Verily COVID-19 Site Operations Overview

NOTICE

The testing guide below has been developed to align with guidelines provided by federal and state public health authorities. Parties adopting this guide should work with their clinical operations, environmental health and safety teams, and their state and local authorities to ensure compliance with relevant laws.

DISCLAIMER

1. This guide is provided in an effort to assist agencies in establishing “drive-through” COVID-19 sample collection and testing operations. However, each agency’s needs or circumstances may differ from the assumptions behind the practices described in this guide, so we cannot and do not make any warranties or representations about them or anything else in this guide.

2. The situation surrounding COVID-19 is evolving almost daily. Verily has endeavored to accurately describe information that may be helpful in connection with “drive-through” COVID-19 sample collection and testing operations as of the date this guide is made available, but does not have any duty to update this guide and does not take responsibility for any errors or inaccuracies.

3. Any action you take upon the information in the guide is strictly at your own risk. Verily disclaims any liability for any losses and damages in connection with the implementation and operation of any aspect of the Project Baseline COVID-19 program. Each user remains responsible for any personnel operating any testing site the user may establish or authorize.

4. This guide is not intended to provide medical advice, diagnosis, or treatment or to substitute for the advice of independent medical judgement of physicians or compliance with the then-current recommendations of public health experts, which should be followed in evaluating and implementing the information in this guide. Nothing in this guide should be construed as the giving of advice or the making of a recommendation regarding any decision or action related to the user’s health or the health of others.

5. Verily does not guarantee any particular results or the health or safety of any health care providers or their patients if the guide is followed. Following this guide does not guarantee coverage and reimbursement.

6. Inclusion in the guide does not mean that Verily supports or recommends a specific treatment, drug, device, physician, test, institution or testing site.

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Overview of Project Baseline

COVID-19 Community-Based Testing Program

In collaboration with the California Governor's office, federal, state, and local public health authorities, the COVID-19 Community-Based Testing Program has been developed in collaboration with Project Baseline (hereafter referred to as "Baseline COVID-19 Program") in order to expand access to COVID-19 screening and testing.

The Baseline COVID-19 Program provides a software technology platform to triage people who are concerned about their COVID-19 risk for potential appointments at a community-based testing site. The technology platform includes:

1. **Implementing screening criteria** developed by the California Department of Public Health (CDPH) and based on CDC guidelines, to identify people eligible for testing through this program and provide information to public health authorities. These criteria will change over time as the public health needs of COVID-19 response evolve, and may vary by state.

2. **Scheduling eligible participants for appointments** at community-based testing sites available in their area, based on test availability and site capacity.

3. **Returning testing results** to the individuals, physicians, and government health officials whenever possible.

4. **Directing to education and resources** to help people follow authoritative public health guidance around COVID-19.

Program Goals

The goals of the Baseline COVID-19 Program are to:

- Build a process that can prioritize millions of participants and determine who should receive testing.
- Enable centralized screening criteria to avoid unintentional site-by-site variation.
- Avoid data entry time, data entry errors, and contamination risk at testing sites.
- Ensure orderly operations at testing sites through the Baseline Technology Platform scheduling process.
- Expedite the testing process with high throughput and low wait times with digitally enabled processes for lab integrations.
- Provide test results to participants as quickly as possible.
- Provide educational guidance to participants to empower them to more actively manage their health.

Technology Platform Overview

The Baseline Technology Platform supports the operation of Sites through participant screening, scheduling, lab ordering and integration, label creation and printing support, and return of results. Site operators must contract with Verily to use the Baseline platform to support their operations.

Access to the Baseline platform will only be provided to staff of the contracted Site operator and will be linked to their unique business, organization, or government email address. Site operators are responsible for training their staff and for authorizing and revoking access to their data in the Baseline platform.

Technology Platform Overview

Step 1

Participant completes screening and schedules appointment

Participant fills out eligibility screener from the Baseline website and schedules a testing appointment.

Step 2

Verily orders through Physician ordering group

Order is created automatically by the scheduling system. Participant receives an email with their requisition ID.

