

Verily COVID-19 Clinical Lead Guide

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.
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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.

Table of Contents

About This Role	5
Daily Core Responsibilities	5
Clinical Training	6
Clinical Training for Drive-Through Testing Sites	7
Background	7
Terminology	7
Environmental Health and Safety	7
Preparation	8
Process Steps	8
Records and Data	8
Personal Protective Equipment (PPE)	9
PPE	10
Background	10
Terminology	11
Materials	12
Environmental Health and Safety	12
General PPE Regulations for the Sites	13
Recommended Personal Protective Equipment Guidelines	15
Special Circumstances	17
What to do if the Participant rolls down window before instructed:	17
What to do if the Participant exits car:	17
Sample Collection and Transfer	18
Process for Sample Collection and Transfer	19
Background	19
Terminology	19
Preventing Test Not Performed (TNP)	19
Recommended Materials for Mid-Turbinate Specimen Collection	20
Materials	20
Environmental Health and Safety	21
Preparation	21
Process Steps	21
Recommended Materials for Nasopharyngeal Specimen Collection	25
Environmental Health and Safety	26
Preparation	26
Process Steps	26
Medical Biohazard Waste	30
Medical Biohazard Waste Instructions	31
Background	31

Terminology	31
Materials	31
Environmental Health and Safety	31
General Procedures	32
Responsibilities	32
Daily Biohazard Waste Closeout Procedure	33
Medical Waste Work Instruction	33
Appendix	34
Handling Clothes Post-Shift	35
Scope	35
Background	35
Procedure	35
Laundering	36
Additional References	37

About This Role

The Clinical/Medical Unit Lead will work closely with Site operations leadership to ensure safe and efficient clinical operations, systems, and processes. The position requires a clinical leader who will contribute to the development of testing Site goals, as well as support the overall standards of clinical practice. The Clinical/Medical Unit Lead should be an RN (or above, e.g., NP, MD) with a current active license in the state, active BLS and ACLS certification, and have management or charge nurse experience.

Daily Core Responsibilities

- ☐ Oversee the Checkpoint 2 and Sample Station health care professionals (HCPs)
- ☐ Ensure compliance
 - ☐ PPE usage, donning and doffing
 - ☐ Swabbing procedures
 - ☐ Sample reconciliation
 - ☐ Decontamination procedures
- ☐ Develop Medical Plan
 - ☐ Location of AEDs, Medical & First Aid Kits
 - ☐ Identify potentially hazardous areas or conditions
 - ☐ List off-site medical assistance facilities
 - ☐ Procedures for handling complex medical emergencies

Clinical Training

Clinical Training for Drive-Through Testing Sites

Background

The following section describes suggested instructions to train medical personnel on COVID-19 testing sites.

This process instruction applies to Clinical Site Leads who will train and verify training for medical personnel on COVID-19 testing sites.

Terminology

Term/Acronym	Definition
PPE	Personal Protective Equipment
MT	Medical Tech, Medical Assistant, Mid-Turbinate
RN	Registered Nurse

Environmental Health and Safety

General

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

Safety

- Treat all biological samples as potentially infectious.
- Handle in a biosafety cabinet or other physical containment device according to site-specific environmental safety regulations.
- Contact your supervisor if you have any questions about specific samples and their handling.
- Take appropriate precautions when using cleaning agents.
- Read the Safety Data Sheets and follow the handling instructions carefully.

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

Preparation

Prior to medical staff coming on-site, send instruction email to medical staff (nurses and med techs) and provide the following information:

- Site Operations Overview
- Use of [Personal Protective Equipment](#)
- [Sample Collection and Transfer](#)

Medical staff will be asked to read and watch informational videos.

[CDC Donning/Doffing](#)

[Baseline Covid flow and sampling](#)

[Nasopharyngeal specimen collection](#) (note this video also describes oral pharyngeal sampling which we are not using)

[Mid turbinate specimen collection](#)

Medical staff will need to bring Photo ID each day

Process Steps

1. Staff will be asked to arrive **2 hours before the start of participant testing** on their first day.
2. Personnel will show photo I.D. and sign in with the Clinical Site lead, who will verify in COVID19 HCP Tracker.
3. Clinical Site Lead or trained designee will walk medical staff through:
 - a. Each of the Process Instructions
 - b. Physical walk through Checkpoints 1, 2 and Sample Station
4. During the morning daily stand-up clinical staff will discuss updates and assignments.

