

How does the Ellume COVID-19 Home Test work?

The Ellume COVID-19 Home Test is a type of test called an antigen test. When you have COVID-19, the SARS-CoV-2 virus (the virus that causes COVID-19) can be present in your nasal secretions. The Ellume COVID-19 Home Test can detect small parts of SARS-CoV-2 virus in your nasal secretions. These small parts of the SARS-CoV-2 virus are known as proteins or antigens.

What is the difference between a COVID-19 antigen and a molecular test?

There are different kinds of tests for the SARS-CoV-2 virus that causes COVID-19. Molecular tests detect genetic material from the virus. Antigen tests, such as the Ellume COVID-19 Home Test, detect proteins from the virus. Due to the lower sensitivity of antigen tests, there is a higher chance this test will give you a false negative result when you have COVID-19 than a molecular test would.

For more information on COVID-19 testing, please see the following link:

<https://www.fda.gov/consumers/consumer-updates/coronavirus-disease-2019-testing-basics>

Is the test reusable?

No. The Ellume COVID-19 Home Test cannot be reused.

What are the approved available alternatives?

There are no approved available alternative antigen tests. Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here: <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases>.

A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at:

<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

How accurate is the Ellume COVID-19 Home Test?

Clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus that causes COVID-19 when taken multiple times across several days. Repeat testing improves test accuracy. This serial testing approach is recommended to minimize the risk of incorrect results. For more information on the performance of the test and how the performance may apply to you, please refer to the performance data in the Product Overview for Healthcare Professionals, available at <https://www.ellumecovidtest.com/resources/Accessibility-COVID-19-Home-Test-Product-Overview-for-Healthcare-Professionals.pdf>.

What does it mean if I have a positive test result?

A positive result means that it is very likely you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. You should self-isolate from others and contact a healthcare provider for medical advice about your positive result.

What you need to do:

1. **You do not need to perform repeat testing.**
2. **Consult a healthcare professional and tell them that you tested positive for COVID-19. Provide your healthcare professional with:**
 - a. Your Test Result Record (sent to you via email, if selected, and in your COVID-19 Home Test app)
 - b. [The Product Overview for Healthcare Professionals](#)
 - c. [The Fact Sheet for Healthcare Professionals](#)

If you have no symptoms, your healthcare professional may recommend a confirmatory test. Please see FAQ 'Can I have a false positive test result?'

3. **You should self-isolate at home as per CDC recommendations to stop spreading the virus to others.**

Please consult the CDC recommendations regarding self-isolation:

www.cdc.gov/coronavirus/2019-ncov

4. **If you are in a high risk group it is very important to see your Healthcare Professional as there may be treatment options available to you. Further information can be found at <https://combatcovid.hhs.gov> or www.cdc.gov/coronavirus/2019-ncov.**

There is a very small chance that this test can give a positive result that is wrong (a false positive result) especially if you use the test when there are very few COVID-19 infections in your local community. Your healthcare provider may suggest you need molecular testing to confirm whether you have contracted the virus causing COVID-19. Visit FAQ 'Can I have a false positive result' on our website.

What does it mean if I have a negative test result? Can I have a false negative result?

A negative test result indicates that antigens from the virus that causes COVID-19 were not detected in your sample. However, if you have symptoms of COVID-19, and your first test is negative, you should test again in 48 hours since antigen tests are not as sensitive as molecular tests. If you do not have symptoms and received a negative result, you should test at least two more times with 48 hours in between tests for a total of three tests. If you have a negative result, it does not rule out SARS-CoV-2 infection; you may still be infected and you may still infect others. It is important that you work with your healthcare provider to help you understand the next steps you should take.

What does an invalid result mean and how often does the Ellume COVID-19 Home Test produce an invalid result?

An invalid result means the test was not able to tell if you have COVID-19 or not. If the test is invalid, a new swab should be used to collect a new nasal specimen and you should test again with a new test.

In the most recent clinical study, a total of seven-hundred and nineteen (719) tests were performed. Forty (40) Invalid Results were recorded. Overall Invalid Result rate was therefore 5.6%.

Can I have a false positive result?

There is a very small chance that this test can give a positive result that is incorrect (a false positive result).

Anyone who receives a positive test result needs to consult a healthcare professional. If you have any doubt about your test result, please discuss it with a healthcare professional. This is especially important if you belong to a high-risk group (See FAQ Who is considered high risk for severe disease? on our website) or develop emergency warning signs. The healthcare professional will work with you to determine how best to care for you based on your test result along with your medical history and symptoms.

