



ELLUME·LAB USER MANUAL

FOR INVESTIGATIONAL PURPOSES ONLY

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1 INTRODUCTION

1.1 Intended Use

The ellume·lab is a handheld digital 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 tests. Each ellume·lab test is able to detect specific markers of common infectious and non-infectious conditions, e.g. Group A Streptococcus, Influenza A+B, RSV etc. For test specific information, refer to the package inserts supplied with each test kit carton.

1.2 Package Contents

The ellume·lab product box contains:

- 1 x ellume·lab
- 1 x charging adapter
- 1 x charging cradle
- 1 x ellume·lab USB charging cable
- Package inserts (User Manual & Quick Start Guide)

The accessories supplied with the ellume·lab may vary depending on the region. The ellume·lab charger and cradle are designed for use with the ellume·lab only. Do not use with other medical or electronic devices. Check the ellume·lab product box 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 helpline for all inquiries (Section 12). Additional information can be found at ellumelab.com.

1.3 ellume·lab Layout

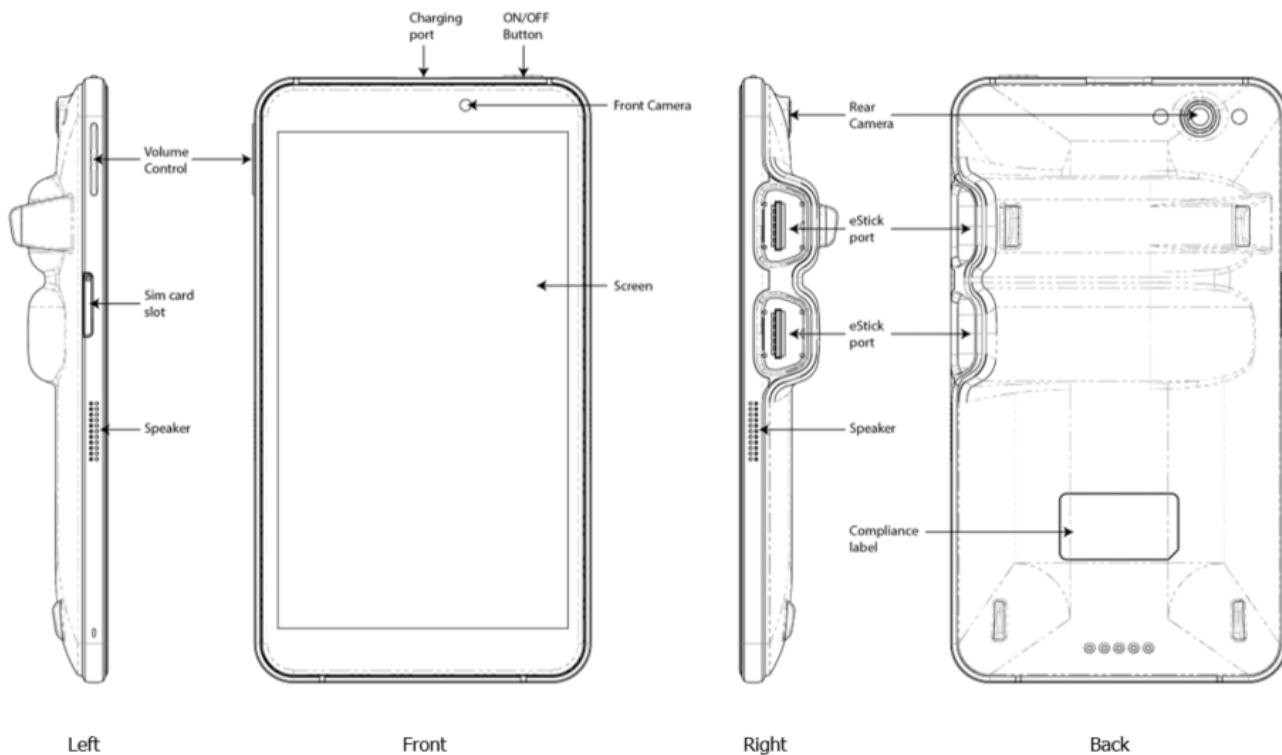


Figure 1 - ellume·lab Layout

2 SAFETY

2.1 Universal Labels and Symbols

	Manufacturer
	In vitro diagnostic medical device
	Consult instructions for use
	Catalogue Number
	Temperature limit
	Declaration of conformity
	Date of manufacture
	Biological risks
	Regulatory Compliance Mark (RCM)
	CAUTION Consult accompanying documents. WARNING Indicates a hazardous situation, which if not avoided, could result in injury to the operator (e.g. electrical shock)

