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1. INTRODUCTION: BASICS OF COVID-19 TESTING IN SCHOOLS

GOAL

The Centers for Disease Control (CDC) and California Department of Public Health (CDPH) share a common foundational principle: all students must have access to safe and full in-person instruction and to as much instructional time as possible. In California, the surest path to safe and full in-person instruction, as well as minimizing missed school days on an ongoing basis, is a strong emphasis on the following: access to a robust COVID-19 testing program in addition to other “layered prevention strategies,” including vaccination for all eligible individuals, universal masking in schools, adequate ventilation, and more targeted quarantine practices.

This playbook describes the California K-12 Antigen Testing Program and provides guidance for K-12 schools who wish to implement the program at their school.

ANTIGEN TESTING STRATEGIES IN SCHOOLS

For more detailed guidance around testing in schools, please visit: CDPH K-12 School-Based COVID-19 Testing Strategies. For any specific questions, please reach out to your local health department.

- All staff and students should be encouraged to stay home when they are ill.

- If students or staff come to school with symptoms of COVID-19 or develop symptoms while at school, they should be tested for COVID-19 and sent home.

- Frequent surveillance testing allows for early identification of COVID-19 infections in individuals without active symptoms (“asymptomatic” or “pre-symptomatic”) can help prevent and mitigate outbreaks in schools. Some individuals who are infected with COVID-19 are contagious before they begin to display symptoms or are contagious even though they never display symptoms.

- Your school is encouraged to implement COVID-19 testing and CDPH offers several free testing options. This playbook is focused on implementing School-Based Antigen 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. Information on other testing platforms for schools can be found at https://schools.covid19.ca.gov/ and https://testing.covid19.ca.gov/school-testing/.
What are the types of free COVID-19 tests available to schools?

There are two main categories of tests that you can use to detect COVID-19: molecular tests and antigen tests. Both types of tests can be collected on school grounds by self-administered nasal swabs.

Antigen Tests are likely to detect infected individuals who are the most contagious. However, antigen tests are more likely than molecular tests to miss some positive cases. Antigen tests are performed at school and results are available in 15 minutes.

Antigen tests offered by CDPH include:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott BinaxNOW Rapid Antigen Tests – School Based</td>
<td>Test is performed on test cards on school grounds and results are available in 15 minutes. Many tests can be performed at once. In some scenarios, schools may elect to perform a confirmatory molecular test or repeat an antigen test in 1-2 days.</td>
</tr>
<tr>
<td>Abbott BinaxNOW Rapid Antigen Tests – Home Based, Limited supply Other At-Home Rapid Antigen Tests</td>
<td>Test is performed on test cards at home and results are available in 10-30 minutes. At-Home testing will become increasingly available as supplies increase.</td>
</tr>
<tr>
<td>CareStart, BD Veritor Flu/COVID-19, other antigen tests</td>
<td>Currently offered by CDPH ONLY in specific circumstances. If your school has not received training in use of these test kits, do not use.</td>
</tr>
</tbody>
</table>

Molecular tests include PCR tests and other nucleic acid amplification tests (NAAT). Molecular tests are very sensitive, meaning that they can pick up very small amounts of virus. However, they may also pick up remnants of virus no longer living or contagious weeks after the infectious periods. PCR tests are sent to a specialized lab with results in 1-3 days.

Molecular tests offered by CDPH include:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual PCR tests</td>
<td>Collected from participants and then sent by courier to be performed at a specialized lab and results are available in 24-72 hours.</td>
</tr>
<tr>
<td>Pooled PCR tests</td>
<td>Collected from a group of participants and then sent by courier to be run at a specialized lab. Results for a group are available in 24-72 hours. If the group test is negative, all members are negative. If the group is positive, then group members each take a rapid antigen test to determine their individual results.</td>
</tr>
<tr>
<td>CUE (non-PCR) tests</td>
<td>Test is performed on a test device on school grounds and results are available in 20-30 minutes. Only one test can be run at a time.</td>
</tr>
</tbody>
</table>
2. JOINING THE SCHOOL-BASED ANTIGEN TESTING PROGRAM

PROGRAM OVERVIEW

ELIGIBILITY

Our program currently accepts applications from the following entities: public school districts, charter schools, and independent schools, afterschool programs, school-related camps, and preschools associated with TK-12 schools/districts.

