

# CDPH Valencia Branch Laboratory

# PLAYBOOK to Stand Up School-Based Collection Sites



Version 4.0

02/17/2021

## Table of Contents

Introduction	3
Objectives	5
State Responsibilities	6
Your Responsibilities as an Organization Supervising Sample Collection	6
8 steps to conduct testing	8
1. Creating your collection plan	11
2. Completing the onboarding forms	11
3. Completing onboarding checklist	13
4. Registering with Color	16
5. Receiving kits	17
6. Supervising sample collection	19
7. Shipping collected samples for processing	24
8. Reporting and billing	28
FAQs	33
Appendix	39

## Introduction

The public-private partnership to build the California Department of Public Health's (CDPH's) Valencia Branch Laboratory in California to significantly increase the state's testing volume. This initiative is in partnership with PerkinElmer, a major diagnostics company.

As part of the state's objective to build COVID-19 testing capacity that is **timely, equitable, and cost-effective**, the new laboratory aims to augment the existing testing marketplace, help break supply chain bottlenecks, and drive down costs for tests in California. This new capacity enables the state to step up testing of disproportionately impacted populations at high risk for contracting COVID-19 (e.g., essential workers, those in congregate settings and communities of color) and continue **reopening our economy** safely.

The laboratory is contractually obligated to have a turnaround time of 24-48 hours (since receipt of sample at the CDPH Valencia Branch Laboratory), which is essential for a disease containment framework that includes testing, tracing, and isolation/support. With the onset of flu season, the CDPH Valencia Branch Laboratory also provides much needed additional capacity. Given symptoms for the flu are similar to COVID-19, healthcare providers will likely test for both, further increasing demand for testing.



Information contained in this document is preliminary | Working draft as of 02/17/2021.

This Playbook has been created with the aim to offer a step-by-step guide to districts<sup>1</sup> on how to partner with the state to ramp-up capacity of COVID-19 testing. It includes eight critical steps: (1) creating your collection plan; (2) completing the onboarding forms; (3) completing an onboarding checklist; (4) registering with Color; (5) ordering kits; (6) supervising sample collection; (7) shipping collected samples for processing; and (8) reporting and billing.

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<sup>1</sup> For the purposes of this document, the term “district” is used in a manner consistent with CDPH’s definition of “Schools and Local Education Agencies” as documented in its [guidance COVID-19 and Reopening In-Person Instruction Framework & Public Health Guidance for K-12 Schools in California, 2020-2021 School Year](#) released on 1/14/2021. If you are a school site interested in partnering with the Valencia Branch Lab, please coordinate directly through your district office.

## Objectives

CDPH Valencia Branch Laboratory's capacity is intended to be additive to the existing capacity of public and private laboratories. This would not supplant existing laboratory capacity, but make testing more accessible and equitable.

	Continue to <b>grow testing capacity</b> to meet Californians' testing needs.
	Improve <b>accessibility</b> of testing so individuals can obtain tests when appropriate.
	Ensure <b>cost sustainability</b> of testing for individuals, healthcare stakeholders, and the state budget over time.
	Increase <b>equity</b> in the distribution of tests by reaching communities most affected by the pandemic.

## State Responsibilities

- Contract with vendors to provision test collection kits
- Provide school-based collection support services, including planning, onboarding, training and ongoing support
- Deliver patient registration system, and test result monitoring / notification system (call and text)
- Oversee sample processing in the laboratory
- Ensure that CDPH Valencia Branch Laboratory delivers results within 24-48 hours of receiving the sample
- Pay for test processing and, as appropriate, recoup costs from insurance companies and the federal government through a third-party biller
- Provide detailed instructions and guidance for operating collection sites including shipping samples to the laboratory
- Ensure individuals with a positive result receive follow-up (when collection site is unable to follow-up)

## Your Responsibilities as an Organization Supervising Sample Collection

- Assess testing demand within your District for staff and/or students
- Reach out to your County Office of Education (COE) to inform them of your decision to partner with VBL and coordinate as appropriate
- Manage test kit inventory and request kits through state vendor
- Provide Personal Protective Equipment (PPE), technology and physical space for sample collection
- Outreach to staff, students, and families for pre-registration, which is submitted via a web-accessible platform
- Securely dispose of any patient data collected on paper
- Collect sample at the collection site

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- Ship via shipping company or courier to CDPH Valencia Branch Laboratory within 24-hours of collection using approved methods
- Support individuals with technology limitations to access test results
- Pay for essential site costs e.g., shipping or courier service, staff, outreach programs, materials etc. (See [Billing](#) for more information and details related to billing for test kits)
  - Note, if your district uses the State's California COVID-19 Courier Network (CCN) to ship samples to VBL, then you are not responsible for the cost of shipping from the CCN drop-box location to VBL. You or your district remain responsible for logistics and cost of transporting samples from their collection site to the drop-box (see [Appendix E](#))

## 8 steps to conduct testing<sup>2</sup>

To stand up the CDPH Valencia Branch Laboratory, the state has partnered with Color and PerkinElmer to offer an end-to-end supply chain from procurement to processing of polymerase chain reaction (PCR) tests and a software platform to support sample collection, enabling districts to efficiently and effectively provide COVID-19 testing to their staff and/or students



Manages lab in Valencia and is responsible for processing specimens within 48 hours of arrival to lab

Provides testing kits and IT platform to collect patient information and deliver result to ordering provider, patient & CCRS

School districts can partner with the state to offer COVID-19 tests by following a simple 8-step process:

### 8 steps to conduct testing



<sup>2</sup> Independent charter or private schools, please see the [Independent charter or private schools addendum](#), which is the last section of this Playbook document.

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**NOTE:** Independent charter or private schools, please see the [Independent charter or private schools addendum](#), which is the last section of this Playbook document.

## 8 steps to conduct testing details

The following is a **consolidated end-to-end checklist for school districts** to follow across the 8-step process.

- 1. [Creating your collection plan](#)
- 2. [Completing the onboarding forms](#)
  - [Receive an onboarding email from Color](#)
  - [Download and complete your school configuration spreadsheet](#)
  - [Complete the district onboarding form](#)
  - [Complete the collection site onboarding forms](#)
  - [\(If required\) Complete Memorandum of Understanding \(MOU\) through DocuSign](#)
- 3. [Completing onboarding checklist](#)
  - [Provide physical space meeting core site requirements](#)
  - [Procure PPE](#)
  - [Recruit/train staff or volunteers](#)
  - [Set up technology hardware](#)
  - [Arrange sample shipping](#)
  - Outreach to staff and/or students \*not included in this document\*
  - Manage on-site logistics \*not included in this document\*
- 4. [Registering with Color](#)
  - [Onboard onto the Color platform](#)
- 5. [Receiving kits](#)
  - [Receive test kits and shipping materials](#)
- 6. [Supervising sample collections](#)
  - [Register patients for testing \(including walk-ins\)](#)
  - [Supervise sample collection and prepare samples for collection](#)

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- 7. [Shipping collected samples for processing](#)
  - [Store samples before shipping](#)
  - [Package and ship samples](#)
- 8. [Reporting and billing](#)
  - [Process sample](#)
  - [Results reporting for participants](#)
  - [Results reporting for parents and guardians](#)
  - [Results reporting for districts and site administrators](#)
  - [Billing](#)

## 1. Creating your collection plan

*[Independent charter or private schools, please see [relevant addendum](#)]*

### Identify testing demand in your district

In order to create a collection plan, please refer to [CDPH's COVID-19 and Reopening In-Person Instruction Framework & Public Health Guidance for K-12 Schools in California, 2020-2021 School Year](#) guidance.

Additionally, CDPH has created an interactive tool on the [TTF School Testing website](#) to help your district estimate the number of tests per week at each testing site.

## 2. Completing the onboarding forms

*[Independent charter or private schools, please see [relevant addendum](#)]*

To complete the 2nd step, as an organization you will need to:

- [Download and complete your school configuration spreadsheet](#)
- [Complete the district onboarding form](#)
- [Complete the collection site onboarding forms](#)
- [\(If required\) Complete Memorandum of Understanding \(MOU\) through DocuSign](#)

### Receive an onboarding email from Color

As part of VBL's efforts to support school-based testing of staff and/or students, your district administrators should have received an outreach email from Color linking your district to the onboarding process. This email was sent the week of January 24<sup>th</sup>, 2021.

If you did not receive such an email, or cannot locate it in your inbox, please visit Color's support page: <https://www.color.com/cdph-color-faqs> and submit a request using the support form.

## Download and complete your school configuration spreadsheet

In the onboarding email from Color, you will receive a “school configuration spreadsheet” as an Excel file. The purpose of this file is for your district to specify each school-based collection site that you plan to set-up with VBL and to provide additional details for each site, including testing program specifics, transportation information etc. This spreadsheet is prepopulated with all the schools in your district based on a CA Department of Education data. You are encouraged to add additional sites (i.e. rows to the spread sheet) or make corrections (e.g., addresses) as needed.

