ellume·lab COVID Antigen

ellume·lab COVID Antigen Instructions for Use

For use in combination with ellume·lab only.

For Emergency Use Authorization only. ℞ Only. For *in vitro* diagnostic use only.

Intended use

The ellume·lab COVID Antigen test is a fluorescent lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct mid-turbinate nasal swab specimens collected by a healthcare provider from individuals who are suspected of COVID-19 within the first six days of symptom onset when tested at least twice over three days with at least 48 hours between tests. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate complexity, high complexity, or waived tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

The ellume·lab COVID Antigen test does not differentiate between SARS-CoV or SARS-CoV-2 viruses.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in mid-turbinate swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

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 measures 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.

The ellume·lab COVID Antigen test is intended for use by medical professionals or operators who are proficient in performing tests in point of care settings. The ellume·lab COVID Antigen 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.

Summary and explanation

SARS-CoV is a highly contagious Coronavirus associated with human disease. There are two strains: SARS-CoV-1 and SARS- CoV-2.

SARS-CoV-2 is responsible for the Coronavirus (COVID-19) pandemic. Infection with SARS-CoV-2 results in a range of symptoms including fever, dry cough, fatigue or in some cases, patients can have no symptoms (asymptomatic). Onset of symptoms occurs 2-14 days after virus exposure. SARS-CoV-2 disease can be mild or lethal. To date, SARS-CoV-2 transmission between humans has been attributed to aerosolized droplets generated during coughing and sneezing. The current guidance from the World Health Organization (WHO) is to practice good respiratory hygiene, maintain social distancing and self-isolate if symptoms occur.

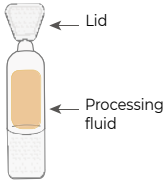
SARS-CoV-1 infection results in Severe Acute Respiratory Syndrome (SARS). SARS-CoV-1 caused the 2002-2003 SARS epidemic in China. Symptoms of SARS include fever, headache, and dry cough. Transmission is thought to occur via aerosolized droplets.

A third strain of Coronavirus, (MERS-CoV) was identified in 2012 and causes Middle Eastern Respiratory Syndrome (MERS). Whilst cases of SARS and MERS have been attributed to isolated outbreaks, COVID-19 has circulated worldwide, resulting in a global pandemic.

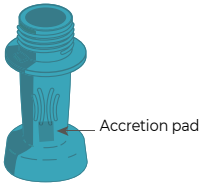
Principle of operation

The ellume·lab COVID Antigen test involves the pre-mixing and binding of fluorophore specific to SARS-CoV with viral nucleocapsid proteins present in a patient sample. First, the Processing Fluid is added into the Dropper to release the fluorophore contained within the conjugate release pad (termed accretion pad). After collecting a mid-turbinate nasal sample from the patient, the Nasal Swab is locked into the Dropper which contains the accretion pad with the fluorophore. The viral antigens released from the patient sample will bind to the fluorophore. The flip-top lid is opened, the Dropper inverted and 6 drops of sample containing the fluorophore-labeled antigen complexes is dispensed into the eStick sample port. The deposited liquid wicks into the test strip by capillary action. The sample flows across a membrane and traverses a series of discrete capture zones, consisting of immobilized complementary antibodies to SARS-CoV nucleocapsid protein. The accumulation of the fluorophore in the detection zones allows for detection of the SARS-CoV nucleocapsid protein antigens when excited by ultraviolet light. The emission signal is captured by a photodetector and the signal is interpreted according to an algorithm within the eStick microprocessor. The microprocessor computes the test outcome and communicates the result to the ellume·lab where the result is made visible to the user on the screen. Results will be available between 3 to 15 minutes of adding the sample into the eStick port.

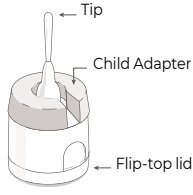
ellume·lab COVID Antigen test kit contents



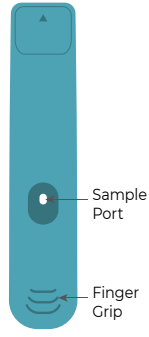
Processing Fluid



Dropper

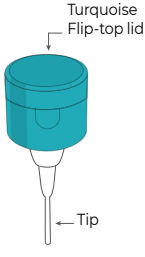


Nasal Swab (Sterile)

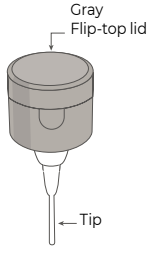


eStick

External quality control (Not for use on patients)



COVID Antigen Positive Control Swab



COVID Antigen Negative Control Swab

Materials supplied

Each ellume·lab COVID Antigen test kit (Catalogue number E-SRS-P-01) contains:

- 25x eStick
- 25x Processing Fluid
- 25x Nasal Swab + Child Adapter
- 25x Dropper
- 1x COVID Antigen Positive Control Swab
- 1x COVID Antigen Negative Control Swab
- 1x Instructions for Use
- 1x Quick Reference Instructions
- 1x Fact Sheet for Healthcare Providers
- 1x Fact Sheet for Patients

