

Wren Laboratories, 688 East Main Street, Branford, CT 06405 Tel: (203) 208-3464
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For Use Under Emergency Use Authorization Only.

For more information about the Wren Covid-19 PCR Test visit www.wrencovidtesting.com

To view Wren Laboratories complete Terms & Conditions, please visit:
www.wrencovidtesting.com/termsandconditions

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; 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.

WARNING

- For use by individuals 18 years and older (self-collected)
 - For use by individuals 14 years and older (self-collected under adult supervision)
 - For use by individuals 5 years and older (collected with adult assistance)
- For any questions, please contact Wren Laboratories at covid@wrenlaboratories.com.
www.wrencovidtesting.com.
(fact sheets, additional instructions), can be downloaded at

Additional Information

Follow directions for use.
Do NOT ingest the stabilizing buffer.
Keep out of reach of children.
Avoid contact with skin and eyes.
If the stabilizing buffer comes in contact with the body, rinse with water. If irritation persists, seek medical advice. It is recommended to use gloves and eyewear when performing the collection procedure.

Welcome to your Wren Laboratories COVID-19 Saliva Test Collection Kit



Your test kit includes the following **components**:

- Paper requisition
- Saliva collection device
- A shipping box
- 2 sealing strips
- A pre-paid return label
- A Biohazard Specimen Bag with absorbent material.

Do not discard biohazard bag. Required for return shipping.

Instructions for use

Step 1: Register Your Test Kit. Use your smartphone camera to scan the QR Code on the enclosed tube. This will take you to a website where you will be prompted to enter your information as directed.

(In case you cannot use a smartphone to enter your personal data and complete the online requisition form, please visit: www.wrencovidtesting.com/start or you can use the paper requisition).

STOP Do not start the saliva collection process before you have completed the registration of your test kit.

Once registration is complete, open your test kit and place all contents on a clean, dry surface. **Now go to Step 2.**



Note: An instructional video demonstrating the saliva collection process is available online (www.wrencovidtesting.com).



Do not eat, drink (even water), brush your teeth, or smoke, for 30 minutes prior to collecting your saliva sample. If you have trouble collecting enough saliva gently rub the outside of your cheeks, just behind your back teeth while performing chewing motions with your mouth.

Collect enough saliva to fill at least up to the red line as marked on the tube.

Step 2: Collecting Saliva Sample

Your sample must be returned/shipped on the same day it was collected to ensure timely receipt at the laboratory for processing.



Attach the funnel to the tube (screw it on gently) until fully attached.



Collect your saliva sample. Fill the tube until the saliva (not including bubbles) is just above the red line. Do not overfill.



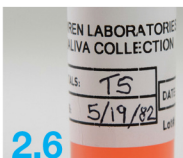
Remove the funnel from the tube and discard the funnel.



Firmly screw the cap down onto the tube. This will release the red solution and seal the tube. You will know this has worked because your saliva will change color. **Firmly tighten the cap to ensure the cap and tube are completely sealed.**

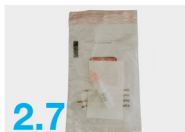


Shake the tube gently for 10 seconds. This will guarantee your sample mixes thoroughly with the stabilizing solution.



WARNING: DO NOT OPEN OR REMOVE CAP ONCE SEALED

Write your initials, date of birth and today's date on the collection tube label using either pen or pencil.



Place the collection tube into the Biohazard Specimen Bag with the absorbent material. **Do not remove any absorbent material from the bag.** Place the paper requisition (if applicable) in the Biohazard Specimen Bag and seal. Wash and dry your hands thoroughly before moving on to Step 3.

Step 3: Ship Sample via FedEx



Place the Specimen Bag with the collected sample into the box.



Attach the pre-paid return shipping label to the top of the box. Write your name under the order number.



Important! Record your FEDEX tracking information in the box below before shipment. Keep this document for your records.



Seal the Box using the two enclosed strips on each side of the box. Deliver the box to a **FedEx drop box** or to a **FedEx location.**

Tracking Information Here

3.5 Your results will be emailed to you and your HCP. If positive, presumptive positive, or invalid, you will be contacted by your HCP for a recommended course of care and follow-up.