



Frequently Asked Questions around Preliminary K-12 Testing Framework for 2022/23 School Year

Last Updated: June 22nd, 2022

The CDPH Testing Taskforce School Testing team has released a <u>Preliminary K-12 Testing Framework for 2022/23 School Year</u>. The questions found in this document were generated from office hours sessions that occurred after the release of the Preliminary K-12 Testing Framework for 2022/2023 School Year.

Additional updates to testing in K-12 schools is forthcoming. Please refer to the following resources for the most current information:

- CDPH Testing Task Force School Testing website
- Subscribe to our School Testing Newsletter
- CA Safe Schools for All Hub

Contents

K-12 School Testing Framework and COVID-19 School Guidance	2
State Supported Testing Options for the 2022/23 School Year	3
Over-the-Counter (OTC)/At-Home Antigen Tests	4
CDPH Professional/At-School Administered Antigen Tests	9
Pooled PCR Program	14
End to End School Testing Program	14
Direct Funding School Testing Program	15
Lab-Based Molecular (LAMP/PCR) Testing/Color Program	16





K-12 School Testing Framework and COVID-19 School Guidance

Question: Are schools required to have a testing program?

Answer: Although schools are not required to maintain a testing program, CDPH strongly recommends that schools facilitate access to testing, particularly for vulnerable populations within their communities. Testing, especially of symptomatic individuals and those exposed to a positive COVID-19 case, remains an important for minimizing transmission and keeping students in the classroom for in-person instruction. Additional information on K-12 COVID-19 mitigation strategies for the 2022/23 School Year are forthcoming and will be posted to the Safe Schools Hub Website.

Question: Is the <u>State Public Health Officer Order "Vaccine Verification for Workers in Schools (August 11th, 2021)"</u> still in effect?

Answer: The Order remains in effect until otherwise noted.

Question: What are the requirements for workplace or employee testing in K-12 Schools for 2022/23?

Answer: In the workplace, employers are subject to the Cal/OSHA COVID-19 Prevention Emergency Temporary Standards (ETS) or in some workplaces the Cal/OSHA Aerosol Transmissible Diseases Standard and should consult those regulations for additional applicable requirements. Additional information regarding testing requirements under ETS can be found in COVID-19 Emergency Temporary Standards Frequently Asked Questions (ca.gov).

For questions on implementation of the Emergency Temporary Standards (ETS) or other CalOSHA requirements in schools, please reach out directly to CalOSHA for support using this email address: schools@dir.ca.gov.

Question: How do schools in Los Angeles County fit into next year's CDPH testing plan for 2022-2023?

Answer: Information is forthcoming. CDPH and LADPH are working closely together to ensure schools in Los Angeles County have robust testing options.





State Supported Testing Options for the 2022/23 School Year

Question: What type of testing support is being offered by the Testing Task Force for the 2022/23 School Year?

- Over the Counter/At-Home Testing (tests sent home for students and parents to test/report before coming to school or when symptomatic)
 - CDPH expects that most testing in school communities can be performed with over the counter (OTC)/at-home antigen testing.
 OTC/at-home tests are provided by CDPH at no cost to schools.
- **Professional/In-School Antigen Testing** for in-school testing (tests overseen and performed on-site by school staff)
 - OTC tests may not meet all school-related testing needs, particularly in communities with limited English proficiency and/or lower health or technology literacy. For this reason, CDPH is recommending that schools join the CDPH K-12 Professional antigen program to allow for the option of in-school testing.
 - Onboarding/application: https://labsupport.powerappsportals.us/K12SchoolsAntigenTestingl
 https://labsupport.powerappsportals.us/K12SchoolsAntigenTestingly
 https://labsupport.powerappsportals.us/K12SchoolsAntigenTestingly
 https://labsupport.powerappsport.powerappsportals.us/K12SchoolsAntigenTestingly
 https://labsupport.powerappsport.powerappsport.powerappsport.powerappsport.power
- Pooled PCR program (testing of an entire group or classroom; positive results are followed up by individual testing)
 - The Pooled PCR program will be ending and will not be available for the 2022/23 School Year.
 - All schools are encouraged to transition to the CDPH professional antigen program.
- End-to-End program (testing resources and staffing provided to schools by CDPH)
 - o The number of schools eligible for End-to-End Program will be significantly reduced. CDPH anticipates the workload for on-site testing to substantially decrease for the 2022-2023 school year given increasing supply and use of OTC tests. More information regarding schools eligible for End-to-End program support will be provided following enactment of the 2022-23 state budget.
- Direct Funding/Personnel Grants (schools contract their own testing operational support using state funding)
 - Direct funding/personnel grants will not be offered for the 2022/23 School Year
- Lab-based molecular testing (PCR/LAMP) (tests collected at school and sent to an off-site laboratory with results provided 24-48 hours later)





