CDPH Valencia Regional Laboratory

PLAYBOOK to stand up Community Based Testing Sites

California Department of PublicHealth
VALENCIA LABORATORY

REQUIRES FINAL CLINICAL REVIEW

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Introduction

The public-private partnership to build the Valencia Regional Laboratory (VRL) in California could enable the state to conduct an additional 150,000 tests per day—doubling the state's current testing volume. This is being in partnership with PerkinElmer, a diagnostics company,

As part of the state's objective to build COVID-19 testing capacity that is **timely, equitable, and cost-effective**, the new lab aims to augment the testing marketplace, help break supply chain bottlenecks and drive down the costs for tests for people in California. This new capacity could enable the state to step up testing of disproportionally 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 fast turnaround time of 24-48 hours (since receipt of sample at VRL), which is essential for a disease containment framework including testing, tracing, and isolation/support. As we approach flu season, the VRL provides much needed additional capacity. Given symptoms for the flu are similar to COVID-19, healthcare providers will likely test for both, only further increasing the demand for testing in the near future.

This Playbook has been created with the aim to offer a step-by-step guide to organizations (e.g., schools, agriculture associations, places of worship) on how to partner with VRL to ramp-up capacity of COVID-19 testing. It includes five critical steps toward doing so, including: (1) creating a test plan for your district; (2) setting up test collections at your local sites; (3) conducting tests; (4) transporting your samples for processing; and (5) reporting and billing.

Objectives

Valencia Regional Laboratory's capacity is intended to be additive to the existing capacity among public and private laboratories. In order to make testing more accessible and equitable, this capacity is not intended to supplant existing capacity.

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

State Responsibilities

- Contract vendors to provision collection kits
- Deliver patient registration system, and test result monitoring / notification system (call and text)
- Oversee sample processing in the laboratory
- Ensure that Valencia Regional Laboratory delivers results within 24-48 hours of receiving the sample
- Pay for test processing and, as appropriate, recoup costs through a third-party biller
- Provide detailed instructions and guidance for operating testing 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 providing testing

- Assess testing demand within your community
- Request kits, to meet demand, through state vendor
- Provide physical space for testing
- Conduct community outreach to drive participation in testing
- Gather patient data and submit via technology web accessible platform
- Collect sample at the testing site
- Transport sample in-person or via courier to VRL within 24-hours of collection
- Support individuals with technology limitations to access test results
- Pay for essential site costs e.g., courier service, staff, outreach programs, materials etc. (See Billing for more information)

NOTE: You can form strategic partnerships with other local organizations to help manage part of your responsibilities

Areas of Focus

As we build up the capacity of this new lab, it will take time to reach the target daily testing rate of 150,000. Initial onboarding of testing sites will be focused on regions and populations demonstrating the following needs:

	**Unmet testing need** (absolute or per capita) based on Testing Strategic Plan
	**Overall testing need** (total or for impacted populations, including schools) based on California's Testing Strategic Plan
	**Risk of disease spread**, based on population density
	**Disease burden**, based on risk categories from Blueprint for a Safer Economy
	**Health equity** score based on California Department of Public Health's (CDPH) Health Equity requirement, which tracks positivity in counties' lowest quartile Healthy Places Index (HPI)census tracts
	**County and other** local interest in participating and specific requests for support

5 steps to conduct testing

To stand up the Valencia Regional Laboratory, the State has partnered with Color and PerkinElmer to offer an end-to-end supply chain from procurement to processing of PCR tests and a software platform to support sample collection, enabling Local Health Jurisdictions (LHJs) and local organizations to efficiently and effectively provide COVID-19 testing to their communities.

California Department of PublicHealth VALENCIA LABORATORY — Powered by PerkinElmer

