

Nasal Specimen Collection Kit Instructions

Before returning kit, confirm:

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).

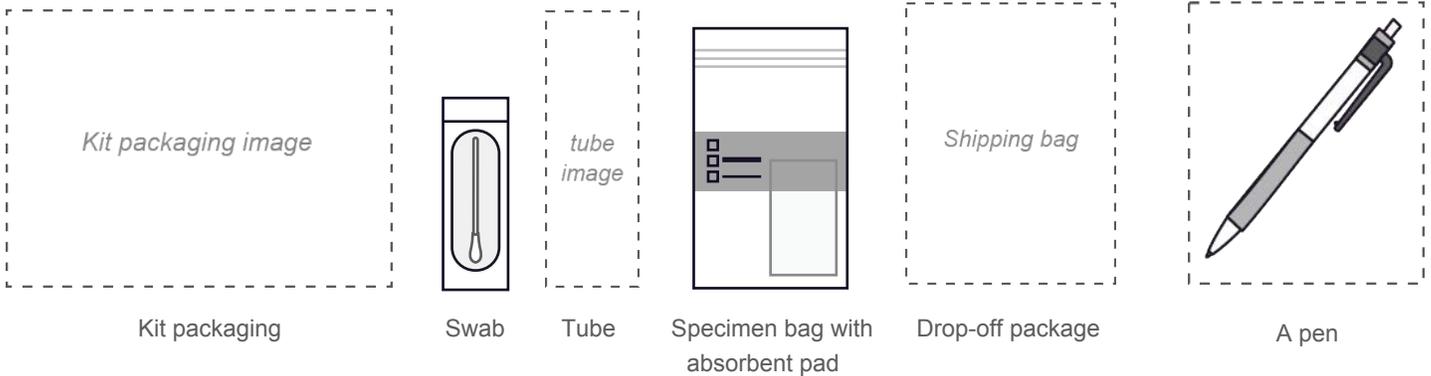
For prescription use, IVD, and Emergency Use Authorization ONLY.

- ➔ Kit was registered. The specimen cannot be processed if it is not registered.
- ➔ Tube is sealed in the provided specimen bag with absorbent pad.
- ➔ Date of birth and the specimen collection date are correct on the tube label
- ➔ You will drop off the specimen on **the same day** it is collected.

Questions?

Enter support site/email/phone number.

Kit Contents



Kit Instructions

1 Register kit

Scan the barcode on the inner box or visit www.xxxxxx.com to register your kit. After registration, the web page will guide you through the steps below.



2 Plan for specimen drop-off

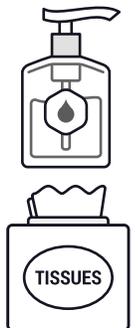
- When you receive your kit, ask where the completed specimen should be dropped off.
- The specimen **MUST** be dropped off the same day it is collected.
- Specimens dropped off too late will not be processed.



3 Blow nose and wash hands

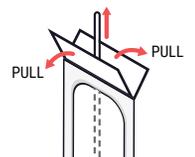
A clear nose and clean hands are important to obtain a good specimen.

- Using a clean tissue, gently blow nose and remove any debris to clear both nostrils.
- Anyone touching supplies must wash their hands with soap and warm water for 20 seconds and dry them thoroughly with a clean towel.



4 Open nasal swab

Remove the nasal swab from the wrapper by pulling the two ends of the wrapper apart (like you would to open a band-aid). Be careful to **only touch the swab handle, not the tip.**



Continue to page 2 ➔

5 Swab both nostrils

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

- 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**.



6 Put swab in tube

- While **holding the swab**, open the tube.
- Put the swab **tip first** into the tube.
- If needed, break swab handle against the side of the tube at the perforated break point.
- Screw the cap back onto the tube **tightly**.



7 Fill out info on tube

- The lab can **only** process the specimen if the correct information is written on the tube.
- Write the date of birth of the person being tested and today's date on the tube label.
- Place the tube in the specimen bag and close the top of the bag securely. Leave the white pad in the bag.

supporting image

8 Wash hands

Before packing up the kit, wash hands with soap and warm water for 20 seconds and dry them thoroughly with a clean towel.