- Schools using the Color PCR testing program will need to transition to the CDPH School Antigen Testing Program.
- o CDPH recommends using antigen testing for school-based testing.
- PCR/LAMP tests are reserved for confirmatory testing with more guidance forthcoming.

Over-the-Counter (OTC)/At-Home Antigen Tests

Question: Why is the Testing Task Force encouraging schools to use Over-the-Counter/At-Home Antigen Testing as the primary option for the 2022/23 School Year? / Why are we moving away from PCR testing?

Answer: Lab-based molecular testing (PCR/LAMP) has several disadvantages in the school setting. It is sensitive enough that it picks up very low levels of virus, both before and after an infection (sometimes for months). Detecting low levels of virus in a person who is not able to transmit can make them unnecessarily miss school, despite feeling well and not being a risk to others. Also, because lab-based molecular tests (PCR/LAMP) need to go to a lab, results are much slower. The time from nose swab to result is often 2-3 days (including time at collecting site, time in transport, and time in lab processing). For someone who has virus levels that are high enough to transmit virus, an antigen test that gives rapid results is much better to guide immediate isolation to prevent transmission. Antigen tests may not catch every early or late case, but they are good at detecting high levels of virus, when it is important to isolate immediately.

Question: What are the differences between professional antigen testing versus the OTC/at-home testing?

Answer: OTC/at-home and professional antigen tests are similar in terms of performance. If you are planning to conduct testing on others, you must participate in a professional antigen testing program. Professional antigen tests can be used at-school on students.

OTC/at-home tests are meant to be used at home by individuals or parents/guardians. If they are used outside the home, they must still be completed (both running and interpreting the test) by individuals or parents/guardians. Users should follow the age parameters for self-administration associated with the particular OTC/at-home test they are using (typically 14 years or older). For those younger than the minimum age, guardians can administer and perform the test for children.





If OTC/at-home tests are performed on others, they are subject to federal laboratory regulations ("CLIA") and require special training. If you plan to use antigen tests in this type of scenario where staff performs tests on others, your organization needs to apply for use for CDPH's School CLIA waiver if your organization serves K-12 students. CDPH's School CLIA only covers Abbot BinaxNow professional antigen tests and not other brands of antigen tests. Application here:

https://labsupport.powerappsportals.us/K12SchoolsAntigenTestingIntake/

CDPH recommends staff should not administer OTC/at-home tests, but rather allow children (if old enough) or parents to conduct the test and read results themselves. Staff should provide educational resources for families to conduct the tests themselves. The goal of relying on OTC/at-home tests is to free up staff time and to move testing operations to parents and students in the 2022/23 school year. Educational materials can be found here:

https://drive.google.com/drive/folders/1SDjfm9Ru VTqygQpjw7KIUtDjAjqN2CE?usp=sharing

Question: Can school staff provide an OTC/at-home kit to a student to self-administer on campus?

Answer: Yes, school staff can provide a student or staff that meets OTC/at-home age requirements to self-administer the OTC/at-home test on campus. Users should follow the age parameters associated with the particular OTC/at-home test they are using. The range is typically 14 years and older but depends on brand. Please note that OTC/at-Home tests are meant to be completed (both swabbing and running the test) by individuals or parents/guardians regardless of where they test (in their home or outside their home). If OTC/at-home tests are performed on others, they are subject to federal laboratory regulations ("CLIA") and require special training.

