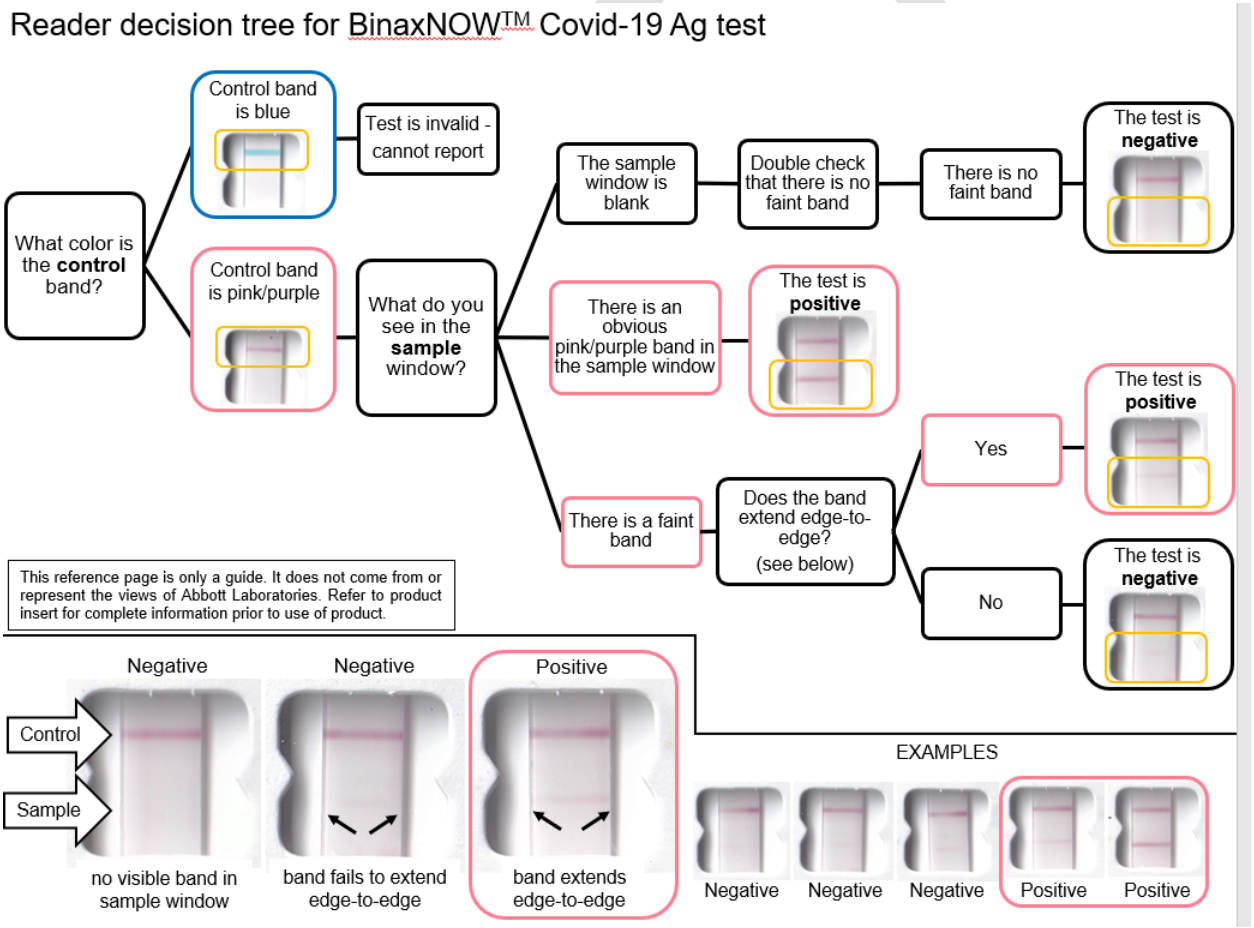



A pink line down the side of the test is normal. As long as the control line appears pink and extends edge to edge the test is valid.

**What should I do if there appears a faint line in the sample window?**

- Photograph test and run the test by health care personnel (nurse).
- Repeat test collection and BinaxNOW test with a new card.
- If the line extends edge to edge, then count it as a positive test.
- If the line does not extend edge to edge reflex to PCR test.
- If repeat does not have a faint line call it 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 the drop does not go in the well, do not count it towards the 6 drops of reagent.

**What if my card was not flat while it was running?**

Repeat the test.

