₹ IVD

<PATH-TEC BARCODE LABEL>

- This home collection kit has not been FDA cleared or approved.
- This home collection kit has been authorized by FDA under an EUA.
- This home collection kit has been authorized only for the home collection and maintenance
 of nasal swab specimens as an aid in detection of nucleic acid from SARS-CoV-2, not for any
 other viruses or pathogens.
- This home collection kit in combination with the authorized test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of medical devices 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.

HOME COLLECTION KIT INSTRUCTIONS

For Use Under an Emergency Use Authorization (EUA) Only

Failure to follow these instructions may lead to inaccurate test results.

REGISTER ONLINE Before you begin

Before you begin collection of your sample, you must register your kit.

When you are ready to collect your sample, register your kit online at:

https://my.empowerdxlab.com/ en/activate and enter the barcode listed above.

Remove the swab from the envelope.

Do not touch the tip of the swab with your hands.

Visit https://bit.ly/fedexdropbox
to view FedEx drop box locations and pickup schedules to determine how you will ship your sample.

You must bring your sample to a drop box on the same day you collect it, before the last Express pick up. Do not deliver sample to a drop box on Saturday or Sunday. Do not take to a FedEx office.

Your sample may not be tested if not shipped on the same day of collection.

Screw off the top of the collection tube. Hold swab in one hand and collection tube in the other, being careful not

to spill the liquid inside the tube.

Do not drink the liquid.

3



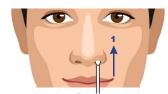
You are now ready to begin your sample Collection. Wash and dry your hands before opening the kit.

Open your kit and place all contents on a clean, dry surface. Write your date of birth on the provided label.

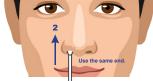


Place sticker with your name/DOB on the collection tube.

6



Insert the tip of the swab into one nostril. The swab does not need to be inserted far – insert just until the tip of the swab is no longer visible. Rotate the swab in a circle around the entire inside edge of your nostril at least three times.



Take the swab out of your nostril. Using the same end of the swab, repeat step 6 in your **other nostril**.

8



of the swab that went into your nose should be placed into the tube first so that it sits in the liquid at the bottom of the tube. Screw the top back on the tube.

9



Wash and dry your hands thoroughly.

Insert collection tube into the biohazard specimen bag. Leave the white absorbent pad in the bag. Seal the bag by closing the zip lock seal.

10



Place the biohazard specimen bag into the provided kit box. Place the box into the FedEx return shipping pack. Remove the adhesive cover strip and seal the FedEx return pack closed.

11



Deliver the postage paid, pre-addressed FedEx return pack to a FedEx drop box, or other preferred method as listed above in Step 2.

You must send your sample via FedEx the day it is collected.