Question: Will OTC/at-home tests continue to be provided by the state?

Answer: Yes. We plan to continue to provide OTC/at-home tests in the future as long as the supply chain remains intact. We anticipate more COE-based distributions in the future and also acknowledge the need for a way for schools to order OTC/at-home tests as needed due to limited storage. More information on specifics will be forthcoming.

Question: Can expired OTC/at-home tests be used beyond their expiration date?

Answer: Please always check for OTC/at-home formal extensions by the FDA. CDPH endorses the emergency use of OTC/at-home COVID-19 Tests beyond their FDA authorized expiration as long as the internal control remains valid. More information





here: https://testing.covid19.ca.gov/wp-content/uploads/sites/332/2022/03/Temporary-Extension-At-Home-Test-Expirations.pdf

Question: What do I do with unwanted or expired OTC/at-home antigen tests?

Answer: Please note that many OTC/at-home test brands have had formal extensions by the FDA that differ from the date printed on the box. CDPH endorses the emergency use of OTC/at-home COVID-19 Tests beyond their FDA authorized expiration as long as the internal control remains valid. More information here:

https://testing.covid19.ca.gov/wp-content/uploads/sites/332/2022/03/Temporary-Extension-At-Home-Test-Expirations.pdf

OTC/at-home tests can be disposed of in the regular trash.

Question: In what scenarios can OTC/at-home tests be used for? Are they just intended for special circumstances (e.g., return from vacation, outbreaks, etc)?

Answer: More specific guidance on the uses of OTC/at-home tests are forthcoming. OTC/at-home tests can be used in any of the same scenarios that professional/at-school antigen tests are used for. Some examples of use of antigen tests include, but is not exhaustive:

- Outbreak response testing
- Testing of school members for end-of-year events such as graduations
- Testing of close contacts and symptomatic school members
- Pre-entry testing for summer school
- Pre-entry testing for return from summer break testing
- Asymptomatic screening testing of high risk groups or during periods of high transmission
- Return to school after minimum of 5 days of isolation with negative test

Question: Do we need to have a CLIA waiver to submit an order for the OTC/at-home antigen tests?

Answer: No CLIA waiver is needed to order OTC/at-home tests, as these are taken at home by the individual and just as you would buy a test at your local pharmacy.

Please note that OTC/at-Home tests are meant to be used at home by individuals or parents/guardians. If they are used outside the home, they must still be completed (both swabbing and running the test) by individuals or parents/guardians. Users should follow the age parameters for self-administration associated with the particular OTC/at-home test they are using (typically 14 years or older). For those younger than the minimum age, guardians can administer the test for children. However, if OTC/at-home





tests are performed on others and interpreted by people other than parents or guardians, they are subject to federal laboratory regulations ("CLIA") and require special training. If you plan to use OTC/at-home tests in this type of scenario where staff performs tests on others, your organization needs to apply for use for CDPH's School CLIA waiver if your organization serves K-12 students. Application here: https://labsupport.powerappsportals.us/K12SchoolsAntigenTestingIntake/

Question: Do sites need to obtain CLIA waivers if they are providing students with OTC/at-home tests but not administering the test?

Answer: No, but it is highly recommended that schools complete the CDPH Professional/at-school Antigen Testing onboarding process to have the option of administering BinaxNOW professional tests on site if needed. This is an important back-up in case of OTC/at-home test kit shortages due to international supply chain problems. Onboarding/application:

https://labsupport.powerappsportals.us/K12SchoolsAntigenTestingIntake/

Question: Can schools track the OTC/at-home test results?

Answer: Yes – schools enrolled in Primary. Health can track their students' results. If your school/LEA is interested in enrolling in Primary. Health to track results, please email CArapidtest@primary.health and indicate you need a school account for OTC/athome only. They will walk you through the steps of generating a registration link to share with your school community.

