ellume
COVID-19 home test

DI0127R0.6

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-andresponse/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

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

In the 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; 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 nucleocapsid protein antigen from the SARS-CoV-2 virus.

This test is authorized for non-prescription home use with self-collected direct mid-turbinate nasal swab samples from individuals aged 16 years or older or adult collected mid-turbinate swab samples from individuals aged 2 years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 4 days of symptom onset when tested at least twice over three days with at least 48 hours between tests and for individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested when tested at least three times over five days with at least 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 which is generally detectable in mid-turbinate nasal swab specimens 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 and the agent detected may not be the definitive 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 provider as additional testing may be necessary.

All 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 patient management decisions, including infection control measure such as isolating from others and wearing masks. 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.

Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

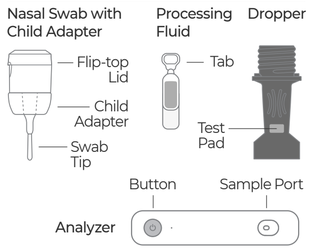
Test results will be reported to relevant public health authorities in accordance with local, state, and federal requirements, using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by the CDC. Automatic test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

The Ellume COVID-19 Home Test is intended for non-prescription self-use and/or as applicable, for an adult lay user testing another aged 2 years or older in a non-laboratory setting. The Ellume COVID-19 Home Test is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization.
This product has not been FDA cleared or approved.

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 **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.

How to use this test

Use this test:

- ✓ As an aid in the diagnosis of **COVID-19 infection** AND;
- ✓ If you are concerned that you have COVID-19.
- ✓ Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19, and with initial negative results, should be tested again after 48 hours and, if the 2nd test is also negative, a 3rd time after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.
- ✓ If you test negative but continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with your healthcare provider.
- ✓ If your test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

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 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. Perform the test within 1 hour after opening the packaging.
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's 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 to 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

Do's and don'ts (Please also see **Warnings and precautions** section)

- ✓ **Follow the App's instructions carefully when performing the test.** 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 specimen 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.**
- ✓ **Individuals aged 16 years and older can self-swab**
- ✓ **Swab small children with the help of a second adult.** One adult should hold and reassure the child while the other takes the swab.
- ✓ **Only open kit component packaging when ready to use the test.** Once opened, the test should be used within 60 minutes.
- ✓ **Only use the kit components provided.** Do not replace the Processing Fluid with any other fluid.
- ✓ **Keep the Analyzer on a flat surface within 3" of your phone until the result is available.** If you receive a call, answer on speaker. 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 test out of reach of children and pets.**
- ✗ **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 Test if any of the packaging is open or damaged .**
- ✗ **Do not touch the Swab Tip.** Ensure the swab does not touch any surfaces before use. A contaminated swab is a health hazard.
- ✗ **Do not re-use. Test components are single use.**
- ✗ **Do not use kit past its expiration date printed on the outside of the box.**
- ✗ **Do not add the sample fluid to the Analyzer before it is connected.**
- ✗ **Do not drop the Analyzer. Handle with care.**
- ✗ **Do not close the App until your result is available as it may cause a technical problem and you will need a new test kit.**
- ✗ **Do not perform the test in unstable (changing) light conditions.**
- ✗ **The desiccant sachet is not for use in the test. Discard the sachet immediately after opening the kit component.**

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 means 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, including any treatments available, based on your test results along with your medical history and symptoms.

What you need to do:

1. **You do not need to perform repeat testing.**
2. **Consult a healthcare professional immediately and tell them 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
3. **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
4. **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 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 very small chance 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?' on our website www.ellumecovidtest.com/FAQ.

YOUR TEST IS NEGATIVE FOR COVID-19

A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If you test negative and continue to experience COVID-19-like symptoms, (e.g., fever, cough, and/or shortness of breath) you should seek follow up care with your health care provider.

What you need to do:

To increase the chance that the negative result for COVID-19 is accurate, you should:

- **Test again in 48 hours if you have symptoms on the first day of testing.** If you test negative but continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with your healthcare provider.
- **Test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing.**

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 health care professional.

