

3EO HEALTH COVID-19 TEST QUICK START GUIDE



FEATURING:



A HELPFUL VIDEO
showing you how to
test – before you test!



EASY TO FOLLOW
step-by-step
instructions



EASY TO USE
swab, test and
reusable reader

For use under an Emergency Use Authorization (EUA) only.

For in vitro diagnostic use.

For over the counter (OTC) use.

For use by Individuals with signs and symptoms of Respiratory Tract Infection.

Hi there! 🖐️

We know you are eager to dive in and get started!

- Before you do, please take a moment to:
- Watch our helpful how-to-test video in its entirety, **before** you begin testing
- After watching the whole video, follow these instructions step by step
- If you are unable to watch the video, read through this entire Quick Start guide in whole before starting your test
- While following these instructions, pay close attention to the stop warnings - they ensure you don't miss critical steps in the 3EO testing process

NOW



3EOHealth.com/test

Watch this video **BEFORE** you test.

We'll give you directions how to scan this QR code on the next page. If you are unable to watch the video, turn to page 3.

NEXT



Follow this guide **step-by-step** to test.

DURING



Pay attention to **STOP** warnings.

STOP warnings ask you to double check important steps – they are there to help you perform the steps correctly.

Find our complete Instructions For Use and Fact Sheet for Individuals at:
<https://3EOhealth.com/test>

WATCH OUR HOW-TO-TEST VIDEO

Before you test, watch how its done!

We made a quick video to demonstrate each step of the 3EO testing process. **Watch the entire video**, then follow these instructions to take the test step by step.

Please resist the urge to do the test while watching the video for the first time! You will have the best testing experience if you watch first, then test step-by-step.

To watch the video:

Go to 3EOhealth.com/test

OR

Text **"TEST"** to **(205) 973-2550**

to receive a one-time text with a link to watch the video

OR

SCAN THIS QR CODE

- A** Open the camera app on your mobile phone
- B** Hold the camera directly in front of the QR code
- C** Your camera will "read" the QR code – you won't take a picture
- D** Tap the "qr.go3eo.com" link that appears on your screen
- E** You will be brought to our video located at: 3EOhealth.com/test



3EOHealth.com/test



Unable to watch the video?
Continue to the next page.

YOUR TEST ITEMS OVERVIEW

Your 3EO test has three items that you will use to take your test. Below are the important details for each to help you become familiar before you test.

Don't worry – you won't have to remember these details! We will remind you later, at the correct step on the following pages.

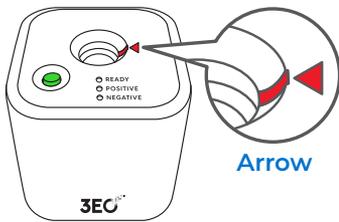
STOP

Do not not use the test kit beyond the expiration date.

STOP

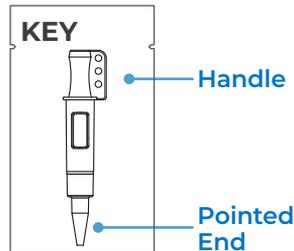
Do not open Key or Swab pouches until the instructions tell you to do so at the correct step.

3EO Cube



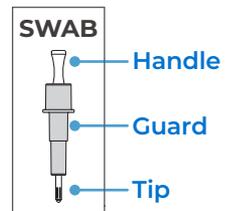
- Place on clear, clean, flat surface
- Needs to be plugged in to operate
- Power adapter is included

3EO Key



- Once you take the Key out of the pouch, you will hold the Key by its handle
- You will then activate the Key
- Once activated, you will plug the Key into the Cube

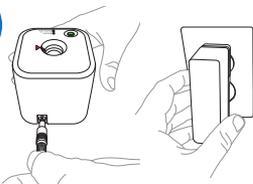
3EO Swab



- You will hold the Swab by its handle
- Remove the swab guard only after swabbing
- You will plug the Swab into the Key **immediately** after removing the guard

PREPARE TO TEST

A



- Place Cube on clear, clean, flat surface.
- Plug Cube in.
- All lights will come on.

B



- Place Key and Swab pouches next to Cube.
- Put this Quick Start Guide flat in front of you.