If your school opts not to create your own individualized profile on Primary. Health, please encourage reporting through a general California Schools link: https://my.primary.health/l/caschools

Primary

Test Your Student Flyer (ca.gov)

California Schools At-Home Testing · Schedule Appointment (primary.health)

Question: How can students report their OTC/at-home test results?

Answer: We STRONGLY encourage individuals to report their results from their OTC/athome test on Primary. Health, which is an online platform that allows individuals to securely consent to testing and report their results automatically to state and local health jurisdictions (including photos of test results). Schools can share their unique registration link with students that allow the school to see the students' results, or if the





school does not want a Primary. Health account, they can share the generic reporting link.

Can parents upload any OTC/at-home test result to Primary. Health?

Yes, they can report specifically any brand of OTC/at-home tests under "OTC tests other". Students who have already registered for at-school professional antigen testing can find their OTC/at-home reporting link here:

https://my.primary.health/appointment recoveries.

Question: Who can report OTC/at-home tests on Primary.Health?

Students, staff and school community members can use Primary. Health to report OTC/at-home tests results. Schools/districts can request a Primary. Health account or use a preexisting account to track results.

Question: What brand are the OTC/at-home tests that will be distributed in the future?

Answer: For OTC/at-home tests provided by CDPH/COE, you could see any number of OTC/at-home tests, including iHealth, Flowflex, or Carestart.

Question: Can you explain the difference between professional antigen testing program versus only the OTC/at-home testing program?

Answer: Both programs allow you to track results in Primary. Health and allow for robust testing. We anticipate most schools will primarily rely on OTC/at-home testing as it shifts the burden of testing into the home environment from the school environment. We anticipate most schools will need a small amount of at-school testing. For example, testing symptomatic students on campus that will require participation in the professional antigen program. We recommend onboarding into the CDPH Professional/At-School Antigen Program and training at least two staff members in professional antigen test administration. A small number of professional tests should be stored in case of OTC/at-home shortages and for specific testing scenarios that require a CLIA waiver.

Question: Will OTC/at-home test distribution be linked to use of Primary. Health?

Reporting in Primary. Health is recommended but not required. OTC/at-home test distribution will not be linked to reporting. However reporting is very helpful for local and state departments of public health to track OTC/at-home test usage and COVID-19 rates in the community.





Question: Some of our staff and families have used OTC/at-home antigen tests and have been negative for 2 or 3 days and then test positive on day 4 or 5. Can we trust OTC/at-home results?

Answer: This phenomenon has been reported with both professional and OTC/at-home antigen test results. Antigen tests are about 60% sensitive when compared with PCR tests. However, when you restrict to PCR viral loads that are high and considered infectious or transmissible, antigen test sensitivity increases into the 90% range. What this means is that antigen tests are very good at letting someone know if they can infect others and results are available in 15 minutes. For best results in symptomatic patients, we recommend serial antigen testing with at least 24-48 hours between tests. Before returning to school, symptoms should be improving. For those who are at high risk such as a close contact or during times of high transmission, schools should consider multiple criteria for return to school such as improving symptoms, and serial antigen testing. Studies have shown that home administered antigen tests have similar sensitivity to professionally administered antigen tests.

Question: Will CDPH be changing how we measure spread of COVID-19 if OTC/at-home tests are not included in case counts?

Answer: This phenomenon is already occurring and the state is taking into consideration multiple data points to determine the community transmission levels including wastewater surveillance, case counts, probable case count (antigen tests), and hospitalization data.

CDPH Professional/At-School Administered Antigen Tests

Please note that the Professional At-School Antigen Program playbook was updated in spring of 2022 and answers many commonly asked questions about the antigen program and onboarding: https://testing.covid19.ca.gov/wp-content/uploads/sites/332/2021/04/School_Antigen_Testing_Playbook.pdf

Question: How do I onboard my school into the CDPH/Primary.Health professional (atschool) antigen program?

