**General test information**

Please read this leaflet carefully before using the test. You should follow the Ellume COVID-19 Home Test instructions exactly. If you have any questions, see FAQ’s for you. This product has been authorized only for use by or on the order of and to perform procedures directed by healthcare professionals licensed to use the device only for the purpose of COVID-19 testing. Consult a healthcare professional to determine the best course of action if you have a positive result.

**Do’s and don’ts**

- Do use this test on children under 12 years of age or pregnant women.
- Do follow the test instructions carefully.
- Do not use leftover components.
- Do not use the test components if they are damaged or show signs of contamination.
- Do not mix or combine different lots of test kits.
- Do not detach the child adapter.
- Do not use the test kit if the components have expired.
- Do not drop the Analyzer. Handle with care.
- Do not add the sample fluid to the Analyzer before it is 30 minutes after you inserted the Swab.
- Do not share the Analyzer with someone else.
- Do not open the Swab Tip.
- Do not use the test kit if the components have expired.
- Do not use the test kit if the components have been damaged or show signs of contamination.
- Do not mix or combine different lots of test kits.
- Do not detach the child adapter.
- Do not use the test kit if the components have expired.

**Preparing to do the test**

- Before you have an internet connection:
  - Connect your phone to Wi-Fi before starting the test.
- Before you have an internet connection:
  - Connect your phone to Wi-Fi before starting the test.

**During the test**

- Before you have an internet connection:
  - Connect your phone to Wi-Fi before starting the test.
- Before you have an internet connection:
  - Connect your phone to Wi-Fi before starting the test.

**After the test**

- Before you have an internet connection:
  - Connect your phone to Wi-Fi before starting the test.
- Before you have an internet connection:
  - Connect your phone to Wi-Fi before starting the test.

**Important**

The test is not used to rule out COVID-19. If you test negative, your healthcare professional will determine the best course of action. If you test positive, your healthcare professional will determine the best course of action.

**Attention all users**

If you are receiving a positive test result, please consult your healthcare professional. If you have a positive test result, please follow the guidance provided by your healthcare professional.

**INVALID RESULT & TECHNICAL PROBLEM**

If you received a negative test result, please consult your healthcare professional. If you received a positive test result, please follow the guidance provided by your healthcare professional.
# Do's and don'ts

- Avoid close contact with people who are sick.
- Practice social distancing by staying at least 6 feet away from others.
- Wash your hands frequently with soap and water for at least 20 seconds, or use an alcohol-based hand sanitizer if soap and water are not available.
- Cover your mouth and nose with a tissue when you cough or sneeze, or use your sleeve if you do not have a tissue. Wash your hands immediately after coughing or sneezing.
- Clean and disinfect frequently touched objects and surfaces in your home.
- Avoid large gatherings and events.
- Wear a mask when in public.

### Warnings and precautions

- Do not use in persons prone to bleeding, or if you are allergic to any of the test ingredients.
- Do not use if there is a history of severe or potentially serious adverse reactions to COVID-19.
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### Test and sample storage and stability

The test should be stored in a dry location between 18-30°C (64-86°F). The test component should be stored in a cool, dry place, preferably in the refrigerator. The test should not be exposed to high temperatures, such as in a car on a hot summer day. The test should be kept out of reach of children. The test should be used within 60 minutes of opening the foil package. If the test is not used within 60 minutes, it should be discarded.

### Frequently asked questions (FAQs)

#### What is COVID-19?
COVID-19 is a new strain of coronavirus that causes a contagious respiratory illness and can spread to others through respiratory droplets. The illness can range from mild to severe, with some people developing serious illness, including pneumonia.

#### What are the symptoms of COVID-19?
Symptoms of COVID-19 can include:

- Fever or chills
- Cough
- Shortness of breath or difficulty breathing
- Fatigue
- Muscle or body aches
- Loss of taste or smell
- Sore throat
- Runny or stuffy nose
- Headache

If you have symptoms of COVID-19, you should contact your healthcare provider for guidance on how to self-isolate and what to expect.

#### What are the potential risks and benefits of the test?
The risk of a false negative result with antigen tests may be lower than with molecular tests. However, the test may not be able to detect COVID-19 in early stages of infection or in individuals with symptoms.

#### What is a false negative result?
A false negative result means the test was not able to detect COVID-19 in a person who has COVID-19. It is possible for this test to give a negative result even if you still have COVID-19 even though the test is negative. If you have symptoms of COVID-19 and test negative, you should test again with a new test.

#### What kind of medical care should I receive if I test negative?
You should self-isolate from others and contact a healthcare professional to determine how best to care for you based on your symptoms and test result.

#### What if I have a positive test result?
If you have a positive test result, you should self-isolate from others and contact a healthcare professional to determine how best to care for you based on your symptoms and test result.

#### What is sample testing and antigen testing?
Sample testing is the process of taking a sample from the body to test for the presence of COVID-19. Antigen testing uses a small part of the virus to detect proteins (small parts) from the virus. Antigen tests can detect COVID-19 in individuals with symptoms.

#### What is the home test kit?
The COVID-19 Home Test is an antigen test. Antigen tests use a small part of the virus to detect proteins (small parts) from the virus. The test is used at home to test for COVID-19.

#### What is the kit contents?
The test kit contains:

- Test strip
- Sample collection swab
- Battery
- Analyzer
- Instructions for use

#### How do I self-isolate?
Self-isolation involves staying at home and avoiding contact with others, including close family members and roommates, for at least 14 days. This helps prevent the spread of infection.

#### What if I test negative and continue to have symptoms?
If you test negative but continue to have symptoms, you should continue to self-isolate and contact a healthcare professional for guidance on how to care for you.

#### What if there is an invalid result?
An invalid result means the test was not able to tell if you have COVID-19. If you have an invalid result, repeat the test using a new test kit. If you have an invalid result again, contact your healthcare professional for guidance.

#### What should I do if I test positive?
If you test positive, you should self-isolate from others and contact a healthcare professional for guidance on how to care for you.

### Performance of the test

- The performance of the test has been evaluated in clinical studies. The test has a sensitivity of 99% and a specificity of 96%. This means that there is a higher chance of false negative results with antigen tests than with molecular tests. However, the test may not be able to detect COVID-19 in early stages of infection or in individuals with symptoms.

### User safety

- The test should be used within 60 minutes of opening the foil package. If the test is not used within 60 minutes, it should be discarded.

### Test and sample storage

- The test components must remain in the sealed foil on the outer packaging. Do not use beyond the expiration date.

### Disposal

- After use, dispose of the collected sample and used test component in the waste bin.

### Glossary of symbols

- Manufacturer Indicates the medical device manufacturer.
- Part number Indicates the catalog number to identify the medical device.
- Date of manufacture Indicates the date when the medical device was manufactured.
- Date of expiration Indicates the date when the medical device should not be used.
- Bar code Indicates a medical device identifier used to identify the medical device in a database.
- Indications for use Indicates the intended use of the medical device as an in vitro diagnostic device. This information is not to be used for the marketing of the medical device.
- Recalled Indicates that the medical device has been recalled.
- Cautions Indicates the potential risks and benefits of the medical device.
- Warning Indicates a potential risk or contraindication for the medical device.
- Instruction for use Indicates the instructions for using the medical device.
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QUICK START GUIDE

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.

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 Processing Fluid is not added to the Analyzer 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.
✓ If a sample is incorrectly collected or handled, 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 perform the test if a sample is incorrectly collected or handled.

DON’T’S
✓ 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.

Processing Fluid
Nasal Swab
Child Adapter
Dropper
Analyzer

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

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 Cosmetics Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

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.

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

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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.