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

color

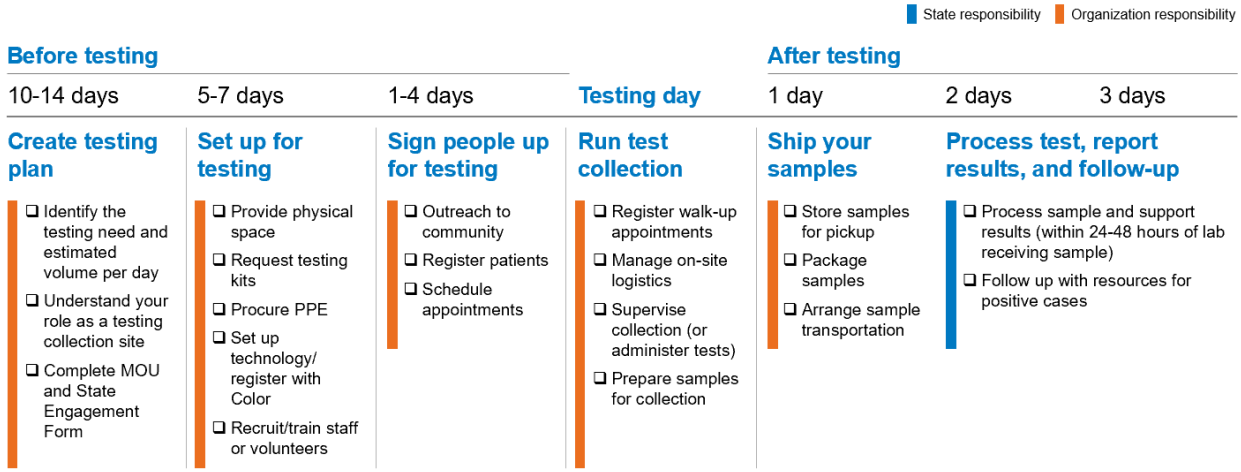
Provides testing kits and IT platform to collect patient information and deliver result to ordering provider, patient & CalREDIE

As an organization, you can partner with the state, to offer COVID-19 tests by following a simple 5-step process:

1. **Creating your test plan** by defining your target population, testing volume and frequency, set-up and execution timeline
2. **Setting up for test collection** by working through your set-up checklist, registering on the Color platform and ordering test kits from the state
3. **Conducting tests** by registering individuals, utilizing the test kits[1] to supervise self-collection, and providing each person with their customized COVID card to access test results via SMS or email
4. **Shipping your specimens to the state** by utilizing shipping materials provided with the collection kit to return tests to the lab
5. **Reporting and Billing**. If applicable, monitor the Color platform for patient results and the lab will take care of billing insurance

1. Tests kits contain anterior nasal swabs

Following the 5-step process, organizations can expect to conduct their first round of testing within 2-3 weeks, followed by 2-3 days for sample processing and reporting.



While the Valencia Regional Laboratory provides the testing capacity, the organization is responsible for the collection of the sample, setting up the collection site, staffing for collection, and transportation of the sample to the laboratory. You should consider partnering with other local organizations who can meet collection needs including community testing sites, pharmacies, clinics, etc. If you believe you have a testing need, but are unable to meet these requirements, the State may be able to connect you with partners to support collection needs/capabilities.

NOTE: If you are partnering with other local organizations, all steps may not be relevant to you, hence only focus on steps of the playbook relevant to your context.

Following is a consolidated end-to-end checklist for organizations to follow across the 5-step process:

- ☐ 1. Creating your testing plan
  - ☐ Identify the testing demand in your community
  - ☐ Complete MOU and State Engagement Form
- ☐ 2. Setting up your testing collection
  - ☐ Provide physical space meeting core site requirements
  - ☐ Procure testing kits and shipping materials
  - ☐ Procure PPE
  - ☐ Set up technology / register with Color
  - ☐ Recruit/train staff or volunteers
- ☐ 3. Conducting tests
  - ☐ Outreach to community *not included in this document*
  - ☐ Schedule appointments *not included in this document*
  - ☐ Manage on-site logistics *not included in this document*
  - ☐ Register patients for testing (incl. walk-ins)
  - ☐ Supervise sample collection and prepare samples for collection
- ☐ 4. Shipping your sample
  - ☐ Store samples for pickup
  - ☐ Package samples
  - ☐ Arrange sample transportation
- ☐ 5. Reporting and Billing
  - ☐ Process sample and results reporting
  - ☐ Billing

1. Creating your test plan

To complete the 1st step 'Creating your test plan', as an organization you will need to:

☐ Identify the testing demand in your community

☐ Complete MOU and State Engagement Form

Identify testing demand in your community

Before proceeding with offering testing in your communities, organizations need to determine their community testing demand and make decisions on the following:

- Target population, e.g., residents within a particular area, workers within a particular industry
- Potential sites to best serve target population
- Frequency for conducting tests e.g., once a week
- Target testing volume per day for each potential site
- Self-administered vs clinician-administered tests (NOTE: The PerkinElmer PCR test and Color test kits have been authorized to be self-administered under supervision)

Complete MOU and State Engagement Form

Each organization interested in partnering with the State will need to complete an online form to engage the State and sign an Memorandum of Understanding (MOU) that attests to the responsibilities of running a collection site. To be formally considered for approval to participate in the program, interested organizations should upload the fully executed copy of the MOU to the California Testing Site Information website and provide the requested information. This must be completed 10 business days in advance of the first day of sample collection.

