

Observed Self-Swab Nasal Collection Instructions

These instructions describe how staff will assemble and distribute materials (CRSP-provided in blue) for sample collection, how participants will receive kits and return specimens, and how staff will collect and ship samples.

Materials needed for check-in and drop-off stations FOR TESTING STAFF

CRSP provides items in blue

- Dymo Labelwriter 450 printer
DISCARD ENCLOSED LABELS. Printer connects to any PC based laptop via USB. We will provide 1 printer for each check-in station (roughly ~200-500 tests per day)
- Printer labels
USE ONLY THESE LABELS Dymo 1"x 2.125" Durable Small Multi-purpose Labels" #1976411
- Cryoboxes with 64 place fiberboard cell dividers (will be used to return collected specimens to Broad)
VWR Cryobox catalog #89128-183 and VWR cell dividers # 82007-152
- Cardboard shipping boxes
- Packing material
- Biohazard trash bin
- Biological Category B shipping materials
- Packing tape
- Windows-based laptop with USB port and WiFi access

Setup- Pre Kit Distribution FOR TESTING STAFF

1. Define eligibility for test (eg. all students and staff expecting to be on campus regularly for the fall semester).
2. Identify ordering physician and submit standing order for testing.
3. Set up CareEvolve application for test requisition submission and reporting.
4. Submit list of individuals to be tested, including all information required for clinical testing.
5. Prepare and laminate consent form to be used at kit pickup and dropoff.
6. Post laminated self-swab instructions at self-swab/drop-off station.
7. Adhere to the Commonwealth of Massachusetts Clinical Laboratory Program: Collection Station Checklist requirements.
 - Provide adequate hand washing stations, hand sanitizer stations, telephone, toilet facilities
 - Written procedure manual detailing steps to be followed in the event of an emergency and readily available to all staff (ie, what to do if a participant faints, gets a bloody nose, there is a fire emergency).
 - Adequate procedure manual for collection, preservation and transportation of specimens

Kit Preparation Instructions FOR TESTING STAFF

1. Testing Site will receive bulk packaged kit components from Broad CRSP which include:
 - Anterior Nasal Swabs
 - Collection Tubes
 - Dymo Labels
 - Dymo Printer(s)



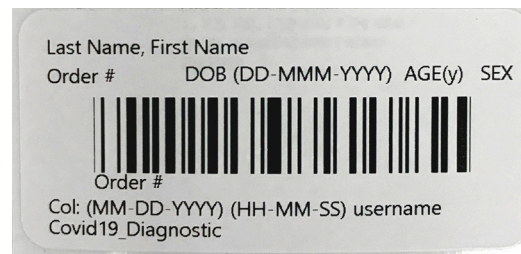
Check-In Instructions FOR PARTICIPANTS

1. If required, participant will download app required by the sponsoring institution to facilitate test ordering and result reporting.
2. Eligible participants will visit collection site as directed by institution.
3. At the check-in station, participant will be shown a consent form and verbally asked to confirm they have read, understand, and agree to it.
4. Participant will confirm that the name, DOB, zip code and information on the barcode label is correct when shown by the testing staff.
5. Participant will receive at the Check-In station:
 - 1, individually wrapped Anterior Nasal Swabs
 - 1, Collection Tube - labeled with barcode and participant information
6. Participant should go to drop-off station.
7. Participant should not open the kit until in front of the staff member.

Check-in Station Instructions FOR TESTING STAFF

Check-in stations require a staff member (or multiple) to affirm consent and confirm identity.

1. Participant shows ID to staff.
2. Enter in and look up name, then make an order under that name, confirming the DOB, address, and name.
3. Confirm that participant is properly pre-registered
4. Ensure all demographics are filled in.
5. Verbally confirm that the participant consents to the test.
6. Verify all the information on the order page.
 - Order Date = today's date
 - Collected Date = enter today's date if Participant affirmed they collected today.
 - Collected by = check-in staff's signed-in portal credentials.
7. Print the barcode using the provided label printer.
Use only the labels provided by CRSP. Discard the labels that come with the printer.
When the barcode prints, visually inspect quality of barcode printed to ensure no scanning issues (no fading, missing info etc.) Example of a label is pictured below.



