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ellume
COVID-19 home test

Product Information Leaflet

For Emergency Use Authorization (EUA) Only.
In vitro diagnostic use only.

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

Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.

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

For the most up to date information on COVID-19, please visit: https://www.cdc.gov/COVID19

In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an EUA.

This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and

The emergency use of 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.

Intended use

The Ellume COVID-19 Home Test is a rapid, lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2 nucleocapsid antigens.

This test is authorized for non-prescription home use with self-collected mid-turbinate swab samples from individuals aged 16 years or older with symptoms of COVID-19 within the first 7 days of symptom onset. This test is also authorized for non-prescription home use with adult-collected mid-turbinate nasal swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 7 days of symptom onset.

This test is also authorized for non-prescription home use with self-collected mid-turbinate swab samples from individuals aged 16 years or older, or adult-collected mid-turbinate nasal swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two to three days with at least 24 hours (and no more than 48 hours) between tests.

The Ellume COVID-19 Home Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of the SARS-CoV-2 nucleocapsid protein antigen. The antigen is generally detectable in mid-turbinate nasal swab samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but the clinical correlation with past medical history and other diagnostic information is necessary to determine infection status.

Positive results do not rule out a bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the Ellume COVID-19 Home Test should self-isolate and seek follow up care with their physician or healthcare professional, as additional testing may be necessary.

Negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or management decisions for the individual, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

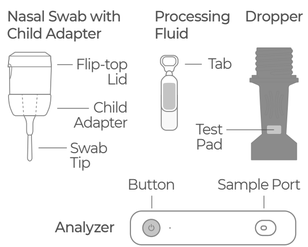
Test results are reported to relevant public health authorities in accordance with local, state, and federal requirements, using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by the CDC. Automatic test result reporting occurs via the Ellume COVID-19 Home Test software application.

The Ellume COVID-19 Home Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

General test 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 inside 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 a **current COVID-19 infection** AND;
- ✓ If you are concerned that you have COVID-19.
- ✓ **With** or **without** symptoms. Testing for asymptomatic individuals should be performed at least twice over two to three days, with at least 24 hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.

Do not use this test:

- × On anyone under 2 years of age;
- × If you are prone to nose bleeds, 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 run the test.**
- ✓ **Ensure your smartphone is compatible:** 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 there is no visible damage to the components' packaging.**
- ✓ **Wash your hands with soap and water or use hand sanitizer.**

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.

1. **Unbox components**
   Only open foil packaging when you are ready to do the test. Perform the test within 1 hour after opening.
2. **Download and open the App**
   Find the free Ellume COVID-19 Home Test App on the Google Play Store, the App Store or use your smartphone browser to visit: www.ellumecovidtest.com
3. **Answer a few questions in the App**
   This will select the right video and instructions for you and enable result personalization and reporting.

4. **Watch information video**
   The video will provide an overview of what to expect.
   Do not perform your test during the video.
5. **Follow instructions**
   Separate step-by-step instructions will be available within the app after the video.
6. **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 (Please also see Warnings and precautions section)

Do's and don'ts

- ✓ **Follow the App's instructions carefully.** Incorrect test use or completing test steps in the wrong order may result in an invalid result or technical problem. Failure to follow directions may produce inaccurate test results.
- ✓ **Correctly collect sample.** False negative test results may occur if a sample is incorrectly collected or handled.
- ✓ **Wear a safety mask or other face-covering when collecting a sample from a child or another individual.**
- ✓ **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.**
- ✓ **Swab small children with the help of a second adult.** One adult should hold & reassure the child while the other takes the swab.
- ✓ **Leave Analyzer and Dropper sealed in their pouches until just before use.** Once opened, the test should be used within 60 minutes.
- ✓ **Only use the test components provided.** Do not replace the Processing Fluid with any other fluid.
- ✓ **Keep the Swab clean.** Do not touch the Swab Tip. Ensure the Swab does not touch any surfaces before use. A contaminated swab is a health hazard.
- ✓ **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 an invalid result or technical error.
- ✓ **If multiple people are testing, connect the Analyzer to your phone and wait 30 secs before another person connects their Analyzer to their phone.**
- ✓ **Keep testing kit and test components away from children and pets before and after use.**

