

GENPAD

Analyzer

USER MANUAL

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Manufacturer

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ABOUT THIS MANUAL

The user manual provides instructions on how to operate the *GenPad* 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 *GenPad* analyzer.

SAFETY INFORMATION

Safety Precautions chapter in this manual provides important safety information that should be used when operating the *GenPad* 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.

TERMS AND DEFINITIONS

Analyzer, Device – the *GenPad* analyzer.

Test Kit for SARS-CoV-2 and Influenza A/B RNA PCR Detection in Biological Material – a medical device produced by K.K. Mirai Genomics and intended for SARS-CoV-2 and Influenza A/B RNA PCR Detection.

Cartridge No.1 – a component of the *Test Kit for SARS-CoV-2 and Influenza A/B RNA PCR Detection in Biological Material*.

Test Kit for SARS-CoV-2 RNA Detection in Biological Material Using PCR Method – a medical device produced by K.K. Mirai Genomics and intended for SARS-CoV-2 RNA PCR Detection.

Cartridge No.2 – a component of the *Test Kit for SARS-CoV-2 RNA Detection in Biological Material Using PCR Method 1*.

Manufacturer – K.K. Mirai Genomics.

User Manual – this user manual.













Software, program, application – the *GenPad* software.

Maintenance – a set of actions to monitor and maintain the Analyzer in good working condition.

NOTE: Color interpretation, photographic elements may differ from those indicated in the Pictures and given as an example.

TABLE OF SYMBOLS

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

	Serial number
	Manufacturer
	Keep away from direct sunlight
	Fragile
	Power supply connection (charge)
	<i>In vitro</i> diagnostic medical device
	Warning! Consult the Instructions for Use
	Consult the Instructions for Use
	USB 2.0 High Speed interface connection
	Waste Electrical and Electronic Equipment (WEEE) directive
	Keep dry
	<i>Conformité Européenne</i> (CE certificate)

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

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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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1. PRODUCT NAME

Table 2. Product name and structure

Pos.	Item	Quantity, (pc.)
GenPad Analyzer		
Version 1		
1.	GenPad Analyzer, SLP.003 model	1
2.	USB type A (m), USB type C (m) cable, Cablexpert, PRC	1
3.	USB type C (m), USB type C (m) cable, Cablexpert, PRC	1
4.	AC charger, CD type, Ugreen Group Limited, PRC	1
5.	User Manual	1 copy
6.	Datasheet	1 copy
7.	Quick Start Guide	1 copy
8.	Packing List	1 copy
Version 2		
1.	GenPad Analyzer, SLP.003 model	1
2.	USB type A (m), USB type C (m) cable, Cablexpert, PRC	1
3.	USB type C (m), USB type C (m) cable, Cablexpert, PRC	1
4.	Satechi charger, ST-UC100WSM model, PCR	1
5.	User Manual	1 copy
6.	Datasheet	1 copy
7.	Quick Start Guide	1 copy
8.	Packing List	1 copy
Version 3		
1.	GenPad Analyzer, SLP.003 model	1
2.	USB type A (m), USB type C (m) cable, Cablexpert, PRC	1
3.	USB type C (m), USB type C (m) cable, Cablexpert, PRC	1
4.	Baseus GaN2 Pro Quick Charger 2C+U 120W EU charger, PCR	1
5.	User Manual	1 copy
6.	Datasheet	1 copy
7.	Quick Start Guide	1 copy
8.	Packing List	1 copy
Version 4		
1.	GenPad Analyzer, SLP.003 model	1

2.	USB type A (m), USB type C (m) cable, Cablexpert, PRC	1
3.	USB type C (m), USB type C (m) cable, Cablexpert, PRC	
4.	Mi 20W Charger (Type-C (m) AD201EU model) NanJing CukTech Electronics Technology Co., Ltd, PCR	1
5.	User Manual	1 copy
6.	Datasheet	1 copy
7.	Quick Start Guide	1 copy
8.	Packing List	1 copy
Version 5		
1.	GenPad Analyzer, SLP.003 model	8
2.	USB type A (m), USB type C (m) cable, Cablexpert, PRC	1
3.	USB type C (m), USB type C (m) cable, Cablexpert, PRC	1
4.	AC charger, CD type, Ugreen Group Limited, PRC	1
5.	User Manual	1 copy
6.	Datasheet	1 copy
7.	Quick Start Guide	1 copy
8.	Packing List	1 copy
Version 6		
1.	GenPad Analyzer, SLP.003 model	8
2.	USB type A (m), USB type C (m) cable, Cablexpert, PRC	1
3.	USB type C (m), USB type C (m) cable, Cablexpert, PRC	1
4.	Satechi charger, ST-UC100WSM model, PCR	1
5.	User Manual	1 copy
6.	Datasheet	1 copy
7.	Quick Start Guide	1 copy
8.	Packing List	1 copy
Version 7		
1.	GenPad Analyzer, SLP.003 model	8
2.	USB type A (m), USB type C (m) cable, Cablexpert, PRC	1
3.	USB type C (m), USB type C (m) cable, Cablexpert, PRC	1
4.	Baseus GaN2 Pro Quick Charger 2C+U 120W EU charger, PRC	1
5.	User Manual	1 copy
6.	Datasheet	1 copy
7.	Quick Start Guide	1 copy
8.	Packing List	1 copy

2. SAFETY PRECAUTIONS

2.1. General

The 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.

Laboratories within the European Union are required to report all results to the appropriate public health authorities.



All biological specimens including used cartridges should be handled using standard precautions and treated as if capable of transmitting infectious agents.

Follow safety procedures set by your institution and local authorities for working with chemicals and handling biological specimens.

Consult your institution's environmental waste personnel on proper disposal of used cartridges, which may contain amplified material. Check the relevant state and local regulations.

2.2. Biosafety regulations



NOTE: BIOLOGICAL HAZARD!

Samples may contain infectious agents.

Be aware of the health hazards caused by such agents.

Follow safety procedures set by your institution and local authorities for working with chemicals and handling biological specimens.

Consult your institution's environmental waste personnel on proper disposal of used cartridges, which may contain amplified material. Check relevant state and local regulations.

Avoid direct contact with biological samples. Avoid spilling or spraying.

Wear protective clothing and gloves, and protect your eyes and face. Never draw the solution into the pipette with your mouth.

Do not eat, drink, smoke or wear cosmetics in the workplace. Wash your hands thoroughly after handling specimens and reagents.

Please read the Instructions for Use provided with *Test Kit for SARS-CoV-2 and Influenza A/B RNA PCR Detection in Biological Material* and *Test Kit for SARS-CoV-2 RNA Detection in Biological Material Using PCR Method* before testing.

2.3. Liquid waste infection

Contacting with liquid waste can lead to infection.

Be sure to use PPE. Be extremely careful when working in medical diagnostic (examination) non-sterile gloves - they are easy to pierce or cut, which can lead to infection.

If biohazardous material is spilled onto the Analyzer, wipe the device immediately and apply a disinfectant.

If liquid waste comes into contact with the skin, immediately wash it off with water and treat with a disinfectant solution. Contact your doctor.

Observe the warning labels on the equipment.

2.4. 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.

Table 3. Fuse characteristics

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	

The fuses are installed in the heating and detection module (Figure 3). Replacement, repair or any other manipulation of fuses by the user is not intended.

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.

2.5. Safety rules during operation

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

Do not move the Analyzer during its operation. In case of moving the Analyzer, contact an authorized service center.

2.6. Emergency actions

Fire emergency response when using the Analyzer:

Improper use or the use of non-approved or incompatible batteries or incomplete chargers may present a fire, explosion or other hazard.

In case of fire or explosion of the Analyzer, immediately extinguish the source of ignition with foam, powder or CO₂ type fire extinguishers. After that air the room well.

2.7. 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 is an *in vitro* diagnostics medical device for and does not pose a direct biological hazard. The Analyzer should be serviced only by specially trained qualified personnel.

Any operation and maintenance not described in the User Manual must be carried out by an authorized service representative only.

2.8. Precautions against electromagnetic factors

The manufacturer is responsible for providing the user and the customer with information on the equipment electromagnetic compatibility.

The user is responsible for maintaining electromagnetic or customer information on the equipment electromagnetic compatibility.

Using the device at low relative humidity, especially when there are synthetic materials (synthetic clothing, carpets, etc.) nearby, may lead to incorrect results due to the influence of electrostatic discharges.

The Analyzer complies with the requirements for noise immunity and electromagnetic emission established by EN IEC 61326-1:2021 Electrical equipment for measurement, control and laboratory use. EMC requirements General requirements.

Do not use the device near sources of strong electromagnetic radiation (such as unshielded intentional RF sources), as they may interfere with its normal operation.

2.9. 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.

3. ANALYZER DESCRIPTION

3.1. Intended use

The Analyzer and its consumables (the Test Cartridge from *Test Kit for SARS-CoV-2 and Influenza A/B RNA PCR Detection in Biological Material* and *Test Kit for SARS-CoV-2 RNA Detection in Biological Material Using PCR Method*) are intended for extraction and qualitative PCR detection of SARS-CoV-2 and Influenza A/B viruses RNA in the patient's nasopharyngeal, oropharyngeal, or combined oro- and nasopharyngeal swabs.

The composition of the consumables is given in Appendix A.

Risks of the Analyzer use, contraindications, expected and predictable side effects associated with the intended use of the Analyzer are not applicable.



Note: the Analyzer is operable only with the Test Cartridge from *Test Kit for SARS-CoV-2 and Influenza A/B RNA PCR Detection in Biological Material* or *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.



Note: *Test Kit for SARS-CoV-2 and Influenza A/B RNA PCR Detection in Biological Material* and *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.

Target analyte:

1. When used together with *Test Kit for SARS-CoV-2 and Influenza A/B RNA PCR Detection in Biological Material*, the Analyzer is used for the qualitative detection of SARS-CoV-2 coronavirus and Influenza A/B RNA (target site of the gene region encoding the non-structural protein Nsp15, which is located in the ORF1b part of the SARS-CoV-2 genome, and target site of the gene region encoding the M1 structural protein, which is located in segment 7 of the Influenza A/B virus genome).
2. When used together with *Test Kit for SARS-CoV-2 RNA Detection in Biological Material Using PCR Method*, the Analyzer is used for the qualitative detection of SARS-CoV-2 coronavirus RNA (target site of the gene region encoding the non-structural protein Nsp15, which is located in the ORF1b part of the SARS-CoV-2 genome).

3.2. Specimen collection, storage, and transport



NOTE: Proper specimen collection, storage, and transport are critical to the test performance. Inadequate specimen collection, improper specimen handling and/or transport may lead to a false result.

Each specimen should be immediately placed in a separate tube with the SSB solution included in the Kit at the site of collection.

Avoid repetitive freezing and thawing of the specimens.

Treat all biological specimens as if capable of transmitting infectious agents. Refer to the WHO Laboratory biosafety guidance related to coronavirus disease (COVID-19) for details ([https://www.who.int/publications/i/item/laboratory-biosafety-guidance-related-to-coronavirus-disease-\(covid-19\)](https://www.who.int/publications/i/item/laboratory-biosafety-guidance-related-to-coronavirus-disease-(covid-19))).

Specimen storage and transportation conditions are:

At room temperature — within 6 hours.

At temperatures from +2 to +8°C — within 3 days.

At a temperature of -20°C — within 1 month.



To achieve the stated analytical sensitivity, the specimen aliquot should be at least 700 µl.

3.3. Performance characteristics

3.3.1. INTERFERING SUBSTANCES

The possible effect of the following interfering substances to the detection efficiency of the Analyzer and the Kit is not observed.

Table 4. Interference study results

Specimen Type	Interfering Substance	Interfering Substance Concentration	Interference
Naso- and oropharyngeal swab	Mucin	5% (v/v)	Not detected
	Hemoglobin	2.5% (v/v)	Not detected
	Chlorhexidine bigluconate aqueous solution	2% (v/v)	Not detected

3.3.2. REPRODUCIBILITY

The coefficient of variation (CV) does not exceed claimed 20% when assessing reproducibility testing with the Analyzer.

3.3.3. ANALYTICAL PERFORMANCE

Analytical sensitivity

The analytical limit of detection (LoD):

- When using the GK2020/1 standard sample of the inactivated SARS-CoV-2 strain is:

- 2 x 10³ copies of SARS-CoV-2 coronavirus RNA per mL (copies/mL).
- b. When using the SmartAmp Liquid Reagent for IPC RNA detection sensitivity control sample, which is a fragment of synthetic RNA of SARS-CoV-2:
 - 2 x 10³ copies of SARS-CoV-2 coronavirus RNA per mL (copies/mL).
- c. When using the SmartAmp Liquid Reagent for IPC RNA detection sensitivity control sample, which is a fragment of synthetic RNA of Influenza A:
 - 2 x 10³ copies of Influenza A RNA per mL (copies/mL).
- d. When using the SmartAmp Liquid Reagent for IPC RNA detection sensitivity control sample, which is a fragment of synthetic RNA of Influenza B:
 - 2 x 10³ copies of Influenza B RNA per mL (copies/mL).

Analytical specificity (Exclusivity)

The maximum concentration of microorganisms at which the analytical system consisting of the Analyzer and the Kit does not cross-react and which does not affect the performance of the device is as follows:

- a. When using the Panel of Respiratory Infections Inactivated Pathogens for the Analytical Specificity Study developed by N. F. Gamaleya Federal Research Center for Epidemiology & Microbiology:
 - *Streptococcus pneumoniae* ATCC® 49619™ – 1x10⁶ CFU per 1 mL (CFU/ mL),
 - *Haemophilus influenzae* ATCC® 49247™ – 1x10⁶ CFU/ mL,
- b. – Influenza A virus A/Anhui/1/2013 (H7N9) – 1x10⁵ TCID₅₀ per 1 ml (TCID₅₀/ mL),
 - *Adenovirus type 5 394* – 1x10⁵ TCID₅₀/ml,
 - *Influenza B virus B/Moscow/46/2019* – 1:32 HAU,
 - *Human metapneumovirus HM-1* – 1x10⁵ TCID₅₀/ mL,
 - *Human bocavirus* – 5.0 lg ID₅₀ per 1 mL (lg ID₅₀/ mL),
 - *Respiratory syncytial virus (hRSV-1)* – 1x10⁵ TCID₅₀/ mL.
- c. When testing nasopharyngeal swab s containing nucleic acids of the following respiratory infection pathogens:
 - *Influenza A virus* at a concentration of at least 1x10³ copies (HAU)/mL;
 - *Adenovirus* at a concentration of at least 5x10³ copies (HAU)/mL;
 - *Influenza B virus* at a concentration of at least 1x10³ copies (HAU)/mL;
 - *Human metapneumovirus* at a concentration of at least 1x10³ copies (HAU)/mL;
 - *Parainfluenza virus type 3* at a concentration of at least 1x10³ copies (HAU)/mL;
 - *Respiratory syncytial virus* at a concentration of at least 1x10³ copies (HAU)/mL;
 - *Rhinovirus* at a concentration of at least 1x10³ copies (HAU)/mL;
 - *Human bocavirus* at a concentration of at least 1x10³ copies (HAU)/mL;
 - *Coronaviruses (NL-63, 229E, HKU-1, OC43)* at a concentration of at least 1x10⁴ copies (HAU)/mL.

Clinical evaluation

The performance the analytical system consisting of the Analyzer and the Kit was evaluated using specimens taken from patients during the treatment and diagnostic process. The diagnostic sensitivity of the SARS-CoV-2 and Influenza A/B RNA detection was evaluated using 100 positive specimens of each

type (100 nasopharyngeal swabs containing the SARS-CoV-2 RNA and 100 nasopharyngeal swabs containing the Influenza A/B RNA) with a confidence interval (CI) equal to 95%.

The diagnostic specificity of the SARS-CoV-2 RNA detection was evaluated using 100 negative specimens of each type (100 nasopharyngeal swabs that do not contain the SARS-CoV-2 RNA and 100 nasopharyngeal swabs that do not contain the Influenza A/B RNA) with a confidence interval of 95%.

Totally tested:

True-positives:	200
False-positives:	0
True-negatives:	200
False-negatives:	4

Diagnostic sensitivity: 98.04% (95% CI 95.06-99.46%).

Diagnostic specificity: 100.00% (95% CI: 98.17-100.00%).

3.3.4. Indications and contraindications for use

The Analyzer is used in clinical laboratory diagnostics for the study of biological material sampled from individuals suspected of COVID-19 and/or Influenza A/B as well as their contact persons.

There are no contraindications within the established purpose.

Do not use the Analyzer if the packaging is broken or the device shows signs of damage.

Do not use the Analyzer in case of non-compliance with the conditions of transportation and storage according to the User Manual.

4. 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 5. Analyzer operating, storage and transportation

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)

5. PACKING

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



Figure 1. Packing Scheme.

6. TECHNICAL CHARACTERISTICS OF THE INSTRUMENT

6.1. Software

The *GenPad* software version is 0.6.11 and higher.

To control the Analyzer and display real-time fluorescence detection data, the pre-installed *GenPad* software is used. The software version numbering system is A.B.C:

A – major version, the change in the software major version number occurs with a global change in the functionality of the product (when new functionality is introduced).

B – minor version number, changes when new functionality is made, leading to software incompatibility with the old version (incompatibility at the data level).

C – the release number, the software release number changes every time a software update is publicly released. Release numbers denote releases of bug fixes that do not change the way the product functions and do not cause incompatibility at the level of data files (no special data conversion/transformation procedures are required to update the software).

The *GenPad* software is written in C#, Unity.

6.2. General

Without packaging, the Analyzer weights 0.575 ± 0.1 kg.

Permissible deviation from parameters is $\pm 10\%$.

The Analyzer **overall dimensions** without consumer packaging (L x W x H) are 130x50x110 mm.

Permissible deviation of overall dimensions (L x W x H) is $\pm 10\%$.

The Analyzer is operable when powered from the AC 100-240V, 50/60 Hz mains using the power supply unit and/or the battery.

Maximum input voltage: DC 20V, maximum input current: 4.8A.

Battery characteristics: Lithium-ion Polymer (LiPo) technology, capacity – 3,000 mAh, voltage - 7.40 V.

Minimum computer hardware requirements for the *GenPad* software, software version 0.6.11:

- OS: Windows 10 or higher.
- Intel processor with a clock frequency of 1,600 MHz or higher.
- RAM: 4,000 MB or higher.
- Free disk space: 1,024 MB or higher.
- Minimum screen resolution: 1280x720 pixels.
- Screen aspect ratio: 16:9.
- Availability of PC free ports complying with the USB 2.0 High-speed standard.

The *GenPad* software, software version 0.6.11, provides:

- Testing start, finish and emergency stop.
- Display of optical measurement in the form of graphs.
- Graphs autoscaling.
- Graphs per-channel filtering.
- Automatic fluorescence threshold level display.
- Export of current testing results to .xlsx.

Exported data is presented in a table as follows:

- User name (USER).
- Testing date and time (DATE).
- Device ID (GenPad ID).

- Manually entered name of Cartridge (SAMPLE BARCODE).
- Threshold level (Threshold),
- Time for the internal control sample to rise to threshold level (IPC Cq).
- Rise time of the signal of a possible positive sample to the threshold level (COVID-19, FluA, FluB Cq).
- The results of the study for each channel should indicate a value that fixes the signal rise to the threshold level, above which the study is accepted as positive (POSITIVE), in other cases negative (NEGATIVE).
- The test completion status (STATUS): ERROR, CANCELLED or FINISH.
- Fluorescence curve coordinates.
- The Analyzer analytical information display.
- The Analyzer connection status.
- Testing time (in X min format).
- Testing progress (in percent).

The Analyzer maximum allowable run mode set time after switching on is no more than 1 minute.

The Analyzer maximum continuous run time is 8 hours, the shortest recovery time is 5 minutes.

The *GenPad* software specifications:

- The distribution kit size is no more than 1 GB.
- The installed software size is no more than 1 GB.
- Automatic restoration of the signal graphs of running tests is provided in case of unintentional disconnection of the Analyzer from the PC.
- Response time of the software for performing functions is no more than 10 s.
- Supported data formats (.xlsx).

Protection against unauthorized access should be provided using standard user authorization on a PC.

Table 6. Device components parameters.

Pos.	Name	Parameter
<i>GenPad</i> Analyzer		
Version 1, consisting of:		
1.	<i>GenPad</i> Analyzer, SLP.003 model – 1 pc.	Overall dimensions (LxWxH): <ul style="list-style-type: none"> • Without consumer package: 130x50x110 mm. • In consumer package: 160x160x75 mm. Weight: <ul style="list-style-type: none"> • Without consumer package: 0.575 ± 0.12 kg.

