VERMONT AGENCY OF EDUCATION DEPARTMENT OF HEALTH

CIC Health

Vermont Department of Health COVID-19 Specimen Collection CIC Health/Broad Testing Guide

VT School Administrator Guide Updated Feb. 4, 2021

Hello and welcome to Assurance Testing with CIC Health! The following is an outline of what to prepare for on specimen collection day.

For questions regarding specimen collection please contact Cara Fisher from CIC Health: caralina.fisher@cic.com, (267) 750-8130

For questions regarding materials and registration please contact the AOE COVID-19 Response Team at AOE.COVID19Testing@vermont.gov.

For IT support, please contact COVID19TeacherTesting@vermont.gov.

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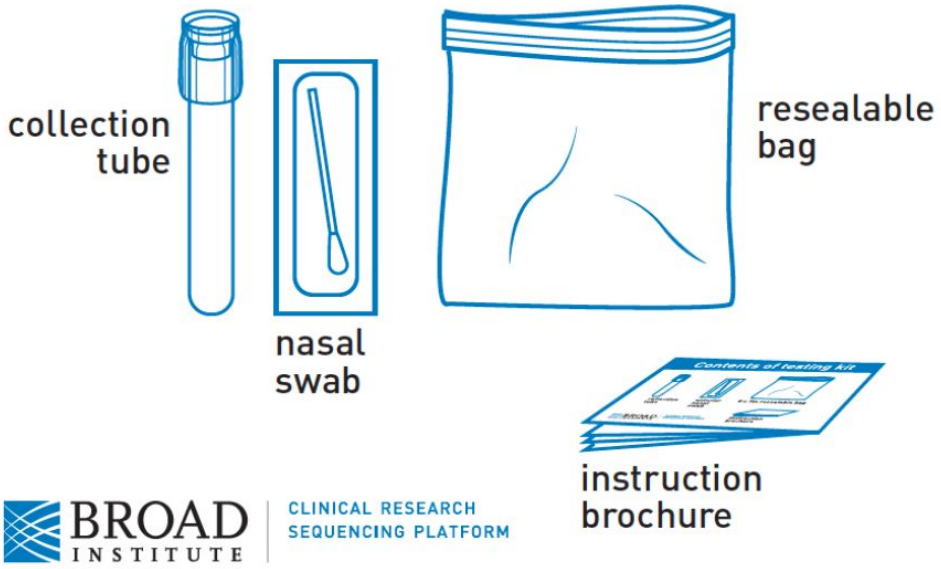
I. Overview of initial package

The package you'll receive will contain the following:

- Cryoboxes with divider inserts: These are the boxes in which submitted collection tubes will be placed upright when being packaged for shipping
- Cardboard box for shipping
- Category B labels: These labels are needed for shipping and are described in more detail in the shipping section
- A packing slip list: This will detail the list of patients that there is an allocated test kit for. Please utilize this at the end of the day to reconcile with the submitted collection tubes.
- Sheets of barcoded labels: Each label is designated for a patient's test tube which will be applied to the tube upon completion of specimen collection.
- Testing kits: Here's a sneak peek at what's inside each testing kit:



II. Onsite Flow Instructions for Site Administrators

A. Determine a Test Kit Drop off Location & Flow

Before distributing the collection kits, you'll want to **determine a secure drop off spot and deadline for returning samples** and communicate this to all individuals being tested. 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 confirm identity, inspect and label each sample.

Each site is responsible for operating the Drop off Locations. Consider the flow of participants at your site based on CDC guidelines, including adequate PPE in the case of asymptomatic surveillance testing, gloves for handling completed kits and cloth face masks and sanitizing procedures and maintaining a minimum of 6 feet distance between participants.

B. Distribution of Testing Kits

At the beginning of the testing day, distribute the kits to your patients, along with the patient guidelines document (see Appendix B). We recommend you require all patients to collect their samples as soon as possible and return them no later than two hours before you plan to ship them out. We also recommend provision of tissues and hand sanitizing supplies for test participants (See Appendix A.)

C. Drop Off Procedures for Site Administrators/Staff

These are steps to outline the flow for site administrators at the drop off station, while the patient is physically present returning their specimen.

