

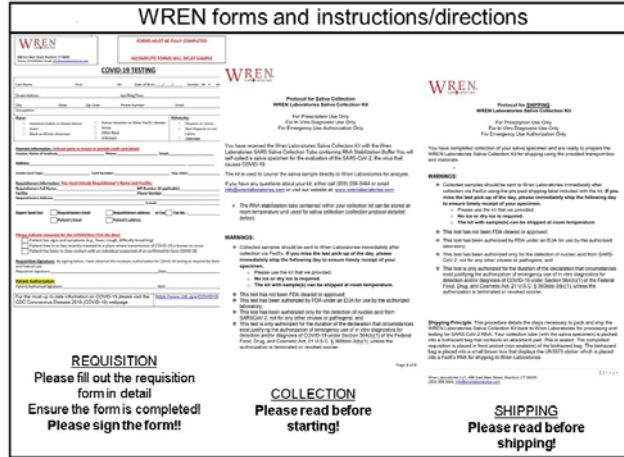
WREN Laboratories Saliva Collection Kit

*For Prescription Use Only
For In Vitro Diagnostic Use Only
For Emergency Use Authorization Only*

You have received the WREN Laboratories Saliva Collection Kit. You will self-collect a saliva specimen that will be shipped to WREN Laboratories for COVID-19 testing. Please ship your sample the same day it is collected to ensure timely receipt and processing. Your sample can be shipped any day of the week.

Components of the Saliva Collection Kit:

Collection	Shipping
<ul style="list-style-type: none"> ❖ Collection mouthpiece/funnel ❖ Buffer Cap ❖ Collection Tube ❖ Requisition Form ❖ Collection Instructions 	<ul style="list-style-type: none"> ❖ Biohazard bag with absorbent pad ❖ Cardboard box with 2nd absorbent pad ❖ FedEx envelope ❖ Pre-paid FedEx return address label ❖ Shipping Instructions



WARNINGS:

This product has not been FDA cleared or approved;
 This product has been authorized by FDA under an EUA for use by the authorized laboratory;
 This product has been authorized only for the detection of nucleic acid from SARSCoV-2, not for any other viruses or pathogens; and
 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 authorization is terminated or revoked sooner.

If you have any questions about your kit, either call (203) 208-3464 or email info@wrenlaboratories.com or visit our website at: www.wrenlaboratories.com



Wren Laboratories LLC, 688 East Main Street, Branford, CT 06405
(203) 208-3464, info@wrenlaboratories.com

Protocol for SALIVA COLLECTION **WREN Laboratories Saliva Collection Kit**

Detailed Collection Protocol:

DO NOT EAT, DRINK, SMOKE, CHEW GUM, BRUSH TEETH OR USE MOUTHWASH 30 MINUTES PRIOR TO PERFORMING SALIVA COLLECTION.

PERFORMING THESE ACTIVITIES COULD CAUSE A FALSE RESULT.

- ❖ **Before starting, remember to wash your hands thoroughly (with soap and water – for at least 15 seconds).**
- ❖ **Please read all instructions before proceeding.**

Step 1: Complete the requisition form. Please ensure all fields are completed.
***Incomplete forms will delay sample processing and results.**

Step 2: Using an ordinary pen or marker, write your initials, your date of birth (DOB) and today's date on the white label on the tube.

Step 3: Gently screw the collection mouthpiece onto your labeled tube.

Step 4: Pool saliva in your mouth.

- a. Bring the mouthpiece to your lips.
- b. Gently release the saliva into the mouthpiece which will enter into the attached collection tube.
- c. Allow the saliva to collect in the tube until the **red** line mark is reached (at 0.5ml). Make sure that the liquid saliva reaches the **red line**; any bubbles should be above the line. This will ensure that a sufficient saliva sample is collected for processing. An insufficient saliva volume could result in a false result or rejection of your sample by the laboratory.

Step 5: Gently unscrew the mouthpiece and discard in regular trash. Gently attach buffer cap containing the sealed red liquid to the top of the tube.

Step 6: Tightly screw the cap onto the tube and ensure the cap is properly tightened.

- a. The red liquid will automatically flow into the saliva collection tube.
- b. Shake the capped tube vigorously 10 seconds to mix saliva sample and buffer.

** The buffer liquid in the cap is an irritant. If you come into contact with the liquid, immediately wash the area with running water and soap for 10 minutes. If irritation persists, seek medical attention.*

Step 7: Wash your hands again (with soap and water – for at least 15 seconds).

Proceed to Shipping Instructions.