		<ul style="list-style-type: none"> In consumer package: 1 ± 0.2 kg.
2.	USB type A (m), USB type C (m) cable, Cablexpert, PRC – 1 pc.	<p>Interface: USB 2.0.</p> <p>Connectors: USB type A (m), USB type C (m).</p> <p>Length: 1,000 mm.</p>
3.	USB type C (m), USB type C (m) cable, Cablexpert, PRC – 1 pc.	<p>Interface: USB Type C (m).</p> <p>Connectors: USB type C (m), USB type C (m).</p> <p>Length: 1,000 mm.</p>
4.	AC charger, CD type, Ugreen Group Limited, PRC – 1 pc.	<p>Max output current: 5 A.</p> <p>Max output power: 100W.</p> <p>Max output voltage: 21V.</p>
5.	User Manual – 1 pc.	---
6.	Datasheet – 1 pc.	---
7.	Quick Start Guide – 1 pc.	---
8.	Packing List – 1 pc.	---
Version 2, consisting of:		
1.	<i>GenPad</i> Analyzer, SLP.003 model – 1 pc.	<p>Overall dimensions (LxWxH):</p> <ul style="list-style-type: none"> Without consumer package: 130x50x110 mm. In consumer package: 160x160x75 mm. <p>Weight:</p> <ul style="list-style-type: none"> Without consumer package: 0.575 ± 0.12 kg. In consumer package: 1 ± 0.2 kg.
2.	USB type A (m), USB type C (m) cable, Cablexpert, PRC – 1 pc.	<p>Interface: USB 2.0.</p> <p>Connectors: USB type A (m), USB type C (m).</p> <p>Length: 1,000 mm.</p>

3.	USB type C (m), USB type C (m) cable, Cablexpert, PRC – 1 pc.	Interface: USB Type C (m). Connectors: USB type C (m), USB type C (m). Length: 1,000 mm.
4.	Satechi charger, ST-UC100WSM model, PCR	Max output current: 5 A. Max output power: 100W. Max output voltage: 20V.
5.	User Manual – 1 pc.	---
6.	Datasheet – 1 pc.	---
7.	Quick Start Guide – 1 pc.	---
8.	Packing List – 1 pc.	---
Version 3, consisting of:		
1.	<i>GenPad</i> Analyzer, SLP.003 model – 1 pc.	Overall dimensions (LxWxH): <ul style="list-style-type: none"> Without consumer package: 130x50x110 mm. In consumer package: 160x160x75 mm. Weight: <ul style="list-style-type: none"> Without consumer package: 0.575 ± 0.12 kg. In consumer package: 1 ± 0.2 kg.
2.	USB type A (m), USB type C (m) cable, Cablexpert, PRC – 1 pc.	Interface: USB 2.0. Connectors: USB type A (m), USB type C (m). Length: 1,000 mm.
3.	USB type C (m), USB type C (m) cable, Cablexpert, PRC – 1 pc.	Interface: USB Type C (m). Connectors: USB type C (m), USB type C (m). Length: 1,000 mm.

4.	Baseus GaN2 Pro Quick Charger 2C+U 120W EU charger, PRC	<p>Max output current: 5 A.</p> <p>Max output power: 100W.</p> <p>Max output voltage: 20V.</p>
5.	User Manual – 1 pc.	---
6.	Datasheet – 1 pc.	---
7.	Quick Start Guide – 1 pc.	---
8.	Packing List – 1 pc.	---
Version 4, consisting of:		
1.	GenPad Analyzer, SLP.003 model – 1 pc.	<p>Overall dimensions (LxWxH):</p> <ul style="list-style-type: none"> Without consumer package: 130x50x110 mm. In consumer package: 160x160x75 mm. <p>Weight:</p> <ul style="list-style-type: none"> Without consumer package: 0.575 ± 0.12 kg. In consumer package: 1 ± 0.2 kg.
2.	USB type A (m), USB type C (m) cable, Cablexpert, PRC – 1 pc.	<p>Interface: USB 2.0.</p> <p>Connectors: USB type A (m), USB type C (m).</p> <p>Length: 1,000 mm.</p>
3.	USB type C (m), USB type C (m) cable, Cablexpert, PRC – 1 pc.	<p>Interface: USB Type C (m).</p> <p>Connectors: USB type C (m), USB type C (m).</p> <p>Length: 1,000 mm.</p>
4.	Mi 20W Charger (Type-C (m) AD201EU model) NanJing CukTech Electronics Technology Co., Ltd, PCR	<p>Max output current: 3 A.</p> <p>Max output power: 20W.</p> <p>Max output voltage: 12V.</p>
5.	User Manual – 1 pc.	---

6.	Datasheet – 1 pc.	---
7.	Quick Start Guide – 1 pc.	---
8.	Packing List – 1 pc.	---
Version 5, consisting of:		
1.	<i>GenPad</i> Analyzer, SLP.003 model – 8 pcs.	<p>Overall dimensions (LxWxH):</p> <ul style="list-style-type: none"> Without consumer package: 130x50x110 mm. In consumer package: 160x160x75 mm. <p>Weight:</p> <ul style="list-style-type: none"> Without consumer package: 4.0 ± 0.3 kg. In consumer package: 6.5 ± 0.2 kg.
2.	USB type A (m), USB type C (m) cable, Cablexpert, PRC – 1 pc.	<p>Interface: USB 2.0.</p> <p>Connectors: USB type A (m), USB type C (m).</p> <p>Length: 1,000 mm.</p>
3.	USB type C (m), USB type C (m) cable, Cablexpert, PRC – 1 pc.	<p>Interface: USB Type C (m).</p> <p>Connectors: USB type C (m), USB type C (m).</p> <p>Length: 1,000 mm.</p>
4.	AC charger, CD type, Ugreen Group Limited, PRC – 1 pc.	<p>Max output current: 5 A.</p> <p>Max output power: 100W.</p> <p>Max output voltage: 20V.</p>
5.	User Manual – 1 pc.	---
6.	Datasheet – 1 pc.	---
7.	Quick Start Guide – 1 pc.	---
8.	Packing List – 1 pc.	---
Version 6, consisting of:		

1.	<i>GenPad</i> Analyzer, SLP.003 model – 8 pcs.	<p>Overall dimensions (LxWxH):</p> <ul style="list-style-type: none"> Without consumer package: 130x50x110 mm. In consumer package: 160x160x75 mm. <p>Weight:</p> <ul style="list-style-type: none"> Without consumer package: 4.0 ± 0.3 kg. In consumer package: 6.5 ± 0.2 kg.
2.	USB type A (m), USB type C (m) cable, Cablexpert, PRC – 1 pc.	<p>Interface: USB 2.0.</p> <p>Connectors: USB type A (m), USB type C (m).</p> <p>Length: 1,000 mm.</p>
3.	USB type C (m), USB type C (m) cable, Cablexpert, PRC – 1 pc.	<p>Interface: USB Type C (m).</p> <p>Connectors: USB type C (m), USB type C (m).</p> <p>Length: 1,000 mm.</p>
4.	Satechi charger, ST-UC100WSM model, PCR	<p>Max output current: 5 A.</p> <p>Max output power: 100W.</p> <p>Max output voltage: 20V.</p>
5.	User Manual – 1 pc.	---
6.	Datasheet – 1 pc.	---
7.	Quick Start Guide – 1 pc.	---
8.	Packing List – 1 pc.	---
Version 7, consisting of:		
1.	<i>GenPad</i> Analyzer, SLP.003 model – 8 pcs.	<p>Overall dimensions (LxWxH):</p> <ul style="list-style-type: none"> Without consumer package: 130x50x110 mm. In consumer package: 160x160x75 mm. <p>Weight:</p> <ul style="list-style-type: none"> Without consumer package: 4.0 ± 0.3 kg.

		<ul style="list-style-type: none"> In consumer package: 6.5 ± 0.2 kg.
2.	USB type A (m), USB type C (m) cable, Cablexpert, PRC – 1 pc.	Interface: USB 2.0. Connectors: USB type A (m), USB type C (m). Length: 1,000 mm.
3.	USB type C (m), USB type C (m) cable, Cablexpert, PRC – 1 pc.	Interface: USB Type C (m). Connectors: USB type C (m), USB type C (m). Length: 1,000 mm.
4.	Baseus GaN2 Pro Quick Charger 2C+U 120W EU charger, PRC	Max output current: 5 A. Max output power: 100W. Max output voltage: 20V.
5.	User Manual – 1 pc.	---
6.	Datasheet – 1 pc.	---
7.	Quick Start Guide – 1 pc.	---
8.	Packing List – 1 pc.	---
Recommended accessories not included in Analyzer:		
PC – 1 pc.		OS: Windows 10 or higher. <ul style="list-style-type: none"> Intel processor with a clock frequency of 1,600 MHz or higher. RAM: 4,000 MB or higher. Free disk space: 1,024 MB or higher. Minimum screen resolution: 1280x720 pixels. Screen aspect ratio: 16:9. Availability of PC free ports complying with the USB 2.0 High-speed standard.
Mobile phone, smartphone – 1 pc.		OS: Android, iOS.

	<p>GSM -900/1800, UMTS900/200, LTE in the operating frequency ranges 1,3,7,8,20,38,40; 802.11a/b/g/n/ac; 802.15 (Bluetooth), NFC.</p> <p>Memory capacity: 3 GB or higher.</p> <p>Minimum display resolution: 1280x720 pixels.</p>
Barcode scanner – 1 pc.	<p>Supported interfaces: USB-HID; USB-COM - emulation.</p> <p>Decoding Capabilities: 1D/2D.</p> <p>Protection class: IP54.</p>

7. ANALYZER OUTER APPEARANCE

The appearance of the Analyzer is shown in Figure 2



Figure 2. Analyzer Outer Appearance.

Information about the Analyzer functional modules location (Figure 3) and their functional purposes (Table 7) are as follows:

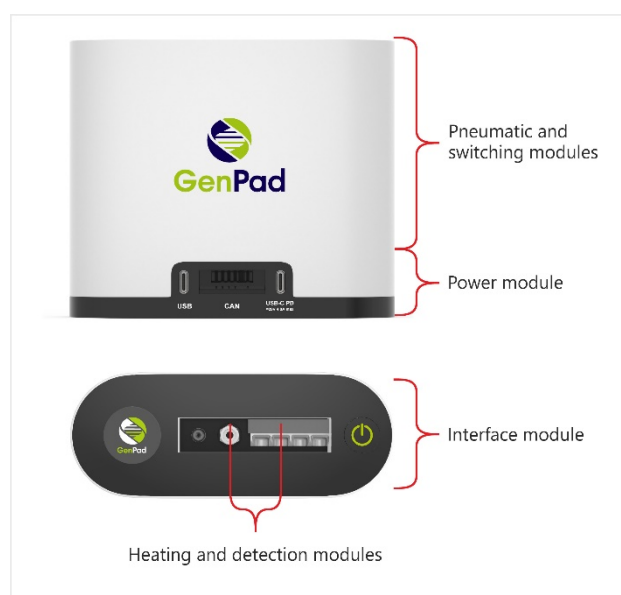



Figure 3. Information about the Analyzer Functional Modules Location.





Table 7. Analyzer module function purpose




Pos.	Module	Functional purpose
1.	Pneumatic module and switching module	– Movement control of the Cartridge liquids.
2.	Heating and detection module	– Heating of the reaction mixture and luorescence level. – Determination of the presence/ absence of the Cartridge in the Analyzer.
3.	Interface module	– Control from a pc. – Data transfer. – Clustering. – Reading and writing the Cartridge data. – Display of the Analyzer current status.
4.	Power module	– Analyzer power and battery management.




8. ANALYZER COMPLETE SET





Table 8. Analyzer components overview




Pos.	Name	Appearance	Functional characteristics
Version 1			
1.	<i>GenPad</i> Analyzer, SLP.003 model.		<p>The Analyzer is intended for extraction and qualitative PCR detection of SARS-CoV-2 and Influenza A/B viruses RNA in the patient's nasopharyngeal, oropharyngeal, or combined oro- and nasopharyngeal swabs.</p> <p>The Analyzer is operable with <i>Test Kit for SARS-CoV-2 and Influenza A/B RNA PCR Detection in Biological Material</i> or <i>Test Kit for SARS-CoV-2 RNA Detection in Biological Material Using PCR Method</i> (Mirai Genomics, Japan).</p>




2.	USB type A (m), USB type C (m) cable, Cablexpert, PRC		Communication with a personal computer.
3.	USB type C (m), USB type C (m) cable, Cablexpert, PRC		Connection to a power adapter.
4.	AC charger, CD type, Ugreen Group Limited, PRC		Generation of an output voltage of a given value and power to the Analyzer.
5.	User Manual		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
6.	Datasheet		





7.	Quick Start Guide		operation during the specified service life.
8.	Packing List		
Version 2			
1.	<i>GenPad</i> Analyzer, SLP.003 model.		<p>The Analyzer is intended for extraction and qualitative PCR detection of SARS-CoV-2 and Influenza A/B viruses RNA in the patient's nasopharyngeal, oropharyngeal, or combined oro- and nasopharyngeal swabs.</p> <p>The Analyzer is operable with <i>Test Kit for SARS-CoV-2 and Influenza A/B RNA PCR Detection in Biological Material</i> or <i>Test Kit for SARS-CoV-2 RNA Detection in Biological Material Using PCR Method</i> (Mirai Genomics, Japan).</p>
2.	USB type A (m), USB type C (m) cable, Cablexpert, PRC		Communication with a personal computer.
3.	USB type C (m), USB type C (m) cable, Cablexpert, PRC		Connection to a power adapter.




4.	Satechi charger, ST-UC100WSM model, PCR		Generation of an output voltage of a given value and power to the Analyzer.
5.	User Manual		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.
6.	Datasheet		
7.	Quick Start Guide		
8.	Packing List		
Version 3			
1.	GenPad Analyzer, SLP.003 model.		<p>The Analyzer is intended for extraction and qualitative PCR detection of SARS-CoV-2 and Influenza A/B viruses RNA in the patient's nasopharyngeal, oropharyngeal, or combined oro- and nasopharyngeal swabs.</p> <p>The Analyzer is operable with <i>Test Kit for SARS-CoV-2 and Influenza A/B RNA PCR Detection in Biological Material</i> or <i>Test Kit for SARS-CoV-2 RNA Detection in Biological Material Using PCR Method</i> (Mirai Genomics, Japan).</p>




2.	USB type A (m), USB type C (m) cable, Cablexpert, PRC		Communication with a personal computer.
3.	USB type C (m), USB type C (m) cable, Cablexpert, PRC		Connection to a power adapter.
4.	Baseus GaN2 Pro Quick Charger 2C+U 120W EU charger, PRC		Generation of an output voltage of a given value and power to the Analyzer.
5.	User Manual		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.
6.	Datasheet		
7.	Quick Start Guide		





8.	Packing List		
Version 4			
1.	<i>GenPad</i> Analyzer, SLP.003 model.		<p>The Analyzer is intended for extraction and qualitative PCR detection of SARS-CoV-2 and Influenza A/B viruses RNA in the patient's nasopharyngeal, oropharyngeal, or combined oro-and nasopharyngeal swabs.</p> <p>The Analyzer is operable with <i>Test Kit for SARS-CoV-2 and Influenza A/B RNA PCR Detection in Biological Material</i> or <i>Test Kit for SARS-CoV-2 RNA Detection in Biological Material Using PCR Method</i> (Mirai Genomics, Japan).</p>
2.	USB type A (m), USB type C (m) cable, Cablexpert, PRC		Communication with a personal computer.
3.	USB type C (m), USB type C (m) cable, Cablexpert, PRC		Connection to a power adapter.




4.	Mi 20W Charger (Type-C (m) AD201EU model) NanJing CukTech Electronics Technology Co., Ltd, PCR		Generation of an output voltage of a given value and power to the Analyzer.
5.	User Manual		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.
6.	Datasheet		
7.	Quick Start Guide		
8.	Packing List		
Version 5			
1.	GenPad Analyzer, SLP.003 model.		<p>The Analyzer is intended for extraction and qualitative PCR detection of SARS-CoV-2 and Influenza A/B viruses RNA in the patient's nasopharyngeal, oropharyngeal, or combined oro- and nasopharyngeal swabs.</p> <p>The Analyzer is operable with <i>Test Kit for SARS-CoV-2 and Influenza A/B RNA PCR Detection in Biological Material</i> or <i>Test Kit for SARS-CoV-2 RNA Detection in Biological Material Using PCR Method</i> (Mirai Genomics, Japan).</p>

2.	USB type A (m), USB type C (m) cable, Cablexpert, PRC		Communication with a personal computer.
3.	USB type C (m), USB type C (m) cable, Cablexpert, PRC		Connection to a power adapter.
4.	AC charger, CD type, Ugreen Group Limited, PRC – 1 pc.		Generation of an output voltage of a given value and power to the Analyzer.
5.	User Manual		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.
6.	Datasheet		
7.	Quick Start Guide		

8.	Packing List		
Version 6			
1.	<i>GenPad</i> Analyzer, SLP.003 model.		<p>The Analyzer is intended for extraction and qualitative PCR detection of SARS-CoV-2 and Influenza A/B viruses RNA in the patient's nasopharyngeal, oropharyngeal, or combined oro- and nasopharyngeal swabs.</p> <p>The Analyzer is operable with <i>Test Kit for SARS-CoV-2 and Influenza A/B RNA PCR Detection in Biological Material</i> or <i>Test Kit for SARS-CoV-2 RNA Detection in Biological Material Using PCR Method</i> (Mirai Genomics, Japan).</p>
2.	USB type A (m), USB type C (m) cable, Cablexpert, PRC		Communication with a personal computer.
3.	USB type C (m), USB type C (m) cable, Cablexpert, PRC		Connection to a power adapter.

4.	Satechi charger, ST-UC100WSM model, PCR		Generation of an output voltage of a given value and power to the Analyzer.
5.	User Manual		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.
6.	Datasheet		
7.	Quick Start Guide		
8.	Packing List		
Version 7			
1.	GenPad Analyzer, SLP.003 model.		<p>The Analyzer is intended for extraction and qualitative PCR detection of SARS-CoV-2 and Influenza A/B viruses RNA in the patient's nasopharyngeal, oropharyngeal, or combined oro- and nasopharyngeal swabs.</p> <p>The Analyzer is operable with <i>Test Kit for SARS-CoV-2 and Influenza A/B RNA PCR Detection in Biological Material</i> or <i>Test Kit for SARS-CoV-2 RNA Detection in Biological Material Using PCR Method</i> (Mirai Genomics, Japan).</p>

2.	USB type A (m), USB type C (m) cable, Cablexpert, PRC		Communication with a personal computer.
3.	USB type C (m), USB type C (m) cable, Cablexpert, PRC		Connection to a power adapter.
4.	Baseus GaN2 Pro Quick Charger 2C+U 120W EU charger, PRC		Generation of an output voltage of a given value and power to the Analyzer.
5.	User Manual		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.
6.	Datasheet		
7.	Quick Start Guide		

8.	Packing List		
Recommended accessories not included in Analyzer:			
PC		Automated operation of the <i>GenPad</i> software, software version 0.6.11.	
Mobile phone, smartphone		Automated operation of the <i>GenPad</i> software, software version 0.6.11.	
Barcode scanner		for automated operation: reading and decoding the contents of the tag in the <i>GenPad</i> software, software version 0.6.11.	

9. ANALYZER OPERATION

9.1. Carrying / Installation

Install the Analyzer in a place convenient for operation with sufficient ventilation to prevent the condensation.

Make sure that there is a free access to the device.

Keep the Analyzer away from the direct sunlight.

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

9.2. Electrical connection

Connect the PC and the Analyzer to 220 V AC mains. Make sure that the AC outlet is equipped with a grounding conductor.

Place the Analyzer in such a way that it is easy to connect/disconnect it.

Connect a pc with the pre-installed *GenPad* software via USB interface to the Analyzer using the appropriate connector on the Analyzer panel.



Figure 4. Analyzer Input and Output Connections.

Table 9. Analyzer connections

Pos.	Analyzer input/output connections	Operating procedure
1.	USB data cable	Data transfer from the Analyzer to a PC.
2.	CAN service connector	Input connector for clustering.
3.	USB-C PD mains power cable connector 20V, 4.8A max	AC mains device

9.3. 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.

9.4. Single mode

Each device is connected to a PC via a separate USB cable and is charged using an individual charger (see Figure 5). Up to 96 Analyzers could be connected to one PC.

9.5. Cluster mode

Cluster connection scheme allows for optimizing the number of connections and cables in the workplace by daisy-chaining devices to each other using a built-in connector. 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.

To connect two devices to each other using the built-in connectors, turn the A toggle switch counterclockwise by 180° until it stops. The retracted connector B must be inserted into the corresponding connector of the second Analyzer marked with the CAN letters (see Figure 4 and Figure 6).



