### Step 1: Inspect and Register Your Test Kit



Once you have received your test kit, complete the following steps:

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



2. On the day you collect your saliva specimen, go to www.register.azova.com to register your test kit ID barcode. This will link your specimen with your order and test results. Your test report will show the collection date as the date you register your kit.



3. Complete the Information Sheet on the perforated edge of the instruction card and place in the document pouch of the biohazard bag.

# **Step 2: Collect Your Saliva Sample**

You may complete your specimen on your own or under the supervision of a healthcare provider. Avoid collecting and sending back samples on the weekend.

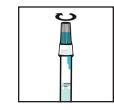
- IMPORTANT: Do not eat, drink, smoke, or chew gum 30 minutes before collecting your saliva specimen. Wash your hands thoroughly for 20 seconds then dry your hands before starting the collection.
- Open your kit and place all the contents on a clean, dry surface. Remove the saliva collection device from its packaging and collect your specimen.



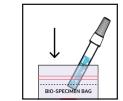
1. Fill the tube with saliva to the black wavy 2. Replace the funnel with the fluid cap. line. Fill the tube until your saliva (not including bubbles) is at or just above the wavy line. DO NOT OVERFILL.



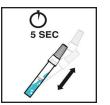
Remove the funnel from the tube. Screw on the enclosed cap **TIGHTLY** to release the solution that will stabilize the DNA in your saliva.



3. Firmly screw cap down to release solution and seal tube. You will know it works when the blue solution from the cap is released into the tube. Firmly tighten cap to assure the cap and tube is completely sealed.

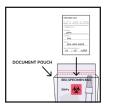


5. Place the tube into the biohazard bag and seal the bag shut.



4. Shake the tube for at least five seconds.

This will ensure your sample mixes thoroughly with the stabilizing solution.



6. Complete the information sheet on the perforated section of the instruction card and place in document pouch of the biohazard bag.

Information	Sheet
IMPORTANT:	Complete

IMPORTANT: Complete the following. Detach and insert this sheet into the document pouch of the biohazard bag prior to shipping your kit.

First	Name
11136	Ivallic

Last	Name	

Phone #

Date of Birth (mm/dd/yyyy)

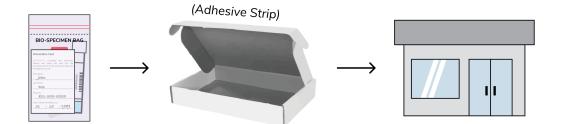
/		
/		
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IMPORTANT: Read complete instructions prior to providing a specimen.

# 801-555-5555 DOCUMENT POUCH

Complete the other side of this form and insert this card in the document pouch of the biohazard bag.

## **Step 3: Send Back Your Saliva Sample**



- IMPORTANT: Wash your hands thoroughly for 20 seconds again, then dry your hands before placing the biohazard bag into the return shipper. 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 again and deliver the sealed, prepaid, pre-addressed shipping box to the specified carrier's store location. IMPORTANT: Ship your sample the SAME day you take your sample. Do not deliver sample to a drop box on the weekend.
- 3. IMPORTANT: Wash your hands thoroughly for 20 seconds again, then dry your hands.

# Step 4: Results Are Ready Within 72 Hours Once the Lab Recieves the Kit







IMPORTANT: You must register your barcode at

www.register.azova.com. We recommend you

take a photo or copy of the barcode for your

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.

- This test has not been FDA cleared or approved.
- This test has been authorized by FDA under an EUA for use by the authorized laboratories.
- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens
- This test 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.



FDA Authorized | Infinity BiologiX TagPath SARS-CoV-2 Assay

**Self-Collection Kit Instructions for Patients** 



Do not eat, drink, smoke, or chew gum 30 minutes before collecting your saliva specimen.





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