2. Setting up for test collection

To complete the 2nd step 'Setting up for test collection', as an organization you will need to (See Appendix C for expanded site checklist):

- ☐ Provide physical space meeting core site requirements
- ☐ Procure testing kits and shipping materials
- ☐ Procure PPE
- ☐ Set up technology / register with Color
- ☐ Recruit/train staff or volunteers

Provide physical space meeting core site requirements

You are responsible for ensuring there is an appropriate location and adequate space for physical distancing of all individuals during the testing process. For example, testing sites can be public space (e.g., park), or private spaces (e.g., parking lot/field associated with an employer). You must provide all on-site logistics e.g., electricity, reliable internet access (cellular and/or WiFi as appropriate), appropriate hand washing/sanitizer stations, waste pick-up, etc.

Administering tests at a site has two different flow types: walk-in and drive-through. Consider both options when planning as they require different spaces and space layouts and serve different patients. While drive-through may be more convenient for some patients, it is essential to have pedestrian options for those community individuals who do not have automobiles. Detailed site set-up checklist to set up the physical space is provided in Appendix B.

Procure test kits and shipping materials

For the first shipment, once the organization has completed and uploaded signed a MOU on the California Testing Site Information website, collection kits and ship-back boxes from Color covering the first 2 weeks of testing plus a 10% buffer will be shipped to the requested location.

For subsequent shipments, the organization will need to order additional kits or ship-back boxes through Color's Order Management Form (link to be provided once launched), pending the order is under the pre-approved limit for the site

established by the CDPH. Unless expedited shipping is used (at an additional cost), each order takes up to 5 business days to arrive at sites, therefore, planning in advance is essential. Color's Order Management Form has a tool to predict and manage kit and ship-back box ordering, enabling organizations to order an efficient amount of supplies. Color will provide two sizes of ship-back boxes (holding 100 kits or 200 kits) depending on a site's request.

Color will also provide appropriate materials to ship samples to the laboratory. There are two sizes of ship-back boxes (holding 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. Organizations must use the provide ship-back boxes to ship the samples to the lab.

NOTE: Before kits are used for testing, they should be stored somewhere secure with no direct exposure to sunlight or heat. The ideal environment is to store 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.

Procure PPE

Your organization is responsible for ensuring all staff/volunteers have appropriate 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

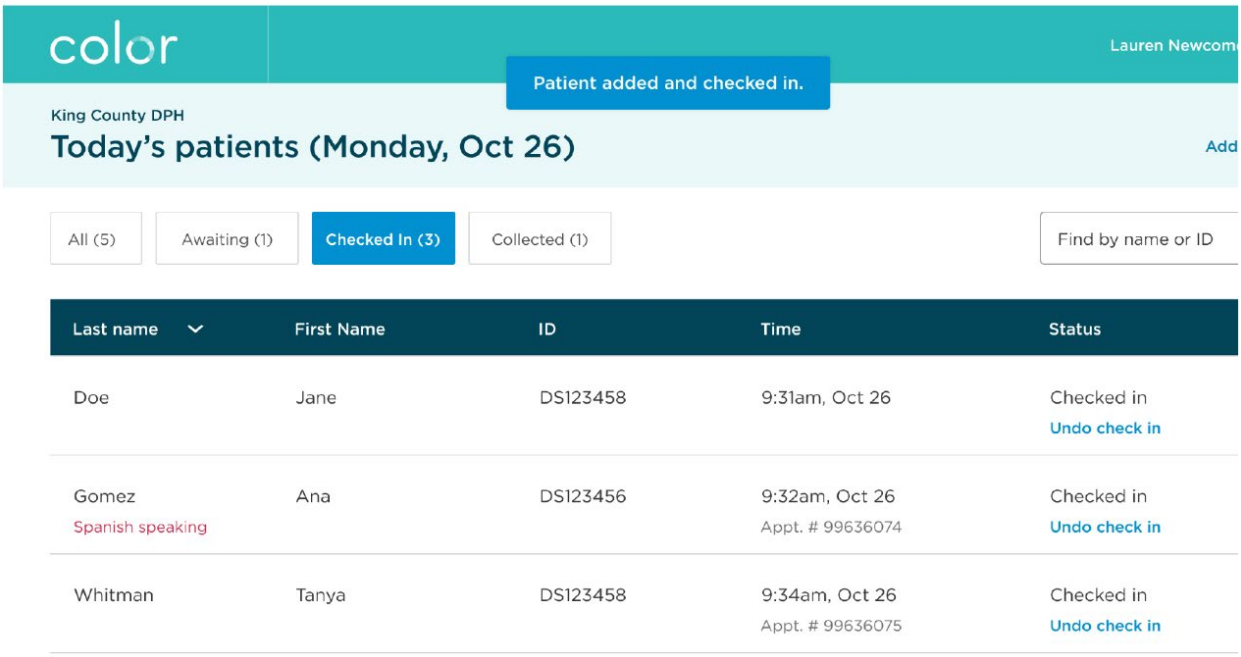
N95 or higher-level respirator (or facemask if a respirator is not available), eye protection, gloves, and a gown, when collecting samples

