



LIFEPAD Analyzer

USER MANUAL

for use with Test Kit for SARS-CoV-2 RNA Detection in Biological Material Using PCR Method

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About This Manual

The user manual provides instructions on how to operate the LifePad Analyzer (the Analyzer). The software-related instructions in this operator manual assume you have basic computer skills.

A new user should carefully read this manual before using the LifePad Analyzer.

Safety Information

Safety Precautions chapter in this manual provides important safety information that should be used when operating the Analyzer. Read and understand the safety information thoroughly before beginning to operate the instrument. Using the instrument without reading the safety precautions chapter or without proper training can result in serious injury, damage to the instrument, invalid results, or loss of data.

Table of Symbols

The following symbols and icons are used in this manual and on the Analyzer labels:



For In vitro diagnostic use



Conformité Européenne



Manufacturer



Keep away from direct sunlight



Keep dry



Fragile



Consult the User Manual



Waste Electrical and Electronic Equipment (WEEE) directive



Caution



Serial Number



Power supply connection
(charge)



USB 2.0 High Speed interface
connection

Warranty

The Manufacturer warrants compliance of the Analyzer with technical specifications provided that the operating (usage), transportation and storage conditions are observed. Routine maintenance is provided by an authorized service provider. Warranty claims should be addressed to the Manufacturer at:

K.K. Mirai Genomics

Ask Sanshin Building 3F, 2-6-29, Tsurumi-Chuo, Tsurumi-ku, Yokohama, Kanagawa, Japan

Postal code: 230-0051

Phone: +81 45 510 0607

email: miraigenomics@miraigenomics.com

Table 1. WARRANTY AND OPERATION CONDITIONS

Parameter	Value
Warranty period	12 (twelve) months from the initial start-up
Service life	5 years if used strictly in accordance with the User Manual
Warranty storage life	3 years from the production date, if the storage conditions are observed

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Safety Precautions

General

The LifePad Analyzer (the Analyzer) is designed and manufactured in accordance with safety guidelines for electronic and medical measuring devices.

The Manufacturer uses its best endeavors to ensure both electrical and machine safety of the Analyzer. The Manufacturer tests the mechanical and electrical parts of the Analyzer and supplies them only in case of safe and reliable operation.

The user must follow all recommendations and safety precautions specified in the User Manual to ensure safe operation of the Analyzer.

Any maintenance activities not described in the User Manual must be performed by an authorized service provider.



Manufacturer is not responsible for any injury or damage to health caused by the use of the Analyzer for other purposes or its self-repair and modification.

The Analyzer use is not recommended if the humidity exceeds 85% in the room. Condensation can lead to the Analyzer electronic components failure.

Protect the Analyzer from bumps and falls.

Before connecting to a power source, dry the Analyzer (within 2-3 hours) after transportation or storage in wet and cold conditions. Please note that the Analyzer turning on during drying could lead to internal protection damage.

Avoid getting any liquids or objects inside the Analyzer, it could lead to the breakdown.

Install the Analyzer on a flat surface. Ensure that its vertical position is displayed on the screen.

Install the Analyzer in such a way that the ventilation openings on its back are not blocked.

There are no special requirements for the room ventilation to maintain the protection and efficiency of the operator.

Provide easy access to the *OFF* button or the mains plug when installing the Analyzer.

Do not use the Analyzer if there are any visible signs of damage to its components.

Due to possible contamination, follow the usual laboratory precautions when working with the Analyzer:

- Do not eat, drink or smoke at the workplace.
- Wash hands thoroughly with water and soap after handling samples and reagents.

If sample components or used reagents are on the surface of the Analyzer, disinfect the surfaces by wiping in compliance with relevant local guidelines.



Wearing personal protective equipment (PPE) prevents exposure to chemical and biologically potentially hazardous materials. Wear disposable gloves, eye protection and other personal protective equipment according to your institution's safety policies while performing this cleaning procedure.

Electrical Safety

Before connecting the Analyzer to the network, ensure its grounding by checking the presence of a protective grounding in the outlet to where the Analyzer will be connected and the integrity of the connector cord. Do not plug the Analyzer into an outlet without a grounding conductor. To connect to the power supply, use the connector cord included in the Analyzer package.

The Analyzer is equipped with fuses with an established list of nominal parameters and characteristics.

Purpose of the fuses is:

- Protection of cable lines from overloads and short circuits;
- As a current limiting element.

Rated voltage with a frequency of 50 Hz, 250 V.

Rated operating current range: 0.2A ~20 A.

Operating temperature range: +60...+85°C.

Nominal current In	2.1 In	2.75 In		4 In		10 In	
	min	min	max	min	min	min	max
HVDC, H520T - delayed response							
VAC, H520T - delayed response	2 min.	200 ms	10 seconds	40 ms	3 seconds	10 ms	300 ms
100 mA- 6 A	2 min	600 ms	11 seconds	150 ms		20 ms	
8 – 16 A	30 min	600 ms	12 seconds	150 ms		20 ms	
VPB, N520B - high-speed							
16 – 100 mA	30 min	10 ms	500 ms	3 ms	100 ms	100 ms	20 ms
100 mA- 6 A		50 ms	2 seconds	10 ms	300 ms	300 ms	

No hindered access to the network switch of the Analyzer is allowed.

If liquid gets inside the Analyzer, disconnect it from the mains and contact an authorized service center.

Safety Rules during Operation

Do not expose the Analyzer to heat and sunlight or other strong light sources.

If you need to stop the Analyzer, use the Pause button.

Service rules

Do not open the Analyzer on your own. The internal part of the Analyzer does not contain any user-serviceable components.

The Analyzer should be serviced only by specially trained qualified personnel.

Operating Limitations

When using the Analyzer, take precautions regarding the effects of magnetic fields, external electrical influences, electrostatic discharges, pressure or pressure drops, restarting, and sources of thermal ignition.

Strong electromagnetic fields (generated by unshielded radio frequency sources) can interfere with proper operation and may lead to the device malfunction and incorrect results.

- Do not use the Analyzer near sources of strong electromagnetic fields as these fields may interfere with its proper operation.
- Assess the electromagnetic environment before operating the Analyzer.
- Mitigate interference.

Virus handling and biological material recording, storage, transfer, and transportation should be performed in strict compliance with local guidelines.

Follow safety procedures set by your institution and local authorities for disposing of the biological material.

When operating, always follow these guidelines:

- Treat biological samples being tested as potentially infectious.
- Ensure the staff complies with biosafety rules and guidelines and takes the required actions to prevent nucleic acid contamination of the samples being tested as well as the rooms and equipment.

Precautions against Electromagnetic Factors

During the Analyzer operation, take precautions against the influence of magnetic fields, external electrical influences, electrostatic discharges, pressure or pressure drops, reloading, and sources of thermal ignition. Strong electromagnetic fields (originating from unshielded radio frequency sources) can interfere with proper operation and lead to the Analyzer malfunction and incorrect results.

Do not use the Analyzer near sources of strong electromagnetic fields, as these fields may interfere with proper operation.

Evaluate the electromagnetic environment before operating the Analyzer and take measures to mitigate the interference.

Environmental Impact

The Analyzer does not pose a biological hazard under normal operating conditions.

Disposal of the Analyzer is carried out in accordance with applicable local regulations. The Analyzer contains no substances posing an immediate threat to the environment.

Analyzer Description

Intended Use

The Analyzer and its consumables (the Test Cartridge from the *Test Kit for SARS-CoV-2 RNA Detection in Biological Material Using PCR Method*) are intended for *in vitro* diagnostics, i.e., a virus detection in the patient's nasopharyngeal, oropharyngeal, or combined oro- and nasopharyngeal swabs sampled from individuals suspected of COVID-19.

The Analyzer is designed to perform the viral RNA extraction from the patient's nasopharyngeal, oropharyngeal or combined oro- and nasopharyngeal swab, and subsequent real-time amplification.

The Analyzer's operating principle is based on three main procedures:

Lysis - viral envelope destruction in chaotropic salts.

RNA extraction from a specimen - RNA binding to the glass filter.

Detection - real-time amplification.



Note: Analyzer is operable only with the *Test Cartridge from Test Kit for SARS-CoV-2 RNA Detection in Biological Material Using PCR Method* (Mirai Genomics, Japan). The system is completely closed. The Test Cartridge contains all the required reagents. The Analyzer does not interact with the reagents inside the Test Cartridge in any way.



***Test Kit for SARS-CoV-2 RNA Detection in Biological Material Using PCR Method* are not supplied with the system and must be purchased separately. For ordering information, contact Mirai Genomics.**

The Analyzer is intended for use in clinical diagnostic laboratories, as well as research institutes laboratories.

The Analyzer is intended for *in vitro* diagnostics only.

The Analyzer is intended for trained staff use only.

Table 2. ANALYZER TECHNICAL CHARACTERISTICS





Table 2. ANALYZER TECHNICAL CHARACTERISTICS





Parameter	Value
Weight	0.575 ± 0.05 kg
Power consumption	20 V DC, 4.8 A Max
Power adapter (user-supplied)	USB Type C connector Power Delivery 1.0/2.0/3.0
Battery	LiPo 3,000mAh 8.4 V
Continuous run time	Not less than 8 hours
Time to start the operating mode	No more than 60 s
Computer interface	USB 2.0
OS	Windows, MacOS
Test type	PCR amplification
Heater temperature	67 °C
Detection wavelength	525 nm
Excitation wavelength	500 nm



Picture 1. Analyzer Overall Dimensions

Table 3. ANALYZER COMPONENTS OVERVIEW

Pos.	Name	Appearance	Functional characteristics
LifePad Analyzer consists of:			
1.	LifePad Analyzer		The Analyzer intended to perform the SARS-CoV-2 viral RNA extraction in nasopharyngeal or oropharyngeal swab collected from a patient, master mix preparation and further SARS-CoV-2 viral RNA detection in the specimen
2.	USB Type A (m), USB Type C (m) cable		Communication with a personal computer
3.	USB Type C cable (optional)		Connection to a power adapter
4.	Power adapter (optional)		Generation of an output voltage of a given value and power to the Analyzer

5.	Personal computer (optional)		Automated functioning of the LifePad software
6.	Portable data storage device with software (optional)		Storage of the LifePad software information and temporarily connection to a PC via a standard connector
7.	Operational documents		Defines the operation rules and (or) reflects information certifying the values of the main parameters and characteristics of the device guaranteed by the manufacturer, as well as the information on its operation during the specified service life
7.1.	User manual		
7.2.	Datasheet		
7.3	Quick start guide		
8.	Package		Protection of the medical device from damage and loss, protection of the environment from pollution, as well as ensuring the medical device application process

The Analyzer, together with the Test Cartridge and the *LifePad* software, performs the nucleic acid extraction from a patient's nasopharyngeal and/or oropharyngeal swab and the target RNAs detection using real-time nucleic acid amplification.

The Analyzer's functions:

- Detection of the Test Cartridge insertion to the Analyzer.
- Validity (expiry date, type) detection of the Test Cartridge.
- Extraction, amplification, and detection of the target RNA.
- Result interpretation (in the *LifePad* software).
- Test results storage (in the *LifePad* software).
- Test results saving in .pdf format, test results printing.
- Last test results storage (in the Analyzer).

The Analyzer performance is controlled by an external computer under Windows/Mac OS. The Analyzer connects the computer via an USB Type-C cable. To operate the Analyzer, the *LifePad* software must be preinstalled. The software is available for downloading on the *Mirai Genomics official website* at <https://miraigenomics.com/>. One computer can work with several Analyzers at the same time.

To indicate the Analyzer current status, there is a display located on the Analyzer front panel.

The Analyzer is powered by a built-in battery. The batteries are charged via a USB Power Delivery compatible AC adapter.



