

COVID-19 Sample Collection and Transfer

NOTICE

The COVID-19 community-based testing program is a federally supported, state-directed program in collaboration with Verily's Project Baseline.

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

- 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.
- 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.
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- 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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1. Background

This Instructions manual describes steps for processing participants through nasopharyngeal swab collection in pop-up drive-through clinics, where the swabs are sent to a clinical lab for COVID-19 testing. This guide captures step-by-step the actions of a process to get participants up to the sample collection station. Before implementation, we recommend discussing with the lab you have contracted with and making any necessary changes to this procedure.

We recommend discussing this document with your own site Lead and site specific Clinical Lead to ensure guidelines are suitable to your own environment, and modifying as appropriate.

2. Scope

This process instruction applies to the collection of nasopharyngeal swabs for COVID-19 drive-through testing only.

3. Terminology

Term/Acronym	Definition
PPE	Personal Protective Equipment - all equipment used to protect an individual from potential contamination. This includes, but is not limited to, masks, gloves, and gowns.
MA	Medical Assistant
RN	Registered Nurse
Hot Zone	Area of site where participants in vehicles lower window and potentially expose workers to contamination. For our purposes 'Hot Zone' refers to the area surrounding and including Station 3 (Sample Collection Station).
Don	The process of putting on PPE.
Doff	The process of taking off PPE. Requires a specific order to ensure no personal contamination occurs via transfer from contaminated PPE.

4. Materials

4.1. Equipment

- 1 Table on each side of sampling Bay
- 1 Biohazard waste bin per sampling Bay
- Radios/Walkie-Talkies for communication between stations
- Cooler for dry ice (if not provided by testing lab)
- Cooler for wet ice or refrigerator (if ambient temperatures are expected to be higher than 25 °C/77 °F, transport media will have to be kept on wet ice)
- Bucket for specimens
- Large bag for specimen count

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4.2. Sampling consumables

- Test requisition
- Copies of the participant label
- Swabs and viral transport tubes (e.g., BD 220529 or similar for RT-qPCR testing through LabCorp or Quest. Confirm collection supplies with your testing provider. Testing capacity and test types are evolving quickly. Please note that collection supplies are dependent on test type and testing supplier.)
- Sample/specimen transport bags
- Rubber bands for attaching sample kits to car mirrors

4.3. Information/lists

- List of names of scheduled participants for guard station
- Station participant log form

4.4. Other Consumables

- See **COVID-19 Personal Protective Equipment** for PPE consumables
- Handwash station / alcohol hand sanitizer
- Tissues in case participant needs to clear nose of mucus for swab
- Biohazard bags
- Wet ice (if ambient temperatures are expected to be higher than 25 °C/77 °F)
- Dry ice

5. Environmental Health and Safety

We recommend discussing this document with your own Environmental Health and Safety personnel to ensure guidelines are suitable to your own environment, and modifying as appropriate.

5.1. General

- 5.1.1. Read through the entire document to assure overall understanding of the contents.
- 5.1.2. Verify that training to this document, if applicable, is completed before carrying out the process.

5.2. Safety

- 5.2.1. Assume all samples are infectious and follow PPE and process instructions carefully. Contact your supervisor if you have any questions about specific samples and their handling.
- 5.2.2. Take appropriate precautions when using cleaning agents. Read the Safety Data Sheets and follow the handling instructions carefully.

5.3. Waste

- 5.3.1. Assume all waste generated by this process is infectious and dispose of it in a red biohazard bin/bag.

5.4. Information

- 5.4.1. Please note that you may be exposed to sensitive personally identifiable information (SPII). Take appropriate precautions and do not discuss or disclose.

6. Preparation

- 6.1. If ambient temperatures may exceed 25 °C / 77 °F, store viral transport tubes on ice or in a refrigerator until required for sampling.
- 6.2. Follow PPE recommendations per role, donning and doffing protocols, and special exposure instructions at **COVID-19 Personal Protective Equipment**.