You must run the 3EO Health COVID-19 Test at room temperature (between 59°F (15°C) to 86°F (30°C))

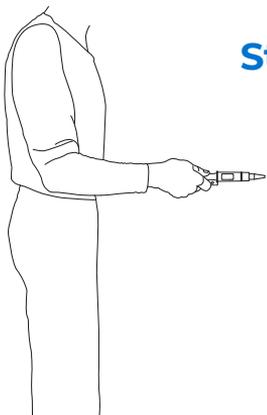
STEP 1: ACTIVATE KEY

Be sure to wash or sanitize your hands before and after testing.

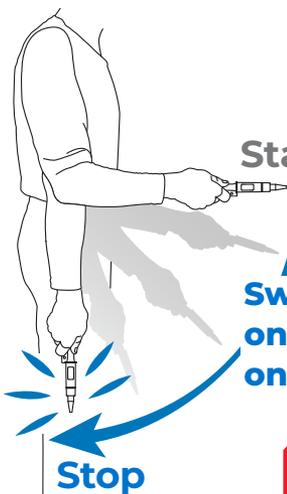
There is liquid inside the Key. This step helps to ensure proper liquid placement.

To activate Key:

- **Remove Key from pouch when ready to begin testing**
- Hold Key with pointed end facing away from you.
- Swing arm quickly with force down one time only.
- Do not swing arm back up.
- Keep Key pointed down.
- Do not shake key.

A**Start**

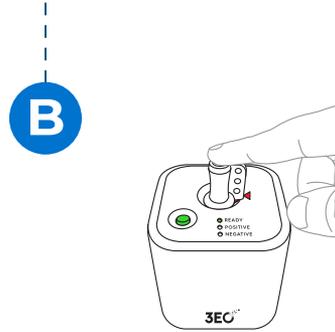
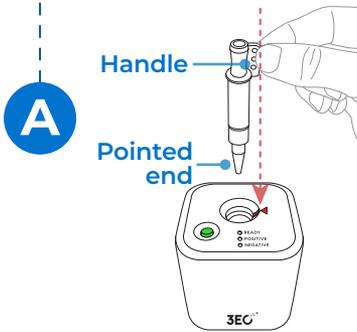
- Hold Key with pointed end facing away from you.

B**Start****Swing down
one time
only!****Stop**

- Swing arm quickly with force down one time only.
- Do not swing arm back up.
- Keep Key pointed down.
- Do not shake Key.

**Are you keeping your
Key pointed down?**

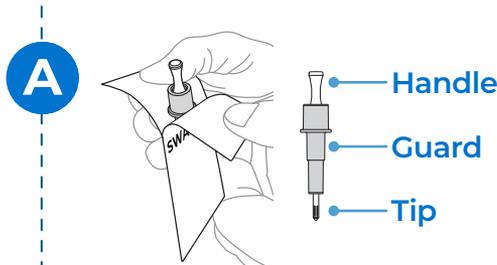
STEP 2: INSERT KEY



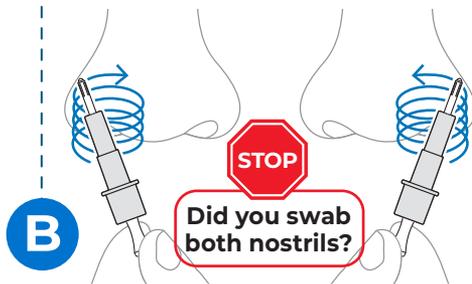
- Keep the pointed end of the Key down.
- Line up the handle with the arrow on the Cube.
- Insert the pointed end of the Key into the hole in the Cube.
- Push the Key down firmly until only the READY light glows steady **GREEN**.
- If READY light does not glow steady **GREEN**, check that the Key is inserted fully into the Cube.

STEP 3: SWAB BOTH NOSTRILS

Blow your nose before swabbing to clear excess mucus.



