

ellume·lab COVID Antigen Instructions for Use

For use in combination with ellume·lab only.

For Emergency Use Authorization only. Rx 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 from individuals who are suspected of COVID-19 by their healthcare provider within the first six days of symptom onset. 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. Antigen is generally detectable in mid-turbinate swab specimens during the acute phase of infection. A positive test result indicates the presence of the viral antigen, but clinical correlation with patient history and other diagnostic information is necessary to determine 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.

Negative results should be treated as 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 decisions. Negative results should be considered in the context of a patient'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 trained clinical laboratory personnel and individuals trained in point of care. The ellume·lab COVID Antigen test is only for use under the Food and Drug Administration's Emergency Use Authorization.

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.

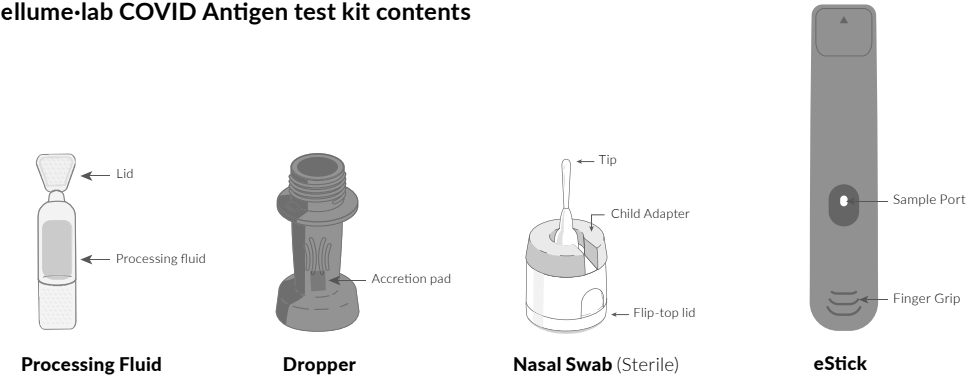
SARS-CoV-1 infection results in Severe Acute Respiratory Syndrome (SARS). SARS-CoV-1 caused the 2002-2003 SARS epidemic in China. Symptoms of SARS include fever, headache, and dry cough. Transmission is thought to occur via aerosolized droplets.

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.

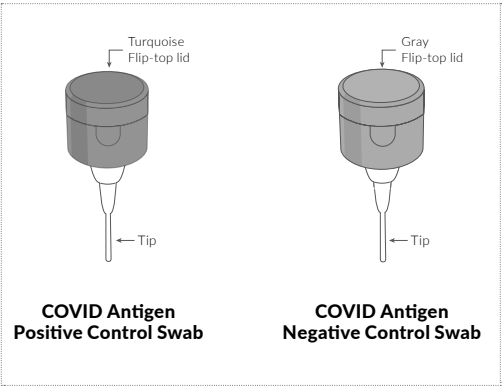
Principle of operation

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



External quality control (Not for use on patients)



Warnings and precautions

- 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.
 - 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.
- For *in vitro* diagnostic use only.
- For prescription use only.
- 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 or authorization is revoked sooner.
- Federal Law restricts this device to sale by or on the order of a licensed practitioner (US only).
- The product is authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- To obtain accurate results, the Instructions for Use must be followed.
- 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.
- 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.



WARNING

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

Chemical and safety information

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


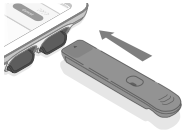


Reagents	Hazards	Link to MSDS
Proclin™ 300	<ul style="list-style-type: none">• Harmful if swallowed or if inhaled.• Causes severe skin burns and eye damage.• May cause an allergic skin reaction.• Very toxic to aquatic life with long lasting effects	https://www.sigmaaldrich.com/AU/en/sds/sial/48912-u

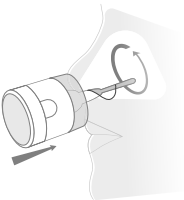
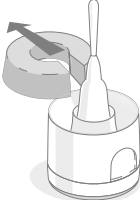
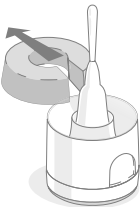


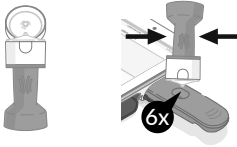

The extraction buffer solution in the Processing Fluid ampoule contains Proclin™ 300 which is a hazardous ingredient as shown in above table. If the extraction buffer solution contacts the skin or eye, immediately wash with plenty of running water. In case the irritation persists, please seek medical advice at: <https://www.poison.org/contact-us> 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. <ul style="list-style-type: none">• 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. <ul style="list-style-type: none">• 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		Patient 13+ 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.		5. Remove Child Adapter by pulling to the side before collecting a swab sample.	
6. Remove Child Adapter by pulling to the side.		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.	<div><div>POSITIVE SARS-CoV</div><div>Patient details</div><div><div>+</div>COVID Antigen</div></div>		

Interpretation of results		
Negative for SARS-CoV	Upon completion of the test the ellume-lab will display this symbol on-screen for a negative ellume-lab COVID Antigen result. This symbol indicates that the viral nucleocapsid protein of SARS-CoV was not detected in the patient sample.	
Positive for SARS-CoV	Upon completion of the test the ellume-lab will display this symbol on-screen for a positive ellume-lab COVID Antigen result. This symbol indicates that the viral nucleocapsid protein of SARS-CoV was detected in the patient sample. This result does not preclude co-infections with other pathogens and does not differentiate between SARS-CoV-1 and SARS-CoV-2.	
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]



COVID Antigen

[Unique ID: XXXXXXX]

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.

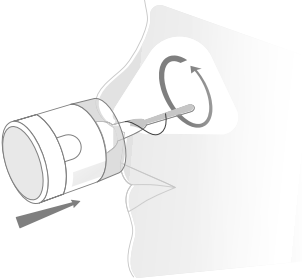
Mid-turbinate nasal swab sampling procedure

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.