Materials required but not supplied

- ellume·lab and Accessories
- ellume·lab User Manual and Quick Start Guide

Warnings and precautions

- For *in vitro* diagnostic use only.
- For prescription use only.
- Read all the instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- In the U.S.A. this product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet the requirements to perform moderate complexity, high complexity, or waived tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation
- 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 Act, 21 U.S.C. § 360bbb- 3(b)(1), unless the declaration is terminated of authorization is revoked sooner.
- Federal Law restricts this device to sale by or on the order of a licensed practitioner (US only).
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- **If you have had symptoms longer than 6 days you should consider testing at least three times over five days with at least 48 hours between tests.**
- The product is authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- Do not perform the test in direct sunlight.
- Ensure test is in a stable light setting before starting a test.
- Allow all test kit components and External Quality Control Swabs to come to 59-86°F (15-30°C) before use.
- Keep ellume·lab horizontal on a flat surface while test is in progress. Rotating the device beyond any angle whilst running a test may result in a test error or incorrect result.
- All test kit components are single use only. Do not re-use.
- The Nasal Swab supplied with the kit is single use only. Reuse may cause risk of infection, contamination with test reagents, and/or inaccurate results.
- The test kit contains color-coded components. If you have a condition causing color blindness, please seek assistance with identifying the color-coded components before using the test.
- Leave the eStick, Dropper and External Quality Control Swabs in sealed foil pouch until just before use. Components should not be used if exposed to ambient conditions for longer than 60 minutes.
- Do not remove accretion pad from Dropper.
- Do not use the eStick, Dropper and External Quality Control Swabs if the indicating desiccant sachet has changed from orange to green.
- Do not use the test kit components if packaging or components are visibly damaged (i.e. the Nasal Swab tip or Nasal Swab shaft is broken).
- Do not drop eStick as this may lead to a false result.
- The test is validated for use only with the Nasal Swab supplied with the kit. Do not use alternative swabs.
- The eStick cannot be used by ellume·lab beyond its expiration date.
- Do not mix components from test kits with different lot numbers.
- Do not use any of the kit components beyond the expiration date printed on the outside of the test kit carton.
- The Child Adapter must be used to collect a mid-turbinate nasal swab specimen from a patient aged 12 years and under.
- The Child Adapter must be removed before collecting a mid-turbinate nasal swab specimen from a patient aged 13 years and over.
- Inadequate or inappropriate mid-turbinate nasal swab specimen collection and processing may lead to false test results.

- Once a mid-turbinate nasal swab specimen has been collected, the operator shall immediately proceed with the testing. Performance has not been validated if there is a delay between collection and testing or if the Nasal Swab is transported or stored after specimen collection. Avoid touching the Nasal Swab tip.
- Do not re-sterilize unused Nasal Swabs.
- Do not re-pack the provided test kit components including the Nasal Swab.
- Do not use an External Quality Control Swab on a patient.
- Avoid touching the tip of the External Quality Control Swab.
- Ensure not to touch the Processing Fluid nozzle against any other material.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure.
- Used tests, specimens and potentially contaminated material should be disposed of according to local, state and/or federal regulations.
- Wash hands thoroughly after use.
- The eStick should be handled with appropriate precaution due to presence of residual sample or fluid.
- The test processing duration is not indicative of the test outcome.
- This product contains small amounts of animal sourced materials.
- Wear a safety mask or other face-covering when collecting a specimen
- Do not touch the swab tip.
- For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-and-response/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

WARNING

- The Processing Fluid contains a mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one [EC No 247-500-7] & 2-Methyl-4-isothiazolin-3-one [EC No 220-239-6](3:1)
  - May cause an allergic skin reaction.
  - Keep out of reach of children.
  - Wear appropriate personal protective equipment (PPE) including gloves, protective clothing and eye protection.
  - If skin irritation or rash occurs: get medical advice/attention.
  - Wash contaminated clothing before reuse.

Chemical and safety information

The extraction buffer contained within the ellume·lab COVID Antigen kit contains the following hazardous ingredients:

Reagents	Hazards	Link to MSDS
Proclin™ 300	· Harmful if swallowed or if inhaled. · Causes severe skin burns and eye damage. · May cause an allergic skin reaction. · Very toxic to aquatic life with long lasting effects	https://www.sigmaaldrich.com/AU/en/sds/sial/48912-u

The extraction buffer solution in the Processing Fluid ampoule contains Proclin™ 300 which is a hazardous ingredient as shown in above table. Keep testing kit and kit components away from children and pets before and after use. Avoid contact with skin, and eyes. Do not ingest any kit components. If the extraction buffer solution contacts the skin or eye, immediately wash with plenty of running water. **In case the irritation persists, please seek medical advice at: https://www.poisonhelp.org or 1-800-222-1222.**

Test procedure and principles of the test

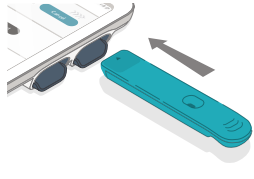
Before commencing a test, ensure:

- The ellume·lab is turned on and charged with at least 20% battery charge.
- The ellume·lab and test kit components are used within 59-86°F (15-30°C), 20% - 90% RH (non-condensing).
- The operator is wearing appropriate personal protective equipment (PPE) including gloves, protective clothing and eye protection.
- Ensure test is in a stable light setting before starting a test.
- The test is performed within 60 minutes of inserting the eStick into an ellume·lab port.
- The Nasal Swab and/or patient sample is not transported or stored.
- The patient test is performed immediately after collecting the patient sample.

Users should read the complete test procedure, including recommended QC procedures before performing the test. The following instructions are for performing a patient test procedure. A healthcare professional is required to complete the following steps to successfully perform the test:

1. Press the Patient Test icon and select COVID Antigen test. Select the patient's age group, enter the patient's details and press the START button.

2. Insert the eStick into the indicated ellume·lab port.
   - Confirm the indicating desiccant sachet is orange. Do not use the test if the desiccant sachet has turned from orange to green.
   - Do not remove the eStick from ellume·lab until the result is available.
   - Keep ellume·lab horizontal on a flat surface while test is in progress. Rotating the device in any direction during a test may result in a test error or incorrect result.

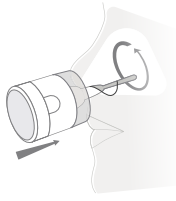


3. Remove the Dropper from its packaging and place it upright on a flat surface.
   - Confirm the indicating desiccant sachet is orange. Do not use the Dropper if the desiccant sachet has turned from orange to green.

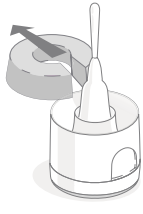
4. Twist and pull the lid off the Processing Fluid and squeeze all the fluid into the Dropper.

