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## PRODUCT INFORMATION LEAFLET

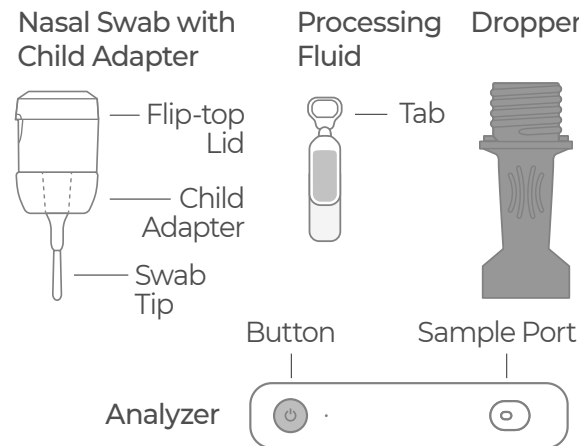
Refer to the Quick Start Guide for a summary of the key information of this leaflet.

**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.**

## General Information

Please read this leaflet before using the test. You should follow the Ellume COVID-19 Home Test App when performing the test. The test is intended to be used as an aid in the diagnosis of a **current COVID-19 infection**. Please consult a healthcare professional to discuss your results and if additional testing is necessary.

### COVID-19 Home Test – What is included in the Box



Product Information Leaflet and Quick Start Guide are also included.

### When to use this kit

#### Use this test:

- ✓ As an aid in the diagnosis of **current COVID-19 infection** AND;
- ✓ If you are concerned that you have COVID-19.

#### Do not use this test:

- ✗ On anyone under 2 years of age;
- ✗ If you are prone to nosebleeds, OR;
- ✗ If you have had a facial or head injury/surgery in the last 6 months.

## 1 Before you start

### Preparing to do the test

- ✓ **Ensure you have an internet connection to download the App.** Features like emailing of test result record and result sharing also require an internet connection.
- ✓ **Ensure you are using a compatible smartphone.** For a full list of compatible devices visit: [www.ellumecovidtest.com](http://www.ellumecovidtest.com)
- ✓ **Ensure your phone is charged** (at least 20% battery) or is charging.
- ✓ **Ensure your test is at room temperature** 59-77°F (15-25°C).
- ✓ **Ensure all packaging is intact.** Do not use the test if there is visible damage to the foil packaging.
- ✓ **Only open the foil packaging when you are ready to do the test.** Use test within 1 hour after opening.
- ✓ **Wash your hands with soap and water or use hand sanitizer before using the test.**
- ✓ **Keep the Swab clean.** Avoid touching the Swab Tip and ensure it does not touch any surfaces before use.

### Step-By-Step Instructions

This leaflet only describes the key steps of the test. Step-by-step instructions on how to perform this test are in the Ellume COVID-19 Home Test App.

#### 1 Unbox components

Only open foil packaging when you are ready to do the test. Use within 1 hour after opening.

#### 2 Download and open App

Find the free Ellume COVID-19 Home Test App on the Google Play Store, the App Store or use your smartphone's browser to visit: [www.ellumecovidtest.com](http://www.ellumecovidtest.com)

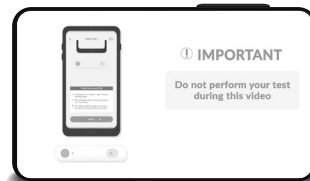


#### 3 Answer a few questions in the App

This will select the right video and instructions for you and enable health authorities to monitor COVID-19 infection and test positivity rates.

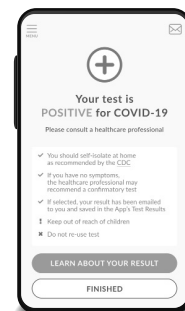
#### 4 Watch info video

The video will provide an overview of what to expect. There will be separate step-by-step instructions later in the App.



#### 5 Follow instructions

Separate step-by-step instructions will be available within the App after the video.



