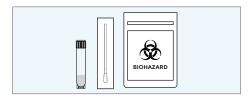


Helix Self-Collection Kit Instructions (Unsupervised)

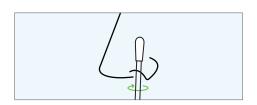
Read ALL steps before collecting your sample. Make sure to collect and drop off on the same day.



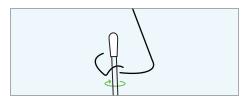
1) You will receive supplies to self-collect your sample. You will collect your sample unsupervised on your own. Wash and dry your hands before starting the self-collection process.



2) When you are ready to collect, take the swab out of its sleeve. Do not touch the tip of the swab with your hands.



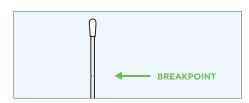
3) Insert the tip of the swab into one nostril. The tip of the swab should no longer be visible. Give the swab a gentle push against the inside of your nose and rotate it in a circle. Rotate the swab at least 3 times.



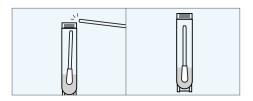
4) Repeat step 4 in your other nostril.



5) After collecting your sample, hold the swab in one hand and screw off the top of the collection tube with the other. Put the tube's top in a safe place because you will need it again.



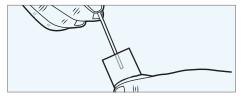
6) Look for the breakpoint on the swab's handle. It is about half way on the handle.



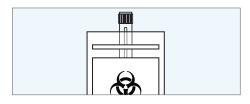
7) Place the swab in the collection tube and break off the swab from its handle at the breakpoint. DO NOT PLACE THE USED HANDLE IN THE BIOHAZARD BAG.



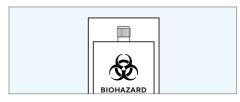
8) Make sure you screw the top back on the collection tube tightly.



 Place the swab's handle back in its sleeve and discard in the trash.
REMINDER: DO NOT PLACE THE USED HANDLE IN THE BIOHAZARD BAG.



10) Wash and dry your hands after the self-collection process. After, insert the collection tube into the biohazard bag. DO NOT REMOVE THE ABSORBENT PAD FROM THE BAG.



11) Seal the biohazard bag with the collection tube and absorbent pad inside. Return the biohazard bag to the healthcare professional or to the collection site drop box.

Questions?

For additional information on the test, process or Helix please contact the Helix Customer Success team at 844-211-2070. You can also email us at support@helix.com.

To access the **Patient Fact Sheet**: https://cdn.shopify.com/s/ files/1/2718/3202/files/Helix_COVID_ Patient_FS_FINAL_2020Jul23. pdf?v=1595542856pdf?v=1595542856

Helix Self-Collection Kit Information



The Helix Self-Collection Kit has been authorized only for the unsupervised collection and maintenance of nasal specimens as an aid in the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.

The Helix Self-Collection Kit has not been FDA cleared or approved. This kit is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests 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)(10), unless the authorization is terminated or revoked sooner.