

Patient Self-Collection Kit and Collection Process SOP - Telehealth

Test package dispatched and sent via express carrier or USPS including:



IVD Use; Rx Only; For use under an Emergency Use Authorization (EUA) only

Warnings:

This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories. This product has been 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 Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the authorization is revoked sooner.

1

Register for test



Register the test online at [link here] and type in the 12-digit test ID located on the collection tube beneath the barcode.

2



Before performing collection, confirm the nearest USPS, FedEx, or UPS drop off location and hours of operation. Ship the sample on the same day as collection before the last pick up.

3



Wash hands before opening the test package. Do not eat, drink, smoke or chew gum within 30 minutes of the collection. Do not open the Spectrum SDNA-1000 saliva collection kit until you are advised during your medically supervised telehealth visit.

4



Login to HIPAA compliant telemedicine platform using [this link] to virtually meet with a trained healthcare provider who will guide the saliva self-collection.

5



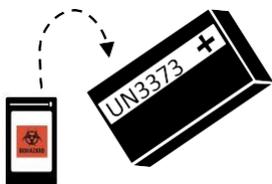
Provide government ID for verification. Open the package containing the SDNA-1000 saliva collection device. The healthcare provider will confirm the test ID and tracking number of the pre-paid return envelope*. Perform the supervised collection to the black line on the tube (2 ml). Remove funnel and screw on cap to release blue preservation agent into the tube. Shake the specimen for 5 seconds to mix preservative with sample.

6



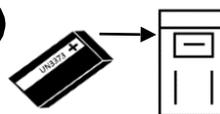
Wash hands thoroughly again. Place specimen in the provided biohazard bag. Seal the biohazard bag by closing the zip lock seal. Wipe the bag with the provided alcohol wipe. Wash hands thoroughly again.

7



Place the biohazard bag into the return package. Remove the adhesive cover strip and seal the package closed. Wipe the package with the provided alcohol wipe.

8



Immediately deliver package to a USPS, FedEx or UPS drop box using the prepaid, pre-addressed return package. Ship the sample on the same day as collection before the last pick up.

9



Lab inspects package and logs specimen serial number upon receipt of package. Test results are delivered to health care provider identified by kit serial number. Results are reported to patient by healthcare provider

Patient Self-Collection Kit and Collection Process SOP

Test package dispatched and sent via express carrier or USPS including:



Instruction card

Spectrum SDNA-1000 Saliva Collection Device

Lab-Loc Specimen Bag for Biohazard

Alcohol Prep Pad

Overnight carrier overpack UN 3373 Biological Substance Category B

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1

Register for test



Register test with health care provider using 12-digit test ID located on the collection tube beneath the barcode.

2



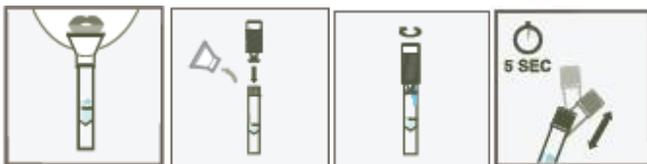
Before performing collection, confirm the nearest USPS, FedEx, or UPS drop off location and hours of operation. Ship the sample on the same day as collection before the last pick up.

3



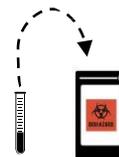
Wash hands before opening the test package. Do not eat, drink, smoke or chew gum within 30 minutes of the collection. Open test kit on a clean surface

4



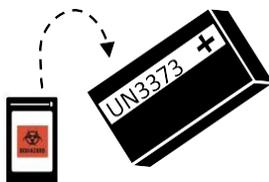
Open the package containing the SDNA-1000 saliva collection device. Perform the collection as per the instructions for use card and spit into the funnel until your saliva reaches the black line on the tube (2 ml). Remove funnel and screw on cap to release blue preservation agent into the tube. Shake the specimen for 5 seconds to mix preservative with sample. If needed a video that illustrates sample collection can be found at [\[link here\]](#)

5



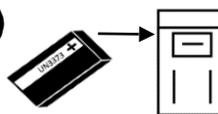
Wash hands thoroughly again. Place specimen in the provided biohazard bag. Seal the biohazard bag by closing the zip lock seal. Wipe the bag with the provided alcohol wipe. Wash hands thoroughly again.

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Place the biohazard bag into the return package. Remove the adhesive cover strip and seal the package closed. Wipe the package with the provided alcohol wipe.

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