Answer: The CDPH professional (at-school) antigen testing program grants you access to CDPH's CLIA waiver. A CLIA waiver is a federal regulation that grants your school laboratory status. To onboard please complete the intake form (https://labsupport.powerappsportals.us/K12SchoolsAntigenTestingIntake/). After filling out the form, you will be sent an email with further instructions and a link to our Memorandum of Understanding (MOU) to sign. You will also receive an invitation to





attend our FAQ Meeting. This is a meeting where we discuss the enrollment process and answer questions.

Question: Can we continue to order professional Binax Now kits once we are enrolled in the professional/at-school antigen program even if we are participating in the OTC/at-home program?

Answer: Yes, we anticipate most schools will have some at-school testing needs and will need to participate in both the OTC/at-home and the professional antigen programs.

Question: I am already participating in the CPDH/Primary.Health professional (atschool) antigen testing program, how do I go about renewing my memorandum of understanding (MOU)?

Answer: If you have completed enrollment and/or are actively testing, then you need to renew your MOU by completing our MOU amendment for the 2022/2023 school year. If you have not received a new MOU, please email schoolbinax@cdph.ca.gov. If you have not completed enrollment and are part-way through the application process, we ask that you begin the intake process again

(https://labsupport.powerappsportals.us/K12SchoolsAntigenTestingIntake/), and complete a new MOU to cover you for the 2022/2023 school year.

Question: How do I get a new test group in Primary. Health for the 2022-23 school year?

Answer: Please reach out to Primary. Health at <u>CArapidtest@primary.health</u> so they can help configure either your professional or OTC testing group for the 2022-23 school year. Please note you will need to renew consents for the 2022-23 school year. We recommend incorporating this paperwork as part of the back-to-school paperwork/tasks for parents.

Question: Will antigen tests continue to be provided to schools?

Answer: Both professional and OTC/at-home antigen tests will continue to be provided by the State at no cost.

Question: Will we still be able to use the CLIA waiver we were originally issued as long as the new MOU was signed and received?

Answer: Yes, as long as you sign the new MOU for the 2022-2023 and continue to meet requirements of the program, you can continue to use the CDPH School CLIA waiver.





Question: We are starting our summer programming soon. Will we be able to continue to use the unused, on-site rapid antigen tests during the summer?

Answer: Yes, you can use the unused, on-site rapid antigen tests during your summer program on campus, as long as you are still reporting in Primary. Health and have signed the 2022-2023 MOU.

Question: For schools that are participating in the CDPH Antigen Testing program who already have the CLIA certificate; how do we get newly hired staff trained and set up with Primary. Health?

Answer: Please have new staff register for CDPH training using this link: Hands-on training for new members

10 am Monday & Wednesday Trainings

https://cdph-ca-gov.zoom.us/meeting/register/tZcuceuurDosGNRgyeC1-

BYM_ewV9cnBCUB6

3pm Wednesday Training

https://cdph-ca-gov.zoom.us/meeting/register/tZUpf--ppjMvHd24E6EzDDdXM-Mzo5OomUnD

To set up their Primary. Health account, the administrator can create new team members account or you can email CArapidtest@primary. health.

Question: Does the CLIA Waiver have to be renewed yearly?

Answer: Yes, we will require MOU to be signed yearly to continue using CLIA waiver.

Question: How do we order more professional (at-school) Binax antigen test kits?

Answer: Please use this link to place an order for professional antigen tests. https://labsupport.powerappsportals.us/antigenreorder/. Please note you need to be onboarding or already have completed enrollment in the antigen program to order professional kits.

Question: Currently LEAs that are participating in a CDPH school-based PCR program is free of cost to the districts. As we transition to primarily using antigen tests, will CDPH be covering the costs if the district uses an approved antigen testing program? Will there be approved on-site vendors districts can contract with?

Answer: CDPH will continue to provide the CLIA waiver program and professional antigen tests at no cost to California schools. Many schools currently in the program contract with a variety of vendors and receive professional tests at no cost from the





state. These schools who contract with outside vendors do not use the state's CLIA and testing occurs under the vendor's CLIA.

