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 swaddled 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 Leaflet 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.ponconhelp.org or 1-800-232-1222.

**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.

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

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)(3) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360bb-30(b)(2), unless the declaration is terminated or authorization is revoked sooner.

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

Before you start

Do’s and don’ts

1. Follow the App instructions carefully. Your test result is invalid if you do not follow the instructions.
2. Ensure your phone is charged and has a strong Wi-Fi signal.
3. Ensure your test is at room temperature prior to beginning the test.
4. Ensure your test is tightly sealed.
5. Do not use a test if it has expired.
6. Do not cut the opening of the dropper off the nasal swab.
7. Do not open the container in which the dropper tip is stored.
8. Do not perform the test in an unhygienic environment.
9. Do not store the test kit out of its packaging.
10. Do not touch or handle the test kit.

During the test

You will receive negative and positive test results.

A negative result means that you do not have COVID-19. A positive result means that you do have COVID-19.

Valid test results are indicated by your phone. You may receive a code you will need to provide to the Ellume COVID-19 Home Test – Your Test Result Record (sent to you via email, phone or text). If you have questions about your test result record, please visit www.ellumecovidtest.com. If your symptoms persist or become worse or if you are concerned about your test result record, please visit www.fda.gov/coronavirus.

Attention all users

If you are not receiving text messages, see your healthcare professional. Regardless of your result, you should follow your local public health guidelines and your health care provider’s instructions.

What you need to do

1. Do not touch or handle the test kit.
2. Do not perform the test in an unhygienic environment.
3. Do not use the test if it has expired.
4. Do not cut the opening of the dropper off the nasal swab.
5. Do not open the container in which the dropper tip is stored.
6. Do not perform the test in an unhygienic environment.
7. Do not store the test kit out of its packaging.
8. Do not touch or handle the test kit.
9. Do not perform the test in an unhygienic environment.
10. Do not store the test kit out of its packaging.

Inaccurate test results

Inaccurate test results can occur if the test is not performed correctly or if the level of antigen from the virus causing COVID-19 is less than the threshold for detection.

Important

The test is designed to be used as an aid in the diagnosis of COVID-19 infection only. The test should not be used as a substitute for medical advice. Your healthcare professional will determine the best course of treatment for you.

INVALID RESULT

If you are not receiving text messages, see your healthcare professional. Regardless of your result, you should follow your local public health guidelines and your health care provider’s instructions.

Invalid result

A negative result means that you do not have COVID-19. A positive result means that you do have COVID-19.

Valid test results are indicated by your phone. You may receive a code you will need to provide to the Ellume COVID-19 Home Test – Your Test Result Record (sent to you via email, phone or text). If you have questions about your test result record, please visit www.ellumecovidtest.com. If your symptoms persist or become worse or if you are concerned about your test result record, please visit www.fda.gov/coronavirus.

Test result record

You will receive a positive result if you are sick and have COVID-19. You should follow your local public health guidelines and your health care provider’s instructions. If you are sick and have COVID-19, you should self-isolate.

What you need to do

1. Take the test again in 2 days to confirm the result.
2. Take the test again in 7 days to confirm the result.
3. If you have COVID-19 and are contagious, your healthcare professional will provide you with contact tracing and isolation instructions.
4. If you are sick and have COVID-19, you should self-isolate.
5. If you are not sick and do not have COVID-19, you should follow your local public health guidelines and your health care provider’s instructions.
6. If you receive a positive test result, your healthcare professional will provide you with contact tracing and isolation instructions.
7. If you are sick and have COVID-19, you should self-isolate.
8. If you are not sick and do not have COVID-19, you should follow your local public health guidelines and your health care provider’s instructions.

Test result record

You will receive a negative result if you are not sick and do not have COVID-19. You should follow your local public health guidelines and your health care provider’s instructions. If you are not sick and do not have COVID-19, you should follow your local public health guidelines and your health care provider’s instructions.

What you need to do

1. Take the test again in 2 days to confirm the result.
2. Take the test again in 7 days to confirm the result.
3. If you have COVID-19 and are contagious, your healthcare professional will provide you with contact tracing and isolation instructions.
4. If you are sick and have COVID-19, you should self-isolate.
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7. If you are sick and have COVID-19, you should self-isolate.
8. If you are not sick and do not have COVID-19, you should follow your local public health guidelines and your health care provider’s instructions.

Test result record

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8. If you are not sick and do not have COVID-19, you should follow your local public health guidelines and your health care provider’s instructions.
**Signifies European technical signs, visit:** https://www.cdc.gov/coronavirus

For the following emergency warning signs please see real-time advice from your healthcare professional as it is possible your result is invalid:

**Emergency Warning Signs**

- Trouble breathing
- Persistent pain or pressure in the chest
- Pale, gray, or blue-colored skin, lips, or nail beds

**What is a false negative result?**

A negative result does not rule out a COVID-19 infection. If you have symptoms of COVID-19 and test negative, you should continue to isolate at home and seek advice from your healthcare professional. If you do not have symptoms and test negative, your healthcare professional may recommend additional tests.

**What should I do if my phone cannot connect to the Analyzer?**

You can use a different phone or try to move your phone closer to the Analyzer. If you experience a poor Bluetooth connection between your phone and the Analyzer, your test results may be incorrect. It is not common, but technical issues can occur.

**What does an invalid test result mean?**

An invalid result means the test was not able to tell if COVID-19 was detected in your sample. An invalid result can occur for several reasons:

- The test could not detect genetic material from the virus. The Ellume COVID-19 Home Test has a sample quality test to detect genetic material from the virus. The overall invalid result rate on first test for the 209 positive samples and 100% of negative samples was very low.
- There may have been a change in the storage temperature of your sample. This can happen if your sample was not stored between 2 and 25 degrees Celsius.
- There were technical issues with your phone. This can happen if your phone is not compatible with the Analyzer or is not able to connect to the Analyzer.
- There were technical issues with the Analyzer. This can happen if the Analyzer is not able to connect to your phone or if there is a problem with the Analyzer.
- There were technical issues with the Ellume COVID-19 Home Test. This can happen if there is a problem with the Ellume COVID-19 Home Test.

**What is serial testing?**

Serial testing is testing multiple samples over time to ensure the most accurate result. This can happen if you test multiple samples over time to ensure the most accurate result.

**What should I do if my first test result is invalid?**

If your first test result is invalid, you should follow the steps outlined in the instructions for use and try again. If your second test result is invalid, you should continue to isolate at home and seek advice from your healthcare professional.

**What is a false positive result?**

A positive result does not rule out a COVID-19 infection. If you have symptoms of COVID-19 and test positive, you should continue to isolate at home and seek advice from your healthcare professional. If you do not have symptoms and test positive, your healthcare professional may recommend additional tests.

**How do I check for interference?**

**What does an invalid test result mean?**

An invalid result means the test was not able to tell if COVID-19 was detected in your sample. An invalid result can occur for several reasons:

- The test could not detect genetic material from the virus. The Ellume COVID-19 Home Test has a sample quality test to detect genetic material from the virus. The overall invalid result rate on first test for the 209 positive samples and 100% of negative samples was very low.
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