The Processing Fluid contains a harmful chemical (see table below). Avoid contact of Processing Fluid with your skin, eyes, nose, or mouth. Do not ingest any kit components. If contact with the Processing Fluid occurs, flush with copious amounts of water.
If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222

Chemical Name	GHS Codes	Concentration (%weight/ weight)
Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one & 2-Methyl-4-isothiazolin-3-one (3:1) (ProClin™ 300	H301: Toxic if swallowed H311: Toxic in contact with skin H331: Toxic if inhaled H314: Causes severe skin burns and eye damage H317: May cause an allergic skin reaction H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long-lasting effects	0.002 – 0.005

- × **Do not use this test on children under 2 years of age.**
- × **Do not add fewer or more drops of the sample fluid than instructed.**
- × **Do not use if any of the test kit contents or packaging is open or damaged.**
- × **Do not perform the test in unstable (changing) light conditions.**
- × **Do not re-use. Test components are single-use.**
- × **Do not add the sample fluid to the Analyzer before it is turned on and connected.**
- × **Do not drop the Analyzer. Handle with care.**
- × **Do not close the App while the test is processing as it will cause a technical problem and you will need a new test kit.**
- × **The orange desiccant sachet is not for use in the test. Discard the sachet immediately after opening the kit component.**

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 a false negative 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 & 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.

Attention all users

If you are not recovering, feeling worse, or are concerned about your health, please consult a healthcare professional. Regardless of your result, if you develop one of the emergency warning signs (see user safety section) you should seek medical attention immediately.

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 NEGATIVE FOR COVID-19

A negative result means that antigens from SARS-CoV-2 were not detected in your sample. **A negative result does not rule out COVID-19**. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. For example, you may get a false negative result if you did not perform the test correctly or if the level of antigen from the virus causing COVID-19 was below the test's detection limits.

There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19. If you test negative and continue to experience COVID-19 like symptoms of fever, cough, and/or shortness of breath you should seek follow up care with your healthcare professional. **If you do not have symptoms of COVID-19 and test negative, you should test again with at least 24 hours and no more than 48 hours between tests.**

Your healthcare professional will determine the best way to care for you based on your test results, likelihood of COVID-19 infection, symptoms and medical history. Your healthcare professional may suggest you need molecular testing to confirm whether you have contracted the virus that causes COVID-19. Confirmatory testing is especially important for people without symptoms. It is important that you work with your healthcare professional to help you understand the next steps you should take. See FAQ 'What is a false negative test result' or visit www.ellumecovidtest.com/FAQ.

INVALID RESULT OR TECHNICAL PROBLEM

Your test has resulted in an invalid result or technical problem.
You will need to retest with a new test kit.
If there is a **technical problem** with your test, you may receive a code you will need to provide to the Ellume Customer Support team.
What you need to do:
Visit www.ellumecovidtest.com or call 1-888-885-6121. You will need to provide your Analyzer ID and the code you received, which are displayed on the result screen.

YOUR TEST IS POSITIVE FOR COVID-19

A positive result means that antigens from SARS-CoV-2 were detected in your sample and it is very likely you have COVID-19 and are contagious. Your healthcare professional will work with you to determine how best to care for you based on your test results along with your medical history and symptoms.
What you need to do:

1. **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 result?
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/isolation.html
3. **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 https://www.cdc.gov/coronavirus/2019-ncov**

Press the LEARN ABOUT YOUR RESULT button on the result screen in the App to find out more about your result.
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 may suggest you need molecular testing to confirm if you have contracted the virus causing COVID-19.
Refer to FAQ 'Can I have a false positive result?'.

Test result record

If you provided your email address, you will be emailed a test result record. This record can be used to share your test result with others, including healthcare professionals, employers, or educators. To access past test results, use the menu in the App.

! At all times

User safety

High risk groups

Some people are at an increased risk for severe illness with COVID-19. This includes the elderly, those with chronic lung or heart disease and other types of chronic disease.

For a full list of specific groups of people who may be at increased risk visit https://www.cdc.gov/coronavirus.

If you are in a high-risk group and experiencing symptoms you should see a healthcare professional as soon as possible, regardless of your result. Your healthcare professional will determine if there are any treatments available to you.