Picture 2. Main Controls Location

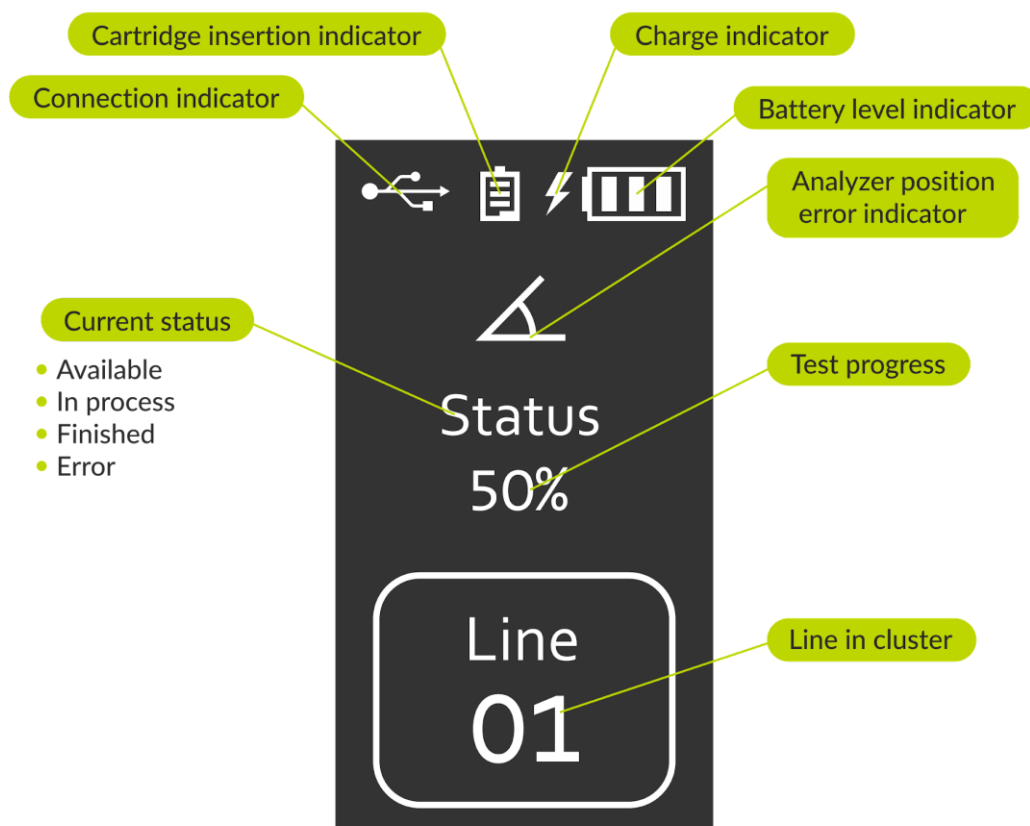
The Analyzer is a combination of pneumatic, mechanical, heating, and detection modules. The modules affect the reagents in the Test Cartridge, enabling motion from one well to another, mixing, filtering to ensure the viral RNAs extraction and detection in a clinical specimen.

Table 5. ANALYZER MODULES

Module	Intended purpose
1. Pneumatic and switching modules	Fluids controlled motion in the Test Cartridge
2. Heating and detection modules	The reaction mixture heating and the fluorescence level detection
3. Interface module	PC control Data transfer Clustering Read / Write Test Cartridge Data Displaying the device current status
4. Power module	Device power and battery charge control

Analyzer Indication

The Analyzer has a display to indicate the device current status (Picture 3).



Picture 3. Analyzer Display

Operating, Storage and Transportation Conditions

The Analyzer is transported by all types of enclosed shipping in accordance with rules of cargo transportation applicable to this type of transport. Vehicles must be covered, dry and clean.

During loading, unloading, as well as transportation and storage, measures must be taken to protect the Analyzer from damage and contamination.

The Analyzer is transported in the Manufacturer's packaging.

Table 4. ANALYZER OPERATING, STORAGE AND TRANSPORTATION CONDITIONS

Parameter	Value
Operating conditions	Temperature: +15 ... +35 °C. Relative humidity: 30 - 85 % (non-condensing)
Storage conditions	Temperature: -20 ... +40 °C Relative humidity: 30 - 85 % (non-condensing) In a well-ventilated room
Transportation conditions	Temperature: -40 ... +65 °C Relative humidity: 10 - 90 % (non-condensing)

Packing

To ensure the safe delivery, the Analyzer is packaged in a cardboard box with protective inserts.



Picture 4. Packing Scheme

Analyzer Operation

Biological Material Use Limitations

To extract the RNA and detect the virus presence, only the Test Cartridge from the *Test Kit for SARS-CoV-2 RNA Detection in Biological Material Using PCR Method* can be used. After sampling, the specimen is placed into the SSB tube to inactivate the sample at the sampling point according to the instruction for use. After that, the sample is transported to the extraction site. To achieve the stated analytical sensitivity, the sample aliquot should be at least 100 µl.

Carrying / Installation

The Analyzer is intended for indoor use only.

Place the Analyzer in the upright position on a stable work surface.

Keep the Analyzer away from the direct sunlight.

Do not install the Analyzer nearby other devices that could generate vibration (for example, a centrifuge).

Install the Analyzer near an AC outlet.

Single and Cluster Modes

There are 2 connection options for the Analyzer: single and cluster ones. In case of a cluster connection scheme, up to 8 devices can be connected in one cluster in series.

Single Mode

Each device is connected to a PC via a separate USB cable and is charged using an individual charger.



Picture 5. Single Mode Connection Options

Cluster Mode

Cluster connection scheme allows for optimizing the number of connections and cables in the workplace by daisy-chaining devices to each other. The power and interface of the devices in the cluster are provided through the first Analyzer (this does not change the functionality of the other Analyzers in the cluster). Several clusters can be connected to one PC via a USB hub.



Limitations: Up to 8 Analyzers can be connected to one cluster. Up to 12 clusters can be connected to one PC.



Picture 6. Cluster Consisting of 8 Analyzers



Picture 7. 12 Clusters Connection

To connect the Analyzers into a cluster, pull out the panel with the connector on the Analyzer bottom until it clicks and connect the Analyzer to the next device. Select the *Cluster* operating mode in the software. Please refer to the *Software Description* section for details.



Picture 8. Analyzers Clustering

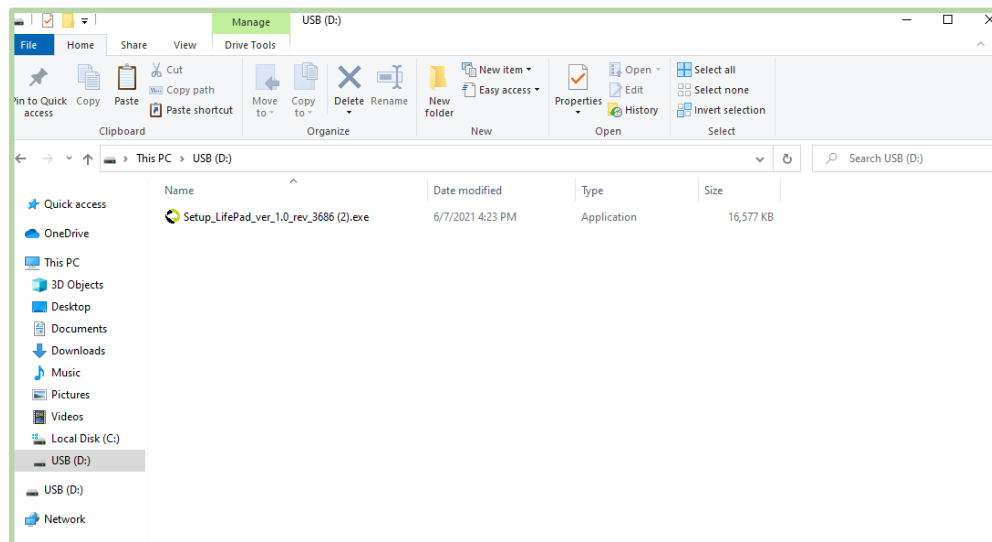
Software Installation



To provide functionality, embedded software (software) version 2.0.0 or higher is used, which is an integral part of the Analyzer.

To control the Analyzer and display data on the process of the procedure for analyzing biological samples, the LifePad software, and software version 2.0.0 is used.

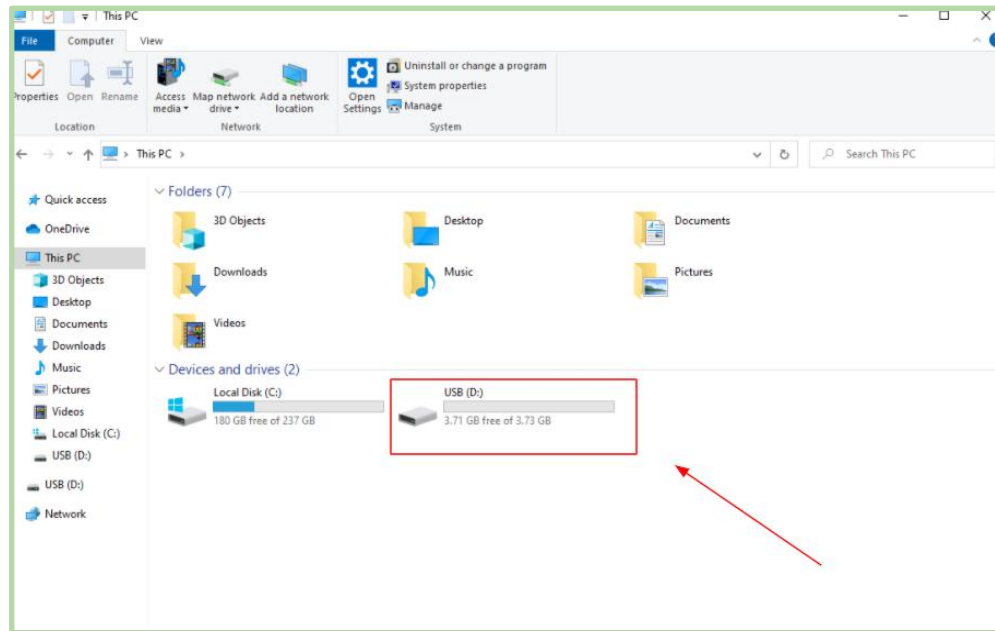
- Turn on your PC.
- Connect the portable data storage device with software to any of the available USB ports of the PC or download the software from the official website of the Manufacturer <https://miraigenomics.com>
- When connecting the portable data storage device with software, a window with the portable data storage device contents opens (Picture 9), The windows contains the



setup_lifepad_ver_1.0_rev_3686 (2) Analyzer software installation files:

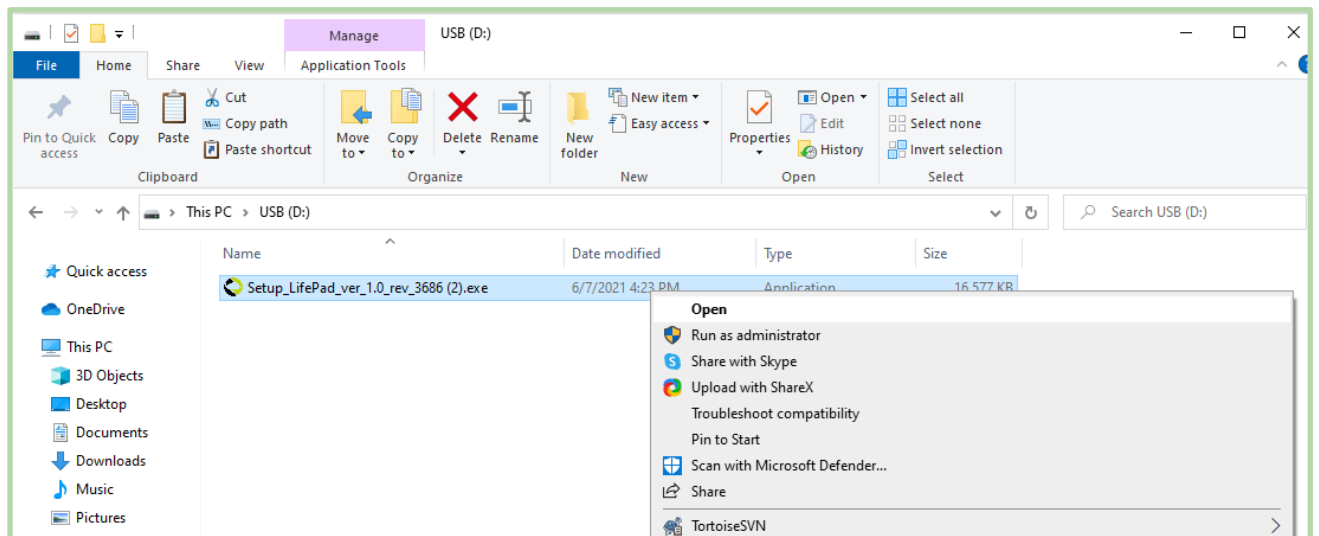
Picture 9. Portable Data Storage Device Contents

- In case when the folder with the contents does not automatically open on the desktop, open it manually. To do this, find and open the reportable data storage device in Computer - the *Devices and Disks* section (Picture 10).