## Complete the district onboarding form

In the onboarding email from Color, you will also find a link to your unique district onboarding form. This form asks for district-specific information such as address, billing preferences, etc. You will upload your school configuration spreadsheet as the last step of the district onboarding form and then hit “Submit” on the form. Once submitted, you will receive an email from Color within **3 to 5 business days**.

**NOTE:** Districts that submit an onboarding form will be approved to set up testing sites after Testing Task Force Review. Districts not approved will hear from the Testing Task Force, most often to seek more information.

## Complete the collection site onboarding forms

After you submit the district onboarding form and it is approved, each school site point of contact (as specified by you in the school configuration spreadsheet) will receive an email from Color asking them to complete a school collection site onboarding form. Please alert the site point of contacts to expect these emails. This simple form asks for collection site-specific information such as administrator details, testing program details (e.g., start date of testing), collection site staff/volunteer information, etc.

**NOTE:** Both onboarding forms must be completed at least five business days in advance of the first day of sample collection.

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**NOTE:** After completing the onboarding form, Color will automatically place the first order of test kits and return supplies on your collection site's behalf. Your site will receive them within 4-5 business days. The number of test kits will be based on your anticipated testing levels, once approved by the Testing Task Force (2 weeks' worth of approved test kits plus an additional 10% buffer).

## Complete Memorandum of Understanding (MOU) through DocuSign

After completing the district onboarding form, the State will send districts a Memorandum of Understanding (MOU) that districts must then complete that attests to the responsibilities of running a collection site (details for submission to be provided after site is approved).

If a district's relevant County Office of Education (COE) has already completed an MOU on behalf of all districts, then no additional MOU is required, and none will be sent.

**NOTE:** If your district is required to complete an MOU, the State will inform you by sending the MOU through DocuSign.

### 3. Completing onboarding checklist

To complete the 3rd step, as an organization you will need to (See [Appendix B](#) for expanded site checklist):

- [Provide physical space meeting core site requirements](#)
- [Procure PPE](#)
- [Recruit/train staff or volunteers](#)
- [Set up technology hardware](#)
- [Arrange sample shipping](#)
- Outreach to staff and/or students \*not included in this document\*
- Manage on-site logistics \*not included in this document\*

## Provide physical space meeting core site requirements

Your organization is responsible for ensuring there is an appropriate location and adequate space for physical distancing of all individuals during the testing process. You must provide all on-site logistics e.g., electricity, reliable internet access (cellular and/or Wi-Fi as appropriate), appropriate hand washing/sanitizer stations, waste pick-up, etc.

Detailed site set-up checklist to set up the physical space is provided in [Appendix B](#).

## Procure PPE

Your organization is responsible for ensuring all staff/volunteers have appropriate personal protective equipment (PPE). For personnel:

- Handling samples, but are not directly involved in collection (e.g., self-collection) and not working within 6 feet of the patient, should follow [Standard Precautions](#). Healthcare personnel are recommended to wear a form of [source control](#) (face mask) at all times while in the sample collection facility.
- Collecting samples or within 6 feet of patients suspected to be infected with COVID-19, should maintain [proper infection control](#) and use recommended personal protective equipment (PPE), which includes an N95 or higher-level respirator (or facemask if a respirator is not available), eye protection, gloves, and a gown, when collecting samples.

**NOTE:** Please review the CA Department of General Services' [PPE Master Agreement](#), which may allow your district to purchase PPE at a discounted rate.

## Recruit/train staff or volunteers

Collection sites must have trained staff on site to oversee all test administration. Based on CDC Guidance, staff requirements at the collection site will vary based on size but should include personnel focused on:

- Guiding patients and managing traffic flow

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- Registering patients or assisting patients with self-registration
- Checking patients in and collecting samples (monitoring or administering)
- Preparing samples for shipping to the lab

Additionally, there are staff requirements for self-administered tests:

- **Staff Requirements for Self-Administered tests** - [Self-administration](#) requires supervision by trained personnel (see [Supervising sample collection](#) for more information) which can be any trained adult and can be done from 6 feet away. The CDC recommends that the test supervisor wears gloves and face mask and requires that the patient understand and be able to perform procedure. All samples sent to the Valencia Branch Laboratory (following the full process described in this document) can be completed via a Blanket Order issued by the State Public Health Officer. This means that as long as there is someone trained to supervise self-collection, no clinician is required.

**NOTE:** Self-administered tests are generally recommended over clinician-administered tests due to its [comparable effectiveness](#) and decreased [patient discomfort](#).

## Set up technology hardware

Participating organizations are responsible for ensuring all equipment needed to run the Color platform is available at the collection site e.g., laptop or tablet, internet connection, and scanner. Please review recommendations below:

Requirements	Details
Tech Materials Required	<b>Modern tablet or laptop</b> 3 computers and tablets for every 250 participants per day, 1 device needs a scanning function. Device should run latest version of Google Chrome and have 1 USB-A port if using a wired barcode scanner
	<b>Scanner</b> Scanner needed to scan barcodes on collection tube. If using iPad: recommend using ScanKey iOS app. If using handheld scanner, scanner needs to support scanning of 1D barcode labels. Color recommends using wired USB scanners (instead of wireless or Bluetooth scanners). If handheld USB scanner is preferred, site will also need a Lightning to USB 3 Camera Adapter (for iPad) or a USB OTG adapter like Micro USB or USB-C (for Android tablet)
	<b>Wi-Fi</b> Strong Wi-Fi signal through router or hotspots
	<b>Electrical</b> Every check-in and testing lane needs direct access to electrical. Each lane will have iPads and Wi-Fi hotspots plugged in

## Arrange sample shipping

Collection sites are responsible for arranging shipping for samples to the CDPH Valencia Branch Laboratory. It is advised to utilize a courier / transportation service that is authorized to ship Category B Infectious Substances; a list of potential couriers can be found in [Appendix C](#). The State of California has launched the California COVID-19 Courier Network (CCN) through which collection sites are able to drop off samples at a nearby assigned CCN drop-box location. For more details on state transportation support, please see [Appendix E](#). While it is possible to ‘hand-deliver’ samples to the lab, it is **strongly** advised against unless the individual delivering the samples has appropriate hazmat training.

Collection sites are encouraged to send samples to the VBL within 24 hours (preferably the same day as collection) to ensure rapid results from the lab. NOTE: For planning purposes, a 100-kit ship-back box fully filled 100 kits is 12" x 12" x 10" and approximately 6lbs and a 200-kit ship back box fully filled with 200 kits is 12" x 12" x 20" and approximately 12lbs.

## 4. Registering with Color

To complete the 4<sup>th</sup> step, you will need to:

[Onboard onto the Color platform](#)

### Onboard onto the Color platform

Color’s platform allows for the collection of important patient information and links the sample to the patient using a barcode maintained in the patient record and on the physical sample. The platform requires staff members to review training materials that explains how to use the platform to enter participant data and scan in the barcode from the test kit.

After both onboarding forms are completed for a given site, Color will reach out via email to collection site administrators and staff. Note, this section is relevant for “staff” that is running and supporting testing events at the collection site, not all teachers and staff being tested at the collection site. In this communication, Color will provide information on registering for an account and collection-site

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specific, pre-registration links for staff and student testing events (see section [Register patients for testing](#)).

color Lauren Newcom

King County DPH Add

**Today's patients (Monday, Oct 26)**

Patient added and checked in.

All (5) Awaiting (1) **Checked In (3)** Collected (1) Find by name or ID

Last name	First Name	ID	Time	Status
Doe	Jane	DS123458	9:31am, Oct 26	Checked in <a href="#">Undo check in</a>
Gomez	Ana	DS123456	9:32am, Oct 26 Appt. # 99636074	Checked in <a href="#">Undo check in</a>
Whitman	Tanya	DS123458	9:34am, Oct 26 Appt. # 99636075	Checked in <a href="#">Undo check in</a>

Patient registration information must be loaded into the Color platform online. Paper forms will be included for sites that receive test kits as an emergency back-up in case the Internet is not available. However, if paper forms are used all information collected must be entered in the online platform by collection site staff to complete the sample collection process. **Samples cannot be shipped to the lab until this has been done.** In addition, if patient data is collected using paper forms, the site is responsible for securely shredding these documents. This is necessary because the data is considered personal health information (PHI) which is protected by HIPAA. In addition, if additional paper forms are required, the site will need to order these specifically through CDPH.