9 Drop off specimen

- Confirm the kit was registered as described in Step 1.
- Place the specimen bag with the tube into the original kit box.
- Drop off the specimen at your designated location.

supporting image

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 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 manufactured for Audere (healthpulse.now.org).

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Questions?

Enter support site/email/phone number.

➔ Kit was registered. The specimen cannot be processed if it is not registered.

➔ Date of birth and the specimen collection date are written on the tube label

➔ Tube is sealed in the provided specimen bag with absorbent pad.

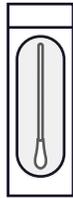
➔ You can return the specimen on **the same day** it is collected. Before the last Express pick-up.

DO NOT collect specimen on a FRIDAY.

Kit Contents



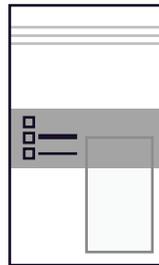
Kit packaging



Swab



tube image

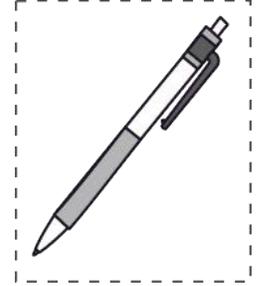


Specimen bag with absorbent pad



Shipping bag

Return shipping pack



A pen

You need:

Kit Instructions

1 Register kit

Scan the barcode on the inner box or visit www.xxxxxx.com to register your kit. After registration, the web page will guide you through the steps below.



supporting image

2 Plan for specimen return

Visit www.fedex.com/labreturns to locate a drop box accepting lab specimens.

Review the Latest Express Drop-Off hours for last pickup timing.

Or, to schedule a pickup at your location, call (800) 463-3339.

The specimen **MUST** be shipped immediately (the same day it is collected). Specimens arriving at the lab too late will not be processed.



supporting image

3 Blow nose and wash hands

A clear nose and clean hands are important to obtain a good specimen.

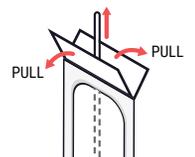
- Using a clean tissue, gently blow nose and remove any debris to clear both nostrils.
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4 Open nasal swab

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Be careful to **only touch the swab handle, not the tip.**



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5 Swab both nostrils

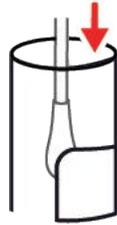
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- Screw the cap back onto the tube **tightly**.



7 Fill out info on tube

- The lab can **only** process the specimen if the correct information is written on the tube.
- Write the date of birth of the person being tested and today's date on the tube label.
- Place the tube in the specimen bag and close the top of the bag securely. Leave the white pad in the bag.

supporting image

8 Wash hands

Before packing up the kit, wash hands with soap and warm water for 20 seconds and dry them thoroughly with a clean towel.



9 Prepare and send kit

- Confirm the kit was registered online as described in Step 1. The specimen cannot be processed if the kit is not registered.
- Place the specimen bag with the tube into the original kit box.
- Place the kit box inside the postage paid, pre-addressed FedEx shipping bag.
- Remove the clear liner at the top of the FedEx shipping bag to expose the adhesive, then seal the bag closed.
- Be ready for your scheduled pickup or drop off the package today before the last Express pick-up.

supporting image

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



HealthPulse
@HOME

COVID-19 Specimen
Collection Kit

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 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.

IVD Rx Only

For use under Emergency Use
Authorization (EUA) Only

This box contains one specimen collection kit.

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

Keep at room temperature, 60°- 85° F

Distributed by:

[Insert lab name here (lab web address)]

Manufactured for:

Audere (healthpulsenow.org) by [Insert manufacturer name here]

Questions?

Visit us at healthpulsenow.org/contact or (XXX) XXX-XXXX

UN3373

**BIOLOGICAL SUBSTANCE
CATEGORY B**