Records and Data

After training trained medical personnel will have to sign and date one of each Project Baseline Training Log corresponding to each SOP trained on. The Project Baseline Training Log can be found in the Site Lead Guide.

Personal Protective Equipment (PPE)

PPE

Background

The safety of all members of our healthcare team is a top priority as we navigate the rapidly evolving clinical situation around COVID-19. Based on available evidence and expert opinion, the COVID-19 virus, similar to other coronaviruses and influenza, is primarily transmitted through close contact and large droplets.

Staff who interact directly with high-risk potential COVID individuals should maintain airborne/droplet/contact precautions with eye protection. This includes staff that have exposure to respiratory secretions such as swabbers or swab assistants.

Staff that do not directly interact with the participants are recommended to comply with PPE as directed below based on their role.

This process instruction applies to the protection of workers during collection of swabs for COVID-19 mobile testing stations.

Why are we following these guidelines?

Standard/droplet/contact precautions are clinically appropriate for non-critically ill participant care and are consistent with guidelines from WHO and other countries.

Nasopharyngeal and mid-turbinate swabs often generate a strong cough reflex which increases risk of exposure to secretions which warrants Standard/Contact/Droplet precautions.

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, gowns, and biohazard suits.
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.
Surgical Mask	Loose-fitting mask that is fluid resistant and provides the wearer protection against large droplets, and splashes or sprays of bodily fluids. Protects the patient from the wearers respiratory emissions. Leakage occurs around the edge. Small particles can get through so the mask is not considered respiratory protection.
N95	Tight-fitting respirator that reduces the wearer's exposure to particles including small particle aerosols and large droplets. (Only non-oil aerosols). A seal check is required each time donning the respirator. It filters out at least 95% of airborne particles. NIOSH approved.
Surgical N95	Surgical respirators are both certified by NIOSH as an N95 respirator and also cleared by the FDA as a surgical mask.

Materials

Equipment Needed

- Biohazard Waste Bins

Consumables Needed

- N95 Respirators
- [CDC recommendation guidelines about extended use](#) in Healthcare settings
- Surgical Masks
- Face shields
- Goggles/Protective eyewear
- Gowns
- Nitrile gloves
- Bouffant/Surgical cap
- Handwashing station / alcohol hand sanitizer
- Biohazard Waste Bags
- Shoe Covers

Environmental Health and Safety

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

- 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
- Take appropriate precautions when using cleaning agents
- Read the Safety Data Sheets and follow the handling instructions carefully
- Assume all waste generated by this process is infectious and dispose of it in a red biohazard bin/bag

General PPE Regulations for the Sites

PPE should be donned before entering any Hot Zone.

Order for Donning PPE:

1. Gown or Coverall
2. Mask or Respirator
3. Goggles/Glasses/Face Shield
4. Gloves (1 or 2 pairs, based on need)

Proper donning and seal check of the N95 respirator, after performing hand sanitization and donning gown includes:

1. Lift chin and place N95 respirator over nose and mouth.
2. Stretch the bottom strap over head and place on the back of neck; Ensure that strap is on bare skin only; no loose hairs.
3. Place the top strap on the crown of head; insure that straps are not overlapping or crossed.
4. Check if mask is properly formed to face; ensure no fold by running fingers along the edges of the mask.
5. Mold the metal nose strip to conform to the shape of your nose; do this by placing both middle fingers at bridge of nose and use index fingers to press along the edge of mask along the sides of nose into the cheeks creating a good seal; repeat pressing index fingers with pressure, especially alongside the nose.
6. Perform a seal check by placing your hands at the side of your face at eyebrow level without touching the mask. Exhale quickly once to check if air escapes the mask and hits the palms of the hands. If you feel leakage, readjust the fit of your mask and perform another seal check.
7. Personnel assigned for N95 mandatory use: The use of N95 respirators is reserved for those personnel at the highest risk of exposure during the sampling process. For mobile units, personnel designated to wear N95 masks: Checkpoint 2 Admission/ Identifier confirming participant information with the car window down, Sample Station Swabber and Swabbing Assistant.

PPE should be doffed every time the Hot Zone is exited or after a potentially hazardous exposure occurs.