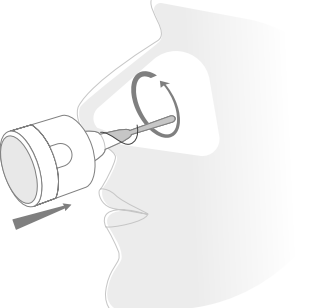
Sampling procedure on patients ≤12 years old

- Remove the Nasal Swab from its packaging by opening the peel.
- DO NOT REMOVE THE CHILD ADAPTER - Patients aged 12 years and under must be swabbed with the Child Adapter in place.
- Fully insert the Nasal Swab deep into the patient's nostril until the Child Adapter touches the tip of their nose.
- Gently rub the swab tip around the inside of the nose cavity 3 times.
- Gently remove the Nasal Swab and repeat steps 3 and 4 in the patient's other nostril.
- 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

- Remove the Nasal Swab from its packaging by opening the peel.
- Remove the Child Adapter by pulling it to the side.
- 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.
- Gently rub the swab tip around the inside of the nose cavity 3 times.
- Gently remove the Nasal Swab and repeat steps 3 and 4 in the patient's other nostril.
- 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


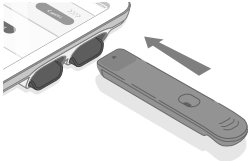
An indicating desiccant sachet is included within each eStick, Dropper and External Quality Control Swab foil pouch. The color of the silica gel contained within the sachet changes from orange to green when exposed to unacceptable humidity levels, warning the user that the component should not be used.




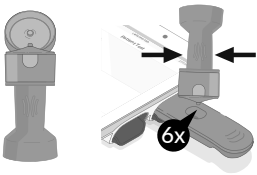

Procedure for executing external quality controls







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. <ul style="list-style-type: none">• 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.	<div>Sample type</div> <div><div>⊕ COVID Antigen Positive</div><div>⊖ COVID Antigen Negative</div></div>
4. Remove the Dropper from its packaging and place it upright on a flat surface. <ul style="list-style-type: none">• 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. <ul style="list-style-type: none">• 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.	<div>Result as Expected</div> <div><div>✓</div><div>COVID Antigen</div></div>

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:

Start second test

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 and non-viable SARS-CoV viral antigens and may yield a positive result in the absence of living micro-organisms.
- 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.
- A negative test result may occur if the level of antigen in the sample is below the detection limit of the test or if the sample was 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.

- 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.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- 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 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

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%)		

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 x 10⁷ TCID₅₀/mL. Virus was diluted in natural clinical matrix consisting of pooled SARS-CoV-2 negative clinical human nasopharyngeal swabs collected in Viral Transport Media. 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 x 10³ TCID₅₀/mL.

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 x 10⁵ TCID₅₀/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 4.

Table 4: 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
<i>Haemophilus influenzae</i>	10 ⁶ CFU/mL	No
<i>Streptococcus pneumoniae</i>	10 ⁶ CFU/mL	No
<i>Streptococcus pyogenes</i>	10 ⁶ CFU/mL	No
<i>Staphylococcus aureus</i>	10 ⁶ CFU/mL	No
<i>Staphylococcus epidermidis</i>	10 ⁶ CFU/mL	No
<i>Candida albicans</i>	10 ⁶ CFU/mL	No
<i>Bordetella pertussis</i>	10 ⁶ CFU/mL	No
<i>Mycoplasma pneumoniae</i>	10 ⁶ CFU/mL	No
<i>Chlamydia pneumoniae</i>	10 ⁶ CFU/mL	No
<i>Legionella pneumophila</i>	10 ⁶ CFU/mL	No
<i>Mycobacterium tuberculosis</i>	10 ⁶ CFU/mL	No
<i>Pneumocystis jirovecii</i> (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 5).

Table 5: 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
	In vitro diagnostic medical device	Indicates a medical device that is intended to be used as an <i>in vitro</i> diagnostic medical device
	For prescription use only	Indicates medical device is for prescription use only
	Catalog number	Indicates the manufacturer's catalog number to identify the medical device
	Product number	Indicates the manufacturer's material number to identify the product
	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
	Contains sufficient for 25 tests	Indicates it contains sufficient material for 25 tests
	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

For Emergency Use Authorization only. **Rx 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 from individuals who are suspected of COVID-19 by their healthcare provider within the first six days of symptom onset. 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. Antigen is generally detectable in mid-turbinate swab specimens during the acute phase of infection. A positive test result indicates the presence of the viral antigen, but clinical correlation with patient history and other diagnostic information is necessary to determine 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.

Negative results should be treated as 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 decisions. Negative results should be considered in the context of a patient'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 trained clinical laboratory personnel and individuals trained in point of care. The ellume-lab COVID Antigen test is only for use under the Food and Drug Administration's Emergency Use Authorization.

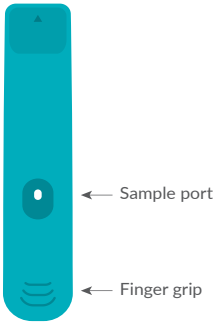
Test procedure and principles of the test

- 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.

