

Unobserved Self-Swab Site Instructions

These instructions describe how staff will distribute kits for sample collection, how participants will drop off their samples and how staff will register and ship samples.

Materials needed for self-swab collection

CRSP provides items in [blue](#)

- Unobserved Self-Swab Nasal Collection device which include the below items in a sealable bag:
 - 1 anterior nasal swab
 - 1 collection tube
 - Instruction sheet
- Dymo Labelwriter 450 printer
 - DISCARD ENCLOSED LABELS.
 - Printer connects to any PC based laptop via USB. We will provide 1 printer for each drop-off station (roughly 200-500 tests per day).
- Printer labels
 - USE ONLY THESE LABELS
 - Dymo 1"x2.125" Durable Small Labels #1976411
- Cryoboxes with 64 place fiberboard cell dividers (will be used to return collected specimens to Broad)
 - VWR Cryobox #89128-183 and VWR cell dividers #82007-152
- CRSP address labels
- Cardboard shipping boxes
- Packing material
- Biological Category B shipping materials (if shipping via FedEx or UPS or air)
- Packing tape
- Rubber bands
- Biohazard trash bin
- Windows-based laptop with USB port and WiFi access

Distribution of Unobserved Testing Devices FOR TESTING STAFF

Unobserved Devices can be distributed to participants if the following criteria are met:

1. The ordering physician determines that the participant should be tested.
2. The participant has been determined to be eligible for the test by their institution.
3. The participant has appropriately consented for the test.

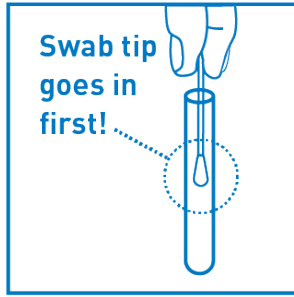
Unobserved devices can be taken home by the participant or used on-site at the time of collection. Medical professionals are no longer needed on site to supervise or observe collection.

Drop-off Station Instructions FOR TESTING STAFF

The drop-off stations are not required to follow the full guidelines for a collection site regarding emergency procedures, telephones, restrooms, etc. However, adequate hand washing/hand sanitizing stations are highly recommended given that re-collection of some swabs may be required. Drop-off stations require a staff member (or multiple) to affirm consent, confirm identity and inspect the sample.

Sample Inspection:

1. Receive the bagged sample from the patient.
2. Open bag to retrieve the sample and discard bag.
3. Inspect sample tube ensuring that:
 - Tube contains one swab.
If zero or more than one swab is in the tube, reject sample and discard. Issue a new device and direct participant to recollect.
 - The existing single swab in tube is oriented correctly - with soft tip facing down (away from cap).
If swab is incorrectly oriented, reject sample and discard. Issue a new device and direct participant to private area to recollect.
 - Check to see if 'solid biological contents' are in tube.
Swab may be 'dry' or 'moist' or slightly 'bloody' without issue, but solids can cause issues with automation downstream. If there is significant visible matter on the swab (a.k.a. boogers or excessive mucus), reject sample and discard. Issue a new device and direct participant to recollect.

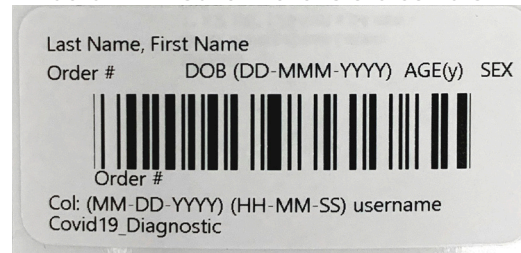


Instructions FOR PARTICIPANTS

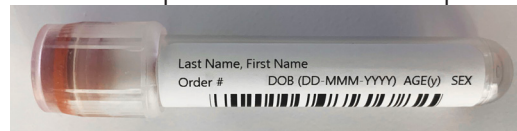
1. If required, participant will download app required by the sponsoring institution to facilitate test ordering and result reporting.
2. Eligible participants will be given sample collection device(s) by their institution.
3. Participants will be instructed by their institution on frequency of performing the test and schedule of dropping off the sample.
4. **Participants will be instructed to Test ONLY on the day of scheduled drop-off date.**
5. Follow device instructions on how to self-swab.
6. After sample collection, visit drop-off site as directed by the institution.
7. At the drop-off station, participant will be shown a consent form and verbally asked to confirm they have read, understand, and agree to it.
8. Participant will confirm that the name, DOB, zip code and information on the barcode label is correct when shown by the staff member.
9. Participant will provide collection date and time for specimen.
10. Participant will hand resealable bag with collection tube to the staff member.

Confirmation of Collection Time and Sample Registration:

1. Collected Time = ask participant when they collected their sample. Confirm that participant collected sample today. Record the time and today's date.
If sample collection was not same day as drop-off, reject sample and discard. Issue a new device and direct participant to recollect.
2. When the barcode prints, **visually inspect quality of barcode printed to ensure no scanning issues (no fading, blurry lines, missing info etc.).** Example of a well printed label is pictured below. Ensure there is a clear distinction of black and white lines.



3. If the barcode has any abnormality in print quality, reprint.
 - Staff member will show the printed barcode to the participant and ask for final confirmation that this information is correct.
 - If the barcode has any abnormality in print quality, reprint.
4. Affix the barcode label to the collection tube - making sure it is upright and flat on the tube (not crooked or creased) and flush with the top of the cap.
 - Do not put barcode sideways.
 - Do not put barcode on top of any other label.
 - Do not tape down barcode.
 - Do not place barcode over cap.



5. Place the sample tube in the Crybox with inserts for scheduled transportation to the laboratory.
6. The participant sample drop off process is complete.
7. Repeat for next participant.