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 COVID-19 infection. Do not use this test as the only guide to manage your illness.

**DO’S**

- Follow the App’s instructions carefully when performing the test.
- 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.
- Only open kit component packaging when ready to use the test.
- Only use the kit components provided.
- Keep the Analyzer on a flat surface within 3” of your phone 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 test out of reach of children and pets.

**DON’T’S**

- Do not use Test if any of the packaging is open or damaged.
- Do not touch the Swab Tip.
- Do not add fewer or more drops of the sample fluid than instructed.
- Do not add the sample fluid to the Analyzer before it is connected.
- Do not close the App until your result is available.
- Do not perform the test in unstable (changing) light conditions.
- The desiccant sachet is not for use in the test.

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

**GETTING STARTED**

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, 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.

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.

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.

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

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

For in vitro diagnostic use. No test component to be used inside the body except the Nasal Swab as directed.
Intended use
The Ellume COVID-19 Home Test is a rapid lateral flow immunoassay intended to provide a qualitative detection of SARS-CoV-2 virus antigen in human nasal secretions. This test is for in vitro use only. It should only be performed by a professional healthcare practitioner. If you are concerned that you have COVID-19, see your healthcare professional. This test is not a substitute for testing recommended by your healthcare professional. Test results should be used in conjunction with clinical judgment. The Ellume COVID-19 Home Test is not intended for individual use. This test is not recommended for use in individuals less than the age of 2 years.

General test information
You should follow the Ellume COVID-19 Home Test instructions. If you follow the instructions incorrectly or use the product outside of the test kit, the test result may not be accurate. The kit includes a series of instructions that you can follow during the video. Your result and what it means for you

Preparing to do the test

Do’s and don’ts
- Follow the App’s instructions carefully when performing the test.
- Ensure your smartphone is compatible; ensure it’s capable of scanning 1D barcodes.
- Ensure your phone is charged.
- Your test result is available within one hour of the last test being done in the App.
- Test results may not be accurate if you have an immune deficiency.
- Test results may include an invalid result.
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Important: The test home is a sample from your nose. When using the test, try to pick at least 1cm of the nasal mucosa (lining of the nose) as this may be required to be visible under a microscope. This test uses a cotton swab to collect a sample and then uses this sample to perform a test. Failed test results may occur if a specimen sample is not collected or is collected from non-sweat areas of the body. It is recommended to keep the test home from being damaged or opened. Deposit this product only in accordance with local waste disposal regulations. A failed test result is subsequently the same test result that has been failed twice in a row.

Avoid performing the test in a very dry environment (e.g., near a heater or air conditioner). Do not wash the test home before testing.

Avoid using the kit past its expiration date. For the most current information on emergency warning signs, visit: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/NN1surv.html for more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-response-epreparedness/coronavirus-covid-19-coronavirus-2019/Coronavirus-testing. In the USA, this product has not been FDA cleared or approved.

The Ellume COVID-19 Home Test is a self-test in a single procedure that detects the SARS-CoV-2 virus. The SARS-CoV-2 virus causes COVID-19. The test is a nucleic acid amplification test that detects specific genetic material from the virus. Antigen tests, such as this test, detect specific proteins that the virus uses to infect human cells. This test is for people who have symptoms of COVID-19. The test is performed by individuals at home. This test comes in two parts. The first part is the test kit. This kit contains everything needed to perform the test. The second part is the test home, which you use to collect a sample. The test home is a swab that is used to collect a sample. The test kit and the test home are labeled with Batch Code, Use by date, and Date of manufacture. The test home contains small amounts of animal derived material. This product contains small amounts of animal derived material.
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.

Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

Results in 15 mins

Easy to use

Fluorescent Detection technology

Clear Results in words

Suitable for ages 2+ years

For in vitro diagnostic use. No test component to be used inside the body except the Nasal Swab as directed.

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

For the most current expiration dates of this test, please refer to: https://www.fda.gov/covid-tests