Order for Doffing PPE:

1. Remove and dispose of shoe covers at the station. Walk to hotzone exit
2. Remove gloves:
 - a. Grasp the outside of one glove at the wrist (do not touch bare skin)
 - b. Peel the glove away from your body, pulling it inside out
 - c. Hold the glove you just removed in your gloved hand
 - d. Peel off the second glove by putting your fingers inside the glove at the top of your wrist
 - e. Turn the second glove inside out while pulling it away from your body, leaving the first glove inside the second
3. Dispose of gloves into the biohazard bag
 - a. If 2 pairs of gloves are worn, take off only the outer pair. Leave the inner pair until all other PPE is removed
4. Remove gown
 - a. Assume front and sleeves are contaminated
 - b. Unfasten ties
 - c. Pull away from neck and shoulders, touching the inside of the gown only
 - d. Turn gown inside out
 - e. Fold or roll into a bundle and discard into a biohazard bag
5. Perform hand hygiene immediately after removing the gown
6. Remove goggles and/or face shield
 - a. Assume the outside of goggles/face shield are contaminated
 - b. Remove by headband or ear pieces
 - c. Place in a designated receptacle for cleaning or into a biohazard bag
7. Removing mask/respirator
 - a. DO NOT TOUCH the front of the mask/respirator as it may be contaminated
 - b. Remove by pulling the bottom strap over the back of head followed by the top strap without touching the respirator
8. Discard mask/respirator and gloves in biohazard container
9. Remove inner gloves if 2 pairs of gloves were worn
10. Use same technique to remove gloves as described above
11. Perform hand hygiene immediately after removing all PPE. Wash hands thoroughly with soap and water or use hand sanitizer

Precautions while operating in Hot Zones

- Use of personal objects (including cellular phones, tablets, and laptops) is not permitted in the Hot Zone. Notes, papers, books, and other items taken into the Hot Zone should not be transferred out
- Food or drink is not permitted
- Hair should be tied back when feasible
- Do not stick head into the participant's vehicle
- Wipe down all surfaces (tables, pens, etc) mid-shift and end of shift
- All PPE needs to be doffed and discarded in biohazard bin after use or at end of shift

Recommended Personal Protective Equipment Guidelines

Roles may vary per Site, but PPE should align with worker conditions and anticipated level of contact. 'Proposed PPE' should be followed to ensure safety of workers, according to updated CDC and WHO recommendations.

Nasopharyngeal or mid-turbinate swabs often generate a strong cough reflex which increases risk of exposure to secretions which warrants Standard/Contact/Droplet precautions. Respirators (along with hand hygiene, eye protection, gown and gloves) are useful for healthcare workers during discrete episodes of direct participant care that may result in close contact. Surgical masks are more appropriate for workers outside of direct participant care.

In Checkpoint 2 and Sample Station, Admission lead, Swabber and Swabber assistant **MUST change gloves** after each participant encounter.

Checkpoint	Role	Proposed PPE (Check CDC guidelines)
Checkpoint 1	Security (Law Enforcement Officer)	No PPE required
	Check-in Staff (MA or volunteer)	Surgical mask Glasses/Goggles Gloves
Checkpoint 2	Admission/Identifier (MA or higher)	N95 mask Glasses/Goggles Gown Gloves
	Admission Assistant/Requisition Finder (MA or trained volunteer) Proposed PPE if less than 6 feet from car	Surgical Mask Gown Gloves Glasses/Goggles
Sample Station	Swabber (EMT or higher)	N95 mask Face Shield Gown Shoe covers Bouffant/surgical cap Gloves ¹ Sleeves ²
	Swabbing Assistant (MA or higher)	N95 mask Face Shield Gown Shoe covers Bouffant/surgical cap Gloves ¹ Sleeves ²
	Runner (Volunteer)	[Inside Hot Zone]

		Surgical mask Gloves
	Traffic Control (Volunteer)	[Inside Hot Zone] Surgical mask Gloves
	Waste Management ³	Surgical mask Gown Gloves Shoe Covers
Outside Hot Zone	Anyone	Mask or facial covering

¹ For these roles 1 pair of gloves is the minimum necessary, however, gloves should be doffed after each participant/participant vehicle interaction and hands should be washed or sanitized. Another option is to don 2 pairs of gloves and doff outer pair of gloves after each participant/participant vehicle contact and replace with a fresh pair of gloves. No other PPE change is necessary unless exposure has occurred.

²Recommended if PPE on site exposes the skin.

³Waste Management can be performed by Healthcare Personnel, or other personnel who are trained in science or medical waste management and have been trained in **COVID-19 Medical Biohazard Waste Instruction**.

