

Please carefully read all instructions. Failure to follow instructions may lead to incorrect results.

For use by individuals age 16 years or older (self-collected), or 2 years and older (collected with adult assistance, including adults that require support).

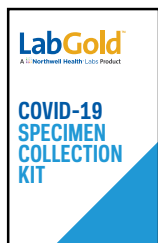
For prescription use, IVD, and Emergency Use Authorization ONLY.

For questions visit us online at:
Northwell.edu/LabGold

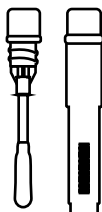
BEFORE RETURNING KIT, CONFIRM...

- ✓ **KIT WAS ACTIVATED.** The specimen cannot be processed if it is not activated.
- ✓ **TUBE IS SEALED** in the specimen bag (if provided).
- ✓ You will drop off the specimen on the **SAME DAY** it is collected.
- ✓ You have reviewed **DROP-OFF HOURS** of your selected location at Northwell.edu/LabGold.

KIT CONTENTS



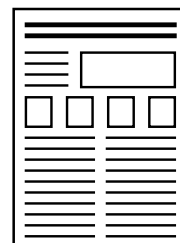
KIT BOX



SWAB AND TUBE



SPECIMEN BAG
(IF PROVIDED)



INSTRUCTIONS

KIT INSTRUCTIONS

1 Register kit

- Scan the LabGold QR code or visit us at www.northwell.edu/LabGold and click "Register Now" to register your kit.
- After registration, the web page will guide you through the steps below.

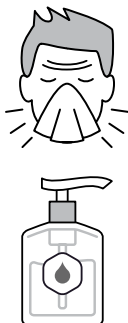


2 Plan for specimen drop-off

- When you receive your kit, visit us at Northwell.edu/LabGold for a complete list of drop-off locations.
- Before specimen drop-off, ensure you have received a text confirming that your specimen has been linked.
- The specimen must be dropped off the same day it is collected.

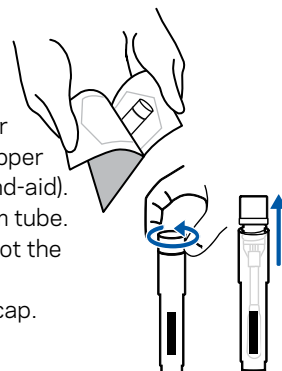
3 Blow nose and clean hands

- A clear nose and clean hands are important to obtain a good specimen.
- Using a clean tissue, gently blow nose and remove any debris to clear both nostrils. *If around other people, blow nose in a private area.*
 - Anyone touching supplies must clean their hands. Use sanitizer or wash hands with soap and warm water for 20 seconds and dry them thoroughly with a clean towel.



4 Open swab tube

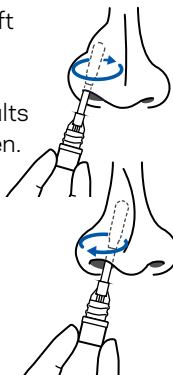
- Remove the tube from the wrapper by pulling the two ends of the wrapper apart (like you would to open a band-aid).
- Twist the cap to remove swab from tube.
- Be careful to only touch the cap, not the swab tip.
- Do not detach the swab from the cap.



5 Swab both nostrils

Note: Children under 16 years of age should be swabbed an adult.

- While holding cap, gently insert the **entire** soft tip of the swab into one nostril until you feel a bit of resistance.
- Insert **less than 1 inch** into the nostril for adults and **less than 1/2 an inch** for younger children.
- Using medium pressure, rub the swab slowly in a circular motion around the inside wall of the nostril **four times**.
- The swab tip should be touching the inside wall of the nostril through each rotation.
- Repeat the same process with the **same swab** in the **other nostril**.

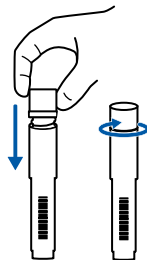


continued on back

KIT INSTRUCTIONS *continued from front*

6 Put swab in tube

- While holding swab cap, put the swab back into the original tube, tip first.
- Screw the cap back onto the tube until it is secure and the cap no longer turns.



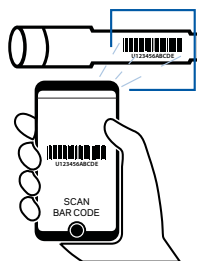
7 Clean hands

- Use sanitizer or wash hands with soap and warm water for 20 seconds and dry them thoroughly with a clean towel.



8 Scan tube and drop off specimen

- Scan the tube barcode to link your specimen to your registration. The lab can only process the specimen if the tube barcode has been scanned and your specimen linked to your registration.
- You will receive a text notification confirming your tube has been linked to your registration.
- If a specimen bag is provided, place your tube in the bag and securely close the top of the bag.

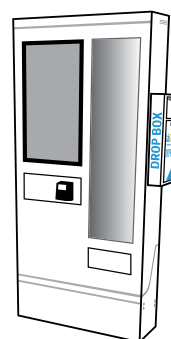


Drop-off locations

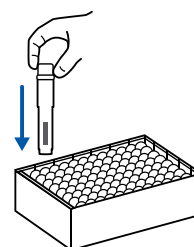
- Visit us at www.Northwell.edu/LabGold for an up-to-date list of drop-off locations.
- For **drop box return**, place your LabGold™ specimen bag in the drop box.
- For **vending machine return**, place your LabGold™ specimen bag in the drop box on the side of the vending machine.
- For **return at a staffed drop-off location**, place your specimen in the collection rack.
- You will receive a text notification when your specimen has arrived in the lab.



DROP BOX



**VENDING MACHINE
DROP BOX**



**STAFFED
LOCATION RACK**

WHEN YOUR RESULTS ARE READY YOU WILL RECEIVE A TEXT AND EMAIL

- The text will direct you to click a link to have your results sent via email with a PDF report attachment
- If you do not receive your results within 48-72 hours of your specimen arriving in-lab, please email LabGold@northwell.edu

WARNINGS

- To prevent injury, use only the components provided in the kit to collect your specimen and do not use swab if package seal is broken.
- Do not perform test on an individual under the age of 2.
- 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 anterior nasal swab 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.

PLEASE READ

Seek immediate medical care from a healthcare professional if seriously ill—do NOT wait for the results of this test. Call 9-1-1 if having a medical emergency. Signs of a serious medical condition include, but are not limited to: severe shortness of breath or difficulty breathing, coughing up blood, chest pain, irregular heartbeat, persistent vomiting or diarrhea.

This kit is distributed by Northwell Health Labs.

This kit is manufactured for Audere (healthpulsenow.org) by SteriPack.