EMERGENCY WARNING SIGNS

If at any time you experience 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
- Pale, gray, or blue-colored skin, lips or nail beds depending on skin tone

This list is not all inclusive. Please consult your healthcare professional about any other symptoms that are severe or may be concerning you. For the most current information on emergency warning signs, visit: https://www.cdc.gov/coronavirus

Warnings and precautions

Please also see **Do's and don'ts**

- Do not use on anyone prone to nosebleeds, or who has had facial or head injury/surgery in the last 6 months.
- Do not use the test if it has been exposed to household cleaning products (especially bleach).
- 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.
- When collecting a mid-turbinate nasal swab sample, use only the Nasal Swab supplied in the kit.
- Do not use test components inside the body except the Nasal Swab, as directed.
- 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.

Serial testing information and limitations

- If you have symptoms of COVID-19 that started within the last 7 days, you can use a single test.
- For serial (repeat) testing, if your first test result is negative, you should test again with a new test in 24 to 48 hours.
- Testing for asymptomatic individuals should be performed at least twice over two to three days, with at least 24 hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial testing. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.
- Serial testing is more likely to detect COVID-19, especially when you do not have any symptoms.
- If your first or second test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.
- If both your first and second tests are negative, you may not have COVID-19, however you should follow-up with your healthcare professional if you are at high risk for COVID-19.

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

Test and sample storage and stability

Store this test in a dry location between 36-86°F (2-30°C).

Ensure the test is at room temperature 59-77°F (15-25°C) prior to testing.

Kit contents are stable until the expiration date printed on the outer packaging. Do not use beyond the expiration date.

The Test components must remain in the sealed foil pouches until use. Once the pouches have been opened, the test should be used within 60 minutes.

Place samples immediately into Processing Fluid after sample collection. Samples should be added to the Analyzer port when instructed by the App. Do not delay, otherwise the test may produce an invalid result.

Frequently asked questions (FAQs)

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. COVID-19 can be spread to others even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.

2 What are the potential risks and benefits of this test?

Potential risks:

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

Potential benefits:

- 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.

3 What is serial testing?

Serial testing is when one person tests themselves multiple times for COVID-19 on a routine basis, such as every day or every other day. By testing more frequently, you may detect COVID-19 more quickly and reduce spread of infection. Serial testing (i.e. testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms. Testing for asymptomatic individuals should be performed at least twice over three days, with at least 24 hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.

4 What is the difference between an antigen, a molecular and an antibody test? 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. This means that a positive result is highly accurate, but a negative result does not rule out infection. If your test result is negative, you should discuss with your healthcare professional whether an additional test is necessary and if you should continue isolating at home. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19 than a molecular test would.

A COVID-19 antibody test detects antibodies that have been made by your immune system in response to a past or recent COVID-19 infection or vaccination.

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

Follow the on-screen trouble-shooting instructions in the App or try to connect the Test to a different phone that you trust. If you cannot connect the Analyzer to your phone, call 1-888-885-6121.

6 Why did I get an invalid result or technical problem?

The Ellume COVID-19 Home Test has a sample quality control which makes sure that the Test has enough sample (nasal secretions) to generate a reliable test result. If there is not enough sample the test will give an invalid result rather than a negative result, which could be incorrect. It is not common, but technical problems with the Test can also occur. In these instances, you will need to retest with a new test or consult a healthcare professional.

7 What if I have a positive test result?

A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely you have COVID-19 and are contagious. You should self-isolate from others and contact a healthcare professional for medical advice about your positive result. Your healthcare professional will work with you to determine how best to care for you based on your test result, medical history, and your symptoms.

8 What is a false negative result?

A negative test result means antigens from the virus that causes COVID-19, were not detected in your sample. **A negative result does not rule out COVID-19**. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. For example, you may get a false negative result if you did not perform the test correctly or if the level of antigen from the virus causing COVID-19 was below the test's detection limits.

There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19. If you test negative and continue to experience COVID-19 like symptoms of fever, cough, and/or shortness of breath you should seek follow up care with your healthcare professional. If you do not have symptoms of COVID-19 and test negative, you should test again with at least 24 hours and no more than 48 hours between tests.

Your healthcare professional will determine the best way to care for you based on your test results, likelihood of COVID-19 infection, symptoms and medical history. Your healthcare professional may suggest you need molecular testing to confirm if you have contracted the virus causing COVID-19. Confirmatory testing is especially important for people without symptoms.