## 5. Receiving kits

[Independent charter or private schools, please see [relevant addendum](#)]

To complete the 5<sup>th</sup> step, as an organization you will need to:

[Receive test kits and shipping materials](#)

## Receive test kits and shipping materials

Once the organization has completed the onboarding forms, Color will use the information provided to estimate the number of collection kits and ship-back boxes needed. The first order of test kits and return supplies will automatically be placed on your collection site's behalf. Your site will receive them within 4-5 business days. The number of test kits will be based on your approved allocation from CDPH (1 weeks' worth of approved test kits plus an additional 10% buffer). See [Color's Test Kits webpage](#) for more information.

Once testing begins at a site (based on when barcode scanning of test kits commences), Color will automatically ship an additional two weeks' worth of kits and ship-back materials to that site. Going forward, Color will monitor kit inventory levels at a given site (using barcode scanning data) and will automatically ship kits and ship-back materials to ensure a site always maintains roughly a two-week supply of kits and ship-back materials.

**Organizations must use the provided ship-back boxes to ship the samples to the lab.** There are two ship-back box sizes (12x12x10 and 12x12x20) boxes, which hold either 100 kits or 200 kits. In addition to estimating the number of samples to be collected, sites will also need to estimate the number of shipments that will be made to the lab each week. This information will be used to determine how many ship-back boxes and what size will be provided to the site.

**NOTE:** Kits have a shelf life of 1-2 years. If not all kits are used in each week, they can be used in the next weeks if stored properly. That said, sites are heavily encouraged to order the amount of kits needed each week for their site so the State can ensure all sites have access to the number of kits needed each week.

**NOTE:** Before kits are used for testing, they should be stored somewhere secure with no direct exposure to sunlight or heat. The ideal environment to store test kits is at room temperature (between 72 and 76 degrees Fahrenheit).

**NOTE: These collection kits use PrimeStore transport media (the small amount of liquid in each tube) to stabilize and inactivate the virus. This media contains guanidine thiocyanate, which produces a dangerous chemical reaction that releases cyanide gas when exposed to bleach (sodium hypochlorite). DO NOT USE bleach products near collection kits.**

## 6. Supervising sample collection

To complete the 6<sup>th</sup> step, as an organization you will need to:

- Register patients for testing
- [Supervise sample collection and prepare samples for collection](#)

### Register patients for testing

The Color platform both allows you to register walk-in patients and enables patients to self-register through a site-specific URL ([See FAQ for more info](#)). Patients should pre-register for school-based collection sites. This is because patient information recorded in walk-in registration is NOT stored for future testing events. Patient information is stored for future testing events if the patient uses pre-registration. That said, to register a walk-in patient, a staff member must complete a few simple steps on behalf of the patient (see pictures below). The staff member will collect answers to a series of questions for the system, including necessary contact information for each patient (e.g., phone number, name, date of birth, health insurance – if applicable, parent/guardian information if applicable, etc.) before they are able to submit their sample.

**NOTE:** Patients who **pre-register will have their information stored and their profile can be resurfaced for future use**. Therefore, to save patient information for future purposes, pre-registration is the best option.

**NOTE:** Patients will be prompted to sign HIPAA authorization at registration; patient cannot get tested at site without signing authorization.

**NOTE:** If a student under 13 years of age **does not preregister, a parent/guardian will need to be present in order to register them on-site**.

The image shows two side-by-side form sections from a web application. The left section is titled 'Add patient' and contains three sub-sections: 'Contact information' with a phone number field and an optional email address field; 'Patient information' with fields for first name, middle initial (MI), last name, date of birth, home street address, home city, home state, and home ZIP; and 'Gender identity' with a dropdown menu and a note about adding gender information. Below this is a 'Sex' section with radio buttons for Female, Male, and Non-binary, and 'Continue' and 'Cancel' buttons. The right section is titled 'Health insurance information' and includes a note that the user won't be charged for the test. It has a 'Do you have health insurance?' section with radio buttons for 'Yes, I have health insurance.' (selected) and 'No, I do not have health insurance.'. Below that is an 'Insurance information' section with fields for 'Insurance company name' and 'Member identification number'. A 'Who is the policy holder?' section has radio buttons for 'I am' (selected), 'My spouse or partner', 'My child', and 'Someone else'. At the bottom of this section are 'Continue' and 'Previous' buttons.

## Additional details on registration process for children (by age group)

- **For children 13 and older:** Children who are 13 and older can provide consent and administer the tests themselves. If they do so, results will only be delivered to them, and not to a parent/guardian. If a parent/guardian registers for a child age 13-18, the parent/guardian can consent and can provide their contact details in the registration process to receive the results on behalf of the child.
- **Under 13:** Children who are under 13 must have parental or guardian consent during the registration process, and it is the parent or guardian's best judgement on whether they or the child will administer the test themselves. Following testing, the parent or guardian that registered and consented on behalf of the child will receive the results.

## Supervise sample collection and prepare samples for collection

The swabs included in the state provided test kits are Anterior Nares (nasal) samples which when both properly [self-administered](#) ([Spanish version](#)) or clinically-administered, have been [scientifically shown](#) to have similar performance to other testing alternatives, such as nasopharyngeal or oropharyngeal swabs, while being less invasive and generally more comfortable for patients.

For self-administered tests, the individuals collecting their own sample must be supervised and each individual must follow the following steps as shown in the printable flyers can be downloaded, [here](#) and [Spanish version here](#). When available, video or animated instructions may provide added clarity for patients. For example, the [Lower Nasal Swab Collection instructions](#), developed by [Audere](#), contains an animation to demonstrate proper technique. Audere, a Washington State nonprofit corporation, has granted a general right of reference to any organization who wishes to access and use these instructions for lower nasal swabs administered at a collection site.

**NOTE:** These collection kits use PrimeStore transport media (the small amount of liquid in each tube) to stabilize and inactivate the virus. This media contains guanidine thiocyanate, which produces a dangerous chemical reaction that releases cyanide gas when exposed to bleach (sodium hypochlorite). **DO NOT USE bleach products near collection kits.**

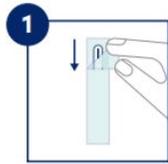
### Supervising self-administration to young children and children with special needs

Self-administration is an appropriate option for all age groups, although there may be exceptions.

For sites where supervision of self-administration by young children is required, VBL has put together a “Student Self Swabbing Resource” to support this process. Ultimately, it is the collection sites discretion when (if at all) to provide additional support to young children and children with special needs in self-administration.

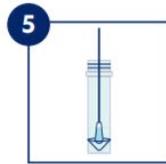
## Administering a Nasal Sample

### Providing a Nasal Swab Sample



**1** **Open the package with the swab.**

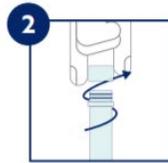
Peel open where indicated. Leave the swab in the package for now.



**5** **Put the swab into the collection tube.**

The soft tip of the swab that went into your nose should go into the tube first.

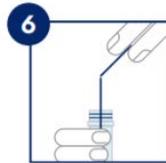
**Note:** The handle will be sticking out.



**2** **Unscrew the lid of the collection tube.**

Keep the lid somewhere you can easily find it.

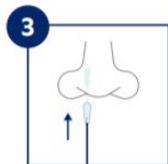
**Careful:** Don't spill the liquid inside the tube.



**6** **Snap the handle off.**

Holding firmly onto the tube, snap the handle off where it naturally bends.

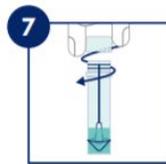
**Careful:** Don't spill the liquid inside the tube.



**3** **Rotate the swab tip in the first nostril, 3 times.**

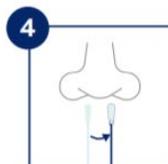
Pull swab out of its packaging and insert it into one nostril just until the soft tip is no longer visible. Rotate it in a circle around the inside edge of your nostril at least 3 times.

**Careful:** Don't touch the soft tip with your hands.



**7** **Screw on the top of the collection tube.**

You're almost done! Make sure the top is screwed on tightly.



**4** **Repeat in the other nostril, 3 times.**

Use the same soft tip to repeat the previous step in the second nostril.

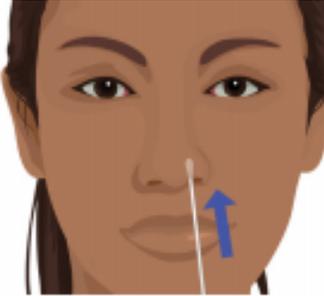


**8** **Put the tube into the specimen bag.**

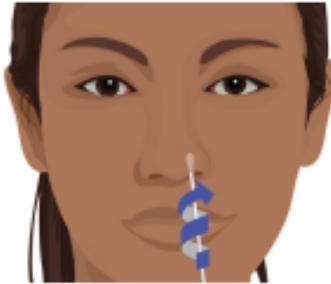
Seal the bag by closing the ziplock seal.

