



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).

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.

- Instructions for use**
- A Biohazard Specimen Bag with absorbent material.
 - 2 sealing strips
 - Saliva collection device
 - Fact Sheet for Individuals
 - Pre-paid/pre-addressed return label
 - Shipping box
- Your test kit includes the following **components**:

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

Additional Information

(fact sheets, additional instructions), can be downloaded at www.wrencovidtesting.com.

For any questions, please contact Wren Laboratories at covid@wrenlaboratories.com.

- 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)

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.

WARNING

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 home collection and maintenance of saliva specimens as an aid in 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 medical devices 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.

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

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

Wren Laboratories, 688 East Main Street, Branford, CT 06405 Tel: (203) 208-3464

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For Use Under Emergency Use Authorization Only.



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.



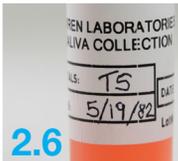
Remove the funnel from the tube and discard the funnel.



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.** Seal the Biohazard Specimen Bag. 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. If positive, presumptive positive or invalid, you will be contacted by a HCP for a recommended course of care and appropriate follow-up action.

Wren Saliva Test Kit Sleeve Template



Expiration Date:

Scan for Information about This Product



For IVD use. For use under emergency use authorization only. WREN Laboratories offers this product with a FDA Emergency Use Authorization (EUA). This means that 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 home collection and maintenance of saliva specimens as an aid in 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 medical devices 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. Store at room temperature.

Receive Your Results Fast and Online

Easily Collect Your Saliva Sample and Ship

Register Your Kit Online

The use of this test kit requires access to the internet and an email account.

- Your kit includes:
- Instructions
 - Mouthpiece
 - Collection tube
 - Cap
 - Biohazard bag with absorbent material
 - 2 sealing strips
 - Fact Sheet for Individuals
 - Return shipping box
 - Pre-paid/pre-addressed FedEx return label



For Ages 5 years+

WREN LABORATORIES COVID-19 SALIVA TEST COLLECTION KIT DTC

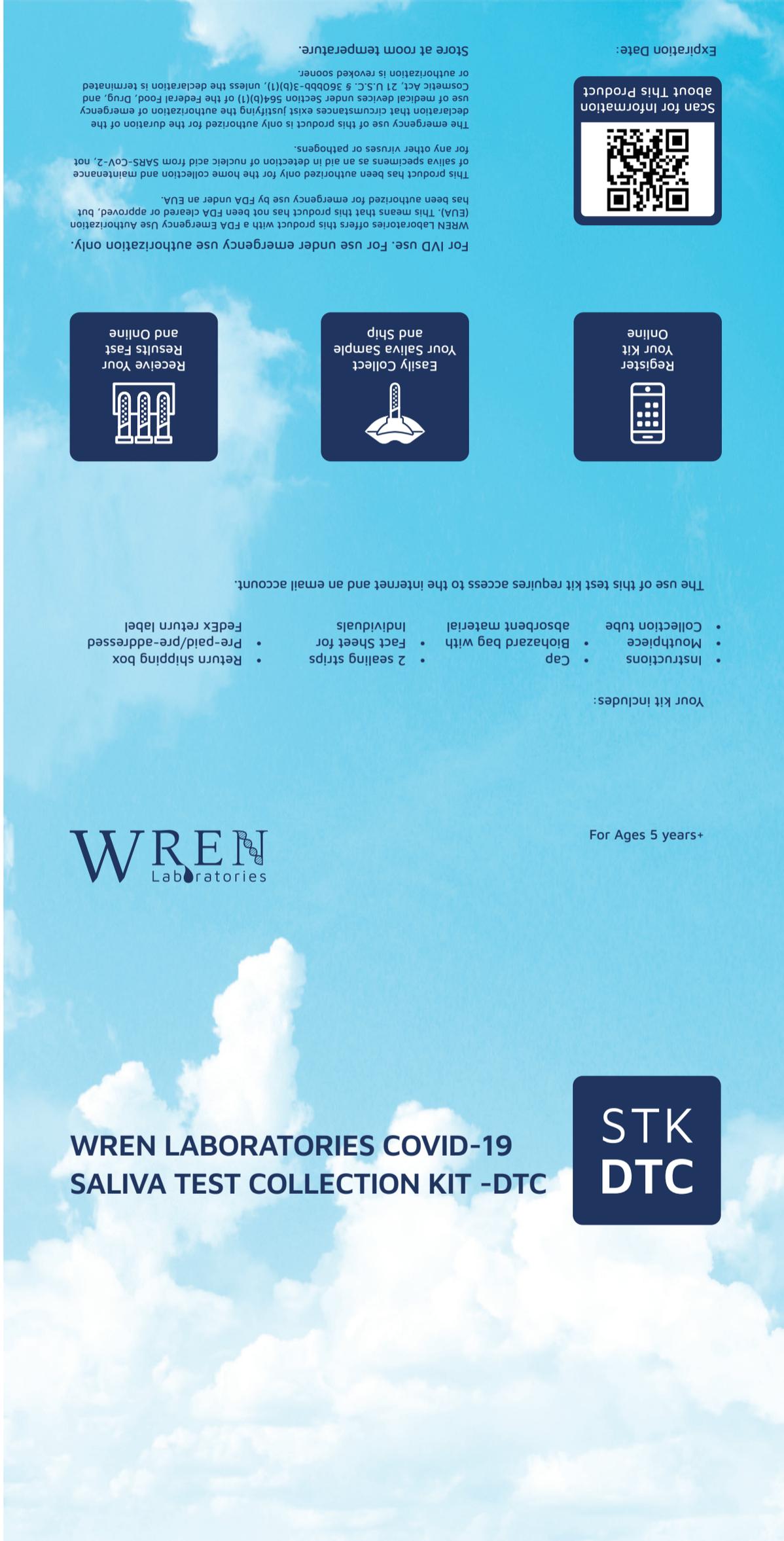


CMYK: 56,0,5,0
Pantone: 310C

CMYK: 95,84,34,28
Pantone: 648C

CMYK: 0,0,0,0
White

Wren Saliva Test Kit Sleeve Template



For Ages 5 years+

WREN LABORATORIES COVID-19 SALIVA TEST COLLECTION KIT -DTC



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