

COVID-19 home test

FREQUENTLY ASKED QUESTIONS

IVD No test component to be used inside the body except the Nasal Swab as directed.

www.ellumecovidtest.com

Will this test hurt?

To obtain an accurate test result it is important that you swab correctly. You must insert the Nasal Swab until the Swab Cap (or the Child Adapter in the case of children aged 2-12 years) touches the nose. When taking your sample, you can expect some discomfort, but you should not have sharp pain. Do not insert the Swab any further if you experience sharp pain.

What are the known and potential benefits and risks of the test?

Potential benefits:

- The results can detect if you have COVID-19 or not.
- The results, along with other information, can help your healthcare professional make informed recommendations about your care.
- If positive for COVID-19 you can help limit the spread of the disease by self-isolating at home and avoiding other family members.
- If positive for COVID-19 you can advise those you have been in close contact with, or locations you have visited in the last 14 days, to test for possible COVID-19 infection.

Potential risks:

- Possible discomfort or other complications (e.g. minor nosebleed) that can happen during sample collection.
- Possible incorrect test result (either false positive or false negative). See below for more information.

Is this test FDA-approved or cleared?

No. This test is not yet approved or cleared by the United States FDA. When there are no FDA-approved or cleared tests available, and other criteria are met, FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA for this test is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the



emergency use of in vitro diagnostics for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).

What are the approved alternatives?

There are no approved available alternative tests. 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 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, molecular, and antibody test?

There are different kinds of tests for diagnosing COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus. The Ellume COVID-19 Home Test is an antigen test which detects small parts or proteins from the virus. Antigen tests are very specific for the virus but are not as sensitive as molecular tests.

Another type of test is an antibody test. A COVID-19 antibody test detects antibodies that have been made by your immune system in response to a previous COVID-19 infection. Antibody tests are not suitable to diagnose an active COVID-19 infection.

For more information on COVID-19 testing, please see the following link: <https://www.fda.gov/consumers/consumer-updates/coronavirus-disease-2019-testing-basics>

How accurate is the Ellume COVID-19 Home Test?

The Ellume COVID-19 Home Test correctly identified 96% of positive samples and 100% of negative samples in individuals with symptoms. In people without symptoms the test correctly identified 91% of positive samples and 96% of negative samples. This performance was measured during a clinical study conducted in the USA from October 2020 to November 2020, comparing the Ellume COVID-19 Home Test results to a FDA Emergency Use Authorized high sensitivity PCR (molecular) test.

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

A positive test result means it is very likely that you have COVID-19 disease if you have symptoms because proteins from the virus that causes COVID-19 were found in your sample. You should self-isolate at home as per CDC recommendations to stop spreading the virus to others (<https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/index.html>)

If you have received a positive test result especially if you are considered high risk (refer to FAQ 'Who is considered high risk for severe disease'), you should take the following steps:

1. Consult a healthcare professional as soon as possible. Please tell them that you tested positive for COVID-19. Provide your healthcare professional with:

- Your Test Result Record (sent to you via email, if selected, and in your COVID-19 Home Test app)
- The Product Overview for Healthcare Professionals
- 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?' on our website.

2. 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 (<https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/index.html>)

There is a 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 professional will work with you to determine how best to care for you based on the test results along with medical history, and your symptoms.

Who is considered high risk for severe disease?

The following people are considered high risk for severe disease:

- People aged 65 and older
- People in nursing homes or long-term care facilities

- People of all ages with underlying medical conditions, particularly if they are not well controlled:
- Cancer
- Chronic obstructive pulmonary disease
- Chronic kidney disease
- Immunosuppressed following solid organ transplant
- Obesity (BMI >30)
- Serious heart conditions such as heart failure, coronary artery disease or cardiomyopathies
- Sickle cell disease
- Type II Diabetes

People may be at increased risk due to the following conditions:

- Asthma (moderate-severe)
- Cerebrovascular disease (affecting blood vessels to the brain)
- Cystic fibrosis
- High blood pressure
- Immunocompromised (weakened immune system) from blood or bone marrow transplants, immune deficiencies, HIV, use of corticosteroids, use of other immune weakening medications
- Neurologic conditions such as dementia
- Liver disease
- Pregnancy
- Pulmonary fibrosis
- Smoking
- Thalassemia
- Type I Diabetes

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

A negative test result indicates that you are unlikely to currently have COVID-19 disease. A negative test result means that proteins, which are small parts of the virus that causes COVID-19, were not found in your sample. However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19 (refer to FAQ Can I have a false negative test result?). This means that you could possibly still have COVID-19 even though the test is negative. If your test result is negative, your healthcare professional will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you. The amount of antigen in a sample may decrease as the duration of illness increases. As days post-symptom onset increase, antigen test results may be more likely to be negative compared to a molecular SARS-CoV-2 test. You may also test negative at the very beginning of your infection before you develop symptoms.

