

SynergyDx Home Collection Kit for COVID-19

Kit Components

For Rx Only
For *in vitro* Diagnostic Use
For Emergency Use Authorization (EUA) only
For individuals 18 years of age or older

For Questions, Comments or Concerns, CONTACT US @ 1-877-9COV190

Before you begin your collection:

Please confirm FedEx is operating on a normal service schedule.
Please confirm all kit components are included.
The use of gloves [not included] is recommended.



Wash your hands

Wash and dry hands before opening the kit.

Open your Home Collection Kit Box to find the following items. If all items are not included IMMEDIATELY Contact Customer Support at 1-877-9COV190

Open the box and place all components on a clean surface.



Instruction Sheet



Registration Card



PreLabeled Return FedEx UN 3373 LabPak bag



Labeled BioHazard Bag with Absorbent Pad



Front of the BioHazard bag



Back of the BioHazard bag
Confirm Label is Attached

Individually Wrapped Swab Confirm the packaging is sealed



Labeled Collection Tube



1. Confirm there is liquid* in the tube.
2. Confirm Label is attached.

WARNING! THE SOLUTION IN THE COLLECTION TUBE CONTAINS SUBSTANCES LISTED BELOW AT CONCENTRATIONS <1% OF THE SOLUTION. INGREDIENTS INCLUDE: HANKS' BALANCE SALTS, BOVINE SERUM ALBUMIN, SUCROSE, PENICILLIN, GENTAMICIN, STREPTOMYCIN SULFATE, AMPHOTERICIN B, NONESSENTIAL AMINO ACID, PHENOL RED. DO NOT DRINK SOLUTION. IF THE SOLUTION CONTACTS THE SKIN OR EYE, FLUSH WITH PLENTY OF WATER. IF IRRITATION PERSISTS, SEEK MEDICAL ADVICE. [HTTPS://WWW.POISON.ORG/CONTACT-US](https://www.poison.org/contact-us) OR 1-800-222-1222

Synergy Diagnostic Laboratory Inc. offers this product with an FDA Emergency Use Authorization (EUA). This means that 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 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 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 declaration is terminated or authorization is revoked sooner.

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Synergy Diagnostic Laboratory Inc.

4081 SW 47th Ave, Suite 2
Davie, Florida 33314
www.synergydx.com

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1 Let's get started!



Please read all of the instructions before beginning collection.

2 Register



When you are ready to collect your sample, register your kit by scanning the above QR code, and typing in the 12 digit registration code that is located on the registration card, collection tube, and biohazard bag sticker.

3 Prepare for shipping



Visit <https://bit.ly/fedexdropbox> to view FedEx drop box locations and pickup schedules. It's important to bring your sample to a drop box on the same day you collect it before the last Express pickup.

4 Open the test kit.



Place all the contents on a clean, dry surface. Items needed for collection:

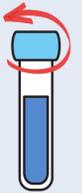
- Single Tip Swab
- Collection Tube With VTM with Label
- BioHazard Bag with Label
- UN3373 FedEx LabPak Bag

5 Blow your Nose



Taking a tissue and blowing your nose. Wipe the exterior of your nose ONLY, do not wipe the inside of your nose. Dispose of tissue.

6 Uncap the tube



Unscrew the top of the collection tube. Place the cap face up on a clean surface. Stand the open tube on a clean surface so the liquid does not spill. Do not drink the liquid.

7 Unwrap the Swab



Take the swab out of its package. Do not touch the tip of the swab with your hands. Do not place the swab on any surface.

8 Swab 1st Nostril



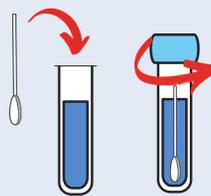
Insert the tip of the swab into the left nostril, insert just until the tip of the swab is no longer visible. Rotate the swab in a circle around the entire inside wall of your nostril at least 10 times.

9 Swab 2nd Nostril



Using the same end of the same swab repeat in the right nostril. Rotate the swab in a circle around the entire inside wall of your nostril at least 10 times.

10 Insert Swab into Tube



Remove the swab from your second nostril and while holding the collection tube place the end of the flocked side of the swab into the tube. Screw the top of the collection tube back on.

11 Pack/Prepare Your Sample



Place tube inside specimen bag. Do not remove the absorbent pad. Seal the specime bag.

12 Before you Prepare for Ship



Wash and dry hands after collecting your sample.

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Shipping Instructions

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Prepare to Ship

1



Place the specimen bag back into your shipping box with all the paper work and close the lid.

2



Place the shipping box into the FedEx return pack. Remove the adhesive cover strip and seal the return pack closed.

Lastly...

Deliver the postage paid, pre-addressed FedEx return pack to a FedEx drop box. It's important to bring your sample to a drop box on the same day you collect it **before the last Express pickup.**



What's Next?

Within 24 hours of drop off your specimen will reach the SynergyDx Laboratory for RT-PCR Processing. Once your sample has completed testing, analysis, and resulting; you will receive test results via your healthcare provider.

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