COMPONENTS OF THE K-12 SCHOOL ANTIGEN TESTING PROGRAM

1. Free COVID-19 Test Supplies
   Abbott BinaxNOW antigen tests for in-school use, antigen tests for at-home use (limited program), COLOR PCR tests and CUE tests; at-home test options added as available

2. Free Training on Collecting and Running Antigen Tests
   Virtual hands-on training with CDPH trainers

   Manages testing consent forms
   Tracks and shares individual results of antigen and molecular tests securely (compliant with laws protecting private health information – referred to as “HIPAA”)
   Reports results to local and state health departments

4. Regulatory/Quality Control support for In-School Testing
   When antigen testing is done in a school facility, the school is considered a medical lab by the State of California. Our program takes care of this registration and oversight (we provide a “CLIA” waiver) for your school.

Although antigen tests are now available over-the-counter, schools using antigen testing on the school campus need to participate in the CDPH School Antigen Testing program or have their own certification (called a CLIA waiver) for regulatory reasons. For more information, see “Regulatory/Legal Considerations below.”
PROGRAM ONBOARDING PROCESS

STEP 1: LEARN ABOUT THE K-12 SCHOOL ANTIGEN TESTING PROGRAM

☐ Fill out onboarding form: https://labsupport.powerappsportals.us/K12SchoolsAntigenTestingIntake/
☐ Read the K-12 School Antigen Playbook (this document)
☐ Attend FAQ meeting: https://youtu.be/EW3XuaGRPNA

STEP 2: AGREE TO PARTICIPATE IN THE TK-12 SCHOOL ANTIGEN TESTING PROGRAM

☐ Sign a Memorandum of Understanding ("MOU"), which is a participation agreement between your school/district and CDPH. This will be sent to you when you fill out the onboarding form. If you haven’t received it within 1-2 business days, email schoolbinax@cdph.ca.gov
☐ Expect an invitation to set up a Primary.Health tracking software account within 1-3 business days of MOU submission.

While the MOU is in process, please complete Steps 3 and 5: Assembling Team and Training Team.

STEP 3: ASSEMBLE YOUR TEAM AND PREPARE YOUR TESTING ENVIRONMENT

Assemble your Team for Training:
☐ Order the training test kits here https://labsupport.powerappsportals.us/antigenreorder/. Order at least 40 tests per staff member that need to be trained and allow 7-10 days for processing and shipping.
☐ Identify a “Binax Lead” at each school site and have them fill out a form here. The responsibilities of a Binax Lead can be found in the appendices.
☐ Identify additional team members who will be trained to help check-in students for testing on Primary.Health, observe self-swabbing, run the antigen tests, and log the results on Primary.Health.
   o Team members can be trained school staff members (such as administrators or teachers)
   o You may have trained healthcare workers, but this is not necessary for the program.
Prepare your School Testing Environment:

☐ Reach out to your local health department to create a plan for a potential positive test. If you need help reaching out to your local health department, please use the California Schools Readiness Hub https://schools.covid19.ca.gov/

☐ Determine testing frequency and schedule.

☐ Develop communication plan to educate staff and families.

☐ Designate temperature-stable areas for storing tests and equipment, as well as safe, well-ventilated and/or outdoor areas for collecting nasal swabs and running tests. For more guidance on this, visit this section.

☐ In some situations, you may need or want to perform a PCR test. PCR supplies can be ordered at the same link as antigen tests. For more information on PCR tests, read attachment on PCR orders.

STEP 4: ENROLL IN PRIMARY.HEALTH SOFTWARE PROGRAM

Primary.Health is an online software platform that allows for consenting students and staff, reporting results in a HIPAA compliant way and sharing results with state and local health departments. Your designated organization lead will receive an email inviting you to create an account with Primary.Health after your MOU is signed.

☐ Receive an email from Primary.Health within 2-3 days of completing your MOU via DocuSign. If you have not received this email, contact carapidtest@primary.health.

☐ Attend office hour sessions provided by Primary.Health. Please contact your liaison at Primary.Health to find out more.

☐ Set up your Primary.Health organization profile.

STEP 5: TRAIN YOUR TEAM

☐ Everyone must review all training materials (videos including test performance and privacy training).
  o See full materials list here.

☐ All staff MUST attend CDPH Hands-On Virtual Training (REQUIRED). To sign up, email schoolbinax@cdph.ca.gov.

