Intended use
The ELUMEDx COVID-19 Home Test is a rapid flow-through assay for qualitative detection of the SARS-CoV-2 virus in mid-turbinate nasal swab samples.

The test is intended to be used as an additional diagnostic test with PCR testing in the diagnosis of COVID-19. Before use, please consult a healthcare professional to discuss the appropriate use of this test and additional testing is necessary.

General test information
Please follow the test instructions using the test. You should follow the ELUMEDx COVID-19 Home Test Kit User Guide and the instructions for the use of the test before using the test. The test is an in vitro diagnostic (IVD) test for qualitative detection of SARS-CoV-2 virus RNA by using reverse transcription polymerase chain reaction (RT-PCR) method.

COVID-19 Home Test – What is inside the Box
Nasal Swab with Child Swab Adapter
Processing Pad
Dropper
Flip Adapter
Test Pad
Button
Sample Port
Analyzer
Product Information Leaflet and Quick Start Guide are also included.

When to use this kit
Use this test:
- If you have symptoms of COVID-19
- If you have been exposed to someone with COVID-19
- If you have been contact-traced by public health authorities
- If you have been asked to take a COVID-19 test by healthcare providers

Do’s and don’ts
- Brand the test if you have been asked or concerned that you have COVID-19
- Answer a few questions

Preparing to do the test
- Have a smartphone
- Ensure your phone is charged
- Your phone should be connected to the Internet

During the test
- Wear a safety mask or other face-covering when using the test
- Place your phone to a flat surface
- Place the bottom of your phone against the back of the test pad
- Hold the Adapter in your hand as you lift the Dropper
- Place the Dropper on the Test Pad
- Press the LEARN ABOUT YOUR RESULT button on the test result screen in the App to find out more about your test result
- If you provided your email address, you will be emailed a test result report

After the test
- If you would like to experience COVID-19 like symptoms of fever, cough, difficulty breathing or other symptoms of COVID-19
- If you have been asked to test
- If you have been asked by your healthcare professional to take a test
- If you have been asked to test by your local public health authority
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**What is COVID-19?**

COVID-19 is a new virus in humans causing a contagious respiratory illness that can cause severe illness or death. Some people infected with COVID-19 can have no symptoms at all, but many develop symptoms such as cough, fever, and fatigue. Others can have severe symptoms requiring hospitalization.

Testing for asymptomatic individuals should be performed at least twice over three days, with a new sample (nasal secretions) to generate a reliable test result. You can share this test result with your healthcare provider to help you understand your next steps.

**What is serial testing?**

Serial testing is more likely to detect COVID-19, especially if you have symptoms of COVID-19 that started within the last 6 months. If you have symptoms of COVID-19 and test negative, you should discuss this with your healthcare provider.

**What is a false negative result?**

A negative result does not rule out COVID-19. This includes the elderly, those with underlying conditions, and those who have been exposed to COVID-19. If your nose starts bleeding, apply pressure to your nose with your fingers or a folded bandage until it stops. If the bleeding does not stop after 10 minutes, call 9-1-1 for emergency medical attention.

**What should I do?**

\[\text{See the full list of symptoms at https://www.cdc.gov/coronavirus.} \]

**Warnings and precautions**

- Do not use on anyone prone to bleeding, as a nosebleed may result.
- Do not use the Nasal Swab if the tip is damaged or opened.
- Do not use more than once per individual.
- Do not use if the expiration date has passed.
- Do not return the Nasal Swab to your healthcare provider.

**Test and sample collection and storage**

**How does the test work?**

The test is a dry laboratory (DRI) assay. The test components are contained in a VersaPack pouch, and the test should be used within 60 minutes of opening the pouch. The sample (nasal secretions) should be placed into the provided test sample (nasal secretions) to generate a reliable test result. You can share this test result with your healthcare provider to help you understand your next steps.

**How is the test performed?**

Follow the instructions on the VersaPack sample collection. Sample collection is subject to the test kit. Your sample should be used within 60 minutes of opening the pouch. The sample should be placed into the provided test sample (nasal secretions) to generate a reliable test result. You can share this test result with your healthcare provider to help you understand your next steps.

**Frequently asked questions (FAQs)**

- A high fever, cough, shortness of breath, and sore throat are among the most common symptoms of COVID-19. This includes the elderly, those with underlying conditions, and those who have been exposed to COVID-19. If your nose starts bleeding, apply pressure to your nose with your fingers or a folded bandage until it stops. If the bleeding does not stop after 10 minutes, call 9-1-1 for emergency medical attention.

**Disposal**

- Dispose of the battery and the remainder of the test kit after use in a safe location.
- Place a coin in the gap.
- Twist the coin to break off the bottom end of the swab.
- Place the swab in the provided test sample (nasal secretions) to generate a reliable test result. You can share this test result with your healthcare provider to help you understand your next steps.

**Manufacturer**

ELume Limited.

57 Didsbury St, Edinburgh, Scotland.

www.ellumecovidtest.com

For more information, please visit the following websites:

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

**Visit www.ellumecovidtest.com**