



SalivaDirect Sample Collection

This protocol details the procedure for collecting saliva for SARS-CoV-2 detection, under the observation of a healthcare professional. The 'sample provider' is the individual providing saliva for testing by SalivaDirect and may include patients or research study participants, and the 'sample collector' is the individual providing supplies and instructions and observing the collection.

Before you begin

Before collecting a sample, first carefully read through this overview to familiarize yourself with how to provide clear guidance for the collection of a good saliva sample for testing by SalivaDirect.

Important notes on saliva collection

- The **sample provider** should only remove their mask when ready to pass their sample into the collection tube, replacing it immediately after sample collection.
- The **sample collector** must maintain 6 feet of distance from the individual providing the sample.
- SalivaDirect tests the saliva that is normally present in the mouth.
 - Samples should be clear to white in color.
 - **Coughing or sniffing before or during sample collection must be avoided.**
 - **Do not use the word 'spit' as this is an action that must be avoided.**
 - **Words such as 'dribbling' or 'drooling' better describe the process.**
 - Saliva should instead be gently expelled from the mouth into the collection tube.
- No water should be consumed by the sample provider for at least 10 minutes prior to collection.
- Other drinks, food, smoking, nasal sprays, teeth cleaning and chewing gum should be avoided for at least 30 minutes before sample collection.
- **Doing any of these could interfere with the test and lead to a false negative result.**

How to collect a good saliva sample

1. Prior to sample collection, you will need to confirm the identity of the **sample provider** and that an acceptable sample will be collected.
 - Your testing laboratory will inform you what details should be collected to confirm the identity of the **sample provider**.
 - i. This may include asking for their name, date of birth, or seeing a photo ID.
 - ii. Be sure to confirm what questions need to be asked with your testing laboratory.
 - Important questions relating to sample collection include:
 - i. When is the last time you ate or drank anything?
 - ii. Have you chewed any gum or had any candy in the last 30 minutes?
 - iii. When did you last clean your teeth or use mouth wash?
 - If needed, have the **sample provider** take a drink of water to clean out their mouth and wait 10 minutes before proceeding with collection.

2. The **sample collector** must don PPE (surgical or N95 mask, nitrile or latex gloves) prior to contact with the **sample provider**.
3. The **sample provider** must clean their hands using alcohol-based sanitizer or soap and water (no fragrances).
4. The **sample collector** will ensure all collection materials are labelled with the correct identifying information by verifying with the **sample provider**.
5. The **sample collector** can encourage saliva production by telling the **sample provider** to think about food (favorite foods, upcoming meals, something sour etc.). Even just thinking about the saliva collection itself can help to stimulate production.
 - Thinking about this while preparing to collect the sample can help ensure enough can be pooled in the mouth quickly and easily.
6. The **sample collector** will give the collection container to the **sample provider**.
7. The **sample collector** will ask the **sample provider** to remove one side of their mask.
8. The **sample provider** will remove the lid of the collection container and gently expel saliva into the collection tube until at least 0.5 mL has been collected.
 - The total volume measured is to exclude any bubbles.
 - **Reminder:** this is the collection of normal saliva, sniffing or coughing up deeper material must be avoided.
9. If the **sample provider** is struggling to produce a sample, have them close the tube, replace their mask and take a few minutes to relax and pool more saliva into their mouth, before trying again.
10. If anything other than saliva is collected (e.g. mucus, a lot of food particles), dispose of the sample in a sealed biohazard bag in a biohazard container, wait a few minutes and start the process again.
11. Once at least 0.5 mL has been collected, the **sample provider** will securely replace the lid of the collection container.
12. The **sample provider** must again clean their hands using alcohol-based sanitizer or soap and water.
13. The **sample collector** will sterilize the collection tube with 70% ethanol or a disinfecting wipe.
14. The **sample collector** will register the sample collection and place the sample in a secondary container or a biohazard bag with a biohazard label.
15. The **sample collector** will transfer samples at room temperature to the laboratory for sample processing. The virus RNA in saliva remains stable at room temperature for at least 7 days.
16. If cold storage is available: to mitigate fluctuations in temperatures, samples can also be stored at 2-8°C until sample transport or processing (up to 7 days) or at -80°C for longer term storage.

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

The emergency use of 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 Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.