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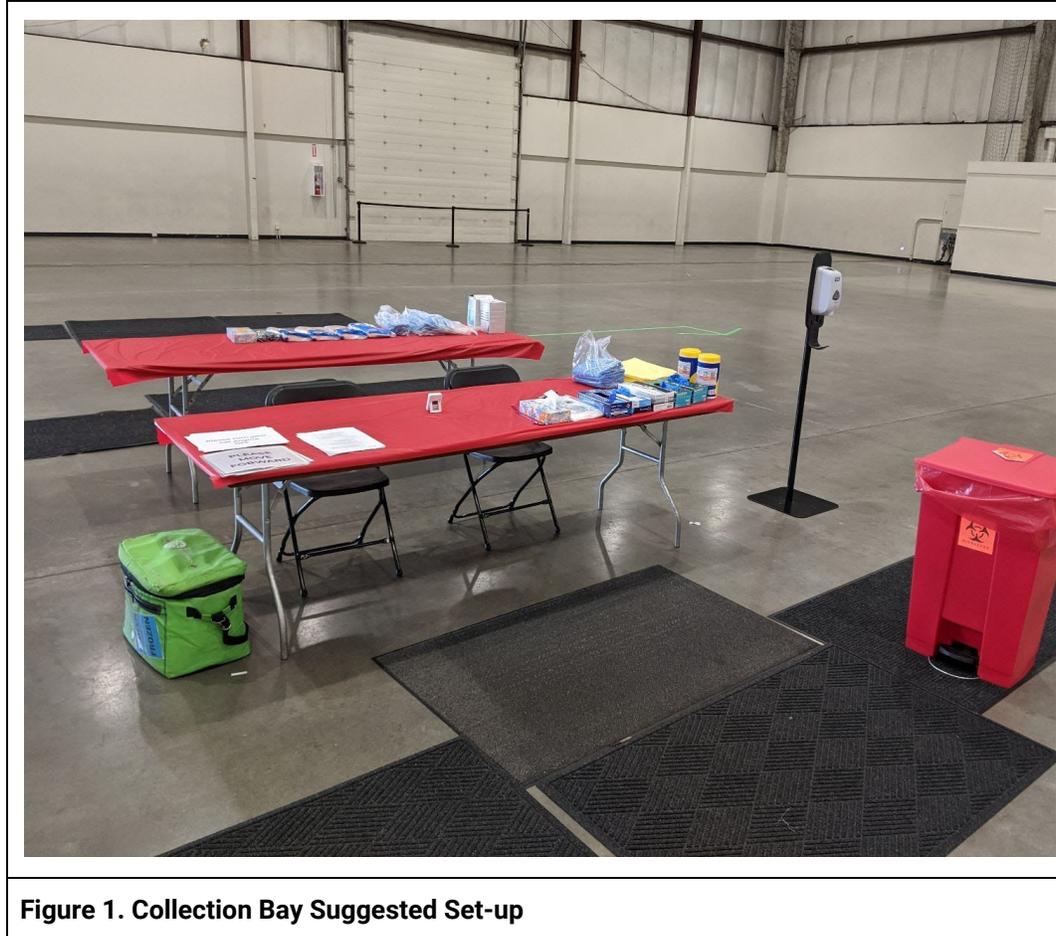
- 6.3. Sample Collection process assumes verification of participant identification, participant test requisition, and general process preparation as outlined in **COVID-19 Participant Workflow**.