Patient ≤12 years old only

5. Use Nasal Swab to collect a mid-turbinate sample by swabbing **each nostril** of the patient **3 times**. Refer to the 'Sampling procedure on patients ≤12 years old' section for detailed information. **Correct sample collection is essential for test accuracy**.

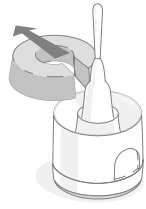


6. Remove Child Adapter by pulling to the side.

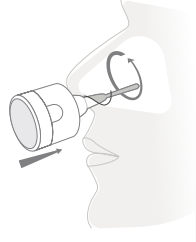


Patient 13+ years old only

5. Remove Child Adapter by pulling to the side **before** collecting a swab sample.



6. Use Nasal Swab to collect a mid-turbinate sample by swabbing **each nostril** of the patient **3 times**. Refer to the 'Sample procedure on patients 13+ years old' section for detailed information. **Correct sample collection is essential for test accuracy**.



7. Screw the Nasal Swab into the Dropper as tightly as possible or until you feel it "click" after tightening. **The Child Adapter must first be removed**.

8. Open the flip-top lid. **Squeeze 6 drops** of fluid into the sample port of the eStick. **Note: If experiencing difficulties dispensing fluid, screw the Nasal Swab tighter into the Dropper and ensure the Dropper is held vertically. Do not shake the Dropper**.

9. Wait up to 30 seconds for the test to start analyzing. The message "Analyzing, please wait" and a countdown timer will be displayed on-screen. **Do not remove eStick until result is available**.

10. A result will be displayed on-screen. The eStick may be removed once a result is displayed. **Do not remove eStick until result is available**.

Interpretation of results

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	Interpretation
With Symptoms	Positive	N/A	Positive for COVID-19
	Negative	Positive	Positive for COVID-19
	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.

COVID-19 Negative (-)	**To increase the chance that the negative result for COVID-19 is accurate, you should test again in 48 hours.** A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider. All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. 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 decisions.	

COVID-19 Positive (+)	**Repeat testing does not need to be performed if patients have a positive result at any time.** A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive). Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the ellume·lab COVID Antigen test should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection	
Error	The ellume·lab will display an error symbol on-screen when an invalid result has been generated. Please see 'Common test errors and alerts' below for more information.	

Common test errors and alerts

In the event of a test error, the screen will immediately display the test error type and follow up action for the operator. Each test error type may have one or more follow up actions, therefore it is essential for the operator to follow the information provided on-screen.

If an error persists, please contact Ellume customer support on 1-888-919-0779 or support@ellumelab.com.

Error Type	Action	Explanation
Test Error	Discard and use a new eStick	The eStick has failed or been compromised. You are required to use a new eStick and test components.
Test Error	Re-insert eStick	The eStick has not registered. The eStick can be used again. Please remove and re-insert the eStick. If the problem persists, discard and use a new eStick and test components.
Connection Error	Re-insert eStick	The eStick has not made sufficient connection with the ellume·lab. The eStick can be used again. Please remove and re-insert the eStick. If the problem persists, discard and use a new eStick and test components.
eStick Has Expired	Discard and use a new eStick	The test must be used within 60 minutes of insertion into the ellume·lab. You are required to use a new eStick and test components.
eStick Past Expiration Date	Discard and use a new eStick	The eStick has passed its expiry date and cannot be used. You are required to use a new eStick and test components within the expiration date.
Used Test	Discard and use a new eStick	The eStick has been used previously and cannot be used again. Each eStick is single use only. You are required to use a new eStick and test components.

Sample type

Use only freshly collected mid-turbinate nasal samples collected using the supplied Nasal Swab. The test has not been validated for use with other sample types, including nasopharyngeal samples, nasopharyngeal aspirates and nasopharyngeal washes. The test has not been validated for use with samples collected using a nasal swab other than the one supplied with the kit. The test has not been validated for use with nasal swab samples stored in transport media or frozen nasal swab samples. Processed samples should not be tested if stored greater than 90 minutes after insertion of the swab into the extraction buffer.

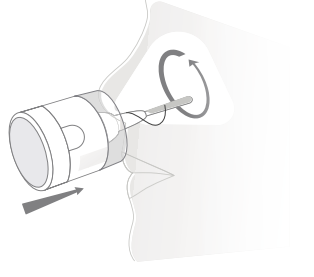
Mid-turbinate nasal swab sampling procedure

The test must be performed immediately after sampling. Appropriate collection of mucosal secretions at the mid-turbinate level is crucial to test performance. NOTE: The Nasal Swab provided is a sterile, ready to use system for clinical sample collection. The Nasal Swab is suitable for brief contact in the human body and should only be used as directed.

Wear appropriate personal protective equipment (PPE) including gloves, protective clothing and eye protection when collecting the sample. Do not use excessive force, pressure or bending when collecting the sample as this may result in accidental breakage of the Nasal Swab. Alternate nasal swabs have not been validated for this test. The patient may experience mild discomfort. Do not proceed if the patient reports sharp pain.

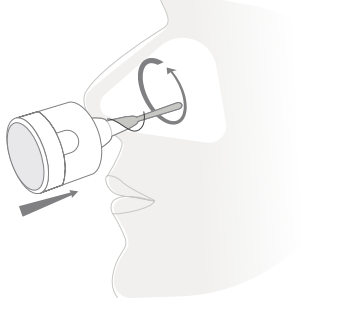
Sampling procedure on patients ≤12 years old

1. Remove the Nasal Swab from its packaging by opening the peel.
2. DO NOT REMOVE THE CHILD ADAPTER - Patients aged 12 years and under must be swabbed with the Child Adapter in place.
3. Fully insert the Nasal Swab deep into the patient's nostril until the Child Adapter touches the tip of their nose.
4. Gently rub the swab tip around the inside of the nose cavity 3 times.
5. Gently remove the Nasal Swab and repeat steps 3 and 4 in the patient's other nostril.
6. Remove the Child Adapter by pulling it to the side, then perform the test according to the 'Test procedure and principles of the test' section.



