

! At all times

User safety

High Risk Groups

The following people are considered high risk for severe disease:

- People aged 65 years 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
 - Immunocompromise such as those post solid-organ transplant
 - Obesity (BMI >30)
 - Serious heart conditions such as heart failure, coronary artery disease, cardiomyopathies
 - Sickle cell disease
 - Type II Diabetes

Other conditions that may have an increased risk of severe illness:

- 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

For the most current information on high-risk groups refer to: <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/index.html>

EMERGENCY WARNING SIGNS

If you develop any of the following emergency warning signs please seek medical attention immediately:

- 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 the most current information on emergency warning signs refer to: <https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/steps-when-sick.html>

Warnings and precautions

- Do not use on anyone under 2 years of age
- Do not use on anyone who is prone to nosebleeds or has had facial or head injury/surgery in the last 6 months
- Do not use the test kit contents beyond the expiration date printed on the outside of the box.
- Do not reuse any used kit components
- Do not use if any of the foil packaging is opened or damaged
- Do not open any of the foil packaging until you are ready to begin your test
- Use the test within 60 minutes of opening the Analyzer and Dropper foil packaging
- Do not use the test if it has been exposed to household cleaning products (especially bleach).
- Keep the Analyzer on a flat surface until the result is available
- Do not drop the Analyzer. Handle with care
- Do not perform the test in direct sunlight
- Add no more or less than five drops into the Analyzer. False negative or invalid test results may occur
- Do not perform the test within 30 feet of another Ellume COVID-19 Home Test
- Do not close the Ellume COVID-19 Test App

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Frequently asked questions (FAQs)

1 What is the difference between a COVID-19 antigen, molecular and an antibody test, and what kind of test is the Ellume COVID-19 Home 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. Antigen tests detect proteins, small parts, 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.

2 How does the Ellume COVID-19 Home Test work? The Ellume COVID-19 Home Test is 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. This test can detect small parts of SARS-CoV-2 virus in your nasal secretions.

- During processing as it will cause an error and you will need a new test kit
- Ensure your test is at room temperature 59-77°F (15-25°C) prior to testing
- To obtain accurate results, the in-app instructions should be followed
- 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 get medical advice/attention
- Inadequate or inappropriate sample collection may yield Test Error results and you will have to test again with a new test kit. Pay particular attention to appropriate sample collection technique, especially in asymptomatic individuals
- When collecting a mid-turbinate Nasal Swab sample, use only the Nasal Swab supplied in the kit
- Keep out of reach of children. The test contains small parts that may present a choking hazard
- Do not use this test as the only guide to manage your illness, particularly if your test has been negative for COVID-19
- For in vitro diagnostic use only

Please consult a healthcare professional if you are concerned about your health, if your symptoms persist, or if symptoms become more severe.

- Avoid performing the test in a very dry environment (very low humidity) to prevent a build up of static electricity that could damage the electronics of the test
- A test result will be less reliable when there is very little COVID-19 in the community
- No test components to be used inside the body except the Nasal Swab
- 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

5 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.

6 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.

7 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.

8 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.

9 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 the Ellume COVID-19 Home Test toll free Customer Helpline 1-888-885-6121.

For further FAQs visit www.ellumecovidtest.com

Clinical performance

In a clinical study conducted in the USA from October 2020 to November 2020, the Ellume COVID-19 Home Test correctly identified 96% of positive samples and 100% of negative samples in patients with symptoms. In people without symptoms the test correctly identified 91% of positive samples and 96% of negative samples. If you or a healthcare professional would like to know more about how the test works you will find more details in the Test Result Record saved in the App. Alternatively, you or the healthcare professional can call the Ellume COVID-19 Home Test toll free Customer Helpline 1-888-885-6121 at any time. The Fact Sheet for Healthcare Professionals and Product Overview for Healthcare Professionals are available via the App, and at www.ellumecovidtest.com.

Invalid Test Rate

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.

2 What are common symptoms of COVID-19? Symptoms may appear 2-14 days after exposure and may include fever, cough, shortness of breath, fatigue, muscle or body aches, headaches, loss of sense of taste or smell, sore throat, congestion or a runny nose, nausea or vomiting and diarrhea.

5 What can I do to stay healthy during the COVID-19 pandemic? To protect your friends, family, community, and yourself, follow these hygiene practices to help stop the spread of infections.

3 How does the virus spread? The virus that causes COVID-19 is thought to spread mainly from person to person, mainly through respiratory droplets produced when an infected person coughs or sneezes. These droplets can land in the mouths or noses of people who are nearby or possibly be inhaled into the lungs. These respiratory droplets contain virus particles which can also survive on surfaces for several hours. This is another important source of spread with COVID-19 when people touch these infected surfaces and then touch their faces (mouth, nose, eyes).

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More about the test

• Some technologies inside the test are licensed from Thermo Fisher.

• This product contains small amounts of animal sourced materials.

• This device complies with the emission and immunity requirements described in IEC 60601-1-2. Interference from other electronically driven equipment is not expected.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

1 What is COVID-19? COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness.

2 Why is the App asking me for my personal details? 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, employer or educator. For the App to be able to generate this record it requires some personal details from the patient.

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