Step 3

Prepare kits

Sites receive and print requisitions / labels. Then assemble participants' kits prior to visits.

Step 4

Participant attends appointment

Participant drives to the testing site, a Healthcare Professional labels the swab collection tube, and a sample is collected from nose or throat.

Step 5

Samples are sent to the lab

Sample kits are labeled & and matched with the corresponding requisition.

Step 6

Participant receives results

Participant receives an email directing them to check results.

Discovery and Screening

The Baseline COVID-19 Program recruits and screens participants through the Project Baseline COVID-19 website (www.projectbaseline.com/covid-19).

After qualification, the participant is invited to create an account for the Baseline COVID-19 Program using a Google Account. This account enables collecting the participant's answers to the screening survey, contacting them for scheduling, and delivering test results back. The data collected by Verily through the testing program will never be joined with the participant's data stored in Google products without their explicit permission.

Then, the participant reviews and signs an authorization form that provides detail about the sample that will be collected, and how the sample will be processed and shared.

After virtually signing the authorization and lab consent forms, the participant can take the COVID-19 Screener, which provides information to public health authorities and helps prioritize individuals for scheduling based on site capacity. The COVID-19 Screener asks for basic information about participants so that they can be identified at the Site, and uses screening criteria developed in conjunction with health officials and based on CDC guidelines.

Discovery and Screening Overview

Step 1

Discover the COVID-19 Program

Participant can find out whether they qualify for testing **through the landing page and initial survey.**

Step 2

Complete screening

Participant finds out whether they are eligible for testing. This includes: **signing Authorization Form, completing screener and more.**

Step 3

Schedule appointment

Participant finds out about eligibility after Step 2. Eligible participant signs the lab consent and **schedules the onsite appointment.**

Step 4

Attend appointment

Participant drives to the testing site. Participant's identity is verified, and a Healthcare Professional labels the swab collection tube, and **takes sample from nose or throat.**

Step 5

Receive results

Participant receives an email directing them to check results.

Scheduling Appointments

Participants who complete the COVID-19 Screener and are determined to be eligible for testing through this program are then offered one or more appointments at participating Sites. The Baseline platform completes scheduling for Sites to ensure that a Site's stated capacity isn't exceeded. Sites have access to a daily list of scheduled appointments. Eligible participants will receive a notification if appointments are full, and asked to return at a later time to check in on appointment availability.

Once an appointment is scheduled, participants receive an email with appointment details, requirements, and instructions. Participants can see their upcoming appointment after they sign in to their Baseline COVID-19 Program home page.

Lab Ordering and Integration

Sites that use the Baseline platform are provided with a procedure for lab ordering through the integrations described here. Sites that don't use the Baseline platform will need to follow the appropriate steps to integrate with another lab provider and physician ordering network.

Label and Printing Integration

Every day, the Baseline platform generates a set of requisitions and specimen sample labels that can be printed. Sites must integrate with the Baseline COVID-19 Program and support the IT requirements necessary to obtain and print these labels and requisitions as described in the Appendix.

What happens to the swab after the sample is collected?

Step 1

The swab is transported to the lab

After the swab has been collected by a medical professional, it is transported to a clinical laboratory. Some health institutions and hospitals have their laboratories onsite.

Step 2

The swab is processed

The sample is mixed with chemicals to isolate and then make many copies of specific regions of the viral genetic material through Polymerase Chain Reaction (PCR). If there is no virus in the sample, no copies are made.

Step 3

The sample is analyzed

A fluorescent molecule labels each copy of SARS-CoV-2 created by the PCR and the fluorescent light is detected by a specspecialized instrument.

Step 4

The results are shared back

Test results are reviewed and shared back to the participant and county and state public health departments.

Return of Results

Results are returned to health departments by the physician ordering group and lab services provider. The physician ordering group will call participants who receive positive test results, and all participants will receive an email directing them to a portal to check their test results.