Set up technology / register with Color

Collection sites are responsible for ensuring all necessary equipment is available at the testing site e.g., laptop or tablet with internet connection and scanner. Please review materials provided by Color describing hardware needs and recommendations as shown below:

Requirements		Details
Tech Materials Required	Modern tablet or laptop	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
	Scanner	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)
	Wi-Fi	Strong Wi-Fi signal through router or hotspots
	Electrical	Every check-in and testing lane needs direct access to electrical. Each lane will have iPads and Wi-Fi hotspots plugged in

The web-accessible Color platform allows patient registration and links the sample to the patient information (through the barcode). Color will provide training materials to collection sites explaining how to use the participant registration and intake platform. Each organization must provide information about their testing plan and collection site to Color at least 5 business days in advance of site launch. This information will be used to determine how many test kits are required and to set up the site within the platform. Each organization will need to provide a list of the email addresses for all staff who will be registering participants and/or collecting or monitoring self-administered samples. After the State Engagement Form (part of Step 1) submitted by an organization is approved, these staff members will each need to create individual Color accounts to access the system atleast two-days before testing.



Sites are encouraged to use the Color platform where feasible and to discuss their particular needs with CDPH and Color. The Color solution has been utilized in many different collection sites and workflows, including school districts, universities, community sites, jails, skilled nursing facilities, primary care clinics, processing plants, and more. It is simple to use, for site managers and collection staff, and we encourage you to evaluate how it could fit into your workflow. With potentially hundreds of collection sites across the state, priority will be given to those who can utilize the system as is.

Patient registration information must be loaded into the Color platform online. Paper forms will be included for sites that will be provided with test kits supplied by Color as an emergency back-up in case the Internet is not available, but all information must then be loaded into the online tool by collection site staff to complete the sample collection process. Samples cannot be shipped to the lab until this has been done. If patient data is collected using paper forms, the site is responsible for securely shredding these documents which contain 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.

NOTE: Testing sites are responsible for determining how to schedule tests. Current portal capabilities do not include test scheduling.

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 testing site will vary based on size but should include personnel focused on:

- Check-in
- Guide/traffic flow
- Testing (monitoring or administering)
- Bagging/packing
- Check-out

Additionally, there are different staff requirements depending if test is self-administered vs clinician-administered:

- **Staff Requirements for Self-Administered tests (may not be appropriate for children under the age of 13)** - Self-administration requires supervision by trained personnel (any trained adult) which can be done from 6 feet away. CDC recommends that the test supervisor wears gloves and face mask and requires that the patient understand and be able to perform procedure.
- **Staff Requirements for Clinician-Administered tests:** Clinician-administration requires clinician availability (e.g., Physicians, Physician assistants and nurse practitioners, Nurses such as RNs or LVNs, Pharmacists, EMTs, Medical Assistants). According to the CDC, clinician-administration requires maintaining proper infection control and use of recommended personal protective equipment (PPE), including an N95 or higher-level respirator (or facemask if a respirator is not available), eye protection, gloves, and a gown, when collecting samples.