☐ All staff must pass a quiz and receive a 100% score

☐ Review Primary.Health video library, attend office hours, or request one-on-one support.

STEP 6: OBTAIN FINAL APPROVAL

When training is complete and your Primary.Health account is set up, contact Primary.Health at carapidtest@primary.health.

You can later add additional staff for testing if needed. They also must complete all required trainings.
PERFORMING THE ABBOTT BINAXNOW ANTIGEN TEST AT SCHOOL/ “CLIA” WAIVER

According to current federal and state laws, any facility performing the BinaxNOW test on participants needs to have a special laboratory certification called a Clinical Laboratory Improvement Amendment (CLIA) Certificate of Waiver and a California clinical laboratory registration. CDPH has obtained these certifications on behalf of any participating school if the school agrees to complete our training requirements.

What does your school need to do to use the CDPH “CLIA Waiver?”

- All testing personnel must complete CDPH Virtual Hands-On Training, including those who are hired through third party contractors.
- All tests, positive, inconclusive, and negative, must be reported on Primary.Health.
- Perform and report quality control logs on a quarterly basis.

Schools or districts can obtain their own CLIA waiver and still receive free test kits.
- This also includes schools which choose to hire third party vendors under the vendor CLIA.
- Please let us know if you have your own CLIA. We are required to collect limited information about your testing programs.

REPORTING

Because schools running tests on-site are considered laboratories and will be covered by the CLIA waiver, all test results must be reported to the state. This legal obligation is fulfilled by using the Primary.Health online platform. (California Code of Regulations, Title 17, Section 2505), and all test results are automatically shared to CalREDIE – the state’s infectious disease reporting system.

Please note: All tests done through our program must be reported via Primary.Health regardless of result (positives, inconclusive, AND negatives must be reported). There are no exceptions. If your site fails to report tests, your testing program may be halted.

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, CONFIDENTIALITY AND CONSENT

Privacy and Confidentiality: 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 departments and key school administrators.

Consent: A consent form will be provided electronically by Primary.Health. It is available in multiple languages.

The general consent form includes consent for:

- **Self-swabbing (not to be done by parents) for students > 4 years, 9 months (TK-aged)**
- **PCR and Antigen tests**

We cannot accommodate any individual adjustments to consent forms. However, if your school needs additional consent for having a healthcare provider on-site to perform nasal swabs on very young children (2 years – 4 years 9 months) or for those who cannot self-swab, please email carapidtest@primary.health to request this consent.

Parents are NOT permitted to swab students on campus.

### Consent Requirements by Age

<table>
<thead>
<tr>
<th>Age Range</th>
<th>Consent</th>
<th>Results Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 13</td>
<td>Parent required</td>
<td>Parent only</td>
</tr>
<tr>
<td>13-17</td>
<td>Parent possible, but not necessary</td>
<td>Registrant (parent or student depending on who registered)</td>
</tr>
<tr>
<td>&gt;=18</td>
<td>No parent required</td>
<td>Student only</td>
</tr>
</tbody>
</table>

### Swabbing Options by Age

<table>
<thead>
<tr>
<th>Age</th>
<th>Who can swab</th>
</tr>
</thead>
<tbody>
<tr>
<td>At-school testing with school staff</td>
<td>&gt; 4 years 9 months</td>
</tr>
<tr>
<td>At-school testing with a qualified healthcare professional in PPE (FIT-tested N95 etc.)</td>
<td>&gt; 2 years</td>
</tr>
<tr>
<td>At-home testing with the OTC Abbott BinaxNOW or other Self-Test</td>
<td>&gt; 2 years</td>
</tr>
</tbody>
</table>
TESTING MANAGEMENT SOFTWARE: PRIMARY.HEALTH

Using Primary.Health to manage your school testing program is mandatory for sites using the CDPH CLIA waiver. Primary.Health provides management tools to register and document consent for students and staff, track test results, and report results to program participants and to the local Department of Health. For more information on Primary.Health, please see Appendix G.

The entire registration and consent process can be managed online through the Primary.Health platform. Paper forms can also be used to register and consent participants if individuals or families do not have internet or technology access. If paper forms are used, all information must be entered in the Primary.Health platform.