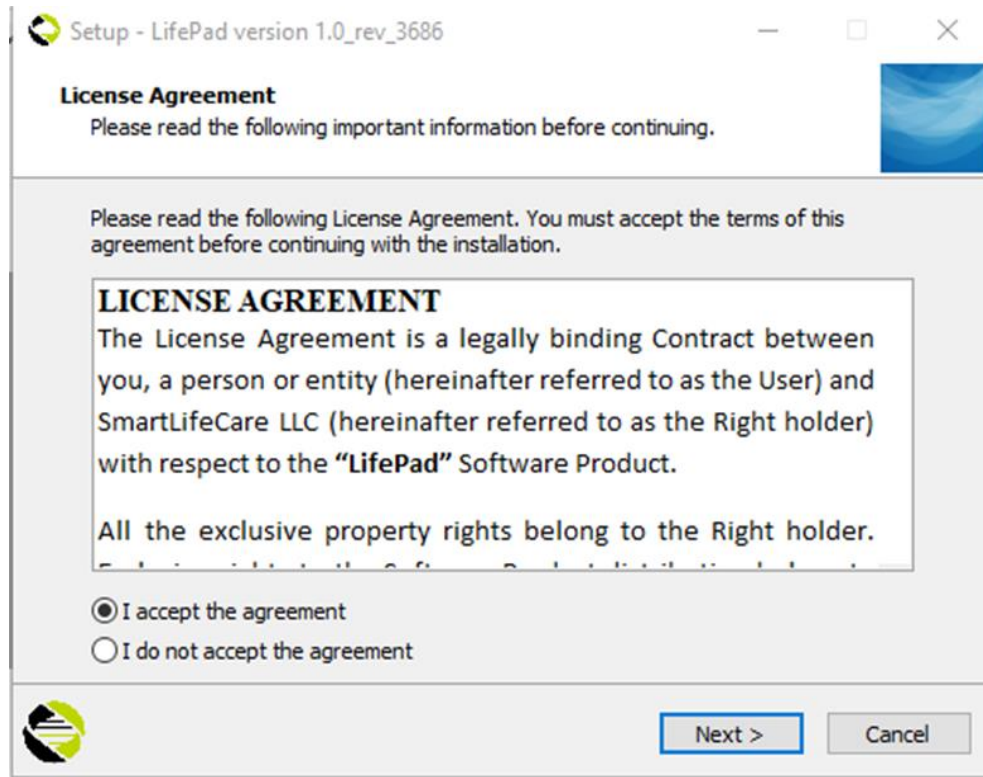
Picture 10. Computer – Devices and Disks

- Run the *setup_lifepad_ver_1.0_rev_3686 (2)* installation file (Picture 11).

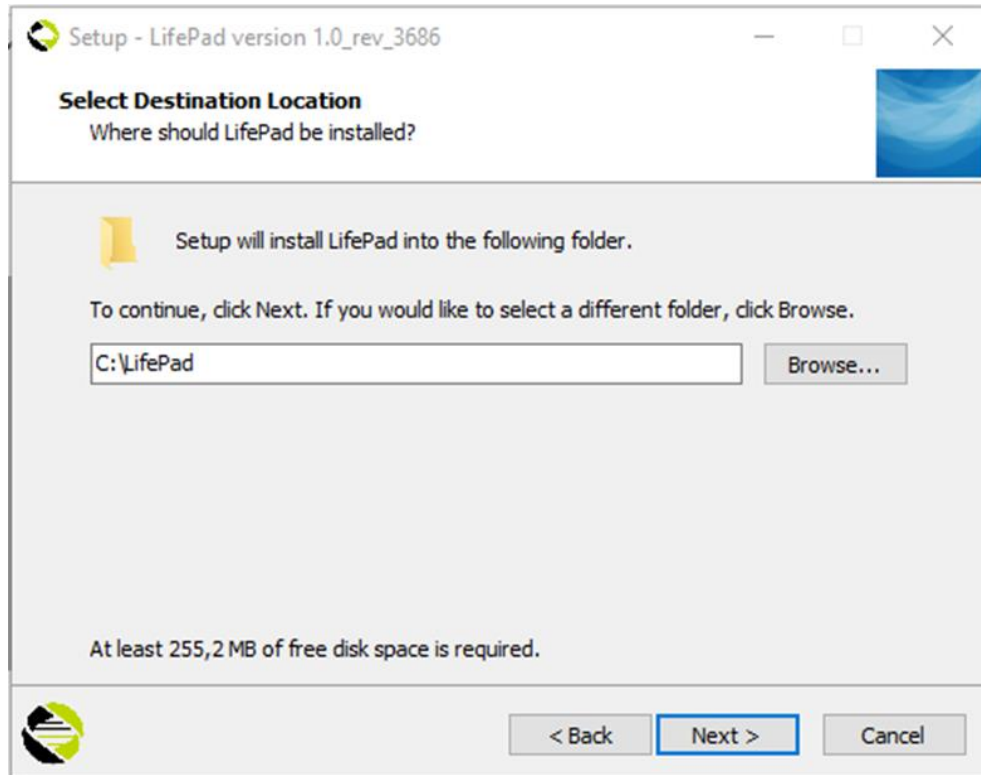
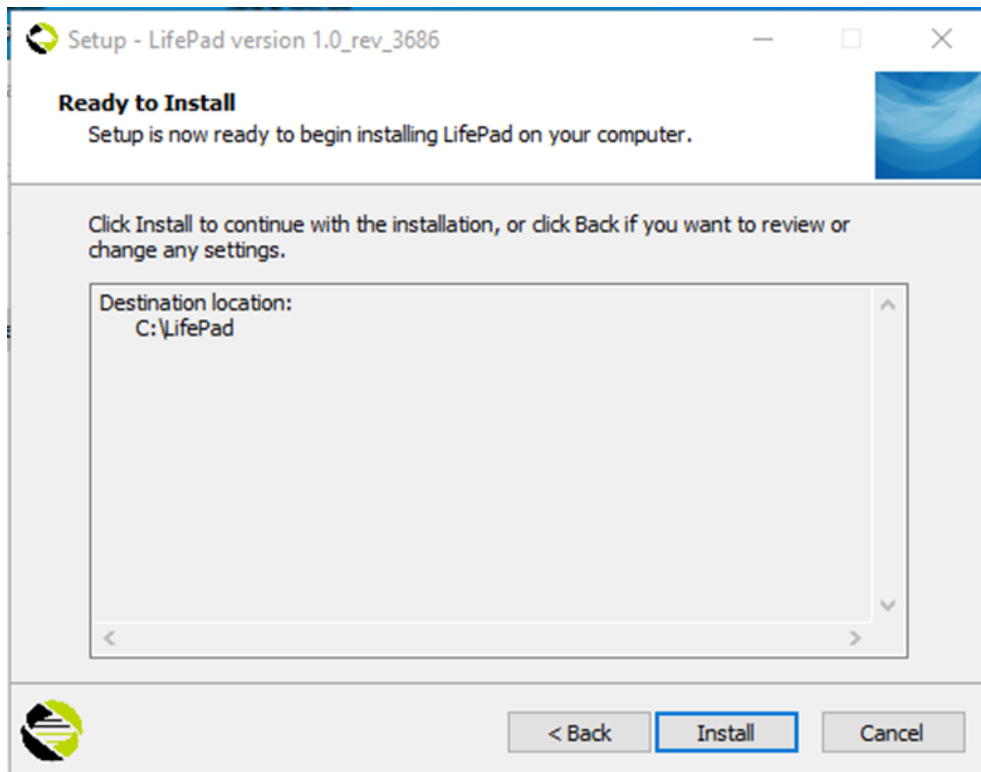


Picture 11. LifePad Software Installation Start

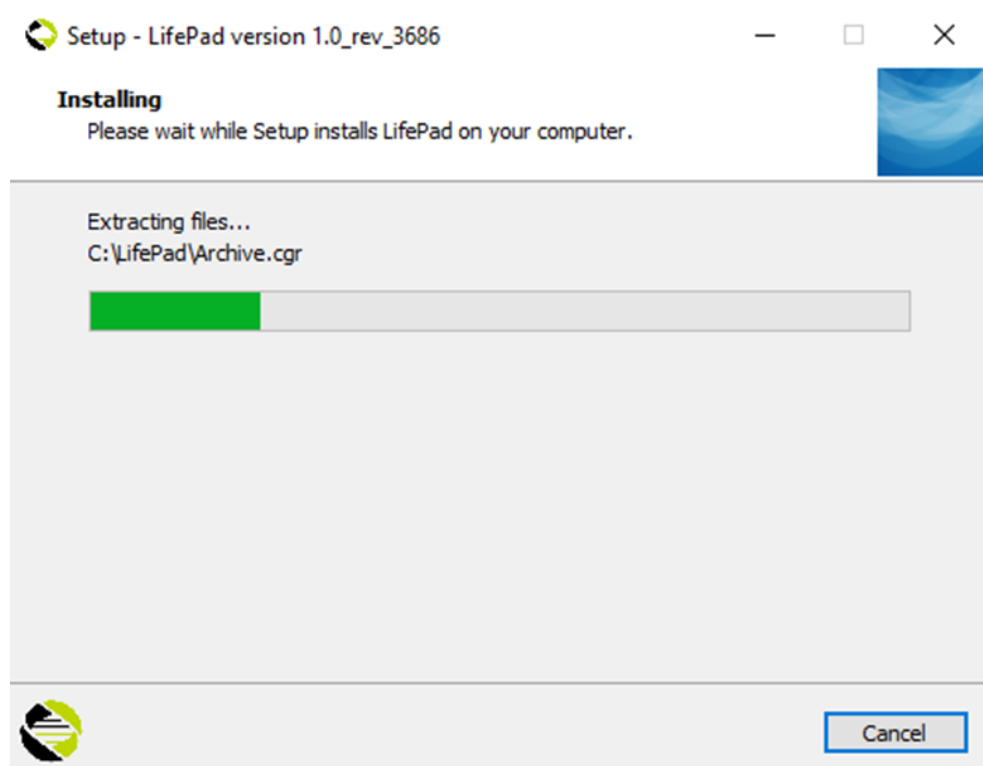
- Follow the prompts during installation. It is recommended not to change the default settings (Picture 12- Picture 15):



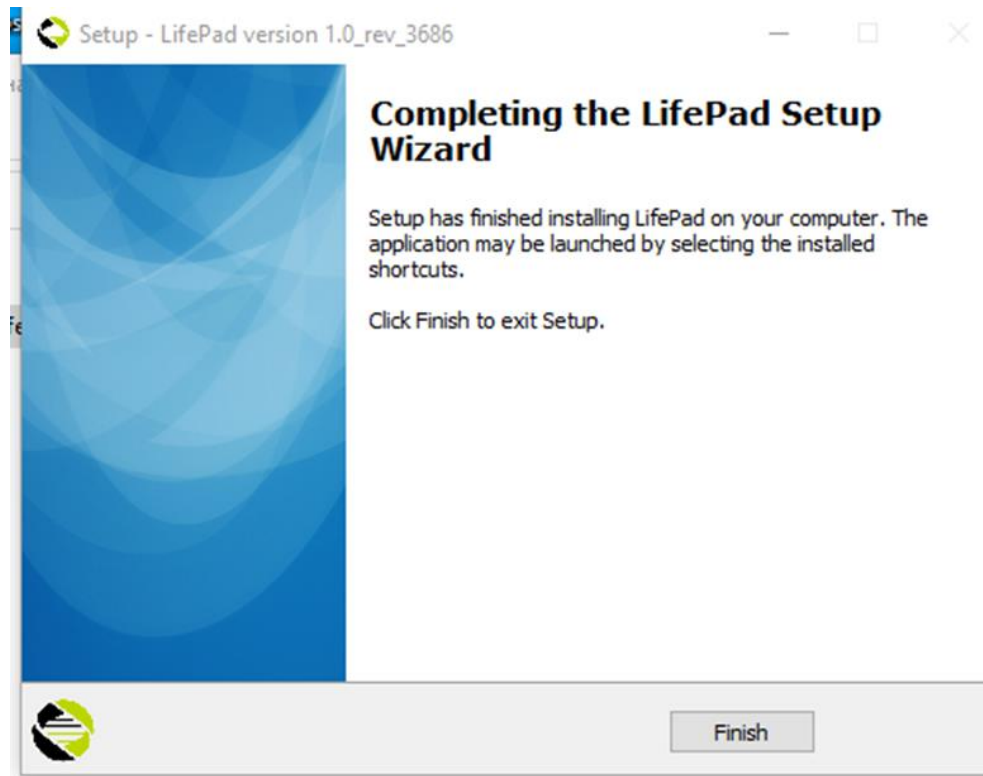
Picture 12. Press *Next*

Picture 13. Press *Next*Picture 14. Press *Install*

Picture 15. LifePad Software Installation Process



- Upon completion of the installation, close the installer by clicking the *Finish* button (Picture 16):



Picture 16. LifePad Software Installation Completion

- Connect the Analyzer to the computer using the USB cable.