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

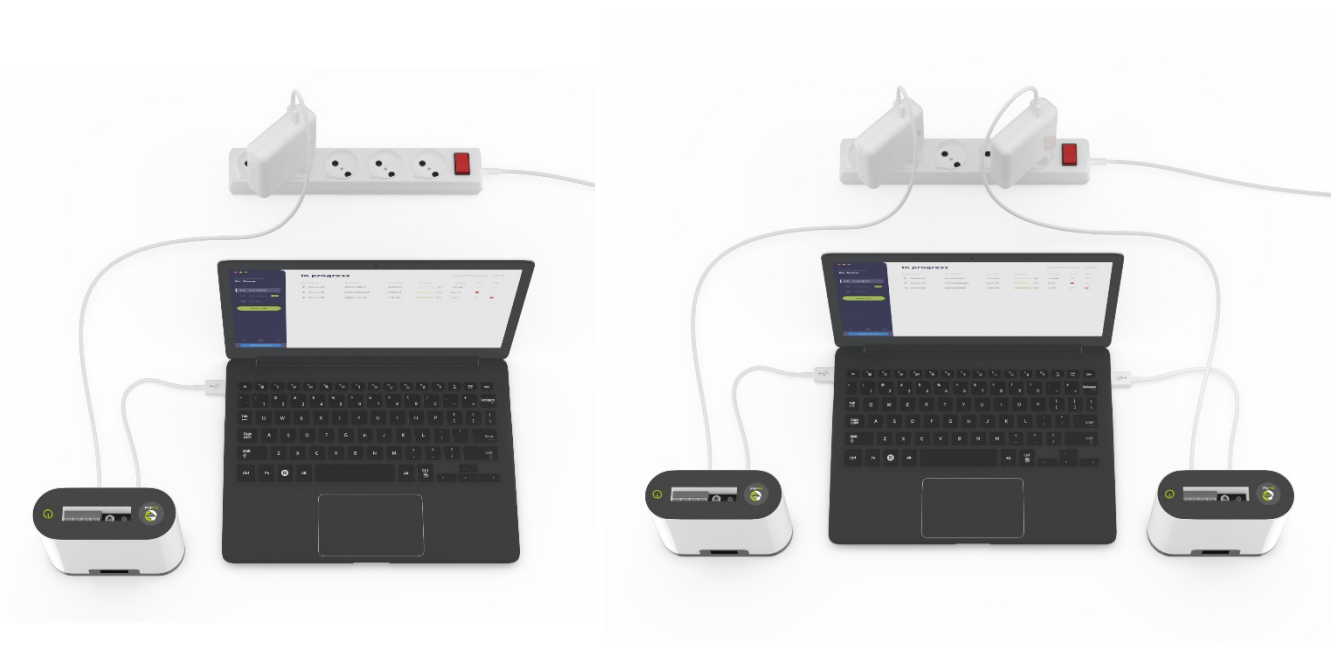


Figure 5. Single Mode Connection Options.



Figure 6. Retractable Connector (on the left). Cluster Mode Connection Option for Connecting Two Devices Via a Connector (on the right).

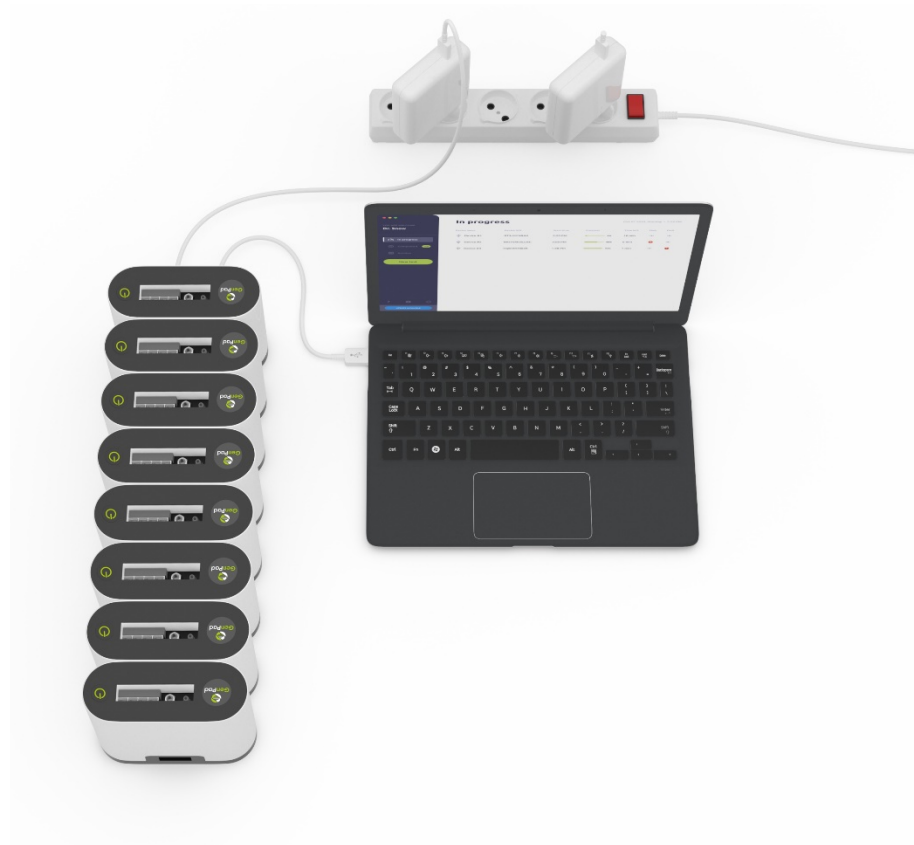


Figure 7. Cluster Consisting of 8 Analyzers.

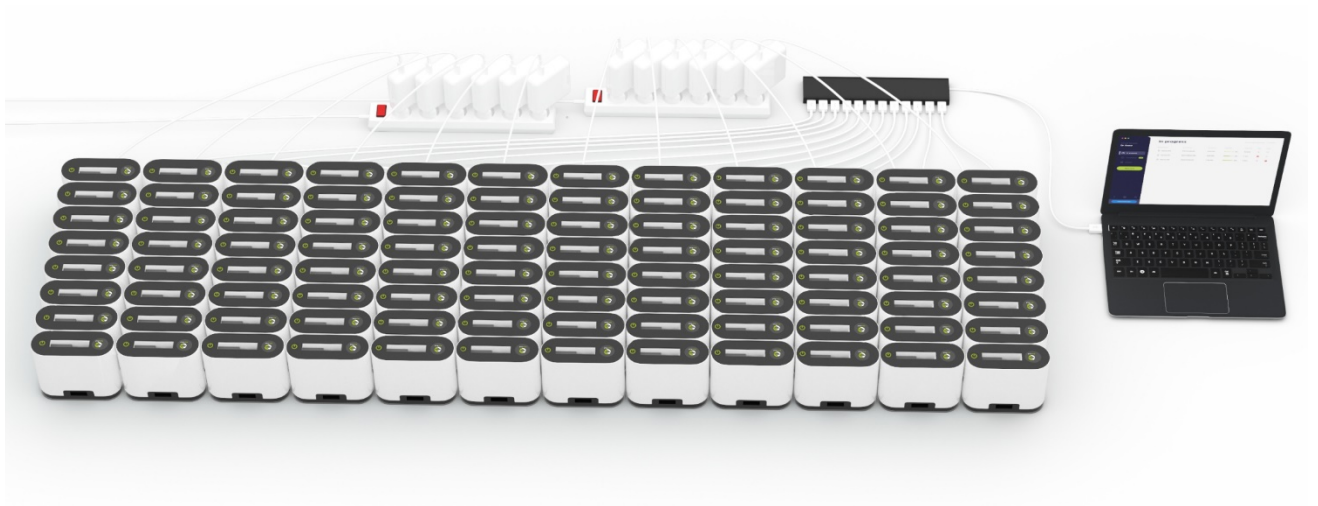


Figure 8. Twelve Clusters Connection

9.6. Software installation to PC

Access to the *GenPad* software is provided free of charge. To download the software, follow the link: <https://miraigenomics.com/downloads.php>

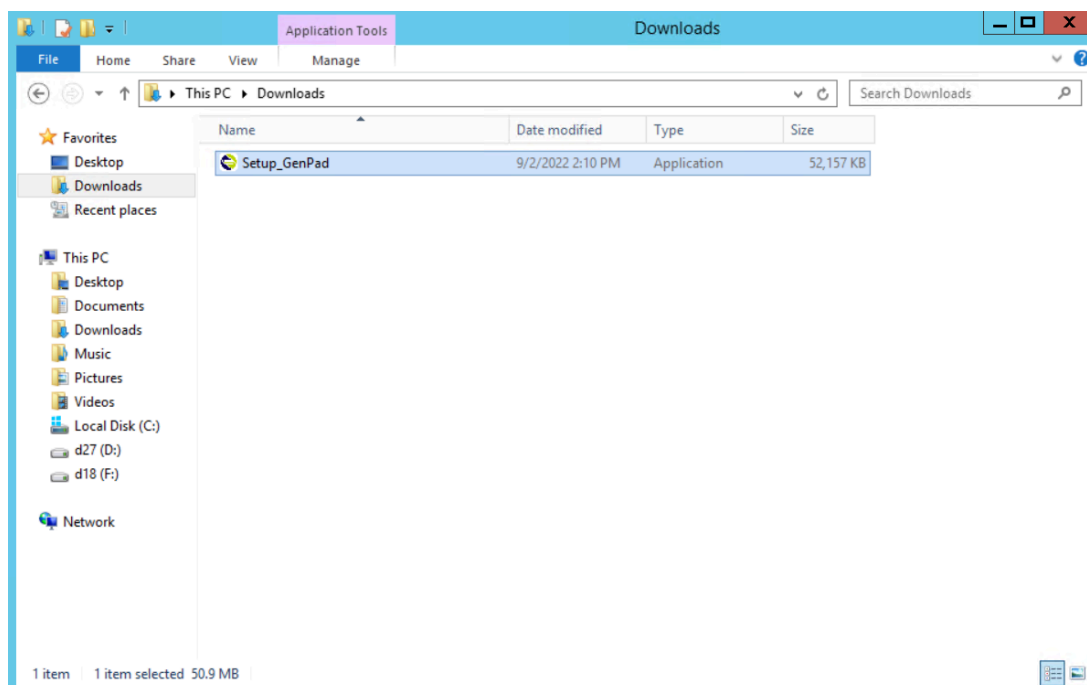


Figure 9. Downloaded Installation File.

Run the *Setup_GenPad.exe* installation file (the file name may differ depending on the current software version).

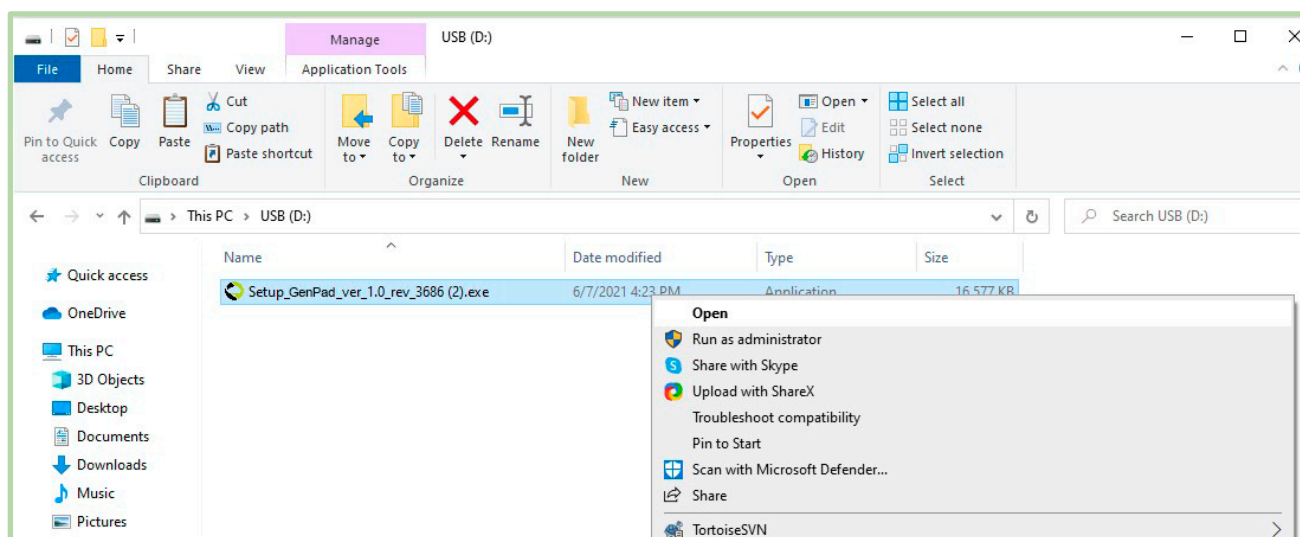


Figure 10. GenPad Software Installation Start.

Follow the prompts during installation. It is recommended not to change the default settings (Figure 11-Figure 14):

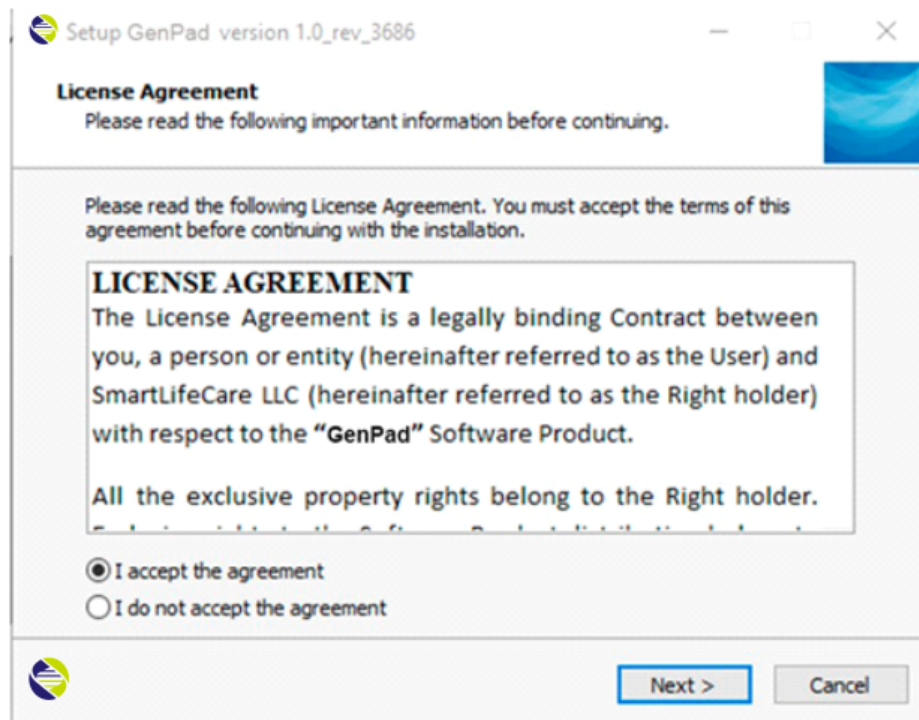


Figure 11. Press Next.

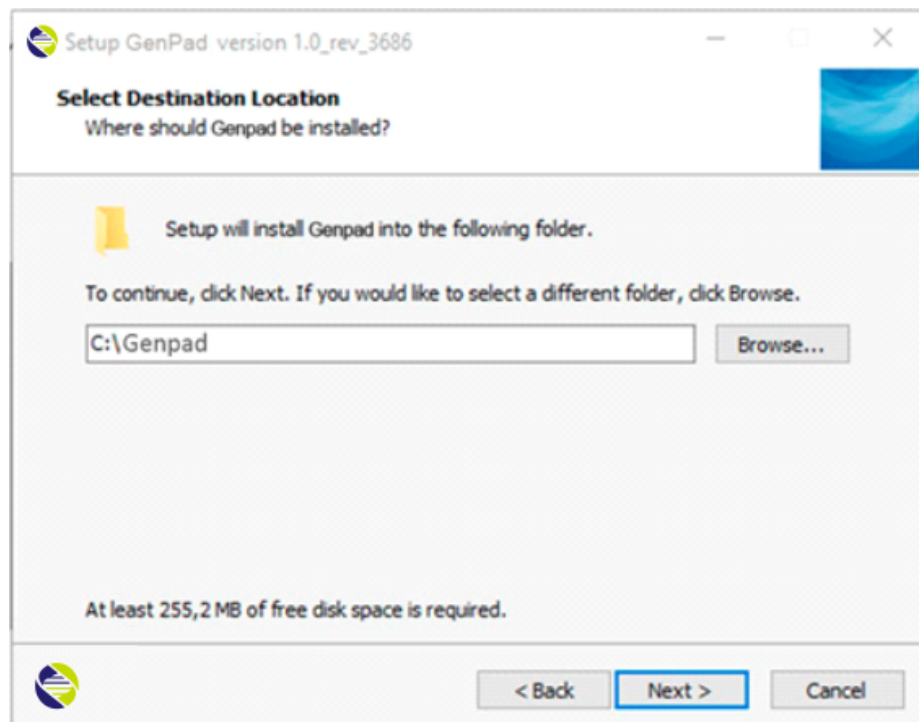


Figure 12. Press Next.

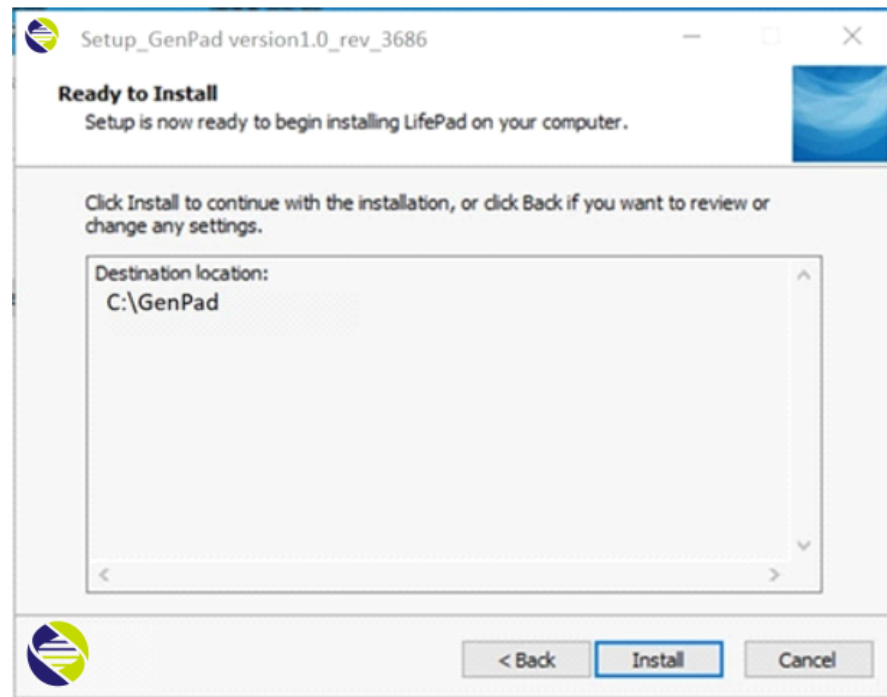


Figure 13. Press Install.

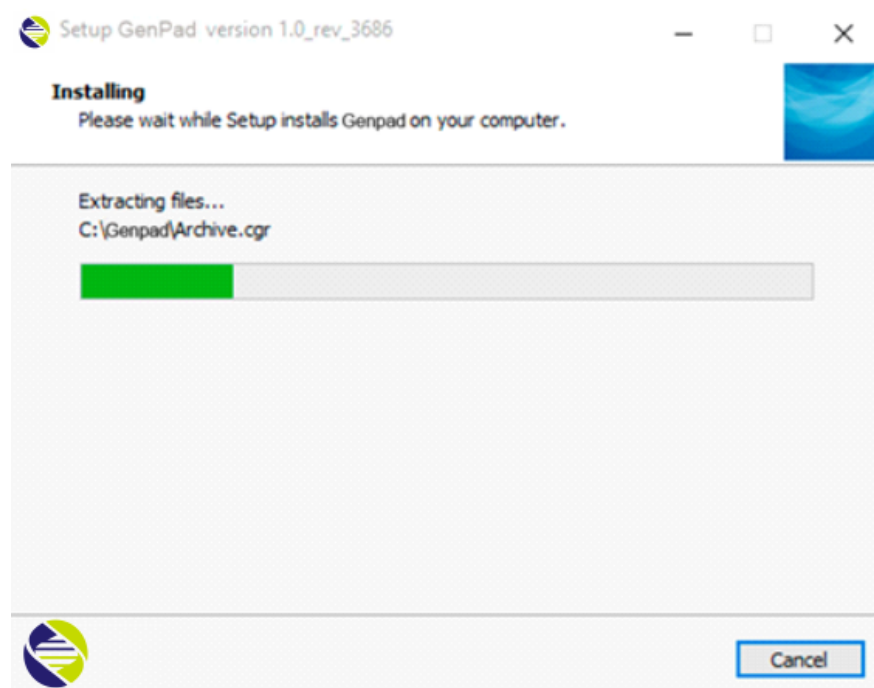


Figure 14. GenPad Software Installation Process.