It is important that you work with your healthcare professional to help you understand the next steps you should take.

9 What does an invalid test result mean?

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 sample and the test should be run again, using a new test kit.

10 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 with your healthcare professional, for example. You are required to provide your date of birth, zip code and state as they are shared with the relevant health authorities to support the monitoring of COVID-19 infection and test positivity rates across the country.

11 Will the 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 professional.

12 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.

13 How accurate is this test?

The performance of the Ellume COVID-19 Home Test was established in a prospective clinical study comparing Ellume COVID-19 Home Test results to a FDA Emergency Use Authorized high sensitivity PCR (molecular) test and correctly identified 96% of positive samples and 100% of negative samples in individuals with symptoms. This clinical study was conducted in the USA from October 2020 to November 2020. The performance of the test is still being studied in patients without signs and symptoms of respiratory infection and for serial screening. Performance may differ in these populations. Clinical performance of the test has not been established with subsequent variants of COVID-19 including the Delta and Omicron variants.

For further FAQs visit www.ellumecovidtest.com/FAQ.
For up-to-date information on COVID-19 visit https://www.cdc.gov/coronavirus.

The Fact Sheet for Healthcare Professionals and Product Overview for Healthcare Professionals are available via the App, or visit www.ellumecovidtest.com

Alternatively, you or the healthcare professional can call 1-888-885-6121.

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 additional tests.

Disposal

- Before disposal of the Analyzer, we recommend removing the battery using the following steps:
  - Locate the gap at the end (short side) of the Analyzer, close to the button.
  - 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.
- Keep the battery out of reach of children.
- Do not incinerate.
- Dispose of the battery and the remainder of the test in general waste unless otherwise indicated by local regulations.

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

Manufacturer

Need help? Visit www.ellumecovidtest.com or call 1-888-885-6121

TMs are owned by or licensed by Ellume Limited.

IVD No test component to be used inside the body except the nasal swab as directed.

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

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Glossary of symbols

Symbol	Symbol Title	Explanatory Text
	Manufacturer	Indicates the medical device manufacturer
	Date of Manufacture	Indicates the date when the medical device was manufactured
	Use by date	Indicates the date after which the medical device is not to be used
LOT	Batch code	Indicates the manufacturer's batch code to identify the batch or lot
REF	Catalog number	Indicates the manufacturer's catalog number to identify the medical device
P/N	Part number	Indicates the manufacturer's part number
STERILE EO	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed
	Do not reuse	Indicates a medical device that is intended for one use, or for uses on a single patient during a single procedure
	Consult instructions for use	Indicates the need for the user to consult the instructions for use
IVD	In vitro diagnostic medical device	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device
	Do not use if package is damaged	Indicates a medical device that should not be used if the packaging has been damaged or opened
CE	CE marking	Signifies European technical conformity
MD	Medical Device	Indicates the item is a medical device
FC	Federal Communications Commission (FCC) Logo	Meets FCC requirements per 47 CFR § 15.247
	Bluetooth® Logo	Indicates that the device is Bluetooth® enabled
	For self-testing	Indicates the device is a self-test in vitro diagnostic device. This means a lay person can use it without formal healthcare or medical experience.

The Ellume COVID-19 Home Test is a self-test in vitro diagnostic device.

03/2022

ellume

COVID-19 home test

QUICK START GUIDE

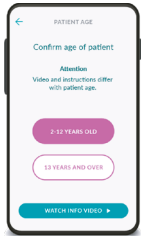
D101808F

1 UNBOX COMPONENTS

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

2 DOWNLOAD & OPEN APP

Download the free Ellume COVID-19 Home Test App from the Google Play Store, the App Store or visit: www.ellumecovidtest.com

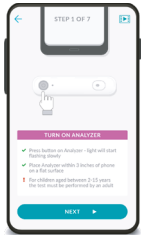


3 ANSWER A FEW QUESTIONS IN THE APP

This will select the right video and instructions for you and enable result personalization and reporting.

4 WATCH INFORMATION VIDEO

Get familiar with the test.
Do not perform the test during the video.



5 FOLLOW INSTRUCTIONS

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

Regardless of your test result, please consult a healthcare professional if your symptoms persist or become more severe.

