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

- Consult instructions for use
- Use by date (Collect saliva by)
- Catalog number
- Caution, consult instructions for use
- Temperature limit
- Manufacturer
- Batch code

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.
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.