Upon completion of the installation, close the installer by clicking the *Finish* button (Figure 15).
GenPad Software Installation Completion.):

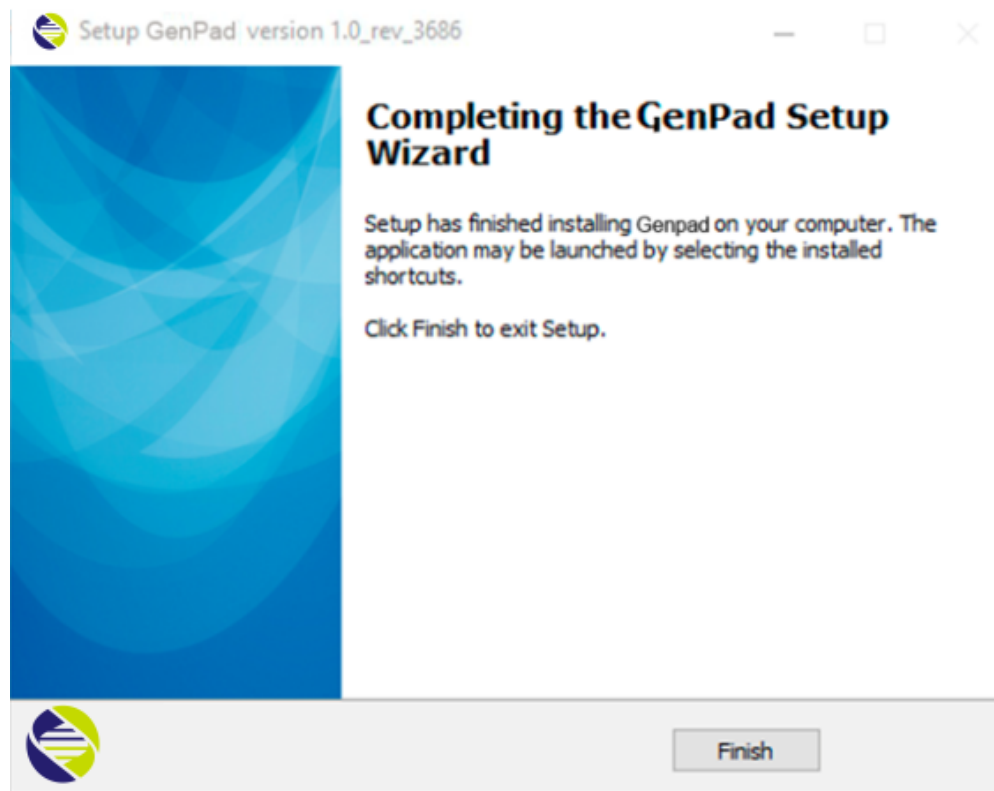


Figure 15. GenPad Software Installation Completion.

9.7. Analyzer turning ON / OFF

To turn on the Analyzer, press the power button on the top panel (Figure 16).



Make sure that the USB cable is connected if after turning on the computer screen displays a message about the lack of connection with the Analyzer.

To turn off the Analyzer:

1. Make sure the Cartridge is removed from the Analyzer.
2. Exit the GenPad program by clicking on the button in the upper left corner.
3. Press and hold the power button for more than 1 second.
4. Disconnect the Analyzer from the charger.
5. Clean and disinfect the accessories used with the Analyzer by wiping the external surfaces with a disinfectant solution. Clean and dry accessories.

If it is necessary to shut down as the test progresses, first stop the test by pressing the Stop button, then remove the cartridge from the Analyzer and turn off the Analyzer by holding down the power button.



Figure 16. Analyzer Power Button.

9.8. Display indication

The Analyzer has a display to show the current status of the instrument (Table 10).

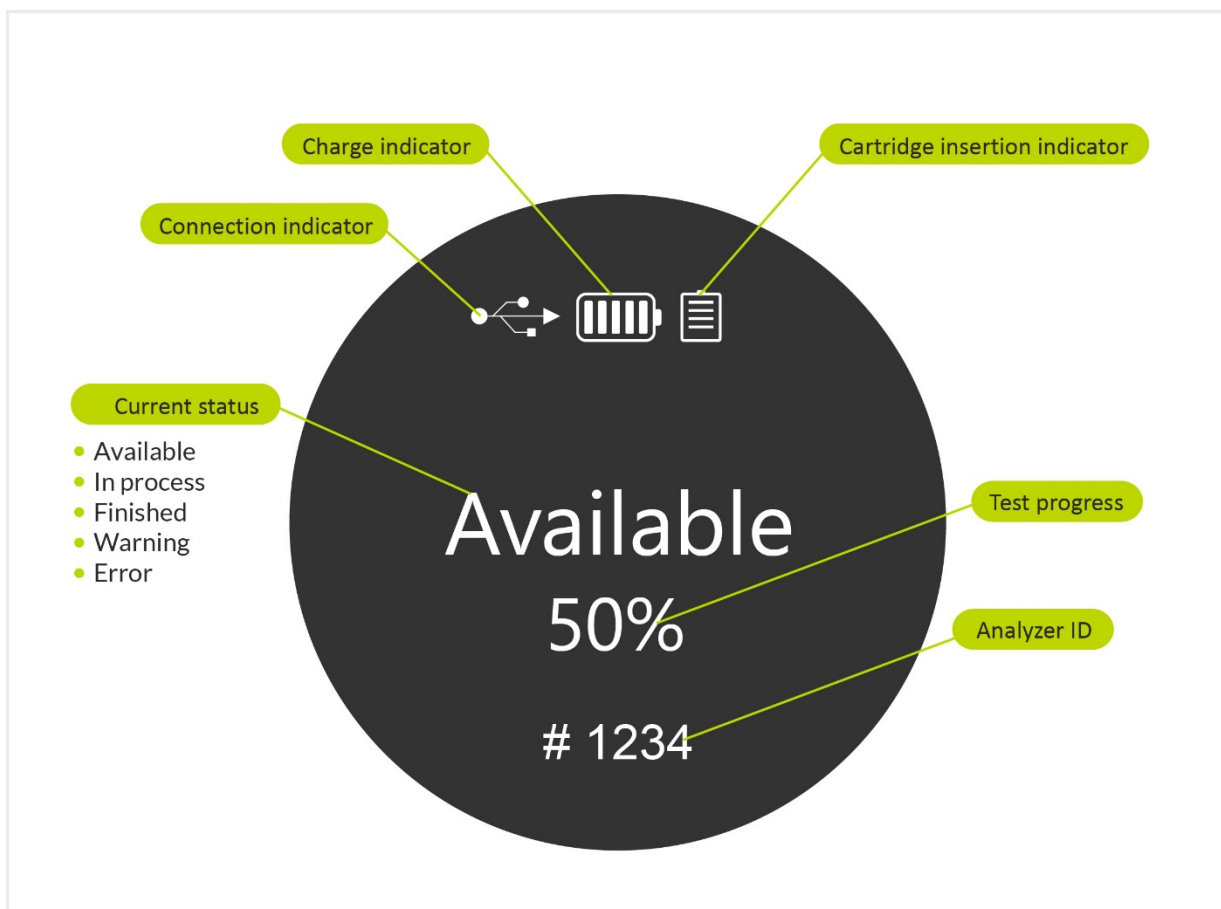


Figure 17. Analyzer Display Appearance.

9.9. Checking device correct installation and readiness for safe operation




Figure 18. Test Cartridge Correct Positioning.



Figure 19. Test Cartridge Incorrect Positioning.

To check the Analyzer is installed correctly and ready for work:

- Make sure that the 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 *GenPad* software does not display a warning message on the display about the incorrect installation of the Cartridge in the device (see Figure 20 and Figure 21).
- 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 Figure 25).
- Make sure there is no warning signs () on the display showing the Analyzer incorrect position.

Turn on the PC and run the *GenPad* software.

Manually enter the requested data in the *GenPad* software, as shown in Figure 26.

Make sure the Cartridge tear-off sticker is completely removed and the *GenPad* software does not display a warning message on (Figure 22).

Start the test (please refer to the *Test Start* section for details).

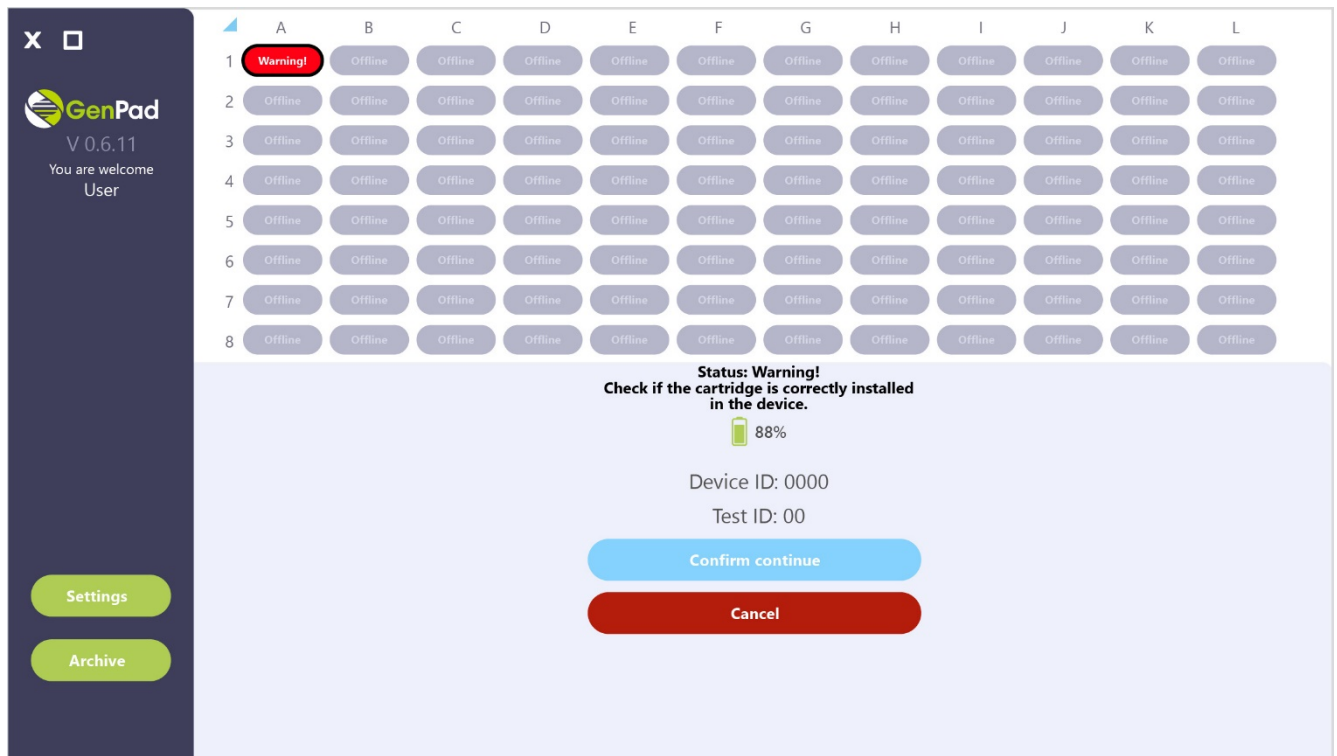


Figure 20. *GenPad* Software Informing about the Cartridge Incorrect Installation When Using a PC.

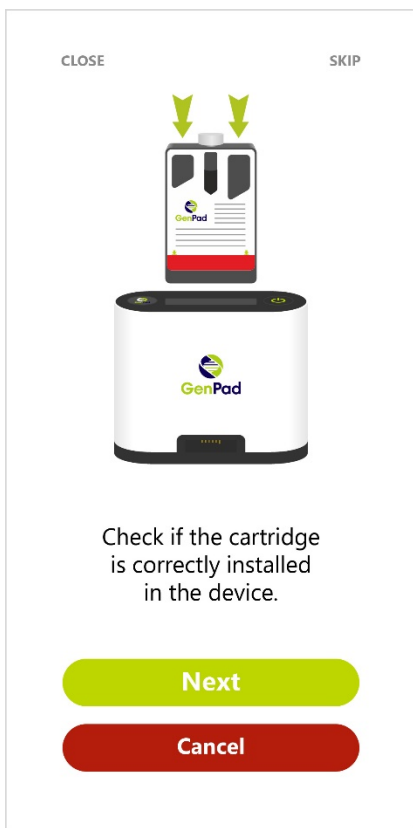


Figure 21. GenPad Software Informing about the Cartridge Incorrect Installation When Using a Smartphone.

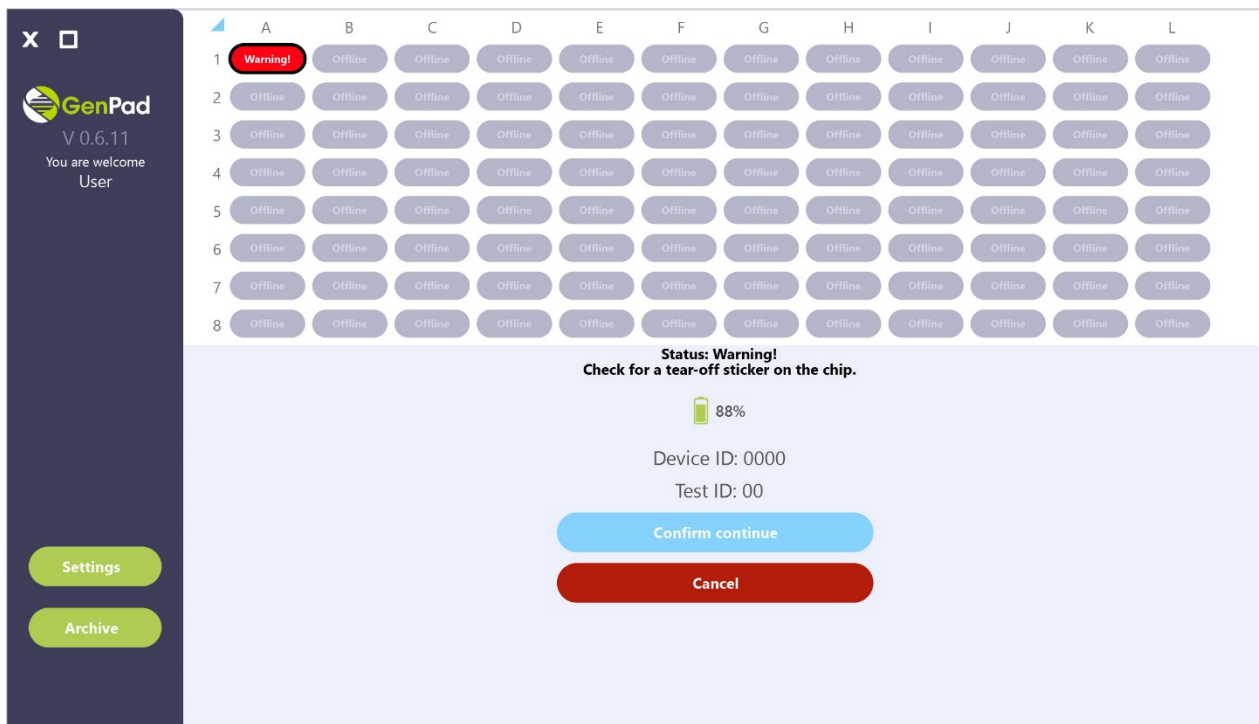


Figure 22. . GenPad Software Informing about the Cartridge Tear-off Sticker Presence When Using a PC.

10. CONTROL METHOD ON A PC

In case of the Analyzer incorrect operation, the **INCORRECT RESULT** status will appear in the main window of the *GenPad* software (Figure 23) and the Analyzer will not start the test. The device has its own algorithm for faults diagnosing and in case of faults, the **ERROR** status will appear on the display (see Figure 24) and in the operating window (see Figure 27).

The operation of the device as part of the analytical system is considered correct if the fluorescence accumulation curve for the positive control sample has a characteristic "sigmoid" shape and crosses the threshold line. The value of the reaction time at the moment of exit should not exceed 38 minutes, the amplitude of the signal does not matter (see Figure 42). If the reaction time at the time of release of the positive control sample exceeds 38 minutes, the result is considered doubtful. In this case, stop using the product and contact an authorized service center.

The fluorescence accumulation curve for the internal control sample (IPC) should have a characteristic "sigmoid" shape and cross the threshold line. The value of the reaction time at the time of exit should be from the 15 to the 35 minutes, the amplitude of the signal does not matter. If the reaction time at the time of release of the internal control sample exceeds 35 minutes, the result is considered invalid. The sample should be retested. If you receive an invalid result again, stop using the product and contact an authorized service center (Table 10).

In the event of problems that are not listed in this manual, please contact an authorized service center.

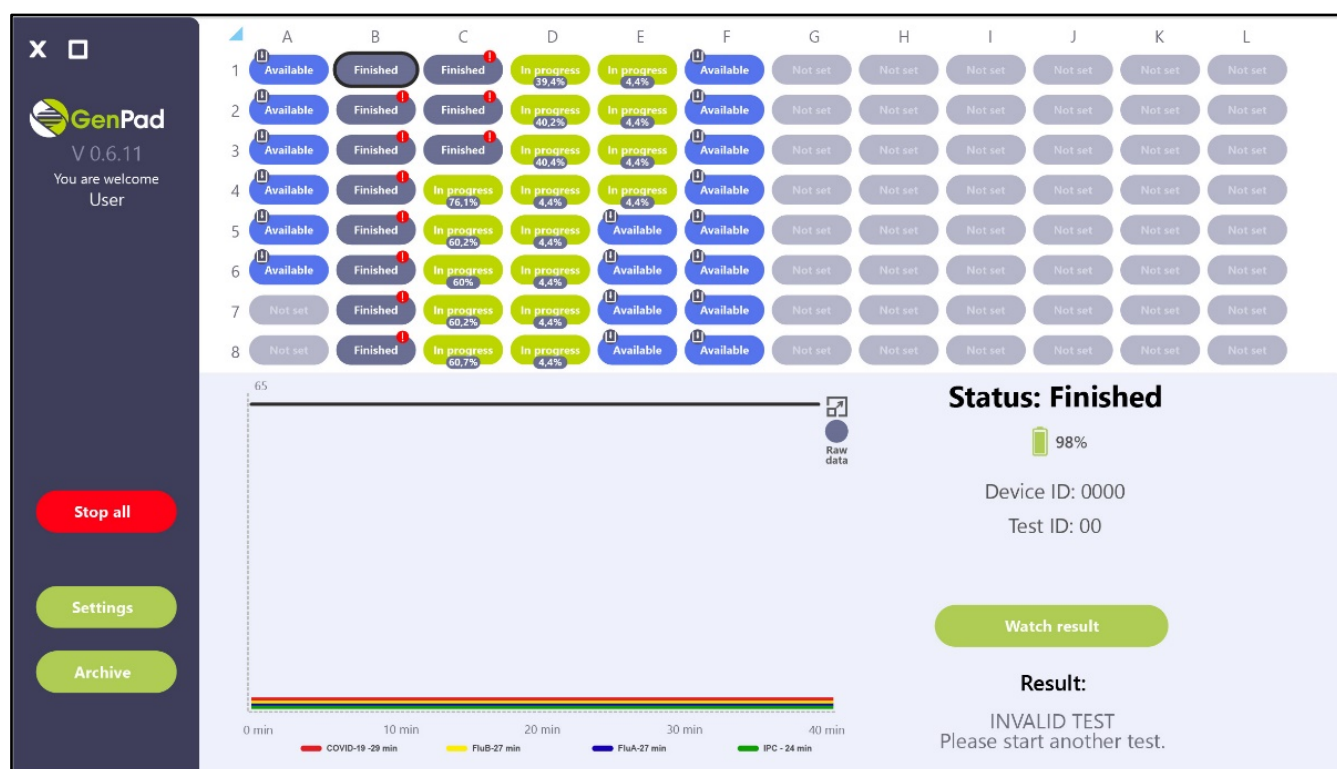


Figure 23. Genpad Software Main Window Showing **INCORRECT RESULT** Status.



Figure 24. ERROR Analyzer Display.


11. ANALYZER OPERATION

11.1. Getting started

Connect the Analyzer to the PC using the cable, turn on the Analyzer and the PC (Figure 25).



Figure 25. Analyzer Connection Scheme.

Launch the *GenPad* software by double-clicking the GenPad software shortcut () located on the desktop.

