

# Quick & easy, self-collected COVID-19 testing to fit your needs.

1

## FDA AUTHORIZED EUA\*

Emergency Use Authorization (EUA) for self-collected RT-PCR SARS-CoV-2 test kit.

2

## HIGHLY SPECIFIC

During validation, no false positives and no cross-reactivity from viruses that cause the common cold.

3

## HIGHLY SENSITIVE

High sensitivity revealed during the initial laboratory validation study.

4

## DETECTS VIRUS

A positive test result means that the COVID-19 virus was detected in the nose sample. Detects as low as 180 NDU/mL.



5

## 48 HR RESULTS

Orders are shipped overnight & test results are ready 48 hours after return shipping on our secure, online portal.

6

## PAINLESS SWAB

The shallow & pain-free self-collected nasal swab you've been waiting for. No more deep discomfort.

7

## RT-PCR TECH

Reverse transcriptase polymerase chain reaction is used to look for SARS-CoV-2 RNA in the nose.

8

## RETURN SHIPPING

The empowerDX kit includes a pre-labeled return shipping envelope for your convenience.

\*Not available in NY, NJ, RI & MD. Individuals being tested must be 18+ years old. This home-collection kit has not been FDA cleared or approved; rather it has been authorized by FDA under an EUA only for the self-collection and maintenance of nasal swab specimens as an aid in detection of nucleic acid from SARS-CoV-2, and not for any other viruses or pathogens, and only for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in medical devices during the COVID-19 outbreak under Section 64(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.

# COVID-19 TESTING OPTIONS, TAILORED TO YOU

1

## SWAB PARTY

*Bulk delivery + group collection + bulk return*

### **Ideal solution for...**

All customers needing to test a large group at one time.

#### **Collection**

Self-collected at the dedicated site on a specific date.

#### **Shipping**

Kits are bulk shipped /returned. Overnight M-F. No Sat returns.

#### **Results**

Individual gets an email notification to access results. Dashboard analytics for customer.

2

## GRAB & GO

*Bulk delivery + individual collection + individual return*

### **Ideal solution for...**

Corporations that store kits for ad-hoc use. Back to business travel.

#### **Collection**

Self-collect anywhere. Online registration & consent.

#### **Shipping**

Bulk shipped to customer. Individuals FedEx return M-F (not Sat).

#### **Results**

Individual accesses results online at [my.empowertxlab.com](http://my.empowertxlab.com). No customer dashboard analytics.

3

## INDIVIDUAL

*Individual delivery + individual collection + individual return*

### **Ideal solution for...**

Cruise ship customers that require passenger screening.

#### **Collection**

Self-collect anywhere. Online registration & consent.

#### **Shipping**

Kit shipped to individual. FedEx return M-F (not Sat).

#### **Results**

Individual accesses results online at [my.empowertxlab.com](http://my.empowertxlab.com). No customer dashboard analytics.



We'd love to hear from you: [partner@empowertxlab.com](mailto:partner@empowertxlab.com).

# WHAT'S INSIDE YOUR KIT

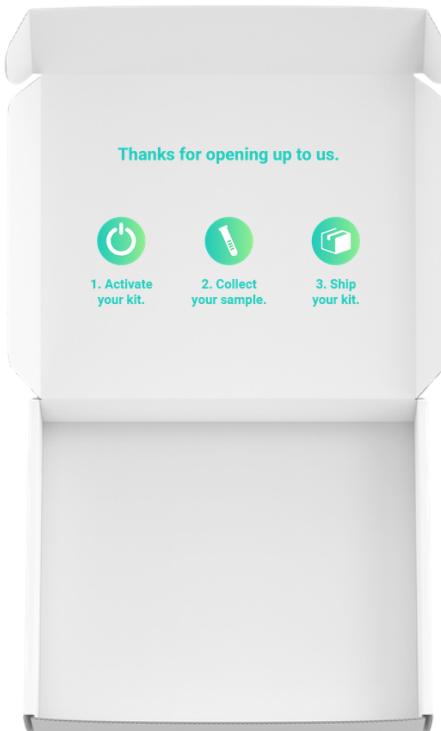
## Collection Instructions

8-1/2" x 11"



## The Kit

6-3/4" x 5-11/16" x 1-13/16"