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 instructions in the App when performing the test. Failure to follow directions may cause inaccurate test results.
- ✓ Correctly collect samples. False negative test results may occur if a sample is incorrectly collected or handled.
- ✓ Wear a safety mask or other face-covering when collecting a sample from a child or another individual.
- ✓ 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.
- ✓ Swab small children with the help of a second adult. One adult should hold & reassure the child while the other takes the Swab.
- ✓ Leave Analyzer and Dropper sealed in their pouches until just before use. Once opened, the Analyzer and Dropper should be used within 60 minutes.
- ✓ Only use the test components provided. Do not replace the Processing Fluid with any other fluid.
- ✓ Keep the Swab clean. Do not touch the Swab Tip. Ensure the Swab does not touch any surfaces before use. A contaminated Swab is a health hazard.
- ✓ 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.
- ✓ If multiple people are testing, connect the Analyzer to your phone and wait 30 secs before another person connects their Analyzer to their phone.
- ✓ Keep testing kit and kit components away from children and pets before and after use.

The Processing Fluid contains a harmful chemical. Please refer to the Product Information Lea et for information regarding this. Avoid contact of Processing Fluid with your skin, eyes, nose, or mouth. Do not ingest any kit components. If contact with the Processing Fluid occurs, flush with copious amounts of water. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.

DON'TS

- × Do not use on children under 2 years of age.
- × Do not add fewer or more drops of the sample fluid than instructed.
- × Do not use if any of the test kit contents or packaging is open or damaged.
- × Do not perform the test in unstable (changing) light conditions.
- × Do not re-use. Test components are single-use.
- × Do not add the sample fluid to the Analyzer before it is turned on and connected.
- × Do not drop the Analyzer. Handle with care.
- × Do not close the App while the test is processing as it will cause a technical problem and you will need a new test kit.
- × The orange desiccant sachet is not for use in the test. Discard the sachet immediately after opening the kit component.

Need help?
Visit ellumecovidtest.com or call 1-888-885-6121.

Scan this code
to view a digital version of this Quick Start Guide.

Refer to the Product Information Leaflet for more complete information.

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

In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an EUA. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and, the emergency use of 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.

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

ellume
COVID-19 home test

ellumecovidtest.com

ellume
COVID-19 home test

DO USE

- ✓ As an aid in the diagnosis of **current COVID-19 infection**
- ✓ If you are concerned that you have COVID-19
- ✓ **With** or **without** symptoms

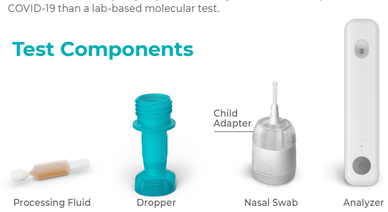
DO NOT USE

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

The Ellume COVID-19 Home Test is a digital fluorescent immunoassay for the qualitative detection of COVID-19 antigens from mid-turbinate nasal swab specimens.

This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

Test Components



Processing Fluid | Dropper | Nasal Swab | Analyzer

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In USA - For use under an Emergency Use Authorization (EUA) only.

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

2°C 36°F 30°C 86°F

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ellume
COVID-19 home test

- ✓ If you have COVID-19 symptoms, use a single test
- ✓ If you do not have COVID-19 symptoms, use at least two tests
- ✓ You may need to purchase additional tests to perform serial (repeat) testing

Keep out of reach of children
Store in a dry location between 36 86˚F [2 30˚C]

Made in USA

8 50021 86001 1

ellume

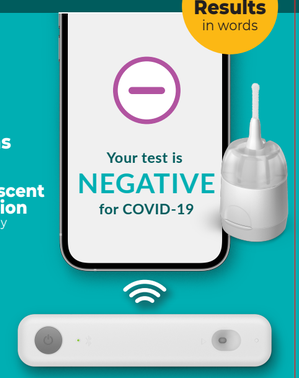
COVID-19 home test

Clear Results in words

Easy to use

Results in **15 mins**

Fluorescent Detection technology



1x Test
Suitable for ages 2+ years
Phone not included

ellume
COVID-19 home test

To use this test, you will need to:

- ✓ Download the free Ellume COVID-19 Home Test App
- ✓ Open the App and carefully follow the instructions on your smartphone

Bluetooth® compatible with most iPhones and Androids

Scan to check if your smartphone is compatible or visit ellumecovidtest.com

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