1. Receive the bagged sample from the patient.
2. Open bag to retrieve the sample and discard bag. Please note: while these are biohazard bags, they can go in regular trash because they should never have specimen in them.
3. Inspect sample tube ensuring that:
    a. Tube contains one swab. *If zero or more than one swab is in the tube, wear gloves when handling and discard all swabs in the regular trash. Issue a new swab and direct participant to a private area to recollect.*
    b. The existing single swab in the tube is oriented correctly - with soft tip facing down (away from cap). *If swab is incorrectly oriented, use wear gloves when handling and discard the swab in the regular trash. Issue a new swab and direct participant to a private area to recollect.*
    c. Check to see if 'solid biological contents' are in the 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.*

snot or excessive mucus), wear gloves when handling and discard the swab in the regular trash. Issue a new swab and direct participant to recollect.

***Please see section III for visual aids in sample inspection procedures.**

4. Confirmation of Sample Registration
    a. Confirm that participant collected sample today.
    b. Confirm the name, DOB, zip code, and information on the patient's barcode label is correct.
    c. 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.
        i. Do not put barcode sideways.
        ii. Do not put barcode on top of any other label.
        iii. Do not tape down barcode
        iv. Do not place barcode over cap.
    d. The reason the labels need to be put on so precisely is because the barcode scanner that the Broad uses is very particular, and won't be able to read the barcode unless put on correctly. **If the label is not properly placed on the test tube it is likely the sample will be discarded by the lab and thus not yielding a result.**
    e. If for any reason you need to hand-write a label, please flag that for CIC Health by emailing caralina.fisher@cic.com with the Subject Line: Handwritten Labels. Please **do not** include any patient information, just share the number of handwritten labels and the sending institution indicated on your Manifest.

Image Description: A properly placed label with no creases or on an angle

    f. Place the now properly labeled sample tube upright in the cryobox with inserts for scheduled transportation to the laboratory.

Image Description: Organized test tubes standing upright in a cryobox with inserts

III. Sample Inspection

As you receive samples from each patient at the drop off location, remove each tube from its plastic bag and inspect the sample for any errors that require retesting (see below). Then verify the appropriate label and apply the label to the tube. The following are errors that may result in a sample being discarded by the lab and thus not yielding a result:

Label Application Errors to Avoid

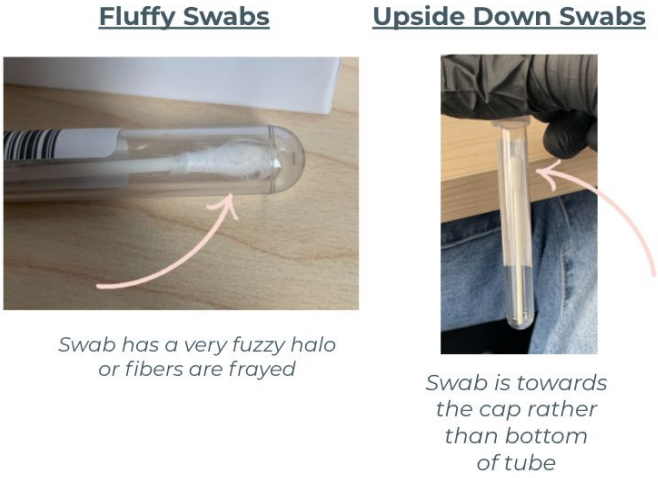
- Wrinkled/Creased/Angled label
- Label smudged or otherwise obscured
- Patient information cut off

Errors that require a patient to reswab

- Swab oriented incorrectly
- Blood, mucus on swab

- Fluffy swabs

If one you see a sample with the swab upside down, an overly fluffy (pictured on the following page), or a sample with blood or mucus, you should discard the swab and ask the individual in question to recollect.



IIII. Packing & Shipping

A. Establishing Delivery Plan

Prior to test day, confirm samples can be picked up by FedEx or UPS or dropped off at a FedEx or UPS drop off location prior to last drop off time.

Through your shipping service, select a shipping speed that will ensure your samples arrive to the lab within 48 hours of collection. Shipping Address:

CIC Health
245 Main Street
Cambridge, MA 02142
857-270-2707

Contact number: 857-270-2707
Delivery Instructions: M-F, 9am-5pm, please bring packages up to the second floor Concierge; outside of business hours, please instruct couriers to ring the doorbell at the entrance to 245 Main Street or call 857-270-2707 and wait for someone from our team to come down to retrieve the packages.