11.2. Program entry

The *GenPad* 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 (Figure 26). When re-entering the program, enter the username and password used for the user registration and click on the *Log In* button.

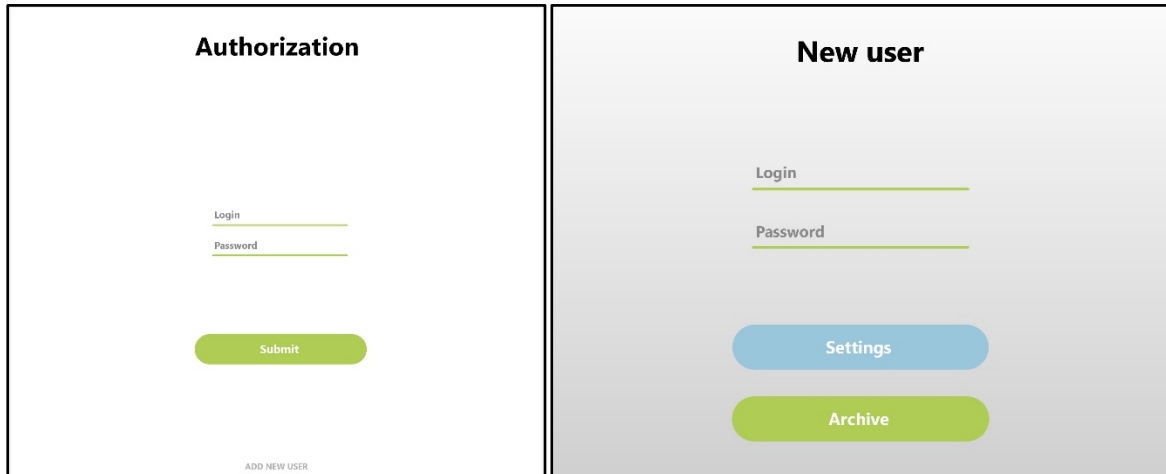


Figure 26. Log In and Password Entry Window. New User Creation Window.

11.3. Main window

The program main window is shown in Figure 27. The main tabs are displayed on the main program window left side:

<i>Archive</i>	Displaying information about archived tests.
<i>Setup</i>	Test run settings.

The following buttons are available in the lower right part of the main window after certain conditions are met:

<i>Start All</i>	Start tests on all devices with the <i>READY</i> status.
<i>Stop All</i>	Abort tests on all devices with the <i>IN PROGRESS</i> status.

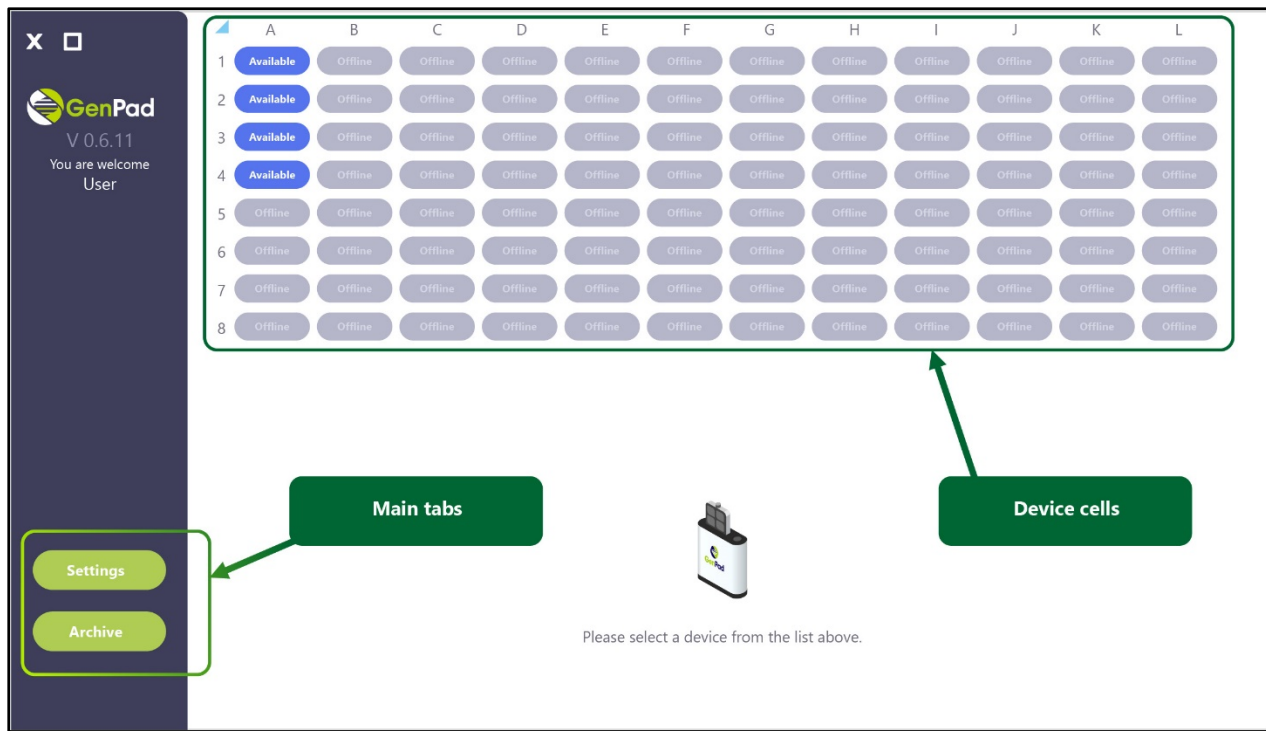


Figure 27. GenPad Software Main Window.

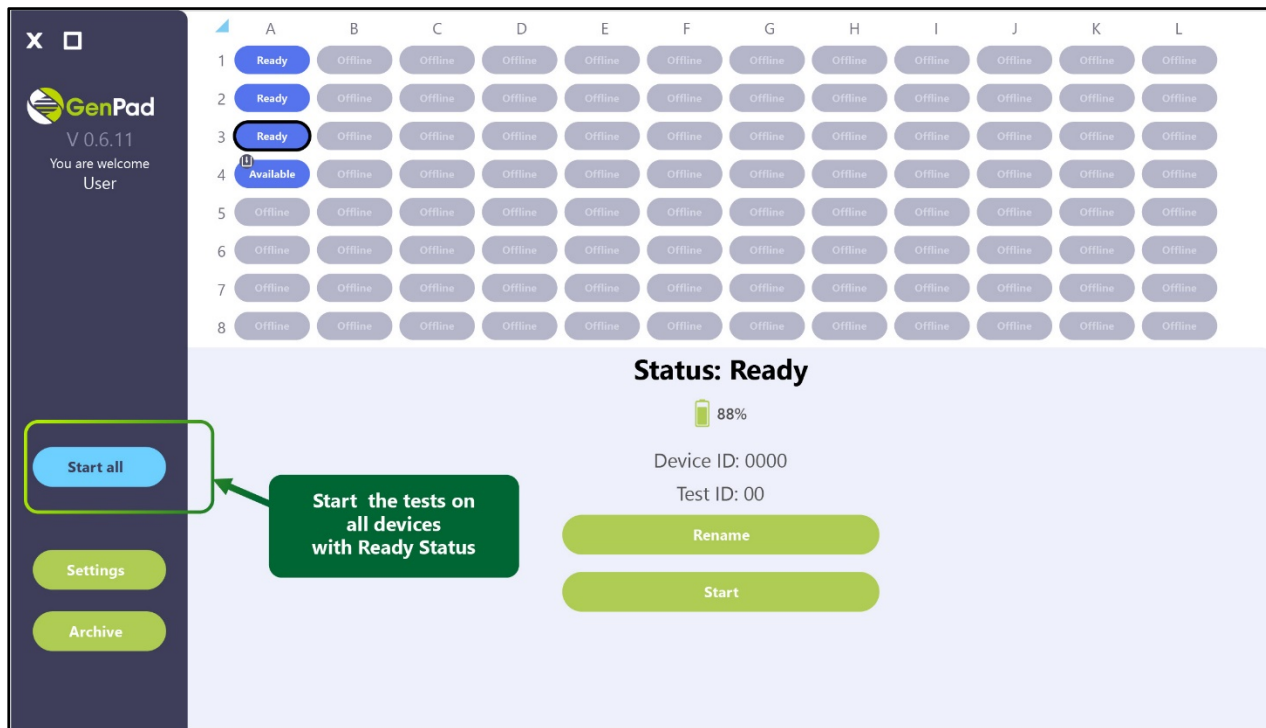


Figure 28. Button To Run Tests on Multiple devices.

11.4. Test start

Checking the readiness of the Analyzer for testing is carried out automatically every time the device is turned on, while temperature regimes are checked for compliance with permissible values.

The Analyzer does not require editing the heating program, selecting detection channels and is optimized for working with *Test Kit for SARS-CoV-2 and Influenza A/B RNA PCR Detection in Biological Material* and *Test Kit for SARS-CoV-2 RNA Detection in Biological Material Using PCR Method* (both K.K. Mirai Genomics).

The amplification is carried out at a set temperature, the registration of the product occurs at excitation/detection wavelengths of 525 nm and 500 nm, respectively.

To prepare for test, connect the Analyzer to the computer via USB and turn it on. The connected Analyzer will be displayed in one of the device cells in the main program window (see Figure 29). When clicking on a cell with a device in the lower part of the main program window, information about the connected device is displayed (see Table 10):

AVAILABLE STATUS

Selected Analyzer status.

GenPad ID

Analyzer serial number.

Test ID

Cartridge (patient) identifier.

Error

Absence/present of the Analyzer run-time errors.

The device battery level

Symbol showing the Cartridge presence/absence in the device

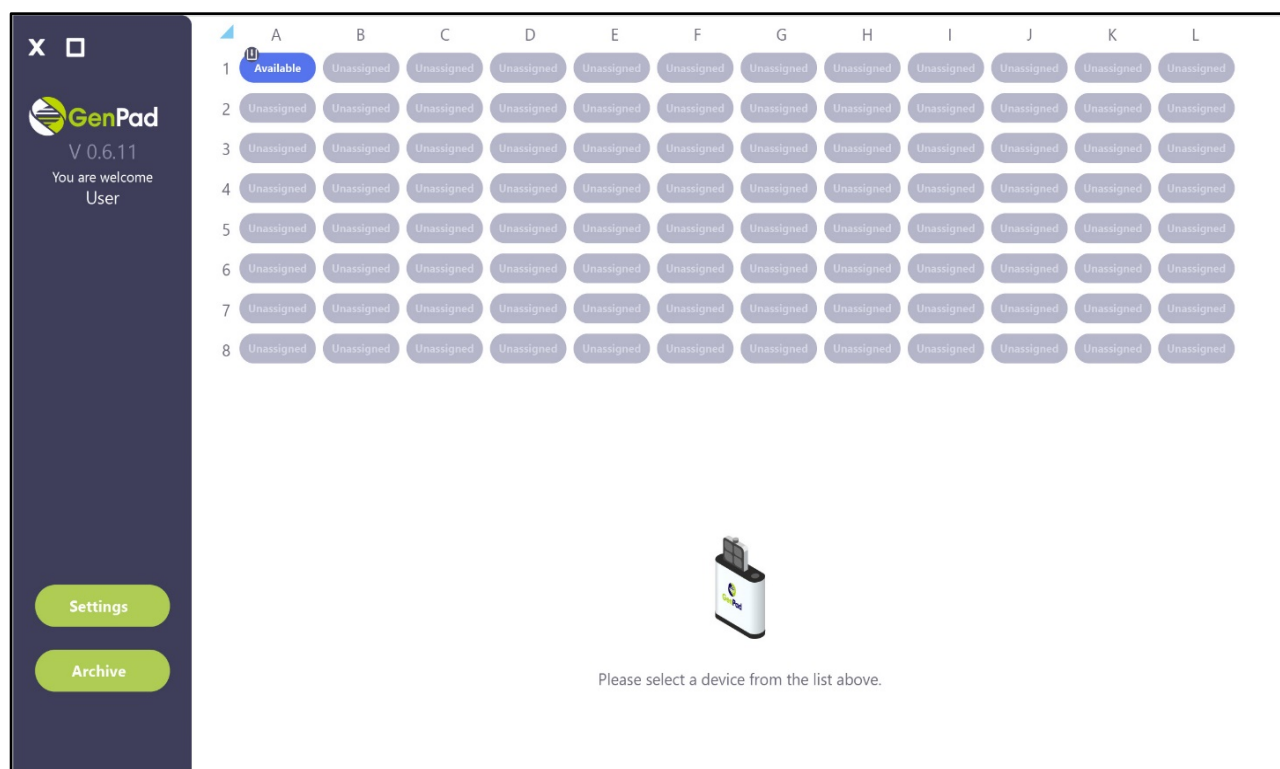


Figure 29. (a) Connected Device in One of the Cells and the Analyzer Information Display.

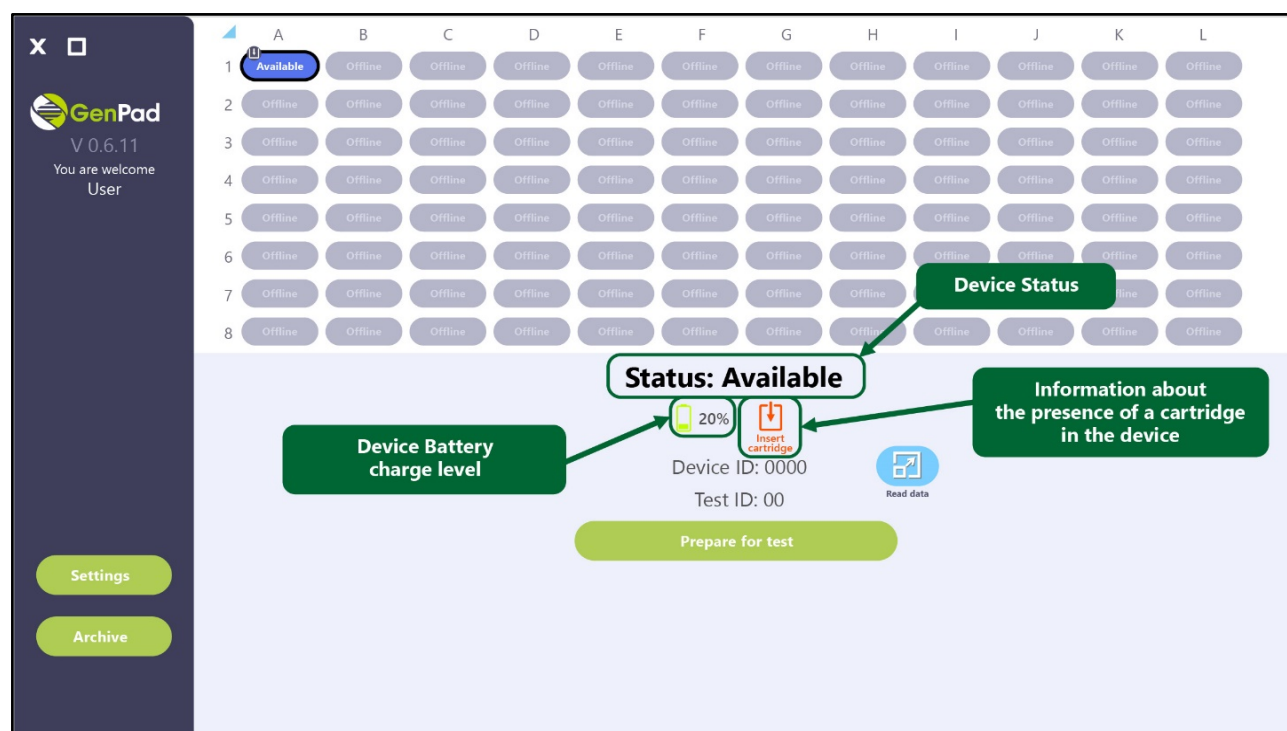


Figure 29. (b) Connected Device in One of the Cells and the Analyzer Information Display.

The connected Analyzer can have one of the statuses described in Table 10. The Analyzer status is shown on the display and in the device cell in the main program window (see Figure 17).

Table 10. Analyzer statuses

Device status	Description
INITIALIZATION	The Analyzer initialization after its detection.
AVAILABLE	The Analyzer is ready for use.
READY	The Analyzer is connected to the software. The Cartridge is inserted into the Analyzer. The Analyzer is ready to run the test.
IN PROGRESS	Test is running.
FINISHED	The test is over. The Cartridge is in the Analyzer.
ERROR	An error was detected during the Analyzer initialization/when checking the Cartridge/ during the Analyzer operation.
WARNING	During the test, the parameters turned out to be different from the calculated ones. Check whether all the steps to prepare the cartridge for work were done correctly.
FIRMWARE UPDATE	The Analyzer firmware updating.

When the Analyzer is turned on, its initialization takes 5-10 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 Cartridge with the specimen into the corresponding Analyzer. The Analyzer checks the Cartridge for its expiry date, the Cartridge and the Analyzer versions matching, and the test start mark absence. If the Cartridge meets the criteria, the Analyzer status changes to **READY**.

Click on the *Prepare for Test* button at the bottom of the main program window, enter the four-digit code indicated on the cartridge, or scan the QR code, check the test parameters, enter the cartridge (patient) ID manually, or using a barcode scanner. After saving, the name of the button will change to *Rename*.

To start the test, click on the *Start* button, displayed on the at the bottom of the main program window (Figure 28). After pressing the *Start* button, the Analyzer status will change to **IN PROGRESS**.

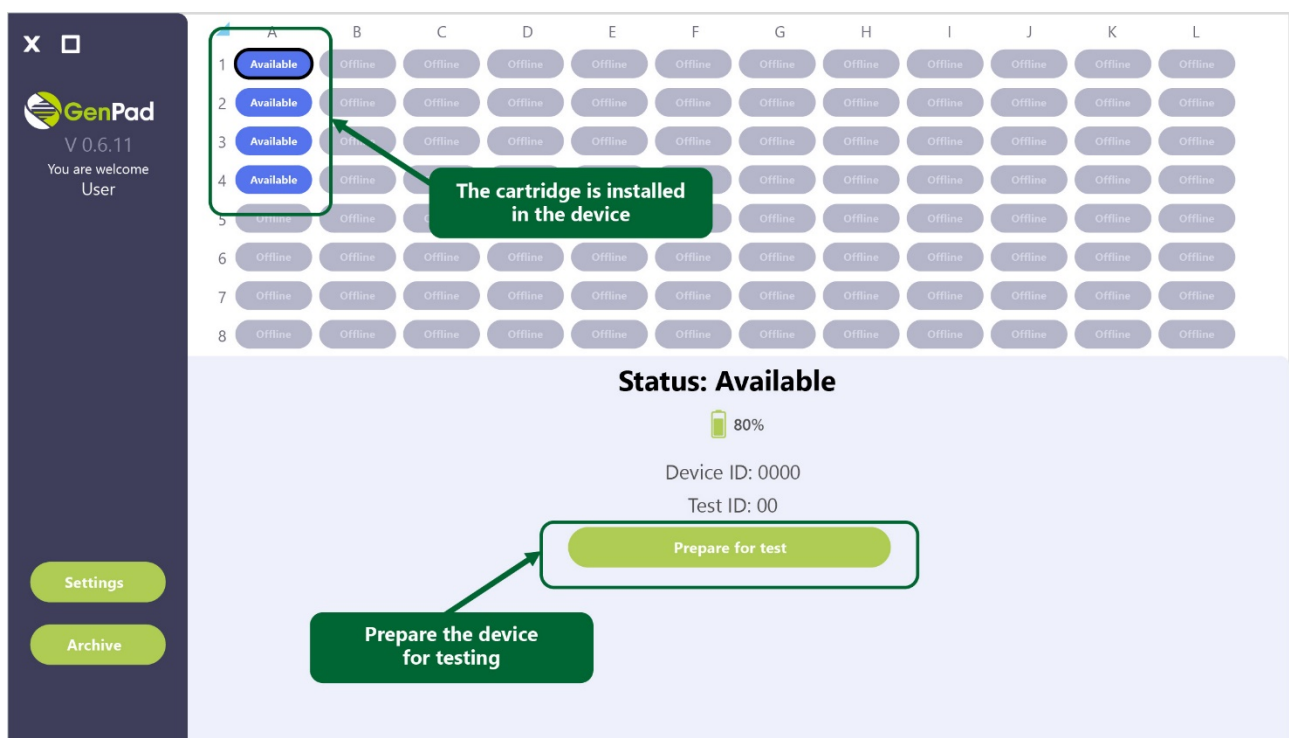


Figure 30. (a) Analyzer is Ready to Test.