## 2 During the test

### Do's and don'ts

- ✓ **Follow the App's instructions carefully.** Incorrect use or use in the wrong order may result in a test failure or an incorrect result.
- ✓ **Children aged 2-15 years should be tested by an adult (18+ years old).**
- ✓ **Children aged 2-12 years should be swabbed with the Child Adapter in place.**
- ✓ **Keep out of reach of children.** Small kit parts may be a choking hazard.
- ✓ **Only use the test components provided.** Do not replace the Processing Fluid with any other fluid.
- ✓ **Keep the Swab clean.** Avoid touching the Swab Tip and ensure it does not touch any surfaces before use. a contaminated swab is a health hazard.
- ✓ **Immediately after taking the sample, screw the Swab into the Dropper.**
- ✓ **Keep your phone within 3 inches of the Analyzer until the test result is available.** If you receive a call, answer on speaker.
- ✓ **Keep the Analyzer on a flat surface until the result is available.** Tilting the Analyzer could result in a test error.
- ✓ **Keep foreign substances away from the test during the testing process.** Contact with foreign substances, specifically bleach, may result in an incorrect test result.

- ✗ **Do not use this test on anyone under 2 years of age.**
- ✗ **Do not drop the Analyzer. Handle with care.**
- ✗ **Do not perform the test in direct sunlight.**
- ✗ **Avoid contact with Processing Fluid.** Do not insert Swab into your nose once it has been in contact with Processing Fluid and do not ingest Processing Fluid. Only a clean Swab should be inserted into your nose.

- ✗ **Do not perform your test within 30 feet of another person using an Ellume COVID-19 Home Test.**
- ✗ **Do not close the Ellume COVID-19 Home Test App during processing as it will cause an error and you will need a new test kit.**

### Correct swabbing

This test involves taking a sample from deep inside your nose. When doing the test, pay particular attention to the instructions on how to swab your nose. Incorrect swabbing may lead to an inaccurate test result. This is particularly important if you do not have symptoms.

#### Swabbing a small child.

We recommend swabbing small children with the help of a second adult. One adult should hold and reassure the child while the other takes the swab.

### Important

This test is intended to be used as an aid in the clinical diagnosis of a **current COVID-19 infection**. Do not use this test as the only guide to manage your illness. Please consult a healthcare professional if your symptoms persist or become more severe, or if you are concerned at any time.

## 3 After the test

### Your result and what it means for you

The Ellume COVID-19 Home Test App will show one of the following results on your phone's screen:

#### YOUR TEST IS POSITIVE FOR COVID-19

**A positive test result indicates that you very likely currently have COVID-19 disease.**

COVID-19 is a viral illness that causes multiple symptoms including fever, a cough, sore throat and shortness of breath (refer to COVID-19 information section).

#### What you need to do:

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 and in your COVID-19 Home Test App)
  - The Product Overview for Healthcare Professionals (in your COVID-19 Home Test App)
  - The Fact Sheet for Healthcare Professionals (in your COVID-19 Home Test App)

**If you have no symptoms, particularly if you live in an area with low numbers of COVID-19 infections and have had no exposure to anyone diagnosed with COVID-19, additional molecular testing to confirm your result may be required. Please advise the healthcare professional you have tested positive and have no symptoms. See FAQ 'Can I have a false positive test result' on our website <http://ellumecovidtest.com/FAQ>.**

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 [www.cdc.gov/coronavirus](http://www.cdc.gov/coronavirus).**

Press the YOUR RESULT & WHAT IT MEANS button on the result screen in the App to find out more about your result and when you can be with others again.

#### YOUR TEST IS NEGATIVE FOR COVID-19

**A negative test result indicates that you are unlikely to currently have COVID-19 disease.**

A negative test result means that proteins, small parts of the virus that causes COVID-19, were not found in your sample. However, you may have had COVID-19 previously. To confirm a previous infection, you will need to take a different type of test (antibody test).

#### What you need to do:

**Please consult a healthcare professional if you develop symptoms, symptoms persist or become more severe.**

Negative results, particularly if you have no symptoms of COVID-19, may require additional molecular testing to confirm your result. Please see FAQ 'Can I have a false negative test result' on our website <http://ellumecovidtest.com/FAQ>.

**So, what is making you sick?** There are many other viruses that cause similar symptoms to COVID-19 and these may be the cause of your symptoms. Regardless of the test result, it is important that while you are sick you should practice social distancing and good hygiene and should not attend work.