Pre-Launch Planning

Example Timeline of a Site Launch

Note: Your Site timeline may vary. This is just an example.

Day 0: Establish Site location, partnerships, and supplies

- Confirm partnerships and points of contact
- Choose location that meets all requirements (e.g., size, connectivity, security)
- Obtain appropriate clearances (e.g., municipality, county, state)
- Source and schedule equipment, supply, security, and staff (ongoing)

Day 1: Set up Site and conduct dry run

- Schedule participants for Day 2 (25% of Site capacity) and Day 3 (50% of Site capacity) and Day 4+ (100% of Site capacity)
- Install connectivity and run print test for sample labels and signage
- Define and share a traffic flow map (e.g., municipality, county, state)
- Set up facility, Checkpoints, signage, and traffic control
- Train staff and execute a dry run

Day 2: Open to first participants

- Confirm partnerships and points of contact
- Choose location that meets all requirements (e.g., size, connectivity, security)
- Obtain appropriate clearances (e.g., municipality, county, state)
- Run at 25% capacity to identify areas for improvement
- Manage inventory and staff

Day 3: Ramp up to 50%

- Run at 50% capacity to identify areas for improvement
- Manage inventory and staff

Day 4+: Maintain steady state

- Run at 100% capacity
- Manage inventory and staff

Logistics

Location Selection

Choosing a good location will help ensure proper access, security, and operations for sample collection. Work with your local government partners to find and reserve an appropriate venue, such as a community center, exposition hall, fairground, stadium, parking garage, event center, park, or other recreational area.

Checklist for location requirements

- ❑ Access to electricity, WiFi connectivity, and cell service
- ❑ Possible to set up a single designated, controllable entry point and a single designated, controllable exit point, with a clear and direct path for participants to travel between them
- ❑ Provisions to ensure safe and efficient participant vehicle traffic control, including sufficient space at each Checkpoint and Sample Station for one vehicle to safely enter and exit and sufficient space for vehicles to turn around at each Checkpoint
- ❑ Provisions to ensure safe and efficient participant pedestrian traffic control, including adequate social distancing demarcations, guidance to ensure staff utilizes adequate PPE when in proximity to pedestrians, and sufficient space at each Checkpoint and Sample Station to ensure participant and staff social distancing guidelines can be maintained
- ❑ Enough space to set up multiple Sample Stations far enough apart to adhere to social distancing guidelines and clinical protocols for sample collection
- ❑ Enough space to set up a command center (e.g. office, bus, or trailer) away from the Sample Station
- ❑ Well-ventilated, covered space or enough space for large tents to protect staff and participants from the elements
- ❑ Central location within the community that's easy to find and accessible by public transportation, highways, or ride-sharing apps
- ❑ Clean restrooms, handwash facilities, and rest area available to Site staff (not participants)
- ❑ Possible to set up a secure perimeter (e.g., fences, walls, traffic cones)
- ❑ Ability to secure supplies at Sample Stations overnight (ideally enough space to store seven days' worth of supplies if they are available)
- ❑ Ability to clearly delineate areas requiring PPE in "hot" zones, such as using yellow caution tape or barriers
- ❑ Arrangements for appropriate collection and removal of biohazardous waste, including PPE and collection supplies

Third-Party Vendors

Each Site will likely need a number of critical third-party support providers to successfully establish and maintain sampling, including:

- An employer of health care providers to provide staff that will collect samples from participants
- A lab services provider
- A physician ordering group or standing orders from the county health director
- Biohazardous waste management
- Security during daily operations, traffic management, and overnight security if supplies or other equipment are kept onsite. Local law enforcement may provide some of these functions but other providers may be required
- [Optional] Supply chain manager
- [Optional] Logistical communications (e.g., WiFi) management
- [Optional] Comfort management (e.g., food services)
- [Optional] Onsite foreign language translation services

Testing Provider Selection

These are some of the recommended considerations for finding a clinical test provider that matches your Site's requirements.

