



# ellume COVID-19 home test



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## PRODUCT INFORMATION LEAFLET

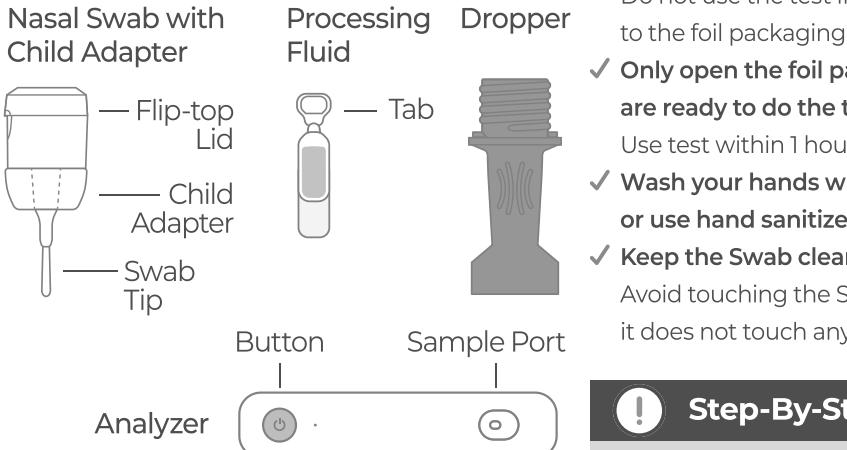
Refer to the Quick Start Guide for a summary of the key information of this leaflet.

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.

### What is included in the box



Product Information Leaflet and Quick Start Guide are also included.

### When to use the test kit

#### Use this test:

- ✓ As an aid in the diagnosis of **current COVID-19 infection** AND;
- ✓ If you are concerned that you have been exposed to 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 the 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 the test are in the Ellume COVID-19 Home Test App.

### Your test result

After finishing the testing process wait 15 minutes for your result to appear on your phone screen. The App will store your result and if selected a test result record will be sent to your email.

## 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 must be tested by an adult (18+ years old).

- ✓ Children aged 2-12 years must 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 collecting 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.

- ✓ 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.

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.

## 3 After the test

### Correct swabbing

#### 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 must be tested by an adult (18+ years old).

- ✓ Children aged 2-12 years must 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 collecting 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.

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- ✗ 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.

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.

## 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.

#### Important

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

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.

#### 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.

Tilting the Analyzer could result in a test error. Avoiding 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.

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.

#### 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.

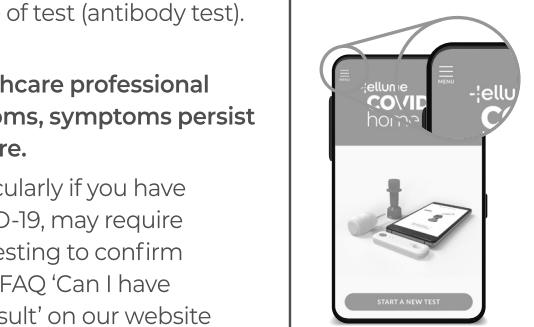
Call us toll free on 1-888-885-6121 and have your test result and test packaging handy. We will need the Error Code, Lot Number and Analyzer ID on the result screen.

### 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.
  - Immunocompromised, 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>



Information



Warning



Caution



Exclamation



Information



Warning



# ellume COVID-19 home test

## QUICK START GUIDE

 Refer to the Product Information Leaflet for more complete information.

This test is intended to be used as an aid to the clinical diagnosis of a current COVID-19 infection. Do not use this test as the only guide to manage your illness.

### DO'S

- ✓ Follow the in-app instructions when performing the test.
- ✓ Keep your phone within 3 inches of the Analyzer until the test result is available.
- ✓ Keep the Analyzer on a flat surface.
- ✓ Children aged 2-15 must be tested by an adult (18+ years old).
- ✓ Children aged 2-12 must be swabbed with the Child Adapter in place.
- ✓ Small children should be swabbed with the help of a second adult.
- ✓ Keep out of reach of children.

### DON'TS

- ✗ Do not perform the test within 30 feet of another person using an Ellume COVID-19 Home Test.
- ✗ Do not use the test if foil packaging is damaged.
- ✗ Do not perform the test in direct sunlight.
- ✗ Do not touch the Tip of the Swab.
- ✗ Do not close the App until your result is available.
- ✗ Do not replace the Processing Fluid with any other fluid. Avoid contact.
- ✗ Do not add less than 5 drops of fluid to the Analyzer.
- ✗ Do not use on children under 2 years of age.

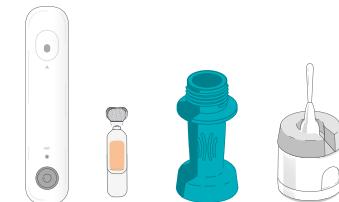
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## GETTING STARTED

### 1 UNBOX COMPONENTS

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



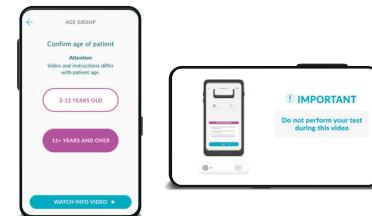
### 2 DOWNLOAD & OPEN APP

Find the free Ellume COVID-19 Home Test App on Google Play, the App Store or 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

Get familiar with the test.



### 5 FOLLOW INSTRUCTIONS

The App has step-by-step instructions to guide you through the test after the video.

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**Need help?** Call us toll free on 1-888-885-6121

 Ellume Limited  
57 Didsbury St, East Brisbane, Qld 4169, Australia

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