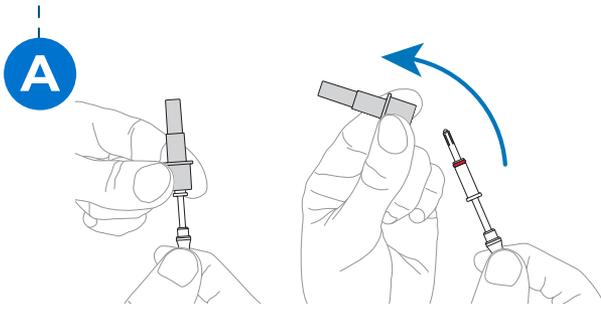
- Peel pouch to remove 3EO Swab.
- Remove Swab, holding upright by its handle.
- **Do not touch Swab to any surface.**
- **Do not remove swab guard** - you will remove it after swabbing.



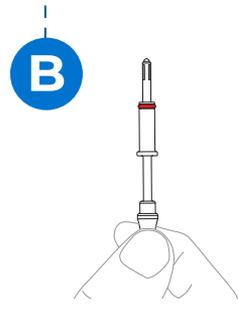
- Hold swab upright by its handle only.
- Be sure tip of swab is visible and fingers are not touching Guard.
- Insert Swab 3/4 of an inch in each nostril (1/2 inch if swabbing a child).
- Do **5 circles** around the wall of each nostril.
- **Make sure Swab tip touches inside walls of nose.**

Do not exert excessive force while swabbing or insert the swab beyond the recommended depth.

STEP 4: REMOVE GUARD FROM SWAB



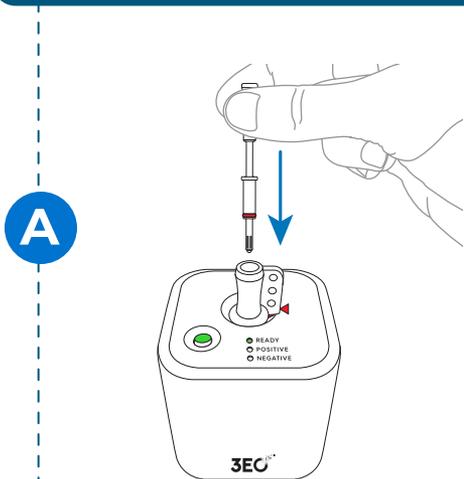
Remove guard from Swab.
Discard guard.



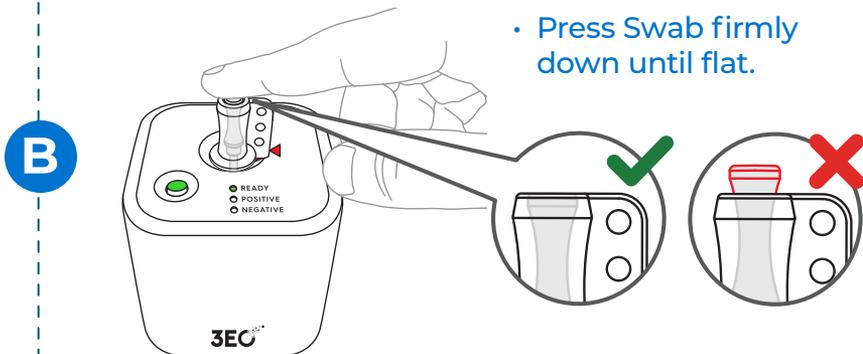
Continue to hold Swab by handle.

Do not set the Swab down or allow the Swab tip to come in contact with other surfaces before or after you swab your nose.

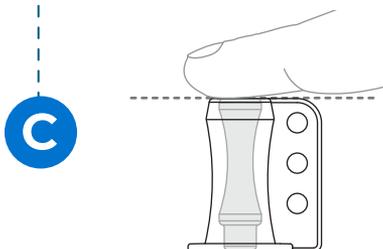
STEP 5: INSERT SWAB INTO KEY IMMEDIATELY



- Insert the Swab into top of Key **immediately** after sample collection and removing the Swab Guard.
- Do not attempt to insert a Swab that still has the guard attached.



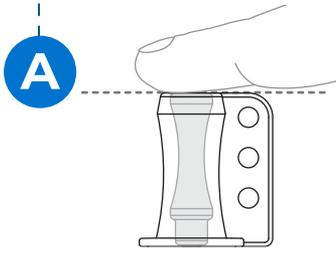
- Press Swab firmly down until flat.



