

IMPORTANT: The specimen should be collected on the same day as the pickup is scheduled. Samples should only be collected Monday-Friday, as shipping services do not operate on the weekends.



COVID-19 (RT-PCR) Patient Take Home Collection Kit – Nasal Sample Instructions

IVD, Rx only, for use under an Emergency Use Authorization (EUA) only

These instructions should be read before beginning testing.

FOLLOWING THESE STEPS ENSURES ACCURATE TESTING

SAFETY FIRST

- You must be 18+ to use this sample collection kit.
- If you come into contact with the saline solution liquid in the sample tube, you should wash your hands immediately

MUST COLLECT AND SHIP ON THE SAME WEEK DAY. MONDAY-FRIDAY ONLY. DO NOT COLLECT ON WEEKENDS!

1. Call FedEx at 800-463-3339 for same day pick up and say you have a pre-paid express label.

If they cannot pick up, please go to nearest FedEx drop off location(s) and drop off package before the last express pick up.

Visit <https://www.fedex.com/en-us/shipping/dropbox.html> to view FedEx drop box locations and pick up schedules.

Keep a copy of your tracking number. (Tracking number can be found on reverse side of these instructions.)



2. Call QDx Client Services at (908) 349-2444 and give them the FedEx tracking number.

IMPORTANT: Please mention you are sending a CoVID kit.



PREPARE FOR SAMPLE COLLECTION

1. Wash hands with soap and water and dry thoroughly.



2. Open kit and place all items on a clean, dry surface. Make sure all items shown to the right were received.



1 Kit/Box



1 Swab



1 Saline Collection Tube



1 Gel Pack
Do Not Freeze



1 Order Form



1 Biohazard Bag



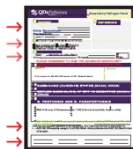
1 Silver Pouch



1 FedEx Prepaid Return Envelope

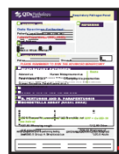
3. **Patient Information Order Form**

Fill out any missing information on the order form. Ensure that the patient information section is completely filled.



4. **LABELS**

Fill out one label at the bottom of the order form. Make sure label is filled with date of collection, patient's name, date of birth and telephone number.



labels

Peel off label and place it on saline collection tube.

Note: If this step is not completed, your sample will not be processed by the lab.



Please call QDx Pathology Services at (866) 909-7284 and ask for our Client Services Department with any questions.



SPECIMEN COLLECTION

- Loosen top of the collection tube and place it on a flat surface.
Do not spill the saline solution. If you spill any liquid, the test should not be returned and you should contact QDx Pathology. If you come into contact with any liquid, you should wash your hands immediately.



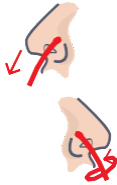
- Remove swab from its package.
Do not touch tip of swab and do not lay the swab on any surface.



- Insert swab in one nostril until the tip of swab is no longer visible. Rotate in a circle around the inside edge of nostril for **10 seconds**, then gently remove from the nose. Do not force the swab any further up and into your nose at any point.
You must collect your sample from both nostrils before placing into the specimen container.



- Gently insert the same swab into the other nostril and repeat instructions in number 3 above.

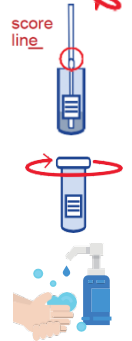


- Immediately after swabbing both nostrils, remove the cap from saline collection tube. Insert swab in saline collection tube so the swab tip sits in the saline solution.

Carefully snap off the handle at score line by pushing against the side of the saline collection tube. Discard the top portion of the swab.

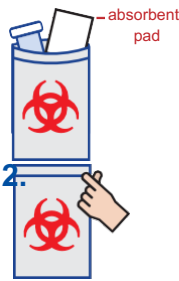
Screw the lid tightly onto the saline collection tube. This will ensure that the lid does not come off during shipping, which could prevent your sample from being processed by the lab.

Wash hands with soap and water again and dry thoroughly.

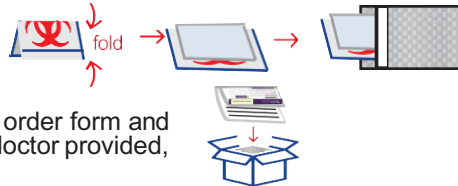


PACKAGING AND SHIPMENT FOR SPECIMEN

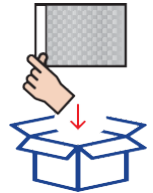
- Insert sealed saline collection tube in the biohazard zip lock bag that contains an absorbent pad and seal it. **Do not remove the absorbent pad!**



- Fold the specimen bag in half and place the gel pack (do not freeze or refrigerate) on top of folded specimen bag. Put both the folded specimen bag and gel pack inside the silver pouch.
NOTE: Your sample may be rejected if you fail to include both the sample and gel pack in the silver pouch.

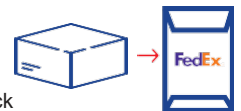


- Remove the adhesive strip and seal. Place the silver pouch into the box/kit and close lid.



- Fold and place the completely filled out order form and any attached paperwork that your doctor provided, inside the box/kit. Close box/kit.

- Place the box/kit into the FedEx return pack and seal it. It is important that FedEx receives your sample on the same day as the collection.



IMPORTANT! If dropping your sample via FedEx drop box, ensure your sample is dropped off before the last express pick up of the day. The FedEx drop box will indicate the time for the last pick up of the day.

IMPORTANT! Do not deliver sample to a drop box on a weekend (Saturday or Sunday).

IMPORTANT! We will not accept or process specimens if:

- There is no nasal swab inside the saline collection tube.
- The saline sample volume is low due to spillage or leakage.
- There is no specimen label on the collection tube.
- Patient did not write date of collection.
- The specimen is not shipped in the provided FedEx envelope.
- The sample arrived at the laboratory more than 48 hours after collection.

This is an important step as your sample won't stay stable for a long time. Getting your sample on time helps ensure the results accuracy.

FedEx Tracking #



Visit the CDC website and follow the advice provided in the up to date guidelines here: www.cdc.gov/coronavirus/2019-ncov Most people who contract coronavirus are unlikely to have severe symptoms, if you feel very unwell, are experiencing breathing difficulties or feel that you need treatment from a medical professional, you should NOT wait for the results of this test and you should immediately call your healthcare provider, or in a medical emergency, call the emergency services. CAUTION: You should collect this sample yourself.

This self-collection kit has:

- Not been FDA cleared or approved
- Been authorized by FDA under an EUA
- Been authorized only for the unsupervised self-collection and maintenance of nasal specimens as an aid in detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.

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)(1), unless the authorization is terminated or revoked sooner.

Please call QDx Pathology Services at (866) 909-7284 and ask for our Client Services Department with any questions.



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