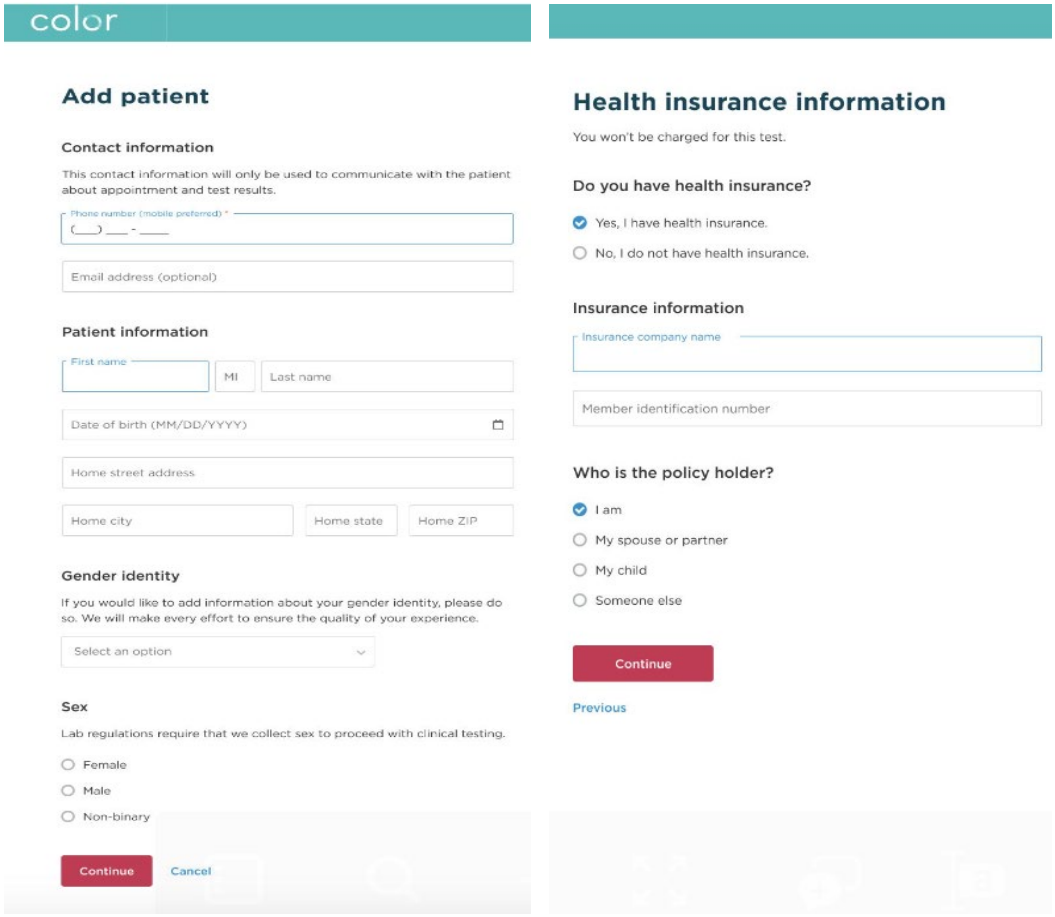
3. Conducting tests

To complete the 3rd step 'Conducting tests', as an organization you will need to:

- ☐ Outreach to community *not included in this document*
- ☐ Schedule appointments *not included in this document*
- ☐ Manage on-site logistics *not included in this document*
- ☐ Register patients for testing (incl. walk-ins)
- ☐ Supervise sample collection and prepare samples for collection

Register patients for testing (incl. walk ins)

The Color platform allows you to register walk-in patients and enables patients to self-register when they book online appointments. To register a walk-in patient, a staff member only needs to complete a few simple steps on behalf of the patient for them to be able to receive their test information (see pictures below). The staff member should receive their necessary contact information (e.g., phone number, name, date of birth, health insurance – if applicable, parent/guardian information if applicable, etc.), which will allow them to receive their test results.



Supervise sample collection and prepare samples for collection

Anterior nares (nasal) samples (the tests swabs provided by Color) that are both properly self-administered and clinically-administered have been scientifically shown to have similar performance to other testing alternatives while being less invasive and generally more comfortable for patients.

For self-administered tests, individuals must be supervised when collecting their own sample and each individual must follow the following steps. Printable flyer can be downloaded, here. When available, video or animated instructions may provide added clarity for patients. For example, Lower Nasal Swab Collection instructions, which was 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 testing site.

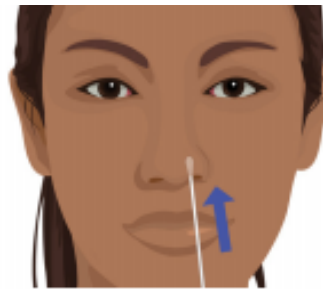
NOTE: These collection kits use PrimeStore transport media (the small amount of liquid in each tube) to stabilize and inactivate the virus. This media contains guanidine thiocyanate, which produces a dangerous chemical reaction that releases cyanide gas when exposed to bleach (sodium hypochlorite). DO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

Administering a Nasal Sample

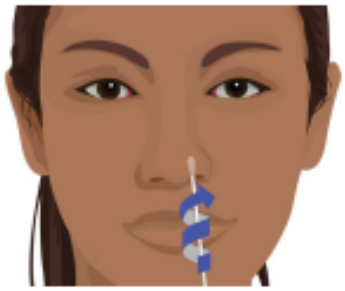
Providing a Nasal Swab Sample

Following is additional guidance from CDC on collecting the sample

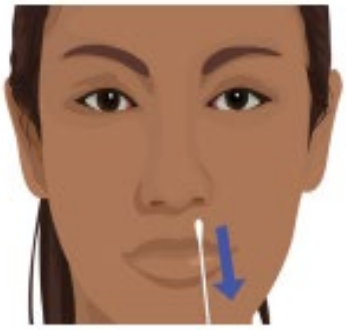
Insert the swab into your nostril. Do not insert it more than half an inch into your nostril.