We provide Abbott BinaxNOW kits to schools with their own CLIA. If you are a school with your own CLIA and you want Abbot BinaxNOW kits provided by the state, you will need to report to CDPH monthly by either using Primary. Health for free or use a monthly survey to report number of tests conducted and number of positive tests monthly. To receive kits and this monthly survey, please email schoolbinax@cdph.ca.gov with your CLIA number, fill out the onboarding form

(https://labsupport.powerappsportals.us/K12SchoolsAntigenTestingIntake/) and confirm your point of contact's name, email and phone number. Then place your order for tests here: https://labsupport.powerappsportals.us/antigenreorder/

You will receive an email monthly asking for the number of tests you performed and number of positive and negative tests.

Question: What do I do with unwanted or expired professional antigen tests?

Answer: For expired tests: the CDPH School Program is allowing for use of expired tests beyond their expiration dates. Please email schoolbinax@cdph.ca.gov for more information. Expired tests must pass a monthly quality control (QC) check to validate their use. If your QC fails please reach out via email for next steps.

Unwanted professional tests cannot be returned to CDPH for reuse due to federal regulations. We cannot help directly facilitate transfer of tests due to regulatory reasons. Please note there are many resources who can provide contacts of nearby school districts who are participating in the professional antigen program to learn more about how schools are using their extra professional antigen tests. These include CDPH, your local COE and your local health department. Before deciding to dispose of your unwanted tests, please ensure there are no other ways your school might use these tests. If tests are truly not needed elsewhere, please reach out to schoolbinax@cdph.ca.gov for disposal instructions.

Question: Will CLIA certification open up to testing children under 5 years of age?

Answer: CDPH School Antigen Program allows for testing children under 5 years of age if a school can demonstrate they are able to meet requirements of assisted swabbing. OTC/at-home tests are a perfect use for this age group. A preschool or a pre-K program that is associated with a school (including a kindergarten) can participate in the CDPH At-School Antigen program.





Our program operates with supervised self-swabbing. There are no healthcare personnel requirements to supervise self-swabbing and our general consent covers tests completed by self-swabbing.

Age Guidelines

7190 00100111103			
	Age	Who can swab	
At-school testing with school staff	Older than 4 years 9 months	Participants must self-swab while under observation	
At-school testing with a qualified healthcare professional in PPE (FIT-tested N95 etc.)	,	Qualified healthcare provider swabs (assisted swabbing) individuals unable to self-swab or those ages 2 years to 4 years 9 months with an additional consent needed	
At-home testing with the OTC/at-home tests	Older than 2 years on average (depends on brand, please check IFU)	Guardians swab children or participants self-swab and then guardian performs and interprets OTC test	

If your school would like to offer assisted swabbing at school to participants who are too young or cannot self-swab, please note that:

- 1. Swabbing must be done by a certified healthcare provider who is in proper PPE (N95 that has been FIT tested etc).
- 2. School districts can have access to an additional consent via Primary. Health for those students who cannot self-swab or who are not old enough. Please email carapidtest@primary.health with the subject line "Self-Swab Consent"

Please refer to the <u>School Antigen Professional Testing Program</u> playbook for more information.

Question: Do you have a list of schools/districts who have been granted a CLIA waiver? I am not sure if our district has one?

Answer: If you are unsure if your school/district has completed the onboarding process for the CLIA waiver, please email schoolbinax@cdph.ca.gov to find out.

Question: Our program is transitioning staff leadership around testing. How do we help transition?

Answer: Make sure new employees are receiving communications by having them join our listserv: https://cdph-marketing.powerappsportals.com/antigen-subscribe/

Please email Primary. Health and ensure that your new leadership has an account with correct access at CArapidtest@primary.health





Please ensure they have completed our CDPH Hands-On Antigen Training.

Please email <u>schoolbinax@cpdh.ca.gov</u> informing our program of the name of your organization and who is leaving and the new person and their contact information (email and phone number) so we can update our records.

