

P23 AT-HOME COVID-19 TEST COLLECTION KIT SALIVA - HCP SUPERVISED INSTRUCTIONS FOR PATIENTS

FOR RX USE ONLY FOR IVD USE ONLY FOR EMERGENCY USE **AUTHORIZATION ONLY**

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:

- a. The HCP will provide a P23 At-Home Covid-19 Test Collection Kit and shipping supplies directly to you; or
- b. 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

- 1. Go to P23 Lab's website at www.P23Labs/covid19
- 2. Verify your identity by uploading your driver license or a current photo of yourself.
- 3. 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.

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



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
- 2. Inspect your P23 At-Home Covid-19 Test Collection Kit to ensure all components are included.



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.

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











- · This test has not been FDA cleared or approved;
- · This test has been authorized by FDA under an EUA for use by the authorized laboratories:
- · This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- · This test 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.



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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=l0bkXhjPVlU

Step 1. Collection appointment

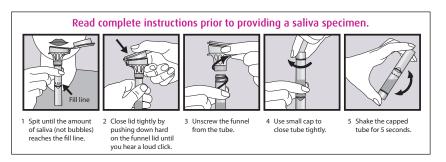
Under the **supervision** of your HCP during your appointment, you will collect your saliva specimen. Note: This may be done in person at the HCP office or via online Telemedicine.

Step 2. Specimen collection

Complete the specimen collection with your HCP's guidance:

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





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

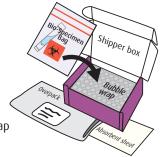
Step 4. Specimen shipping preparation with your HCP

- 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. 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.
- 4. **IMPORTANT:** Wash your hands **thoroughly for 20 seconds** again, then dry your hands **after** completing the shipping preparation.
- 5. 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.

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.



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