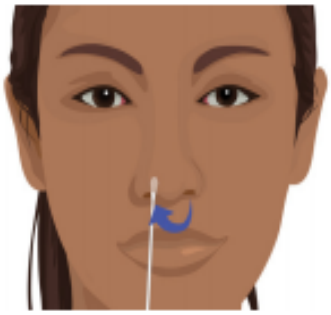
Slowly twist the swab, rubbing it along the insides of your nostril for 15 seconds.



Gently remove the swab.



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



4. Shipping your samples

To complete the 4th step 'Shipping your samples', as an organization you will need to:

- ☐ Store samples for pickup
- ☐ Package samples
- ☐ Arrange sample transportation

Store samples for pick-up

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 should be transported to the lab within 24-hours.

Package samples

Collection sites are responsible for properly packaging 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.

Items received from Color

Test kits provided by Color will include a 6" x 9" biohazard bag that contains:

- Absorbent pad
- Tube containing Medical Transportation Management (MTM) labeled with a barcode
- AN/OP individually packaged Swab
- 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

You will also receive the following ship back materials from Color

- Large sealable biohazard bag (watertight)
- Shipping box (100 kit and 200 kit size)
- UN3373 label for the shipping box
- Paper manifest

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
4. Seal the bag closed 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
7. Place the completed paper manifest on top of the bag
8. Seal the cardboard box
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

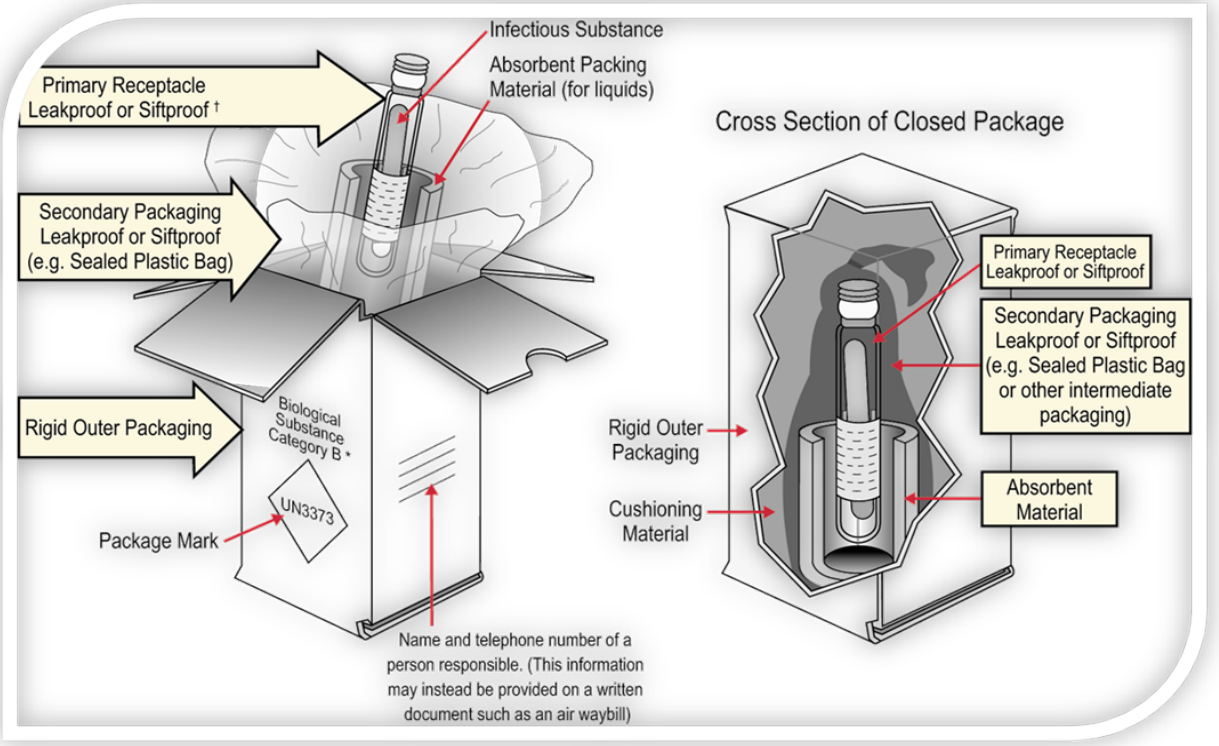
A paper manifest with sample information must be fully completed and included with every sample shipment sent to the lab. The form will be provided with the test kits by Color and can also be found at this link.