The percent of positive test results that are true positives (also known as Positive Predictive Value or PPV) varies with how common infection is in a population. As the number of infections in the community decreases, the number of test results that are false positives increases. When numbers of infections are low (low prevalence), false positive results may be more likely than true positive results. For example, if prevalence of infection in a community is 5%, 37 out of 100 positive results from the Ellume COVID-19 Home Test would be false positives. If disease prevalence is only 1%, 75 out of 100 positive results would be false positives. It is difficult to determine how many infections are in asymptomatic individuals and false positive results may be more likely if you do not have symptoms of infection.

If you do not have symptoms of COVID-19 and get a positive result, your test results should be confirmed with a molecular SARS-COV-2 test. Positive results from the Ellume COVID-19 Home Test are presumptive in asymptomatic patients, and have a higher risk of being false positives, particularly if you do not have a known SARS-CoV-2 exposure and/or live in an area known to have low numbers of SARS-CoV-2 infections. The CDC recommends that persons who receive a positive antigen test should isolate until they can be confirmed by a molecular test.

When can I be with others again?

Please see the following link for the current recommendations for quarantine and isolation:

<https://www.cdc.gov/coronavirus/2019-ncov>

Can the Ellume COVID-19 Home Test be used in children under age two?

No, the Ellume COVID-19 Home Test should not be used in children under the age of two. The test has not been validated for use in this age group, and the swab is specifically designed for children over age two and may not collect acceptable samples from younger children. If you are concerned that your under two year-old child has COVID-19 you should see a healthcare professional for advice and further management.

Why is the app asking me for my personal details?

The App will send you a record of your test result if you input your email address. You can share this record with your healthcare professional or employer, for example. Information supplied supports the monitoring of COVID-19 infection rates across the country.

Will this test hurt?

No, the nasal swab is not sharp, and it should not hurt. Sometimes the swab can feel slightly uncomfortable. If you feel pain, please stop the test and seek advice from your healthcare provider.

What are the known and potential benefits and risks of the test?**Potential risks include:**

- Possible discomfort during sample collection.
- Possible incorrect results. (see Warnings and Result Interpretation sections in the Product Information Leaflet for more information).

Potential benefits include:

- The results, along with other information, can help your healthcare professional make informed recommendations about your care.
- The results of this test may help you to limit the spread of disease to your family and others within your community.

For more information on EUAs go here: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>

Will I be able to use my phone (receive calls, send messages and browse the internet) while the test is running?

You will be able to receive calls on speaker but you must keep your phone within 3 inches of the Analyzer while the test is running. Please note that the Analyzer will need to remain on a flat surface. We recommend keeping the Ellume COVID-19 Home Test App on the screen until you have received your result. Leaving the app may result in the test being interrupted and not obtaining a result. If that happens, the test kit cannot be reused and you will need to acquire a new test kit to perform another test.

Can I connect the test with my computer or tablet?

No. The test is only compatible with smartphones included on the list of [compatible devices](#).

Can I connect the test with my phone?

The test is only compatible with smartphones included on the list of [compatible devices](#).

How long after I open the test kit from its packaging do I have to perform the Ellume COVID-19 Home Test?

Once you open the foil packaging, you have one hour to do the test.

How far do I insert the Nasal Swab?

You need to insert the Swab as far back into your nasal cavity as possible to increase the likelihood of detecting COVID-19. Insert the Swab into your nostril until the cap of the Swab touches your nose. If the individual is a child aged 2-12 years, insert the Swab until the Child Adapter touches their nose. Do not insert the Swab any further if you experience sharp pain or severe discomfort. Do not use this test on children under the age of 2 years.

Why do I swab both nostrils?

Swabbing both nostrils gives you the best chance of collecting sufficient sample to generate an accurate result. It has been observed in some cases that only one nostril has detectable virus, so it is important to collect from both nostrils. Correct swabbing is important to obtain a correct result.

Can I injure myself using the swab?

The Swab is sterile and safe to use and the Cap (or Child Adapter for children 2-12 years old) will prevent you from inserting it too far into your nose and causing injury. You may experience some discomfort when swabbing your nose but this is to be expected. Do not insert the Swab any further if you experience sharp pain.

Can I perform the test if I don't have a blocked or runny nose?