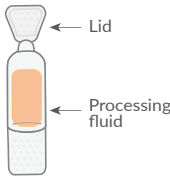
D1012169B

Patient Test Components and Procedure

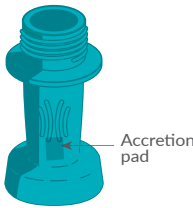
Test Components (For use on patients)



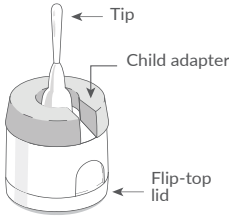
eStick



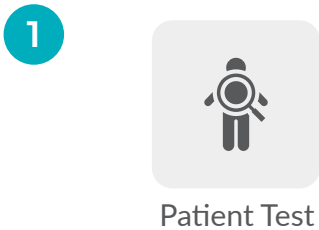
Processing Fluid



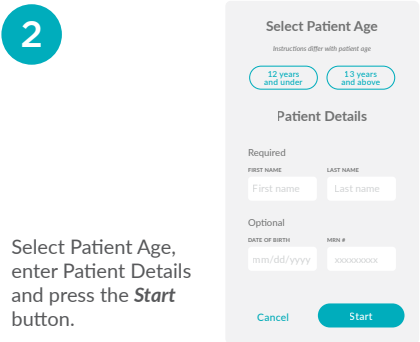
Dropper



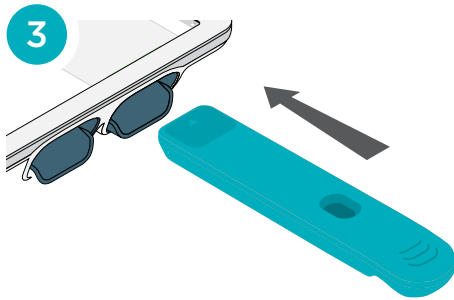
Nasal Swab (Sterile)



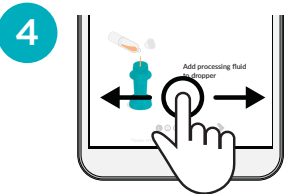
Press the *Patient Test* icon.
Select *COVID Antigen* test.



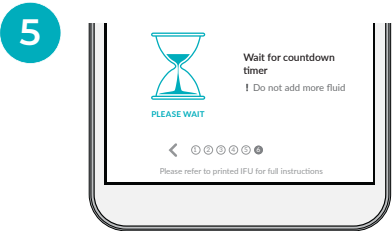
Select Patient Age,
enter Patient Details
and press the *Start*
button.



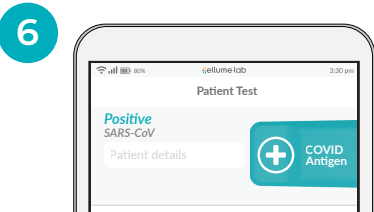
Insert eStick into the indicated
ellume-lab port.



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



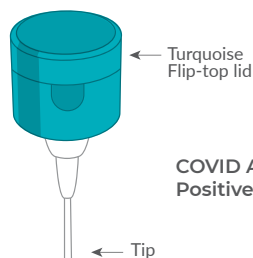
Wait for countdown timer to appear.



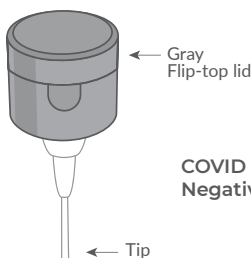
Do not remove eStick until result is available.
Result is displayed on-screen.

External Quality Control Test Components and Procedure

External Quality Control Swabs (Not for use on patients)



COVID Antigen Positive Control Swab



COVID Antigen Negative Control Swab

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.

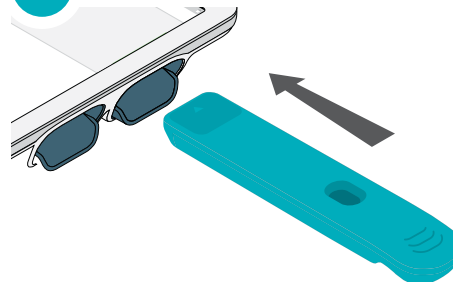
1



Control Test

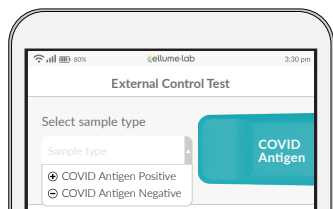
Press the **Control Test** icon. Select **COVID Antigen** test.

2



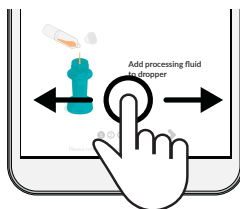
Insert eStick into the indicated ellume·lab port.

3



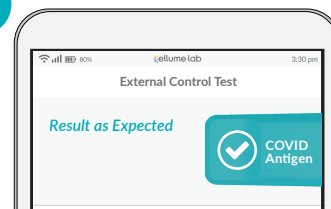
Ensure the selected sample type matches the information on the External Quality Control Swab packaging.

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

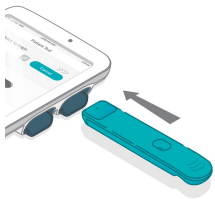
Ellume Limited
57 Didsbury St, East Brisbane
QLD 4169 Australia

www.ellumelab.com

ellume-lab COVID Antigen

Patient Test Step Instructions (Patient ≤12 years old only)

1



Insert eStick

! Ensure eStick is inserted the correct way

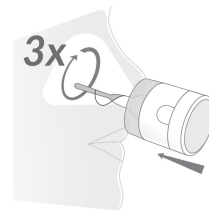
2



Add processing fluid to dropper

1 2 3 4 5 6 >

3



Swab both nostrils

! Ensure swab tip rubs around nose cavity 3 times on each side

< 1 2 3 4 5 6 >

4



Remove child adapter

! Avoid touching swab tip

< 1 2 3 4 5 6 >

5

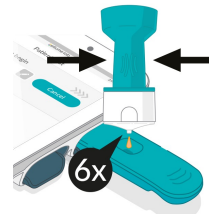


Screw swab into dropper

! Ensure swab is screwed in as tightly as possible

< 1 2 3 4 5 6 >

6



Add 6 drops to sample port

! If no fluid comes out, ensure swab is screwed in tightly and dropper is held vertically

< 1 2 3 4 5 6 >

7



PLEASE WAIT

Wait for countdown timer

! Do not add more fluid

< 1 2 3 4 5 6

8

Negative
SARS-CoV

Patient identifier



COVID
Antigen

9

Positive
SARS-CoV

Patient identifier



COVID
Antigen

Patient Test Step Instructions (Patient 13+ years old only)