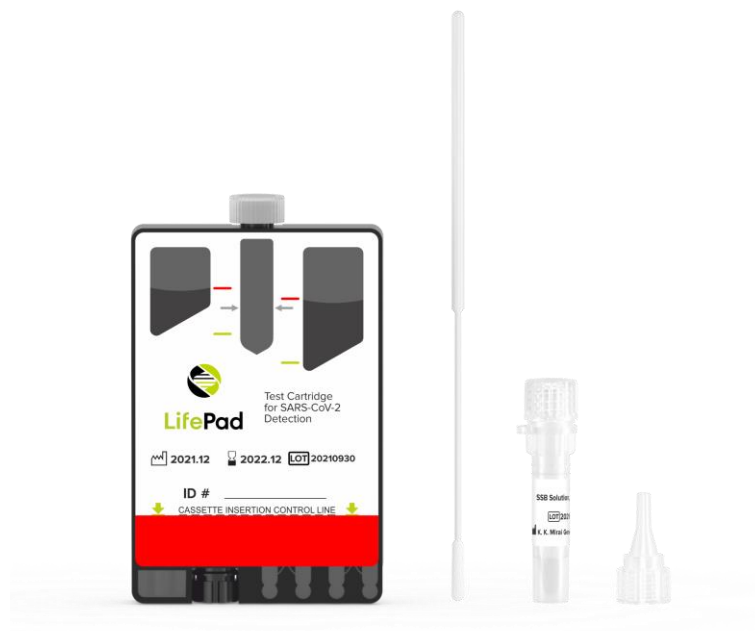
Picture 17. PC Connection

- Check the battery charge level; if the charge level is low, connect the power adapter.



Picture 18. Charging Analyzer from the Mains

- Prepare the Test Cartridge, the swab and the tube with the SSB solution from *Test Kit for SARS-CoV-2 RNA Detection in Biological Material Using PCR Method*.



Picture 19. Test Cartridge and Consumables

Turning On / Off

Turn on the Analyzer by short pressing the power button on the top panel. To turn the Analyzer off, press and hold the power button for more than 1 second.

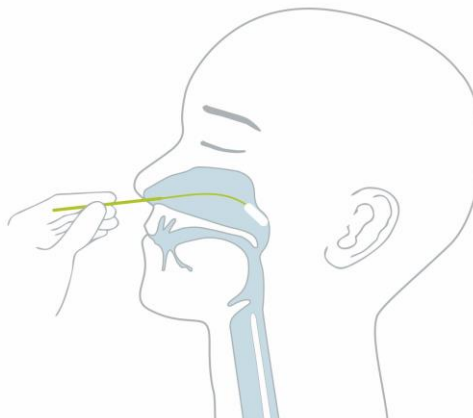
For a prolonged work break, disconnect the battery using the switch on the Analyzer bottom.



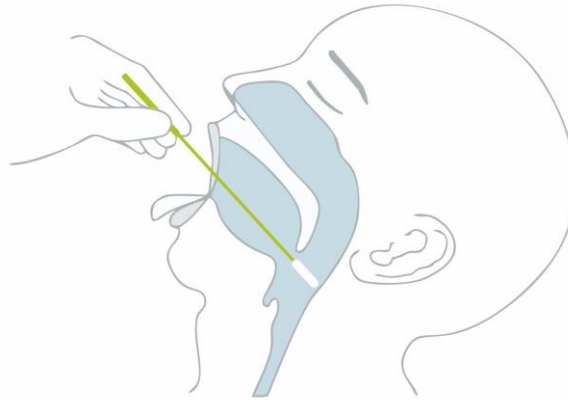
Picture 20. Analyzer Turning On

Before Starting the Test

- Take a nasopharyngeal, oropharyngeal, or combined naso- and oropharyngeal swab.

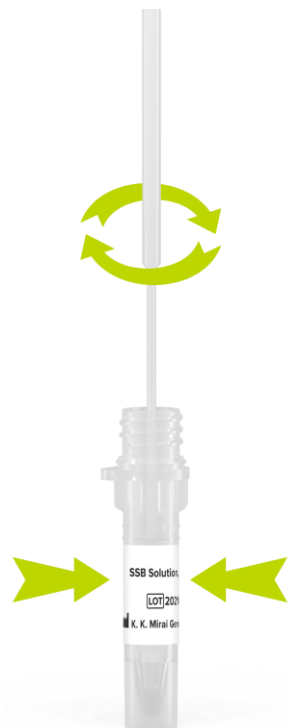


Picture 21. Nasopharyngeal Swabbing



Picture 22. Oropharyngeal Swabbing

- Insert the sample into the tube with the SSB solution and rotate carefully.



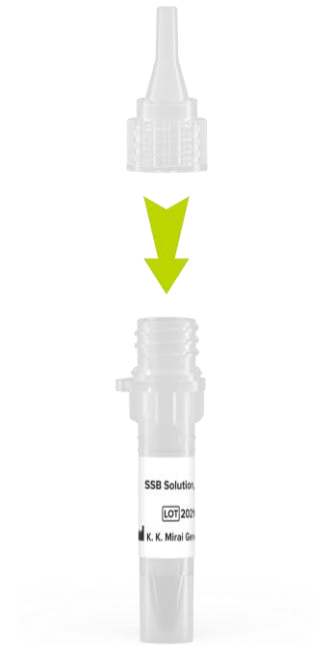
Picture 23. Swab Insertion into SSB

- Remove the swab from the tube with the SSB solution and discard it in a biohazardous waste container.



If immediate testing is not possible, recap the SSB tube. The prepared sample may be stored at room temperature for up to 24 hours and up to 7 days at +2...+4°C.

- Place the cap with a dropper nozzle onto the tube.



Picture 24. Tube Closing

- Transfer the liquid to the Test Cartridge inlet up to the mark and close the Test Cartridge tightly. The rest of the SSB can be kept for re-analysis.



Picture 25. Placing the Sample into Test Cartridge

- Remove the protective sticker from the Test Cartridge.



Picture 26. Protective Sticker Removal

- Insert the Test Cartridge into the Analyzer up to the red insertion line. Ensure the Test Cartridge is positioned correctly (see Picture 28, Picture 29).




Picture 27. Test Cartridge Insertion into Analyzer



Picture 28. Test Cartridge Correct Positioning



Picture 29. Test Cartridge Incorrect Positioning

- To check the Analyzer is installed correctly and ready for work:
 - Make sure that the Test Cartridge is properly installed.
 - Make sure that the Analyzer display shows AVAILABLE ready-to-work status.
 - Make sure that the Analyzer displays no ERROR status.
 - Make sure that the battery charge level is sufficient to perform testing.
 - Check Analyzer external connections: network power cable, USB cable to a PC (as shown in Pictures 17-18).
 - Turn on the Analyzer by setting the switch on the Analyzer back to the I position.
- Make sure there is no warning signs () on the display showing the Analyzer incorrect position.
- Turn on the PC and run the *LifePad* software.
- Enter the patient ID in the software.
- Start the test (please refer to the *Test Start* section for details).
- Once the test is over, take out the Test Cartridge and dispose of it according to the applicable local waste disposal guidelines.



Picture 30. Test Cartridge Taking Out



Opening of the used Test Cartridge is strictly prohibited!

Software Review

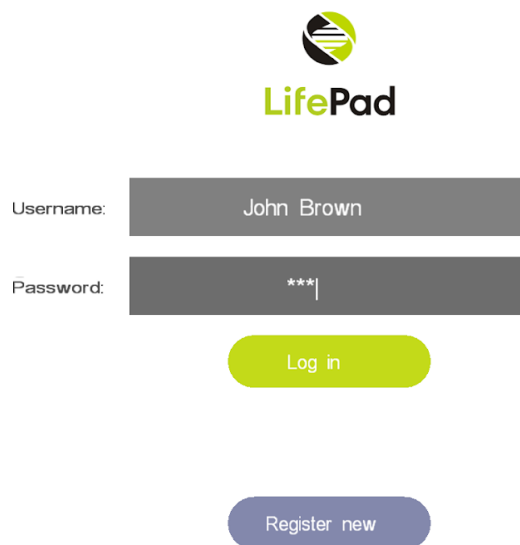
To provide functionality, embedded software (software) version 2.0.0 or higher is used, which is an integral part of the Analyzer.


To control the Analyzer and display data on the process of the procedure for analyzing biological samples, the LifePad software, and software version 2.0.0 and higher, installed on a personal computer is used.

Program Entry

The *LifePad* software may only be used by authorized users. When starting the software for the first time, enter the username and password of a new user and click on the *Register New* button (Picture 31). When re-entering the program, enter the username and password used for the user registration and click on the *Log In* button.

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LifePad

Username:

Password:

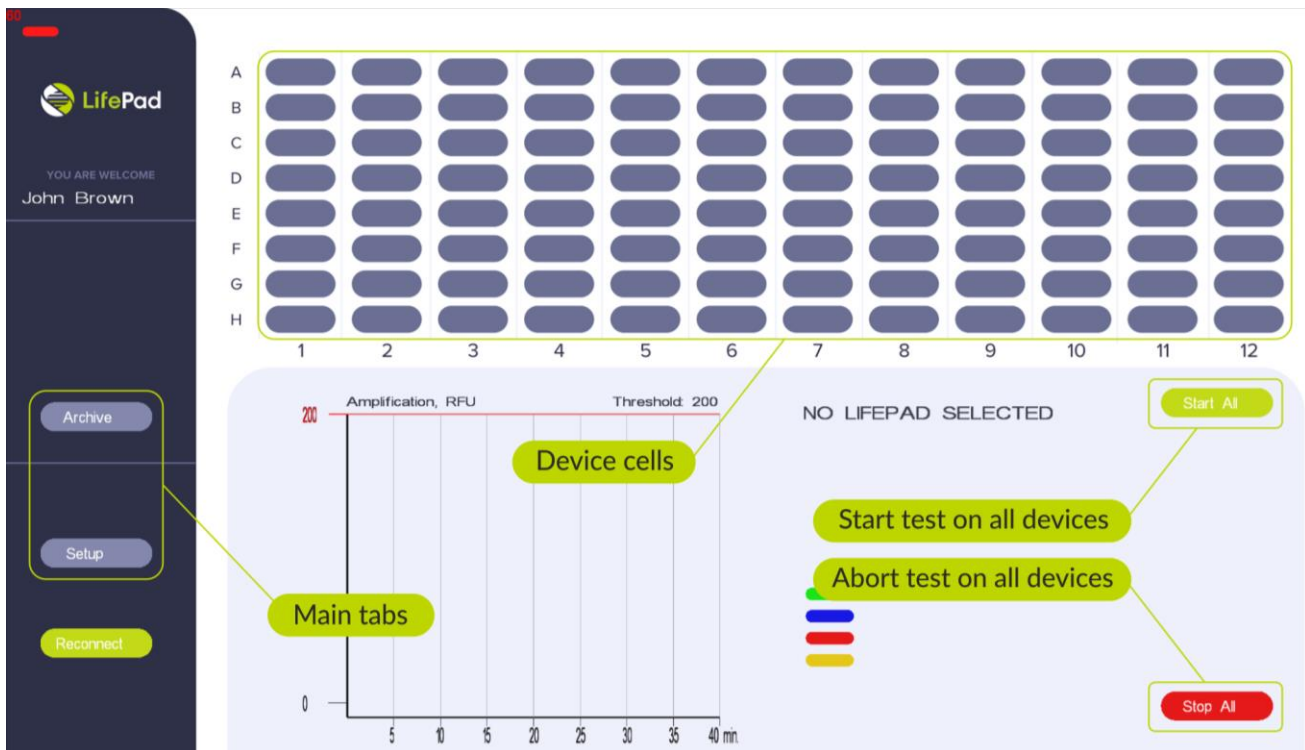
Picture 31. Log In and Password Entry Window

Main Window

The program main window is shown in Picture 32. The main tabs are displayed on the main program window left side:

- Archive*** Displaying information about archived tests.
- Setup*** Test run settings.
- Reconnect*** Connected devices search.