Special Circumstances

This document makes recommendations for PPE for sites. Staff may need more PPE depending on exposure to the Hot Zone. Please consult with your Site Clinical Lead to ensure guidelines are suitable to your own environment, and modifying as appropriate.

What to do if the Participant rolls down window before instructed:

If anyone inside the participant vehicle rolls down the window before instructed, any workers in the vicinity should step back 6 feet and instruct the participant to roll the window back up. At no point should there be any contact with the participant or anyone from the vehicle. If any accidental exposure has occurred, they should doff any affected PPE and don fresh PPE.

What to do if the Participant exits car:

If anyone inside the participant vehicle exits the car, any workers in the vicinity should step back and maintain a 6 foot distance and instruct the participant to get back inside the vehicle. At no point should there be any contact with the participant or anyone from the vehicle. If any accidental exposure has occurred, they should doff any affected PPE and don fresh PPE.

Sample Collection and Transfer

Process for Sample Collection and Transfer

Background

This instruction manual describes steps for processing participants through **both Mid-turbinate and 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.

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

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.
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.
MT Swab	Specimen collected by swabbing the Nasal Middle-Turbinate region of the nasal cavity.
NP Swab	Specimen collected by swabbing the Nasopharyngeal Region of the nasal cavity.

Preventing Test Not Performed (TNP)

It is essential that the vial cap is closed securely to prevent the leakage of transport fluid. If there is leakage, the test will not be processed by the lab. For both HCP-collected and participant-collected samples, please check that the swab handle is not interfering with cap closure and the labeled sample vial cap is secured prior to putting the vial in the specimen bag.

Recommended Materials for Mid-Turbinate Specimen Collection

Materials

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 clear sealable (ziploc) bag for specimen count

Sampling consumables

(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.)

- Test requisition which includes participant labels (see the [Sample Requisition Example in the appendix](#))
- Swab for MT Specimen Collection (CDC recommendation: flocked, tapered swab)
- Appropriate Specimen Transport tube with Transport Liquid
- Sample/specimen transport bags
- Rubber bands for attaching sample kits to car mirrors

Information/lists

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

Other Consumables

- See [Personal Protective Equipment section](#) 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

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.

- 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.
- Take appropriate precautions when using cleaning agents. Read the Safety Data Sheets and follow the handling instructions carefully.
- Assume all waste generated by this process is infectious and dispose of it in a red biohazard bin/bag.

Preparation

- If ambient temperatures may exceed 25 °C / 77 °F, store viral transport tubes on ice or in a refrigerator until required for sampling.
- Follow PPE recommendations per role, donning and doffing protocols, and special exposure instructions in the [Personal Protective Equipment](#) section.
- Sample Collection process assumes verification of participant identification, participant test requisition, and general process preparation as outlined in the process steps listed below.

Process Steps

1. Confirm participant Information

- a. Prior to the participant entering the sample collection area, Swabber (medical assistant, medical lab technician 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. Double gloving recommended.
 1. If only one pair of gloves was worn and discarded, then Swabber should wash hands or use hand sanitizer.
 2. If an assistant is involved with swab collection then they should follow the same glove change protocol between each participant/sample interaction.
 3. Swabber (and assistant, if applicable) don a fresh pair of gloves and wave participant vehicle into bay (**Figure 1**).
- b. Prior to the participant entering the sample collection area, if applicable, the Swabber shall use sanitizing wipes to disinfect the cart/table which will be used for transferring the test kit. Dispose of wipes into the biohazard bag.
- c. Participant pulls into the designated sample collection bay and is directed to turn off their vehicle.
 1. If participant lowers window, Swabber should be 6 feet away from the vehicle and deliver instructions from this distance.
 2. Note: If significant participant distress is observed, the situation should be escalated to clinical lead for assessment. If a participant requires immediate medical attention, call 911.
- d. Swabber takes the specimen bag with requisition and labels off the participant's vehicle and double checks the participant's identity by asking the participant to verbally verify name and date of birth (DOB).
- e. Swabber checks that labels match requisition.

1. If the participant's name or DOB are mismatched or incorrect, the requisition can be corrected on-site prior to swabbing. Ideally any errors will be detected at station 2 prior to entering the sample collection area.
2. If the participant's name and DOB match, Swabber or assistant adds one label to the sample collection tube, one to the Specimen Log Sheet, and leaves the third label in place on the requisition.