Drop off is available 24/7: Please communicate to your hand delivery team member or to your courier that they must hand off the packages in lieu of leaving them outside; if they ring the doorbell and there is a delay, it is likely because it is taking two minutes or more to come down to the door from upper floors.

Weekend Delivery

If you are planning to ship your samples during the weekend, please provide the Agency of Education with **the shipping service and tracking number(s) for your shipping boxes** so that they are able to monitor the progress of your shipment. Please email this information to aoe.covid19testing@vermont.gov.

If Shipping with FedEx or UPS: please note the sender **needs to check "Saturday delivery"** on the shipping form or else the box may not be delivered until Monday.

B. Packaging Materials Needed

Provided in your initial package:

- Cryoboxes and Dividers
- Test kits
- Cardboard shipping box
- Category B UN3373 shipping label - (Feel free to print out this label for each shipping box if this was not included)

To acquire for your testing site:

- Sender's address label (to create with your shipping service)
- Packing tape
- Packing materials, i.e., bubble wrap, peanuts, material to prevent Cryoboxes from shifting
- Rubber bands
- Manifest/Packing Slip - print out the attached document. Please Note: You should be shipping your samples to CIC at 245 Main Street, Cambridge, MA 02142. The Charles Street address on the manifest is for CIC internal use.

C. Packing & Shipping Specimens

1. As test tubes are collected at the designated drop off station, please consolidate the samples in the sample cryobox dividers to make complete racks of 64 tubes per Cryobox. (The cryoboxes were given to you in your initial package.)

2. Physically count all the sample tubes and complete the Manifest/Packing Slip (Appendix C.) Complete the Vermont School Staff Surveillance Testing: Unused Test Kits

online survey to report unused test kits and tests not included in the shipment due to no-show or testing error.

3. Seal the Cryobox lid shut with tape or elastic band. Consolidate sealed Cryoboxes into as few shipping kits as possible. **Do not use any wet ice for packaging.** Dry specimens are stable long term at room temperature.

4. Place the completed manifest/packing list (Appendix C) in the shipping box. If you have multiple shipping boxes, please include a copy on the Manifest/Packing Slip in each shipment.

5. Pack the shipping box with packing materials so the cryoboxes do not shift around during transport.

6. Seal the shipping box shut with tape.

7. Through your shipping service, create your shipping label for expedited delivery to the following address. Shipping Address:

CIC Health
245 Main Street
Cambridge, MA 02142
857-270-2707

8. Affix the sender's label to the outside of the shipping box. Ensure that the sender's company name, address, contact name, and contact phone number are included on the label.

Examples of sender's address labels. If using FedEx or UPS for shipment, please include UN3373 labels and mark the shipment as "Biological substance, Category B" in addition to the sender's address labels specific to that courier in compliance with UN 3373 Biological Substance, Category B shipping regulations.

9. When shipping with FedEx or UPS, ensure we follow the Category B shipping requirements for packages containing biological substances. Affix a UN 3373 Biological Substance, Category B Air Label to the outside of the shipping box. Per the CDC shipping recommendations, place the label on one side of the box and cover the label completely with clear tape (do not tape just the edges of the label).

10. Ensure your samples are packaged and available for handoff at your arranged UPS pick up time or bring to a UPS drop off location prior to last drop off time. The shipping service should be **next day delivery**.

Appendix A: Broad Instructions for Unobserved Self-Swabbing

(Included in each Self-Swab Kit)

BROAD INSTITUTE | CLINICAL RESEARCH SEQUENCING PLATFORM

IVD Rx only

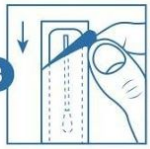
CRSP Self-Swab Kit is for use under Emergency Use Authorization only. For people 18 years or older.

How to collect a nasal swab sample

Read instructions entirely. Failure to follow the instructions entirely may lead to false or incomplete results. Only collect the sample on the day you are scheduled to drop it off and only drop off your own sample.

1. **Blow your nose.** Thoroughly blow and wipe your nose to clear thick mucus (snot).

2. **Wash your hands.** Wash with soap and water for at least 20 seconds or use hand sanitizer and dry completely.