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OVERVIEW OF SALIVA COLLECTION

PLEASE ENSURE TO WASH YOUR HANDS THOROUGHLY BEFORE BEGINNING COLLECTION

<p>Step 1. Fill out requisition</p> <p>FORMS MUST BE FULLY COMPLETED INCOMPLETE FORMS WILL DELAY SAMPLE</p> <p>COVID-19 TESTING</p> <p>Please fill out the requisition form in detail Ensure the form is completed! Please sign the form!!</p>	<p>Step 2. Personal Identification information on Tube</p> <table border="1"> <tr> <td>Use a Marker or regular pen</td> <td>Print Initials and date of collection</td> <td>Print Date of birth MM/DD/YYYY</td> </tr> </table>	Use a Marker or regular pen	Print Initials and date of collection	Print Date of birth MM/DD/YYYY	<p>Step 3. Saliva collection device set-up</p> <table border="1"> <tr> <td>Gently screw the mouthpiece onto your labeled tube</td> <td>The tube is now ready for saliva collection</td> </tr> </table>	Gently screw the mouthpiece onto your labeled tube	The tube is now ready for saliva collection	<p>Step 4. Saliva collection step</p> <table border="1"> <tr> <td>Allow saliva to pool in your mouth. Then bring mouthpiece to your lips and gently release saliva into the tube</td> <td>You only need to collect 0.5ml of saliva. Saliva volume should reach the red line on the side of the tube (bubbles OK above the line). If you go a little over, that's OK</td> </tr> </table>	Allow saliva to pool in your mouth. Then bring mouthpiece to your lips and gently release saliva into the tube	You only need to collect 0.5ml of saliva. Saliva volume should reach the red line on the side of the tube (bubbles OK above the line). If you go a little over, that's OK
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<p>Step 5. Setting up the buffer cap</p> <table border="1"> <tr> <td>Gently unscrew and remove the mouthpiece from the tube. Discard mouthpiece into refuse container</td> <td>Take the buffer collection cap (contains red liquid) and gently place it on top of the saliva collection tube</td> </tr> </table>		Gently unscrew and remove the mouthpiece from the tube. Discard mouthpiece into refuse container	Take the buffer collection cap (contains red liquid) and gently place it on top of the saliva collection tube	<p>Step 6. Buffer addition to Saliva Tube</p> <table border="1"> <tr> <td>1. Screw buffer cap clockwise tight onto saliva tube. Red liquid flows into saliva tube</td> <td>2. Shake joined tubes VIGOROUSLY for 10 seconds to mix saliva and buffer</td> </tr> </table>	1. Screw buffer cap clockwise tight onto saliva tube. Red liquid flows into saliva tube	2. Shake joined tubes VIGOROUSLY for 10 seconds to mix saliva and buffer				
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Protocol for **SHIPPING** WREN Laboratories Saliva Collection Kit

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You have completed collection of your saliva specimen and are ready to prepare the WREN Laboratories Saliva Collection Kit for shipping using the provided transport box and materials. No ice or dry ice is required. The kit can be shipped at room temperature.

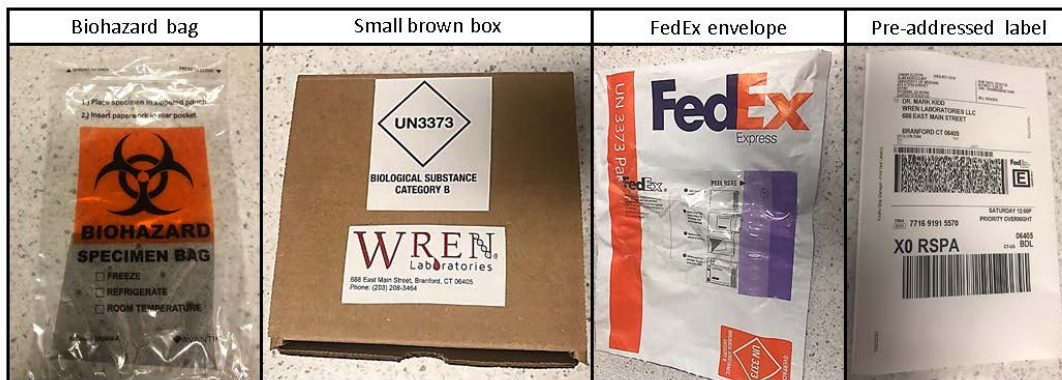
This procedure details the steps necessary to pack and ship the WREN Laboratories Saliva Collection Kit back to WREN Laboratories for COVID-19 testing.

Collected samples should be sent to WREN Laboratories immediately after collection via FedEx using the pre-paid shipping label and envelope included with the kit. If you miss the last pick-up of the day, please immediately ship the following day to avoid further delays in processing.

For a list of FedEx locations near you and the latest drop-off times, please visit:
<https://www.fedex.com/en-us/shipping/dropbox.html>

Supplies and Reagents for Shipping:

- ❖ Biohazard bag with absorbent pad
 - Front pocket for requisition form and collected saliva sample
- ❖ Small brown cardboard box (6.5x6.5x2.5 inches) with 2nd absorbent pad
- ❖ FedEx envelope
- ❖ Pre-paid FedEx return address label



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Detailed Send Out Protocol:

Step 1: Place saliva tube in the biohazard bag that contains the absorbent pad and seal the biohazard bag by removing the adhesive liner and pressing close.

Step 2: Fold and place the signed requisition form in the front pocket of the biohazard bag (non-sealable).

Step 3: Put the biohazard bag (which contains your specimen) into the brown cardboard box.

Step 4: Close the lid of the box. No seal or tape is needed.

Step 5: Put the box into the FedEx envelope.

Step 6: Seal the envelope by removing the adhesive tape.

Step 7: Place the pre-paid return address label in the sleeve on the outside of the envelope.

Step 8: Your sample is ready to be shipped. Please drop the sealed envelope at your nearest FedEx store.