2.2 Warnings and 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.

Minimise the risk of personal injury:

- Remove the ellume·lab from the charging cradle or unplug the charging cable before performing a test
- Do not immerse the ellume·lab in water or cleaning solutions. Refer to Section 10 '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.

Minimise 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 5°C – 35°C (41°F - 95°F)
- 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 on device function and void warranty
- Incorrect use of the ellume·lab charger, charging cradle and charging cable may damage the device
- Clean the device using disinfecting wipes containing isopropyl alcohol (70% minimum). Off-the-shelf wipes (MEDI-9 Wipes, Clinell Wipes) have been validating for effective cleaning of the ellume·lab. See Section 10 '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 cradle are damaged
- Please follow all precautions



Minimise the risk of infection from contact with the ellume·lab:

- The ellume·lab requires cleaning after every test procedure or potential contact with infectious substances. Please refer to Section 10 'Maintenance and Cleaning' for cleaning procedures
- Clean the device using disinfecting wipes containing isopropyl alcohol (70% minimum). Off-the-shelf wipes (MEDI-9 Wipes, Clinell Wipes) have been validating for effective cleaning of the ellume·lab. See Section 10 'Maintenance and Cleaning' for cleaning procedures. Do not clean the ellume·lab with unapproved products



Minimise 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 10 '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
- Use personal protective equipment (gloves and safety glasses) when handling patient samples



Other precautions:

- 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 insertions per testing port. Do not use the device for more than the recommended number of 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 CISPR 11 Class A. In a domestic environment, it may cause radio interference in which case you may need to take measures to mitigate the interference. Do not use this device near sources of strong electromagnetic radiation e.g. unshielded intentional radio frequency sources, as these can interfere with the proper operation.
- This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.



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

3 SET UP

3.1 Initial Setup

The first time you switch on the ellume·lab, connect to the internet and time zone through the *Settings* app.

3.1.1 Accessing Settings

Once the ellume·lab has booted, you will see the Home Screen (Figure 2). Press the *Settings* icon (Figure 9).

3.1.2 Wi-Fi Connection Setup

You may require assistance from your network administrator.

1. From the Home Screen (Figure 2) press the *Settings* Icon.
2. Press *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 in the list, it can be manually added by select *+Add network*.
 - a. Input the Wi-Fi network name (SSID).
 - b. Select the security type.
 - c. Enter password (if required).
 - d. Press *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 (Section 4.2) is next to the network name.
6. Press the *Wi-Fi* back button in the top left hand corner to return to the Settings menu.

3.1.3 Setting Time Zone

1. From the Home Screen (Figure 2) press the *Settings* icon.
2. Press *Date & Time*.
3. Move the *Automatic time zone* toggle to ON, so that it changes color to green.
4. Press the *Date and Time* back button in the top left hand corner to return to the Settings menu.

3.1.4 Manually set Time Zone

1. From the Home Screen (Figure 2) press the *Settings* icon.
2. Press *Date & Time*.
3. Move the *Automatic time zone* toggle to OFF, so that it changes color to grey.
4. Press *Select time zone* and select the preferred option.
5. Press the *Date and Time* back button in the top left hand corner to return to the Settings menu.

3.2 Initial Charging

Prior to initial use the battery must be fully charged. Use only approved ellume·lab chargers and cables. Unapproved accessories may cause damage to the device and its battery.

1. Connect the USB charging cable to the charging adaptor.
2. Insert the end of the USB charging cable into the charging cradle.
3. Place the ellume·lab into the charging cradle in an upright orientation.
4. To commence charging insert the charging plug into an electric wall socket that is on.
5. There will be 5-10 seconds delay before the Battery Charging icon appears (Section 4.2).

