

WARNING

This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by DxTerity Diagnostics, Inc. which is certified under CLIA and meets the requirements to perform high complexity tests. This test is authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. 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 Cosmetics Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

© DxTerity Inc. All Rights Reserved. RX Only. For in vitro diagnostic use. For use under Emergency Use Authorization (EUA) only. LAB-0309 02 | DXT-INSTCARD-02

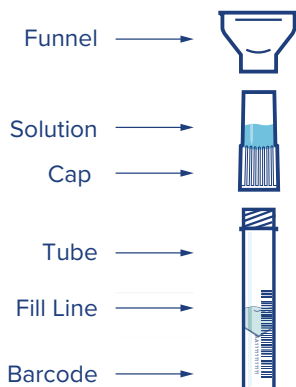


DxTerity® Test Kit

Instructions for use

Your Kit Includes:

Saliva Collection Device



REF SDNA-1000

Return Shipping Supplies



Biohazard Specimen Bag with Absorbent Material



Pre-Labeled UN3373 FedEx Return Pack



Shipping Box

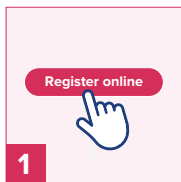


You MUST collect your sample on the same day you ship it. Do Not collect on Saturday or Sunday.



Do NOT eat, drink (even water) or smoke for **30 minutes** before giving your saliva sample. If you are having trouble collecting saliva in your mouth, try closing your mouth and wiggling your tongue. Gently rubbing the outside of your cheeks, just behind your back teeth. Making chewing motions with your mouth. You **MUST** collect your sample on the same day you ship it. Wash your hands prior collection and after collection. For questions contact us at 1.800.997.6896 or email homesupport@dxterity.com

LABEL LEGEND: Consult instructions for use Use by date (Collect saliva by) Catalog number CE Marking Caution, consult instructions for use Temperature limit Manufacturer Batch code



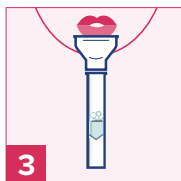
Register your kit online. Open the kit and place all the contents on a clean, dry surface. Register your kit online in the at home portal by typing in the 14-digit barcode (format LLNNNNNNNNNNNNNN) located on your collection tube. Ensure to register at time of collection. Your 14 digit serial number will be assigned to you and registration date stamped at the time. The 14 digit barcode must be entered correctly to process your test.

DO NOT Discard the return shipping supplies (image in the back). They are required to ship the sample back to the lab.



Identify your local FedEx drop box location and pickup schedules.

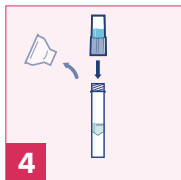
Visit <https://bit.ly/fedexdropbox> to view FedEx drop box locations and pickup schedules. Or Call 1.800.GoFedEx 1.800.463.3339 and speak to a customer service representative. It's important to bring your sample to a drop box on the same day you collect it before the last Express pick up. **Do not deliver sample to a drop box on Saturday or Sunday.** Failure to do so may result in a failure to process your sample.



Collect your saliva sample. Fill the tube with saliva to the black wavy line.

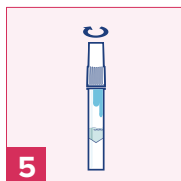
Fill the tube until your saliva (**not including bubbles**) is at or just above the wavy line.

DO NOT OVERFILL OR UNDERFILL.



Replace the funnel with the fluid cap.

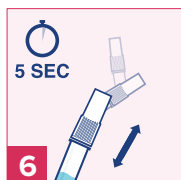
Remove the funnel from the tube. Discard the funnel and screw on the enclosed cap **TIGHTLY** to release the viral RNA inactivating and stabilization solution into your saliva.



Firmly screw cap down to release solution and seal tube.

You will know it works when the blue solution from the cap is released into the tube.

Firmly tighten cap to assure the cap and tube is completely sealed.



Shake the tube for at least five seconds.

This will ensure your sample mixes thoroughly with the stabilizing solution.

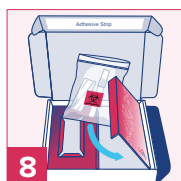


Insert collection tube into the Biohazard Specimen Bag with Absorbent Material.

DO NOT remove Absorbent Material from the Bag.

Insert collection tube into the biohazard specimen bag. Seal the Biohazard Specimen Bag.

Wash and dry your hands thoroughly before going to next step.



Place the collected sample back in the shipping box, close and seal.

Place the box in the pre-labeled FedEx UN3373 Pack and seal the pack.

Place the Specimen Bag with collected sample into the shipping box in the designated area inside the box. Remove the adhesive cover strip from the lid of the box and close and seal the box. Place the shipping box 8 into the FedEx return pack. Remove the adhesive cover strip from the FedEx box and seal the return pack closed.



Deliver the postage paid, pre-addressed FedEx Return Pack to a FedEx drop box.

It's important to bring your sample to a drop box on the same day you collect it before last Express pick up. **Do not deliver sample to a drop box on Saturday or Sunday. Do not take to a FedEx office.**