

AZOVA COVID-19 Test Collection Kit for use with the Advanta™ Dx SARS-CoV-2 RT-PCR Assay

For use under FDA emergency use authorization only

Self-Collection Kit Instructions for Patients



Do not eat, drink, smoke, chew gum, or use oral products such as toothpaste and mouth rinse or nasal gel products for at least 30 minutes prior to collecting the saliva specimen.

IMPORTANT: SHIP BACK YOUR SALIVA SPECIMEN THE SAME DAY IT WAS COLLECTED.

FOR IN VITRO DIAGNOSTIC USE

FOR RX USE ONLY • FOR INDIVIDUAL USE ONLY

CHILDREN UNDER 18 YEARS OF AGE

MAY USE THIS TEST UNDER ADULT SUPERVISION

FOR EMERGENCY USE AUTHORIZATION ONLY

AZOVA™
We Make Healthcare Simple



FLUIDIGM™

This home collection kit has not been FDA cleared or approved but has been authorized for emergency use under an EUA (Emergency Use Authorization). The emergency use of this home collection kit in combination with the Advanta Dx SARS-CoV-2 RT-PCR Assay is only authorized for the duration of the declaration that circumstances exist justifying the 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.



Before You Begin

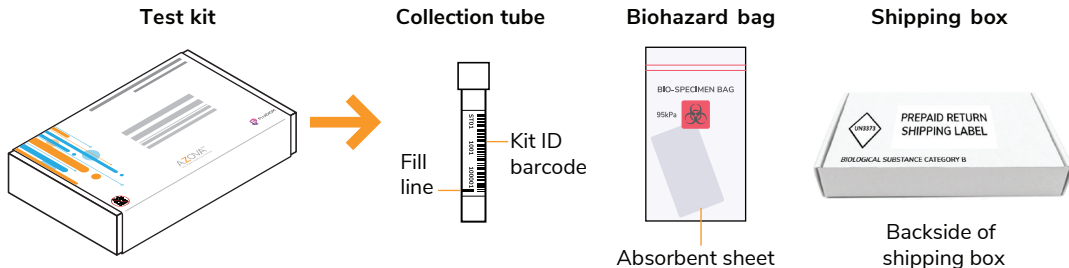
Your kit comes with prepaid same-day shipping with UPS®. UPS does not ship on Sunday, therefore do not collect your saliva sample on Sunday.

To find a UPS Store near you, go to www.theupsstore.com/tools/find-a-store

IMPORTANT: Ship back your saliva specimen on the same day it was collected.

Step 1: Inspect Your Kit

Inspect your test kit to ensure all components are included: the collection tube with test kit ID barcode and cap, biohazard bag with absorbent sheet, and the original shipping box with the attached prepaid return shipping label.



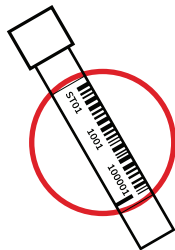
NOTE: Take a photo of your test kit ID barcode and the return shipping label for your records.

Step 2: Register Your Test Kit When You Take Your Test



- If you are taking your test under video observation, register your kit while you are on the video call.
- If you purchased a kit without the video observation, register your test kit when you are ready to take your test.

To register your test kit, go to **www.register.azova.com** and enter the 14-digit code found on your tube. This links your specimen with your test results. The date and time that you do this will be reported as the collection time on your test report. **You will not receive results without doing this step.**



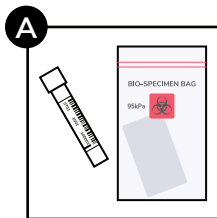
Step 3: Collect Your Saliva Specimen

Read the following instructions completely prior to collecting your saliva specimen. You may complete your specimen collection on your own, with video observation, or under the supervision of a health care provider.