**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 to 86 degrees Fahrenheit. However, tests have been performed outside of these temperature parameters and that has not affected functioning of the tests. If raining, we recommend ensuring that the cards are kept in a dry location.

### Self-Swabbing Questions

## 7. Reporting

### Legal Requirements

CG-insert

### CalREDIE

In order to report you will need a CLIA number for reporting to CalREDIE. Contact CalREDIE at (866) 866-1428 or CalREDIEHelp@cdph.ca.gov.

## 8. Testing Frequency

In considering testing frequency, it is recommended that testing be completed at 1-2x/week at each potential site. See table below for suggested cadence https://schools.covid19.ca.gov/.

Ideal cadence for antigen is still under discussion for various tiers.

**Table 1**. Testing Cadences with Committed Support from the State of California for K-12 schools

| | Yellow<br>CR <1.0*<br>TP<2% | Orange<br>CR 1-3.9*<br>TP 2-4.9% | Red<br>CR 4-7*<br>TP 5-8% | Purple<br>CR >7-13.9*<br>TP >8% | CR >14* |
|---|---|---|---|---|---|
| **Staff** | Symptomatic and response testing. | Symptomatic and response testing. | Symptomatic and response testing + Every 2 weeks asymptomatic testing. | Symptomatic and response testing + Every 2 weeks asymptomatic testing. | Symptomatic and response testing + Weekly asymptomatic (PCR or twice weekly antigen testing)**. |
| **Students K-12** | Symptomatic and response testing. | Symptomatic and response testing. | Symptomatic and response testing + Every 2 weeks asymptomatic testing. | Symptomatic and response testing + Every 2 weeks asymptomatic testing. | Symptomatic and response testing + Weekly asymptomatic (PCR or twice weekly antigen testing)**. |

TP = test positivity

** The case rates above are adjusted case rates.*

*** Weekly asymptomatic testing assumes the use of a PCR test. If antigen testing is used, testing should be at a twice weekly cadence.*

Students or staff who have tested positive for active infection with SARS-CoV-2 virus within the last 90 days are exempt from asymptomatic testing.

Any school currently open is subject to the minimum testing requirement standards established by Cal/OSHA. These standards include response testing for exposed cases and outbreak testing for everyone weekly until no longer considered an outbreak. Please refer to Cal/OSHA guidance for complete details.

# 9. Appendices

## Appendix A: Enrollment and additional personnel information

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

Enrollment Phase II upon completion of training and competency quiz:

https://forms.office.com/Pages/ResponsePage.aspx?id=URsxH9n2U0GbrFXg75ZBuIH02axXNqRKmpoKrfn-QMZUMFZBVTBKWkJJV005MVVRQlI4U09RVUVPVy4u

Competency quiz upon completion of training:

https://forms.office.com/Pages/ResponsePage.aspx?id=URsxH9n2U0GbrFXg75ZBuIH02axXNqRKmpoKrfn-QMZUQVpBNVBVNzFRQjUzMTdRTjA2VUpTUk5PSC4u

Laboratory Field Services Guidance for Schools:
https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/SchoolsGuidance.aspx

**BPC 1206.5 Who can perform the test?**

**Who Can Perform Waived Testing**

Personnel who are authorized under BPC section 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), bioanalysts, 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 personal protective equipment (PPE), State and federal requirements, including privacy laws, and performance of the specific test they are using.

**Who can collect specimens?**

Collecting specimens using swabs, including nasopharyngeal (NP) can be collected by:

- 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 collections 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. Additional information about the local option scope of practice allowing them to do this is available on the California Emergency Medical Services Authority webpage.
- 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.

## Appendix B: Information on software platforms Primary and Color

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

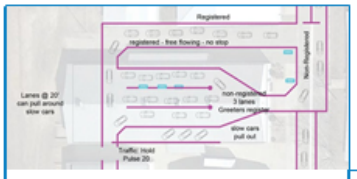
For more information. visit Primary.Health

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

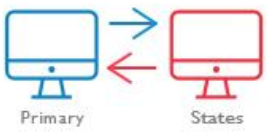
We design a program that meets the needs of your locations, populations, and program goals.

### 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

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PLACEHOLDER

for

# COLOR SOFTWARE PLATFORM

## Appendix C: Guidelines for student self-swabbing

Since students will have to remove their masks, we recommend that testing is done in an outdoor, well ventilated setting and that when the masks are removed, all staff and students remain at least 6 feet from each other.

We recommend taking small groups of students outside to the testing area and guiding the students in self-swabbing together. Consider how many tests you can run at one time to calculate groups appropriately.