ASSEMBLING TESTING TEAM AND SCHOOL ENVIRONMENT CONSIDERATIONS

Team Roles:
Staff requirements will vary based on size and organization, and one person can perform multiple roles if necessary.
Roles include:

- **Check-in**: Performs check-in and associates the BinaxNOW card with the staff member or student by scanning a QR code.
- **Swab Supervisor**: Monitors self-collection.
- **Tester**: Runs the BinaxNOW test (applies reagent, inserts swab, closes card).
- **Reader**: Tracks the time of the test and reads the results, labels cards with results.
- **Data Entry**: Enters the data into the software platform including a photograph of the test card.

**Binax Lead**
The Binax Lead is responsible for performing quality control checks and receiving and disseminating updates from the CDPH School Antigen team.
Each school site will have a binder provided after completion of enrollment that holds:
- Printed training materials
- Training records
- Quality control records
- Instructions for Use (IFU)
- Product inserts

INFORM YOUR COMMUNITY
Create a plan to inform the school community about your testing program. Example documents are in the appendices.
Special care should be taken in communicating with students, particularly about self-collection of nasal swabs. A video (https://youtu.be/DU_G-D_sL3I) should be shown to students so they understand what the sample...
collection process looks like. 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).

SELECT YOUR LOCATION AND CROWD MANAGEMENT STRATEGIES
Outdoor locations are ideal to reduce COVID-19 transmission. 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. Indoor location options should have sufficient space for social distancing and have good ventilation (examples: gymnasium or auditorium).
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.
Certain measures must be used when testing large groups of people to avoid 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.
- Consider using an appointment model or having assigned times for participants to avoid crowding.

PERSONAL PROTECTIVE EQUIPMENT
Personal protective equipment (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.
TESTING SITE SUPPLIES AND MATERIALS CHECKLIST:

Materials needed:

☐ BinaxNOW tests
☐ Table space to lay the necessary number of cards flat during the 10-30 minutes when the tests will be running and read
☐ Personal protective equipment (gloves and disposable surgical masks are necessary, face shields and gowns are optional)
☐ 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
☐ 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 (below) and BinaxNOW Binder
☐ Appropriate technology devices (tablets/laptops with USB compatible webcams; NOTE: 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.
☐ Optional tape to tape down cards in case of windy conditions.
5. TESTING WITH BINAXNOW

TESTING STEPS OVERVIEW

Step 1. Participants register and complete consent
Step 2. Participants check-in for testing
Step 3. Collect self-swab sample
Step 4. Perform tests
Step 5. Read tests and communicate results

STEP 1: PARTICIPANTS REGISTER AND CONSENT PRIOR TO TESTING DAY
- Staff and students/parents register electronically through Primary.Health (preferably ahead of time, but can be done on-site)

STEP 2: CHECK-IN
- Identify staff or student in Primary.Health
  - Confirm their identity and information
- Open a test kit and mark it with participant’s initials. Do NOT write full name.
- Using the QR code on the BinaxNOW card, associate the test with the person.
- Return card to the foil pouch.

STEP 3: SELF-SWABBING
- Swab supervisor should hand participant a swab (handle side out).
- Supervise self-collection of nasal swabs. If your school has obtained consent from participants, selected healthcare providers can collect nasal swabs.
- Once swabbing is complete, staff or students give the swabs to the personnel assigned to perform and read the tests along with their associated test card.

STEP 4: PERFORMING THE TESTS
- See below for instructions from the manufacturer’s instructions.
  - Tester will first take test card and add reagent.
  - Tester will examine card to ensure control line is present and is blue and in proper location.
  - Tester will then take the swab and run the test as per manufacturer’s instructions.
  - Tester will label card with start and end time of test reading.
• Tester will lay card on a flat surface for the duration of the test.
• Tester should sanitize gloves or change gloves if the glove has become contaminated, the tester handled a COVID-19 positive swab or has been used for more than 6 tests.