If you are unwell, your symptoms are worsening, you develop new symptoms, or you are concerned, it is important that you see a healthcare professional, especially if you belong to a high-risk group (refer to FAQ Who is considered high risk for severe disease?). The healthcare professional will consider the test result with all other aspects of your medical history (such as symptoms, possible exposures, local community spread and places you have recently visited) in deciding how to care for you. It is important that you work with a healthcare professional to help you understand the next steps you should take.

How often does the Ellume COVID-19 Home Test produce an invalid result?

The overall invalid result rate on first test for the 209 subjects that performed testing in a clinical study in October and November 2020 was 8% (17/209). Nine (9) of the seventeen (17) invalid results recorded were generated by the Analyzer as a failsafe control to indicate to the user that insufficient sample had been collected for the test to give a valid result. All 9 were generated by asymptomatic subjects. It is therefore very important that a user with no symptoms pays close attention to sampling technique to avoid having to retest with a new test.

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 years. The test has not been validated for use in this age group and if you are concerned that your under two year-old child has COVID-19 you should see a health care professional for advice and further management.

Why is the app asking me for my personal details?

Your test result is saved within the COVID-19 Home Test App and if selected, the App will email you a record of your test result. You can share this record as a proof of COVID-19 testing with your healthcare professional, for example. Your date of birth and zip code are information you are required to provide because they are shared with the relevant health authorities to support monitoring of COVID-19 infection and test positivity rates across the country. Other personal information may be shared with the relevant health authorities, however, only if you choose to enter details in the optional information fields.

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 light indicates that the Analyzer is faulty. Call our toll free Customer Helpline 1-888-885-6121.

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 a test error. You must dispense the Processing Fluid into the Dropper. You will need to acquire a new test kit.

Can I connect the Analyzer with my computer or tablet?

No. The test is only compatible with smartphones included on the list of compatible devices.

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.

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.

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 onto 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.

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.

Is the test reusable?

No. The Ellume COVID-19 Home Test is a single use test and cannot be reused.

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

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

Can I injure myself using the Swab?

The Swab is sterile and safe to use and the Cap (or the Child Adapter for children aged 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.

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 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.

I received an error 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.

My test did not detect COVID-19. What is making me sick?

There are other respiratory illnesses that could be making you sick. This test cannot detect other respiratory viruses or bacteria that could be making you ill.

In a small number of cases your test will be negative when you do in fact have COVID-19 (false negative) (refer to FAQ Can I have a false negative test result?). If you develop any of the emergency warning signs listed below, please seek medical attention immediately. Please also consult a healthcare professional if you develop symptoms, symptoms persist or become more severe.

Emergency warning signs include:

- Trouble breathing
- Persistent pain in the chest
- New confusion or inability to wake or stay awake
- Bluish color of lips or face

This list is not all inclusive. For most current information on emergency warning signs refer to: <https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/steps-when-sick.html>

Can I have a false negative test result?

It is possible for this test to give a negative result that is incorrect (a false negative result). This means that you could possibly have COVID-19 even though the test is negative.

The amount of antigen in a sample may decrease as the duration of illness increases. As days post-symptom onset increase, antigen test results may be more likely to be negative compared to a molecular SARS-CoV-2 test. You may also test negative at the very beginning of your infection before you develop symptoms.

Specimens collected from people who do not have symptoms of COVID-19 are more likely to be falsely negative compared to people who do have symptoms of COVID-19. **Negative results, particularly in people without symptoms of COVID-19, are considered to be presumptive which means that additional testing with a highly sensitive molecular assay may be recommended to determine if you have COVID-19.**

If you develop symptoms, symptoms persist or become more severe, if you are concerned about your health or if you develop any of the emergency warning signs then you should seek medical attention immediately. If you have any doubt about your test result, please discuss with a healthcare professional.

Can I have a false positive test result?

There is a 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 (link to FAQ Who is considered high risk for severe disease?) 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.

For low-risk individuals, the CDC recommends that persons who receive a positive antigen test should isolate until they can be confirmed by a molecular test. For further recommendations regarding antigen tests, please see the link provided in "Where can I go for updates and more information?" section.

When can I be with others again?

If you test positive and you have symptoms at time of testing or develop symptoms:

- After self-isolating for at least 10 days since symptoms first appeared

and

- At least 24 hours with no fever (without fever-reducing medications)

and

- Other symptoms of COVID-19 are improving (excluding loss of taste and smell, which may persist for weeks or months after recovery).

If you test positive and you have no symptoms at time of testing and continue to have no symptoms:

- After self-isolating for 10 days since your positive test.

If you test negative and you have no symptoms at time of testing:

- CDC recommends 14 days of quarantine after exposure to someone with COVID-19 based on the time it takes to develop illness if infected. Please discuss your potential options to reduce your quarantine period with a healthcare professional

In USA - This product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization (EUA). This product has been authorized only for the detection of proteins from SARS- CoV-2, not for any other viruses or pathogens. 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.