1



Insert eStick

! Ensure eStick is inserted the correct way

2



Add processing fluid to dropper

1 2 3 4 5 6 >

3

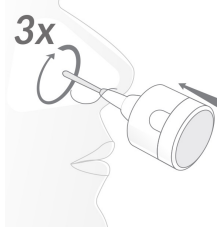


Remove child adapter

! Avoid touching swab tip

< 1 2 3 4 5 6 >

4



Swab both nostrils

! Ensure swab tip rubs around nose cavity 3 times on each side

< 1 2 3 4 5 6 >

5

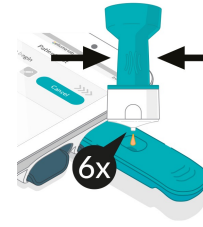


Screw swab into dropper

! Ensure swab is screwed in as tightly as possible

< 1 2 3 4 5 6 >

6



Add 6 drops to sample port

! If no fluid comes out, ensure swab is screwed in tightly and dropper is held vertically

< 1 2 3 4 5 6 >

7



Wait for countdown timer

! Do not add more fluid

PLEASE WAIT

< 1 2 3 4 5 6

8

Negative
SARS-CoV

Patient identifier



COVID
Antigen

9

Positive
SARS-CoV

Patient identifier



COVID
Antigen

Test Errors

1

Used Test

Discard and use a new eStick.



Unique ID: XXXXXXXX

2

Test Error

Discard and use a new eStick.



Unique ID: XXXXXXXX

3

Test Error

Re-insert eStick. If error persists, discard and use a new eStick.



Unique ID: XXXXXXXX

4

Test Error

Re-insert eStick. If error persists, discard and use a new eStick. Review instructions before starting a new test.



Unique ID: XXXXXXXX

5

Test Error

Discard and use a new eStick. Review instructions before starting a new test.



Unique ID: XXXXXXXX

6

Test Error

Discard and use a new eStick. Ensure test is in stable light setting before starting a new test.



Unique ID: XXXXXXXX

7

Test Error

Discard and use a new eStick. Wait for a result before removing eStick.



Unique ID: XXXXXXXX

8

eStick Has Expired

Discard and use a new eStick. Test must be used within 60 minutes.



Unique ID: XXXXXXXX

9

eStick Past Expiration Date

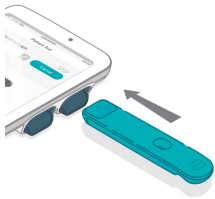
Discard and use a new eStick.



Unique ID: XXXXXXXX

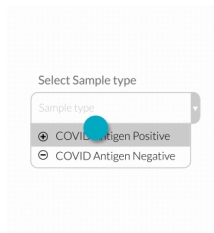
External Quality Control Test Step Instructions

1

**Insert eStick**

! Ensure eStick is inserted the correct way

2

**Select sample type**

! Match with information on control swab packaging

3



Add processing fluid to dropper

1 2 3 4 >

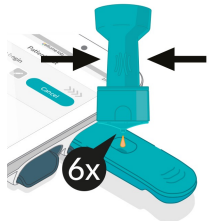
4

**Screw turquoise control swab into dropper**

! Ensure swab is screwed in as tightly as possible

< 1 2 3 4 >

5

**Add 6 drops to sample port**

! If no fluid comes out, ensure swab is screwed in tightly and dropper is held vertically

< 1 2 3 4 >

6



Wait for countdown timer

! Do not add more fluid

PLEASE WAIT

< 1 2 3 4 >

7

Result as Expected

8

Quality Review Needed

Discard and use a new eStick.



Unique ID: XXXXXXXX



Quick Start Guide

Getting Started

- 1 Activate your account via the link in your welcome email
**Ensure to remember your password*
- 2 Fully charge the ellume-lab before initial use
- 3 Turn on by pressing and holding the power button for 2-3 seconds
- 4 Connect to a secure Wi-Fi network
- 5 Select User:

Admin and Registered Users

- Select your account from the user list
- Enter your account password
- Create a PIN

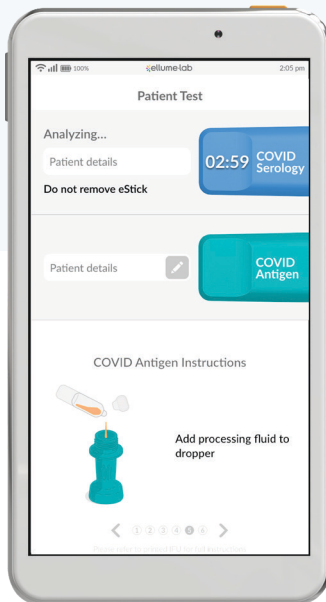
or

New User

- Tap the 'New User' button from the user list
- Fill in the Email Request form

** You will receive a welcome email once the ellume-lab administrator approves your request*

- 6 You are now ready to use the ellume-lab



Important Information

- Completion of test specific training is required before performing a Patient Test or Control Test. Tap the Training icon on the Home Screen to begin.
- For test specific information, please refer to the Instructions for Use and Quick Reference Instructions in the test carton.

