Implementing K-12 Cue Testing in 5 Easy Steps

If you are interested in choosing Option 1 – the School-Run COVID Testing option.

LDH will provide all the materials to run this program.

What now, you ask?



- 1. Have you filled out the COVID Testing program. Fill out this survey to Register for the program: <u>https://laredcap.oph.dhh.la.gov/surveys/?s=HJMHW3RPXJ</u>
- 2. Now here is the info you need to understand Cue tests from LDH
- 3. Next step will be to receive the materials needed to operate the program,
- 4. Then, your team will be trained and we can start testing in the new School year!

I. Consent Forms

Please see the appendix for the current version of the consent form that will be embedded in the Patient Portal. In the fall, your school will send out a link for parents to fill out at their homes to consent to routine testing on behalf of their student.

II. Request Cue Tests and technology needed from LDH

To obtain Cue tests (or any other testing supplies) for your K-12 institution, you may either:

- Email: <u>K-12covidtesting@la.gov</u>
- FILL OUT THIS REQUEST FORM: <u>https://laredcap.oph.dhh.la.gov/surveys/?s=3HPA3LN94Y</u>

Note: You can run **1** Cue test per reader in ~20 min timespan. If you plan on administering more than 1 test in 20 minutes, you will need to request the appropriate number of test readers and answer the questions in the above survey appropriately.

You can use up to to 6 readers per iPhone or tablet.

III. Reporting through Color

Each user must have their own username/password, and you need to designate and admin for your facility. The admin can then provide access to other users for specific tasks such as entering the data.



IV. Get trained – and start testing!

You will have an opportunity to be trained in-person! LDH will be in touch with you to set up the training.

If you'd like to get a head start and preview please contact Victoria Hudak (<u>Victoria.Hudak@cue.me</u>) to register for an upcoming virtual CUE training. There are virtual trainings held every Tuesday.



FAQs:

- 1. The Cartridge is a single-use, disposable unit that contains the reagents and associated materials required for detection of the SARS-CoV-2 virus in direct nasal swabs.
- 2. The sample is collected using a lower nasal swab.
- **3.** The results are delivered in 20 minutes to patients' families or patients over 18 through email and text.
- **4.** This test can be self-administered while trained professionals observe for accurate collection.
- 5. This test can be used on asymptomatic and symptomatic individuals
- **6.** Asymptomatic and symptomatic individuals (*as long as the symptoms are not severe*) who test negative are allowed to stay on school campus.
- 7. Where can I find more information on Cue?
- https://www.cuehealth.com/
- https://www.cuehealth.com/what-is-cue/how-cue-detects-covid-19
- https://www.cuehealth.com/what-is-cue/help-and-support/faqs/

APPENDIX 1: Current Consent Form

LDH K12 COVID-19 testing consent

Please review this important information about COVID-19 testing.

The purpose of this program is to assist efforts to monitor the spread of COVID-19 in school-aged children within the community. There are different types of testing strategies that may be used for school-aged children in participating schools, and staff within those participating schools, which include, but are not limited to:

- With **pooled tests**, samples from several people are combined. A test is performed on the combined pool of samples. Pooled testing can detect if someone in the group was infected with SARS-CoV-2 at the time of the testing. However, it **cannot detect which individual was infected at the time of testing**.
- With **individual testing**, also known as diagnostic testing or screening, samples from individuals are tested individually. Individual testing can detect whether an individual was infected with SARS-CoV-2 at the time of testing.
- Neither of these tests will test for immunity or if the individual tested had the virus in the past.

In the event that the pooled test results in a positive sample, each person within that pooled group will need to be tested individually.

If an individual's testing result is positive, it means that the person tested likely has COVID-19.

• Even if there no symptoms present with an individual who tests positive, it is recommended that the party be isolated and immediately contact their healthcare provider.

In the event that the pooled test results in a negative sample, or the individual's testing result is negative, the virus that causes COVID-19 was not detected.

- There have been limited incidents where testing results in a false negative. False negatives occur because the tests are not 100% accurate.
- If an individual has symptoms or develop symptoms, it is recommended that they isolate and immediately contact their healthcare provider.

Color Health, Inc. ("Color") does not give medical advice or provide medical care. Follow up with your doctor about your results. Your test results will be shared with the testing partner sponsoring the program and certain federal, state, or local agencies for public health purposes as required by law.

Provide your consent.

By completing and submitting this form, I confirm that I have the legal authority to provide consent for the patient identified during registration (who is myself if I am of the age of majority or my minor child) who is seeking COVID-19 testing (referred to below as "the patient") and that:

A. Program Administrator: I understand that the patient's school administers the testing program that the patient has been asked to participate in, and that I may ask the patient's school for additional information about the testing program.