- ❏ Does the test provider's capacity for COVID-19 testing match your current and future plans for the number of patients tested?
- ❏ Does the type of test the test provider is running meet the sensitivity requirements you need for COVID-19 diagnosis?
- ❏ What kind of swab collection materials and practices are needed to work with the test? For example, what are the acceptable collection media, specimen collection tools (e.g., swabs), and specimen transport and storage conditions required for the test?

A selection of commercial laboratories that are able to perform RT-PCR are detailed below. Please note, we are providing the list below as a courtesy. We do not endorse or provide any guarantee in regards to the use of any of the commercial laboratories listed.

- Quest Diagnostics
- LabCorp

Site Safety Considerations

Checklist for partnering with local officials

- ❑ If the Site is in a building, contact local fire services to review a plan for driving cars inside, including carbon monoxide management strategies
- ❑ Contact local police and county sheriff's office to coordinate sufficient law enforcement staffing onsite (plan four to six officers per day when staff are onsite, although this number may depend on site layout)
- ❑ Coordinate onsite visits with local responders and invite them to the daily briefing
- ❑ Coordinate with local EMS to be ready to respond to medical needs onsite
- ❑ Contact county and state Office of Emergency Services to ensure that they are aware of incident plans
- ❑ Include all local agencies in the daily dissemination of ICS 201 briefing (see Link: 'FEMA ICS 201: Incident Command System Form: Incident Briefing') for the previous day's operation
- ❑ Establish a communications plan in partnership with local officials and local health systems and providers

IT Equipment and Infrastructure Needs

Reliable Internet access is essential to process participants in a timely and accurate manner. If your venue doesn't have existing IT infrastructure, or you can't contact the venue's tech team, you should reach out to a provider who can deploy Wi-Fi and physical connections, and potentially support daily tech operations. Consider having a backup tech plan as well.

Signage

To ensure the safety of staff and participants, we recommend the use of clear, specific signage to communicate to participants where to drive, and what to do at each checkpoint. The COVID-19 Mobile Testing Site Signage Kit is meant to aid COVID-19 testing Site organizers in setting up physical signage at their testing Sites. The kit contains designs for posters and hand signs for use onsite as well as recommendations for how the signs should be used and where they can be printed.

Staffing

Teams and Roles

The Site Lead (Incident Commander) should designate a Clinical Lead, and Participant Data Specialist.

You can plan the number and type of onsite staff you'll need depending on the location of your Site and your expected capacity. Daily needs may change as the number of participants fluctuates. To help your Site regularly forecast your staffing and allocation needs, see the Site Lead Guide.

Clinical Workflows and Training

The Clinical Team should review all referenced procedures before coming onsite. The Clinical Lead will provide onsite training on safety and universal precautions, appropriate use of PPE, and workflow operations. Site Clinical Teams should be trained per guidance in the 'Clinical Lead Guide.' Sites may adapt training per your needs and workflows, but daily training and acknowledgement of training (e.g., Resource within the Site Lead Guide: 'Project Baseline Training Log') by the Clinical Lead is essential.

The Site Lead or Clinical Lead may halt operations at any time to ensure safety, security, or sample integrity. Other staff should report concerns to the Site Lead or Clinical Lead.

Supplies

Clinical Operation Supplies

The supply of PPE is dependent on local availability and demand, which may change over time. The Clinical Lead Guide represents Project Baseline's best practices at the time of writing and will evolve with time. Your Site's Clinical Lead should determine how to best allocate PPE on a regular basis.

Sample collection supplies depend on the diagnostic test requirements and provider. Additionally, testing capacity and test types are evolving quickly. You should confirm appropriate collection supplies with your testing provider prior to ordering and the start of testing.

Inventory Maintenance

Every Site is different in its inventory capacity and limitations. Refer to your Clinical Team Lead to understand how to make your PPE supplies last.

All supplies should be counted and documented before sampling begins and should be updated on a regular basis. Inventory should be logged in a central document that is accessible by a central purchasing or logistics organization so that stocks can be replenished as needed.