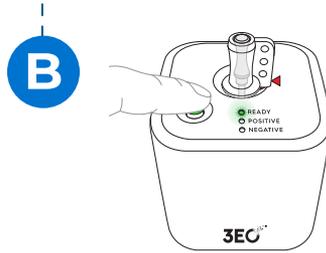
- Ensure Swab is even with top of Key

STOP Did you push the swab down flat?

STEP 6: START TEST



Double-check to make sure top of Swab is flat and even with top of Key.



Press and hold **GREEN** button until the **READY** light starts flashing.

*If **READY** light does not begin flashing, press and hold **GREEN** button again.*

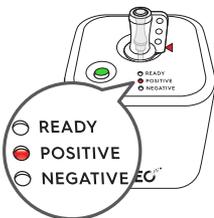
If you forget to press the **GREEN** button within 60 minutes of inserting the Swab into the Key, you will need to retest. Remove the Key and Swab from the Cube. Start a new test with a new Key and a new Swab.

STEP 7: GET TEST RESULT

- Your test will take approximately 30 minutes to display a result.
- The **GREEN** **READY** light will flash until your result is ready.
- Once ready, your result will be displayed via a steady light on the top of the Cube.
- If you have waited more than 35 minutes and there are lights flashing on the top of the Cube, you will need to retest. Go to page 9 for more details.

POSITIVE RESULT

● Steady **RED** light next to **POSITIVE**



- It is very likely you have COVID-19 and it is important to be under the care of a healthcare provider.
- A positive result means that SARS-CoV-2, the virus that causes COVID-19, has been detected in your sample.
- Consult your healthcare provider for treatment.
- Continue to the next page for more details.

NEGATIVE RESULT

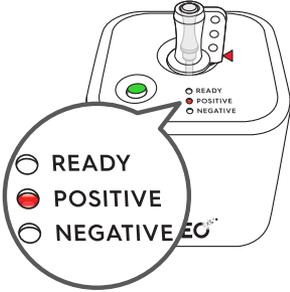
● Steady **GREEN** light next to **NEGATIVE**



- A Negative Result means that SARS-CoV-2, the virus that causes COVID-19, was not detected in your sample.
- Negative results should be taken within the contexts of possible exposure and symptoms. A negative result in no way indicates the absence of other respiratory or non-respiratory viruses or other infections.
- Continue to the next page for more details.

POSITIVE RESULT DETAILS

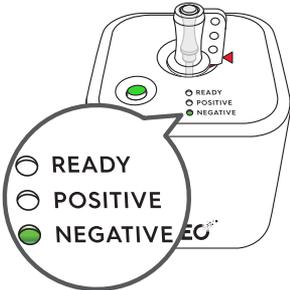
POSITIVE RESULT: Steady **RED** light next to **POSITIVE**



- It is very likely you have COVID-19 and it is important to be under the care of a healthcare provider.
- A positive result means that SARS-CoV-2, the virus that causes COVID-19, has been detected in your sample. Consult your healthcare provider for treatment.
- Those with difficulty breathing or other serious symptoms should seek emergency care immediately. Your healthcare provider will work with you to determine how best to care for you based on your test results along with medical history and your symptoms.

NEGATIVE RESULT DETAILS

NEGATIVE RESULT: Steady **GREEN** light next to **NEGATIVE**



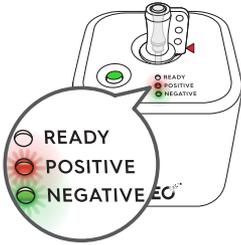
- A Negative Result means that SARS-CoV-2, the virus that causes COVID-19, was not detected in your sample.
- Negative results should be taken within the contexts of possible exposure and symptoms. A negative result in no way indicates the absence of other respiratory or non-respiratory viruses or other infections.
- It is possible for this test to give a negative result that is incorrect (a false negative) in some people with COVID-19. This means you could possibly still have COVID-19 even though the test is negative. If this is the case, your healthcare provider will consider your overall health and history to decide how to care for you.
- It is important you work with your healthcare provider to help you understand the next steps you should take.