B. Collection and Testing of Samples: I authorize the collection of one or more samples from the patient and administration of COVID-19 tests on the patient's samples, which shall include pooled testing and may also include individual diagnostic testing through molecular or antigen tests, as further explained below. When the patient arrives at the testing location at the designated time, the patient will receive the materials they should use to collect their samples and instructions on how to use these materials. These instructions will include a request to swirl the cotton tip of a swab in both nostrils to collect the sample, and additional details will be provided before the collection process begins. I understand that any personnel assisting in the administration of tests will have received training on safe and proper test administration.

C. Pooled Tests: I understand the patient may be asked to provide one or more samples for a "pooled test". In this type of test, the patient's sample will be collected and deposited with those of one or more other individuals in a test tube. The tube will be identified by a randomly generated barcode. Color operates an information system and related software (the "Platform") which associates the barcode with the individuals who provided samples. The patient's school will send the test tubes containing multiple samples to an independent laboratory with authority to conduct COVID-19 tests. The laboratory will not have access to names or other identifiers relating to the individuals who provided samples except as required or permitted by law. The laboratory will conduct testing and will enter the pooled test results in the Platform. I understand that these results will generally either be (1) negative, indicating that none of the samples in the pool tested positive, or (2) positive, indicating that one or more samples in the pool tested positive. I understand that it is not possible to determine from positive pooled test results alone which member or members of the pool tested positive without additional individual testing. In case of a positive pooled test result or suspected exposure to a positive individual, if the school's protocol requires additional individual diagnostic testing (which will be separately communicated to you by the school), I understand and agree that the patient may be asked to undergo an additional individual diagnostic test to determine whether the patient tests positive for COVID-19.

D. Individual Tests: I understand that the patient may be asked to provide one or more samples for an "individual diagnostic test". This may occur if the patient is a member of a pool for which the pooled test result was positive, or in other circumstances when a diagnostic test may be deemed necessary. In this type of test, the patient's sample will be collected and deposited in a test tube without any other individuals' samples. The tube will be identified by a randomly generated barcode. The Platform associates the barcode with the individual who provided the sample. The patient's school will send the test tube containing the sample to an independent laboratory with authority to conduct COVID-19 tests. The test may be either a molecular or antigen test. The laboratory will conduct testing and will enter the individual diagnostic test results in the Platform. I understand that these results will generally be (1) positive, (2) negative or (3) inconclusive, in which case further testing may be recommended.

E. Possibility of Error: I understand that there is the potential for a false positive or false negative COVID-19 test result for pooled or diagnostic tests, and that individual antigen tests have a higher chance of a false negative than individual molecular tests.

F. Safety Guidance and Protocols: I understand that the patient should continue to follow all applicable COVID-19 safety guidance, including mask-wearing and social distancing as appropriate, and follow the protocols that the patient's school has implemented for isolating and testing in the event of a positive result or if the patient develops symptoms of COVID-19.

G. Collection, Use and Disclosure of Personal Information: I understand that Color may collect and use the personal information that I enter into the Platform about myself and the patient, if different, and the patient's COVID-19 test results for the purposes of administering the COVID-19 tests and facilitating the communication of test results to me, the patient (if different), and the patient's school. I understand that Color collects, uses and discloses my personal information in accordance with its <u>Privacy Policy</u> and <u>Terms of Service</u>. I understand that the patient's samples, information and COVID-19 testing results items may also be shared, when required by law, with certain federal, state, or local agencies for public health purposes. I understand that diagnostic test results will be shared with the ordering provider (if applicable) in compliance with applicable regulations. I will be required to sign a separate HIPAA Authorization regarding sharing of patient information and results with their school to enable the patient to participate in the school's testing program.

H. No Cost: I understand that testing through this program will be at no cost to the patient.

I. Application: I understand that this consent applies each time the patient takes a COVID-19 test through the testing program over the next six (6) months, unless I revoke my consent for subsequent testing. To revoke my consent, I need to contact support@color.com. Such cancellation will apply to future activity only and will not affect tests the patient has already taken or information I already permitted to be collected or released.

[Unchecked checkbox] By checking the box, I am signing this consent electronically and agree that my electronic signature is the legal equivalent of my manual signature. I agree that I have been informed about the test purpose, procedures, possible benefits and risks. I understand that I will have the opportunity to ask questions before the patient provides a specimen for testing, and that I can ask additional questions of the program administrator at any time. I voluntarily agree to and consent to COVID -19 testing for the patient.

HIPAA Authorization

[Unchecked checkbox] I confirm that I have the legal authority to, and hereby authorize that the registered patient (either myself if I am of the age of majority or my minor child)'s information and results may be shared with the patient's organization to guide decisions on health, safety, and/or returning to work/school (<u>read full HIPAA authorization</u>). I understand that this authorization applies to each time the patient gets tested through this program.