

## Step 1. Complete COVID-19 Medical Questionnaire and obtain a prescription for the P23 At-Home Covid-19 Test Collection Kit

The process starts with the Healthcare Professional (HCP) ordering the P23 At-Home Covid-19 Test Collection Kit for you and scheduling an appointment for your specimen collection.

The HCP ordering the P23 At-Home Covid-19 Test Collection Kit will initiate one of two options:

- The HCP will provide a P23 At-Home Covid-19 Test Collection Kit and shipping supplies directly to you; or
- P23 Lab will ship a P23 At-Home Covid-19 Test Collection Kit overnight directly to your home after you authenticate your order (Step 2 below). A valid email address will be required.



## Step 2. Authenticate your order

- Go to P23 Lab's website at [www.P23Labs/covid19](http://www.P23Labs/covid19)
- Verify your identity by uploading your driver license or a current photo of yourself.
- You will be prompted for a response to the following question:

**Did you elect to receive a P23 At-Home Covid-19 Test Collection Kit via the HCP's office?**

**If the answer is yes**, do you have a scheduled appointment for your supervised specimen collection? *The specimen collection and packaging must be supervised by a HCP.*

**If the answer is no**, contact your HCP to schedule your specimen collection appointment.

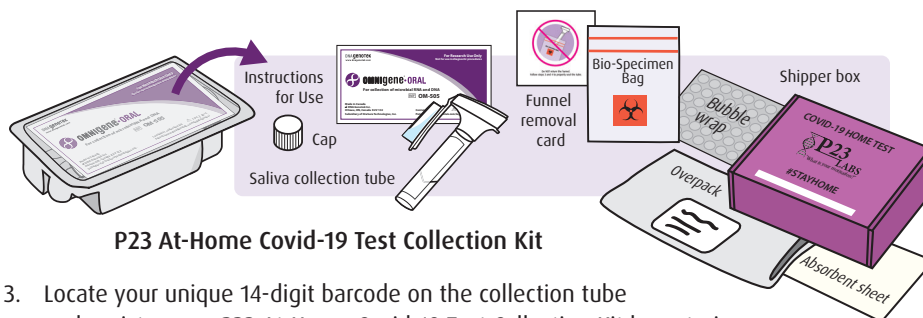
- If payment is required, you will be asked to pay at this time.



## Step 3. Receive your P23 At-Home Covid-19 Test Collection Kit

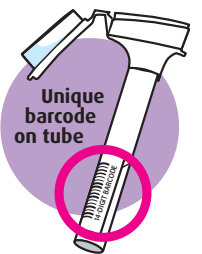
Once you have received your P23 At-Home Covid-19 Test Collection Kit, initiate the following steps:

- Go to P23 Lab's website at [www.P23Labs/register](http://www.P23Labs/register)
- Inspect your P23 At-Home Covid-19 Test Collection Kit to ensure all components are included.



P23 At-Home Covid-19 Test Collection Kit

- Locate your unique 14-digit barcode on the collection tube and register your P23 At-Home Covid-19 Test Collection Kit by entering the barcode on the secure patient portal.



**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 HCP. 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.

This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA;

This product has been authorized only for the home collection and maintenance of saliva specimens as an aid in detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and,

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 medical devices 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 authorization is revoked sooner.

For questions at any time, please call the laboratory help line at **901-341-6464**. Our professionals are available to guide you.



**IMPORTANT:** Do NOT eat, drink, smoke or chew gum for 30 minutes before giving a saliva specimen.

Healthcare Professionals (HCP) trained according to 49CFR 172.700 can find additional guidance at:

Collection steps: <https://www.dnagenotek.com/US/support/collection-instructions/omnigene-oral/om-505.html>

Collection video: <https://www.youtube.com/watch?v=l0bkXhjPVIU>

## Step 1. Collection appointment

Under the **supervision** of your HCP during your appointment, you will collect your saliva specimen.

Note: This may be done in person at the HCP office or via online Telemedicine.

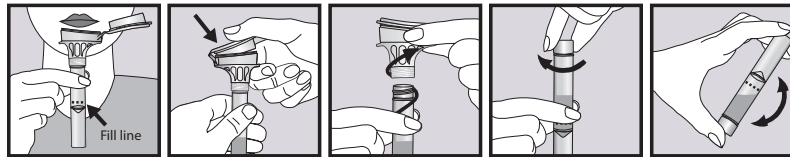
## Step 2. Specimen collection

Complete the specimen collection with your HCP's guidance:

- IMPORTANT:** Wash your hands **thoroughly for 20 seconds** then dry your hands **before** starting the collection.
- Open your P23 At-Home Covid-19 Test Collection Kit and place all of the contents on a clean, dry surface.
- Remove the saliva collection device from its packaging and collect your specimen.



Read complete instructions prior to providing a saliva specimen.



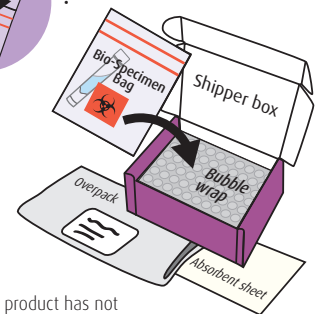
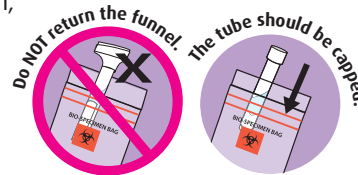
- 1 Spit until the amount of saliva (not bubbles) reaches the fill line.
- 2 Close lid tightly by pushing down hard on the funnel lid until you hear a loud click.
- 3 Unscrew the funnel from the tube.
- 4 Use small cap to close tube tightly.
- 5 Shake the capped tube for 5 seconds.

- IMPORTANT:** Wash your hands **thoroughly for 20 seconds** again, then dry your hands **after** completing the collection.

## Step 4. Specimen shipping preparation with your HCP

- Make sure the cap on your specimen tube is tightly closed.  
**Do not return the funnel.**
- Place specimen into the bio hazard bag and press firmly across the closure to securely zip.
- Follow HCP instructions for placing the bagged specimen onto the protective bubble wrap in the shipping box. Place the absorbent sheet on top and close the shipping box lid.
- IMPORTANT:** Wash your hands **thoroughly for 20 seconds** again, then dry your hands **after** completing the shipping preparation.
- The shipping box goes into the labeled return overpack, remove the adhesive liner and seal overpack closed.
- Drop off the sealed return overpack containing your specimen at the closest FedEx or UPS depot as determined by the shipping label with P23 Lab's address.

**IMPORTANT:** Drop off the return overpack at the shipping depot within **24 hours of specimen collection.**



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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 medical devices 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 authorization is revoked sooner.

## Step 5. Results are ready within 72 hours

Your HCP will contact you when your results are available.

For questions at any time, please call the laboratory help line at **901-341-6464**.  
Our professionals are available to guide you.