Sampling procedure on patients 13+ years old

1. Remove the Nasal Swab from its packaging by opening the peel.
2. Remove the Child Adapter by pulling it to the side.
3. Fully insert the Nasal Swab deep into the patient's nostril until the plastic cap touches the tip of their nose, and a slight resistance is felt.
4. Gently rub the swab tip around the inside of the nose cavity 3 times.
5. Gently remove the Nasal Swab and repeat steps 3 and 4 in the patient's other nostril.
6. Gently remove the Nasal Swab and perform the test according to the 'Test procedure and principles of the test' section.



Quality control

Procedural controls

After being connected to the ellume·lab device, the ellume·lab COVID Antigen test performs timed measurements of the detection zones to continually monitor progress. Release of the dried fluorophore and binding of the antigen at the detection zone is monitored throughout the test. Internal monitoring ensures that an alert will appear if the internal automatic processing steps of ellume·lab COVID Antigen test have not been successful. This will show as an Error symbol appearing on ellume·lab on-screen.

External quality controls

Controls may be used to demonstrate the supplied reagents and assays perform as intended. Ellume recommends that the External Quality Controls Swabs be tested for:

- Each new lot
- Each new shipment of materials, even if it is the same lot previously received
- Each new operator (or operator who has not performed the test recently)
- As deemed necessary by internal quality control procedures and in accordance with Local, State and Federal regulations and/or accreditation requirements

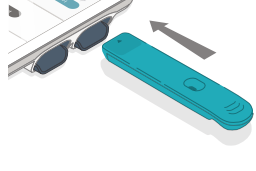
An indicating desiccant sachet is included within each eStick, Dropper and External Quality Control Swab foil pouch. The color of the silica gel contained within the sachet changes from orange to green when exposed to unacceptable humidity levels, warning the user that the component should not be used.

Procedure for executing external quality controls

Before commencing a test, ensure:

- The ellume·lab is turned on and charged with at least 20% battery charge.
- The ellume·lab and the test kit components are used within 59-86°F (15-30°C), 20% - 90% RH (non-condensing).
- The operator is wearing appropriate personal protective equipment (PPE) including gloves, protective clothing and eye protection.
- Ensure test is in a stable light setting before starting a test.
- The test is performed within 60 minutes of inserting the eStick into an ellume·lab port.

The following instructions are for performing the control test procedure only. A healthcare professional is required to complete the following steps to successfully run the test:

1. Press the Control Test icon and select COVID Antigen.	
2. Insert eStick into the indicated ellume·lab port. · Confirm the indicating desiccant sachet is orange. Do not use the test if the desiccant sachet has turned from orange to green. · Do not remove the eStick from ellume·lab until the result is available. · Keep ellume·lab horizontal on a flat surface while test is in progress. Rotating the device in any direction during a test may result in a test error or incorrect result.	

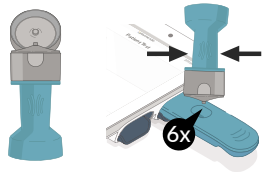
3. From the drop-down list, select the control sample type being tested. Ensure the selected sample type matches the information on the External Quality Control Swab packaging.

4. Remove the Dropper from its packaging and place it upright on a flat surface.
   - Confirm the indicating desiccant sachet is orange. Do not use the Dropper if the desiccant sachet has turned from orange to green.

5. Twist and pull lid off the Processing Fluid and squeeze all the fluid into the Dropper.

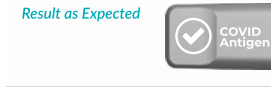
6. Remove the External Quality Control Swab from its packaging. Avoid touching the swab tip. Screw the swab into the Dropper as tightly as possible.
   - Confirm that the indicating silica sachet is orange. Do not use if the indicating desiccant sachet has turned from orange to green.

7. Open the flip-top lid. **Squeeze 6 drops** of fluid into the sample port of the eStick. **Note: If experiencing difficulties dispensing fluid, screw the swab tighter into the Dropper and ensure the Dropper is held vertically. Do not shake the Dropper**.



8. Wait up to 30 seconds for the test to start analyzing. The message "Analyzing, please wait" and a countdown timer will be displayed on-screen. **Do not remove eStick until result is available**.

9. A result will be displayed on-screen. The eStick may be removed once a result is displayed. **Do not remove eStick until result is available**.



Interpretation of results

Result as expected	The Quality Control Test completed successfully. Test outcome is saved in Previous Results.	
Quality review needed	The test result was incorrect or different to the sample type chosen by the user. Please perform another Quality Control Test. If an error persists, please contact Ellume customer support on 1-888-919-0779 or support@ellumelab.com.	
Error	An error has occurred. Please see 'Common test errors and alerts' for more information.	

Performing two tests

The ellume·lab is designed with two eStick ports, allowing the user to perform two patient tests simultaneously or two control tests simultaneously. To perform two tests:

1. Begin a single patient test or a single control test.
2. Once the testing screen has been launched, press the 'Start second test' button at any time to begin a second test.

DO NOT perform a Patient Test and a Quality Control Test at the same time.

While performing two tests, you can toggle between them by pressing the eStick image next to the relevant eStick port. It is recommended to perform the test steps of each test sequentially. Complete the test steps of the single test, and once it is analyzing, begin performing the next test instructions. An eStick may be removed once a result is displayed. Test results will be available between 3 to 15 minutes - tests may finish running in a different order than they were initiated.

Storage and stability

Store the kit at 36-86°F (2-30°C) until the expiration date printed on the outer packaging. If stored below 59°F (15°C), ensure that the test components are brought to 59-86°F (15-30°C) before use. Do not freeze.

