Rx only IVD

For use under Emergency Use Authorization For use by people 18 years of age or older.

The test that will be used to test the self-collected specimen has not been FDA cleared or approved.

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:

- I NasalSwab
- I Viral Transport Media (VTM) Vial
- I Ethos Specimen Bag w/absorbent sheet
- I Ethos Order Form
- I Pre-labeled UPS Shipping Bag

#### **COLLECTION INSTRUCTIONS:**

the collection instructions to prevent injury to nasal cavity, rejection of specimen due to improper ing, loss of sample, cross contamination, or incorrect results due to improper collection.
I. Review the order form and complete any highlighted sections. Read all instructions carefully before starting
<ul> <li>2. Using the guidelines on the back of this sheet, collect your specimen using the Nasal Swab.</li> <li>a. Be careful not to touch the tip of the swab with your hands.</li> <li>b. Do not use the liquid in the tube to wet the swab prior to specimen collection.</li> <li>c. Do not use the swab on more than one person</li> </ul>
<ol> <li>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.         <ol> <li>a. Be sure to place the swab portion into the VTM vial, and ensure the swab is completely immersed into the VTM (liquid)</li> </ol> </li> </ol>
4. Ensure the VTM vial is labeled with the correct Patient Name and Date of Birth. Unlabeled specimens will not be tested. The patient should record the date and time of collection on the VTM vial.

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
<ul> <li>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.</li> <li>a. Multiple samples can be sent in the same UPS shipping bag.</li> <li>b. Seal the UPS bag by removing the strip and pressing the edges together.</li> </ul>
<ol> <li>Ensure the return shipping label is already attached to the outside of the UPS shipping bag.</li> <li>Deliver the UPS shipping bag to your nearest UPS store or drop-box location to send to Ethos Labs for testing.</li> </ol>



# INSTRUCTIONS FOR USE ANTERIOR NARES SAMPLE COLLECTION

USING NASAL SWAB AND VTM™ VIRAL TRANSPORT MEDIA

### **COLLECTION SUPPLIES**

- VTMVial(I)
- Nasal Swab(I)



Break at breaking point (notall swabs have red line)

Insert in

### COLLECT THE SAMPLE



Wash hands with soap and water.



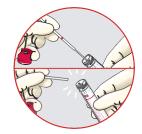
Remove the swab from its packaging, holding by the end of the applicator and identify the breaking point.



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.