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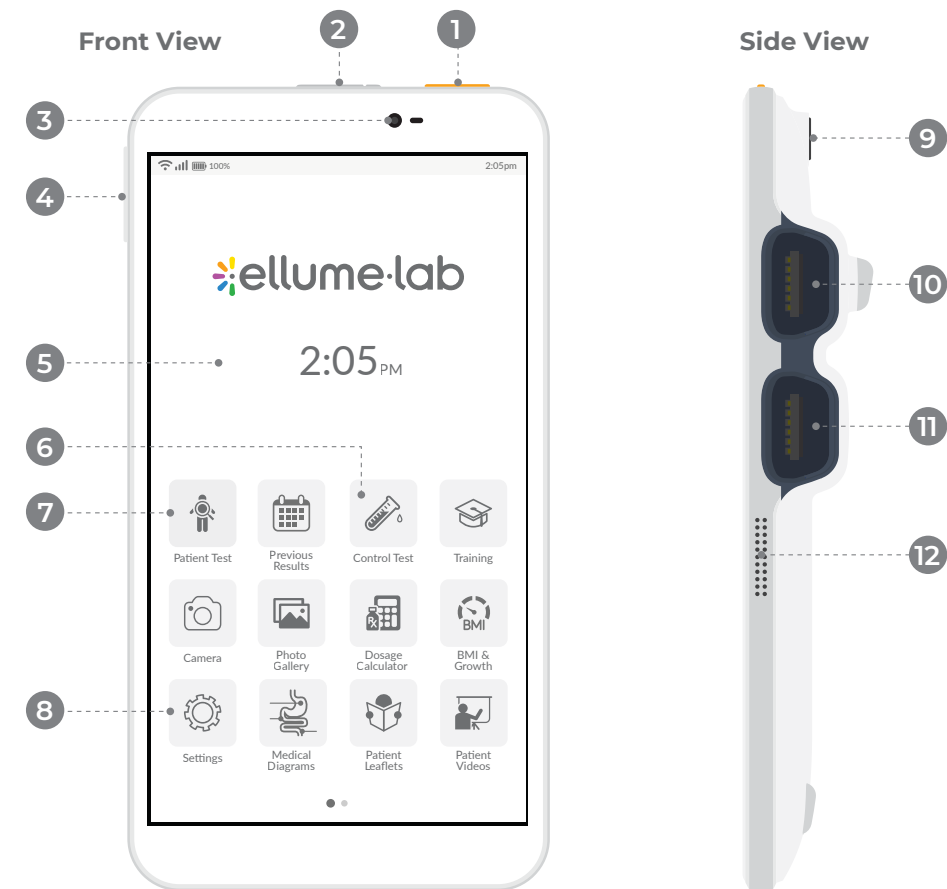


Please see the Package Insert (Instructions for Use) and User Manual for complete information regarding ellume-lab tests. This is not a complete Package Insert.

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



Getting to know your ellume·lab



- | | | |
|------------------|---------------------|-------------------------|
| 1 On/Off Button | 5 Home Screen | 9 Rear Camera |
| 2 Charging Port | 6 Control Test Icon | 10 eStick Port (Top) |
| 3 Front Camera | 7 Patient Test Icon | 11 eStick Port (Bottom) |
| 4 Volume Control | 8 Settings Icon | 12 Speaker |

When used with Ellume's Emergency Use Authorized ellume·lab COVID Antigen test:

For *in vitro* diagnostic use only. For prescription use only. 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 test product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostic tests 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 or authorization is terminated or revoked sooner. The test product is authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.

Welcome to ellume·lab



User Manual

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1 Ellume Contact Information

Contact Ellume customer support:










Tel: 1-888-919-0779

Email: support@ellumelab.com

Website: www.ellumelab.com

2 Safety

2.1 Universal Labels and Symbols

	Manufacturer		Prescription use only
	Date of manufacture		Serial number
	Consult Instructions For Use		CAUTION Consult accompanying documents. WARNING Indicates a hazardous situation, which if not avoided, could result in injury to the operator (e.g. electrical shock)
	Catalog number		
	Temperature limitation		
	Declaration of conformity		

2.2 Warnings & Safety Precautions

The ellume-lab is designed to ensure safe and reliable operation, when used in accordance with this User Manual. If the ellume-lab is used in ways other than specified in this manual, safety of the operator and reliability of results may be compromised. All warnings and precautions must be followed to avoid personal injury or damage to the device.



Minimize the risk of personal injury:

- Remove the ellume-lab from the charging dock or unplug the charging cable before performing a test.
- Do not immerse the ellume-lab in water or cleaning solutions. See Section 14 'Maintenance and Cleaning' for cleaning procedures.
- The ellume-lab must be charged using an approved electrical socket and appropriate charging cable and region-specific adapter.



Minimize the risk of damage to the ellume-lab:

- Handle with care.
- Do not drop.
- Do not expose to moisture, dust, extreme humidity, long periods of direct sunlight or extreme temperatures.
- Store between 59°F - 95°F (15°C - 35°C).
- Do not expose to severe shock or vibration.
- Use with approved ellume-lab tests only. Using non-approved test cartridges, test kit components, chargers, cables, and accessories will impact device function and void warranty.
- Incorrect use of the ellume-lab charger, charging dock and charging cable may damage the device.
- Routinely clean the device using disinfecting wipes containing isopropyl alcohol (70% minimum). Off-the-shelf wipes (e.g. Clinell Wipes) have been validated for routine cleaning of the ellume-lab. See Section 14 'Maintenance and Cleaning' for cleaning procedures.
- For deep cleaning within the ellume-lab testing ports (e.g. for fluid spills), a cleaning solution with a minimum of 10% bleach is required. Ensure cleaning solutions do not come into contact with the electrical contacts within the ePorts. See Section 14 'Maintenance and Cleaning' for cleaning procedures.
- Do not clean the ellume-lab with unapproved products.
- Do not open or disassemble the ellume-lab.
- Do not use if charging cable and/or charging dock are damaged.
- Please follow all precautions.



Minimize the risk of infection from contact with the ellume-lab:

- The ellume-lab requires cleaning after every test or potential contact with infectious substances. See Section 14 'Maintenance and Cleaning' for cleaning procedures.



Minimize the risk of contamination of the ellume-lab:

- Consider and treat all patient samples as infectious/biohazardous material.
- Dispose of specimens and patient samples in accordance with federal, state, and local requirements.
- Clean the ellume-lab as per Section 14 'Maintenance and Cleaning' prior to use, storage, transport, or disposal.
- Ensure you have received specific training in specimen collection and handling procedures before using the ellume-lab.
- Wear appropriate personal protective equipment (PPE) including gloves, protective clothing and eye protection when handling patient samples.