The following buttons are available in the lower right part of the main window:

Start AllStart tests on all devices with the **READY** status.**Stop All**Abort tests on all devices with the **IN PROGRESS** status.

Picture 32. Main Window

Test Start

To prepare for the test run, connect the Analyzer to the computer via USB and turn it on. The connected device will be displayed in one of the device cells in the main window (Picture 31). When clicking on the selected Analyzer cell in the lower part of the main window, the following information is displayed:

Selected LifePad status

Selected Analyzer status.

LifePad ID

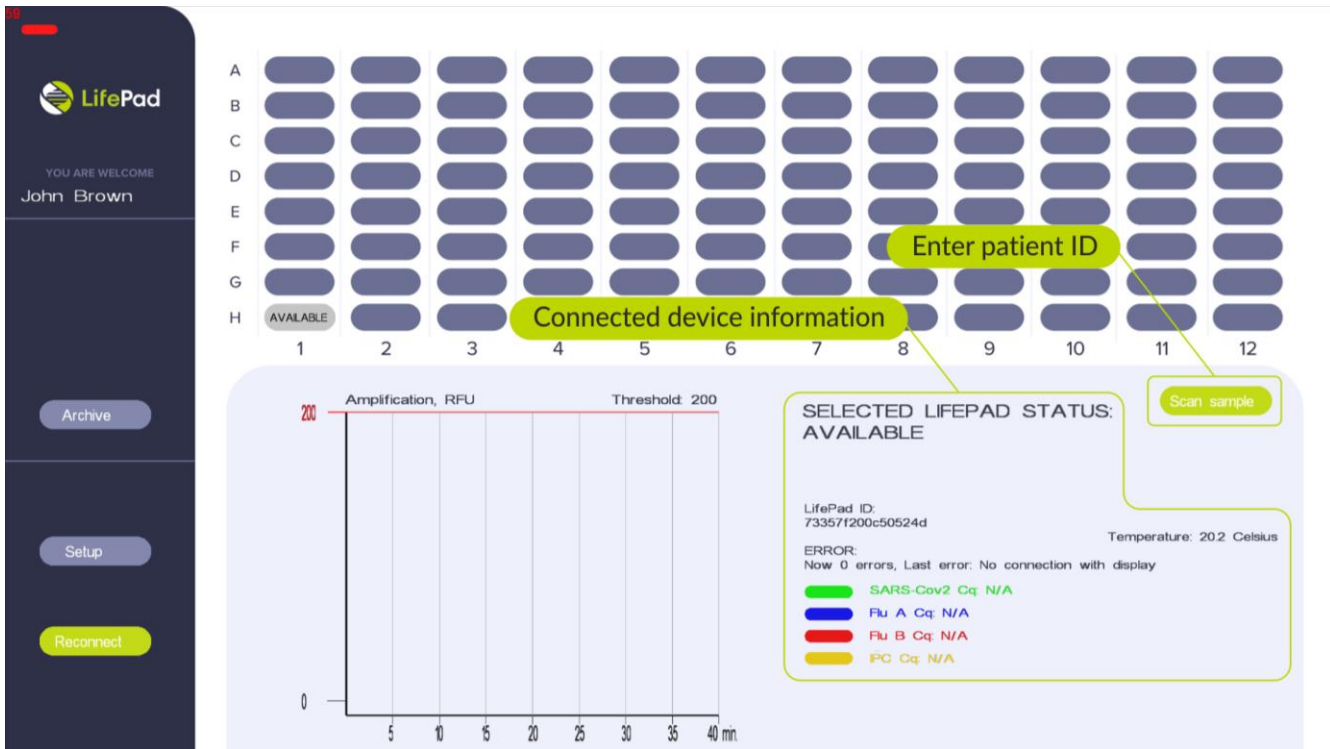
Analyzer serial number.

Error

Absence/present of the Analyzer run-time errors.

Temperature

The current temperature of the Analyzer heater current temperature.



Picture 33. Connected Device in One of the Cells and the Analyzer Information Display

The connected Analyzer can have one of the statuses described in Table 6. The Analyzer status is shown on the display and in the device cell in the main window (Picture 33).

Table 6. ANALYZER STATUSES

Device status	Description
INITIALIZATION	The Analyzer initialization after its detection
AVAILABLE	The Analyzer is ready for use. The Test Cartridge is not inserted into the device.
READY	The Analyzer is connected to the software. The Test Cartridge is inserted into the Analyzer. The Test Cartridge was checked for: <ul style="list-style-type: none"> - Its expiry date. - The Test Cartridge and the Analyzer versions match. - The test start mark absence. The Analyzer is ready to run the test
IN PROGRESS	Test is running
FINISHED	The test is over. The Test Cartridge is in the Analyzer
ERROR	An error was detected during the Analyzer initialization/when checking the Test Cartridge/ during the Analyzer operation
MAINTENANCE	The Analyzer service maintenance
FIRMWARE UPDATE	The Analyzer firmware updating

When the Analyzer is turned on, its initialization takes a few seconds. The status of the Analyzer during this process is **INITIALIZATION**. Upon initialization completion, the Analyzer shows the **AVAILABLE** status.

When the **AVAILABLE** status appears on the Analyzer display and in the device cell in the main window, insert the Test Cartridge with the specimen into the Analyzer. The Analyzer checks the Test Cartridge for its expiry date, the Test Cartridge and the Analyzer versions matching, and the test start mark absence. If the Test Cartridge meets the criteria, the Analyzer status changes to **READY**.

Click on the *Scan Sample* button in the right part of the main window, enter the patient ID and press *Enter*. The user can also scan the patient ID given in the barcode form on the sample tube using a barcode reader. After entering the patient ID, the button name will change to *Rescan sample*.

To start the test, click on the *Start* button, displayed on the right side of the selected line with the device (Picture 34). After pressing the *Start* button, the Analyzer status will change to ***IN PROGRESS***.

Picture 34. Analyzer is Ready to Test

Running Tests Information

After starting the test, in the lower part of the main program window, in addition to the information described above, the following data about the device is displayed:

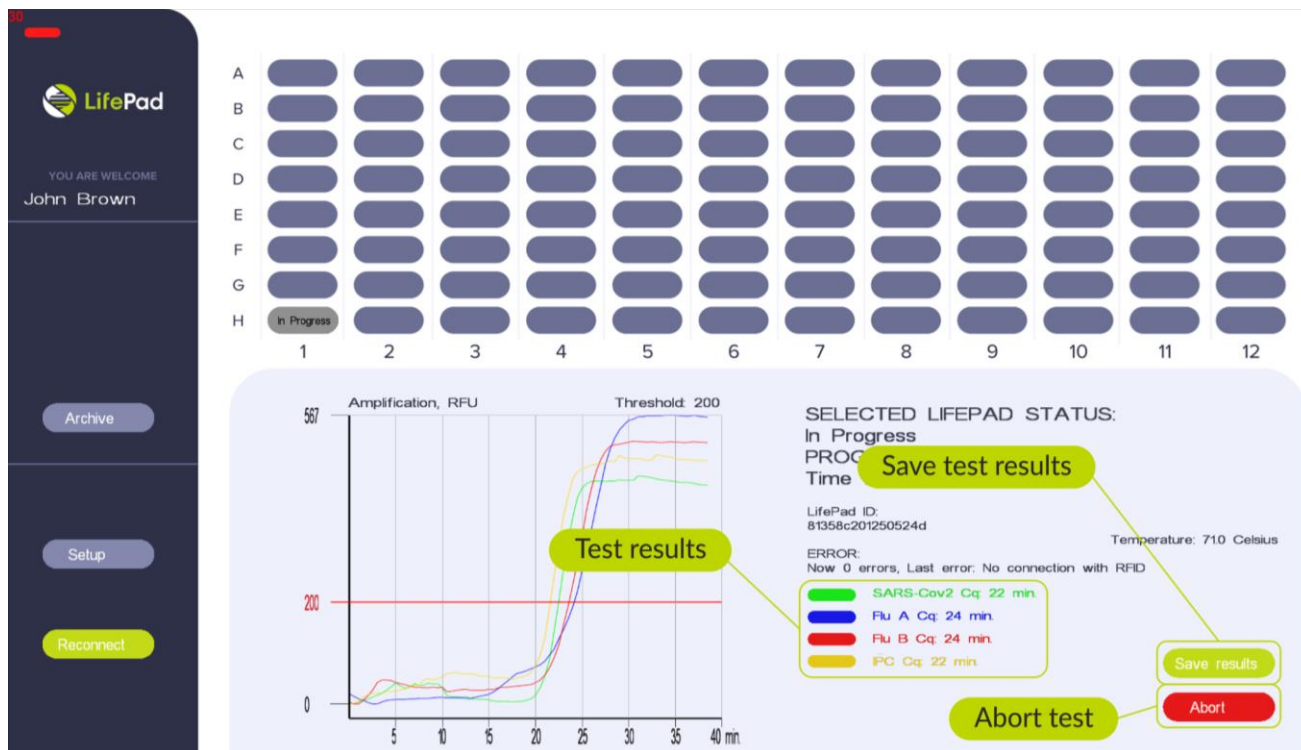
Progress The test completion percentage.

Time from start Time elapsed from the test start (excluding pretreatment).

As fluorescence data is received from the Analyzer, a fluorescence signal graph is displayed at the bottom of the main window (Picture 35). The abscissa of both graphs displays time (minutes), and the ordinate shows the fluorescence signal amplitude (relative fluorescence unit).

The test result for each of the diseases contained in the Test Cartridge is considered ***positive*** if the signal graph of this disease crosses the threshold value of 200 relative fluorescence units.





Picture 35. Fluorescence Signal Graphing

The *Abort* button is located in the lower right part of the main window. The button allows interrupting the test on the Analyzer without waiting for its completion.

In the lower right part of the main window, the *Save Results* button is located. Clicking on this button saves a screenshot of the main window and the fluorescence signal values in a folder selected as the directory for saving test results in the *Setup* tab.

Completed Tests Information

Upon test completion, the Analyzer switches to the **FINISHED** status. The completed test data automatically transfers to the *Archive* tab. The line with the test in the *Archive* tab contains the following data:

User	The name of the user ran the test.
Date	Date and time of the test completion.
LifePad Serial Number	Serial number of the device used for the test.
Sample barcode	Test Cartridge serial number.
SARS-Cov2 Cq	Test results for this disease.
Flu A Cq	Test results for this disease.
Flu B Cq	Test results for this disease.
IPC Cq	Internal control results.



Picture 36. Completed Test in the *Archive* Tab

In the *Archive* tab, each test channel can have one of the following results:

- 1) Test result - **negative** (N/A).
- 2) Test result - **positive** (the time when the positive result was detected is displayed).
- 3) Test result - **invalid**.

