

# Nasal Specimen Collection Kit Instructions

Before returning kit, confirm:

- ➔ Kit was registered. The specimen cannot be processed if it is not registered.
- ➔ Tube is sealed in the provided specimen bag with absorbent pad.
- ➔ You will drop off the specimen on the **same day** it is collected.

**Only collect and return specimens Mon - Fri.**

**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.

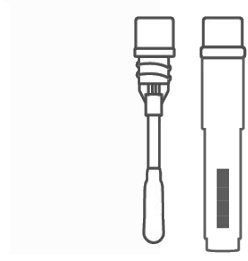
## Questions?

Enter support site/email/phone number.

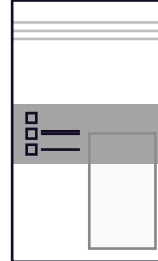
## Kit Contents



Kit packaging



Swab and tube



Specimen bag with absorbent pad (if provided)



Instructions

## Kit Instructions

### 1 Register kit

Scan the barcode on the inner box or visit [www.xxxxxx.com](http://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 clean hands

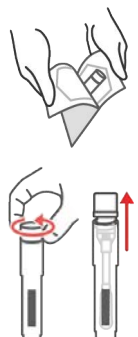
A clear nose and clean hands are important to obtain a good specimen.



- 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.

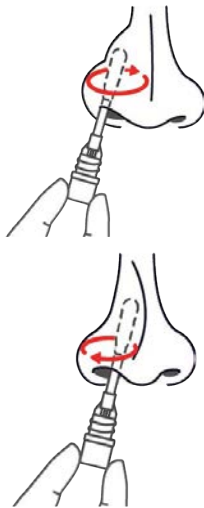


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## 5 Swab both nostrils

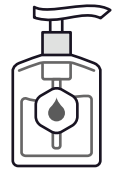
Note: Children under 16 years of age should be swabbed by an adult.

- 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**.



## 7 Clean hands

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



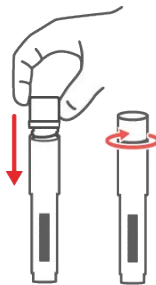
## 8 Drop off specimen

Return your tube to the designated drop-off location on the same day it was collected and place your tube in the specimen bag or rack provided



## 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.



### 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 ([healthpulsenow.org](https://healthpulsenow.org)).

# Nasal Specimen Collection Kit Instructions

Before returning kit, confirm:

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

**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).

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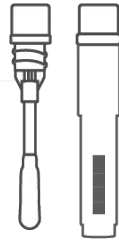
Questions?

Enter support site/email/phone number.

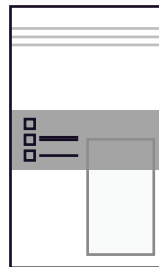
## Kit Contents



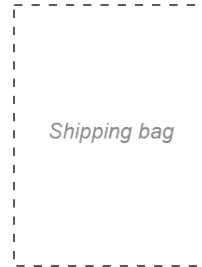
Kit packaging



Swab and tube



Specimen bag with absorbent pad



Return shipping pack



Instructions

## Kit Instructions

### 1 Register kit

Scan the barcode on the inner box or visit [www.xxxxxx.com](http://www.xxxxxx.com) to register your kit. After registration, the web page will guide you through the steps below.



### 2 Plan for specimen return

Visit [www.fedex.com/labreturns](http://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.



### 3 Blow nose and clean hands

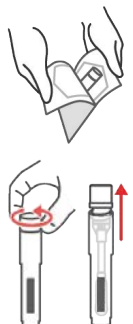
A clear nose and clean hands are important to obtain a good specimen.

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### 4 Open swab tube

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- Do not detach the swab from the cap.

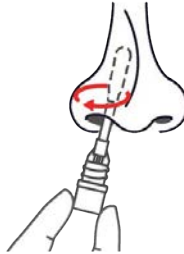
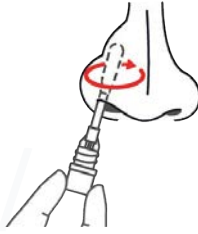


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## 5 Swab both nostrils

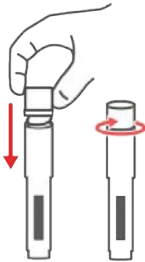
Note: Children under 16 years of age should be swabbed by an adult.

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- 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 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 Put tube in bag

- Place the tube in the specimen bag and close the top of the bag securely. Leave the white pad in the bag.



## 8 Clean hands

Use sanitizer or 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

### 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.
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This kit is manufactured for Audere ([healthpulsenow.org](https://healthpulsenow.org)).



HealthPulse  
@HOME | FUSION

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 aged 16 years and older (self-collected)  
or individuals  $\geq 2$  years (collected by an adult).

Storage temperature: 35°-86° F

*Distributed by:*

[ Insert lab name here (lab web address) ]

*Manufactured for:*

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

**Questions?**

Visit us at [www.website.com/contact](https://www.website.com/contact) or (XXX) XXX-XXXX



**BIOLOGICAL SUBSTANCE  
CATEGORY B**