Date	

SHIPPING MANIFEST

Manifest Number	
Tracking Company and Number	
Date of Sample Collection	
Site Name	
Site Address	
Site Point of Contact (Name, Phone Number, & Email Address)	
Total Number of Samples	
Test Name	Covid-19 Diagnostic
Laboratory	Attn: CDPH Branch Laboratory 28454 Livingston Ave Valencia, CA 91355

NOTE: In order to ship or hand deliver the samples, maintain accuracy and have quick turnaround times, all vial tops must be sealed, all packaging layers must be used properly as detailed in the image below, all vials must be counted correctly and noted in the paper manifest and the box must be sealed with UN3373 label secured on the box.



Arrange sample transportation

Collection sites are responsible for arranging transportation for samples to the VRL. 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. While it is possible to 'hand-deliver' samples to the lab, this is not advised unless the individual delivering the samples has appropriate hazmat training.

Transportation is recommended to be kept to less than 24 hours for rapid results. The lab address is **28454 Livingston Ave, Valencia, CA 91355** and accepts packages 24/7.

5. Reporting and Billing

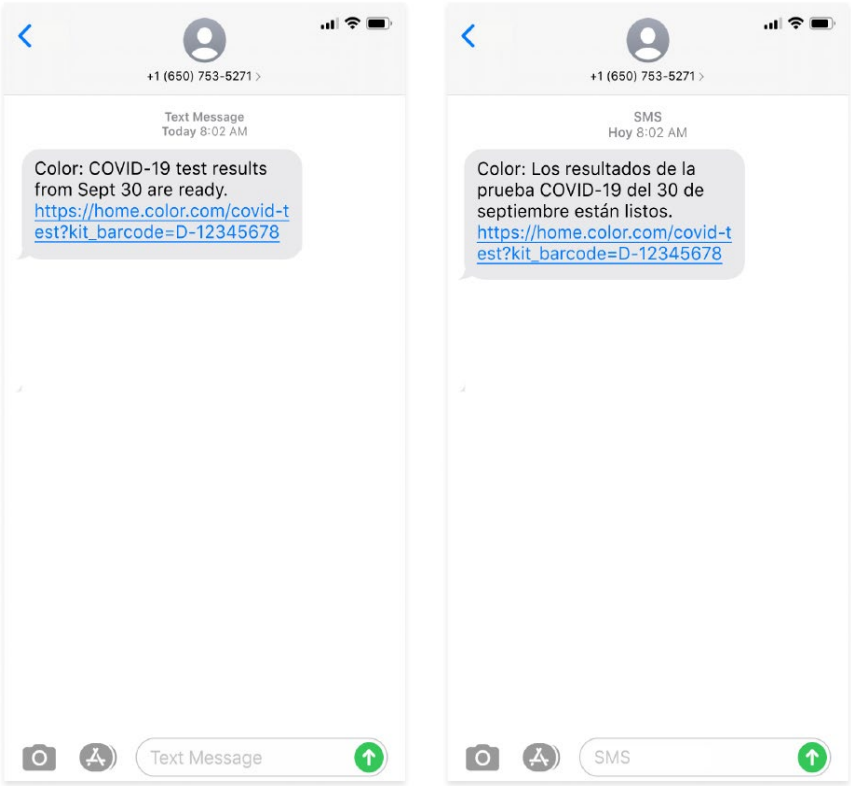
The 5th step 'Reporting and Billing' will be handled by the state's Valencia Regional Laboratory, who will:

- ☐ Process sample and results reporting
- ☐ Billing

Process sample and results reporting

The Valencia Regional laboratory will be responsible for processing all samples within 48 hours of receipt pursuant to the federal Food and Drug Administration Emergency Use Authorization. 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 must 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 a HIPAA compliant website. If the patient loses their Color barcode for their test, they can call the Color support hotline.



Moreover, Color will transmit all results on behalf of Valencia Regional Lab to the State through CalREDIE. For organizations that identify a shared provider (e.g. a clinic, site run by a public health department) during the collection site set-up process, Color will also provide that provider with access to a portal that allows access to results for all patients tested at the site.

NOTE: Sites that identify a shared provider or clinician are responsible for clinical care follow-up for individuals with positive tests results.

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).

Billing

Collection sites will not be responsible for test processing costs but however will be responsible for costs of transportation and other equipment for collection process (e.g., PPE). Where the test is covered by the patient's health coverage (see categories below), the State has contracted with a third-party vendor to submit claims. Initially, the state will also provide the first collection kits, however in the future collection sites may be responsible for the costs associated with these kits.

All costs related to collection site responsibilities are borne by the organization, standing up the test site, including transportation, staff time, and necessary equipment for the collection process (e.g. tents, chairs, PPE, etc.).