Following is [additional guidance from CDC on collecting the sample](#)  
([Spanish version here](#))

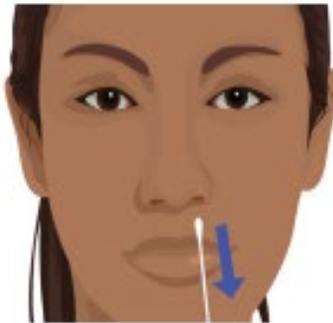
Insert the swab into your nostril. Do not insert it more than half an inch into your nostril.



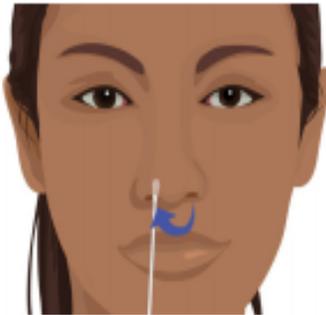
Slowly twist the swab, rubbing it along the insides of your nostril for 15 seconds.



Gently remove the swab.



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



## 7. Shipping collected samples for processing

To complete the 7<sup>th</sup> step, as an organization you will need to:

- [Store samples before shipping](#)
- [Package samples](#)

### Store samples before shipping

Collection sites are responsible for secure storage of samples prior to shipment and selecting and coordinating pick-up by a courier (See [Appendix C](#) for a list of Category B qualified California courier options). Samples should be stored in a secure collection bin in a cool, shaded, and covered area. While refrigeration isn't necessary, it is most important that samples are not kept in direct sunlight. The ideal environment is room temperature (between 72 and 76 degrees Fahrenheit). Once collected, samples are suggested to be transported to the lab within 24-hours (preferably the same day as collection), for faster lab processing and turnaround time on results.

**NOTE:** The State of California has launched the California COVID-19 Courier Network (CCN) through which collection sites are able to drop off samples at a nearby assigned CCN drop-box location. For more details on state transportation support, please see [Appendix E](#).

Collection sites are responsible for properly packaging (see [common packaging and shipping mistakes](#) for additional information) all samples appropriately for transportation. This requires compliance with [Biological substance Category B shipping](#). Test kits provided by the state, through Color, will come with specific packaging materials to help streamline the return process.

#### Test kit materials (see [Color test kits](#) for more information)

- 6" x 9" biohazard bag that contains:
  - Small absorbent pad
  - Tube containing (Molecular Transport Media) MTM labeled with a barcode
  - AN/OP individually packaged Swab

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- Bilingual takeaway card with the same barcode as on the tube which will be given to each participant to help them access their test results



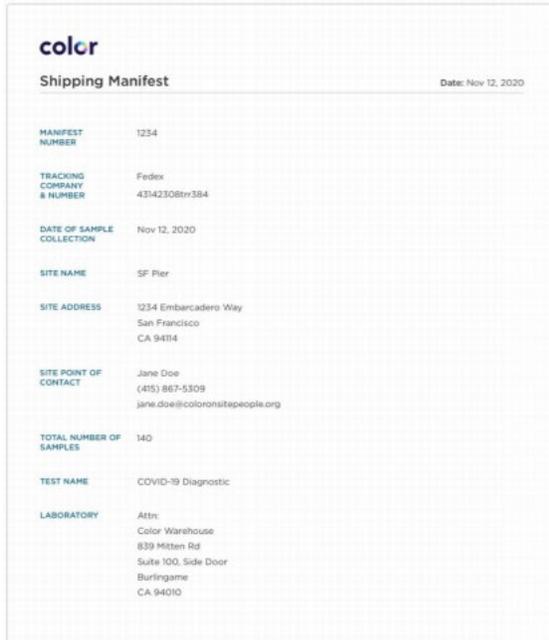
**Ship back materials (see [Color test kits](#) for more information)**

- Large sealable biohazard bag (watertight)
- Shipping box (100 kit and 200 kit size)
- UN3373 label (to be affixed to the outside of the box before shipping)
- Electronic manifest and batch shipping tool



**Electronic manifest and batch shipping tool (see [Color Batch Shipping Tool Training](#) for more information)**

Color provides an electronic manifest and batch shipping tool to all sites, to help track samples as they are transported from the collection site to VBL and ensure that VBL only receives activated samples that can be processed. Once the samples have been collected, an electronic manifest will need to be completed on the Batch Shipment tool for each shipment. A printout of the manifest will need to be included with every sample shipment sent to the lab. Paper manifest for your site are also provided (if needed).



color	
Shipping Manifest	
Date: Nov 12, 2020	
MANIFEST NUMBER	1234
TRACKING COMPANY & NUMBER	Fedex 43142308tr384
DATE OF SAMPLE COLLECTION	Nov 12, 2020
SITE NAME	SF Pier
SITE ADDRESS	1234 Embarcadero Way San Francisco CA 94114
SITE POINT OF CONTACT	Jane Doe (415) 867-5309 jane.doe@coloronsitepeople.org
TOTAL NUMBER OF SAMPLES	140
TEST NAME	COVID-19 Diagnostic
LABORATORY	Atrn Color Warehouse 839 Mitten Rd Suite 100, Side Door Burlingame CA 94010

## 11 Steps to package samples for shipping (See [Appendix A](#) for general packing requirements)

1. Make sure the caps are tightly sealed on each tube
2. Package each sample in the individual biohazard bag with small absorbent pad
3. Place individual samples in the large biohazard bag. Note: The biohazard bag should only contain up to either 100 or 200 individual kits, depending on the size of your return box. You do not have to fill the bag up to the capacity if you have not performed the full number of tests over a timeframe. Feel free to ship bags with less than the full capacity
4. Seal the large biohazard bag tightly
5. Place the biohazard bag inside the return shipping box provided
6. Make sure the return shipping box has a UN 3373 label affixed to the outside of the box
7. Place the completed paper manifest on top of the bag
8. Seal the cardboard box. If possible, label the outside of the package with the manifest ID.
9. Affix the return shipping label if applicable (not included)

10. Provide the box to the courier or carrier as appropriate
11. Note down the tracking number if appropriate

## 8. Reporting and billing

The 8<sup>th</sup> step will be handled by the state's Valencia Branch Laboratory, who will:

- [Process sample](#)
- [Results reporting for participants](#)
- [Results reporting for parents and guardians](#)
- [Results reporting for districts and site administrators](#)
- [Billing](#)

### Process sample

The CDPH Valencia Branch Laboratory will be responsible for processing all samples within 48 hours of receipt.

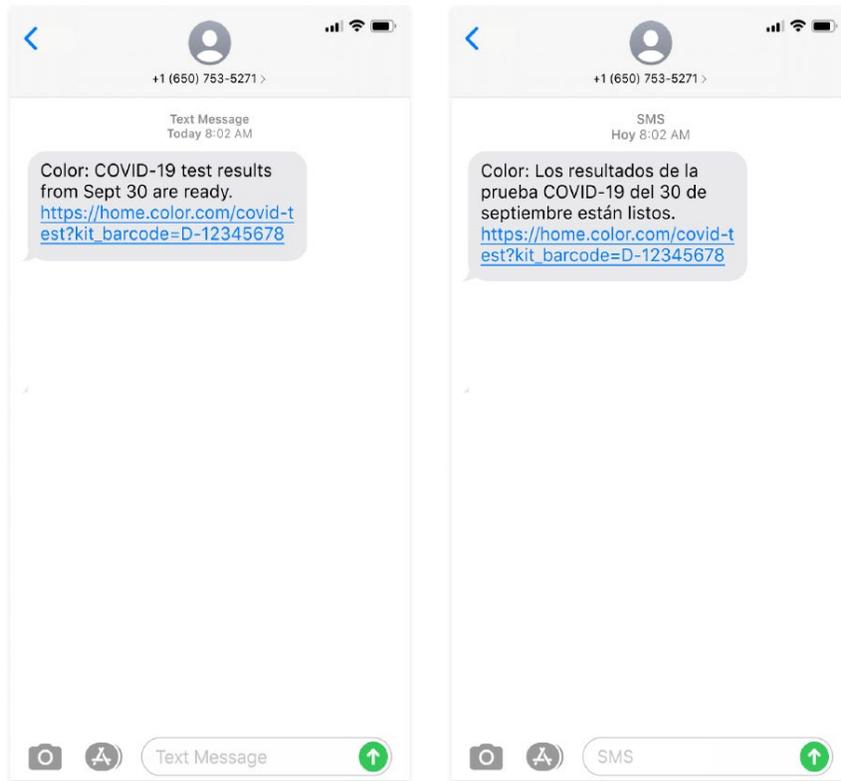
### Results reporting for participants

When results are available, Color will notify patients through SMS and/or email (using the mobile phone number and/or email provided through the registration process) that results are available.

Patients can use their date of birth and the barcode number associated with their sample (which is provided on a take-away card for sites that will be provided kits by the state) to access their results through Color's HIPAA compliant [website](#). If the patient loses their Color barcode for their test, they can call the Color support hotline. Patients can also access their results by clicking on the link from their email or text notification.