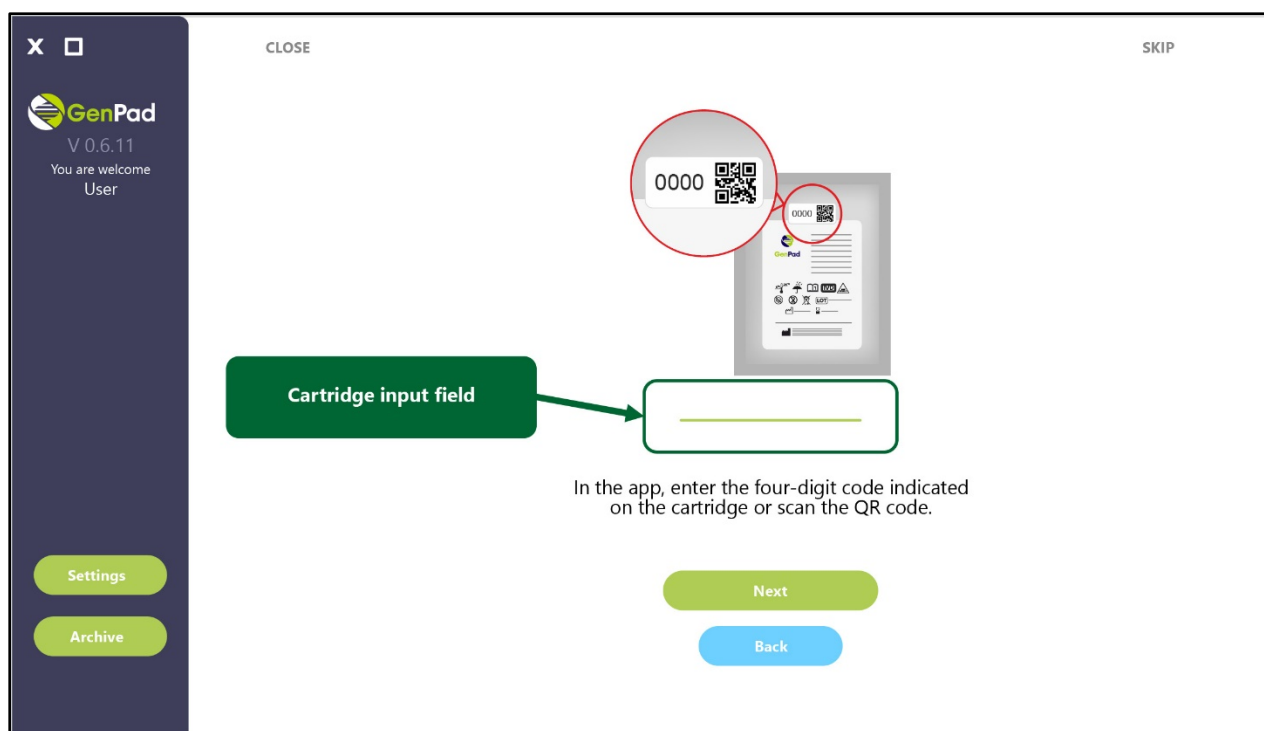


Figure 30. (b) Analyzer is Ready to Test.

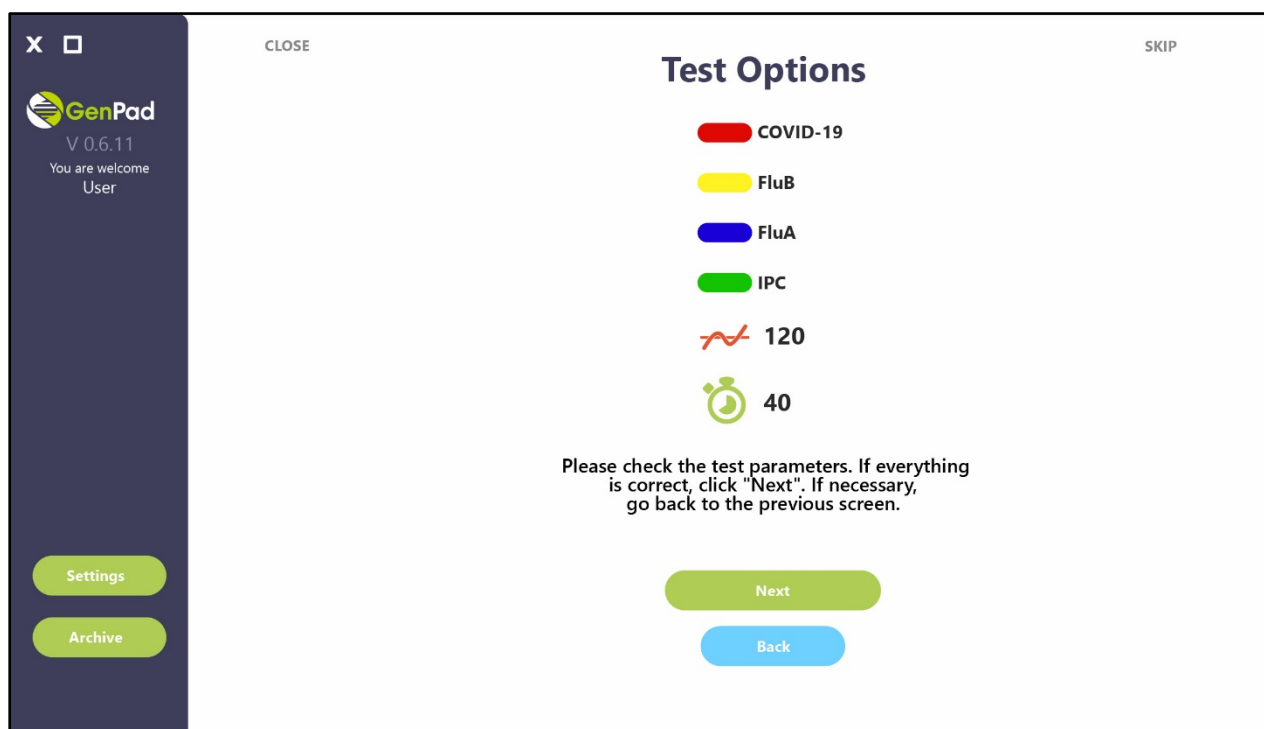


Figure 30. (c) Analyzer is Ready to Test.

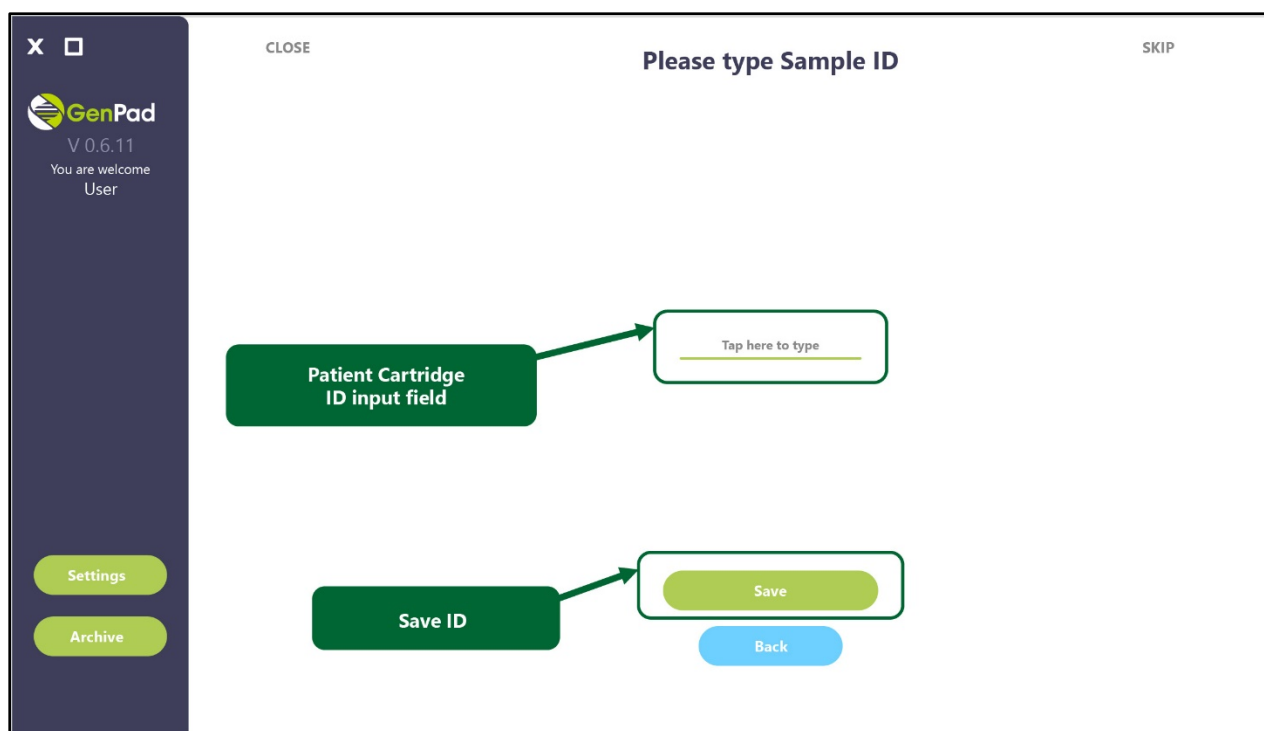


Figure 30. (d) Analyzer is Ready to Test.

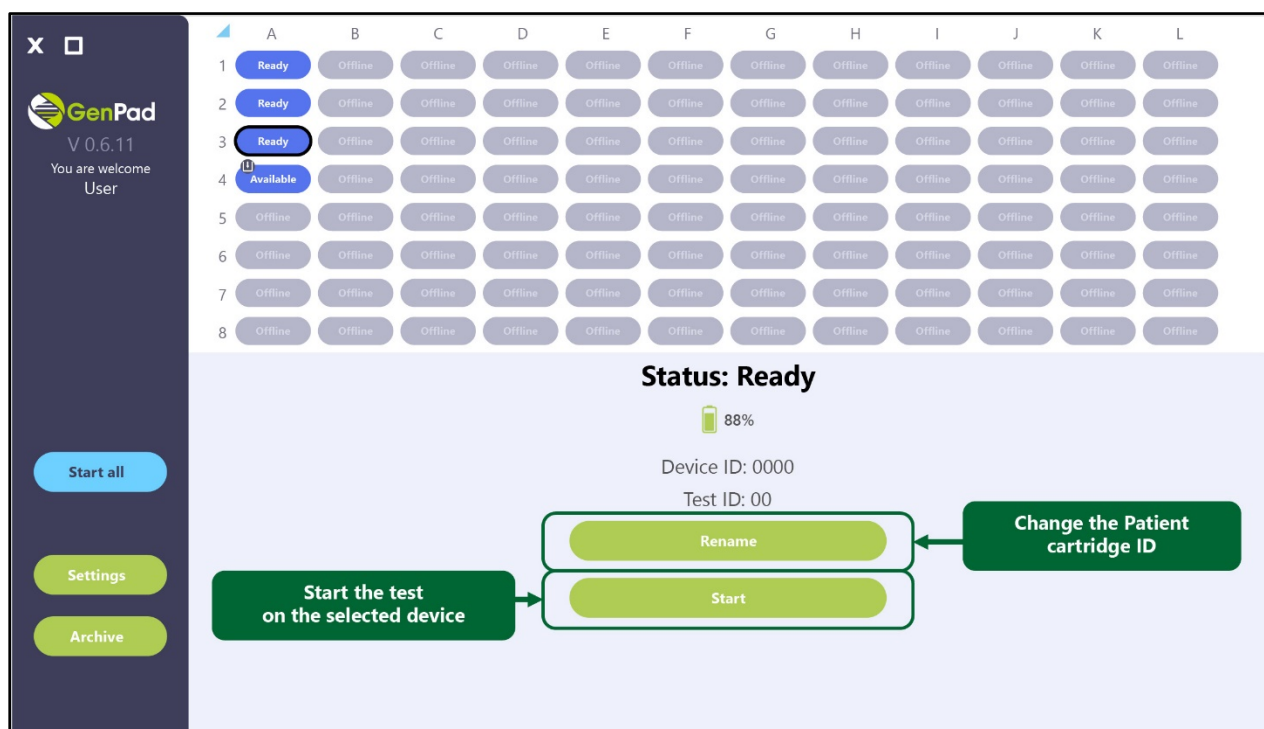


Figure 30. (e) Analyzer is Ready to Test.

11.5. Running tests information

After starting the test, the bottom part of the main program window displays information about the progress of the test and the time elapsed since the test start (see Figure 31). As fluorescence data is received from the Analyzer, a graph of the fluorescence signal is displayed at the bottom of the main

application window (see Figure 32 and Figure 33). 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 Cartridge is considered **positive** if the signal graph of this disease crosses the threshold value.

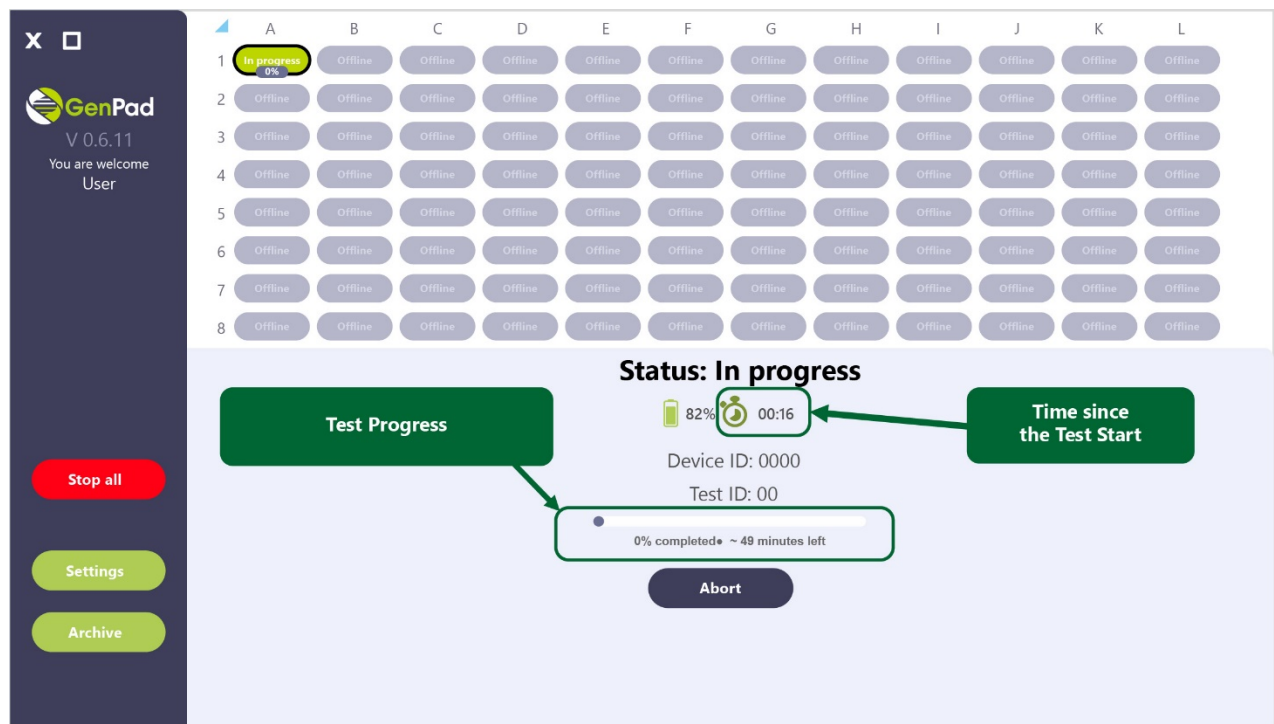


Figure 31. Test Progress Information.

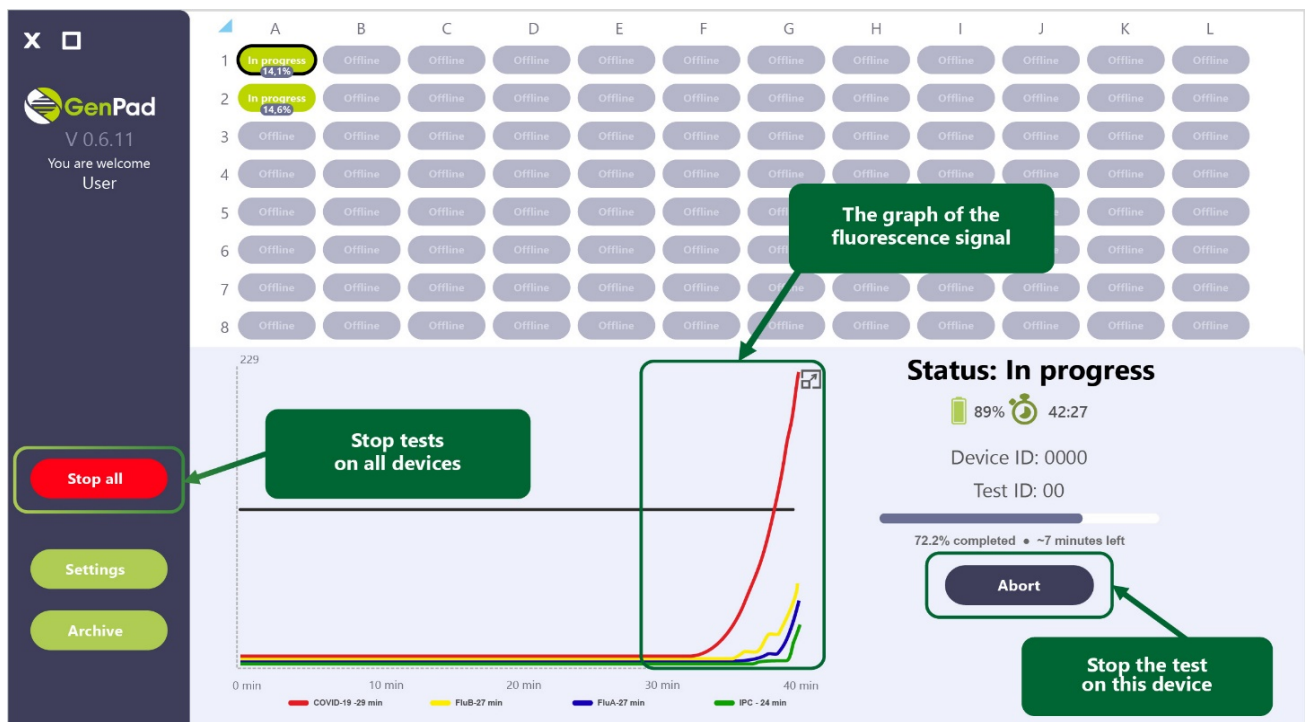


Figure 32. Fluorescence Signal Graph During Testing.

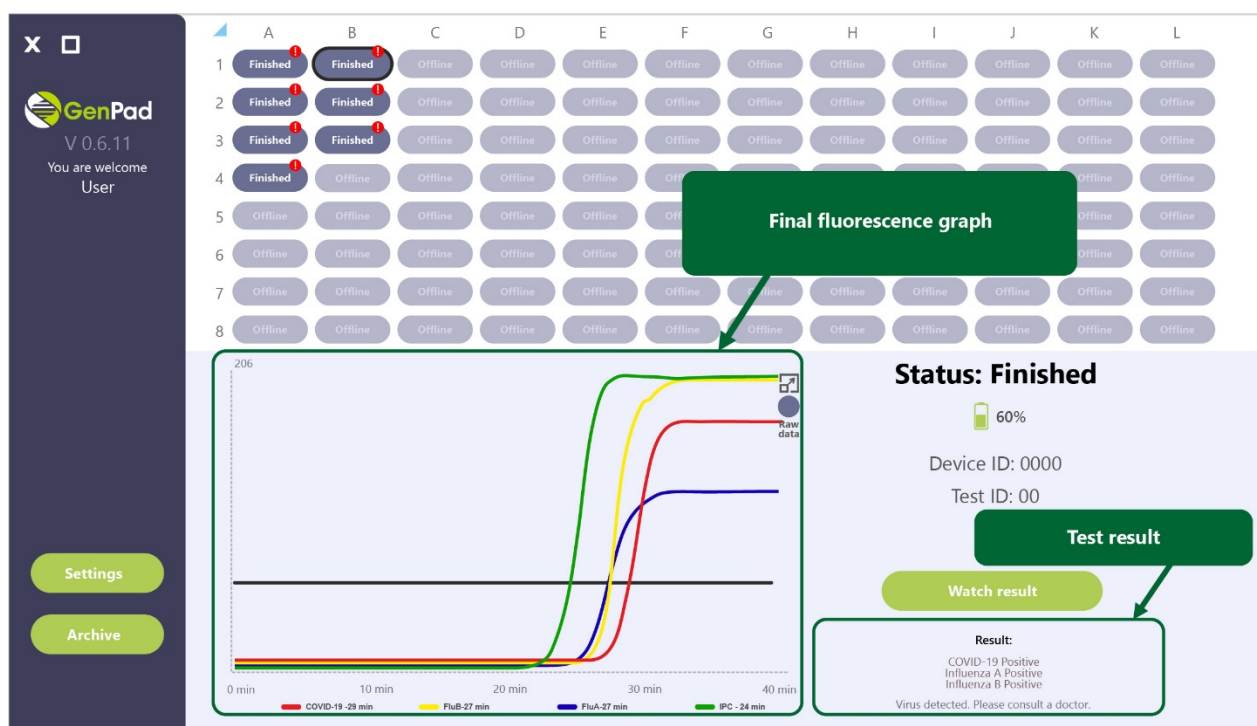


Figure 33. Plotting the Fluorescence Signal.