Once fully charged remove the ellume·lab from the cradle and then remove the plug from the wall socket.

3.3 Power On

To turn on the device, press and hold the Power button located on the top right side of the device (Figure 1) for 2-3 seconds.

3.4 Power Off

To turn off the device, press and hold the Power button (Figure 1), then tap the Power off icon on the touch screen.

4 USER INTERFACE

4.1 Home Screen

The Home Screen (Figure 2) is the starting point for accessing features and applications of the ellume·lab. The *Patient Test* icon allows the users to perform a diagnostic test on a patient (Section 5). The *Control Test* icon allows the users to perform an External Quality Control (Section 5). You can also access other apps such as *Training*, *Previous Results*, *Instructions*, *Settings* and *Flashlight*.

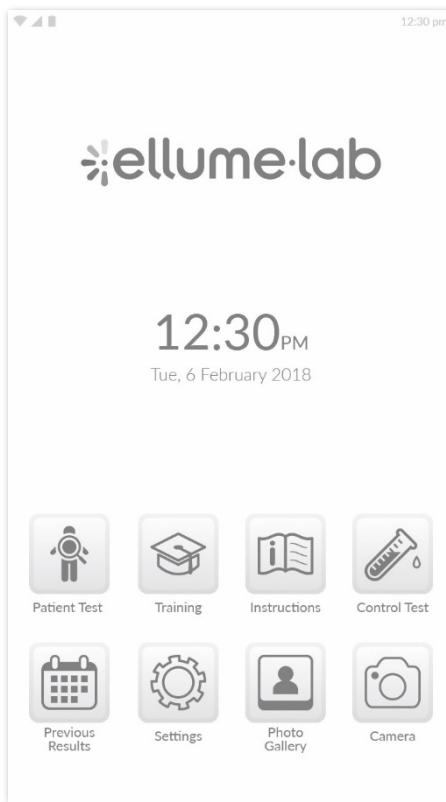


Figure 2 - Home Screen

4.2 Indicator Icons

Across the top of all screens are indicator icons for Wi-Fi and battery status.

The Wi-Fi icon indicates whether the ellume-lab is connected to a wireless network.

The battery status icon indicates what level of charge remains in the battery and whether the ellume-lab is charging.

The battery status icon will turn red when there is less than 40% battery charge left and if not connected to charging. Low battery notification sounds are played when the battery level is 20% or below and if not connected to charging.

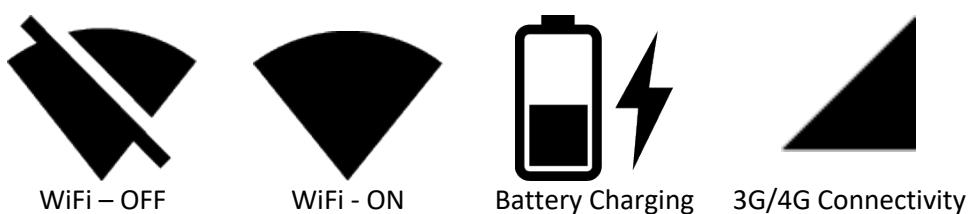


Figure 3 - Indicator Icons

5 PREPARATION FOR PATIENT/EXTERNAL QUALITY CONTROLS TEST

1. Ensure the ellume-lab is turned on and charged to a minimum of 20% battery.
2. Check that the test kit and specimen have been in ambient conditions for 20 or more minutes to be equilibrated to room temperature.
3. Do not remove the eStick and other components from their packaging until ready to test.
4. Remove an eStick from its packaging immediately before testing.



Once a test package has been opened, the test is deemed used and the customer will be invoiced.

- ⚠ The eStick must be used within 60 minutes from insertion into the ellume-lab. eStick will be voided if no sample is loaded within 60 minutes from insertion.**
- ⚠ Keep the ellume-lab horizontal while test is in progress. Rotating the device while performing a test will prompt a warning message.**
- ⚠ The ellume-lab will notify the user if the eStick is exposed to unsuitable lighting conditions. Remove the ellume-lab and eStick from fluctuating light sources if a warning is displayed.**

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

Test specific Instructions for Use and Quick Reference Instructions for patient testing are available in the product box. They can also be accessed digitally through the Instructions app (Figure 8) on the ellume-lab.