Patients with positive (or presumptive positive) test results who do not check their test results on the Color website will receive up to 10 autodial attempts from the state's clinical call center within 48 hours to ensure they receive their test results.

**NOTE:** Spanish and other languages are available on these calls through the language line.



**NOTE: Patients who do not have a reliable mobile phone number and/or email address can still be registered through the Color platform if they utilize the contact information (mobile phone and/or email) from a proxy. In this case, the proxy is responsible for communicating results to the patient. Color is not able to provide results outside of the HIPAA compliant website, which is accessed using the Internet and providing the patient's date of birth and the barcode number associated with their sample (which is provided on a take-away card for sites that will be provided kits by the state).**



There are four potential results that a patient can receive after taking the test:

Result	What it means	What to do
Positive	<p>A <b>positive test</b> result means that the COVID-19 virus was detected in your specimen.</p> <p>NOTE: The incubation period for COVID-19 is between 2-14 days. Depending on when you were tested, or the sensitivities of a given test, be aware that future tests may come back negative.</p>	<p>You should self-isolate. You can contact your medical provider or local health department authorities for further instructions. Additionally, your local health department may also contact you.</p> <p>Only a physician can give you a diagnosis. They can also provide information on how to care for yourself and to help protect others from infection.</p>
Presumptive positive	<p>A <b>presumptive positive result</b> indicates that you had a marginal trace of the COVID-19 virus in your specimen. This may mean you are either very early in your COVID infection and the virus is just beginning to rise, or you are later in your COVID infection and the overall amount of virus is declining. It could also mean you are infected with COVID but the sample that was taken for testing only captured a minimal amount of the virus when swabbing.</p>	<p>You should self-isolate. You can contact your medical provider or local health department authorities for further instructions. Additionally, your local health department may also contact you.</p> <p>You will be asked to submit a new specimen so another test can be run.</p>
Negative	<p>A <b>negative test result</b> means that COVID-19 virus was not detected in your specimen at the time of your test.</p>	<p>Negative results mean that the virus was not detected at the time of the tests. If you're feeling symptoms (fevers, chills, cough, shortness of breath, muscle and body aches, fatigue, headache, sore throat, new loss of taste or smell, runny nose, congestion, nausea, vomiting and diarrhea), contact a doctor and ask whether you should be retested because (1) you may have contracted the virus after your test, or; (2) your test may have been a false negative.</p>
Invalid	<p>An <b>invalid test</b> result means that the lab was unable to confirm the presence or absence of COVID-19 in your specimen.</p>	<p>You should self-isolate. You can contact your medical provider or local health department authorities for further instructions. Additionally, your local health department may also contact you. You will be asked to submit a new specimen so another test can be run.</p>

## Results reporting for parents and guardians

- **Children 13 and older:** If a parent/guardian registers for a child age 13-18, the parent/guardian can consent and can provide their contact details in the registration process to receive the results on behalf of the child. Otherwise, if the child completes the registration with their own contact details, the child alone receives the results.
- **Children under 13:** Following testing, the parent or guardian that registered and consented on behalf of the child will receive the results. Please review the [Register patients for testing \(including walk ins\)](#) section for more details.

## Results reporting for districts and site administrators

As a default, the collection site (i.e., school) administrator will receive access to their site's results dashboard. This individual will also be able to review specific patients' results, which is allowed for by the HIPAA authorization during patient registration. If additional personnel require access to a site dashboard, the main point of contact can visit Color's support page: <https://www.color.com/cdph-color-faqs> and submit a request using the support form.

At a district level, district administrators will have superuser access that gives them insights across their jurisdiction's testing sites.

## Billing

Collection sites will not be responsible for test processing costs. However, sites will be responsible for costs of shipping and other equipment for the collection process (e.g., PPE). All costs related to collection site responsibilities are borne by the organization, standing up the test site, including shipping, staff time, and necessary equipment for the collection process (e.g. chairs, PPE, etc.) **Note:** If a collection site uses the State's California COVID-19 Courier Network (CCN) then the site is not responsible for the cost of shipping from the CCN drop-box location to VBL. Collection sites remain responsible for logistics and cost of transporting samples from their collection site to the drop-box.

For all schools partnering with VBL, the state will cover the costs for testing<sup>3</sup> upfront and recoup the costs either by (1) seeking reimbursement from the relevant health insurance providers; or (2) directly billing the local education agency. The following describes the billing process in school settings for teachers, staff and students.

## **Billing for the cost of testing: teachers and staff**

Participating local education agencies (LEAs<sup>4</sup>) can choose one of two scenarios with respect to billing:

- *Scenario 1: Insurance Billing* | The state's third-party billing vendor will bill the individual's health insurers<sup>5</sup> for the cost of tests.
  - If for any reason the teacher or school staff are uninsured, the state will take following steps:
    - The state will bill the [HRSA COVID-19 Uninsured Program](#); **OR**
    - The state will bill the [DHCS COVID-19 Uninsured Group Program](#)<sup>6</sup>
  - That is, no uninsured person will be denied access to a test.
- *Scenario 2: Direct Billing* | The LEA will be billed (i.e., invoiced) directly for the cost of each test. Billing will begin at the end of February and will be backdated to the date of service.

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<sup>3</sup> The testing costs covered by the state include test kits, shipping of kits to sites, software for patient registration and results returning, and general site support. The state will also cover the upfront cost of processing the tests in the VBL—but will work to recoup those costs from LEAs in accordance with this document. If sites utilize the state courier network, costs for shipping specimens to the lab will also be covered by the state.

<sup>4</sup> Local education agencies include school districts, county offices of education, and some charter schools.

<sup>5</sup> Pursuant to the California Department of Managed Health Care [emergency regulations](#), teachers and school staff are defined as essential workers.

<sup>6</sup> If an individual is uninsured and in order to bill the DHCS COVID-19 Uninsured Group Program, the individual will need to be enrolled in the program. Information for enrollment will be provided to LEAs.

## Billing for cost of testing: students

Recouping the cost of testing students is dependent on the situation of the individual student being tested:

- *Scenario 1: Medi-Cal* | For students covered by Medi-Cal, the state will bill the Medi-Cal program for the test conducted for each child.
- *Scenario 2: Direct bill* | For students covered through private health insurance or who are uninsured, the LEA will be billed (i.e., invoiced) directly for the cost of each test. As with direct billing for teachers and staff, billing will begin at the end of February and will be backdated to the date of service.

## FAQs

### Billing

**Q: Why is the health insurance company billed for teachers/school staff and not students?**

A: As part of the emergency regulations promulgated by the California Department of Managed Health Care, which regulates most health insurance plans, teachers and school staff are defined as essential workers, therefore the health insurance companies are to pay for the test.

**Q: Do health insurance companies have to cover asymptomatic testing for teachers and school staff?**

A: Yes. The emergency regulations promulgated by the California Department of Managed Health Care deems testing for essential workers, which includes teachers and school staff, to be medically necessary in all cases, so no utilization management or prior authorization is required or allowed. These regulations apply to most health insurance products regulated by the department, but not all.

**Q: How should schools pay for student testing?**

A: The Governor has proposed \$2 billion as part of his 2021-2022 budget proposal for the Legislature to appropriate immediately for schools to leverage

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in order to reopen safely, particularly for our youngest students. These dollars should be considered, in addition to any available federal funds, to fund testing for students who return to in-classroom instruction.

**Q: Are schools required to use the CDPH Valencia Branch Laboratory?**

A: No. The CDPH Valencia Branch Laboratory has been made available as an option available for schools, but schools are welcome to use other commercial laboratories.

**Q: What if a school or LEA chooses to use a different laboratory?**

A: In this case, the school or laboratory may bill Medi-Cal Fee-For-Service program, and not the managed care health plans. The school would need to work with the laboratory to determine billing mechanism and process.

**Q: Can a LEA use the Medi-Cal Billing Option Program to bill the Medi-Cal program for testing?**

A: No. This effort is separate and apart from the Medi-Cal Billing Option Program that is used by Local Education Agencies. Instead, the state's third-party billing vendor will bill the Medi-Cal directly through the Fee-For-Service program pursuant to a disaster State Plan Amendment.

**Q: How will a school know which students are Medi-Cal beneficiaries?**

A: During the registration process, the parent or guardian will be asked to input insurance information for each child that is tested—even for those that are privately insured. This will provide consistency on the registration form.

**Q: What happens if a parent or guardian does not provide insurance information or the child is uninsured?**

A: Where insurance information is not provided for a student, the State will seek to determine if they are enrolled in Medi-Cal, and the LEA will be directly billed for all students where Medi-Cal enrollment can't be confirmed.