STEP 5: READING THE TESTS AND COMMUNICATING RESULTS

• BinaxNOW cards should be read after 15 minutes, and before 30 minutes.
• Reader will examine the test card and determine if the test is valid by ensuring that the control band is present and pink.
• Next, the reader will examine the sample line area and determine if the result is positive, negative, or ambiguous/inconclusive.
• It is recommended a second trained staff member read the card and confirm the interpretation of the reader.
• If in agreement, the reader should mark the test card with a “+” for positive, “-” for negative, or “invalid” if the test is invalid.
• Record results on the Primary.Health software data platform.
• Photographs are required for cards with positive, inconclusive, or invalid results. Photographs are highly recommended for negative result cards.
• Negative results are communicated electronically to staff and parents of students tested.
• 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.
PERFORMING THE BINAXNOW

TEST PROCEDURE
Procedure for Patient Specimens

Open the test card just prior to use. Lay it flat, and perform assay as follows. The test card must be flat when performing testing, do not perform testing with the test card in any other position.

1. Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the TOP HOLE, slowly add 6 DROPS to the TOP HOLE of the swab well. DO NOT touch the card with the dropper tip while dispensing.

2. Insert sample into BOTTOM HOLE and firmly push upwards so that the swab tip is visible in the TOP HOLE.

3. Rotate (twirl) swab shaft 3 times CLOCKWISE (to the right). Do not remove swab.

Note: False negative results can occur if the sample swab is not rotated (twirled) prior to closing the card.

4. Peel off adhesive liner from the right edge of the test card. Close and securely seal the card. Read result in the window 15 minutes after closing the card. In order to ensure proper test performance, it is important to read the result promptly at 15 minutes, and not before. Results should not be read after 30 minutes.

Note: False negative results can occur if test results are read before 15 minutes.

Note: When reading test results, tilt the card to reduce glare on the result window if necessary. Individuals with color-impaired vision may not be able to adequately interpret test results.
To avoid false results:

- The sample nasal swab should be tested immediately after collection.
- Apply the reagent immediately before inserting swab.
- 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.
- Tests read before 15 minutes or after 30 minutes are invalid and must be repeated.
- Test cards must be used within one hour of opening. If not used immediately, store in an airtight container.

Manufacturer’s instructions for use: [https://www.fda.gov/media/141569/download](https://www.fda.gov/media/141569/download)

**HOW TO READ A TEST**

There are three possible test results: positive, negative and invalid/inconclusive.

**POSITIVE:** (+): Two pink lines appear – one next to “Control” and one next to “Sample.” Note that the “sample” line can be faint, but if it is EXTREMELY faint, then repeat the test (see below).

**NEGATIVE:** (-): One pink line appears next to “Control.”

**INVALID OR INCONCLUSIVE:**

Control Band remains blue.

Control Band not present at all, even if sample line appears.

Sample band is Gray (“shadow band”) or is pink but EXTREMELY faint.

Sample band is difficult to read.

See [Troubleshooting Section](#) if a very faint line appears in the control or sample window.
What color is the control band?

Control band is **BLUE**
- Test is invalid
- Re-run test

Control band is **PINK**
- Test is valid

Is there a band in the SAMPLE window?

Sample window is blank
- Test is **NEGATIVE**

Sample has an obvious **PINK** band
- Test is **POSITIVE**

Sample has a **faint** band
- The Test is **INDETERMINATE**

See indeterminate test workflow
IMPORTANT DEFINITIONS

“Symptomatic” refers to a person with any symptoms. “Asymptomatic” refers to a person with no symptoms.

Please visit the CDC website to see the list of symptoms of COVID-19.

Symptoms highly suggestive of COVID-19 include loss of taste and smell, but are NOT limited to this symptom.

High community rates of COVID-19 may also overall raise concern for COVID-19.
In CONClUSIVe/I NVA LiD TESTS

Indeterminate Test (Faint Band) Workflow

If the test results are invalid or inconclusive/ambiguous (control band remains blue, control band not present at all even if sample line appears, sample band is gray (“shadow band”) or is pink but EXTREMELY faint, or sample band is not end-to-end or is difficult to read), consider the following:

Repeat BinaxNOW test immediately, preferably with a test from a different lot.
   If on repeat, the card has no sample line, the test is negative.
   If on repeat, the card has an obvious sample line, the test is positive. Recommend PCR.
   If on repeat, the card has a faint sample line or is ambiguous, the test is positive. Recommend PCR.

If CUE or other type of point of care test available, consider obtaining as an additional piece of data.

Direct consultation with the school’s Binax Lead for the next steps. Whenever possible, antigen test should be read by two independent readers.
QUALITY CONTROL AND REPORTED DEVIATIONS OF TEST PERFORMANCE

Quality control ensures the reliability and accuracy of test results. As part of this program, your school is a state-registered laboratory! This means quality control is essential.