Figure 1. Collection Bay Suggested Set-up

2. Determine Specimen Collection Method

- a. Swabber briefly explains to the participant how the nasal mid-turbinate (MT) swab test will be performed.
- b. Swabber obtains verbal consent for the specimen collection from the participant.
 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.
- c. Swabber asks participant if he/she is comfortable with self collection.
 1. If participant agrees to perform self-collection of MT specimen, refer to **Specimen Self-Collection**.
 2. If participant declines to perform self-collection of MT specimen then refer to **Specimen Collection by Healthcare Professional** for collection by Swabber.

3. Specimen Self-Collection

- a. Swabber prepares swab by pre-breaking swab at the scored line (if present) while keeping swab in the package.
- b. Swabber will explain the specimen collection by telling the participant to:
 1. Tilt head back.
 2. Insert the swab in the **horizontal** position into one nasal passage until there is gentle resistance, about 2 cm. (Refer to **Figure 2**)
 3. Fully rotate the swab 10 times against the nasal wall.
 4. Remove the swab and repeat the same procedure in the other nasal passage with the same swab.
 5. Remove the cap of the specimen tube and insert the swab tip into the tube. Recap tube.
 6. Lower window and return bagged sample and kit components.

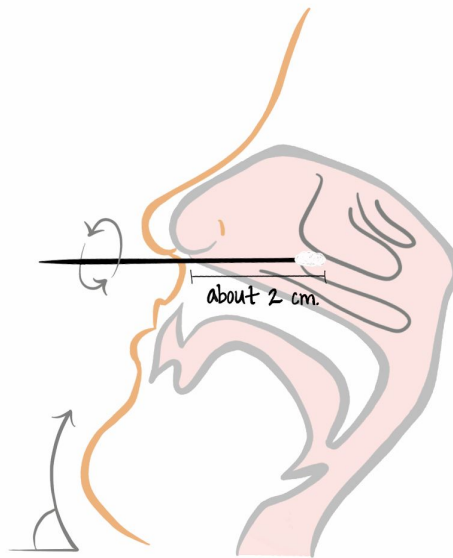


Figure 2. Diagram of correct swab orientation for nasal mid-turbinate specimen collection.

- c. Swabber may also give suggestive tips for proper specimen handling, including:
 1. If you feel a sneeze coming on, remove the swab from your nose and avoid its contact with anything. Then continue testing post-sneeze.
 2. Be careful not to spill or splash the liquid inside the specimen tube.
 3. Please do not set the specimen tube cap face down after uncapping.
 4. Please be sure to not let swab touch anything besides intended sampling area.
 5. Be sure the swab is cut below the cap to ensure secure closure of the transport tube.
 6. Be sure the vial cap is closed securely to prevent the leakage of transport fluid.
 7. Make sure to seal the biohazard bag after inserting specimen tube.

- d. Swabber will let participant know that they will be watching and if he/she has any issues or concerns while self-collecting they are welcome to ask or sign for assistance from the Swabber.
- e. Participant will be directed to lower the window and Swabber will hand over the swab kit and direct the participant to close the window, and perform the self-collection.
 - 1. Swabber will watch participant closely to ensure proper specimen collection is followed.
 - 2. If assistance is needed, Swabber will try to guide participant through closed window.
- f. Once specimen is collected, participant is directed to lower window and return specimen tube.
- g. Swabber confirms participant's requisition in 1st compartment of specimen bag.
- h. Swabber places contaminated specimen tube in the 2nd compartment of the bag and seals the bag.
- i. Swabber or assistant stores sample in the dry ice cooler.

4. Specimen Collection by Healthcare Professional if participant unable to self-swab

- a. Swabber prepares swab by pre-breaking swab at the scored line (if present) while keeping swab in the package.
- b. If participant declines or is unable to perform self-swabbing, Swabber will complete the steps below to perform the swab test:
 - 1. Open the testing swab package in front of the participant.
 - 2. Direct participant to tilt head back.
 - 3. Insert the swab in the **horizontal** position into one nasal passage until there is gentle resistance, about 2 cm. (Refer to **Figure 2**)
 - 4. Fully rotate the swab 10 times against the nasal wall.
 - 5. Remove and repeat the same procedure in the other nasal passage with the same swab.
 - 6. Place the tip of the swab into the specimen tube and seal the tube.
- c. Swabber or assistant confirms participant's requisition in 1st compartment of specimen bag.
- d. Swabber places the contaminated specimen tube in the 2nd compartment of the bag and seals bag.
- e. Swabber or assistant stores sample in the dry ice cooler.
- f. During the event, the Swabber or assistant checks that specimens remain in the cooler on dry ice in the cooler on an hourly basis.