**Q: What is the current cost per test for the CDPH Valencia Branch Laboratory?**

A: The current price per test is \$55, which includes test kits, shipping of kits to sites, lab analysis, software for patient registration and results returning, and general

site support. If sites utilize the state courier network, costs for shipping specimens to the lab will also be covered by the state. This is expected to decrease as the laboratory processes a greater volume of tests. For example, at 100,000 tests per day, the total cost will drop to \$38 per test. Additionally, we are implementing the concept of pooling for schools at the Laboratory, which is a technique that allows the laboratory to test multiple specimens through one test, further decreasing costs.

**Q: Could an individual who is uninsured, and eligible for the Medi-Cal program be enrolled in the program?**

A: Yes. This is an opportunity to ensure that individuals are both aware of the state's Medi-Cal program as well as the state's health insurance exchange, Covered California. Individual about both programs will be made available to schools and LEAs. Additionally, information about both programs will be provided to parents and guardians.

## Testing

**Q: Can we test minors (under the age of 13)?**

A: Yes. For students testing in school settings, the parent/guardian must complete the registration process, provide consent, and use their email/phone to obtain results—and can do so through a pre-registration link at home. For minors testing in other settings, the parent/guardian must be present, in person, in order to complete the registration process, provide consent, and use their email/phone to obtain results. It is up to the parent/guardian's discretion on whether they or the child will administer the test. A parent or guardian can receive the results on behalf of a child (ages under 13) when they provide consent on behalf of that child.

**Q: Do I need a doctor or nurse to set-up a site?**

A: No, not where tests will be self-administered. All such samples sent to the Valencia Branch Laboratory can be completed via a Blanket Order issued by the State Public Health Officer. This means that as long as there is someone trained to supervise self-collection, no clinician is required.

**Q: Do you need training to pack patient samples for transport?**

A: Packing guidance for safe transport is provided with the shipment of kits and must be followed. Personnel handling patient samples must follow their institutional guidelines on safe biological sample handling.

**Q: Do people transporting patient samples need to be trained?**

A: For transporting patient samples, personnel must be trained in the proper safety, packing, and shipping regulations for Division 6.2, UN 3373 Biological Substance, Category B in accordance with the current edition of the [International Air Transport Association \(IATA\) Dangerous Goods Regulations \(DGR\)](#). Personnel should be trained in a manner that corresponds to their function-specific responsibilities.

**Q: What disinfectant should personnel use to decontaminate work surfaces?**

A: Decontaminate work surfaces and equipment with appropriate disinfectants. [Use EPA-registered hospital disinfectants with label claims to be effective against COVID-19](#). Follow manufacturer's recommendations for use, such as dilution, contact time, and safe handling. While CDC guidance includes using bleach for cleaning - **DO NOT USE BLEACH OR PRODUCTS WITH BLEACH**. These samples are transported in Molecular Transport Media (MTM), which can create cyanide gas when it comes in contact with bleach.

**Q: How should the site personnel remove biohazardous waste from the site or testing area for decontamination and disposal?**

A: Handle laboratory waste from testing suspected or confirmed COVID-19 patient samples as all other biohazardous waste in the laboratory. Currently, there is no evidence to suggest that this laboratory waste needs additional packaging or disinfection procedures.

For additional information, refer to the [Biosafety in Microbiological and Biomedical Laboratories \(BMBL\) \(5th edition\)](#)

**Q: What are Standard Precautions?**

A: Standard Precautions are the minimum infection prevention practices that apply to patient care, regardless of suspected or confirmed infection status of

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the patient, in any setting where health care is practiced. They are based on the principle that there is a possible risk of disease transmission from any patient, patient sample, or interaction with infectious material. Standard Precautions include hand hygiene and use of PPE when indicated, in addition to practices to ensure respiratory hygiene, sharps safety, safe injection practices, and effective management of sterilization and disinfection for equipment and environmental surfaces. The exact implementation of Standard Precautions should be determined by an activity-specific risk assessment.

For additional information, refer to the following:

[2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings](#)

[CDC Isolation Precautions](#)

[COVID-19 Overview and Infection Prevention and Control Priorities in Healthcare Settings](#)

**Q: Who can observe self-collection of swabs?**

A: The observation of swab 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. Observers should be trained and this can be done by reviewing the training materials in section 6. Trained observers can supervise self-swabbing remotely.

**Q: Do we need to refrigerate samples either during storage or during the shipping process?**

A: No. While refrigeration isn't necessary, it is most important that samples are not kept in direct sunlight. The ideal environment is room temperature (between 72- and 76-degrees Fahrenheit). Regarding the shipping process, following the packing and shipping guidelines (which does not require refrigeration) is required for secure transportation of the sample while maintaining result accuracy (See [Step 4](#) and [Appendix A](#) for more information).

**Q: How do I register my site to receive a site-specific URL for patients pre-registering online?**

A: Once you are approved as a site by CDPH, Color will begin the process of setting up your site and once completed, within 2 business days of approval, Color will share an onboarding email which will include your site-specific URL. If you have any questions about this process, please visit Color's support page: <https://www.color.com/cdph-color-faqs> and submit a request using the support form.

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

A: Individuals who had a positive viral test in the past three months and are now asymptomatic do not need to be retested; testing should be considered again (e.g., in response to an exposure) if it is more than three months after the date of onset of the prior infection, or if new symptoms occur. For individuals who develop new symptoms consistent with COVID-19 during the three months after the date of initial symptom onset, if an alternative etiology cannot be identified, then retesting can be considered in consultation with infectious disease or infection control experts.

Note that a “presumptive positive” result DOES require an immediate retesting of the individual.

For additional details, refer to the following links:

CDPH All Facilities Letter (as of September 12, 2020):

<https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-20-53.aspx>

CDC Guidance on Duration of Isolation and Precautions for Adults with COVID-19 (as of October 19, 2020):

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html>

## Appendix

### Appendix A: General packing requirements

General Packaging Requirements – all these requirements are met with the proper use of the shipping materials provided with the collection kits from the state.

For Biological Substance, Category B (UN 3373) shipments, cushioning material is required for both liquid and dried samples. You must include four layers of packaging:

1. Primary watertight inner receptacle. Use primary receptacles made of glass, metal, or plastic with a positive means of ensuring a leak-proof seal; a skirted stopper or metal crimp seal must be provided; screw caps must be reinforced with adhesive tape. For liquid samples, the primary receptacle must not contain more than 1 L. For dried samples, the primary receptacle must not exceed the outer packaging weight limit.
2. Absorbent material. Place absorbent material between the primary and secondary receptacles, using enough material to absorb the entire contents of all primary receptacles. Absorbent material is required for Biological Substance, Category B (UN 3373) shipments containing liquids. Acceptable absorbent materials include cellulose wadding, cotton balls, super-absorbent packets, and paper towels.
3. Secondary watertight inner receptacle. Use a secondary container that is leak-proof for liquid samples or sift proof for dried samples. Choose only secondary containers certified by the manufacturer for Biological Substance, Category B (UN 3373) prior to use. Either your primary or secondary receptacle must be able to differential of not less than 95 kPa in the range of -40 C to 55 C (-40 F to 130 F). To prevent contact between multiple fragile primary receptacles, individually wrap or separate them inside the secondary container.
4. Sturdy outer packaging. Use rigid outer packaging constructed of corrugated fiberboard, wood, metal, or plastic, or other equally strong material, including cylinders made of such materials and appropriately sized for the contents. Chipboard or paperboard boxes are unacceptable outer packaging. The

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completed packaging must be of good quality, strong enough to withstand the normal rigors of transportation without loss of contents as a result of vibration, changes in temperature, humidity, or pressure. Limit the total volume for liquid samples to 4 L and the total weight of dried samples to 4 kg per outer container. At least one surface of the outer packaging must have a minimum dimension of 100 mm x 100 mm (4" x 4"). Completed packages must be able to withstand a 4' (1.2-m) impact test. Before sealing the outer packaging, you must make an itemized list of the contents of the package and enclose the list between the secondary packaging and outer packaging.