Yes. The Ellume COVID-19 Home Test can be used with or without any noticeable symptoms of COVID-19. You need to gently rub the tip of the Swab around the inside of your nose cavity 3 times in each nostril to ensure you get sufficient sample to obtain an accurate result.

Who is considered high risk for severe illness with COVID-19?

People who are at increased risk of severe disease and have COVID-19 may be suitable for specific treatments to prevent them getting sicker and needing hospitalization. Please see your healthcare professional if you are experiencing COVID-19 like symptoms and are in one of these groups regardless of your test result. You can also visit <https://combatcovid.hhs.gov> or www.cdc.gov/coronavirus/2019-ncov for more information.

I have a nosebleed after swabbing my nose. What should I do?

If your nose starts bleeding, apply pressure to your nose until the bleeding stops and consult a healthcare professional. Do not insert the Swab again.

What should I do if my phone cannot connect with the Analyzer?

Follow the on-screen trouble-shooting instructions in the App. If you are still unable to connect, call our toll-free Customer Helpline 1-888-885-6121.

What should I do if my phone runs out of charge during the test?

Plug your phone into charge and turn it back on. Ensure the Analyzer is still on (the green light should be flashing/blinking). If it is turned off, press the power button once to turn it on. Then open the App and the Analyzer will automatically reconnect to your phone and display the current state of the test.

The Analyzer light is flashing red. What does this mean?

A flashing red Analyzer light indicates that the battery of the Analyzer is too low to perform the test. Call our toll-free Customer Helpline 1-888-885-6121.

The Analyzer light is solid red. What does this mean?

A solid red Analyzer indicates that the Analyzer is faulty. Call our toll-free Customer Helpline 1-888-885-6121 to request a replacement test

What happens if I mistakenly added the Processing Fluid directly to the sample port of the Analyzer and not to the Dropper?

This will result in an invalid result. You must dispense the Processing Fluid into the Dropper. You will need to acquire a new test kit.

I am trying to squeeze the fluid into the Sample Port but no fluid is coming out. What should I do?
Ensure the Swab is screwed into the Dropper as tightly as possible. Some force will be required to do this. Then try again holding the Dropper completely vertical. If this does not solve the problem, call our toll-free Customer Helpline 1-888-885-6121 for assistance.

How much fluid should I squeeze into the Port of the Analyzer?
Squeeze 5 drops of fluid out of the Dropper into the Sample Port of the Analyzer. If there is less fluid in the Dropper, squeeze in as much as you can. Using less than 5 drops may cause the test to give an inaccurate result or not produce a result at all. You will need to acquire a new test kit.

I screwed the Nasal Swab into the Dropper before I swabbed my nose. Can I unscrew and re-use the Swab?
No. Once the Swab Cap has been screwed into the Dropper it will lock in place and you should not attempt to remove it. You should only insert a dry sterile Swab into your nose. Once screwed into the Dropper, the Swab will be wet with the Processing Fluid and no longer sterile. Avoid contact with the Processing Fluid and do not insert the wet Swab into your nose. You will need to obtain a new test kit.

What should I do if some of the liquid splashes onto my phone?
You should wipe the liquid off your phone as per the recommendations of your phone manufacturer. Please note that you may not have sufficient liquid remaining to perform the test. If that happens, you will need to obtain a new test kit.

What should I do if I spill some Processing Fluid onto myself or the area where I'm using the product?
Wipe up the liquid with a tissue or paper towel and dispose into general waste. Wash the affected area with soapy water. Avoid contact with the fluid with your skin. The reagent in the Processing Fluid contains ProClin® 300 which may cause an allergic skin reaction in some people. If the solution makes contact with the skin or eye, wash/flush with copious amounts of water. If skin irritation or rash occurs seek medical advice/attention.

I received an 'Invalid Result' message when I performed the test and now I need to use a new test kit. Can I use the same sample I used in the previous test?
No, you will need to collect a new sample. You will need to obtain a new test kit.

How does the Ellume swab differ from a nasopharyngeal (NP) swab?
It's smaller than the standard nasopharyngeal swab you may have seen or experienced. And ours is unique to Ellume.

Our patented Nasal Swab is a mid-turbinate swab, which means it is inserted a little under 2 inches into your nose and 1 inch into a child's nose, which is shallower than the nasopharyngeal swab used when testing for COVID-19.

We use our patented Child-Protector, a soft fixture attached to the base of the swab, to ensure you don't swab your child too deeply.

If I'm vaccinated can I still use the Ellume COVID-19 Home Test?