Limitations

- For use under Emergency Use Authorization only.
- The ellume·lab COVID Antigen test has been validated in symptomatic individuals within the first six days from the onset of symptoms. The performance of this test has not yet been clinically validated for use in patients without signs and symptoms of respiratory infection, or for serial screening applications and performance may differ in these populations.
- The contents of this kit are to be used for the qualitative detection of SARS-CoV viral antigens from mid-turbinate swabs (collected using the supplied Nasal Swab).
- The test detects both viable (live) and non-viable SARS-CoV viral antigens and may yield a positive result in the absence of living micro-organisms. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample.
- Additional testing is required to differentiate between SARS-CoV-1 and SARS-CoV-2, in consultation with state or local public health departments.

- The test is not intended to detect MERS-CoV antigens.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- Failure to follow the test procedure correctly may adversely affect the test performance and/or invalidate the test result.
- Test results must be evaluated in conjunction with other clinical data available to the healthcare professional.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and the individual likely has COVID-19.
- Positive test results do not exclude co-infection with other pathogens.
- Positive results may be due to present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1 and SARS-CoV.
- Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.
- Negative test results are not indicative of the presence/absence of other viral or bacterial pathogens.
- 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.
- All COVID-19 Antigen test negative results are presumptive. Confirmatory testing with a molecular assay may be necessary.
- If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19, however additional follow-up may be needed
- Condition, timing, and volume of sample collected for clinical investigation are significant variables in obtaining reliable results. Follow recommended guidelines for sample collection.
- Sample collection must be performed by skilled personnel only.
- Only use freshly collected mid-turbinate swab samples collected using the supplied Nasal Swab. The performance of the test using stored or frozen swab samples has not been validated.
- The test is not suitable for use if a patient has had a recent facial injury.
- Results from antigen testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods of low activity when prevalence is moderate to low.
- The performance of this test for SARS-CoV-2 detection was established based on the evaluation of a limited number of clinical specimens collected between January 2021 and February 2021. The clinical performance has not been established in all circulating variants 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 SARS-CoV-2 and their prevalence, which change over time.

Conditions of authorization for laboratories

The ellume·lab COVID Antigen Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas. Authorized laboratories using the ellume·lab COVID Antigen ("your product" in the conditions below), must adhere to the Conditions of Authorization indicated in the Letter of Authorization as listed below:

- Authorized laboratories* using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

- Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Ellume Limited (via email: support@ellumelab.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
- All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.
- Ellume Limited authorized distributors, and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made to the FDA upon request.

* The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high, moderate or waived complexity tests. This test is authorized for use at the Point of Care (POC) i.e. in patient care settings operating under CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation" as "authorized laboratories".

Performance characteristics

Clinical performance

Prospective Clinical Study 1: January 2021 – February 2021

The clinical performance of the ellume·lab COVID Antigen test was evaluated from January 2021 to February 2021 in a prospective study in the U.S. Two (2) investigational sites participated in the study and testing was performed by six (6) operators with no laboratory experience and who were representative of the intended users at CLIA waived testing sites.

Specimens were collected using the Ellume Nasal Swab and tested fresh as described in the Instructions for Use. The performance of the ellume·lab COVID Antigen test was compared to results of a nasal swab collected from the same subject, eluted in viral transport media and tested with an FDA EUA high sensitivity molecular SARS-CoV-2 assay at a single central laboratory. The order of swab collection was randomized between assays. Minimally trained operators performing the ellume·lab COVID Antigen testing were blinded to the FDA EUA high sensitivity molecular SARS-CoV-2 assay result and any standard of care test result.

The clinical performance of the ellume·lab COVID Antigen test was established with eighty-nine (89) direct mid-turbinate nasal swabs collected from prospectively enrolled symptomatic subjects presenting with COVID-19 symptoms within six (6) days of symptom onset. Thirty-three (33) were positive and fifty-six (56) were negative by an FDA EUA high sensitivity molecular SARS-CoV-2 assay.

Age and gender distribution of the subjects are presented in Table 1 along with the positive rate per age group. Overall positive rate was 30.3%. Ages of subjects ranged from 3 years to 82 years.

Table 1: *Age Group and Gender Distribution and Positivity Rates by ellume·lab COVID Antigen test for Subjects with Symptom Onset ≤ 6 days*

Age group (years)	Total number	Number of females	Number of Males	Number of Positives	Positivity rate
0-21	17	8	9	4	23.5%
22-59	64	39	25	20	31.3%
60+	8	3	5	3	37.5%
Total	**89**	**50**	**39**	**27**	**30.3%**

The positive rate distribution by days since symptom onset is presented in Table 2 along with the number of subjects tested and Positive Percent Agreement (PPA) compared with an FDA EUA high sensitivity molecular SARS-CoV-2 assay

Table 2: *Days since Symptom Onset Distribution, Positivity Rates and Positive Percent Agreement*

Days since Symptom Onset	Number of Specimens	Number of Positives	Positivity Rate	PPA	95% CI
1	18	7	39.9%	100%	64.6% — 100%
2	38	12	31.6%	92.3%	66.7% — 98.6%
3	58	17	29.3%	85.0%	64.0% — 94.8%
4	75	22	29.3%	81.5%	63.3% — 91.8%
5	85	25	29.4%	80.6%	63.7% — 90.8%
6	89	27	30.3%	81.8%	65.6% — 91.4%
7	94	27	28.7%	77.1%	61.0% — 87.9%

Table 3 summarizes the Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) for the ellume·lab COVID Antigen test when compared with an FDA EUA high sensitivity molecular SARS-CoV-2 assay, for all symptomatic subjects within six (6) days of symptom onset.