Setup Tab

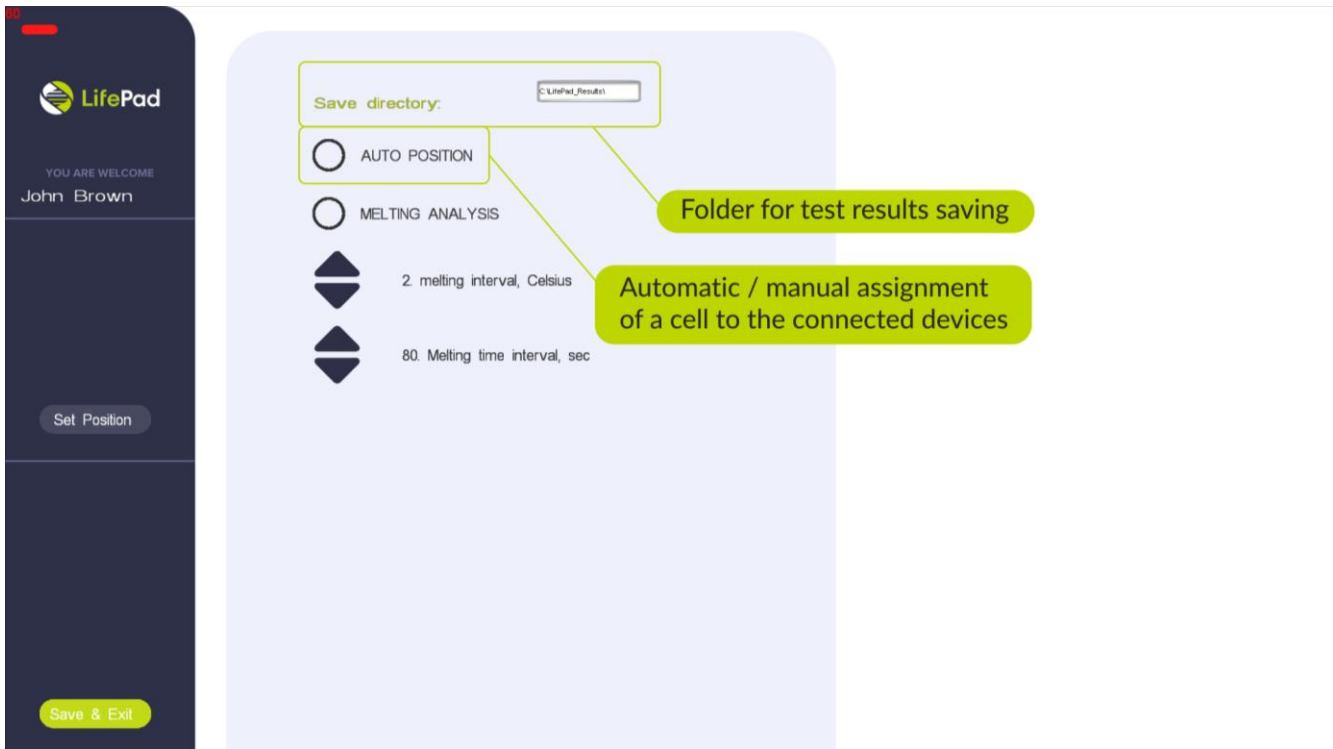
The following settings are available in the *Setup* tab (Picture 37):

Save directory

The folder for saving test results when pressing the *Save Results* button.

Auto position

Automatic/manual assignment of a cell to the connected Analyzers.

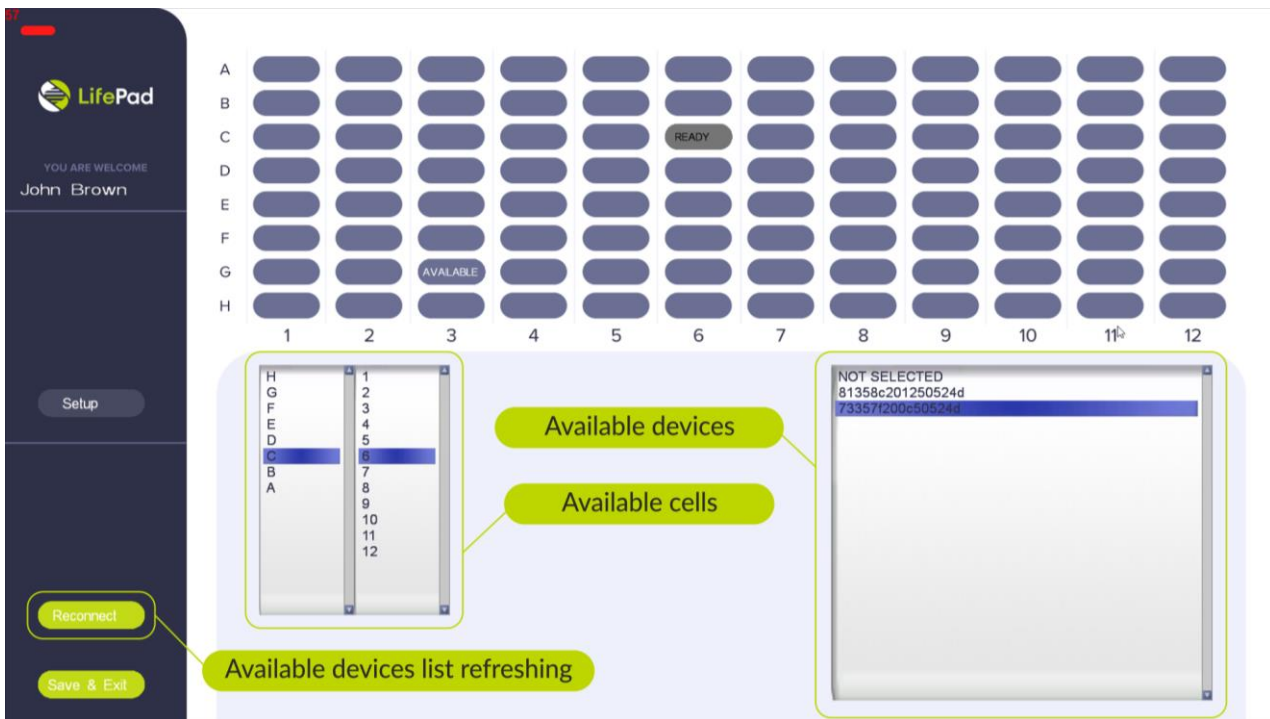


Picture 37. Setup Tab

When unchecking *Auto position*, the user must assign the cell for each connected device manually in the *Set Position* tab; otherwise, the connected devices will not be displayed in the main window.

To assign a cell in the *Set Position* tab, select the device, which cell is being assigned, in the list of devices (on the right) (Picture 38). Then select the device cell assignment in the lists on the left.

To save changes in the *Setup* tab, click on the *Save & Exit* button.



Picture 38. Cells Assignment for Connected Devices in the *Set Position* Tab

Cluster Mode Operation

When clustering several devices (Pictures 6, 7), the software displays the connected Analyzers. The operation of each Analyzer is controlled in the same way as when working with one device.



Picture 39. Displaying Clustered Devices in the Main Window

Results Interpretation

The Analyzer's operability is to be checked using an internal control sample (IPC).

Table 7. RESULTS INTERPRETATION

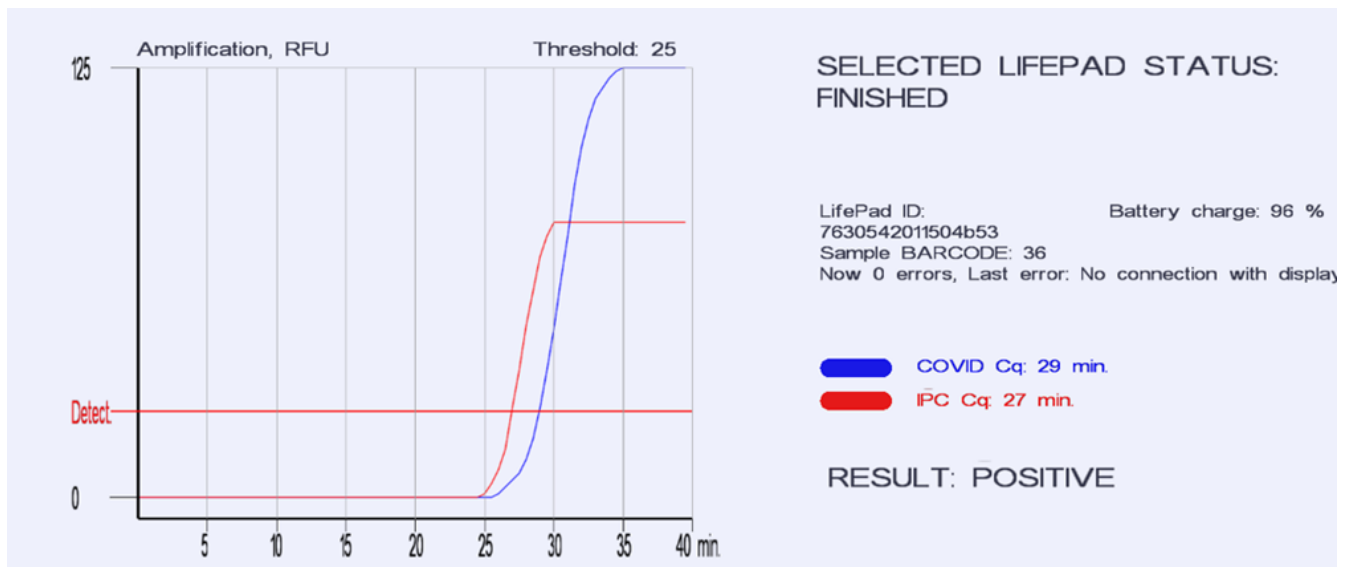
Result	SARS-CoV-2 RNA is detected	SARS-CoV-2 RNA is not detected	SARS-CoV-2 RNA is detected	Invalid*
Internal Control (IPC)	Positive	Positive	Negative	Negative
Specimen	Positive	Negative	Positive	Negative

**Retest the specimen. The result could not be interpreted.*

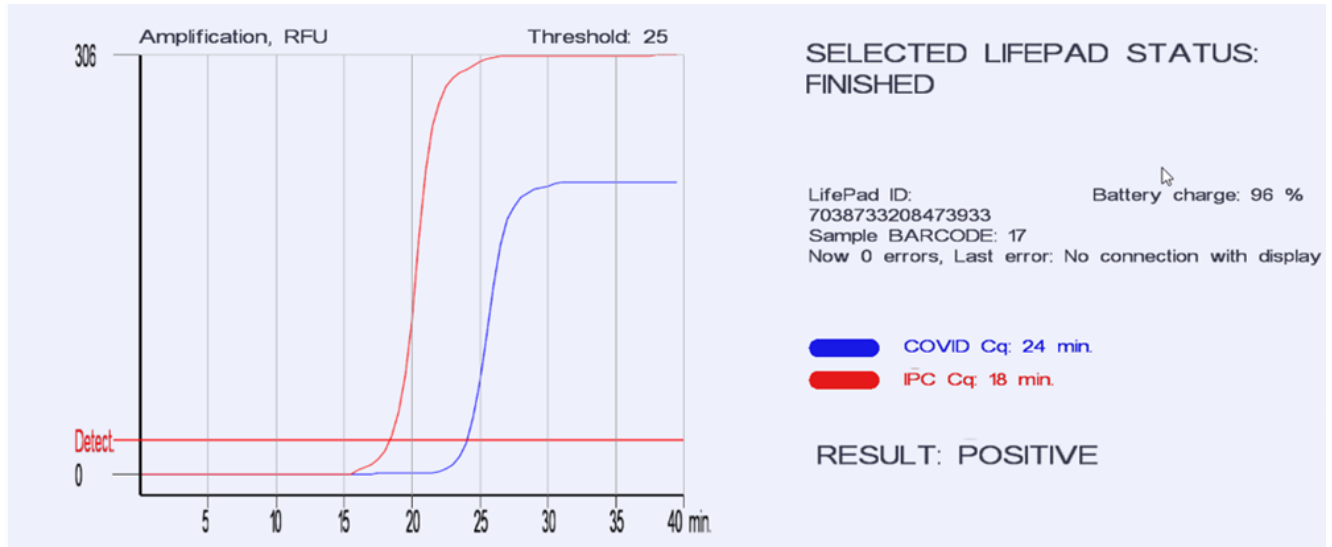
The SARS-CoV-2 positive specimen graphic representation examples are given in Pictures 40.1-40.7.

The blue sigmoid line is a specimen with the detected SARS-CoV-2 coronavirus.

The red sigmoid line is internal positive control (IPC).