6 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 (refer to section TEST PROCEDURE AND PRINCIPLE OF THE TEST in the relevant test Instructions for Use)
2. Once the testing screen has been launched, press the PERFORM 2ND TEST button at any time to begin a second test

⚠ The user must not perform a patient test and 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.

7 PREVIOUS RESULTS



Figure 4 - Previous Results Icon

All previous test results can be accessed by pressing the *Previous Results* icon (Figure 4) from the Home Screen (Figure 2). Previous results are identified by Patient/Control ID, unique eStick identifiers, date and time stamp, test type and outcome.

In the *Previous Results* app, two tabs are available. The *PATIENTS* results tab (Figure 5) lists all previous patient results and the *CONTROLS* results tab (Figure 6) lists all previous results run as a Control. All results are sorted by date, with most recent at the top.

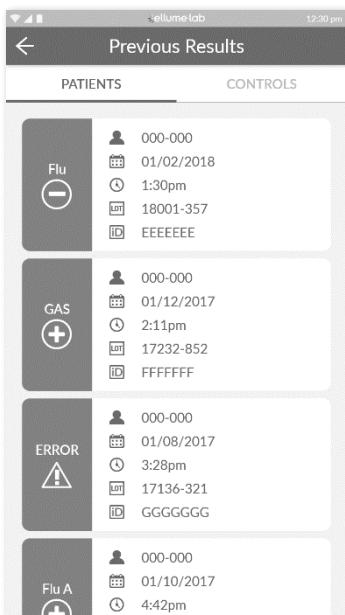


Figure 5 - Previous Results (Patients)

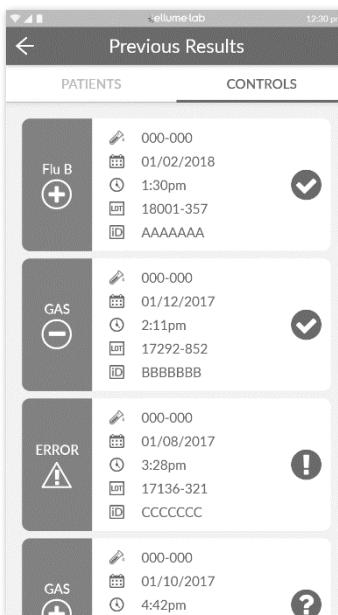


Figure 6 - Previous Results (Controls)



Site/Patient ID number



Site/Control ID number



Date test performed



Time test performed



LOT number



Unique eStick ID number

Figure 7 – Result Legend

8 PREINSTALLED APPS

8.1 Instructions



Figure 8 - Instructions Icon

The *Instructions* app contains all instructional material for the ellume-lab Tests, including Information Videos, Instructions for Use, and Quick Reference Instructions. The *Instructions* app can be opened by pressing the *Instructions* icon (Figure 8) on the home screen (Figure 2).



Figure 9 - Settings Icon

9 SETTINGS

The system settings can be accessed from the *Home Screen* (Figure 2) and pressing the *Settings* icon (Figure 9).

9.1 Screen Brightness

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

9.2 Notification Volume

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

9.3 Change Wi-Fi Connection

You may require assistance from your network administrator.

1. Press the from the Home Screen (Figure 2) press the *Settings* icon.
2. Press *Wi-Fi connection*.
3. Turn the Wi-Fi on by toggling the On/Off switch in the top right corner.
4. Select the new preferred Wi-Fi network from the list and enter the password (if required).
 - a. Input the Wi-Fi network name (SSID).
 - b. Select the security type.

If the preferred Wi-Fi network is not in the list, it can be manually added by select *+Add network*.

- a. Input the Wi-Fi network name (SSID).
- b. Select the security type.

- c. Enter password (if required).
- d. Press *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 (Section 4.2) is next to the network name.
6. Press the *Wi-Fi* back button in the top left hand corner to return to the Settings menu.