5. Sample Reconciliation and Transfer

- a. At the end of the collection period, prior to pickup from the lab vendor, the Participant Data Specialist (PDS) reconciles the Specimen Log Sheet against the number of actual specimens collected as described in the **Participant Data Specialist Guide**.
- b. 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.
- c. PDS completes the specimen transfer form verifying the date, time, and number of specimens collected by the courier.
- d. Courier signs the form after confirmation.
- e. The courier picks up the cooler and returns the specimens to the lab vendor for testing.

6. Clean up

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

Recommended Materials for Nasopharyngeal Specimen Collection

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

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

Other Consumables

- See [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

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.

- 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.
- Take appropriate precautions when using cleaning agents. Read the Safety Data Sheets and follow the handling instructions carefully.
- Assume all waste generated by this process is infectious and dispose of it in a red biohazard bin/bag.

Preparation

- If ambient temperatures may exceed 25 °C / 77 °F, store viral transport tubes on ice or in a refrigerator until required for sampling.
- Follow PPE recommendations per role, donning and doffing protocols, and special exposure instructions at [Personal Protective Equipment](#).
- Sample Collection process assumes verification of participant identification, participant test requisition, and general process preparation.

Process Steps

Confirm participant Information

1. Before participant vehicle enters the sample collection bay, Swabber (RN 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.
 - a. If only one pair of gloves was worn and discarded, then Swabber should wash hands or use hand sanitizer.
2. Swabber dons fresh pair of gloves and waves participant vehicle into the bay (Figure 1).
3. Participant pulls into the designated sample collection bay and is directed to turn off their vehicle and lower the window.
 - a. 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.
4. Swabber 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).
5. Swabber checks that labels and requisition match participant's government ID.
 - a. If the participant's name or DOB are mismatched or incorrect and onsite requisition printing is available, the participant is asked to move to the holding area. If a corrected requisition can be printed, they can be tested. If onsite printing is not available, they are asked to call the Verily User Success team to correct demographic information and reschedule their appointment.

- b. If the participant's name and DOB match, Swabber adds a label to the sample collection tube, the Specimen Log Sheet, and leaves 2 stickers on the requisition. One of these 2 stickers can be used as backup if needed.
6. Swabber asks for verbal confirmation of the participant's full name and DOB. If the participant's name or DOB are mismatched or incorrect, the requisition can be corrected on-site prior to swabbing. Ideally any errors will be detected at station 2 prior to entering the sample collection area.



Figure 1. Collection Bay Suggested Set-up

Test Participant

1. Swabber briefly explains to the participant how the test will be performed.
2. Swabber obtains verbal consent for the nasopharyngeal specimen collection from the participant.
 - a. 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.
3. Swabber completes the steps below to perform the nasopharyngeal (NP) swab test:
 - a. Swabber opens the testing swab package in front of the participant.
 - b. Swabber asks the participant to tilt their head back to ~ 70 degrees.
 - c. Swabber gently inserts the swab while rotating into one nostril.
 1. Swab should reach depth equal to $\frac{1}{2}$ the distance from the nostrils to the opening of the ear.
 - d. Swabber leaves the swab in place for several seconds to absorb secretions.
 - e. Swabber slowly removes the swab while rotating it.
 - f. 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.
 - g. Swabber confirms participant's requisition in 1st compartment of specimen bag and holds the bag open for Swabber.
 - h. Swabber places the contaminated specimen in the 2nd compartment of the bag.
 - i. Swabber stores sample in the dry ice cooler.
4. During the event, the Swabber checks that specimens remain frozen in the cooler on an hourly basis.

Sample Reconciliation and Transfer

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.
 - a. PDS must match the number on the sample log, by going through each individual sample and verifying name and requisition number.
 - b. It is recommended to incorporate a barcode scanner and barcode labels to individually verify the specimens collected.
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.
3. PDS completes the specimen transfer form verifying the date, time, and number of specimens collected by the courier.
4. Courier signs the form after confirmation.
5. The courier picks up the cooler and returns the specimens to the lab vendor for testing.
6. PDS will share sample log with central.