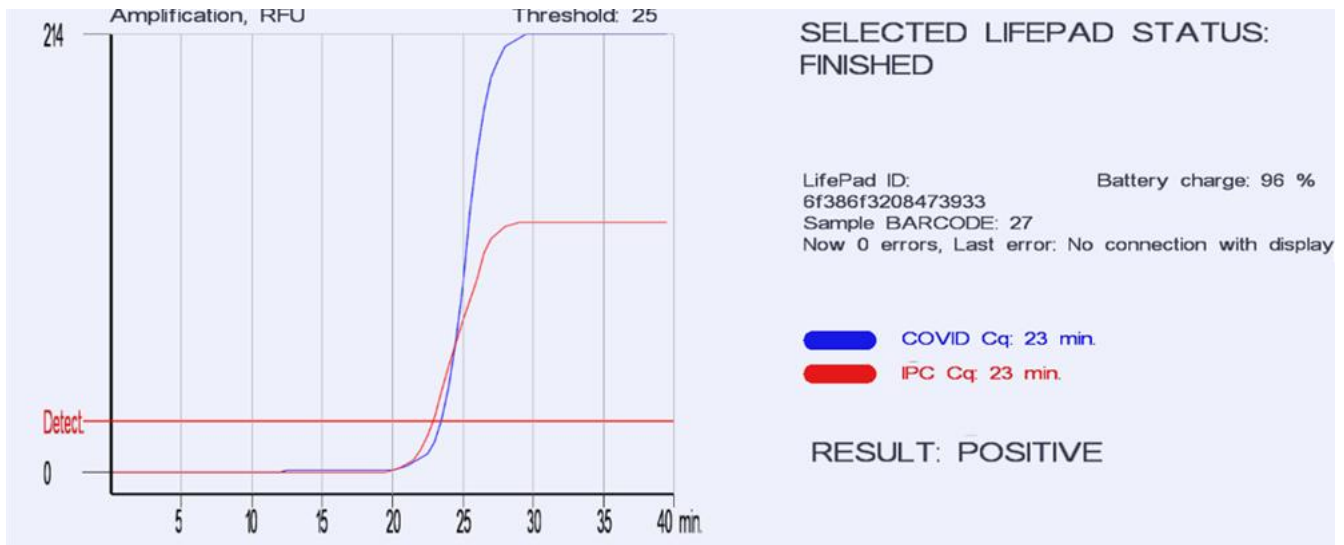
Picture 40-1. Positive Specimen Graphic Representation Example



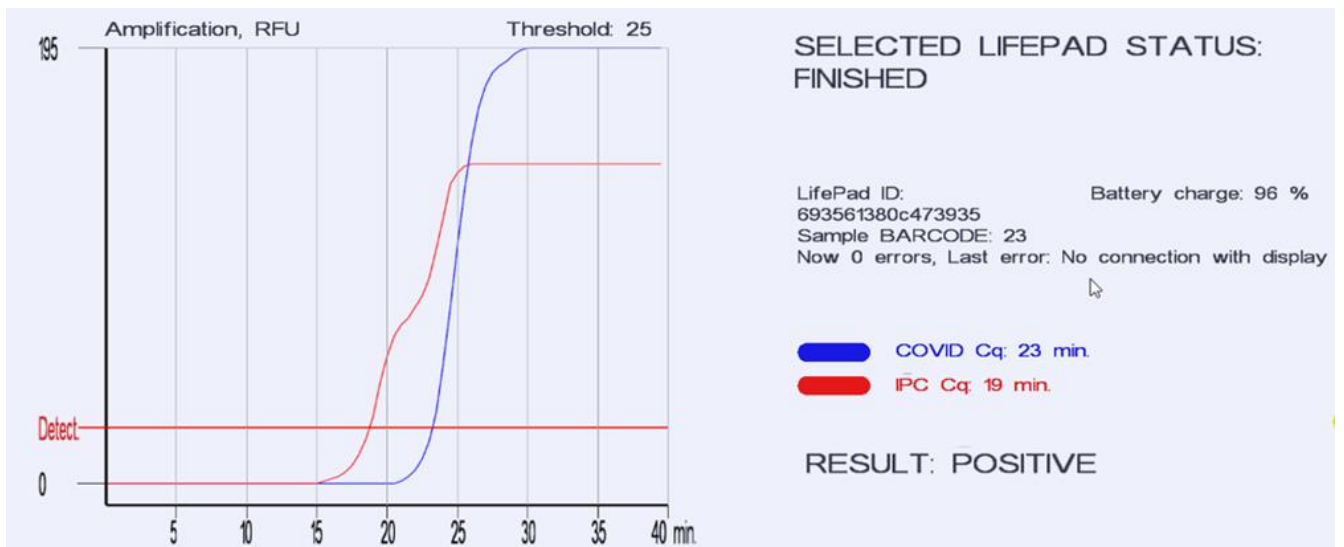
Picture 40-2. Positive Specimen Graphic Representation Example



Picture 40-3. Positive Specimen Graphic Representation Example



Picture 40-4. Positive Specimen Graphic Representation Example



Picture 40-5. Positive Specimen Graphic Representation Example



Picture 40-6. Positive Specimen Graphic Representation Example

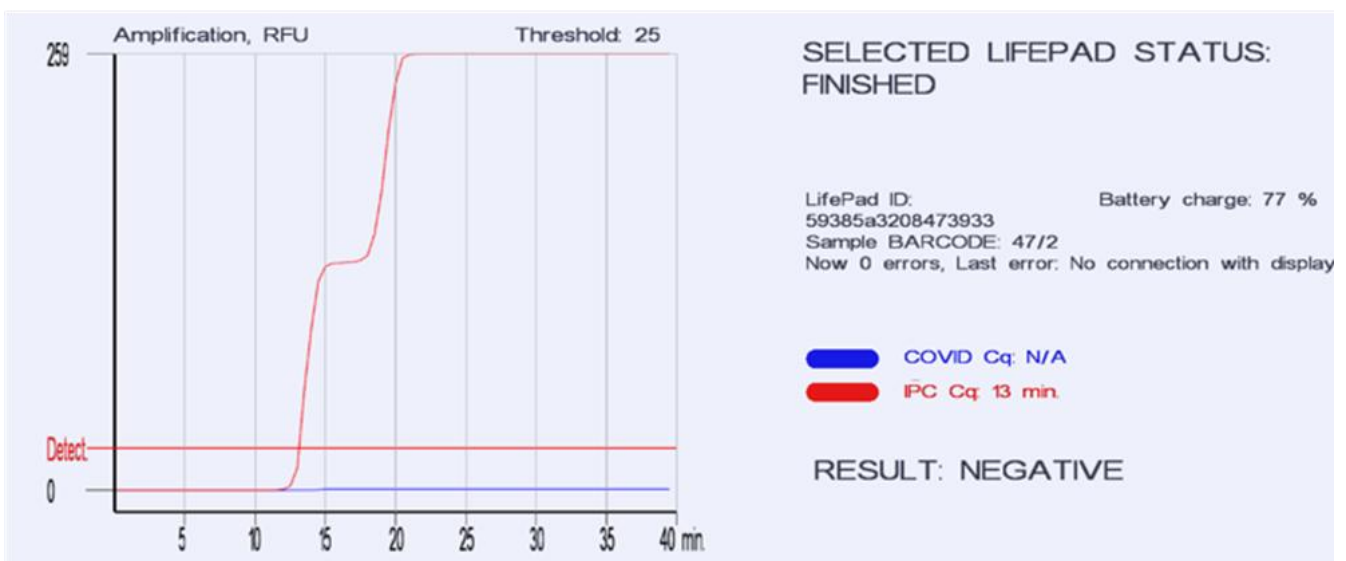


Picture 40-7. Positive Specimen Graphic Representation Example

The SARS-CoV-2 negative specimen graphic representation examples are given in Picture 41.1-41.6.

The blue sigmoid line is a specimen where the SARS-CoV-2 coronavirus was not detected.

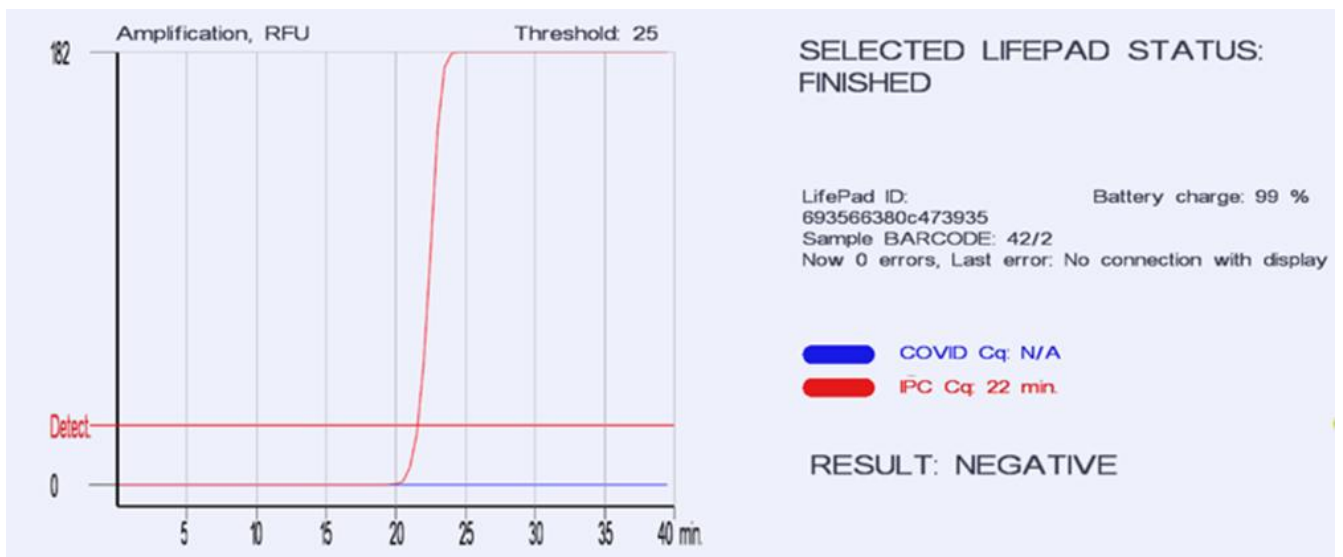
The red sigmoid line is internal positive control (IPC).



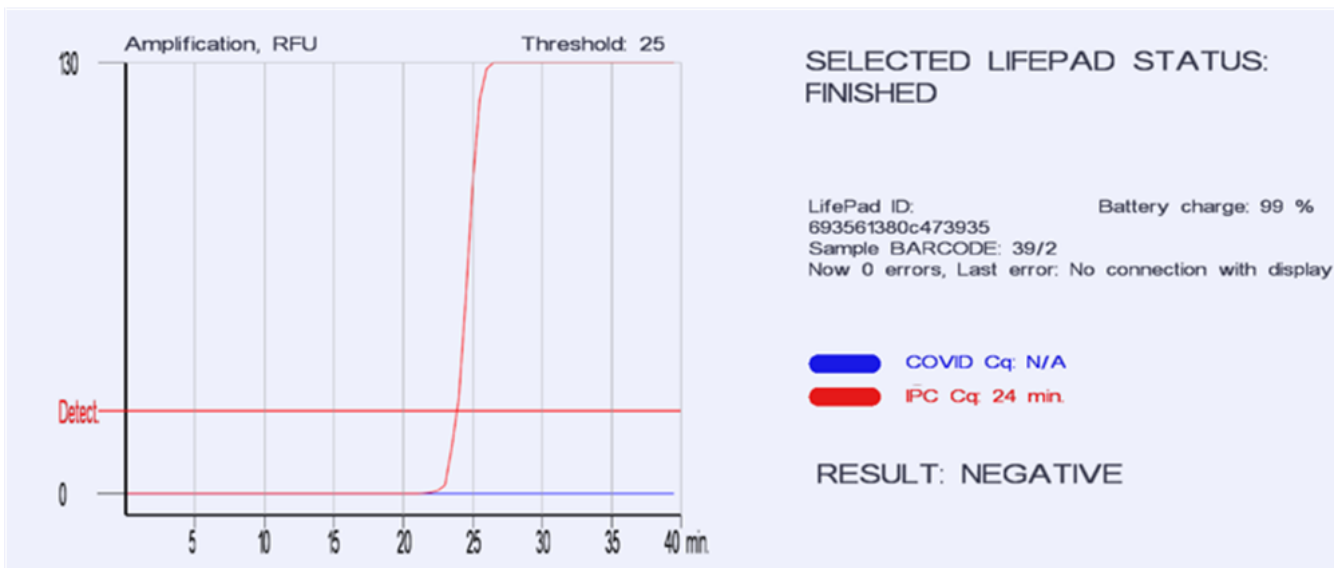
Picture 41-1. Negative Specimen Graphic Representation Example



