

Rx only
IVD
Not been FDA cleared or approved
Authorized for use by the FDA under Emergency Use
Authorization (EUA)

This kit is only authorized for the unsupervised self-collection and maintenance of nasal specimens as an aid in detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.

This 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.



COVID-19 VIRAL TEST INSTRUCTIONS

Collection and Shipping Instructions for COVID-19 Viral Test Nasal Swab:

KIT CONTENTS:

- 1 Nasal Swab
- 1 Viral Transport Media (VTM) Vial
- 1 Ethos Specimen Bag w/ absorbent sheet
- 1 Ethos Registration Card
- 1 Pre-labeled UPS Shipping Bag
- 1 Test Instructions

COLLECTION INSTRUCTIONS:

Follow the collection instructions to prevent injury to nasal cavity, rejection of specimen due to improper packaging, loss of sample, cross contamination, or incorrect results due to improper collection.

1. Register your kit at: u-collectkit.com/registration
2. Using the guidelines on the back of this sheet, collect your specimen using the Nasal Swab.
 - a. The patient must wash their hands before collecting the specimen
 - b. Be careful not to touch the tip of the swab with your hands
 - c. Do not use the liquid in the tube to wet the swab prior to specimen collection
 - d. Do not use the swab on more than one person
3. After specimen collection, place the Nasal Swab in the VTM vial, being careful not to spill the liquid. Snap off the handle at the designated breaking point or cut the applicator handle to allow the swab to fit inside the VTM vial. Tighten the cap on the VTM vial.
 - a. Be sure to place the swab portion into the VTM vial, and ensure the swab is completely immersed into the VTM (liquid)
4. Ensure the VTM vial is labeled with the correct Patient Name and Date of Birth. Unlabeled

specimens will not be tested.

- a. The patient should record the date and time of collection on the VTM vial
 - b. The patient must wash their hands after collecting their specimen
5. Place the VTM vial in the zip-top section of the Ethos specimen bag with the absorbent sheet and seal the zip-top section.
 6. Fold the completed order form, and place it in the back pouch of the Ethos specimen bag.
 7. If you are not shipping your specimen right away, it can be refrigerated for up to 2 days
 8. When you're ready to ship your specimen, **place the sealed Ethos specimen bag in the collection kit box. Place the collection kit box in the UPS shipping bag**, which is in accordance with Department of Transportation (DOT) regulations.
 - a. Multiple samples can be sent in the same UPS shipping bag.
 - b. Seal the UPS bag by removing the strip and pressing the edges together.
 9. Ensure the return shipping label is already attached to the outside of the UPS shipping bag.
 - a. Deliver the UPS shipping bag to your nearest UPS store or drop-box location to send to Ethos Labs for testing.

INSTRUCTIONS FOR USE ANTERIOR NARES SAMPLE COLLECTION

USING NASAL SWAB AND VTM™ VIRAL TRANSPORT MEDIA

COLLECTION SUPPLIES

- VTM Vial (1)
- Nasal Swab (1)



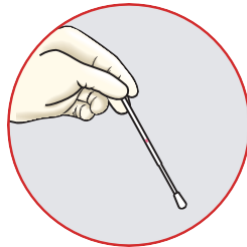
Break at breaking point
 (not all swabs have red line)

Insert in
 nostril

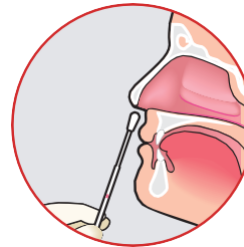
COLLECT THE SAMPLE



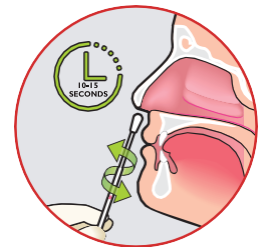
Wash hands with soap
 and water.



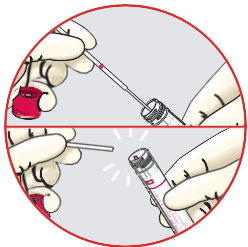
Remove the swab from
 its packaging, holding
 by the end of the
 applicator and identify
 the breaking point.



Position head slightly
 back, and insert the
 swab into the **LEFT**
 nostril and gently push
 the swab until a slight
 resistance is met (less
 than one inch into the
 nostril).



When the swab is in
 place, firmly sample the
 nasal membrane by
 rotating the swab in a
 circular motion for
 10-15 seconds. Repeat
 in the **RIGHT** nostril."



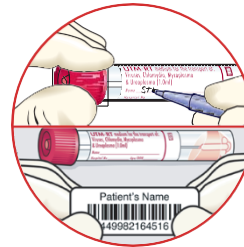
While holding the swab,
 remove the cap from the
 VTM vial.

Insert the swab, tip first,
 into the vial. Bend the
 swab shaft against the
 vial opening to break it
 off at the breaking point.

If it doesn't break, or if it
 is too tall for the vial, use
 scissors to cut the swab
 shaft to fit.



Discard the broken part
 of the applicator and
 the swab wrapper into
 the trash.



Screw the cap back onto
 the vial. If the vial is not
 already labeled with
 your name and date of
 birth, clearly write your
 full name and date of
 birth on the vial with a
 permanent marker.



Wash hands with soap
 and water.

**PLEASE SEE STEPS 6 - 10 ON PAGE 1 FOR PROPER
 OUTBOUND PACKAGING AND SHIPPING INSTRUCTIONS**

THIS GUIDE IS FOR ILLUSTRATION PURPOSES ONLY.
 Items in the U-Collect kit may vary slightly from the images on this guide.
 Read all instructions on Page 1.

For questions regarding specimen collection, packaging, and shipping, call Ethos Laboratories at (877) 496-2570, ext. 1157.