INVALID RESULT OR TECHNICAL PROBLEM

Your test has given an invalid result or had a technical problem.
You will need to retest with a new test kit.
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 Result Code , which are displayed on the result screen.

Test result record

The App will send you a record of your test result if you input your email address. You can share this record with your healthcare professional or employer, for example. Information supplied supports the monitoring of COVID-19 infection rates across the country.

Test Intepretation

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

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.

- Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19, and with initial negative results, should be tested again after 48 hours and, if the 2nd test is also negative, a 3rd time after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.
- If you test negative but continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with your healthcare provider.
- If your test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

! 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

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 **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. Individuals should provide all results obtained with this product to their healthcare provider.

Invalid test rate

In the most recent clinical study, a total of seven-hundred and nineteen (719) tests were performed. Forty (40) Invalid Results were recorded. Overall Invalid Result rate was therefore 5.6%.

Warnings and precautions

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

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. 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.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- If you have had symptoms longer than 4 days you should consider testing at least three times over five days with at least 48 hours between tests.
- 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.
- Individuals aged 16 years and older can self-swab.
- Do not use this test on children under 2 years of age.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Do not use if any of the test kit contents or packaging is damaged.
- Do not re-use. Test components are single use.
- Do not use kit past its expiration date.
- Do not touch the Swab Tip. Ensure the swab does not touch any surfaces before use. A contaminated swab is a health hazard.
- **Keep test out of reach of children and pets.**
- 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.
- No test components to be used 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.
- 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

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

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

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.

! 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.

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 packaging until use. Once the packages 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.

Limitations

- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between October, 2020 and November 2020. A subsequent clinical trial, which is ongoing, was commenced in May 2022 when the dominant circulating strain was the Omicron variant. The clinical performance has not been established for all circulating variants, including Delta variant, but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARSCoV-2 and their prevalence, which change over time.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with a healthcare provider.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and you likely have COVID-19.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.

Frequently asked questions (FAQs)

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

Potential risks include:

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

Potential benefits include:

- 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.

For more information on EUAs go here: https://www.fda.gov/emergencypreparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergencyuse-authorization

2 What is the difference between a COVID-19 antigen and a molecular test?

There are different kinds of tests for the SARS-CoV-2 virus that causes COVID-19. Molecular tests detect genetic material from the virus. Antigen tests, such as the Ellume COVID-19 Home Test, detect proteins from the virus. Due to the lower sensitivity of antigen tests, there is a higher chance this test will give you a false negative result when you have COVID-19 than a molecular test would.

3 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.

4 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.

5 What if I have a positive test result?

A positive result means that it is very likely you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. You should self-isolate from others and contact a healthcare provider for medical advice about your positive result.

6 What if I have a negative test result?

A negative test result indicates that antigens from the virus that causes COVID-19 were not detected in your sample. However, if you have symptoms of COVID-19, and your first test is negative, you should test again in 48 hours since antigen tests are not as sensitive as molecular tests. If you do not have symptoms and received a negative result, you should test at least two more times with 48 hours in between tests for a total of three tests. If you have a negative result, it does not rule out SARS-CoV-2 infection; you may still be infected and you may still infect others. It is important that you work with your healthcare provider to help you understand the next steps you should take.

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

8 Why is the App asking me for my personal details?

The App will send you a record of your test result if you input your email address. You can share this record with your healthcare professional or employer, for example. Information supplied supports the monitoring of COVID-19 infection rates across the country.

9 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.

10 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.

11 How accurate is this test?

Clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus that causes COVID-19 when taken multiple times across several days. Repeat testing improves test accuracy. This serial testing approach is recommended to minimize the risk of incorrect results. For more information on the performance of the test and how the performance may apply to you, please refer to the performance data in the Product Overview for Healthcare Professionals, available at https://www.ellumecovidtest.com/resources#downloadable-resources

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.

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

ellume

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.

02/2023