Clean up

1. Wearing clean gloves, package all unused materials if they need to be placed in a secure site and placed in the specified vehicle for removal from Site.
2. Using sanitizing wipes, disinfect all tables and chairs used during the event and dispose into the biohazard bag.
3. Ensure all used face shields, face masks, gowns, gloves, and pens are discarded into a biohazard waste bag.
4. Please refer to the [Medical Biohazard Waste Instructions](#) in the next section for daily closeout of sample area and proper medical biohazard waste removal.

Medical Biohazard Waste

Medical Biohazard Waste Instructions

Background

This process instruction applies to the disposal of biohazard waste at COVID-19 testing sites only.

Terminology

Term/Acronym	Definition
HCP	Healthcare professionals
PPE	Personal Protective Equipment worn by employees for protection against health and safety hazards

Materials

Equipment

- Biohazard Waste Bins
- Secondary Collection Bin (larger than size of biohazard waste bags)

Consumables

- Biohazard Waste Bags (Red)
- Secondary Bag

Environmental Health and Safety

- 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
- Take appropriate precautions when using cleaning agents
- Read the Safety Data Sheets and follow the handling instructions carefully
- Assume all waste generated by this process is infectious and dispose of it in a red biohazard bin/bag
- Wear gloves, lab coat or smock, eye protection and all other necessary PPE for area when moving any waste bin.

General Procedures

Setting up Biohazard Waste Bin

1. Set up the Biohazard bin by opening the lid with a step pedal and placing a red Biohazard Bag inside.
2. Flip the edges of the bag around the rim of the bin.
3. If the bag is loose on the rim then secure by tying a knot on the side at the top of the bag.

Discarding Biohazard Waste Bag

1. Remove the Biohazard waste bag when it is $\frac{3}{4}$ full.
2. Tie a secure knot in the top with either an overhand knot (twist top of bags until can't twist anymore, and then make a loop and pull end of bag through) or a gooseneck tie (twist and loop like overhand knot, except use a zip tie or duct tape to secure loop).
3. Place the red biohazard bag into a secondary bag.
4. Perform the same securing process on the second bag with either an overhand knot or gooseneck tie.
5. Move secured double-bagged waste to the secondary collection bin.

Responsibilities

Healthcare Professionals are responsible for:

- Placing all potentially contaminated materials into the red biohazardous waste bins provided including, but not limited to, gloves, gowns, face shield, tyvek coverall, and any other PPE when doffing.
- Discarding full biohazard waste bags in the secondary collection bin and replacing with new biohazard bags, according to general protocol.
- Ensuring the biological waste is being managed in accordance with applicable regulations and laws.
- Making this document available to personnel working at the Site.

Site Volunteers are responsible for:

- Ensuring that all personnel are trained to this SOP and all Site-specific regulations.
- Assisting with the traffic flow and Site logistics.

Local Authorities are responsible for:

- Waste removal from Sites where a protocol has been established to transfer responsibility.

Daily Biohazard Waste Closeout Procedure

1. All biohazard bags in the secondary grey bins need to be double bagged and secured. Several primary bags can be in one secondary collection bin.
2. All lids must be fastened.
3. All bins must be wiped with a 10% bleach solution, or another EPA approved antimicrobial such as Clorox or Lysol Disinfecting wipes.

Medical Waste Work Instruction

1. Place all potentially contaminated materials in the red biohazardous waste step bin.
2. Discard all biohazard bags into the collection bins at the Site, using general discard protocol.
 - a. No secondary collection bin should contain waste that is above 35 lbs in weight.
 - b. No loose waste should be placed in the secondary collection bin, all waste must be in a red biohazardous waste bag.
3. All secondary collection bins must remain closed unless waste is being added.
4. Prior to transport, verify that:
 - a. All bags are contained within a second layer of bags, which is also goosenecked and tied.
 - b. The lids are properly secured.
5. Decontaminate the outside of the bins with 10% bleach solution or another EPA approved antimicrobial such as Clorox or Lysol Disinfecting wipes.
6. Bins are then processed according to Site-specific waste removal protocol.

Appendix

Handling Clothes Post-Shift

Scope

To propose a method to manage clothes worn by volunteers/staff during and after working at COVID-19 testing sites.

Background

Currently there is limited specific data on the optimal approach for handling attire worn at a COVID-19 testing site. According to the Centers for Disease Control and Prevention (CDC), the coronavirus is usually transmitted through respiratory droplets (from an infected person sneezing or coughing) rather than through fomites, objects, and materials that when contaminated can transfer disease. However, the CDC notes that evidence suggests that the novel coronavirus may remain viable for hours to days on surfaces made from a variety of materials, which includes clothing. Attire choices should attempt to balance professional appearance, comfort, and practicality with the potential role of apparel in the cross-transmission of pathogens resulting in transmission of disease.