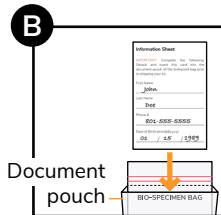
IMPORTANT: Do not eat, drink, smoke, chew gum, or use oral products such as toothpaste and mouth rinse or nasal gel products for at least 30 minutes prior to collecting the saliva specimen.



NOTE: Children under 18 years of age may use this test under adult supervision.

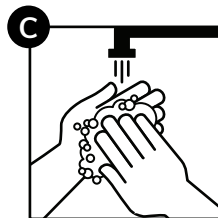


When you are ready to collect your sample, place all contents on a clean, dry surface. Do not open the biohazard bag at this time.

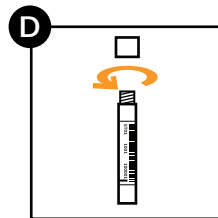


Complete the information sheet on the perforated section of page 5 and place it in the external document pouch of the biohazard bag.

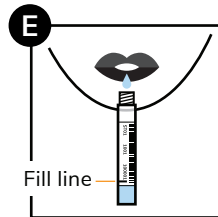
IMPORTANT: Without the information sheet, testing may be delayed or may not occur.



Wash your hands thoroughly for 20 seconds, then dry your hands before you collect your saliva specimen.

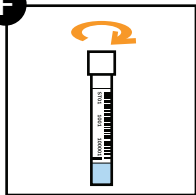


Remove the cap from the collection tube and set it aside on a clean surface. **DO NOT DISCARD CAP.**



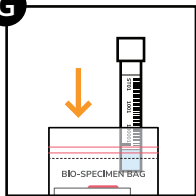
Fill the tube with saliva (not including bubbles) up to the black fill line.

F



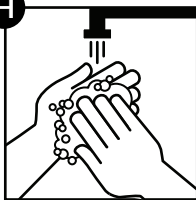
Firmly screw on the cap to seal the tube. Ensure that the cap is sealed tightly on the tube.

G



Place the tube into the biohazard bag and seal the bag shut. Do not remove the absorbent pad from the bag.

H



Wash your hands thoroughly for 20 seconds, then dry your hands before you place the biohazard bag into the shipping box in Step 4.

Information Sheet

IMPORTANT: Complete all the following. Detach and insert this sheet into the external document pouch of the biohazard bag prior to shipping your kit. All fields are required.

First and Last Name

Spell your name exactly as it will appear in your AZOVA account.

Email

Phone #

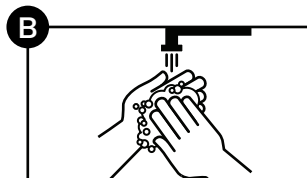
Date of Birth (mm/dd/yyyy)

____/____/____

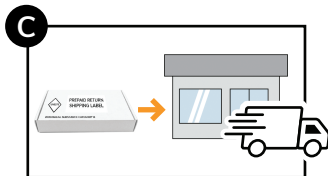
Step 4: Send Back Your Saliva Specimen



Place the biohazard bag into the original shipping box with the prepaid return shipping label attached to it and seal the box flap by peeling the adhesive strip.



Wash your hands thoroughly for 20 seconds again, then dry your hands.



Deliver the sealed, prepaid, pre-addressed shipping box to the UPS Store location before the cutoff time for shipping that day.

IMPORTANT: Ship back your saliva specimen on the same day it was collected.

Step 5: Get Results 12 to 72 Hours After the Lab Receives the Kit



Your results will be sent to you electronically through AZOVA. You will receive an email and SMS with a link to view your results on the AZOVA app or website. If your results are positive or if you have questions, please contact your health care provider. You can get an online video, telephone, or secure messaging visit with a doctor or other health care provider at **www. azova.com**.

Your results will come within **12–72 hours from the time the lab receives your test**. Weekends and holidays may increase lab processing times.

NOTE: These instructions contain personalized barcoded information that will be associated with your test result. Therefore, please keep these instructions with your personal records.





Manufacturer:
Apply Code Here

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