Table 3: *Clinical Performance of ellume·lab COVID Antigen test vs FDA EUA High Sensitivity Molecular SARS-CoV-2 Assay for Subjects with Symptom Onset ≤ 6 days*

ellume·lab COVID Antigen test	FDA EUA High Sensitivity Molecular SARS-CoV-2 Assay		
	Positive	Negative	Total
Positive	27	0	27
Negative	6	56	62
Total	33	56	89
Prevalence	37.1% (33/89)		
PPA	81.8% (27/33) (95% CI: 65.6% - 91.4%)		
NPA	100% (56/56) (95% CI: 93.6% - 100%)		

Prospective Clinical Study 2: January 2021 – May 2022

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 – 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT-PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing. Performance of the antigen test with serial testing in individuals is described in Table 4.

Table 4: *Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.*

Days after first PCR positive test result	Asymptomatic on first day of testing			Symptomatic on first day of testing		
	Ag Positive/PCR Positive (Antigen Test Performance % PPA)					
	1 Test	2 Tests	3 Tests	1 Test	2 Tests	3 Tests
0	9/97 (9.3%)	35/89 (39.3%)	44/78 (56.4%)	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	17/34 (50.0%)	23/34 (67.6%)	25/32 (78.1%)	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	16/21 (76.2%)	15/20 (75.0%)	13/15 (86.7%)	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	20/28 (71.4%)	21/27 (77.8%)	16/18 (88.9%)	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	13/23 (56.5%)	13/22 (59.1%)	4/11 (36.4%)	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	5/9 (55.6%)	5/8 (62.5%)		4/9 (44.4%)	3/7 (42.9%)	

1 Test= one (1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.

2 Tests= two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.

3 Tests= three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

Analytical performance

Limit of detection (analytical sensitivity)

The Limit of Detection (LoD) of the ellume·lab COVID Antigen test was established by performing a serial dilution of heat inactivated SARS-CoV-2 virus. The virus was supplied at a stock concentration of 1.15×10^7 $TCID_{50}$/mL. Virus was diluted in natural clinical matrix consisting of pooled SARS-CoV-2 negative clinical human nasopharyngeal swabs. Inactivated SARS-CoV-2 virus was diluted into natural clinical matrix and applied to the Nasal Swab. The contrived swab samples were processed as per the Instructions for Use. The LoD was estimated as the lowest dilution of virus which resulted in ≥95% positive results (i.e. confirmed by at least 19 out of 20 positive replicates).

The ellume·lab COVID Antigen test LoD in natural clinical matrix as presented to the swab was confirmed as 7.16×10^3 $TCID_{50}$/mL.

NIH/RADx® Variant Testing

The performance of this device in the detection of the Omicron variant of SARS-CoV-2 was evaluated in a dilution series of clinical specimens which were positive for the Omicron variant. This testing was conducted by the National Institutes of Health (NIH) as a component of the Rapid Acceleration of Diagnostics (RADx®) initiative. Specimen pools were prepared by the RADx® team using clinical pooled samples from currently circulating Omicron strains and tested by RADx® to assess performance with the Omicron variant. Results from this dilution series cannot be compared to other specimen pools and do not indicate that a test will have different clinical performance compared to other EUA authorized tests. Compared to an EUA authorized RT-PCR method, this test detected 100% of live virus Omicron samples at a Ct-value of 23.6 (n=5). Testing was also compared to two additional EUA-authorized OTC antigen tests (Assay #1 and Assay #2). Omicron dilutions at lower viral concentrations (Ct-values greater than 23.6) were not detected by this test in this study.

Table 5: *NIH/RADx® variant testing results.*

Omicron Pool 2 - Live Omicron Clinical Samples	Average N2 Ct (n=9)	Assay #1 Percent Positive (n = 5)	Assay #2 Percent Positive (n = 5)	Ellume COVID-19 Antigen Test Percent Positive (n=5)
Dilution 1	19.8	100	100	100
Dilution 2	20.8	100	100	100
Dilution 3	21.5	100	100	100
Dilution 4	22.7	100	100	100
Dilution 5	23.6	100	0	100
Dilution 6	24.0	60	0	40
Dilution 7	24.8	0	0	0
Dilution 8	25.8	0	0	0
Dilution 9	27.4	0	0	0
Dilution 10	28.1	0	0	0
Dilution 11	29.1	0	0	0

High dose hook effect (analytical sensitivity)

The ellume·lab COVID Antigen test does not exhibit a high dose hook effect with heat inactivated SARS-CoV-2 prepared up to 4.83×10^5 $TCID_{50}$/mL.

Cross-reactivity and microbial interference (analytical specificity)

Cross-reactivity of the ellume·lab COVID Antigen test was established by testing a broad range of potentially cross-reacting microbial pathogens (n=16 viruses, n=12 bacteria, n=1 yeast), and pooled human nasal wash that may be present in the nasal cavity. Each of the organisms and the human nasal wash was tested in triplicate in the presence and absence of heat inactivated SARS-CoV-2 virus.

No cross-reactivity or interference was observed with the listed microorganisms and human nasal wash when tested at the concentration presented in Table 6.

