

Mount Sinai SARS-CoV-2 Collection Kit Instructions

Warnings and Precautions

Read all instructions before you start collecting saliva specimen. You must identify the sample drop-off location and drop-off schedule from the kit registration online portal before you start collecting saliva specimen.

Inadequate saliva sample collection, improper handling or transport may lead to sample rejection. Specimen may be rejected if tube is leaking or damaged during transport.

After saliva sample collection, samples should be dropped off within 36 hours. Samples received after 36 hours will be rejected. Specimen that is not collected correctly may lead to incorrect test results.

Small cap may pose choking hazard; keep out of reach of children when not in use.

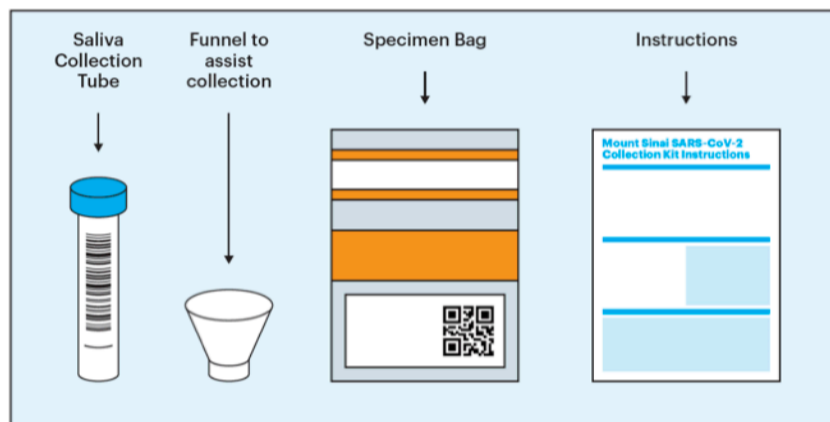
The Kit should be stored at room temperature and in a cool, dry place.

How to Register on the Platform

- Log into the online portal c19dropbox.com using the credentials provided to you by email.
- Once logged in, click on "Provide Consent" and follow all the prompts in the portal to complete the kit registration process.
- After completion, make a note of the drop off location and timing as indicated in the portal before collecting the saliva sample.



Saliva Collection Kit Contents

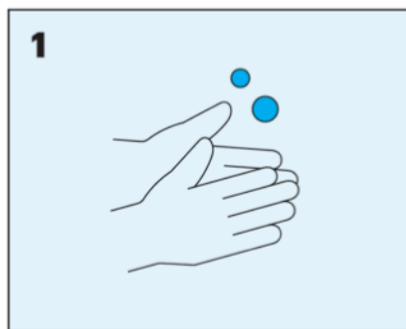


How to Collect the Saliva Sample

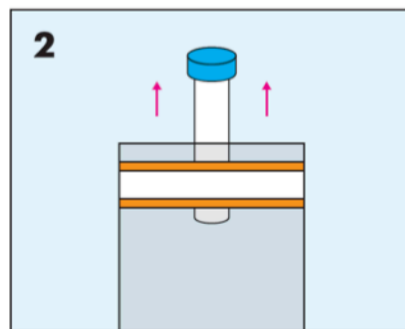
The saliva sample is self-collected by the person being tested.

While the sample collection process is very simple, adults may help minors. Adults assisting the saliva collection from minors/seniors can perform all the steps except saliva collection (Step 5 and 6).

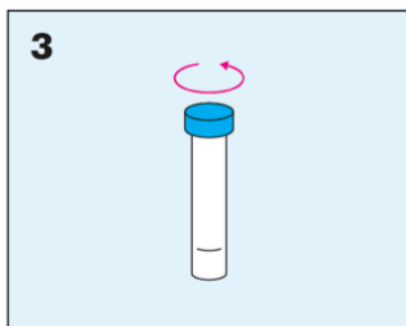
Do not drink, eat, smoke, or chew gum 30 minutes before saliva collection.
Do not mouthwash or brush teeth 2 hours before saliva collection.



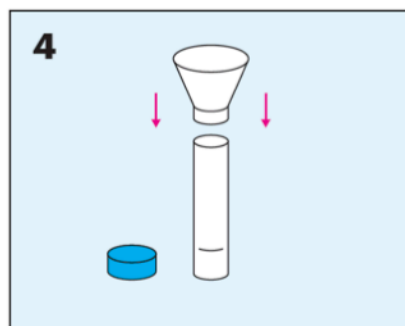
Please wash and dry, or sanitize, your hands.