The BinaxNOW test has two quality control measures which all testers should know.

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 swab 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.

Running Positive and Negative Control Swabs
Positive and negative control swabs must be run:

- On every shipment received at your facility
  - If the shipment contains multiple lots, QC must be performed on each lot, (but does not need to be performed on each box of 40 tests)
  - If a new shipment contains a lot that QC has previously been run on, the QC must be performed again
- For each new user being trained
- If there is any concern that the tests being run are abnormal

The Binax Lead is the point person at each site for Quality Control. They will maintain Quality Control logs and report them to CDPH.

In each 40-test BinaxNOW box there is one marked foil-wrapped 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.

Procedure for BinaxNOW™ Swab Controls

Open the test card just prior to use, lay it flat, and perform assay as follows.

1. Hold Extraction Reagent bottle vertically Hovering 1/2 inch above the TOP HOLE, slowly add 8 DROPS to the TOP HOLE of the swab well. DO NOT touch the card with the dropper tip while dispensing.

2. Follow Steps 2 – 4 of the Test Procedure for Patient Specimens.
For every shipment that arrives, the Binax Lead 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.

If the control swabs do not work as expected, contact Abbott technical service Telephone: (800) 257 9525 Ts.scr@abbott.com and email schoolbinax@cdph.ca.gov for guidance.

Binax Leads are asked to record issues in the Adverse Event and Product Deviation Log and report suspected occurrences to CDPH Laboratory Director (director-reporting@cdph.ca.gov). Deviations include:

1) False positives - testing positive on antigen test and confirmatory PCR is negative
2) False negatives - symptomatic individual tests negative and the PCR comes back positive
3) Significant deviations of test performance
   a. Test kits not performing as expected
   b. Control tests not working
   c. Missing blue control line in untested kits

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.

**DISPOSAL OF USED BINAXNOW CARDS**

- **If the test is negative**, test components can be placed in a **regular trash bag**.
- **If the test is positive**, all test 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.

If you are having difficulty obtaining biohazard containers or a disposal system, consider either contacting your waste management company or contacting a local biohazard waste disposal company. You may also consider partnering with a local health clinic to dispose of your waste. Most schools have sharps containers which you can also use to dispose of biohazard waste. There are many large, national companies that serve schools including: [https://www.stericycle.com/en-us/solutions/regulated-waste-disposal/biohazardous-medical-waste](https://www.stericycle.com/en-us/solutions/regulated-waste-disposal/biohazardous-medical-waste).

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](https://www.cdph.ca.gov/Programs/CEH/DRSEM/Pages/EMB/MedicalWaste/Local-Enforcement-Agencies.aspx)

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**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 6-12 months. The expiration date can be found on the outside of the boxes near the lot number. **There are periodic extensions or changes to expiration dates. If you have questions, please contact schoolbinax@cdph.ca.gov.**

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**TRAINING FOR ALL TEAM MEMBERS**

The State of California will allow the use of the CDPH K-12 School Laboratories CLIA waiver and license if all requirements for training and competency are met. All personnel that will participate in BinaxNOW testing at schools require training. This section describes the training requirements for personnel performing testing with the BinaxNOW.

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**SWABBING AND SUPERVISION OF SELF-SWABBING**

Anterior nares samples collected for this program are to be collected by self-swab except in specified situations. Parents may not swab or aid in swabbing children on site.

**Observing and Instructing Anterior Nares (Nares) Self-Swabbing.** From the Abbott BinaxNOW™ 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](https://www.binaxnow.com/documents/Instrutions_for_use.pdf) state “5 times or more for a total of 15 seconds” which is different from their training materials which have not yet been updated.
Nasal swab collection can be performed by the student or staff member. If specialized consent has been obtained, students may be swabbed by a healthcare professional with proper personal protective equipment.