Table 6: *Cross-reactivity and Microbial Interference Study Results*

Potential Cross-Reactant	Concentration Tested	Cross-Reactivity?
Human Coronavirus 229E	10^5 $TCID_{50}$/mL	No
Human Coronavirus OC43	10^5 $TCID_{50}$/mL	No
Human Coronavirus NL63	10^5 $TCID_{50}$/mL	No
Adenovirus	10^5 $TCID_{50}$/mL	No
Human Metapneumovirus	10^5 $TCID_{50}$/mL	No
Parainfluenza 1	10^5 $TCID_{50}$/mL	No
Parainfluenza 2	10^5 $TCID_{50}$/mL	No
Parainfluenza 3	10^5 $TCID_{50}$/mL	No
Parainfluenza 4	10^5 $TCID_{50}$/mL	No
Influenza A	10^5 $TCID_{50}$/mL	No
Influenza B	10^5 $TCID_{50}$/mL	No
Enterovirus	10^5 $TCID_{50}$/mL	No
Respiratory Syncytial Virus A	10^5 $TCID_{50}$/mL	No
Respiratory Syncytial Virus B	10^5 $TCID_{50}$/mL	No
Rhinovirus	10^5 $TCID_{50}$/mL	No
MERS-Coronavirus (heat inactivated)	10^5 $TCID_{50}$/mL	No
Haemophilus influenzae	10^6 CFU/mL	No
Streptococcus pneumoniae	10^6 CFU/mL	No
Streptococcus pyogenes	10^6 CFU/mL	No
Staphylococcus aureus	10^6 CFU/mL	No
Staphylococcus epidermidis	10^6 CFU/mL	No
Candida albicans	10^6 CFU/mL	No
Bordetella pertussis	10^6 CFU/mL	No
Mycoplasma pneumoniae	10^6 CFU/mL	No
Chlamydia pneumoniae	10^6 CFU/mL	No
Legionella pneumophila	10^6 CFU/mL	No
Mycobacterium tuberculosis	10^6 CFU/mL	No
Pneumocystis jirovecii (PJP)	10^6 CFU/mL	No
Pooled Human Nasal Wash	10% v/v	No

In Silico analysis was used to estimate the likelihood of cross-reactivity of the ellume·lab COVID Antigen test with microorganisms not available for wet testing. The analysis was performed using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI).

- A 37% protein homology exists between the USA-WA1/2020 SARS-CoV-2 nucleocapsid protein and Human Coronavirus HKU1 across 82% of the sequence.
- A 91% protein homology exists between the USA-WA1/2020 SARS-CoV-2 nucleocapsid protein and SARS across 100% of the sequence.

Cross-reactivity with Human Coronavirus HKU1 and SARS cannot be ruled out.

Endogenous interfering substances (analytical specificity)

The ellume·lab COVID Antigen test was screened with a broad range of endogenous substances that may be found in the nasal cavity. Each of the substances was tested in triplicate in the presence and absence of heat inactivated SARS-CoV-2 virus.

No cross-reactivity or interference was observed for any of the substances tested (Table 7).

Table 7: *Endogenous Interfering Substances Study Results*

Substance	Concentration Tested	Interference?
Whole Blood	4% v/v	No
Ricola (Menthol)	1.5mg/mL	No
Sucrets (Dyclonin/Menthol)	1.5mg/mL	No
Chloraseptic (Menthol/Benzocaine)	1.5mg/mL	No
NasoGEL (NeilMed)	5% v/v	No
CVS Nasal Spray (Phenylephrine)	15% v/v	No
Afrin (Oxymetazoline)	15% v/v	No
NasalCrom (Cromolyn)	15% v/v	No
Zicam (with Oxymetazoline)	5% v/v	No
Homeopathic (Alkalol)	10% v/v	No
Fisherman's Friend	1.5mg/mL	No
Sore Throat Phenol Spray	15% v/v	No
Mucin	0.50% v/v	No
Tobramycin	4 µg/mL	No
Mupirocin	10 mg/mL	No
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	No
Fluticasone Propionate	2.5 mg/mL	No

Glossary of symbols

Symbol	Symbol Title	Explanation
IVD	In vitro diagnostic medical device	Indicates a medical device that is intended to be used as an *in vitro* diagnostic medical device
Rx Only	For prescription use only	Indicates medical device is for prescription use only
REF	Catalog number	Indicates the manufacturer's catalog number to identify the medical device
P/N	Product number	Indicates the manufacturer's material number to identify the product
LOT	Batch code	Indicates the manufacturer's batch code to identify the batch or lot
	Use-by date	Indicates the date after which the medical device is not to be used
	Manufacturer	Indicates the medical device manufacturer
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed
	Do not re-use	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
Σ 25	Contains sufficient for 25 tests	Indicates it contains sufficient material for 25 tests
Σ 1	Contains sufficient for 1 test	Indicates it contains sufficient material for 1 test

Assistance

If you have any questions or concerns regarding this product, please contact Ellume customer support on 1-888-919-0779, support@ellumelab.com or visit www.ellumelab.com

Test system problems may also be reported to the FDA through the MedWatch medical products safety reporting program phone: 1-800-FDA (332)-1088; fax: 1-800-FDA (332)-0178; online: www.fda.gov/medwatch

Ellume Limited
57 Didsbury St, East Brisbane, Qld 4169, Australia
www.ellume.com

ellume·lab COVID Antigen

Quick Reference Instructions

For Emergency Use Authorization only. ℞ Only. For *in vitro* diagnostic use only.

Intended use

The ellume·lab COVID Antigen test is a fluorescent lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct mid-turbinate nasal swab specimens collected by a healthcare provider from individuals who are suspected of COVID-19 within the first six days of symptom onset, when tested at least twice over three days with at least 48 hours between tests. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet the requirements to perform moderate complexity, high complexity, or waived tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

The ellume·lab COVID Antigen test does not differentiate between SARS-CoV or SARS-CoV-2 viruses.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in mid-turbinate swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

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 measures 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.

The ellume·lab COVID Antigen test is intended for use by medical professionals or operators who are proficient in performing tests in point of care settings. The ellume·lab COVID Antigen 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.

Warnings and Precautions

Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.

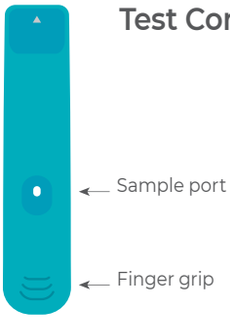
Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing. If you have had symptoms longer than 6 days you should consider testing at least three times over five days with at least 48 hours between tests.

- For use in combination with ellume·lab only.
- Wear appropriate personal protective equipment (PPE) including gloves, protective clothing and eye protection.
- The ellume·lab and test kit components are used within 59-86°F (15-30°C), 20% - 90% RH (non-condensing).
- Ensure test is in stable light setting before starting a test.
- Completion of on-device training is required before performing a Patient Test or Control Test for each new operator (or operator who has not performed the test recently).
- Only use test components if the indicating desiccant sachet is orange.