Where the test is covered by the patient's health coverage (see categories below), sample collection costs may be reimbursable. Organizations may want to consider partnering with a medical provider, clinic, pharmacy or other entity with collection experience to leverage their abilities to do such billing. The state does not provide for billing of sample collection. The state will also seek reimbursement for the un-insured (no cost sharing).

The Department of Managed Health Care, a health plan regulatory agency, has requirements on health plans for covering testing which are best summarized in the following categories:

Category 1: Symptomatic or exposed Individuals

- Federal statutes require coverage:
- No medical/utilization management and no prior authorization requirements
- At any authorized testing site
- Provider reimbursement at negotiated rate or provider's cash price

Category 2: No symptoms/exposure but enrollee is an "essential worker"

- The emergency regulation:
- Defines who are "essential workers"

- Deems testing for essential workers to be medically necessary in all cases, so no UM or prior authorization required or allowed
- Enrollee must try to get appointment in-network but can go out-of-network if plan does not offer an appointment within 48 hours

Category 3: No symptoms, no exposure, not an "essential worker"

- The emergency regulation:
- Deems testing to be an urgent service when medically necessary for the enrollee
- Allows plans to impose prior authorization requirements
- Requires the enrollee to try to get appointment in-network. But the enrollee can go out-of-network if plan does not offer an appointment within 96 hours

FAQs

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

A: Yes, however the parent/guardian must be present, in person, in order to complete the registration process, provide consent, and use their email/phone for results return.

Q: What if someone getting tested does not have insurance?

A: Neither the patient nor the entity will be liable to pay for the test. The State will recoup costs through alternative funds for those without insurance.

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 VRL 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 Medical Transportation Management (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 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 personal protective equipment (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: 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).

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 leakproof seal; a skirted stop- per 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 leakproof 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

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

Requirements	**Details**
Structural	
Storage container pods	• 1 - 2 large storage containers to store site materials, PPE, cleaning supplies, test kits, swabs, etc.
Drive-through entrance *	• Designated entrance for all vehicles
Drive-through exit *	• Designated exit for all vehicles exiting from the testing lanes
Pedestrian entrance **	• Designated entrance that provides direct access to the pedestrian testing lane
Pedestrian exit **	• 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
Walkway	• Walkway needs to be paved and accessible
Staff parking lot	• Staff parking lot for a minimum of 15 cars
Courier pick up locations	• The courier needs direct access to all testing lanes
PPE donning location	• Designated location to don PPE. This can be at a rectangular table near the storage pod.
Guard boxes / tents	• The guard boxes need to be at the entrance and exit
Lighting	• Lights throughout the site
Services & Staffing	
Water	• Water is needed for the restrooms and handwashing station
Electrical	• 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
Portable Staff Restrooms	• Designated staff restrooms that are sanitary and cleaned after each use

Requirements	Details
Handwashing station	• Handwashing station to enable good hygienic practices of washing hands upon entering the site, washing hands before leaving the site, and throughout the day
Wi-Fi	• Strong Wi-Fi signal through router or hotspots
Security	• 24/7 site security to ensure that staff, patients, materials and the site are safe
Cleaning	• 2 cleaning staff that are onsite at all times following the designated cleaning standard operating procedures
Greeters	• 5 greeters to direct traffic and maintain day to day site operations
Site managers	• 2-3 city site managers to be at the site at all times
Traffic Flow	
Testing site identification sign / banner	• Large entrance signs directing patients where to go
Directional and informational signage and stands	• Several signs throughout the site to indicate testing stations, directions to follow, and answers to FAQs
Station specific signage	• Signage on what to expect at the testing station
Traffic cones and barricades	• Hundreds of traffic cones to mark traffic flow plan; barricades to separate pedestrian and drive-through traffic

*Relevant to drive-through testing

**Relevant to walk-in testing

Appendix C: Category B Infectious Substances Couriers in California

Name	Contact Information	Additional Information
Rapid Express Courier Systems	The company's three offices with their contact information are as follows: North Bay (707-526-7633), Napa (707-255-9435), and San Francisco (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.
Apollo Medical Logistics	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-1 Courier Service	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.
Gold Rush Express	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.
Red Line Courier Service	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.
Medical Couriers Incorporated	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". The serve California in Los Angeles, San Francisco, Sacramento, Redding, and Fresno.
VeniExpress, Inc.	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.
California Courier Services	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

Name	Contact Information	Additional Information
		Northern California in Los Angeles, San Diego, Long Beach, Irvine, San Francisco, San Jose, Sacramento, Pasadena, Fremont, and more.
SMEX 24/7 Courier Services	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.
Clockwork Express	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.
Reliable Couriers	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.
UPS	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.
FedEx Express	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.
Airspace Technologies	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.