Once swab is complete, the swab needs to be placed in the BinaxNOW card quickly within 5-10 minutes, the sooner the better. Once the students swab themselves, the swab should be placed in the card and not stored in a wrapper. For this reason, it makes sense to do smaller groups of students at once, for example 5 or less students to better handle the open swabs. You need enough space to lay out the cards flat while running the tests (which take 15 minutes), so location, and table availability are important to consider.

The more preparation the students have the better they will do. Encourage parents to have children practice with soft cotton swabs (Q-tips) at home and watch the video. Talk about the testing 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 just prior to testing. Consider showing students the images below or using a model of a nose (or just a paper image of a nose), to demonstrate how far the swab is inserted in the nose.

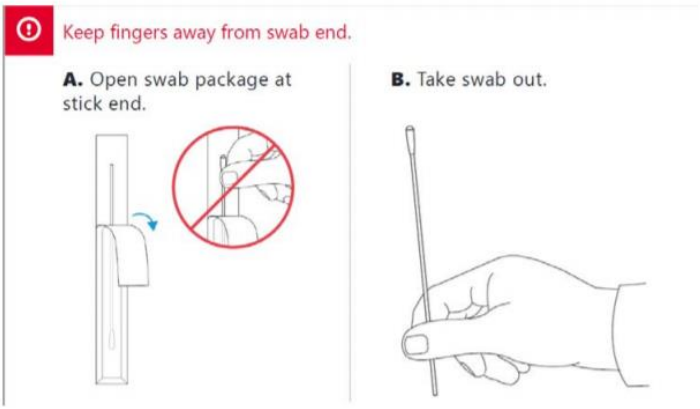
Steps for Self-Swabbing (images below)

1. Take the students outside in a small group to testing site.
2. Have the students space out at least 6 feet apart?
3. Have the students wash their hands or use hand sanitizer prior to testing.
4. Open the swabs using the end of the swab. Do not touch the top of the swab. Depending on the age of the students you will most likely need to do this for them, so they do not accidently touch the swab.
5. Hand out swabs to the students and let students know not to touch the soft cotton end of the swab.
6. Have the students slide their masks below their noses (while maintaining a 6-foot distance from them).
7. Have the students place the swab about a half an inch (about the depth of 2 pencil erasers) into one of their nostrils and twist the swab around rubbing the inside surface of the nose 5 times slowly (should take about 10 seconds), then have the students place the swab in the second nostril and twist the swab around 5 times slowly (again about 10 seconds).
8. Have the child pull their mask back above their nose and carefully take the swab back from the student (again reminding the students who are waiting for their swab to be taken, not to touch the cotton end).
9. Run the test according to manufacturer's instructions.

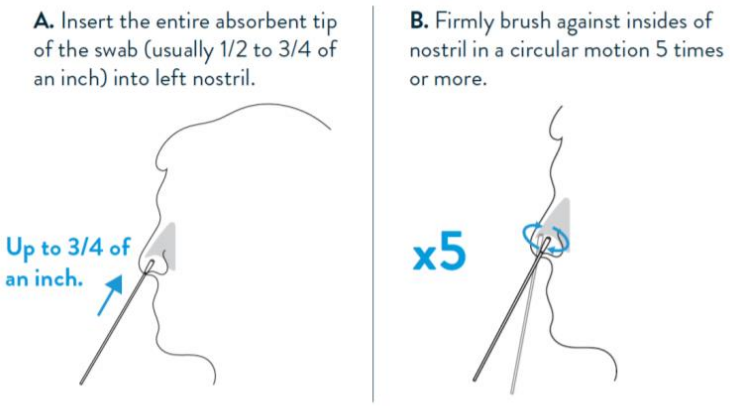
**For a video demonstration**:

Wash or sanitize your hands. Make sure they are dry before starting.

**Open Swab**



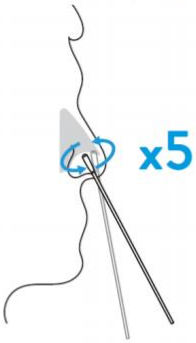

**Swab Left Nostril**



**Swab Right Nostril**

**A.** Remove swab and insert it into right nostril.

**B.** Firmly brush against insides of nostril in a circular motion 5 times or more.




***Note:*** *False negative results may occur if the nasal swab is not properly collected.*

# 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

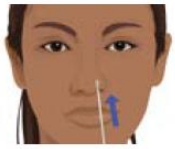
1. Open the sampling kit.