Other precautions and additional information:

- The ellume-lab may influence the surrounding environment due to its Wi-Fi connectivity.
- The ellume-lab has been validated for use of up to 5000 eStick insertions per testing port. Do not use the device for more than the recommended number of eStick insertions.
- The device is designed in accordance with international electrical safety standards (IEC 61010-1, IEC 61010-2-101, and IEC 60601-1-2). This equipment has been designed and tested to CISPR11 Class B.
- This device complies with Part 15 of the FCC Rules. Operation is subject to the following conditions:

- This device may not cause interference; and
- This device must accept any interference, including interference that may cause undesired operation of the device
- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio

frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.



Warning: Any changes or modifications not approved by Ellume could void the user's authority to operate this equipment.

3 Icons & Symbols

	Wi-Fi on
	Wi-Fi unavailable
	Battery status
	Battery low
	Battery charging
	3G/4G unavailable
	3G/4G connected
	Next
	Back (to previous screen)
	Cancel

	Warning / Error
	Time
	Patient Test
	Control Test
	Previous Results
	Settings
	Positive Result
	Negative Result
	Result as Expected
	Quality Review Needed

4 Introduction

4.1 Intended Use

The ellume-lab is a handheld digital diagnostic device intended for use by healthcare professionals at the point of care. It is used in combination with the ellume-lab suite of rapid in vitro diagnostic (IVD) tests to detect specific markers of infectious diseases. Please refer to the IVD-specific Instructions For Use provided with each authorized test kit for details of their intended use.

The ellume-lab also provides educational content and digital services through a wide range of applications.

4.2 Package Contents

The ellume-lab product box contains:

- 1 x ellume-lab
- 1 x charging adapter
- 1 x ellume-lab USB charging cable
- 1 x User Manual
- 1 x Quick Start Guide

Check the ellume-lab package contents to confirm all contents are included and have no signs of damage or defects. Use the ellume-lab with approved ellume-lab tests only. Using non-approved test cartridges, test kit components, chargers, cables, and accessories will impact on device function and void warranty.

Please contact the Ellume Customer Support on 1-888-919-0779 for all inquiries. Additional information can be found at www.ellumelab.com.

4.2.1 ellume-lab Accessories

The accessories (charging cable and charging adapter) supplied are for use with the ellume-lab only and may vary depending on region. Do not use ellume-lab accessories with other medical or electronic devices.

4.3 Calibration and Quality Control (QC)

4.3.1 ellume-lab

The ellume-lab does not require calibration from the user. When an eStick is inserted, it automatically performs a series of self-tests and calibration checks.

4.3.2 External Quality Controls

Please refer to the printed Instructions for Use (IFU) and Quick Reference Instructions (QRI) in each test carton for further information on performing External Quality Controls.

5 Display & Features

5.1 Display & Features



5.2 Power On/Off

To turn on the ellume-lab, tap and hold the Power button located on the top right side of the device for 2-3 seconds. To turn off, hold the Power button, then tap the Power off icon on the screen.

5.3 Standby

To put the ellume-lab on standby, tap the Power button located on the top right side of the device. To take off standby, tap the Power button again. The ellume-lab display will automatically go on standby after being inactive for 5 minutes. The ellume-lab will not automatically go on standby during a test, while in the Patient Test app or while in the Control Test app.

5.4 Volume Control

The volume buttons are located on the left side of the device. Tap the top of the button to increase volume, and the bottom of the button to decrease volume.

5.5 Display

The ellume-lab touchscreen is fully interactive and is sensitive to human touch or interaction with any stylus designed for use with a capacitive touch screen.

6 ellume-lab Account Registration

6.1 Registration of ellume-lab & Administrator

The ellume lab has been registered to a medical clinic and the administrator account has been setup by an Ellume representative. For security, it is required that user accounts be created and registered with Ellume through the online registration link, received via email. If you are experiencing issues with account registration or cannot set up your device, please contact your device administrator or Ellume customer support on 1-888-885-6121 or at support@ellumelab.com.

6.2 User Account Setup

To ensure security and regulatory compliance, creation and use of individual user accounts are required. User accounts can be added by the administrator via portal. ellumecloud.com. New users who have been approved by the administrator will receive a welcome invitation email from noreply@ellumelab.com.

6.2.1 Account Setup

1. Follow the link in the welcome email to complete your account registration
2. Enter your personal details
3. Enter your password and security question

*Your password will be required to login to your account. This can be done through portal.ellumecloud.com, or on the ellume-lab device

4. Select your display icon and color

If you are a new user and are attempting to login to an ellume-lab, you must first be added and authorized by your administrator. Please contact your administrator or send a request (see section 7.2)

6.3 ellume-lab Account

Once you have completed your account registration, you can log in to the ellume-lab using your email address and password.

6.3.1 Log in to ellume-lab

1. Turn on by pressing the power button
2. From the log in screen, tap the Refresh button, located beneath Switch User

*You may need to swipe right from the login screen to locate the Refresh button.

6.3.2 Users & Administrators

Your account can be used to manage and edit your details and security settings. Go to:

1. Account
2. Settings

To log out of your account, go to:

1. Account
2. Logout

6.3.3 Administrators

Administrator access includes ellume-lab user list management. Administrators can view, invite, add, delete and manage ellume-lab users. Go to:

1. Management
2. Manage user list

6.4 Your PIN

Your PIN is initially set up when logging in to the ellume-lab for the first time.

6.4.1 Changing your PIN

You can change your PIN through your account settings.