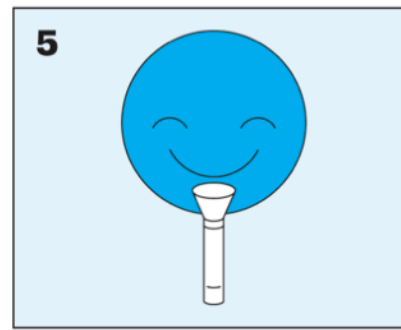
Remove the saliva collection tube from the specimen bag.



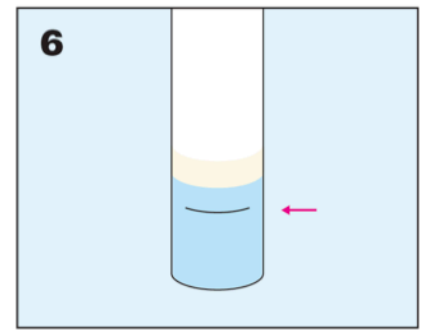
Unscrew tube cap and place the cap on a clean surface.



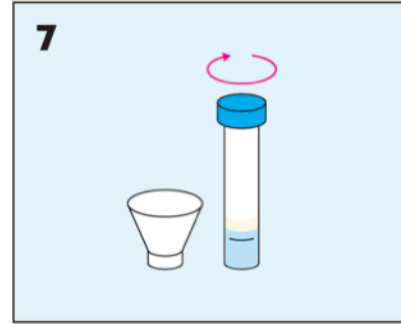
Attach funnel to assist saliva collection.



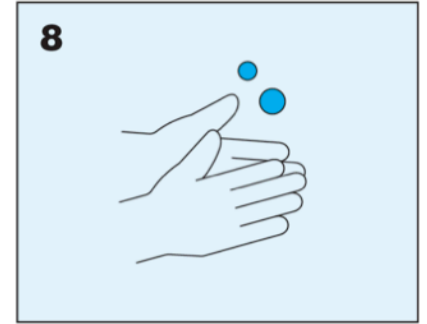
Pool saliva in mouth then drool into the funnel and tube. Repeat as many times as necessary to collect required amount of saliva.



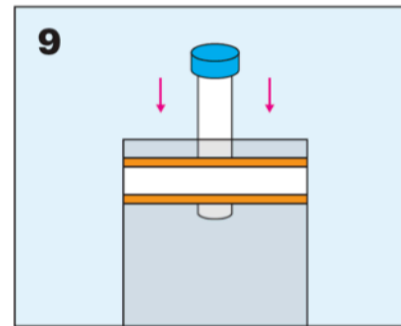
Please make sure you have filled the tube with saliva at least up to the fill mark (red arrow).



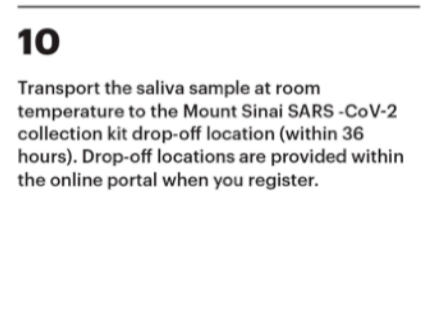
After collection, discard the funnel and close the tube tightly.



Wash and dry, or sanitize, your hands after capping the tube before re-packaging.

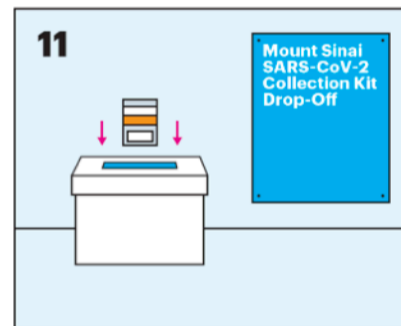


Place the tube in the specimen bag and seal the bag tightly.



10 Transport the saliva sample at room temperature to the Mount Sinai SARS-CoV-2 collection kit drop-off location (within 36 hours). Drop-off locations are provided within the online portal when you register.

How to Collect the Saliva Sample



At the drop off location, scan the collection kit barcode in the kiosk by using the same online portal c19dropbox.com and drop the sample in the drop off box. Mount Sinai Collection site specialist is available onsite for any assistance.

Regulatory Warnings

For In Vitro Diagnostic Use Only.

For Emergency Use Authorization Only.

For Rx Only

For use by individuals 18 years of age and older when self-collected

For use by individuals 14 years of age and older when self-collected under adult supervision

For use by individuals 5 years of age and older when collected with adult assistance

This product 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 product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.

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 Cosmetics Act, 21 U.S.C. § 360bbb-3(b) (1), unless the declaration is terminated or authorization is revoked sooner.

Contact

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