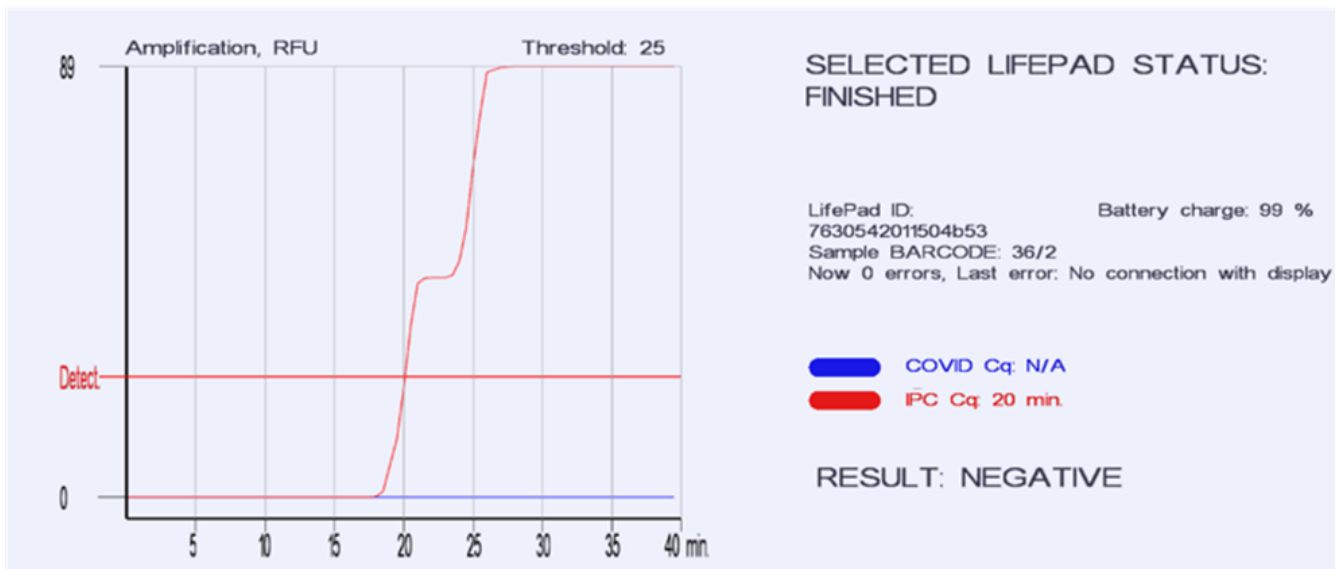
Picture 41-2. Negative Specimen Graphic Representation Example



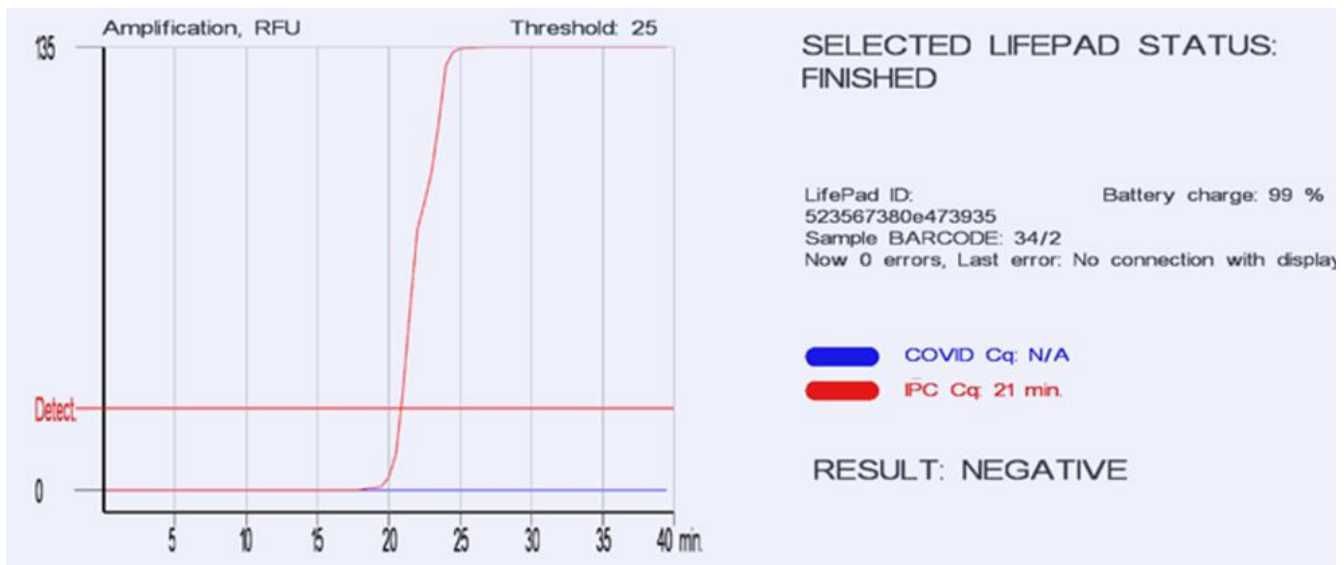
Picture 41-3. Negative Specimen Graphic Representation Example



Picture 41-4. Negative Specimen Graphic Representation Example



Picture 41-5. Negative Specimen Graphic Representation Example



Picture 41-6. Negative Specimen Graphic Representation Example

The results are interpreted based on the fluorescent curve rise presence (or absence) and the threshold cycle (Ct) value in minutes.

The result is considered positive if the fluorescence accumulation curve for the corresponding specimen has a specific sigmoid shape and crosses the threshold line (a red solid line on the graph, fixed at 200 and not changing its value).

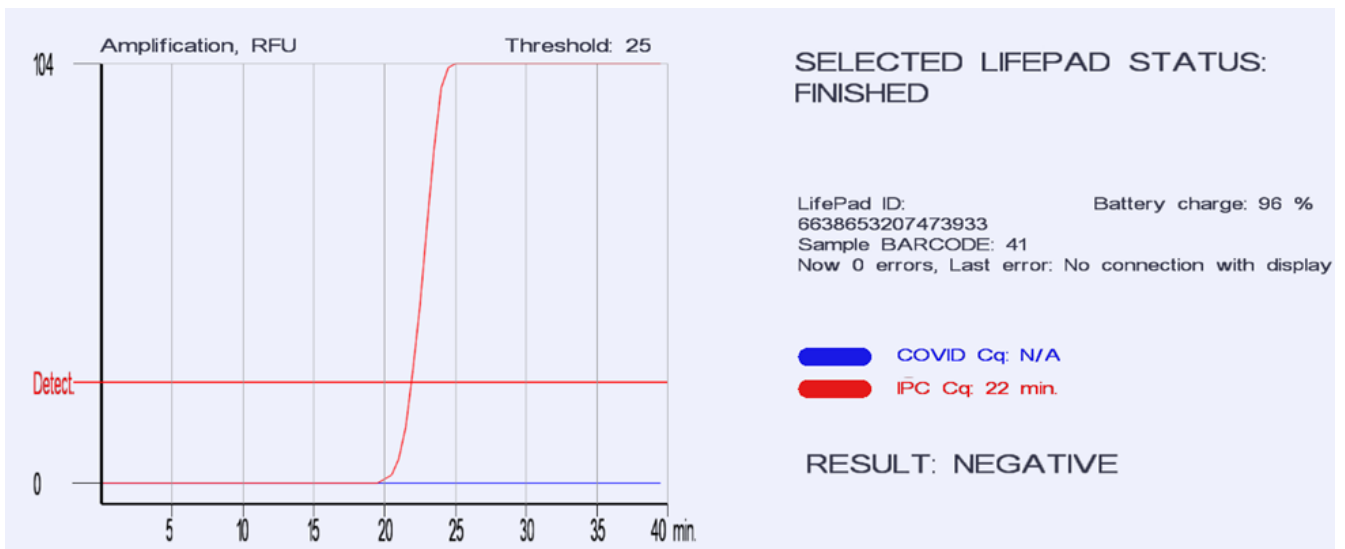
The value of the reaction time at the time of exit should not exceed 35 minutes. The amplitude of the signal does not matter.

Each *Test Kit for SARS-CoV-2 RNA Detection in Biological Material Using PCR Method* contains positive and negative control samples required to check the quality of the kit.



Figure 42. Positive Control Sample Interpretation

The result is considered negative if there is no Ct value (see Picture 43).



Picture 43. Negative Control Sample Interpretation

The report can be uploaded as a document in .pdf/.xlsx by clicking the *Upload as Pdf/Excel* button.

Troubleshooting

The Analyzer performs self-checking after each switch-on as well as during operation. In the event of a malfunction, the *Error* message appears on the device screen, and an error code appears in the status line corresponding to this Analyzer in the software (Picture 36). The list of errors, their codes, and actions to eliminate the errors is shown in Table 8.

Table 8. MALFUNCTIONS AND TROUBLESHOOTING

Error Code	Reason/Source	Where	How to Fix
01 01	No connection	Servo	Please contact the service center
01 02		Heater	
01 03		Optics	
01 04		RFID antenna	
01 05		Battery (temperature sensor)	
01 06		Pressure sensor	
01 07		Charge circuit	
01 08		Power adaptor	
01 09		Accelerometer	
01 0A		Display	
02 01	Insufficient supply voltage/current	Servo	
02 02		Battery	
02 03		Common line	
03 01	Overheating	Servo	
03 02		Heater	
03 03		Heater	

04 01	Incorrect homing position	Servo	Please contact the service center
04 02	Incorrect homing position	Device position according to the accelerometer	Place the device on a horizontal surface
04 03	Inserted Test Cartridge was detected when the device was turned on	RFID module	If ERROR status is displayed, take out the Test Cartridge and/or restart the Analyzer
05 01	Inability to achieve the correct position (value) during the test	Servo	Please contact the service center
05 02	Device incorrect position	Device position according to the accelerometer	
05 03	The Test Cartridge was taken out during the test	RFID module	
06 01	The pressure doesn't change	Pressure sensor	Please contact the service center
06 02	The pressure level is insufficient		
07 01	Heater low temperature on one or all channels	Heater	Please contact the service center
08 01	Incorrect values of the optical module sensors	Optics	
09 01	Errors when recognizing the Test Cartridge		Take out the Test Cartridge and re-insert it
09 02	Errors when writing information to the Test Cartridge		Use another Test Cartridge
0A 01	System update error	Main board	Please contact the service center
0B 01	Battery	Voltage level is exceeded	Please contact the service center
0B 02	Battery	Voltage level is reduced	Plug in the power adapter
0B 03		Battery error	Please contact the service center



In case of any other malfunctions, not described in the User Manual, please immediately contact the Manufacturer.

Analyzer Maintenance

General

The purpose of the Analyzer maintenance is to maintain the Analyzer in its good working condition and ensure its maximum service life.

Maintenance is performed by qualified staff who have read the User Manual carefully.

The Analyzer design requires minimal maintenance in a normal laboratory operation environment.

Prevent any mechanical damage to the Device and do not expose the surface of the Device to any liquids.

Maintenance Procedure

The maintenance staff must do the following (with the indicated frequency):

- 1) Perform external inspection of the Device for any damage to its surface.
- 2) Verify the condition (integrity) of the power adapter and the reliability of its connection to the Analyzer. External inspection frequency: every time before switching on the Device.
- 3) Remove dust and dirt from the surface of the Device in a timely manner using a dry wipe.
- 4) If potentially contaminated samples or used reagents are on the surface of the Analyzer, disinfect the surfaces by wiping out in compliance with effective in-house rules.

Routine Maintenance

The routine maintenance of the Device is carried out by an authorized service provider. It is strictly forbidden to carry out any repairs by your own resources.

Analyzer Disposal

The Analyzer that has become unusable, including due to the expiration of its shelf life, must be disposed of.

EU Waste Electrical and Electronic Equipment (WEEE) Directive

In August of 2005, the European Union (EU) implemented the EU WEEE Directive 2002/96/EC and later the WEEE Recast Directive 2012/19/EU requiring Producers of electronic and electrical equipment (EEE) to manage and finance the collection, reuse, recycling and to appropriately treat WEEE that the Producer places on the EU market after August 13, 2005.

The goal of this directive is to minimize the volume of electrical and electronic waste disposal and to encourage reuse and recycling at the end of life.

K.K. Mirai Genomics has met its national obligations to the EU WEEE Directive by registering in those countries to which **K.K. Mirai Genomics** is an importer. **K.K. Mirai Genomics** has also elected to join WEEE Compliance Schemes in some countries to help manage customer returns at end-of-life.

If you have purchased **K.K. Mirai Genomics**-branded electrical or electronic products in the EU and are intending to discard these products at the end of their useful life, please do not dispose of them with your other household or municipal waste.

K.K. Mirai Genomics has labeled its branded electronic products with the WEEE Symbol to alert our customers that the products bearing this label should not be disposed of in a landfill or with municipal or household waste in the EU.

For professional users in the European Union

If you wish to discard electrical and electronic equipment (EEE), please contact your dealer, supplier or our EU Representative for further information.

For disposal in countries outside of the European Union

This symbol is only valid in the European Union (EU). If you wish to discard this product, please contact your local authorities or dealer and ask for the correct method of disposal.