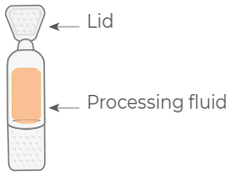
D1012169 C

Patient Test Components and Procedure

Test Components (For use on patients)



eStick



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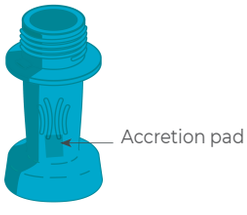
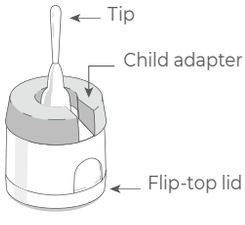


Dropper



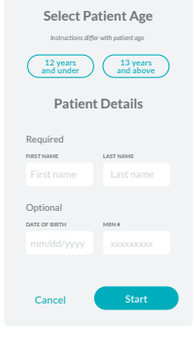
Nasal Swab (Sterile)

1

Patient Test

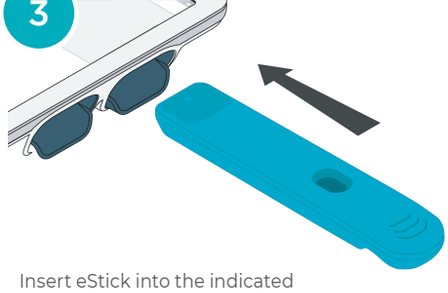
Press the ***Patient Test*** icon.
Select ***COVID Antigen*** test.

2



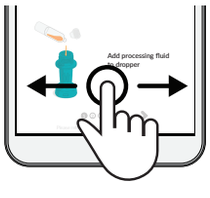
Select Patient Age, enter Patient Details and press the ***Start*** button.

3



Insert eStick into the indicated ellume·lab port.

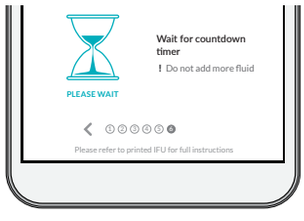
4



Following the specific nasal swab sampling instructions is essential for test accuracy.

Swipe through the on-screen instructions to see detailed information for each test step.

5



Wait for countdown timer to appear.

6

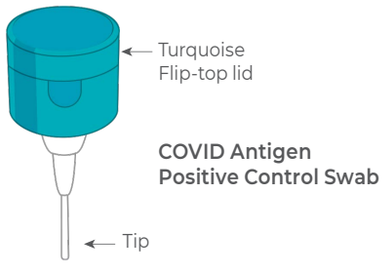
Do not remove eStick until result is available. Result is displayed on-screen.

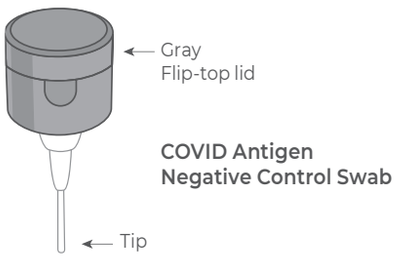
ellume·lab COVID Antigen

For Emergency Use Authorization only.
℞ Only. For *in vitro* diagnostic use only.

External Quality Control Test Components and Procedure

External Quality Control Swabs (Not for use on patients)





The test kit contains color-coded components. If you have a condition causing color blindness, please seek assistance with identifying the color-coded components before using the test.

Errors

If an error occurs, please refer to on-screen instructions or Instructions for Use.

If an error persists, please contact Ellume customer support on 1-888-919-0779, support@ellumelab.com

Ellume recommends that the external controls be tested for:

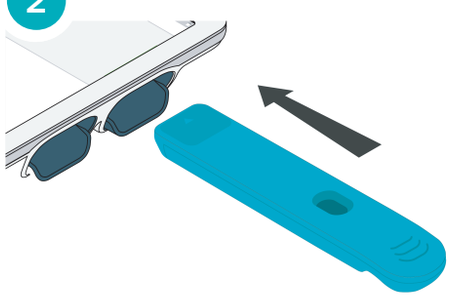
- Each new lot.
- Each new shipment of materials even if it is the same lot previously received.
- Each new operator (or operator who has not performed the test recently).
- As deemed necessary by internal Quality Control procedures and in accordance with Local, State and Federal regulations and/or accreditation requirements.

1

Control Test

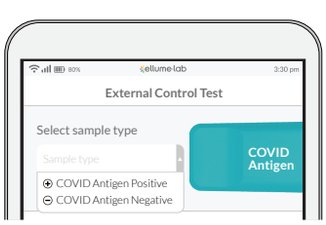
Press the ***Control Test*** icon.
Select ***COVID Antigen*** test.

2



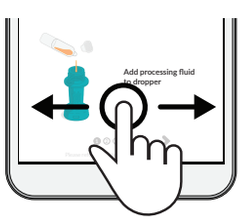
Insert eStick into the indicated ellume·lab port.

3



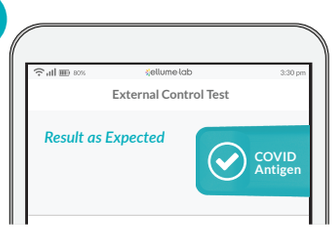
Ensure the selected sample type matches the information on the External Quality Control Swab packaging.

4



Swipe through the on-screen instructions to see detailed information for each test step.

5



Do not remove eStick until result is available. Result is displayed on-screen.

In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high, or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and, in the USA, 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.

Please see the Package Insert and User Manual for complete information regarding the ellume·lab test. This is not a complete Package Insert.

For more information, refer to Package Insert (Instructions for Use) or contact Ellume customer support on 1-888-919-0779 or support@ellumelab.com

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