

How to collect **saliva** for COVID-19 testing

In these instructions you will find information about SalivaDirect™, the specimen collection process, and instructions to ship the kits back to Tempus Labs.

Intended Use

SalivaDirect™ is a real-time reverse transcription polymerase chain reaction (rRT-PCR) test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in saliva collected without preservatives in a sterile container in the presence of a trained observer (adult trained on how to collect saliva samples) from individuals suspected of COVID-19 by their healthcare provider. This test is also intended for use in individuals without symptoms or other epidemiological reasons to suspect COVID-19.

Warnings and Precautions

For in vitro diagnostic use (IVD). Rx Only.

This test has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories.

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.

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.

Prior to Specimen Collection

- The patient should avoid other drinks, food, smoking, nasal sprays, teeth cleaning and chewing gum for at least 30 minutes before sample collection. Engaging in any of these activities can result in an incorrect result.
- Note: This test is designed to test saliva that naturally pools in the mouth. It is important to follow these instructions so that only saliva that naturally pools in the mouth, not sputum (mucus), is collected.
- Coughing anything up from your chest or sniffing back from your nose and into your mouth immediately prior to sample collection must be avoided.
- Do not use the word 'spit' as this is an action that must be avoided.
- Saliva collection should instead be similar to 'drooling' or 'dribbling'.
- Write the patient's Date of Birth on the sticker, before peeling it off from the backing. Without covering the barcode label, apply the sticker to the tube. Without a legible second identifier, the sample will not be processed.

COLLECTION KIT CONTENTS

- 1 Funnel
- 15mL Collection Tube
- 1 Biohazard Specimen Bag with Absorbent Pad
- 1 Alcohol Prep Pad
- 1 Patient Identifier Sticker
- Prelabeled Fedex Clinical Box

Order Placement

Please note that specimen collection information is required to complete the order.

- Visit on your computer or mobile device clinical-portal.securetempus.com/ and login with your credentials.
- Follow the prompts to add all relevant information to the Order Form.
- Once the sample information is entered, submit the order and ensure you see the confirmation screen.

Sample Collection

- 01** The patient must wash their hands with soap and water for at least 20 seconds or clean them with alcohol-based sanitizer.
- 02** Have the patient unscrew the cap of the collection tube and screw on the funnel to the top of the collection tube, ensuring that they do not touch the inside of the funnel.
- 03** Have the patient hold the tube so that it surrounds their mouth and gently release the saliva which has pooled in their mouth into the funnel. Ensure the patient does not "spit."
- 04** Have the patient collect at least enough saliva so the tube is half-filled (or at least 0.5mL).
 - Any bubbles that also collect in the tube do NOT count towards this total volume.
 - If the patient is struggling to produce a sample, have them close the tube and take a few minutes to relax and try to pool more saliva into their mouth, before trying again.
 - If anything other than saliva is collected (e.g. mucus, a lot of food particles), dispose of the sample, wait a few minutes and start the process again, using a new tube, funnel and Date of Birth sticker.
- 05** Once at least 0.5mL of saliva has been collected, have the patient unscrew the funnel from the collection tube and tightly screw the collection tube cap back onto the collection tube. The funnel should be discarded.
- 06** Ensure that the cap of the collection tube is closed tightly and wipe the outside of the collection tube with the alcohol prep pad. DO NOT wipe the printed part of the patient identifier label, as this may damage or smudge the label. Discard the alcohol wipe.
- 07** Place the collection tube into the biohazard bag and seal.
- 08** Have the patient wash their hands with soap and water for at least 20 seconds or clean them with alcohol-based sanitizer.

Shipping

All samples should be kept out of direct sunlight.

- 01** Place all samples, in their individual biohazard bags, into a provided Fedex Clinical Box or other IATA compliant box. It is recommended that you do not place more than 30 bags containing samples in each box.
- 02** Close the cardboard box and seal carefully.
- 03** Return to your FedEx drop-off location, or call 1-800-GoFedEx for pick-up.

QUESTIONS?

Reach out to your account executive or partnership operations lead, or contact Tempus Labs at covidsupport@tempus.com or 800.739.4137.