<table>
<thead>
<tr>
<th>Type</th>
<th>Personnel requirement</th>
<th>Personal Protective requirement/recommendations</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>OBSERVATION of self-collection of anterior nares swabs</td>
<td>Personnel who are observing individuals performing self-collection should be trained on proper technique: <a href="https://www.cdc.gov/coronavirus/2019-ncov/downloads/community/">https://www.cdc.gov/coronavirus/2019-ncov/downloads/community/</a> COVID-19-anterior-self-swab-testing-center.pdf</td>
<td>Facemask and gloves required, eye protection (goggles or face shield) also recommended since children may sneeze when they swab.</td>
<td>Most children can self-collect. (View video at <a href="https://youtu.be/DU_G-D_sL3I">https://youtu.be/DU_G-D_sL3I</a>) 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.</td>
</tr>
<tr>
<td>COLLECTION of anterior nares swab</td>
<td>Trained health care providers: Physician Assistant, Registered Nurse, Licensed Vocational Nurse, Medical Assistant, Psychiatric Technician.</td>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>
The BinaxNOW training requires reviewing the:

1) Reading Material and Training Videos
2) Quality Control (QC) Procedure
3) Workflow

In addition, the trainee will complete the:

4) CDPH Hands-On Training
5) 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.

Prior to hands-on training, trainees are required to review the following:

Reading Material
- COVID-19 Antigen Testing K-12 Schools Playbook (this document)
- Abbott BinaxNOW Fact Sheet for Patients
- Abbott BinaxNOW Fact Sheet for Patients - Spanish

Videos:
- Abbott BinaxNOW training modules
  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
- Confidentiality training (HIPAA), 5 minute video (certification is not required) [https://www.accountablehq.com/free-hipaa-training/privacy-rule](https://www.accountablehq.com/free-hipaa-training/privacy-rule)

PREPARING FOR CDPH VIRTUAL HANDS-ON TRAINING

All staff must be trained on individual computers with video capabilities so that the CDPH trainers can observe technique.

- 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
COMPETENCY QUIZ

All trainees must take a 16 question competency quiz and score 100% in order to be approved for testing. The quiz can be taken multiple times. Trainees will receive the link after completion of Virtual Hands-On Training.

TROUBLESHOOTING

TESTING QUESTIONS

1. 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.

2. What should I do if a faint band appears in the sample window?
   
   This means the test is indeterminate. Please see the “indeterminate test” algorithm.

3. 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.

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

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

6. 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.

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

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

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

10. 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 found in the Binax Binder and via email to antigenlabdirector-reporting@cdph.ca.gov.

11. 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

1. **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. If your school is interested, you can activate a specific consent form that allows for healthcare providers to swab students at school.

2. **Can parents perform the swab at school?**
   
   Parents are not permitted to perform nasal swabs on their children at school under state regulations.

3. **Can I bring my own swab?**
   
   No. This is specifically disallowed in the testing IFU (page 3, number 20). Using outside materials compromises the quality and integrity of the laboratory license. The same way that it would not be allowed to bring your own materials for a test at a doctor’s office, it is not possible to bring your own materials to perform this test.
4. APPENDICES

APPENDIX A: REGULATORY FAQS

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

Antigen BinaxNOW Information:

- Review the package insert/BinaxNOW IFU https://www.fda.gov/media/141570/download
- UCSF website interpreting BinaxNOW results: https://unitedinhealth.org/binax-training
- Video on preparing and running the BinaxNOW test: https://www.youtube.com/watch?v=rRZLDwEHkgY&feature=youtu.be

Self-Swabbing References:


Liability information:

- Public Readiness and Emergency Preparedness Act (PREP Act) Overview: https://sharedsystems.dhsoha.state.or.us/DHSForms/Served/Ie3529.pdf

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 self-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.”


**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.”

APPENDIX B: MATERIALS FOR THE TESTING TABLE

Antigen Test Results

Positive

Asymptomatic

Isolate at home

Symptomatic

Isolate at home

Negative

Asymptomatic

Unlikely to be infectious

Can participate in school

Symptomatic

Unlikely to be infectious

If high concern for COVID-19, recent exposure, or high community rates, repeat antigen test ≥24 hours or consider confirmatory molecular test

If lower concern for COVID-19, participate in school per school guidelines

Ambiguous

Repeat antigen test immediately

If still ambiguous: confirmatory PCR

Isolate at home. Get results before returning to school
Decision Reader Tree for BinaxNOW Rapid Antigen Test

What color is the control band?
- Control band is BLUE: Test is invalid, Re-run test
- Control band is PINK: Test is valid

Is there a band in the SAMPLE window?
- Sample window is blank: Test is NEGATIVE
- Sample has an obvious PINK band: Test is POSITIVE
- Sample has a faint band: The Test is INDETERMINATE.
  See indeterminate test workflow.