7. Process Steps

7.1. Confirm participant Information

- 7.1.1. Before participant vehicle enters the sample collection bay, Swabber (RN or higher) and Swabbing Assistant (MA or higher) should have already removed and discarded gloves (only outer pair if wearing 2 pairs) and any contaminated PPE from previous participant interaction (if any) into a biohazard bin.
 - 7.1.1.1. If only one pair of gloves was worn and discarded, then both Swabber and Swabbing Assistant should wash hands or use hand sanitizer.
- 7.1.2. Both Swabber and Swabbing Assistant don fresh pair of gloves and wave participant vehicle into bay (Figure 1).
- 7.1.3. Participant pulls into the designated sample collection bay and is directed to turn off their vehicle and lower the window.
 - 7.1.3.1. Note: If significant participant distress is observed, situation should be escalated to clinical lead for assessment. If a participant requires immediate medical attention, call 911.
- 7.1.4. Swabbing Assistant takes the specimen bag with requisition and labels off the participant's vehicle and asks the participant to verbally verify name and date of birth (DOB).
- 7.1.5. Swabbing Assistant checks that labels match requisition.
 - 7.1.5.1. If the participant's name or DOB are mismatched or incorrect, the participant is turned away and asked to leave the facilities. Participants are asked to call Verily User Success team to correct demographic information and reschedule their appointment.
 - 7.1.5.2. If the participant's name and DOB match, Swabbing Assistant adds a label to the sample collection tube, the Specimen Log Sheet, and to a blank space in the requisition.
- 7.1.6. Swabber asks for verbal confirmation of the participant's full name and DOB. (If participant does not confirm, refer to **7.1.5.1**)

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7.2. Test participant

- 7.2.1. Swabber briefly explains to the participant how the test will be performed.
- 7.2.2. Swabber obtains verbal consent for the nasopharyngeal specimen collection from the participant.
 - 7.2.2.1. If no consent is given, the participant is instructed to exit the facility and no sample is collected. Specify in sample Log that the participant has refused to provide a sample.
- 7.2.3. Swabber completes the steps below to perform the nasopharyngeal (NP) swab test with help from Swabbing Assistant:
 - 7.2.3.1. Swabber opens the testing swab package in front of the participant.
 - 7.2.3.2. Swabber asks the participant to tilt their head back to 70 degrees.
 - 7.2.3.3. Swabber gently inserts the swab while rotating into one nostril.
 - 7.2.3.3.1. Swab should reach depth equal to $\frac{1}{2}$ the distance from the nostrils to the opening of the ear.
 - 7.2.3.4. Swabber leaves the swab in place for several seconds to absorb secretions.
 - 7.2.3.5. Swabber slowly removes the swab while rotating it.

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- 7.2.3.6. Swabber places the tip of the swab into the specimen tube and snaps the scored applicator stick away from their person to break it off into the tube.
- 7.2.3.7. Swabbing Assistant confirms participant's requisition in 1st compartment of specimen bag and holds the bag open for Swabber.
- 7.2.3.8. Swabber places the contaminated specimen in the 2nd compartment of the bag.
- 7.2.3.9. Swabbing Assistant stores sample in the dry ice cooler.
- 7.2.4. During the event, the Swabbing Assistant or Swabber Relief checks that specimens remain frozen in the cooler on an hourly basis.

7.3. Sample Reconciliation and Transfer

- 7.3.1. At the end of the collection period, prior to pickup from lab vendor, the Participant Data Specialist (PDS) reconciles the Specimen Log Sheet against the number of actual specimens collected. These should be the same.
 - 7.3.1.1. If the number of specimens doesn't match the number on the sample log, the discrepancy should be investigated by going through each individual sample and verifying name and requisition number.
 - 7.3.1.2. It is recommended to incorporate a barcode scanner and barcoded labels to individually verify the specimens collected.
- 7.3.2. Once the PDS verifies that all specimens are accounted for and properly packaged in the dry ice cooler, the outside of the cooler should be disinfected (e.g., Lysol wipes) and placed in a clean/neutral zone for the courier to pick up.
- 7.3.3. PDS completes the specimen transfer form verifying the date, time, and number of specimens collected by the courier.
- 7.3.4. Courier signs the form after confirmation.
- 7.3.5. The courier picks up the cooler and returns the specimens to the lab vendor for testing.
- 7.3.6. PDS will share sample log with central.

7.4. Clean up

- 7.4.1. Wearing clean gloves, package all unused materials if they need to be placed in a secure site and place in specified vehicle for removal from site.
- 7.4.2. Using sanitizing wipes, disinfect all tables and chairs used during the event and dispose into the biohazard bag.
- 7.4.3. Ensure all used face shields, face masks, gowns, gloves, and pens are discarded into a biohazard waste bag.
- 7.4.4. Please refer to the **COVID-19 Medical Biohazard Waste Instruction** for daily closeout of sample area and proper medical biohazard waste removal.