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

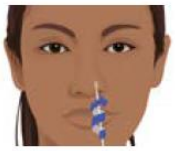

## Sample collection

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

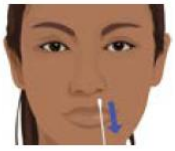
4. Insert the entire absorbent tip of the swab into your nostril, but do not insert the swab more than ¾ of an inch (1.5 cm) into your nose.



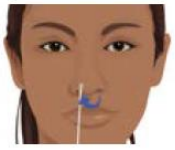
5. Slowly rotate the swab in a circular path against the inside of your nostril at least 4 times for a total of 15 seconds. Be sure to collect any nasal drainage that may be present on the swab.



6. Gently remove the swab.



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



CS 317702-C 11/13/2020

**cdc.gov/coronavirus**

## Appendix D: Sample letter to parents with consent

**COVID-19 Testing Authorization Form and Release of Liability**

**Background**

The purpose of this Test Consent and Authorization for the Release of Information and Test Results ("Authorization") form is to obtain your consent to test for SARS-CoV-2, the virus which causes COVID-19, and to, when necessary, provide information to the agencies handling the COVID-19 response. Your consent gives us permission to test you/your child 1-2 times per week for up to twelve months from when this Authorization is signed or until it is withdrawn. Recent studies and emerging data reveal that frequent testing of school staff and children can greatly reduce the likelihood of COVID-19 spreading in schools.

Preventative measures that have already been put in place in schools include physical distancing, face coverings, enhanced hand hygiene, cleaning, disinfection, decreased class sizes, and staggered class times. COVID-19 testing for students and staff who do not have symptoms can also be another strategy used for safe school re-opening. Testing should be used with other interventions; it does not take their place. Ensuring that teachers, staff, and students stay home when ill is also important in reducing transmission in schools. However, one of the biggest challenges of controlling COVID-19 transmission is that infected individuals without symptoms can spread the infection. It is estimated that 30-60% of infected individuals are "silent spreaders" (individuals who are contagious without realizing they have the virus).

BinaxNOW is an antigen test that, in about fifteen (15) minutes, detects the presence of the virus that causes COVID-19 infection. The specimen for the test is collected with a nasal swab. The test is completely voluntary and will not ever be administered unless this Authorization form is signed.

To collect a specimen for this screening, a swab, like a Q-Tip, will be placed inside the tip of the nose. A school staff member who has been trained to perform this test will observe specimen collection and a trained COVID-19 screening administrator will oversee the process. If the test is positive, a second swab may be collected to be run for molecular (e.g. PCR) testing, which is a type of test that takes longer but is more sensitive. Some individuals who test negative may be asked to collect a second swab for molecular (e.g. PCR) testing as well.

A positive test will be immediately reported to the [NAME OF LOCAL HEALTH DEPARTMENT] (LHD) and the California Department of Public Health (CDPH) so that they can begin contact tracing and other activities to prevent the spread of disease. Additionally, all test results will be shared with select school personnel for the purposes of contact tracing and mandated reporting.

Except as required by law, test results and testing information will be kept confidential by the school district, LHD, and CDPH. By signing this Authorization form I consent for the test to be performed on me/my child at least [FREQUENCY OF TESTING]. Signing is also an acknowledgment of the above statements. Upon request, this completed and signed Authorization form should be provided to the appropriate school district personnel.

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

A. I authorize COVID-19 testing through a nasal swab for myself/my child.

B. I authorize that my/my child's test results be disclosed to the [SCHOOL DISTRICT NAME], local health department, or state health department, or to any other governmental entity as may be required by law.

C. I acknowledge that if the test is positive I/my child must self-isolate as per the instructions of the department of public health.

D. I understand the testing program is not providing medical advice, this testing does not replace treatment by my/my child's medical provider, and I agree I will seek medical advice, care, and treatment from my/my child's medical provider if I have questions or concerns, or if my/my child's condition worsens.

E. 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 I have received a copy of this Informed Consent for myself/my child to participate in COVID-19 testing. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask additional questions at any time.

F. I authorize [SOFTWARE PLATFORM] ("NAME") and each of the parties listed below to release my/my child's information and test results[i] as needed to the following [SOFTWARE PLATFORM] Partners, to facilitate testing for COVID-19 and to make further disclosures as set forth in the [NAME] Privacy Policy, available at [SOFTWARE PLATFORM WEBSITE]:
   - The provider who ordered the COVID-19 test;
   - Various lab partners (to provide confirmation RT-PCR tests and/or providing laboratory reporting to CalREDIE);
   - [SOFTWARE PLATFORM] (to collect test result information and share it with me, other [NAME] Partners and [SCHOOL DISTRICT NAME]); and
   - The California Department of Public Health, and local health department (as required by law) as well as the Public Health Institute.