Pooled PCR Program

Question: Will CDPH continue to partner with/offer pooled testing (through Concentric by Gingko)?

Answer: Gingko is providing pooled testing thru the end of July 2022. We encourage ALL school districts to utilize the free OTC/at-home test kits from CDPH. If interested in testing on your campus in the Fall, then enroll in the Antigen program: schoolbinax@cdph.ca.gov

Question: What should we do with leftover testing supplies?

Answer: If you have leftover pooled test kits, please dispose of the material as you see fit. There are no special handling or disposal requirements. We recommend that you safely store any Abbott BinaxNOW professional antigen kits that were used for reflex testing if you are intending in joining the CDPH Professional/at-School Antigen program. If you have Abbot BinaxNOW professional tests and do not plan to do professional antigen testing next year, please first reach out to CDPH, your local COE and your local health department to determine if there is a need elsewhere for your tests. If not needed elsewhere, reach out to schoolbinax@cdph.ca.gov for disposal information.

End to End School Testing Program

Question: What does this framework mean for programs participating in CDPH End-to-End (E2E) program with contractors such as Vestra, BayPLS, Color, Mobile Med etc.

Answer: More information will be forthcoming when the state budget is finalized about the scope of End-to-End services for schools. Please plan for the potential of significantly reduced or no end-to-end services next year.

Question: Will E2E support be available in the 2022-23 academic school year?

Answer: Yes, but it will be significantly reduced from what it was this past year. Not all districts will remain eligible for vendor support.

Question: How long will my vendor be available to me?

Answer: E2E Support will be available through the end of this academic year and for those schools previously approved for summer school testing this will continue





throughout July 31, 2022. Unless otherwise stated by CDPH, please plan for your vendor to roll off after that date.

Question: How and when will we know if our district qualifies for E2E support in the 2022-23 school year?

Answer: CDPH's operational support team will be reaching out throughout the summer to districts currently enrolled in E2E to discuss their eligibility status for the 2022-23 school vear.

Question: Will our district be able to continue pooled testing in the 2022-23 school year using E2E Vendors?

Answer: No. Pooled testing using an E2E vendor will no longer be supported by CDPH. Rapid Antigen testing will be the primary modality performed by our vendors. If you are not enrolled in the CDPH rapid antigen program, please do so as soon as possible to ensure a smooth transition.

Question: Do we need to let CDPH know that we are not interested in E2E antigen testing for next year?

Yes, if you received end-to-end antigen testing services this year and are NOT interested in end-to-end services next year, please inform CDPH.

Direct Funding School Testing Program

Question: What is the deadline to spend funds?

Answer: All funds must be spent by July 31, 2022. No extensions will be granted.

Question: When will I have to report on how funds were spent?

Answer: Instructions on how to complete the final expenditure report will be sent out on June 30th and will be due August 15^{th} .

Question: What do we do if we have unspent funds?

Answer: Unspent funds will be determined upon reviewing the final expenditure report. Instructions on how to return unspent funds to CDPH will be provided in August.

Question: Will personnel grants be offered to school districts next school year?

Answer: There will be no personnel grants offered for the 2022-23 school year.





Lab-Based Molecular (LAMP/PCR) Testing/Color Program

Question: Will PCR testing be available?

Answer: Molecular/LAMP/PCR testing will not be the primary method of testing at school sites. We recommend that schools plan their testing around using primarily athome antigen tests, and the ability to have at least 2 people on each site trained to do "professional" antigen tests if needed. More specific guidance will be forthcoming.

What is the end date for schools participating in the Color PCR testing program?

Schools that currently test primarily with Molecular/PCR testing should reach out to <u>schooltesting@cdph.ca.gov</u> to begin enrolling in the CDPH School Antigen program. Enroll here: https://labsupport.powerappsportals.us/K12SchoolsAntigenTestingIntake/

Question: How long will we be able to continue using lab-based molecular (PCR/LAMP) tests?

Answer: Please plan to transition to primarily antigen-based testing by the start of your 2022-23 school year. Lab-based molecular (PCR/LAMP) testing will continue throughout the 2022-2023 school year, but only in specific situations, more guidance on these situations is forthcoming.