- Order # = Barcode #
 - Col: = Collection Date & Time (input determined at drop-off)
 - Username = check-in staff's username
 - Test Type = Covid19_Diagnostic
8. 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 the barcode.
 9. 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

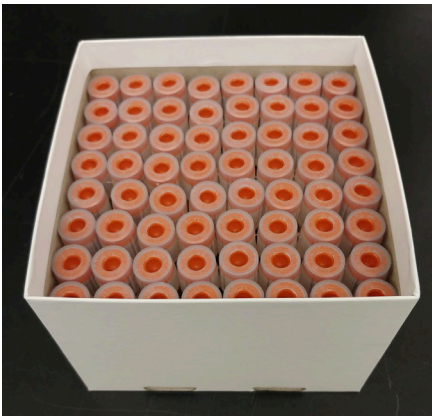
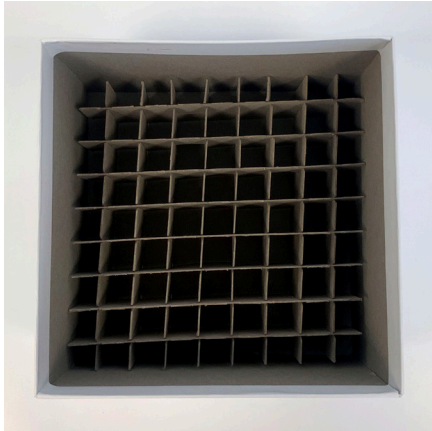


the bottom of the cap.

10. Hand kit with barcoded tube to participant.
11. Instruct participant to go to self-swab/drop-off station.

Specimen Drop-Off Instructions FOR PARTICIPANTS

1. Participant follows posted laminated instructions for swabbing.
2. Participant hands tube to staff member.



Self-Swab/Drop-Off Station FOR TESTING STAFF

A self-swab station for observed self-collection is considered a healthcare setting as long as a medical professional is present on site. Observations of self-swabbing can be done by trained staff under the direction of a medical professional. Staff are also required to manage the storage and packaging of the collected swabs in tubes for transport to the laboratory.

1. Staff member observes while participant follows laminated instructions for swabbing.
2. Participant hands tube to staff member.
3. Staff member ensures the cap is well sealed. *Do not accept samples that do not contain a swab or in which the swab is upside down.*
4. Staff member places the sample tube in the Cryo box rack.
5. The participant is all set.
6. Repeat for next participant.

End of Collection Day FOR TESTING STAFF

1. Consolidate the samples in the sample box racks to make complete racks of 64 tubes per box.
2. Physically count all the sample tubes.
3. **Check that the number of physical samples matches the number of “Collected” samples in the Manifest, then print the Manifest (this completes the whole order).**
DO NOT click Print Manifest until the number of physical tubes versus samples collected in the manifest are confirmed to match.
4. Seal the box lid shut with tape or elastic band.
5. Place the tube boxes in a CRSP-provided cardboard shipping box.
6. Put printed manifest in box.
7. Pack box securely and seal shut with packing tape.
8. Affix to shipping container:
 - Sender’s company, contact name, address, and phone number
 - Recipient’s name and address
CRSP
320 Charles Street
Cambridge, MA 02141
9. Follow Category B shipping requirements if shipping with FedEx or UPS.¹
10. Prepare packed boxes for courier service pick up at your designated time. *Broad will be using STAT Delivery Service and will work with sites to establish scheduled STAT pick up times and locations. For off-cycle and on-demand pickups, contact STAT directly (1-877-522-7828). If using your own courier, you can ship to Broad 24 hours a day, 7 days a week.*