G. I understand that I/my child will only be permitted to participate in the COVID-19 testing program with [SCHOOL DISTRICT NAME] if I sign this Authorization. I understand that if I do not sign this Authorization, I cannot participate in this COVID-19 testing program with [SCHOOL DISTRICT NAME].

H. I understand that I may withdraw this Authorization at any time by notifying [NAME]. I understand I must notify [NAME] of my desire to withdraw the Authorization in writing at: [PHYSICAL ADDRESS AND EMAIL CONTACT INFORMATION FOR SOFTWARE PLATFORM]. In addition, I understand I must also notify [SCHOOL DISTRICT NAME] by email at [SCHOOL EMAIL ADDRESS] or in writing at [SCHOOL DISTRICT ADDRESS]. I understand that any action already taken in reliance on this Authorization prior to when I notify [NAME] and my school cannot be reversed.

I. Unless withdrawn earlier, this Authorization expires 12 months from the date of this Authorization.

J. I represent that I am the person authorized to sign this document for myself/my child (parent or guardian).

K. I understand the [SCHOOL DISTRICT NAME] is also exploring the possibility of providing PCR tests as an additional precautionary measure for anyone that tests positive through the COVID-19 antigen rapid test screener. If this happens the [SCHOOL DISTRICT NAME] 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 or if I do not have insurance, the [SCHOOL DISTRICT NAME] will work with the project partners to ensure that there is no cost to me.

**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, gag reflex, or nosebleed. By consenting to participate, I acknowledge that I understand that the risk of my/my child participating is a low risk and I voluntarily accept these health risks.

**Waiver, Release, and Indemnification**: I know that participating in this screening is an activity that may be a potentially hazardous activity for some students. I hereby assume full and complete responsibility for any injury, illness, or accident which may occur during my/my child's participation. I hereby release, waive, hold harmless and covenant not to file 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.

My child's name is (Please Print):_____

My child's name is (Please Print):_____

My child's name is (Please Print):_____

Parent Name (Please Print):_____

Parent Signature:_____ Date:_____

**THANK YOU FOR COMPLETING AND RETURNING THIS CONSENT FORM TO THE**

**[INSERT SCHOOL NAME]**

Personal information may include name, gender, date of birth, and dependent and/or guardianship information. Contact information may include telephone number, email address, and physical or mailing address. Testing information may include appointment information, transaction identification number, SARS-CoV-2 ("COVID-19") test information and results.

## Appendix E: FAQs

**What is COVID-19?**

COVID-19 is disease caused by a virus knows as SARS-Cov-2. The virus can have no symptoms or cause mild to severe respiratory illness and people who are infected can have symptoms that include cough, shortness of breath or difficulty breathing, fever, chills, muscle pain, headache, sore throat, nausea or vomiting, diarrhea congestion or runny nose, fatigue or new loss of taste or smell.

**What is BINAX NOW?**

BINAX now is a rapid antigen test that was designed to test for the virus that causes COVID-19 and allows for test results in 15 minutes. To collect the specimen, the participant will place a swab, similar to a cotton swab/Q-Tip, inside of the tip of the nose and swirl it around. A staff member who has been trained will help direct the specimen collection.

**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 disinfection of surfaces.

**What are the known potential risks and benefits of the test?**

Potential risks include:

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

Potential benefits include:

- The results of this test can help keep your school community healthy and safe.
- The results of this test can help limit the spread of COVIC-19 to your family and your community.

**What does it mean if I have a positive test result?**

If you have a positive result it is likely you have COVID-19. There is a small chance this test can give a positive result that is wrong (a false positive result), it is for that reason we recommend that a confirmatory PCR test is sent within 24 hours to confirm the result. The participant or the parent/guardians of a minor will be notified if there is a positive test. The school and the department of public health will also be notified.

**What will happen if my child tests positive?**

If there is a positive result, you will be notified. The school will move you or a student to a supervised location away from other staff and students until you can pick up your child. A confirmatory PCR test will need to be sent within 24 hours. The school will help coordinate this test. The school and the department of public health will be notified.

**What does it mean to have a negative test result?**

A negative test means you most likely do not have the virus that causes COVID-19.