Test results should be reported to:
<https://makemytestcount.com>

WHEN TO RETEST

INVALID RESULT

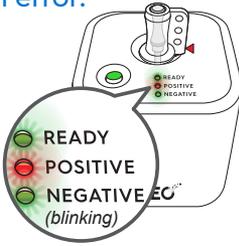
RED AND GREEN LIGHTS FLASH: Test is invalid



- If both of the **Positive and Negative lights flash**, your test is **invalid and must be repeated**.
- Unplug the Cube and plug back in.
- Remove the Key from the Cube.
- Start a new test with a new Key and new Swab, or seek testing by an alternative method.

TEST ERROR

ALL LIGHTS FLASH: Test has an error.



- If, at any time, **all lights flash**, there has been a **testing error**.
- Unplug the Cube and plug back in.
- Remove the Key from the Cube.
- Start a new test with a new Key and new Swab, or seek testing by an alternative method.

Find more information on Troubleshooting and Frequently Asked Questions in our Instructions For Use at:
<https://3EOhealth.com/test>

TEST DISPOSAL



DO NOT BREAK OPEN KEY



THROW KEY AWAY

- After the test is complete, remove the used Key with the contained Swab. Dispose of in a household trash can or per local regulation.
- Care must be taken in disposing of the Key and Swab to not contaminate other surfaces with samples or internal components, for example by forcing open or breaking the Key. Treat all biological samples as capable of transmitting infectious agents.

After each use, wipe the outer surfaces of the Cube with germicidal wipes containing 0.55% sodium hypochlorite as the active ingredient.

INTENDED USE

The 3EO Health COVID-19 Test is a single-use molecular in vitro diagnostic test intended for the qualitative detection of SARS-CoV-2 nucleic acid directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19 (i.e., symptomatic). This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older or adult-collected anterior nasal (nares) swab samples from individuals aged two years or older.

This test utilizes nucleic acid amplification technology, similar to PCR, for the detection of SARS-CoV-2 RNA, which is generally detectable in anterior nasal swab samples during the acute phase of infection.

Positive results indicate the presence of SARS-CoV-2 RNA, but clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definitive cause of disease. Individuals who test positive with the 3EO Health COVID-19 Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or management decisions for the individual, including infection control measures such as isolating from others and wearing masks. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19. Individuals who test negative and continue to experience COVID-19-like symptoms of fever, cough, and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow-up care with their physician or healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting and to receive appropriate healthcare. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by the CDC.

The 3EO Health COVID-19 Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION

The 3EO Health COVID-19 Test™ is an in-vitro diagnostic molecular test for the qualitative detection of SARS-CoV-2 virus that causes the COVID-19 disease.

Samples from anterior nasal swabs are analyzed and results are available within approximately 30 minutes. Each 3EO Health COVID-19 Test Kit contains all components necessary to test for SARS-CoV-2.

WARNING AND PRECAUTIONS

Warnings and Precautions include, but are not limited to:

- Follow directions for use.
- Do not ingest.
- Keep out of reach of children.
- Children aged 2 to 13 years of age should be tested by an adult.
- Do not use on anyone under 2 years of age.
- Avoid contact with skin and eyes. If contact with the body occurs, rinse with water. If irritation persists, seek medical advice.
- Do not use if packaging is opened or damaged before use.
- Do not use any components with visible damage.
- Do not use the 3EO Key past the expiration date
- Key and Swab are one-time use items.
- Nasal sprays, gels, or cream should not be used before collecting a sample.
- Avoid eating or drinking 30 minutes prior or smoking 60 minutes prior to specimen collection.
- Do not move or tilt the Cube during operation. Doing so could lead to false results.
- Do not place the 3EO Cube in direct sunlight.
- Store and use the Key within the below temperature ranges:
 - Storage: between 59°F (15°C) and 86°F (30°C)
 - Use: between 59°F (15°C) to 86°F (30°C)
- Performance of the 3EO Health COVID-19 Test has only been established using the sample types, acquisition, and protocol described here.
- Risks of sample collection include irritation, bleeding, and infection inside the nose.
- This device was not validated for use by individuals with color impaired vision, including individuals with red/green vision impairment.

This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an Emergency Use Authorization (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 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. §360bb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The background is a solid blue color. In the upper left quadrant, there is a cluster of semi-transparent blue circles of various sizes, some overlapping. In the lower half of the page, there are several thin, light blue wavy lines that flow horizontally across the width of the page, creating a sense of motion and depth.

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