

 You **MUST COLLECT** your sample on the same day you ship it. Do **NOT** collect on **SATURDAY** or **SUNDAY**.
For questions, contact us at: 1.800.997.6896 or email: homesupport@dxterity.com

Welcome to Your DxTerity® Test Kit!

Instructions for Use

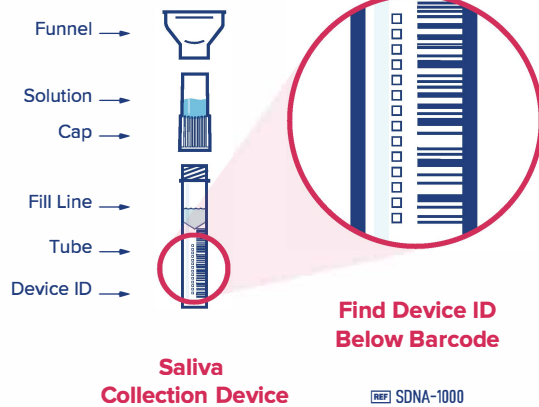


Step 1: Register Your Kit Now at DxTerity.com

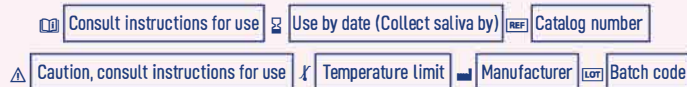
Register, Collect and Ship Same Day

To register your kit, create or log into your account, and type in the **14-digit Device ID** located on your collection tube. The 14-digit Device ID must be entered correctly to process your test.

Open the kit and place all the contents on a clean, dry surface. **Ensure to register at time of collection.** Your 14-digit Device ID number will be assigned to you and registration date electronically stamped at the time.



LABEL LEGEND



WARNING

Individuals exhibiting severe COVID-19 warning symptoms are not allowed to proceed with kit registration and instead directed to seek emergency medical care. This product has not been FDA cleared or approved, but 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 product is authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product 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 declaration is terminated or authorization is revoked sooner. Saliva specimen will be collected at home or other collection sites outside of the healthcare setting from any individuals determined to be appropriate for COVID-19 testing by a HCP including from individuals without symptoms of COVID-19. Federal Law restricts this device to sale by or on the order of a licensed practitioner. Testing of saliva for individuals with or without symptoms of COVID-19 should be prescribed by healthcare provider. Children under the age of 18 may use this test, under adult supervision to assist, as needed, with the steps beyond spitting into the collection tube.

DxTerity Diagnostics Inc. 19500 South Rancho Way, Suite 116, Rancho Dominguez, CA 90220 | T. 310 537 7857

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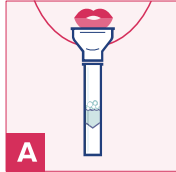
For use under Emergency Use Authorization (EUA) only. LAB-0309 03 / DXT-INST CARD-03



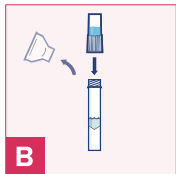
Do NOT eat, drink (even water) or smoke for 30 minutes before giving your saliva sample.

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.

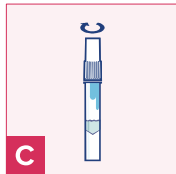
Step 2: Collect Sample



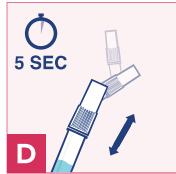
Collect your saliva sample. Fill the tube with saliva to the black wavy line. Fill the tube until your saliva (not including bubbles) is at or just above the wavy line. **DO NOT OVERFILL.**



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.

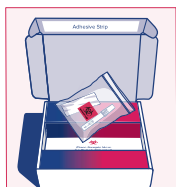


Shake the tube for at least five seconds. This will ensure your sample mixes thoroughly with the stabilizing solution.



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.

Step 3: Ship Sample with FedEx



Place the Specimen Bag with collected sample into the designated area inside the Shipping Box.

Remove the adhesive cover strip from the lid of the box and close and seal the prepaid Shipping Box.

Deliver the Shipping Box 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.



Register, collect and ship the same day. DO NOT deliver sample to FedEx drop box on Saturday or Sunday.

Your Kit Includes Return Shipping Supplies!



Shipping Box with pre-paid return shipping label



Biohazard Specimen Bag with Absorbent Material

DO NOT Discard. Required for return shipping!

DxTernity