6.4.2 Forgot PIN

1. Tap 'Forgot PIN' from the ellume-lab lock screen
2. Login with account password and set new PIN

6.5 Forgot/Change Password

Your account password can be changed through your account at <https://portal.ellumecloud.com>. A password reset can also be requested from the ellume-lab device by selecting 'Forgot password' from the login screen. A password reset link will be emailed to you.

7 ellume-lab Device

7.1 ellume-lab Device Setup

1. Fully charge the ellume-lab before initial use
2. Turn on the ellume-lab by tapping the power button for 2-3 seconds
3. Tap Get Started on the welcome page
4. Connect to secure Wi-Fi network
 - a. Select the Wi-Fi network from the list and enter the password if required. If the preferred Wi-Fi network is not in the list, it can be manually added by selecting Add network
 - b. Input the Wi-Fi network name
 - c. Select the security type
 - d. Enter password if required and tap Connect.
 - e. Tap Next
5. Check registration details and tap Next

7.2 Initial User Setup

1. Select a user from the list or Add New User

*Only ellume-lab administrators are authorized to add new users. To add a new user, please contact your administrator by tapping the Request Now button.

2. Enter the account password and tap Next

*Use your account password that was setup during the user account setup (section 6.2). If you forget your password, it can be reset using the ellume-lab online portal.

3. Enter your PIN and tap Set

*If you have already set up your PIN through the ellume-lab portal or on another ellume-lab device, you will not be prompted to set up your PIN again. Please use your existing PIN.

*PIN cannot contain four repeating or sequential digits.

4. Re-enter your PIN and tap Finish

7.3 Subsequent User Setup

If your administrator has added your account, you can find your name at the bottom of the screen on the sign in page under 'Switch user'.

1. Find your username and icon on the screen or by sliding the user icons to the right
2. Tap your user icon and complete the account set up process

*If your name is not on the user list, select 'New User' and complete the new user request email form. Your administrator will be required to authorize your account before you can complete the full setup process.

7.4 72-hour Security Lock Out

If your account has been inactive for 72 hours or longer, you will be required to enter your account password and PIN.

1. Tap your user icon, then tap Login
2. Enter your account password
3. Enter your PIN

7.5 Switching User Profiles

The current active user will always appear on the lock screen. To switch user profiles.

1. Scroll through the list of users on the lock screen
2. Select your user icon and enter your password and PIN

*All user data is private and cannot be viewed by other users.

7.6 Home Screen & Operation

The home screen is the main screen of the ellume-lab interface for accessing diagnostic features and digital applications. It contains icons such as Patient Test, Control Test, Previous Results and more. You can also access all digital applications from the home screen.

7.7 Charging

Fully charge the ellume-lab prior to first use. Use only ellume-lab approved accessories. Unapproved accessories may cause damage to the device.

7.7.1 Charging (dock)

1. Connect the USB charging cable to the charging adaptor
2. Plug the charging adaptor into an approved socket and turn on
3. Insert the end of the USB charging cable into the charging dock USB port
4. Place the ellume-lab into the charging dock and ensure charging pins are aligned. The charging symbol will appear in the top left corner of the screen

7.7.2 Charging (cable only)

1. Connect the USB charging cable to the charging adaptor
2. Plug the charging adaptor into an approved socket and turn on
3. Remove the ellume-lab charging port cover. Insert the end of the USB charging cable into the ellume-lab charging port. The charging symbol will appear in the top left corner of the screen



8 Software & Security

8.1 Software Updates

The ellume-lab will receive software updates and perform the auto update function during off-peak times, usually between 12am to 6am. The ellume-lab must be connected to Wi-Fi for updates to occur. Leave the ellume-lab plugged into the charging cable, or in the charging cradle overnight to ensure there is sufficient battery for updates.

You can manually check for, and download updates by:

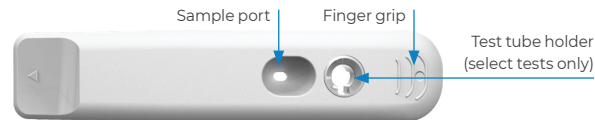
1. Tap the Setting icon from the Home Screen
2. Tap Check For Updates
3. Wait for updates to install and tap the Back button to exit

8.2 Security

While using the ellume-lab, it is recommended to follow safe cyber security practices, including:

1. Always connect the ellume-lab to a known, secure network. Do not connect to public Wi-Fi networks
2. Do not use ellume-lab for medical record keeping purposes. Data should be entered into external patient medical records
3. Do not attempt to change the operating system, settings or side load applications. Detection of system changes and unauthorized applications will immediately notify Ellume
4. All users are required to register and use the same credentials to log into the ellume-lab
5. Change your password and PIN frequently

9 eStick



The ellume-lab diagnostics range uses individual test kits. Each test kit contains various accessories and an eStick, a single-use test cartridge that is inserted into the ellume-lab. More information can be found in the printed Instructions for Use (IFU) and Quick Reference Instructions (QRI) in each test carton.

10 Diagnostic Testing

10.1 Icons

	Patient Test		Control Test
	Previous Results		Training

10.2 Diagnostic Test Preparation

1. Ensure the ellume-lab is turned on and charged to a minimum of 20% battery
2. Tap the Patient Test or Control Test icon from the home screen and follow the on-screen instructions. More information can be found in the printed Instructions for Use (IFU) and Quick Reference Instructions (QRI) in each test carton.

*The remaining testing process has been clinically validated for each ellume-lab test and corresponding external controls.



Caution:

- Do not press the power button while testing.
- Only remove the eStick and test kit components from the packaging immediately before testing.
- The eStick must be used within 60 minutes from insertion into the ellume-lab. The eStick will expire and become unusable if no sample is loaded within 60 minutes from insertion.
- Keep the ellume-lab flat while testing is in progress. Rotating the device while performing a test will prompt a warning message.



- Do not expose the ellume-lab to unstable lighting conditions while testing. If a warning is displayed, remove the ellume-lab and eStick from fluctuating light sources.

