

## SALIVA HOME COLLECTION KIT



### Saliva Home Collection Kit

#### Step-By-Step instruction

Before you start you must read all of the instructions including the warnings in relation to the liquid in the sample transport tube. You must be over the age of 18 to use this sample collection kit.

#### Step 1.

**Complete COVID-19 Saliva Collection Kit request form with Questionnaire and obtain a prescription for the Saliva Collection Kit.**

1. Activate your test online at: <https://ingenuityd.com/saliva-collection-kit-form/>. And follow the Video link on authorized lab website.
2. Saliva Home Collection Kit will be sent via FedEx after ordering online: Please contact FedEx to arrange a pickup before you collect your sample. Follow the instructions on the pack insert in your test kit. You should collect your sample on the same day as per pickup schedule.

#### Step 2.

##### Specimen collection

Wash your hands thoroughly for 20 seconds then dry your hands before starting the saliva collection.

1. Open your Saliva Collection Kit and place all of the contents on a clean, dry surface.
2. Remove the Saliva collection device from its packaging, write your name on the label of the vials, assemble the funnel on 5 mL vial and collect your saliva specimen.
3. Add the saliva up to 1 mL mark on vial and tighten the screw cap.
4. Clean the surface of the vial using alcohol wipe or sanitizer and discard the funnel.



#### Step 3. Specimen shipping preparation with your lab

1. Make sure the cap on your specimen tube is tightly closed.
2. Place specimen into the bio hazard bag and press firmly across the closure to securely zip.
3. Place the bagged specimen onto the in the shipping box.
4. Wash your hands thoroughly for 20 seconds and dry your hands after completing the box packing.
5. Write the Name, patient ID on the address label (provided inside the kit) and paste it on the packed box.
6. Drop off the sealed return over pack containing your specimen at the closest Fedex. **IMPORTANT:** Drop off the return over pack at the shipping depot within 24 hours of specimen collection



**Step 4. Results will be displayed on the website and by text message on the given mobile number within 48 hours.**

Lab will run the sample using COVID-19 RT-PCR and updated the result in InGenutyD / Lab web portal and Lab will send the report to patient through text message or on the website.



**IMPORTANT: Follow all directions carefully to ensure an adequate specimen is collected for testing.**

Do not collect your specimen until your scheduled appointment with your FedEx. Do NOT eat, drink, smoke or chew gum for 30 minutes before giving your saliva specimen. Do not remove the plastic film on the tube's funnel.

**PURPOSE/INTENDED USE OF DEVICE:**

The Saliva Collection Kit is an in-vitro diagnostic medical device intended for qualitative detection of SARS-CoV-2 in nasal swab specimens, self-collected by individuals at Saliva and returned to a partner accredited laboratory for analysis.

- The Saliva Collection Kit has not been FDA cleared or approved; the test has been authorized by FDA under an Emergency Use Authorization (EUA).

- Saliva Collection Kit has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- Saliva Collection Kit is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics tests for detection and/or diagnosis of COVID-19 under section 564(b)(1) of the Act, 21 U.S.C § 360bbb-3 (b)(1), unless the authorization is terminated or revoked sooner.

**Warnings**

- You must be over the age of 18 to use this sample collection kit.
- Do not let the liquid in the sample tube touch your skin or eyes.
- If the liquid gets in your eyes, wash it out immediately with lots of water and get medical advice.
- If the liquid touches your skin wash your skin with soap and water. If you still have any symptoms, you should call a physician.

**Index of Symbols**

- BioGenex Laboratories  
48810, Kato Rd, Suite 100 E,  
Fremont Co. CA 94538, USA
- See outside of kit box for lot number.
- In vitro diagnostic medical device.
- Do not use if the kit or any items included within it, are damaged/faulty, or if any items are absent from the kit.
- See outside of kit box for expiry date.
- Storage temperature: 15°C — 25°C.
- Consult Instructions for use
- You must be aged 18 or over to use this product.
- Don't re-use

**Manufactured by:**

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**Distributed by:**

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**For questions at any time, please call the laboratory help line at 510-824-1400. Our professionals are available to guide you.**

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