

Patients are required to meet specific qualifications in order to receive a Coronavirus (COVID-19) test.

The following criteria recommended by the Center for Disease Control (CDC) helps P23 Labs to conserve our limited tests. Self-isolation is the most effective method of preventing the spread of the virus.

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html>

Who should consider COVID-19 testing?

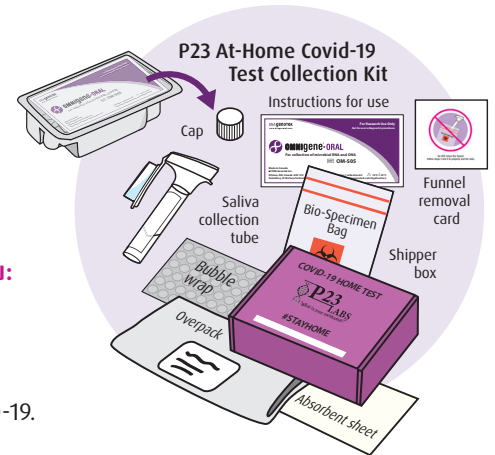
- **If you feel that you are seriously ill, seek immediate medical care from a healthcare professional.**
- **If you feel like you are having a medical emergency, call 9-1-1.**
- **Signs of a serious medical condition include, but are not limited to: severe shortness of breath or difficulty breathing, coughing up blood, chest pain, irregular heartbeat, persistent vomiting or diarrhea.**

The P23 At-Home Covid-19 Test Collection Kit may be right for you, if you:

- Are currently experiencing COVID-19 symptoms.
- Live in or recently traveled to an area with an ongoing spread of COVID-19.
- Have been in close contact with a person known to have COVID-19.
- Think you have been exposed to COVID-19.
- **Note:** This P23 At-Home Covid-19 Test Collection Kit can be used for healthcare provider-collected saliva, self-collection in a healthcare setting, self-collected at-home via telemedicine and self-collected at-home unsupervised.

The P23 At-Home Covid-19 Test Collection Kit may **NOT** be right for you, if you:

- Currently have severe symptoms that limit your daily activities. Seek medical attention right away if this is the case.
- Do not have symptoms and have not been exposed to COVID-19.
- Do not have symptoms and have not been to an area with ongoing spread of COVID-19.



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.

How does the P23 At-Home Covid-19 Test Collection Kit work?

The P23 At-Home Covid-19 Test Collection Kit provides you with a way to get tested for the virus from the comfort and security of your own home by providing a saliva specimen. No trip to the doctor's office or other healthcare provider is required to get COVID-19 testing.

- 1 Complete the COVID-19 Medical Questionnaire:** Visit www.P23Labs/covid19 to complete a short health screening questionnaire online to determine your risk of contracting the disease.
- 2 Order kit:** Purchase the P23 At-Home Covid-19 Test Collection Kit on the website. Once your order has been placed, P23 Labs will send the COVID-19 test kit, registered with your unique barcode, to your home.
- 3 Collect specimen:** The P23 At-Home Covid-19 Test Collection Kit includes everything you need to collect your saliva specimen, including easy to understand instructions. Watch the video (see link on the next page) to learn more about how to collect your specimen.
- 4 Send to the lab:** After your specimen is collected, send it back in the pre-paid packaging for processing within 24 hours of collection. Drop off the sealed return overpack containing your specimen at the closest Fedex or UPS or other approved logistics company depot BEFORE the last pickup of the day.
- 5 Get your result:** You will receive an email notification when your result is ready and you can access it online in your secure P23 account. After receiving your COVID-19 result, you have the opportunity to talk to a licensed physician who can answer any questions you may have about your result.





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

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.

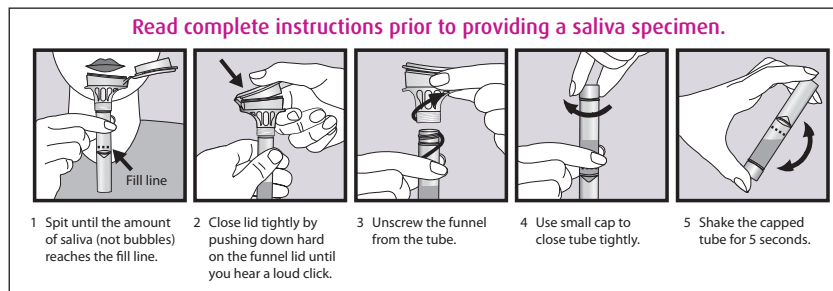
You can find additional guidance at:

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. Specimen collection

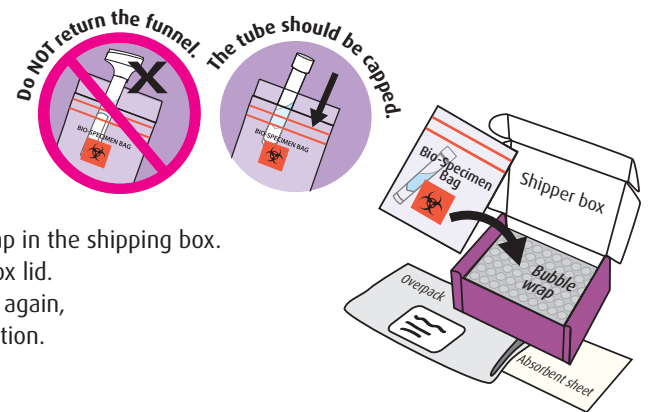
- IMPORTANT:** Wash your hands **thoroughly for 20 seconds** then dry your hands **before** starting the collection.
- Open your P23 At-Home Covid-19 Test Collection Kit and place all of the contents on a clean, dry surface.
- Remove the saliva collection device from its packaging and collect your specimen.



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

Step 2. Specimen shipping preparation

- 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.
- Place 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.**



Step 3. Results are ready within 72 hours

Your results will be available in your secure patient portal and a part of your Electronic Medical Record (EMR), at your physician's request.

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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