10.3 Performing Two Tests

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

Start second test

1. Begin a single Patient Test or a single Control Test by selecting the relevant icon from the Home Screen
2. Once the testing screen has been launched, tap the Start second test button at any time to begin a second test



Caution:






- Only perform two patient tests simultaneously OR two control tests simultaneously.

***A Patient Test and Control Test must not be performed simultaneously.**

- While performing two tests, you can toggle between them by tapping the eStick image on-screen next to the relevant testing 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 steps).
- An eStick may only be removed once a result is displayed. Do not remove the eStick while a test is in progress.

11 Interpreting Test Results

11.1 Icons

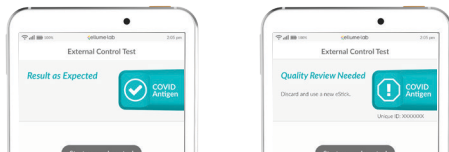
	Positive Result for Patient Test		<ul style="list-style-type: none">• Used test• Test error• eStick has expired• eStick past expiration date
	Negative Result for Patient Test		
	External Quality Control Result as expected		External Quality Control Review needed

11.2 Patient Test Result



Patient test results are displayed on-screen after the test has completed.

11.3 External Control Test Result



External control results are displayed on-screen after the test has completed.

11.4 Test Errors

A test result will display the test error type, the follow up action for the user and additional information. More information can be found in the printed Instructions for Use (IFU) and Quick Reference Instructions (QRI) in each test carton.

12 Previous Results

Previous results can be accessed by tapping the Previous Results icon from the Home Screen. The Previous Results app contains:

- Patient Results tab, listing patient results by the most recent testing time/date
- External Controls tab, listing external control results by the most recent testing time/date
- Search function, allowing users to search for a result using key words

12.1 Icons

	Positive Result for Patient Test		LOT number
	Negative Result for Patient Test		Test date
	External Quality Control Result as expected		Test error
	Patient name		External Quality Control Review needed

13 Settings

The system settings can be accessed from the Home Screen by tapping the settings icon.

13.1 Screen Brightness

Drag the slider to the left to decrease the screen brightness and to the right to increase the screen brightness.

13.2 Notification Volume

Drag the slider to the left to decrease the notification volume and to the right to increase the notification volume.

13.3 Change Wi-Fi Connection

*You may require assistance from your network administrator.

1. From the Home Screen tap the Settings Icon
2. Tap Wi-Fi connection
3. Turn the Wi-Fi on by toggling the on/off switch in the top right corner
4. Select the preferred Wi-Fi network from the list and enter the password (if required). If the preferred Wi-Fi network is not listed, it can be manually added by selecting + Add Network
 - a. Input the Wi-Fi network name (SSID)
 - b. Select the security type
 - c. Enter password (if required)
 - d. Tap Save

5. The ellume-lab should now be connected to the new Wi-Fi network. This can be confirmed by checking that in the list of networks the Wi-Fi ON icon is next to the network name

6. Tap the Back button in the top left-hand corner to return to the Settings menu

13.4 Modify Date/Time

It is recommended that:

- Automatic Date & Time be set to use network-provided time
- Automatic time zone be set to Off, and
- You select your local time zone from the list

To switch between 12 and 24-hour time, toggle the Use 24-hour format switch.

13.5 About

Displays the serial number and the software version number of the ellume-lab.

14 Maintenance & Cleaning

14.1 Cleaning

The ellume-lab should be routinely cleaned:

- Routinely clean the device using disinfecting wipes containing isopropyl alcohol (70% minimum). Off-the-shelf wipes (e.g. Clinell Wipes) have been validated for routine cleaning of the ellume-lab.
- By wiping each surface for at least 30 seconds
- After each use
- Each time a test is processed, and
- After the device has been handled

The ellume-lab testing ports should be deep cleaned:

- Using cleaning solutions with a minimum of 10% bleach
- By wiping inside each ePort for at least 30 seconds
- If there has been a spill of fluid or liquids within the ePort



Caution:

- Do not use non-approved cleaning solutions as they may harm the device.
- Ensure cleaning solutions do not contact the electrical contacts within the testing ports.

14.2 ellume-lab Useful Life

The ellume-lab has been validated for use of up to 5,000 eStick insertions per testing port.





Caution:

- Do not use the device for more than the recommended number of eStick insertions.

14.3 ellume-lab Device Disposal

The ellume-lab contains an internal Lithium Ion battery and should be disposed of according to local regulations.

15 Technical Specifications

Dimensions	7.28 x 4.06 x 1.22 inches
Weight	13.76 ounces
Power Supply Input	ellume-lab: 5V  2A Charging Dock Adapter: 100 ~ 240 VAC ; 50 ~ 60 Hz [Power Supply Maximum Rated Power]
USB-C Input	5V  2A
Display	6.95-inch diagonal – Touch screen
Operating environment	59°F – 95°F [15°C – 35°C], 20% – 90% RH (non-condensing)
Shipping	-4°F – 131°F [-20°C – 55°C], 20% – 90% RH (non-condensing)
Storage	59°F – 95°F [15°C – 35°C]

16 Troubleshooting

16.1 Restarting

If the ellume-lab is unresponsive, press and hold the Power button for more than 4 seconds and tap Restart on-screen.

16.2 Ordering, Inquiries & Complaints

For customer support, contact Ellume customer support on 1-888-919-0779 or at 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: <http://www.fda.gov/medwatch>).

Information correct as of June 30 2021.

17 Additional Information



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

When used with Ellume's Emergency Use Authorized ellume-lab COVID Antigen test:

For *in vitro* diagnostic use only. For prescription use only. 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 test product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostic tests 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 or authorization is terminated or revoked sooner. The test product is authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.



www.ellumelab.com

For Emergency Use Authorization (EUA) only
and for *in vitro* diagnostic use when used with
EUA-authorized ellume·lab test kits. **Rx Only**