Indeterminate Test (Faint Band) Workflow

Valid test, with FAINT BAND in sample window:
- The Test is INDETERMINATE: Repeat test, ideally from a different lot

Sample is CLEAR: Test is NEGATIVE
Sample has an obvious PINK band: Test is POSITIVE
Sample has a FAINT BAND: Test is POSITIVE
Get PCR
<table>
<thead>
<tr>
<th>Test Start Time</th>
<th>Test End Time</th>
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<tbody>
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</table>
You are being given this information sheet because your school is participating in a COVID-19 testing program. This is a voluntary program. This sheet contains information to help you understand the risks and benefits of this testing program. This program is testing for SARS CoV-2, the 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 self-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 include:
- The results of this test can help keep your school community healthy, along with mask wearing, social distancing, and frequent handwashing
- Keep school communities operating in-person
- This test can help limit the spread of COVID-19 to your family and your community
- Results are available in 15-30 minutes
- Free of cost to the student and school.

The risks of taking the test include:
- Possible brief discomfort or bloody nose can arise from sample collection
- Possible incorrect test result (i.e. false positive or false negative)

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. Results are usually 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 likely have COVID-19. The school will immediately contact you and inform you to take your child home. 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
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 (CDPH) in partnership with your school is implementing a COVID-19 testing program. The COVID-19 tests under this program may include, but not be limited to, self-administered over-the-counter antigen tests, school administered antigen tests, and molecular (e.g., PCR) and pooled molecular tests. Students and staff who are studying or working at the school maybe tested one to two times a week for COVID-19. All testing will be free of charge.

This consent is valid through August 1, 2021 through June 30, 2022.

Rapid tests results will generally be available within one hour. If additional confirmatory 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 collecting 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 quarantining procedures, and wear a mask or face covering as directed in an effort to avoid infecting others.

• I authorize that my or my child’s test results may be disclosed to the district, county or state health department, or to any other governmental entity.

• For students between the ages of 13-17 years: I acknowledge that a positive test results will be shared with my parent or guardian on file with the school.

• I authorize Primary Diagnostics, Inc. ("Primary") and each of the parties listed below to release patient personal and test information in order facilitate testing for COVID-19 infection and for making 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 and local public health agencies
  • Any laboratory partner providing confirmation RT-PCR tests and/or providing mandatory reporting to the state health department
  • The participating school and other Primary partners, as necessary and determined by Primary Diagnostics, Inc.
• I understand that "patient personal and test information" includes the following:
  • The patient’s name, gender, date of birth
  • If applicable, dependent and/or guardianship information
  • Contact information including telephone number, email address, and physical or mailing address
  • Appointment information, transaction identification number, COVID-19 test information and results

• I understand that this testing site does not act as a medical provider and that 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 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.

• I understand the school may also request and conduct molecular (e.g., PCR) tests as an additional precautionary measure for certain individuals tested through the COVID antigen rapid test screener. For example if a person who was exposed or has no symptoms tests positive. In this instance, I authorize the California Department of Public Health and designated partners to use my insurance information to ensure that there is no cost to me for this service.

Warning of Risks & Assumption of Risks:
Participating in COVID-19 screening involves inherent health risks. There is a risk that upper respiratory tract swabbing may cause mild discomfort, sneezing, or nosebleed. By consenting to participate, I acknowledge that I understand that the risk of my or my child’s participation is low, and I voluntarily accept any 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 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: __________________________________________
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 on each side.

What is self-swabbing?
Self-swabbing means you collect the sample yourself. A study done at UCSF found that even young children could 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) were 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 and tests positive, it is highly likely that they have COVID-19 and should isolate per CDC guidelines. As with any laboratory test, there is a small chance that the test result was incorrect (falsely positive), but this is overall very unlikely. 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. You should also inform your/your child’s primary care doctor and let them know about your/your child’s test results.

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. It is possible, though unlikely, for this test to give a negative result that is incorrect (a false negative). If a person has
symptoms of COVID-19 (such as loss of taste or smell) and tests negative, especially if they were recently exposed to someone with COVID-19, then a confirmatory test should be performed.

**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 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.”

**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
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.

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.
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 Salamanka, 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
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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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:

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 “it shouldn’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 1/4 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.

cdc.gov/coronavirus