Yes, vaccinated individuals can use the Ellume COVID-19 Home Test.

If you have been vaccinated and you receive a positive result from the Ellume COVID-19 Home Test, please treat this as a positive test result, follow the on-screen instructions and consult a healthcare professional.

Will COVID-19 mutations affect my Ellume COVID-19 Home Test result?

The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between October 2020 and November 2020. A subsequent clinical trial was commenced in May 2022 when the dominant circulating strain was the Omicron variant. The clinical performance has not been established in all circulating variants, including Delta variant but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time. We are continually monitoring to see if mutations impact our Test.

I'm having trouble connecting my Analyzer to my phone via Bluetooth.

If the Analyzer is having problems connecting to your phone:

- 1) Hit the Troubleshooting button in the app and follow the instructions.
- 2) Ensure Bluetooth and Location are ON in settings (allow Bluetooth access).
- 3) Remove your phone case.
- 4) If you connected your phone to the Analyzer manually (through Bluetooth in settings) disconnect and follow the instructions.
- 5) Connect the Analyzer to a different phone you trust and follow the instructions.

If you're still unable to connect, please call our Customer Support team on 1-888-885-6121

Common Invalid Result Codes:

Code 20:

Got a 'Code 20' or 'Not enough sample for an accurate result' message?

You should retest with a new test or consult a healthcare professional.

If you receive this message, please contact our Customer Support team via the Customer Support section of this website or on 1-888-885-6121.

Code 29:

This indicates there was a problem or damage to the Analyzer and the test could not run an accurate test.

When you power on the analyzer it runs a series of internal quality control checks to ensure everything is running as it should. If the analyzer finds there is some internal damage, it presents a Code 29.

This is important as it ensures we do not generate a result when the test may not be operating as planned.

Please call our Customer Support team to organize a replacement. Call us on 1-888-885-6121

Code 14:

This indicates the test has been instructed to start running (by pressing the Run Test button within the app) but no sample has been detected within the Analyzer.

This could mean that there is damage within the analyzer, preventing it from detecting the sample you added, or could mean you didn't add sufficient sample to the analyzer. You should retest with a new test.

Please call our Customer Support team so we can investigate further. Call us on 1-888-885-6121. You will require a new test kit.

Code 9:

This indicates that fluid from the sample was added to the Analyzer too early in the test process.

This could mean that there is damage within the Analyzer preventing it from operating correctly or could mean you added your sample out of sequence with the test instructions.

Please call our Customer Support team so we can investigate further. Call us on 1-888-885-6121. You will require a new test kit.

Code 32:

This indicates there was a problem or damage to the Analyzer and the test could not run an accurate test.

When you power on the Analyzer it runs a series of internal quality control checks to ensure everything is running as it should. If the Analyzer finds there is some internal problem or damage, it presents a Code 32.

This is important as it ensures we do not generate a result when the test may not be operating as planned.

Please call our Customer Support team to organize a replacement. Call us on 1-888-885-6121.

International Travel For information on testing requirements for international travel please visit the CDC website - <https://www.cdc.gov/coronavirus/2019-ncov/travelers/international-travel/index.html>

Before you travel in the US:

Make sure you understand and follow all airline and destination requirements related to travel, mask wearing, testing, or quarantine which may differ from US requirements.

Please check requirement here - <https://www.cdc.gov/coronavirus/2019-ncov/travelers/international-travel-during-covid19.html>

Who has access to the personal information in the secure cloud?

No one has access to the personal information in the secure cloud.

Two things happen when your data is uploaded.

1. It is transmitted to public health authorities such as the HHS and state authorities for mandatory COVID-19 test result reporting via our integration partner. Our integration partner is legally bound to handle your data appropriately under a HIPAA business associate agreement, for public health authority data reporting. If you have chosen to share your information with an organization via the organization IDs and patient codes, your data is shared with them.
2. All personal information is removed and stored in secure storage by the system (in case retransmission to authorities is required). No one is looking at this data.

Is anyone looking at my information and who owns the cloud?

See answer above, no one is looking at your personal information.

Ellume's cloud is hosted on Microsoft Azure services in the United States.

Ellume has no interest in users' personal information except to fulfil our mandatory health authority data reporting requirements and provide services that you have requested of us. We do not analyze, sell or access your personal information in any other way. You can find out more by reading our [privacy policy](https://www.ellumecovidtest.com/privacy) (<https://www.ellumecovidtest.com/privacy>)