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.

11.6. 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.
GenPad ID	Serial number of the device used for the test.
Sample barcode	Cartridge serial number.
Threshold	Cutoff line for registering the test result.
Cq	Results of the sample exit time by channels (IPC, Covid, FluA, FluB).
Status	Device status.

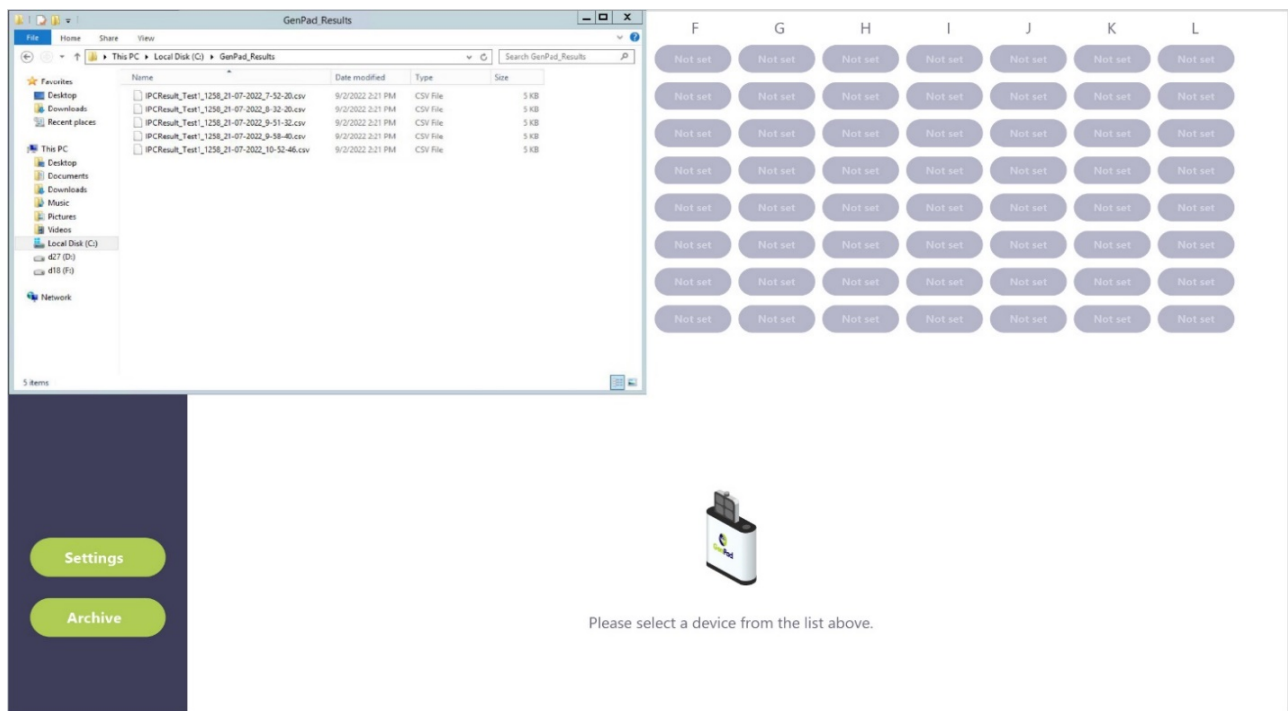


Figure 34 (a). Completed Test in the Archive Tab.

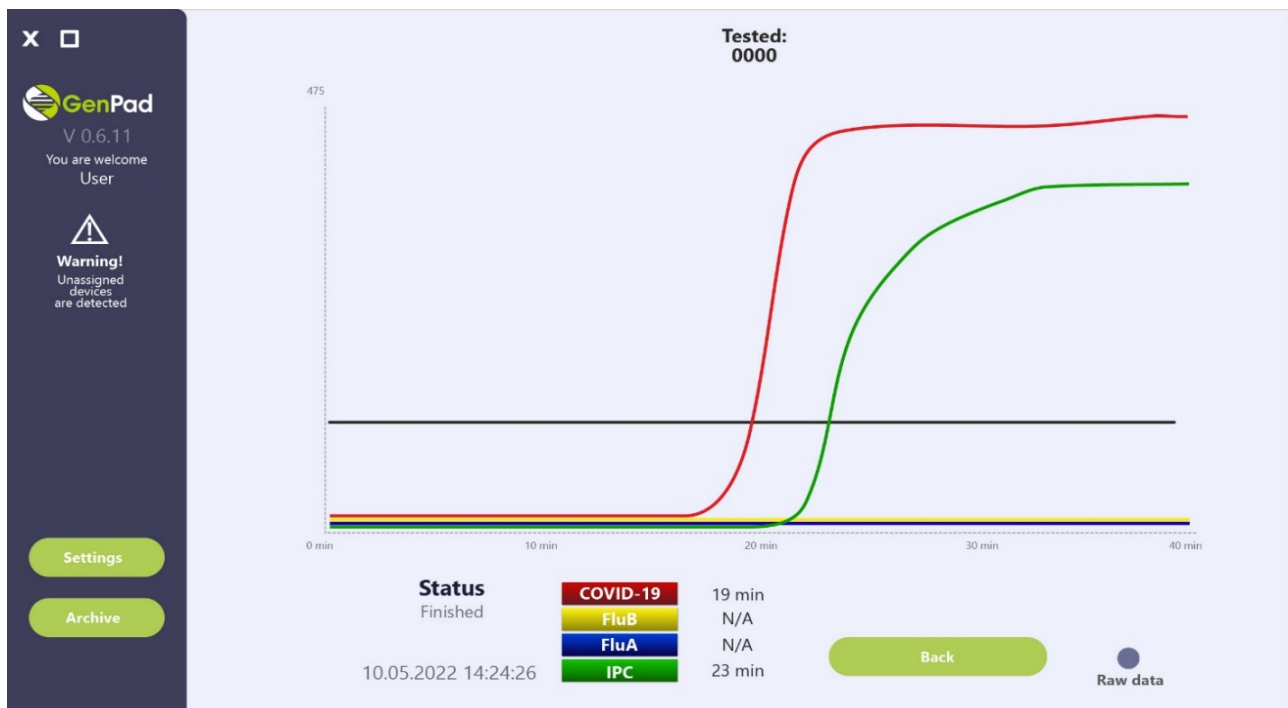


Figure 34. (b). Completed Test in the Archive Tab.

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).

11.7. Setup tab

The following settings are available in the *Setup* tab (Figure 35):

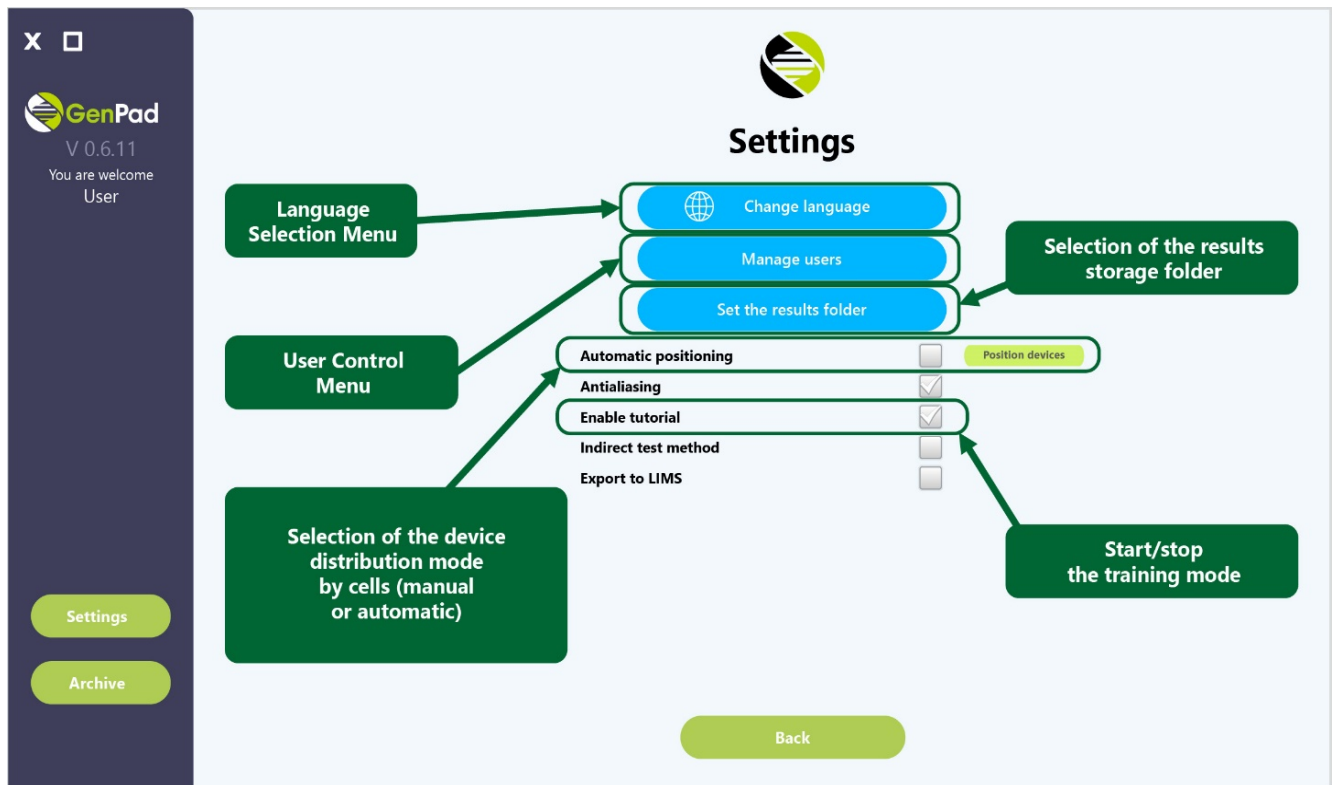


Figure 35. Setup Tab

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) (Figure). 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.

To save changes in the "Settings" tab, you need to click the "Back" button. To save changes in the *Setup* tab, click on the *Back* button.

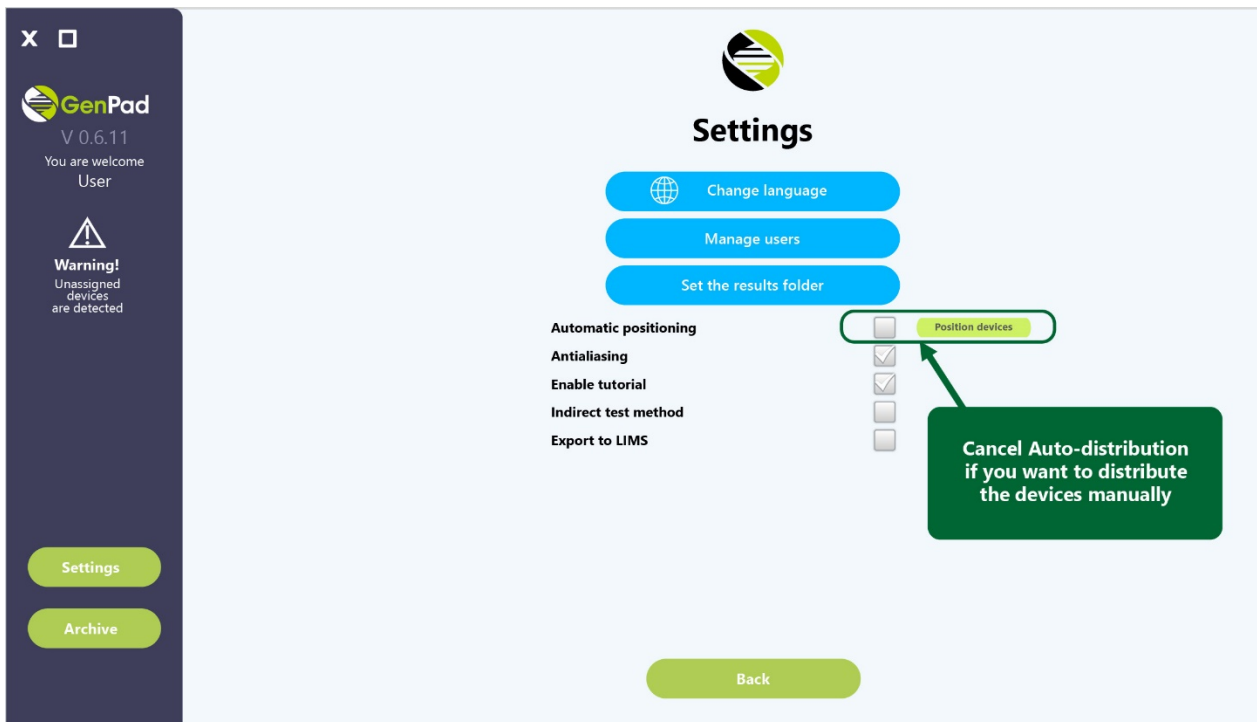


Figure 36. (a) Cells Assignment for Connected Devices in the Set Position Tab.

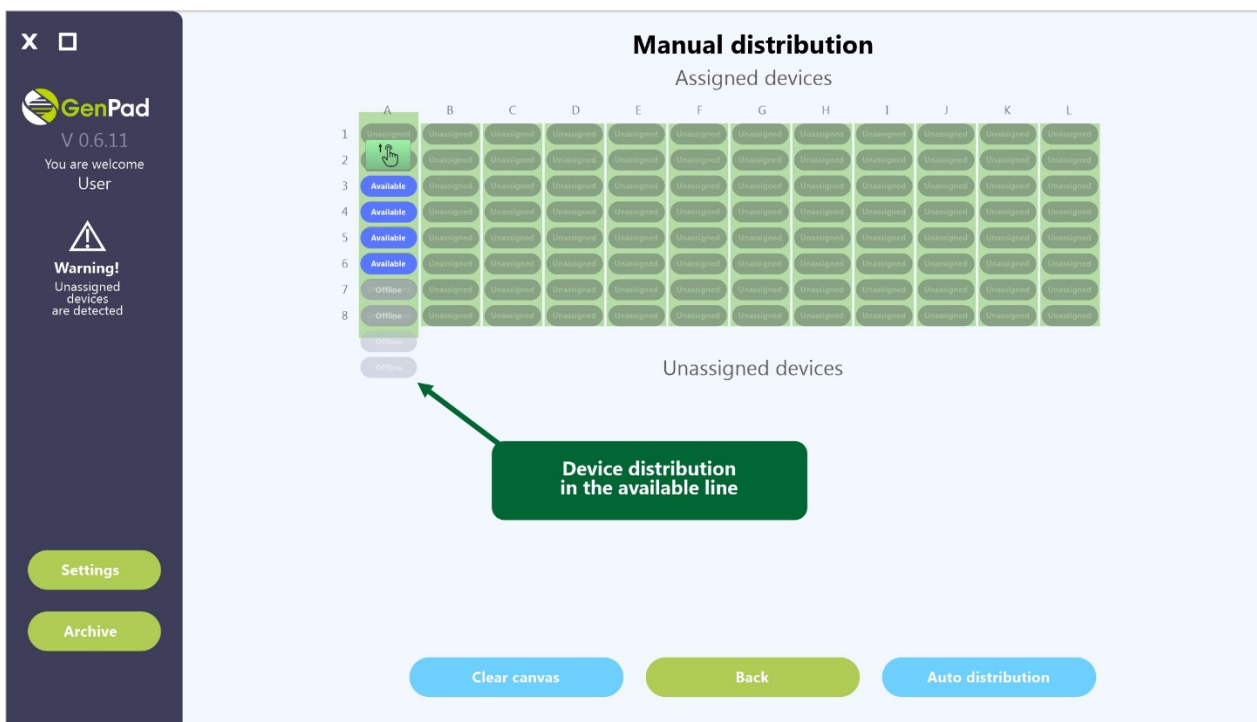


Figure 36. (b) Cells Assignment for Connected Devices in the Set Position Tab

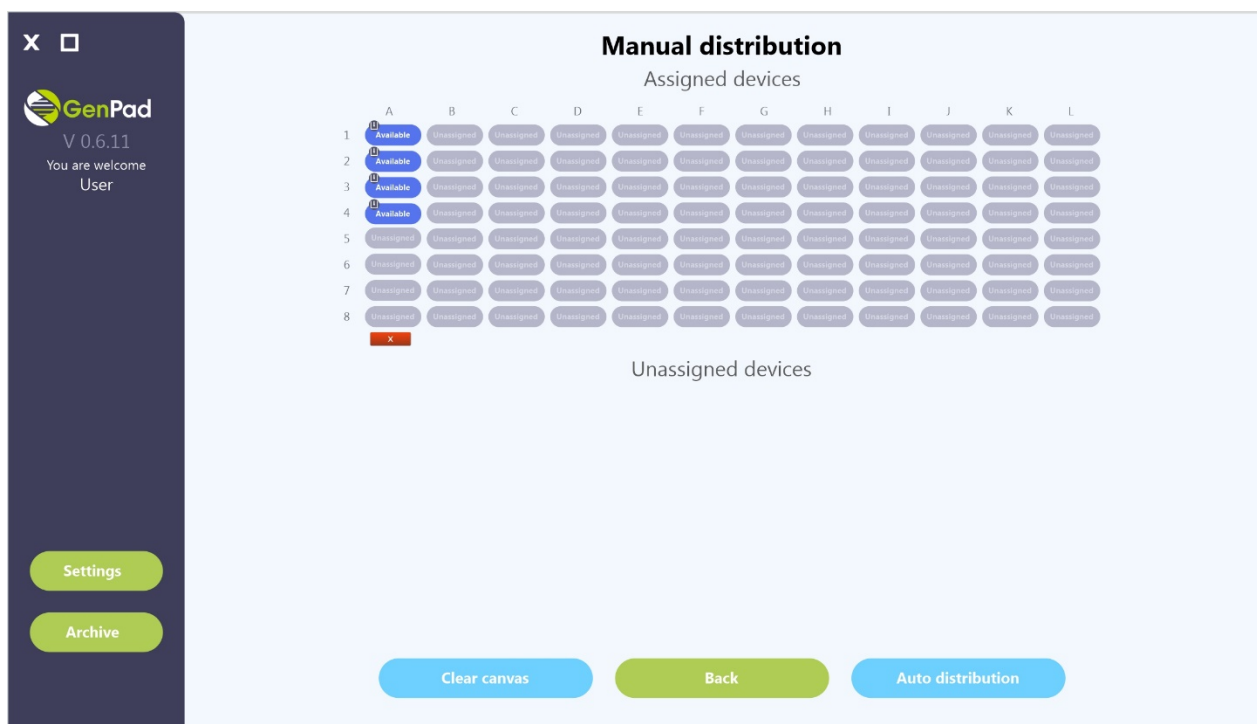


Figure 36. (c) Cells Assignment for Connected Devices in the Set Position Tab.