If you develop symptoms or your symptoms persist or become more severe, if you are concerned about your health or you develop one of the emergency warning signs (see COVID-19 information section) then you should seek medical attention immediately.

#### A TEST ERROR HAS OCCURRED

**Your test has experienced an error. You will need to retest with a new test or consult a healthcare professional. Self-isolate at home.**

Call the Ellume toll free helpline 1-888-885-6121 and have your test result and test packaging handy. We will need the Error Code, Lot Number and Analyzer ID on the result screen.

### Test results record

A record of your test result and detailed information regarding your result will be emailed to you if selected in the App. If you choose not to have the results sent to your email, your results will remain accessible within the App.

This record can be used as a proof of test result for your healthcare professional, employer, or educator.

Once you have your result, you can use the Menu icon to start a new test and to access past test results.



### Attention all users

If you are not recovering, feeling worse, or are concerned about your health, please consult a healthcare professional.

### Disposal

Before disposal of the Analyzer, we recommend removing the battery using the following steps:

- Locate the gap at the end (short side) close to power button of the Analyzer
- Place a coin in the gap
- Twist the coin to break off the bottom end of the Analyzer along the perforation in the plastic
- Remove the battery from the plastic clips of the Analyzer
- Dispose of the battery according to local regulations
- Keep the battery out of reach of children
- Do not incinerate

Dispose the remainder of the test in general waste.

!

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

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

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

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](http://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.

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

Warning: Any changes or modifications not expressly approved by Ellume could void the user's authority to operate this equipment. For a Glossary of Symbols please refer to [www.ellumecovidtest.com](http://www.ellumecovidtest.com)

To review the Ellume COVID-19 Home Test terms of use, visit [ellumecovidtest.com/terms](http://ellumecovidtest.com/terms)

COVID-19 information

- 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. COVID-19 can present with a mild to severe illness although some people infected with COVID-19 may have no symptoms at all. Serious outcomes of COVID-19 can include hospitalization or even death. Older adults and people of any age with underlying medical conditions have a higher risk of severe illness from COVID-19. A full list of symptoms of COVID-19 can be found here: <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html> COVID-19 is contagious and can be spread even before a person shows symptoms of being sick (e.g. fever, coughing, difficulty breathing). Some people may test positive for COVID-19, but not have symptoms of infection. These people are considered asymptomatic but may still be able to transmit infection to others. Studies have suggested that asymptomatic infection may be common.
- 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. It is possible for an infected person to experience no symptoms at all.
- 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).

- Spread is more likely when people are in close contact with one another (within about 6 feet). COVID-19 seems to be spreading easily and sustainably in the community ("community spread") in many affected geographic areas. Community spread means people have been infected with the virus in an area, including some who are not sure how or where they became infected.
- 4

**I tested positive for COVID-19. When can I be with others again?** If you have no symptoms at time of testing and continue to have no symptoms:
  - After self-isolating for 10 days since your positive test result.If 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 have improved (excluding loss of taste and smell, which may persist for weeks or months after recovery)
- 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.
  - Clean and wash your hands often with soap and water or an alcohol-based hand sanitizer.
  - Clean all frequently touched surfaces daily with household disinfectants.
  - Wear a face covering if you must be around other people in public places, in close contact with people outside of your household or where social distancing of 6 ft is difficult to maintain.
- 6

**When should I seek medical attention?** If you develop any of the emergency warning signs (refer to User Safety section) for COVID-19 you must seek medical attention. Emergency warning signs include\*:
  - Trouble breathing
  - Persistent chest pain
  - New confusion or inability to wake up or stay awake
  - Bluish lips or faceIn addition, if you are in the high-risk group (refer to User Safety section) or your symptoms are persisting or worsening, or you have concerns you should seek medical attention. \*This list is not all inclusive. Please see your healthcare professional for any other symptoms that are severe or concerning.

**For up-to-date information on COVID-19 please visit the CDC COVID-19 website: <https://www.cdc.gov/coronavirus/2019-ncov/index.html>**

Manufacturer

 Ellume Limited.  
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**Need help?** Call us any time on 1-888-885-6121

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01/2021

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