9.4 Modify System Date and/or Time

It is recommended that *Automatic Date & Time* be set to *Use network-provided time*.

It is recommended that *Automatic time zone* be set to *Off*, and that you select your local time zone from the list.

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

9.5 About

Displays the serial number of the ellume·lab and the versions of the currently installed applications.

10 MAINTENANCE AND CLEANING

10.1 Cleaning / Disinfecting

The ellume·lab should be cleaned after each use, each time a test is processed and after the device has been handled. Clean by rubbing by hand each surface for at least 30 seconds using disinfection wipes soaked in isopropyl alcohol (70% minimum), or by utilizing off-the-shelf wipes. Cleaners containing other ingredients may harm the device.

10.2 Battery Charging

The battery should be fully charged before first using the ellume·lab, or when it has been unused for extended periods. It is recommended to charge the ellume·lab when it is not in use. ellume·lab may be charged through the charging cradle or directly into the ellume·lab charging port on the top of the device. The USB charging cable must be correctly inserted into either the charging cradle or ellume·lab. Use only approved ellume·lab chargers and cables. Unapproved accessories may cause damage to the device and its battery.

10.2.1 Charging Cradle

1. Connect the USB charging cable to the charging adaptor.
2. Insert the end of the USB charging cable into the charging cradle.
3. Place the ellume·lab into the charging cradle in an upright orientation.
4. To commence charging insert the charging plug into an electric wall socket that is on.
5. There will be 5-10 seconds delay before the Battery Charging icon appears (Section 4.2).

Once fully charged remove the ellume·lab from the cradle and then remove the plug from the wall socket.

10.2.2 ellume·lab Charging Port

1. Connect the USB charging cable to the charging adaptor.
2. Insert the end of the USB charging cable into the ellume·lab charging port (Figure 1).
3. To commence charging insert the charging plug into an electric wall socket that is on.
4. There will be 5-10 seconds delay before the Battery Charging icon appears (Section 4.2).

Once fully charged remove the USB charging cable from the ellume·lab and then remove the plug from the wall socket.

11 APPENDIX

11.1 Technical Specifications

Dimensions	185 x 103 x 31 mm
Weight	390 g
Power Supply Input	100 ~ 240 VAC ; 50 ~ 60 Hz
Display	6.95 inch diagonal – Touch screen
Operating environment	15°C – 35°C, 20% - 90% RH (non-condensing)
Shipping	-20°C – 40°C, 10% - 90% RH (non-condensing)
Storage	5°C - 35°C

11.2 Troubleshooting

11.2.1 Restarting

If the ellume-lab device is unresponsive, press and hold the Power button (Figure 1) for more than 7 seconds to force the ellume-lab to power off. Press the Power button again to turn on the device.

11.2.2 General Complaints or Technical Problems

Call the Ellume helpline or go online via www.ellumelab.com. For country specific helplines refer to Section 12 - Contact.

11.2.3 Ordering

Call the Ellume helpline. For country specific helplines refer to Section 12 - Contact.

12 CONTACT

Contact the toll free Ellume helpline for customer support, ordering, technical problems or general complaints.

AUSTRALIA: 1800 001 120

NEW ZEALAND: 0800 964 567

UNITED STATES: 1 888 299 6376



Ellume Limited
57 Didsbury St
East Brisbane QLD 4169, Australia

FCC Caution:

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation.

This Product meets the government's requirements for exposure to radio waves. The guidelines are based on standards that were developed by independent scientific organizations through periodic and thorough evaluation of scientific studies. The standards include a substantial safety margin designed to assure the safety of all persons regardless of age or health.

FCC RF Exposure Information and Statement the SAR limit of USA (FCC) is 1.6 W/kg averaged over one gram of this Device E-ELR-P-02(FCC ID:2AWR4EELR-P-02) has been tested against this SAR limit. SAR information on this can be viewed on-line at <http://www.fcc.gov/oet/ea/fccid/>. Please use the device FCC ID number for search. This device was tested for typical operations 0mm from the body. To maintain compliance with FCC RF exposure requirements, 0mm separation distance should be maintained to the user's bodies

NOTE:

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.