DOC NO: LBL-10245 REVISION: 1 Effective Date: Sep 15, 2020

Rx only. For Emergency Use Authorization only. For in vitro diagnostic use only.

COVID-19 Nasal Swab Home Collection Kit

COLLECTION KIT CONTENTS











Biohazard Bag (with Absorbent Pad)



Bubble Wrap



Shipping Box

BEFORE YOU COLLECT

- READ THESE 2 PAGES OF INSTRUCTIONS COMPLETELY BEFORE COLLECTING YOUR SAMPLE
- SELF-COLLECTION IS RESTRICTED TO INDIVIDUALS 18 YEARS OF AGE AND OLDER
- PLAN YOUR COLLECTION TIME
 Ship your sample on the <u>same day</u> as your collection.
 Do not collect and ship your sample on Saturday or Sunday. <u>Your sample must be picked up or dropped off before the last UPS pick-up of the day.</u>
- QUESTIONS? CALL CUSTOMER CARE CENTER AT 844-870-8870

IMPORTANT!

To ensure your sample is processed by the lab, you must:

- · Complete and apply the sample label to the tube with your name and date of birth.
- Ensure that the tube is completely closed after the nasal swab collection.
- Ship your package on the same day as your collection. Do not collect and ship your sample on Saturday or Sunday.

Your sample may not be processed and you may not receive a test result if you do not follow these steps.

COLLECT YOUR NASAL SWAB SAMPLE

BEFORE COLLECTING YOUR SAMPLE, prepare the shipping box for shipment and schedule your sample pick-up with UPS.

1. PREPARE YOUR PACKAGE FOR SHIPMENT







The UPS shipping label has a green tear strip that must be removed.

- · Lift the left corner of the tear strip and pull it off.
- · Lift the bottom edge of the top label and pull up.
- Tear the top label off the kit along the perforation.
- · Your return label shows.
- · Your package is ready for shipment following sample collection.

2. SCHEDULE YOUR SAMPLE PICK-UP WITH UPS

DO NOT schedule your pickup via UPS.com.

Option 1: Call UPS special returns line before 10 am: 1-800-823-7459 to

schedule a pick-up

- When UPS asks for the company you are shipping to, say "At Home with Exact".
- Provide the tracking number shown on your prepaid return shipping label, which starts with 1Z.

Option 2: Drop off your kit at a UPS Store or drop box before the last pickup of the day

· Visit www.ups.com/dropoff to locate the nearest UPS Store or drop box and pickup times.

3. WASH YOUR HANDS WITH SOAP AND WATER



Dry your hands with a clean towel. Put all collection materials on a **clean** dry surface.

Turn over to back side of document for additional instructions

Warnings

- This test has not been EDA cleared or approved
- \cdot This test has been authorized by FDA under an EUA for use by the authorized laboratory;
- This test has been authorized only for the detection of nucleic acid from SARSCoV-2, not for any other viruses or pathogens; and
- This test 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.



4. PREPARE THE TUBE LABEL

Patient Name:

Patient DOB:

MM / DD / YYYY

Date of Collection:

MM / DD / YYYYY

AM

AM

PM

Using a blue or black ballpoint pen, write your name, date of birth, and date and time of collection on the Collection Tube Label. Set label aside.

7. SWAB BOTH NOSTRILS



You must collect your sample from both nostrils before placing the swab into the collection tube. Gently insert the entire soft tip of the swab into one nostril until you feel a bit of resistance and rub it in a circle inside the nose 4 times. Using same swab, repeat in other nostril.

10. REPLACE TUBE CAP



Put the cap back on the tube. Securely tighten so liquid does not leak.

13. PLACE BAG IN BUBBLE WRAP

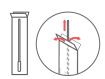


Fold the bubble wrap around sealed biohazard bag.



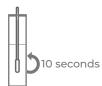
Document Title: IFU Nasal Swab At Home Collection Kit Label Specification Proof

5. OPEN NASAL SWAB



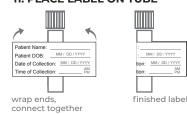
Remove the nasal swab from the wrapper by pulling the two ends of the wrapper apart. Be careful to only touch the swab handle, not the swab tip. Do not let the swab touch any surfaces before or after your collection.

8. ADD SWAB TO TUBE



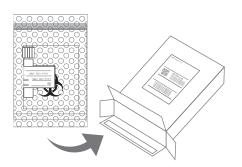
Remove swab from nostril and place in collection tube liquid. **Swirl in tube for 10 seconds.**

11. PLACE LABEL ON TUBE



Using the completed label from Step 4, place middle of label on tube, wrap label ends around tube, stick label ends together. Your information should be visible. **Do not overlap the ends of the label on the tube.**

14. PLACE BUBBLE WRAPPED BAG IN BOX



Place bubble wrapped biohazard bag into shipping box. Remove paper backing from tape, fold box flaps closed, press to seal box closed.

6. REMOVE TUBE CAP



While holding the swab, remove cap from tube. Be careful to not spill liquid. Do not drink liquid. Set cap aside.

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9. REMOVE SWAB FROM TUBE



Press tip against side of tube to squeeze liquid from swab, then throw the swab into the trash.

12. WASH HANDS, ADD TUBE TO BAG



Wash and dry your hands again. Put your tube in the bag with the absorbent pad. Seal the bag.

15. SHIP PACKAGE BY UPS PER THE INSTRUCTIONS PROVIDED ON THE FRONT PAGE

- Ship your sample on the same day as your collection. Do not collect and ship your sample on Saturday or Sunday.
- · Store sample in sealed box away from direct heat and sunlight until pick-up or drop-off at the UPS Store or drop box.