Question: In what situations is lab-based molecular (PCR/LAMP) testing appropriate?

Answer: More specific guidance on when schools use molecular (PCR/LAMP) testing is forthcoming. Examples include lab-based testing is a good option in the situation of inconclusive antigen tests.

Question: Are you still providing courier next year to pick up lab-based molecular testing (PCR/LAMP) tests?

In the limited number of cases when lab tests are needed, a plan for shipping or transport will be part of that plan.

Question: Will Primary still allow for ordering/reporting of lab-based molecular tests (PCR/LAMP)?

Answer: Primary is currently reporting for molecular/PCR results. Primary has been set up for PCR reporting because we use reflex PCR in our antigen testing program and recommend lab-based testing when we have inconclusive antigen test results.





Question: What kind of lab-based molecular testing is Color using? Are the current tests PCRs or the new LAMP Technology?

Answer: All sites for lab-based molecular testing (PCR/LAMP) have now transitioned to the Color Lab Network regardless if the test is ordered via Color or Primary. Health. Most of the tests processed by the network are LAMP tests, some of the overflow lab partners are still using PCR. Before the lab transition, communication was focused on making sure participants were aware of the logistics of changing the lab site. We are happy to share information on the lab processes—the Color Lab Network is posted here (https://www.color.com/cust/cdph-lab-network), and we have requested that they add links to each lab's process for easier community access. LAMP technology was first developed 22 years ago.

Question: Can you give some context to the "fleeting positives" that we are seeing on the Color assay that we weren't seeing previously? We are getting dozens of positives (detected) that are antigen negative and repeat NAAT/PCR negative. We are also seeing an increase in positives that are not confirmed with antigen and a negative repeat on the same laboratory-based test.

There are 288 molecular tests approved by the FDA under EUA for COVID-19. Each lab uses one or more of these tests, and each test has its own specific range of detection, that is also influenced by other factors (such as how much sample is on the specific swab, how long and at what temperatures the swab was stored and processed, if the swab was dry or in viral medium...). This is the information about the specific Color LAMP assay, (https://www.color.com/wp-content/uploads/2020/10/Color-LAMP-Diagnostic-Assay v2 Updated-101420_3.pdf).

Digging into the science, the Limit of Detection, or LoD, can give some general guidance of comparing how much virus needs to be present for a specific test to detect the virus. Tests can be approved but differ up to 10,000 fold! (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7302192/#:~:text=Resolving%20the%20COVID%2D19%20pandemic,per%20milliliter%20of%20transport%20media.)

(https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)

Question: What paperwork needs to be completed in order to continue using the Color NAAT program?

Answer: There is no paperwork update needed. However, we will be recommending programs that are primarily screening testing/testing with PCR/NAAT tests to enroll in the





CDPH Professional/at-school Antigen Testing Program prior to the 2022-23 start of the school year.

Question: Some of us are testing with both PCR and antigen with COLOR. Who will we get the MOU email from?

Answer: No new MOU is needed to continue working with Color for their antigen program.

Question: I've also had cases at our site where one individual tests positive while other household members with the same or similar symptoms continue to test negative with either PCR or rapid antigen tests.

Answer: Yes, people with different immune systems can have different symptoms for a specific level of detectable virus—many symptoms are likely the "primed" immune system (from prior exposure or prior vaccination) responding quickly to virus that is not detected by the tests. More info here:

https://www.nytimes.com/2022/06/02/well/live/covid-testing-household-transmission.html

Question: How do we dispose of tests? What to do with expired or unwanted PCR/lab-based tests?

Answer: If your unused PCR tests are not yet expired, they can be redistributed to your local health department, COE or neighboring participating school.

If your unused PCR tests are expired, wet swab PCR tests must be disposed of at a local hazardous waste facility, dry swab PCR tests can be disposed of in regular trash. If you need assistance with hazardous waste disposal, please email schooltesting@cdph.ca.gov.