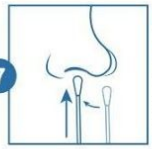


3. **Open the package with the swab.** **Careful: Don't touch the soft tip with your hands.** Peel open where indicated. Leave swab in the package for now.

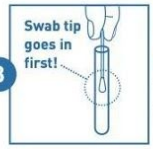
4. **Pull up to remove the cap from the collection tube.** Place it on a clean surface where you can easily find it.

5. **Pick up the swab.** Pull swab out of its packaging, **being careful not to touch the soft tip with your hands**. Have the tube ready to put the swab in after collecting the sample.

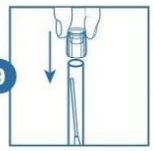
6. **Collect sample from nostril.** Insert the swab into one nostril **just until the soft tip is no longer visible**. Rotate it in a circle around the inside edge of your nostril 3 times.



7. **Collect sample from other nostril.** Use the same soft tip to repeat the previous step in the second nostril 3 times.

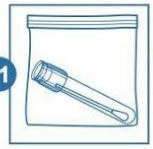


8. **Put the swab in the collection tube.** The soft tip of the swab that went into your nose should go into the tube first.



9. **Push cap down firmly.** Push the cap straight down onto the tube until it cannot go down any farther.

10. **Wash your hands.** Wash with soap and water for at least 20 seconds or use hand sanitizer and dry completely.



11. **Put the tube into the sealable bag.** Seal the bag and write your name on it.

12. **Deliver to collection site *today*.** See instructions on the reverse side.

Questions? Call support line at (617) 714-7590 or e-mail crsp-careevolve@broadinstitute.org

This self-collection kit has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. This self-collection kit has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. This self-collection kit is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Appendix B: Participant Guidelines for Unobserved Sample Collection

(Print for Participants)

Participant Guidelines for Unobserved Sample Collection

1. Participants will be instructed by their school on frequency of performing the test and schedule of pick up and drop off. Participants will be instructed to test ONLY on the day of scheduled drop off date.

2. Pick up a test kit bag from the designated location.

3. Find a secluded area or a spot at least 10 feet away from others to perform the self-swabbing. All participants will need to have **tissues and hand sanitizer** in order to perform the specimen collection.

4. Open up the resealable bag and follow the instructions for specimen collection on the brochure. **Failure to follow the instructions entirely may lead to false or incomplete results.** Make sure to:
    a. Thoroughly blow and wipe your nose to clear thick mucus (snot) before swabbing. Mucus and or blood on your swab could invalidate your test.
    b. Wash or sanitize your hands immediately before swabbing and after placing swab securely in test tube
    c. Collect sample by inserting the swab into one nostril just until the swab tip is no longer visible and rotating it around the inside edge of your nostril three times. Do not insert the swab any further into your nose or you will risk getting blood on your swab, which could invalidate your sample.
    d. Place the swab's **soft tip into the tube facing down (towards the bottom of the tube)**

5. Once the test tube cap is securely closed and the tube is sealed in the bag, please return to the designated drop off area as directed by your school.

6. Participants will hand resealable bag containing the test tube to the staff administrator at the drop off site.
    a. If there is blood or excessive mucus on the swab, the staff administrator will ask you to retest with a new swab. If you notice either blood or excessive mucus please request to retest as these issues may not yield a result.

7. Participants will verbally confirm that the name, DOB, zip code and information on the barcode label is correct to the staff administrator.

Appendix C: Manifest / Packing Slip

(Print to include in shipment to the lab. Please note: You should be shipping your samples to CIC at 245 Main Street, Cambridge, MA 02142. The Charles Street address on the manifest is for CIC internal use.)

Specimen Manifest

Clinical Research Sequencing Platform Covid19_Diagnostic
320 Charles Street
Cambridge, MA 02141-2023

**** Please fill in all 4 of the fields below before shipping to the Broad ****

1. Sending Institution:

Sending Institution and Collection Site Address

PVT_____

_____

_____

2. Collection Date Range:

Date range of specimen collection. Can be a single date if collected on same day

____/ ____/ 20 ____

To:

____/ ____/ 20 ____

3. Total Specimens:

Total count of specimens in this package

_____

4. Package Number

Package number of total in Shipment. ex. Package 2 of 3.

Package _____ of _____