## Appendix B: Sample material required to set-up site

### Structural

Requirements	Details
Storage container pods	<ul style="list-style-type: none"><li>• 1 - 2 large storage containers to store site materials, PPE, cleaning supplies, test kits, swabs, etc.</li></ul>
Drive-through entrance *	<ul style="list-style-type: none"><li>• Designated entrance for all vehicles</li></ul>
Drive-through exit *	<ul style="list-style-type: none"><li>• Designated exit for all vehicles exiting from the testing lanes</li></ul>
Pedestrian entrance **	<ul style="list-style-type: none"><li>• Designated entrance that provides direct access to the pedestrian testing lane</li></ul>
Pedestrian exit **	<ul style="list-style-type: none"><li>• Designated exit from the pedestrian testing lane that enables social distancing from the people who are in line for pedestrian testing and/or are entering the pedestrian testing lane</li></ul>
Walkway	<ul style="list-style-type: none"><li>• Walkway needs to be paved and accessible</li></ul>
Staff parking lot	<ul style="list-style-type: none"><li>• Staff parking lot for a minimum of 15 cars</li></ul>
Courier pick up locations	<ul style="list-style-type: none"><li>• The courier needs direct access to all testing lanes</li></ul>
PPE donning location	<ul style="list-style-type: none"><li>• Designated location to don PPE. This can be at a rectangular table near the storage pod.</li></ul>
Guard boxes / tents	<ul style="list-style-type: none"><li>• The guard boxes need to be at the entrance and exit</li></ul>
Lighting	<ul style="list-style-type: none"><li>• Lights throughout the site</li></ul>

## Services & Staffing

Requirements	Details
Water	<ul style="list-style-type: none"> <li>Water is needed for the restrooms and handwashing station</li> </ul>
Electrical	<ul style="list-style-type: none"> <li>Every check-in and testing lane needs direct access to electrical. Each lane will have iPads and WiFi hotspots plugged in, as well as fridges</li> </ul>
Portable Staff Restrooms	<ul style="list-style-type: none"> <li>Designated staff restrooms that are sanitary and cleaned after each use</li> </ul>
Handwashing station	<ul style="list-style-type: none"> <li>Handwashing station to enable good hygienic practices of washing hands upon entering the site, washing hands before leaving the site, and throughout the day</li> </ul>
Wi-Fi	<ul style="list-style-type: none"> <li>Strong Wi-Fi signal through router or hotspots</li> </ul>
Security	<ul style="list-style-type: none"> <li>24/7 site security to ensure that staff, patients, materials and the site are safe</li> </ul>
Cleaning	<ul style="list-style-type: none"> <li>2 cleaning staff that are onsite at all times following the designated cleaning standard operating procedures</li> </ul>
Greeters	<ul style="list-style-type: none"> <li>5 greeters to direct traffic and maintain day to day site operations</li> </ul>
Site managers	<ul style="list-style-type: none"> <li>2-3 city site managers to be at the site at all times</li> </ul>

## Traffic Flow

Requirements	Details
Collection site identification sign / banner	<ul style="list-style-type: none"> <li>Large entrance signs directing patients where to go</li> </ul>
Directional and informational signage and stands	<ul style="list-style-type: none"> <li>Several signs throughout the site to indicate testing stations, directions to follow, and answers to FAQs</li> </ul>
Station specific signage	<ul style="list-style-type: none"> <li>Signage on what to expect at the testing station</li> </ul>
Traffic cones and barricades	<ul style="list-style-type: none"> <li>Hundreds of traffic cones to mark traffic flow plan; barricades to separate pedestrian and drive-through traffic</li> </ul>

\*Relevant to drive-through testing

\*\*Relevant to walk-in testing

## Appendix C: Category B Infectious Substances Couriers in California

Name	Contact Information	Additional Information
<a href="#">Rapid Express Courier Systems</a>	North Bay Office (707-526-7633), Napa Office (707-255-9435), and San Francisco Office (415-545-8314)	Customers can schedule pick-up & delivery. The company's delivery and pick-up times run 7 days a week and 24 hours a day. Rapid Express also offers same-day pick-up and delivery solutions. They serve California in the North Bay, Napa, Oakland, San Francisco and San Jose.
<a href="#">Apollo Medical Logistics</a>	Inglewood, CA Office (310-337-0377), Orange County Office (949-222-0545), San Diego Office (949-222-0545)	Customers can schedule pick-up & delivery to benefit from on demand solutions. These include: Emergency - 1 hour direct service, Stat - 2 hours, Rush - 3 hours, Routine - 5 hours. The company's delivery & pick-up times run 24 hours a day, 365 days a year. Serving California in San Francisco, Los Angeles, Ontario, Orange County, and San Diego.
<a href="#">A-1 Courier Service</a>	Santa Monica, CA Office (213-622-4000) and Los Angeles CA 90025 (310-450-9000)	Customers can schedule pick-up & delivery online. Delivery & pick-up options are available 24 hours per day, 7 days per week. A-1 Courier Service also offers same-day delivery. They serve all of Southern California.
<a href="#">Gold Rush Express</a>	Telephone (855-684-6201) or (408-357-2160)	Gold Rush Express offers routed and pre-scheduled deliveries. The company's delivery & pick-up times run 24 hours per day, 365 days per year. They serve the San Francisco Bay Area.
<a href="#">Red Line Courier Service</a>	Los Angeles Office (866-427-4258), San Diego Office (866-427-4258), Sacramento Office (866-427-4258), and Orange Office (866-427-4258) or (714-678-0110)	Red Line offers 24 hours a day, 365 days a year scheduled emergency pick-up & delivery options. The company's door to door service runs "24/7, all day and all night, every day of the year." Service ranging throughout California, including Ontario, Orange County, Los Angeles, Fresno, Hollywood, San Diego, San Francisco, and more.
<a href="#">Medical Couriers Incorporated</a>	Telephone (877-653-399)	Customers can schedule a pick-up by filling a form online. The company's pick-up and delivery services are available "anytime". They

		serve California in Los Angeles, San Francisco, Sacramento, Redding, and Fresno.
<a href="#">VeniExpress, Inc.</a>	Telephone (877-670-VENI (8364))	Customers can request and schedule pick-ups and deliveries. They are open 24 hours a day 7 days a week. They serve California in San Diego, Los Angeles, Riverside, and Orange County.
<a href="#">California Courier Services</a>	Telephone (800-914-2931)	Schedule a pick-up and delivery available every day. Same day 24/7 (365 days per year) pick-up and deliveries available. They serve Southern and Northern California in Los Angeles, San Diego, Long Beach, Irvine, San Francisco, San Jose, Sacramento, Pasadena, Fremont, and more.
<a href="#">SMEX 24/7 Courier Services</a>	Telephone (800-245-4502) or (310-458-6000)	Pre-scheduled and emergency last-minute pick-ups and deliveries are available. The company's delivery and pick-up times run 7 days a week and 24 hours a day. They serve surrounding areas in Southern California.
<a href="#">Clockwork Express</a>	Telephone (310-568-9175)	Clockwork Express customers can schedule pick-up & delivery by filling a form online. Delivery time is 24hrs, Service days are Monday–Sunday. Same day delivery is offered under 10,000LBS. They serve all of Southern California.
<a href="#">Reliable Couriers</a>	Telephone (888-415-1781)	Regular scheduled delivery will call or STAT basis available anytime. Open 24 hours a day 7 days a week. They serve California in San Diego, Los Angeles, Sacramento, San Jose, San Francisco, Long Beach, and Irvine.
<a href="#">UPS</a>	Telephone (1-800-554-9964)	Schedule a pick-up and delivery available every day. 24/7. Daily pick-ups and deliveries. Drop off shipments available. Services are available nationwide. However, pick-up locations in California include Fresno and Madera County.
<a href="#">FedEx Express</a>	Telephone (1-800-GoFedEx) or (1-800-463-3339)	Schedule a pick-up and delivery available everyday - 24-hour pick-up and delivery services available. Services are available nationwide. However, pick-up locations in California are at Fresno County.  NOTE: Pickup must be scheduled (online or via phone) before 1pm PST for same day pickup.

		Pickup times vary by location and will be determined when scheduled.
<a href="#">Airspace Technologies</a>	Operations (855-524-7772), Sales (844-839-1559), Driver Relations (844-208-3330)	Operations are 24/7/365. Schedule a pick-up and delivery available every day. They specialize in next flight out, dedicated drive, hand carry and charter transportation.
<a href="#">GoExpress</a>	Telephone (559-274-0168)	Specializes in Same-Day deliveries. Located in Fresno, California, Go Express, LLC's services extend beyond Central California as far south as Bakersfield and north to Sacramento. Current expansion plans will broaden our service area into the Bay Area and Southern California.
<a href="#">GLS</a>	Telephone (800-322-5555)	Deliver to every address in California. Expansive Next-Day Delivery Area. Priority Overnight Services at 40% Less Cost. Per-Pallet Rates for LTL Shipments. Later Pickup Times and Earlier Deliveries. Fewer and Lower Accessorial Fees
<a href="#">Medical Courier</a>	Telephone (877-653-3391)	Has large customizable COVID-19 Specimen delivery network in California with customers from large hospital groups, regional clinical laboratories, healthcare specialty companies and the State of CA itself.
<a href="#">LMC</a>	Telephone (800-562-8782)	If using 2nd Day or Next Day Air, order must be in by 3 p.m. Central Time, Monday through Friday. Delivery can't be guaranteed on holidays. Backorders will be shipped ground when products arrive at warehouse unless other arrangements are made.
<a href="#">Mobile-Med</a>	Telephone (877-899-9959)	No patient minimum needed for us to provide on-site services. Mobile units visit multiple locations for one company, many of the organizations have multiple locations based in multiple states. Mobile-Med work health solutions services are available 7 days a week based on the need of the client.