Procedure

The guidelines for appropriate attire are based on professionalism, common sense, decorum, and the available evidence.

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

Our recommendations are as follow:

What to wear

- Wear clean appropriate professional attire during all participant encounters. Scrubs, t-shirt, or other comfortable clothing that can be changed daily and easily washed after every shift.
- If working in the "hot zone," hair should be worn back to limit the amount of hair on the nape of the neck. Large sideburns and ponytails should be covered or contained.
- Wash hands often while onsite and before leaving the Site and upon arriving home.
- All footwear should have closed toes, low heels, and non-skid soles.

Handling of Clothing

- Covid-19 Personal Protective Equipment should be followed for proper donning and doffing technique.
- When possible, it is recommended to change scrubs or clothes at the end of shift and place them in a plastic bag/trash bag. Work shoes should be placed in a separate plastic bag and staff can change into "traveling" shoes and coat to go home.
- If scrubs/clothes are worn home after a shift, it is recommended staff drive straight home. Avoid stopping at stores, restaurants, or other places along the way.
- Staff should prioritize taking a shower and laundering clothes after their shift or upon arriving home.

- Avoid any physical touch with household members, or common surfaces (e.g. kitchen counter) while still wearing the same clothes from the shift.
- It is recommended to clean shoes with an anti-germ clothing spray. Shoes should be left outside the home until the next shift or a second set of working shoes should be used as an alternate between work shoes.







Laundering

- Optimally, any apparel worn that comes in contact with the participant or participant environment should be laundered after daily use. Jackets or hoodies worn during participant care should be laundered no less frequently than once a week and when visibly soiled.
- Laundering clothes should be done using a hot water wash cycle (ideally with bleach) followed by a cycle in the dryer at the highest setting.
 - Rationale: A combination of washing at higher temperatures and tumble drying or ironing has been associated with elimination of both pathogenic Gram-positive and Gram-negative bacteria.

Additional References

[ICS 206 - Medical Plan](#)

Sample requisition example:

Client #:12345678 Vendor Information: Verily				
	Client #: 12345678 Req #: 1234567890 This order expires 2020-04-03			
Lab Approving Entity: PWNHealth LLC 888-362-4321	For Lab Use	<table><tr><th>Patient Information</th></tr><tr><td>Patient Name: Lastname, Firstname Address: 123 Main St City: Any Town State: CA Zip: 94123</td></tr></table>	Patient Information	Patient Name: Lastname, Firstname Address: 123 Main St City: Any Town State: CA Zip: 94123
Patient Information				
Patient Name: Lastname, Firstname Address: 123 Main St City: Any Town State: CA Zip: 94123				
Collection Date: 2020-04-02 Time: Urine Volume: Hours: Lab Reference ID: 1234567890	Pat ID #: 7654321 State: CA SSN: DOB: 1990-01-01 Sex: M Room/Loc: Result Notification:			
UPIN: A12345 NPI: 1234567893 Ref Physician Provider ID: Staging Physician CA DE ID MO WV WY				
Responsible Party: Lastname, Firstname Bill Type: Client	CLIENT BILL ONLY. NO PATIENT OR THIRD PARTY BILLING ON THIS ACCOUNT.			
Profiles/Tests				
ORDER #	TEST NAME/DESCRIPTION			
39433	SARS CoV 2 RNA, QL Real Time RT PCR			
EMPLOYER SOLUTIONS NATIONAL CLINICAL ACCOUNT MUST BE TESTED IN A QLS LABORATORY. FOR QUEST DIAGNOSIS USE ONLY - QUESTIONS PLEASE CALL 866-226-8046				
<div>Collected: 2020-04-02 Lastname, Firstname 1990-01-01 REQ# 1234567890 </div>				
Collected: 2020-04-02 Lastname, Firstname 1990-01-01 REQ# 1234567890 	Collected: 2020-04-02 Lastname, Firstname 1990-01-01 REQ# 1234567890 	Collected: 2020-04-02 Lastname, Firstname 1990-01-01 REQ# 1234567890 		
Collected: 2020-04-02 Lastname, Firstname 1990-01-01 REQ# 1234567890 