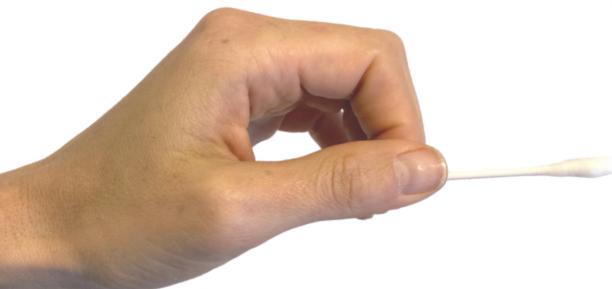
## FedEx Return Pak

UN 3373 Labeled



## Nose Swab

Fisher Scientific  
3" Sterile Polyester  
Spun Swab



## Saline Tube (Plastic Container)

Azer Scientific  
10 mL size with 3mL of Sterile  
Phosphate Buffered Saline



## Name Label

Unique Barcode

## Biohazard Bag

To Store the Sample



# HOW TO PERFORM YOUR NASAL SWAB

**COVID-19  
TEST KIT**

empowerDX

## KIT ACTIVATION CODE activate kit before you ship

**What's inside your kit:** 1X swab, 1X plastic container, 1X biohazard bag, 1X instructions (keep this sheet), 1X name label, 1X FedEx Pak

**1**

**PREP**

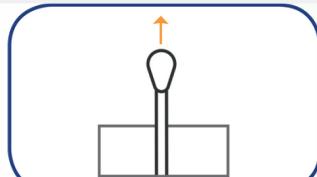
- Wash and dry your hands before opening the kit box
- Open your kit and place all the contents on a clean, dry surface
- Failure to follow these instructions may lead to inaccurate test results – please keep this sheet for your reference



**2**

**SWAB**

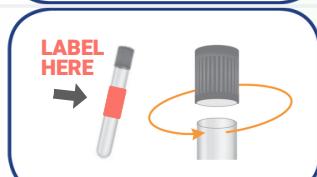
- Take the cotton swab out of its package without touching the tip



**3**

**UNSCREW**

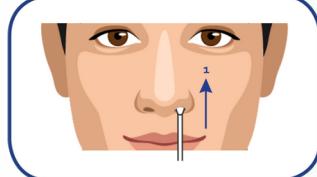
- Write name, date of birth and date of collection on the label provided – stick the label on the tube
- Screw off the top of the collection tube
- Hold swab in one hand & collection tube in the other
- Do not spill or drink the liquid



**4**

**INSERT**

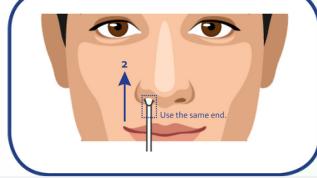
- Insert the tip of the cotton swab into one nostril until the cotton tip of the swab is no longer visible
- Rotate the swab in a circle around the entire inside edge of your nostril at least 3 times



**5**

**REPEAT**

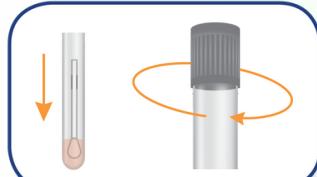
- Take the cotton swab out of your nostril
- Using the same end of the cotton swab, repeat step 4 in your other nostril



**6**

**SCREW**

- Remove the cotton swab from your second nostril
- Place the used end into the collection tube first so it touches the liquid
- Screw on the top of the collection tube



**7**

**INSERT**

- Wash and dry your hands thoroughly again
- Insert collection tube into the biohazard bag, leave the white absorbent pad in the bag and close the zip lock seal
- Place the biohazard bag into the kit box



**8**

**ACTIVATE**

- Activate your kit **today** by clicking the link in the empowerDX email you received and entering the 10 digit kit activation code (or) go directly to [activate.empowerdxlab.com](http://activate.empowerdxlab.com) in your browser
- **Your kit MUST be activated to receive your test results**



**9**

**SHIP**

- Place the kit box in the pre-labeled FedEx Pak, remove the adhesive cover strip and seal the FedEx Pak closed
- Ship the FedEx Pak by (1) ordering a FedEx pickup or (2) finding the nearest FedEx drop box: [bit.ly/fedexdropbox](http://bit.ly/fedexdropbox) (**Monday-Friday only**)
- Ship on the same day as collection or your sample may not be tested





## LABORATORY REPORT

**Patient Name:** SAMPLE, REPORT

Sex: M      DOB: 05/27/1937      Age: 83y

**Viracor Eurofins Patient ID:** 8443217

**Physician:** Unknown, Dr.

**Received:** 09/28/2020 09:19

**Report Delivered:** 09/28/2020 10:37

**Client MRN:** 8046359

**Client:**

1234 1st Street  
Suite B  
Anywhere, Mo 11223

### RESULTS

**At Home COVID-19 PCR (Nasal Swab)**

Viracor Eurofins Accession ID: 2027200982

Performed at: Viracor Eurofins - 1001 NW Technology Dr., Lee's Summit, MO | CLIA# 26D-0983643

Client Accession ID:

Collected: 09/28/2020 08:20

Final - Approved 09/28/2020 10:34

**TEST**

SARS-CoV-2 RT-PCR

**RESULT**

Positive

**FLAG**

A

**REF RANGE**

Negative



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**TEST**

SARS-CoV-2 RT-PCR

**RESULT**

Negative

**FLAG**

**REF RANGE**

Negative