Site Set-up Planning

Logistics

Site Checkpoint Workflow Example

Checkpoint 1: Appointment Confirmation

Step 1

- Staff holds sign “Keep Windows UP”. Vehicle entry is blocked with signs or cones.

Step 2

- Staff approaches vehicle with closed windows with sign “Do you have an appointment?”
- Staff waves through participants with appointment confirmation paperwork or e-mail to Checkpoint 2, and redirects other traffic to an egress or appropriate vendor receiving location.

Checkpoint 2: Participant Identity Verification

Step 3

- HCP 1 approaches vehicle with “Windows Up” sign
- HCP 1 asks for photo ID as well as confirmation email containing Reference ID
- HCP 1 confirms identity with participant list
- HCP 1 relays information to HCP 2 for recording
- HCP 1, with sticker or post-it, marks vehicle window on the side with the participant
- HCP 2 fills out time on participant specimen bag, confirms participant identity
- HCP 2 hands requisition form and labels in specimen bag to HCP 1
- HCP 1 places labeled specimen bag under windshield wiper on the side with the participant

Sample Station

Step 4

- HCP 3 staff member takes over and motions for vehicle to slowly pull forward
- HCP 3 confirms identity matches requisition
- HCP 3 explains to the participant what the swab is and where it will be placed

Step 5

- HCP 3 collects sample from participant
- HCP 3 places participant’s requisition in 1st compartment of specimen bag and holds bag open
- HCP 3 places contaminated specimen into the 2nd compartment of specimen bags
- HCP 3 stores sample in cold storage

Exit

- Staff shows participant to exit
- Specimens remain in cold storage until pick up from Lab partner

Site Operations

During operation, the Site will require effective management of personnel, sampling kits, and supplies. The key components for a successful operation include:

- High integrity of sampling kits and associated requisitions
- Appropriate management of sensitive personally identifiable information (SPII)
- Appropriate training of staff who will have access to SPII
- Strict adherence to operating procedures and protocols
- Strict adherence to manufacturer and lab test requirements for supplies and collected specimens
- Efficient flow of participants for sampling
- Sufficient personnel, while avoiding overstaffing
- Focus on safety for both the physical site and staff, including health care workers

Clinical Protocol

The Clinical Lead Guide describes steps for processing participants through nasopharyngeal swab collection at Sites, after which the swabs are sent to a clinical lab for COVID-19 testing. The collection process is dependent on the test type and testing provider. Before implementing the collection protocol and training the staff, confirm that it is consistent with the requirements of the testing provider you will be using.

Integrity of Requisitions

To ensure the integrity of requisitions, the Site Clinical Team should ensure that orders and sample labels are:

- ❏ Printed on a daily basis the morning of each operating day
- ❏ Verified during the sampling process against participant's name and DOB
- ❏ Reconciled prior to transferring to local lab partner at the end of the day

Information Handling

During operation, sampling kits with SPII of the participants must be appropriately and securely managed and stored. Information must be verified by qualified health care professionals throughout the sampling process and when the sampling kits are collected for processing by your lab partner at the end of each day.

Staffing

Efficiency

Sites are encouraged to complete the highest number of tests possible given personnel, process, and supply constraints. To increase capacity, Sites are encouraged, but not required, to:

1. Have volunteer personnel track timing at and in between each Checkpoint, and to find ways to improve at the bottlenecks
2. Ensure efficient PPE consumption by matching Checkpoint and Sample Station capacity to anticipated demand
3. Ensure adequate relief personnel are available to enable staff to take breaks

Law Enforcement and Emergency Response Support

At the beginning of each day, the Site Lead should confirm that law enforcement (state, local, and/or county) are present onsite. Officers should work in pairs.

Supplies

PPE Requirements and Usage

The safety of all members of the health care team is a top priority while operating Sites. Sites will need to navigate the rapidly evolving clinical and supply situations around COVID-19, sometimes requiring rapid adoption of new operating procedures and practices.

Printable Worksheets and Assets

COVID-19 Testing Site Signage Kit