This product (collection kit in combination with the authorized test) has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by the authorized laboratory;

This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and

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 in vitro diagnostics 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.

For use by individuals age 18 years or older (self-collected), 14 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance).

For Prescription Use Only.



Distributed by INeedaCOVID19Test.com

If you have questions during your specimen collection, please contact

COVID19@eTrueNorth.com or Call (800) 635-8611.

## INeedaCOVID19Test.com

## Self-Collection Kit

# INSTRUCTIONS FOR USE

#### **PRECAUTION** - TIME SENSITIVE TEST - READ BELOW BEFORE STARTING

Follow the sample and packaging instructions closely to prevent inaccurate results or rejected samples.

To activate, collect and package your sample, please visit: www.INeedaCOVID19Test.com

To get a valid diagnostic test result, it is important to return your sample to the store for pickup on the **SAME DAY OF COLLECTION**.

### **INeedaCOVID19Test.com Self-Collection Kit**

#### \* PRECAUTION - TIME SENSITIVE TEST - READ ALL INSTRUCTIONS REFORE STARTING

For use by individuals age 18 years or older (self-collected), 14 years and older (self-collected under adult supervision, i.e., individuals 14-17 years old and adults that require supervision), or 2 years and older (collected with adult assistance, i.e., individuals 2-13 years old and adults that require assistance).

#### **TEST KIT CONTENTS**







Sample swab

Tube

label



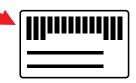
Saline filled collection tube



Biohazard bag with absorbent pad

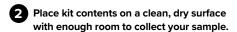






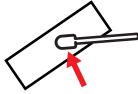
1 Activate your kit before starting the sample collection. Scan the QR code above or go to: www.lNeedaCOVID19Test.com/activate. You MUST log on and enter the tube number located below the barcode on the sticker to receive a test result. If you are under the age of 18 please ask your parent or guardian for help with this kit. Children 14-17 can self-collect under adult supervision, while children ages 2-13 require adult assistance.







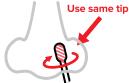
Wash your hands for at least 20 seconds and dry.



**Remove sample swab from its packaging.** Do not touch the tip and do not set the swab down.



Insert the collection tip of the swab into one nostril until it can't be seen (usually about 1/2 inch to 3/4 inch). If you are collecting a sample from a younger child, insert swab less than 1/2 inch). Rotate swab firmly against the inside wall of the nostril 4 times taking about 15 seconds to collect the sample.



Repeat step 5 in your other nostril, using the same tip.



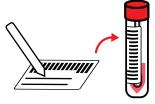




Open pre-filled saline collection tube provided and place sample swab in tube, tip first into the liquid. Screw cap back on.



8 Wash your hands for at least 20 seconds and dry.



Using a pen, neatly write your first & last name, date of birth, the current date and time on the tube label. Peel off the sticker back and place the label length-wise on the tube.



Place tube into biohazard bag with absorbent pad. Seal the bag.



On the day you take the test, return it to the same location where you picked it up.
Follow location instructions for dropoff (i.e., hand to location staff, place in collection bin, etc.). Be sure to check the pharmacy's current hours of operation.

\*FAILURE TO DROP OFF THE SAMPLE SAME DAY OF COLLECTION WILL RESULT IN SAMPLE REJECTION