



SALIVA DIRECT™

HOW TO COLLECT SALIVA FOR COVID-19 TESTING

Collection instructions for using a Funnel

Before you begin

This test is designed to test saliva that naturally pools in your mouth (for example when you think about a delicious meal).

It is very important that you do not try to force yourself to produce a saliva sample. Please do not cough anything up from your chest and please don't sniff anything back from your nose and into your mouth.

For at least 30 minutes before saliva collection, it is important that you **DO NOT**:

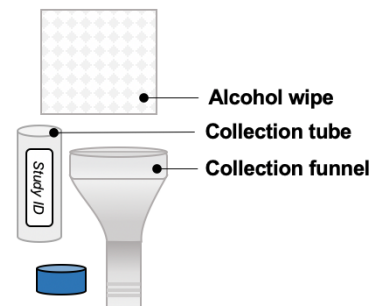
1. Eat or drink
2. Smoke
3. Clean your teeth
4. Chew gum
5. Use nasal sprays

Doing any of these activities could cause you to get an incorrect result.

Collection kit materials

In addition to these instructions, you should receive:

- One (1) identifying information form
- One (1) labeled screw-cap collection tube
- One (1) Funnel
- One (1) single-use alcohol wipe
- One (1) biohazard bag



How to collect saliva

Before providing your sample, first carefully read through the instructions below to familiarize yourself with how to provide a good saliva sample for testing.

1. Wash your hands with soap and water for at least 20 seconds or clean them with alcohol-based sanitizer.

2. Remove everything from the collection kit, place them in front of you and set the bag aside. Avoid touching the inside of the funnel.
3. Confirm that the label either on the outside of the kit or on the collection tube matches your personal details. If the kit is labeled and the collection tube has a blank label, fill in the information requested (name, date of birth, etc.) on the collection tube label.
4. Record your name, date of birth and the collection date and time on the identifying information form
 - **NOTE: if you do not record these details, your sample may not be accepted for testing.**
5. Pick up the funnel and the collection tube and position yourself as shown:



6. Swallow once to clear your mouth.
7. Imagine eating your favorite food, think about an upcoming meal or even a sour lemon and allow saliva to pool in your mouth – be patient and this will start to collect!
 - **Remember to avoid coughing or sniffing.**
8. Hold the funnel up so that it surrounds your mouth and gently release the saliva that has pooled in your mouth into the funnel.
 - **Please do not 'spit' as this can cause droplets or aerosols to spray out at you.**
9. The goal is to collect enough saliva so the tube is half-filled. Please note that any bubbles that may also collect in the tube do not count towards the final volume.
 - **You may have to repeat this process a couple of times until the tube is half-full.**
 - **Be patient, don't force it and just keep thinking about food and you'll get there!**
10. Once you have collected enough saliva, unscrew the funnel from the collection tube and tightly screw the cap back onto the collection tube.
 - **Ensure the cap is secure before proceeding to the next step.**
11. Use the alcohol wipe to wipe your hands and the collection tube, but **DO NOT** wipe the printed part of the label.
12. Place the closed collection tube into the biohazard bag.
13. Discard the alcohol wipe and used funnel.
14. Wash your hands thoroughly with soap and water or clean them with alcohol-based sanitizer.
15. Return your sample to the collection point specified by your healthcare provider or testing laboratory, making sure to keep your sample out of direct sunlight.

If you have any questions during this process, please call [DESIGNATED LAB SHOULD INSERT PHONE NUMBER] or email [DESIGNATED LAB SHOULD INSERT EMAIL ADDRESS].

WARNINGS:

- 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 collection and maintenance of saliva specimens as an aid in the 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 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 authorization is revoked sooner.