It is possible that this test to give a negative result that is incorrect (a false negative) in some people with COVID-19. This means you could still possibly have COVID-19 even though your test results are negative.

**How does this test work?**

This test is a 15-minute antigen test. It works by identifying the COVID-19 virus in nasal mucous. It works similarly to a home pregnancy test and gives a result in about 15 minutes. This test is different from an antibody test that is a blood test that checks whether or not you have had a COVID-19 infection in the past. It is also different from a PCR test that goes to a lab to be run and can take several days to come back.

**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. Wear a mask when around other people, if you are able to. Isolation lasts for at least 10 days from the positive test unless otherwise instructed by your primary care doctor or public health department.



## Appendix F: Definition of Terms and Useful Information/Links

**Definitions:**

**Types Testing:**

Symptomatic testing: This testing is used for individuals with symptoms of COVID-19, either at home or at school. In this situation, the school's guidance requires that these individuals stay home and isolate in case they are infectious. The CDPH school's guidance includes the possibility of return to school in the case of a negative test for SARS-CoV-2 and 24 hours after fever is resolved and symptoms are improving.

Response testing: This testing is used to identify positive individuals once a case has been identified in a given stable group. Response-based testing can be provided for symptomatic individuals or for asymptomatic individuals with known or suspected exposure to an individual infected with SARS-CoV-2.

Asymptomatic testing: This testing can be used for surveillance, usually at a cadence of every 2 weeks or less frequently, to understand whether schools have higher or lower rates of COVID19 rates than the community, to guide decisions about safety for schools and school administrators, and to inform LHDs 3 about district level in-school rates. Asymptomatic testing can also be used for screening, usually at a higher cadence (weekly or twice weekly) than surveillance testing, to identify asymptomatic or pre-symptomatic cases, in order to exclude cases that might otherwise contribute to in-school transmission. Screening testing is indicated for situations associated with higher risk (higher community transmission, individuals at higher risk of transmission (e.g., adults and high school students transmit more effectively than elementary aged students).

**Other terms:**

Quarantine: refers to a strategy used to keep someone who might have been exposed to COVID-19 but does not know if he or she is infected, away from others. Quarantine helps prevent spread of disease that can occur before a person knows that he or she is infected. People in quarantine should stay home, separate themselves from others, monitor their health, and follow directions from their local public health authorities.

Isolation: refers to a strategy used to separate people infected with the SARS-CoV-2 virus (those with and without symptoms) from people who are not infected. The term is used here to refer to people who are isolated at home, a community care center (i.e., isolation shelter), or a health facility. In the home, anyone with COVID-19 symptoms or who has been diagnosed with the disease should separate themselves from others in the home to reduce the risk of transmission to others in the household and should stay home until it is safe for them to be around others. This also includes people who have signs and symptoms consistent with COVID-19, for whom test results are not yet or will not be available.

Close contact: Is defined by CDC as someone who was within 6 feet of an infected person for a cumulative total of 15 minutes or more over a 24-hour period starting from 2 days before illness onset (or, for asymptomatic patients, 2 days prior to test specimen collection) until the time the patient is isolated. The World Health Organization (WHO) additionally includes persons with direct physical contact with a probable or confirmed case, direct care for a patient with probable or confirmed COVID-19 disease without using proper personal protective equipment, and other situations as indicated by local risk assessments.

**Useful information/links:**

See quick guide to obtain CLIA waiver and state registration, and application links below:

- Webpage leading to application: https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/ClinicalandPublicHealthLaboratories.aspx
- Webpage (different site) to create application account and complete application: https://accountportal.cdph.ca.gov/licensing.aspx

Who can perform testing?

- https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/COVID-19FAQ.aspx#TestingandCollectionSites

Antigen BinaxNOW:

- Review the package insert 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
  *Note: Training videos should be watched prior to performing BinaxNOW test collection*
- The following directions are highlights on performing the BinaxNOW test collection and processing. Detailed directions can be found in the BinaxNOW EUA available here: https://www.fda.gov/media/141570/download
- UCSF brief video on 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 of Susan Coffin runs the BinaxNOW test: https://www.youtube.com/watch?v=rRZLDwEHkgY&feature=youtu.be

HIPAA Training:

- For those who do not have a HIPAA certificate, there are online course. Here is an example: (https://www.accountablehq.com/free-hipaa-training/privacy-rule ).

PPE:

- 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

Liability information:

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

## Appendix G: BinaxNOW Training Materials