## Appendix D: Most common packing and shipping mistakes

- **No UN3373 (Category B Biological substance) label affixed to the outside of the ship back box:** In order for transportation services to understand the substances contained in packages and take the proper shipping precautions, ship back boxes must have the UN3373 label box properly adhered in a prominent location.
- **Lack of proper box sealing:** Boxes must be fully sealed to protect the integrity of the samples and ensure patients get accurate results in a timely fashion.
- **No shipping manifest:** Manifests must be completed and included within the shipping boxes for lab intake. VBL counts the number of samples when accepting into lab as a part of the chain of custody (CLIA requirement).
- **Shipping samples not meant for VBL:** VBL is only able to process the approved Color samples. Be sure to only include Color sample kits when shipping.
- **Using bleach near MTM tubes: DO NOT USE BLEACH** near MTM tubes as it will cause a chemical reaction that releases cyanide gas.
- **Not using Color ship back materials:** The ship back materials are provided, so sites can ship the samples in a standardized packaging with proper support and protection. Please use them.

Source: CDPH

## Appendix E: Using the California COVID-19 Courier Network (CCN) to ship samples to VBL

This section outlines COVID-19 sample shipping support via the State's California COVID-19 Courier Network (CCN). The CCN will be available to **already-approved** collection sites affiliated with the VBL.

Through the CCN, already-approved collection sites will be able to drop off samples at specified CCN drop-boxes (Please see the latest live and upcoming drop-box locations at the CCN Drop-Box Mapping Tool at <https://arcg.is/3hNVmms> . Note that the state will continue to update this mapping tool on an ongoing basis as it continues to install drop-boxes across the state). Samples will be picked up from the drop-boxes by CCN's transportation courier, Mobile-Med, and delivered to the VBL. The majority of all samples will have a 12-14 hour transit time from pick-up to delivery to the VBL.

Once a collection site is approved by the state, they can opt in to utilizing CCN during the onboarding process. The collection site point-of-contact will be connected with the courier (Mobile Med) to gain instructions and access (i.e., keys) to the nearest drop-box.

As a collection site using a CCN drop-box, it is your responsibility to:

- Package samples and meet packaging requirements. **Please note that samples must be packaged in biohazard bags and should not be boxed for a CCN drop-box.** Additional directions on how to package samples for CCN drop-boxes will be provided to collection sites upon approval.
- Drop off samples in a pre-assigned CCN drop-box prior to the drop-box pick-up time
- Notify Mobile-Med of any anticipated changes in testing / specimen volume or dates/ times of collection
- Safeguard the key provided to access the drop-box, and notify Mobile-Med in the event that the key is lost or misplaced

Delivery and pick-up details are as follows:

- Standard CCN services deployed Monday through Friday
- Pick-ups from CCN drop-boxes occur between 5 pm and 11 pm PST. Samples must be placed in the drop-box by 5 pm PST to guarantee on-time delivery.

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Based on availability, however, alternate drop-box schedules may potentially be obtained from Mobile-Med.

- Delivery of samples to the VBL occur within 12 to 14 hours of pick-up

Contact information: Mobile-Med can be reached at

[logistics@mobile-med.com](mailto:logistics@mobile-med.com) or at 877/899-9959, extension 3.

Photo of illustrative CCN drop-box (#1)

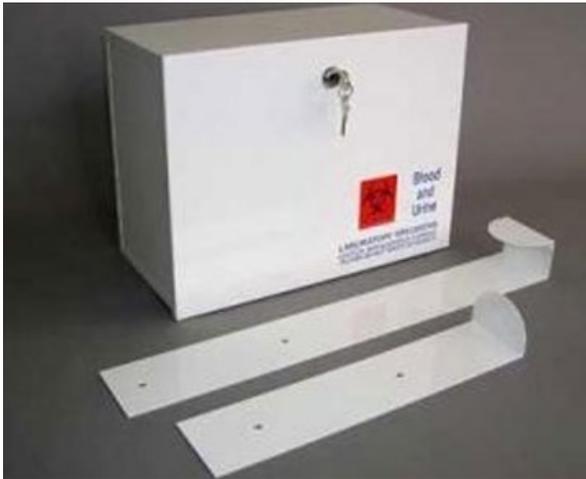


Photo of illustrative CCN drop-box (#2)



## Independent charter or private schools addendum

### Independent charter or private schools: 8 steps to conduct testing

Independent charter or private schools can partner with the state to offer COVID-19 tests by following a simple 8-step process:

[Independent charter or private schools] 8 steps to conduct testing



### Independent charter or private schools: Playbook use guide

To learn more about each of the above 8 steps, please refer to the following sections:

- For steps 1, 2, and 5, refer to the [Independent charter or private schools Addendum \(this section\)](#)
- For steps 3, 4, 6, 7, and 8 refer to [8 steps to conduct testing details](#)

# 1. Creating your collection plan and completing interest form

<p>To complete the 1<sup>st</sup> step, as an organization you will need to:</p> <ul style="list-style-type: none"><li><input type="checkbox"/> <a href="#">Identify testing demand</a></li><li><input type="checkbox"/> <a href="#">Complete interest form</a></li></ul>	
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## Identify testing demand

In order to create a collection plan, please refer to [CDPH's COVID-19 and Reopening In-Person Instruction Framework & Public Health Guidance for K-12 Schools in California, 2020-2021 School Year](#) guidance.

Additionally, CDPH has created an interactive tool on the [TIF School Testing website](#) to help your district estimate the number of tests per week at each testing site.

## Complete interest form

After identifying the testing demand, if your organization is interested in partnering with the CDPH Valencia Branch Laboratory, please submit the [interest form](#) which asks you about your test site readiness, your anticipated weekly testing, and the population you are serving. Once submitted, a representative will reach out to you within 3 business days.

## 2. Completing Memorandum of Understanding (MOU) and onboarding form

To complete the 2<sup>nd</sup> step, as an organization you will need to:

- [Complete MOU](#)
- [Complete the onboarding form](#)

### Complete Memorandum of Understanding (MOU) through DocuSign

After, getting site approval from CDPH through the interest form, the State will release the Memorandum of Understanding (MOU) that sites must then complete that attests to the responsibilities of running a collection site (details for submission to be provided after site is approved).

### Complete the onboarding form

The State will also release the onboarding form which asks for site-specific information such as expected hours and days of operation, site point of contact, estimated daily testing, site address for kit shipping, etc. This must be completed at least five business days in advance of the first day of sample collection.

## 5. Ordering kits

To complete the 5<sup>th</sup> step, as an organization you will need to:

- [Procure test kits and shipping materials](#)

### Procure test kits and shipping materials

Once the organization has completed the onboarding forms, Color will use the information provided to estimate the number of collection kits and ship-back boxes needed. The first order of test kits and return supplies will automatically be placed on your collection site's behalf. Your site will receive them within 4-5 business days. The number of test kits will be based on your approved allocation

Information contained in this document is preliminary | Working draft as of 02/17/2021.

from CDPH (1 weeks' worth of approved test kits plus an additional 10% buffer). See [Color's Test Kits webpage](#) for more information.

For subsequent shipments, each the organization will need to order additional kits and ship-back boxes through the Ordering Portal, pending the order is under the pre-approved limit for the site established in the onboarding forms. As the state provides the ordering physician, test kit orders can be placed without the site needing their own physician sign-off. Unless expedited shipping is used (at an additional cost), each order may take five or more business days to arrive at sites, therefore, planning in advance is essential. Color's Test Kits webpage has a tool that predicts and manages kits and ship-back boxes for site's ordering and inventory allowing sites to have an efficient amount of supplies.

Color will also provide appropriate materials to ship samples to the laboratory.

**Organizations must use the provided ship-back boxes to ship the samples to the lab.** There are two ship-back box sizes (12x12x10 and 12x12x20) boxes, which hold either 100 kits or 200 kits. In addition to estimating the number of samples to be collected, sites will also need to estimate the number of shipments that will be made to the lab each week. This information will be used to determine how many ship-back boxes and what size will be provided to the site.

**NOTE:** Kits have a shelf life of 1-2 years. If not all kits are used in each week, they can be used in the next weeks if stored properly. That said, sites are heavily encouraged to order the amount of kits needed each week for their site so the State can ensure all sites have access to the number of kits needed each week.

**NOTE:** Before kits are used for testing, they should be stored somewhere secure with no direct exposure to sunlight or heat. The ideal environment to store test kits is at room temperature (between 72 and 76 degrees Fahrenheit).

**NOTE: These collection kits use PrimeStore transport media (the small amount of liquid in each tube) to stabilize and inactivate the virus. This media contains guanidine thiocyanate, which produces a dangerous chemical reaction that releases cyanide gas when exposed to bleach (sodium hypochlorite). DO NOT USE bleach products near collection kits.**