11.8. Cluster mode operation

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

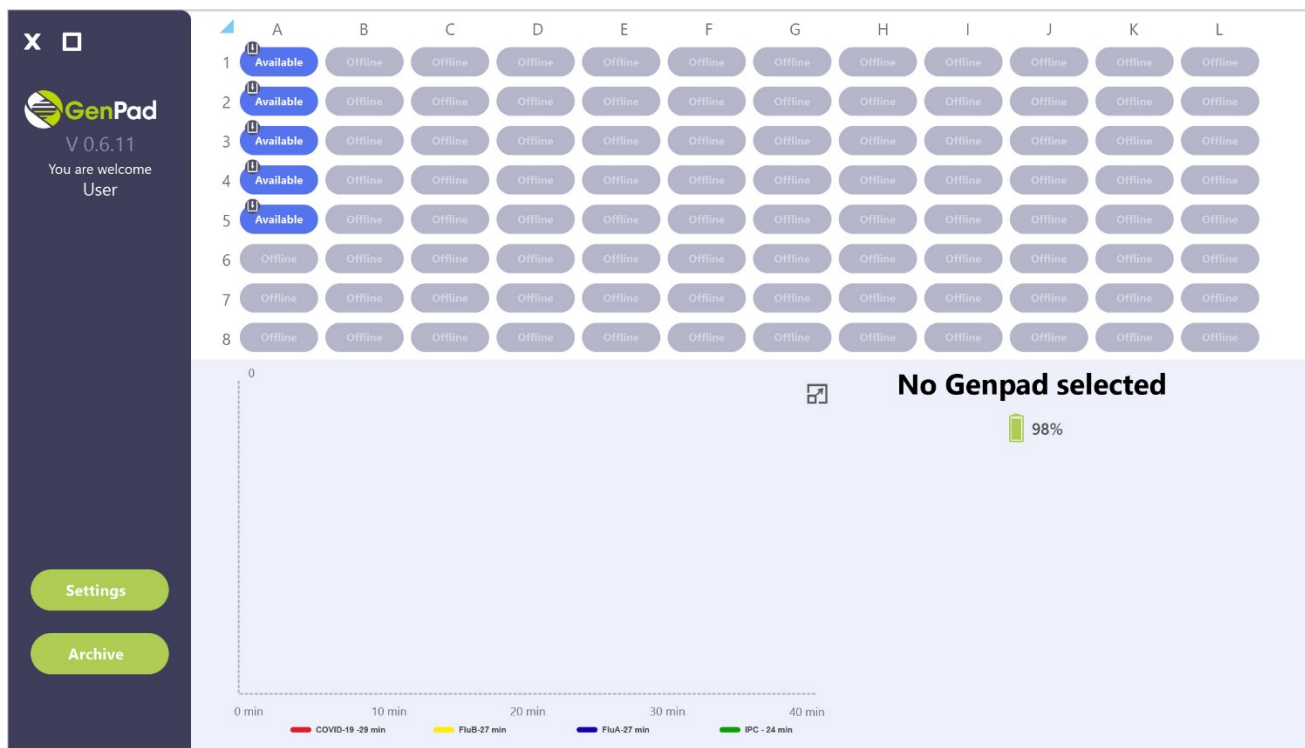


Figure 37. Displaying Clustered Devices in the Main Window

11.9. Running the test

Turn on the Analyzer to reach the optimum temperature for at least 10 seconds before starting the amplification.

- 1) Prepare the Cartridge No.1 or Cartridge No. 2 and install in the Analyzer in accordance with the IFU.
- 2) Prepare the Analyzer for the test according to the instructions, enter the ID data of the person (patient) sample into the *GenPad* software.
- 3) Start the test by clicking the *Start* button in the *GenPad* software.
- 4) Carefully follow the changes in the status lines on the device display.

11.10. Test results interpretation using cartridge No.1 and. Cartridge No.2

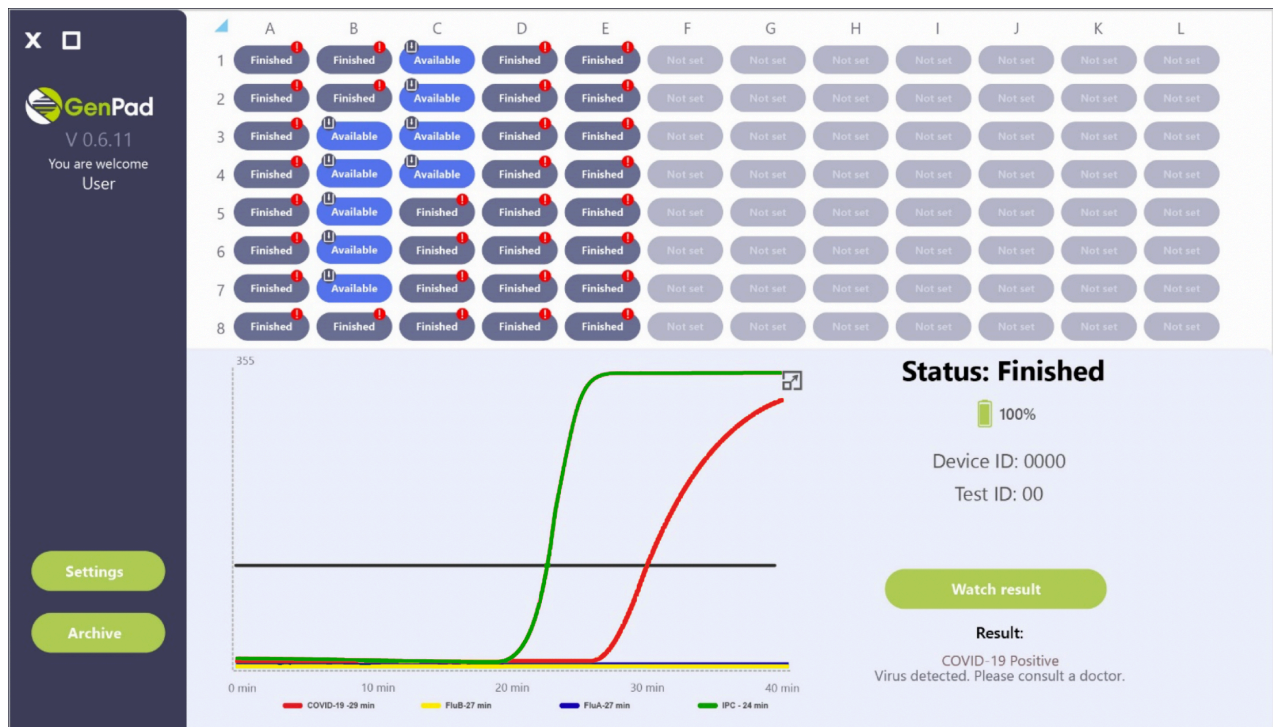


Figure 38. (a) Clinical specimen with detected SARS-CoV-2

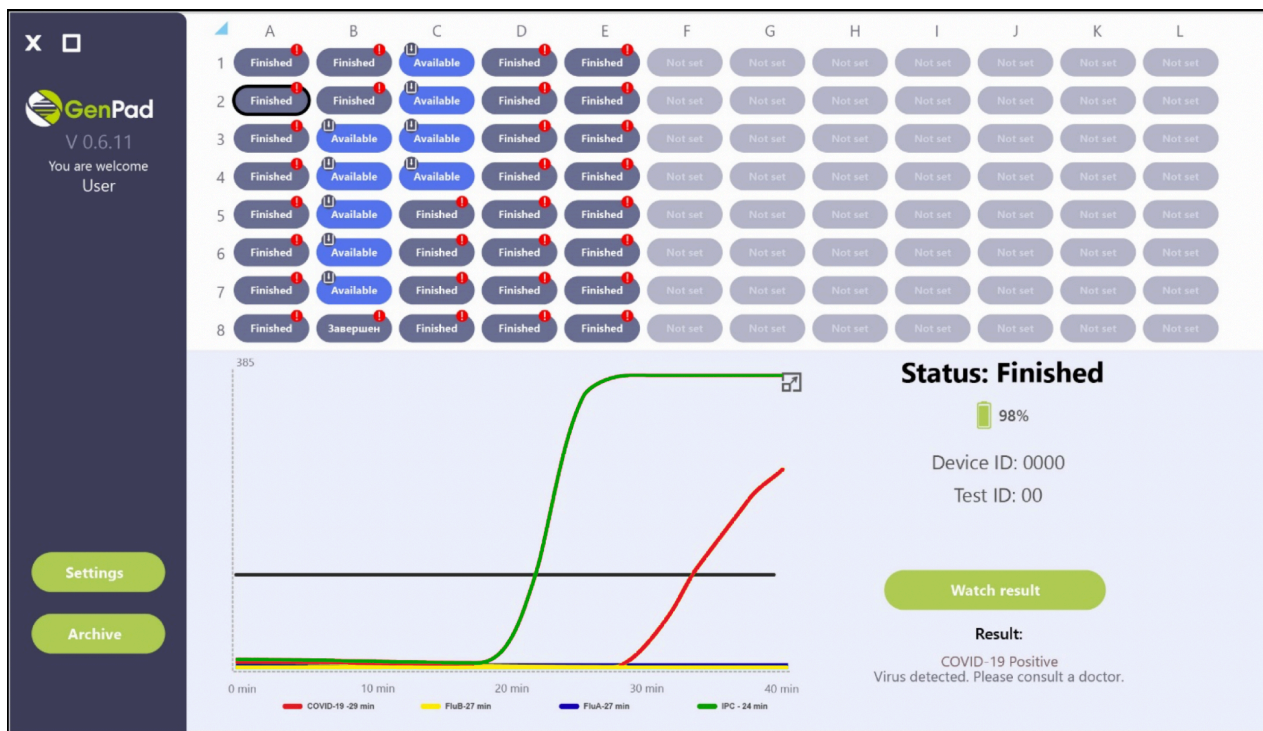


Figure 38. (b) Clinical specimen with detected SARS-CoV-2

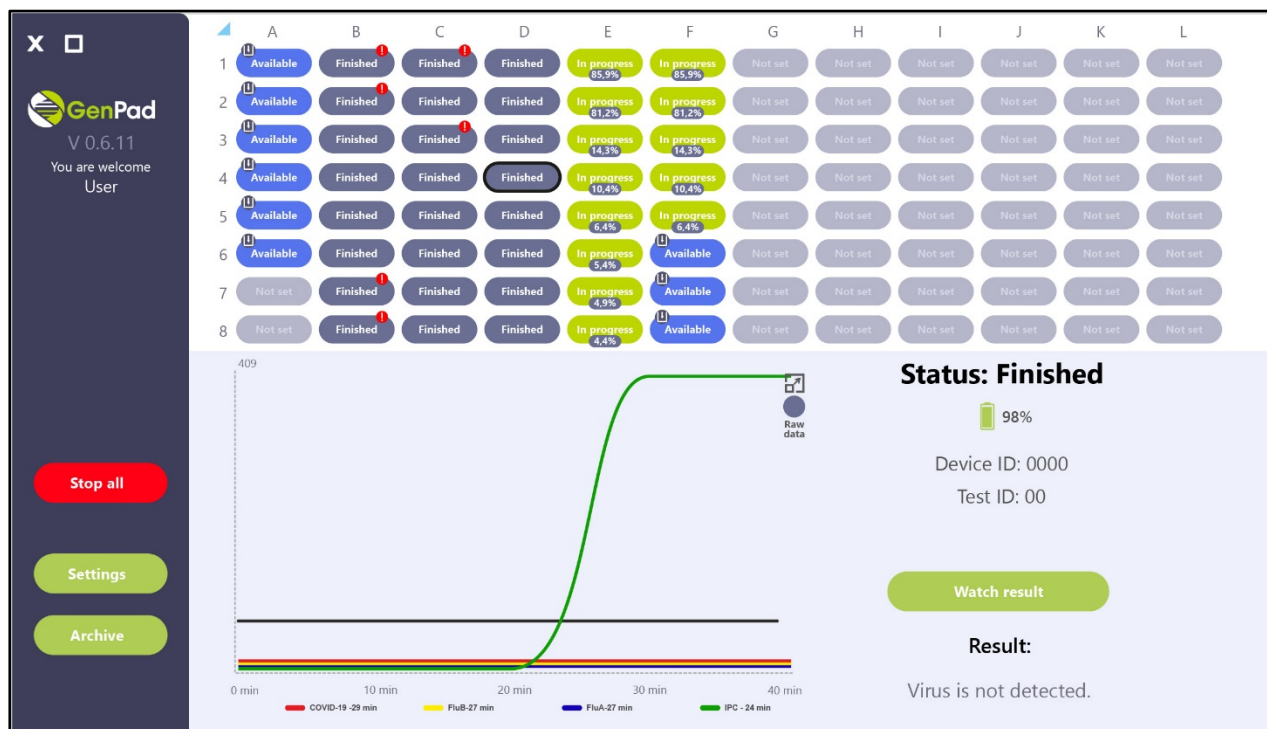


Figure 39. (a) Clinical specimen without detected SARS-CoV-2, Influenza A and Influenza B

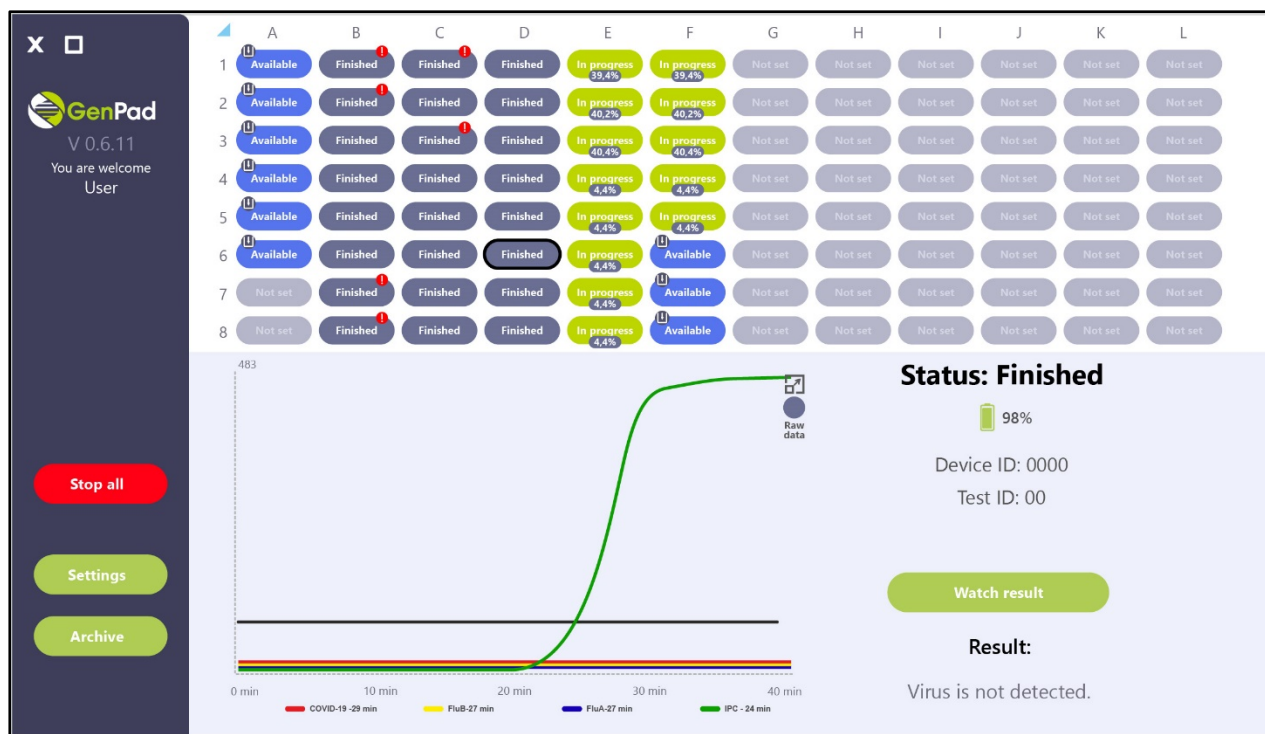


Figure 39. (b) Clinical specimen without detected SARS-CoV-2, Influenza A and Influenza B

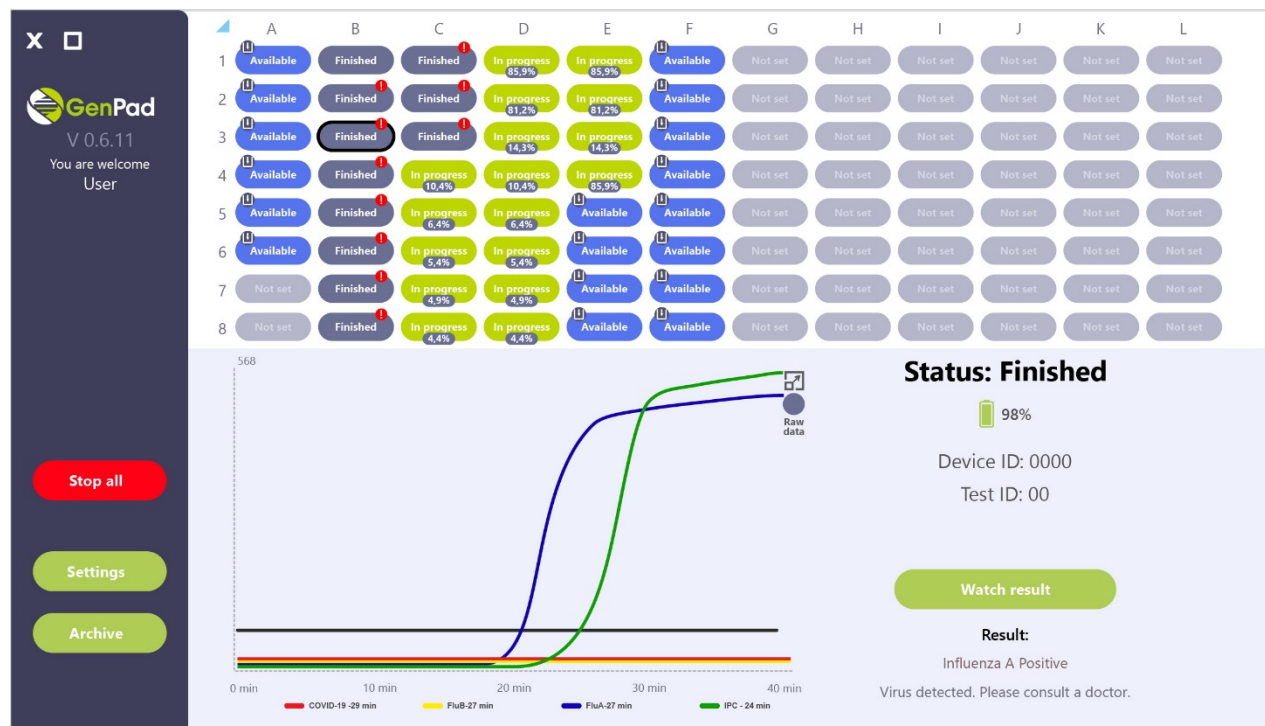


Figure 40. (a) Clinical specimen with detected Influenza A

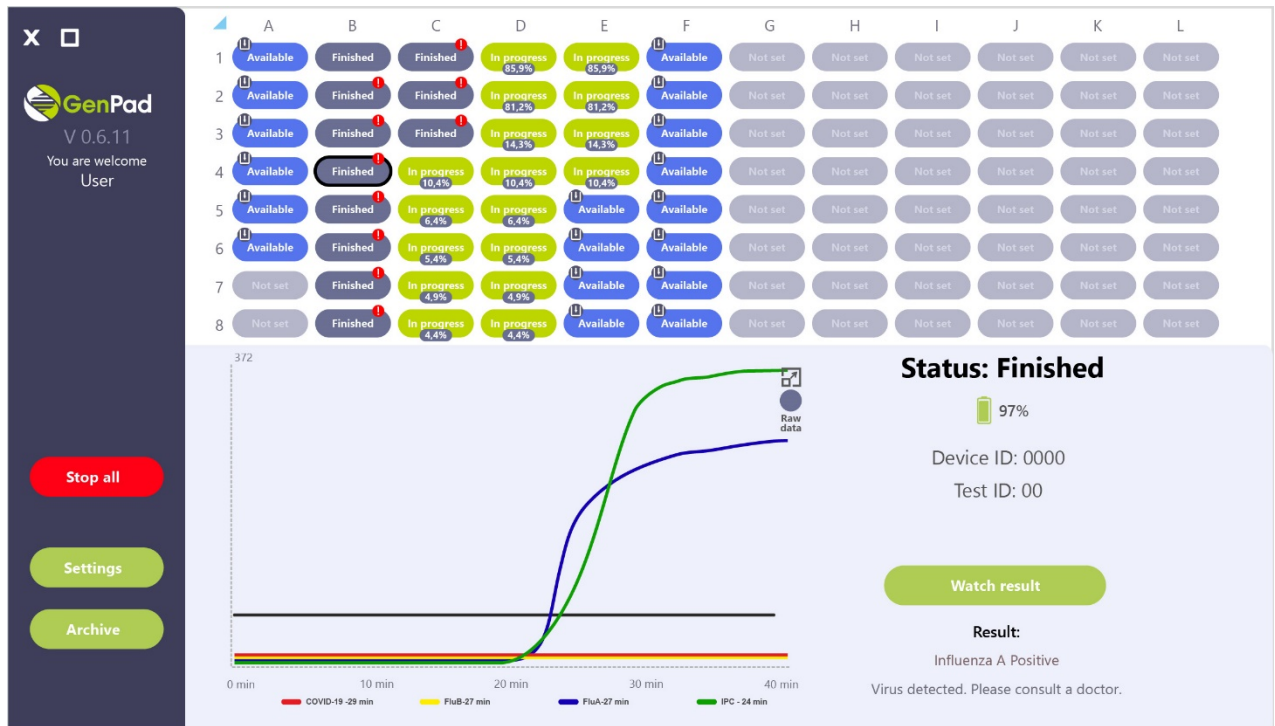


Figure 40. (b) Clinical specimen with detected Influenza A

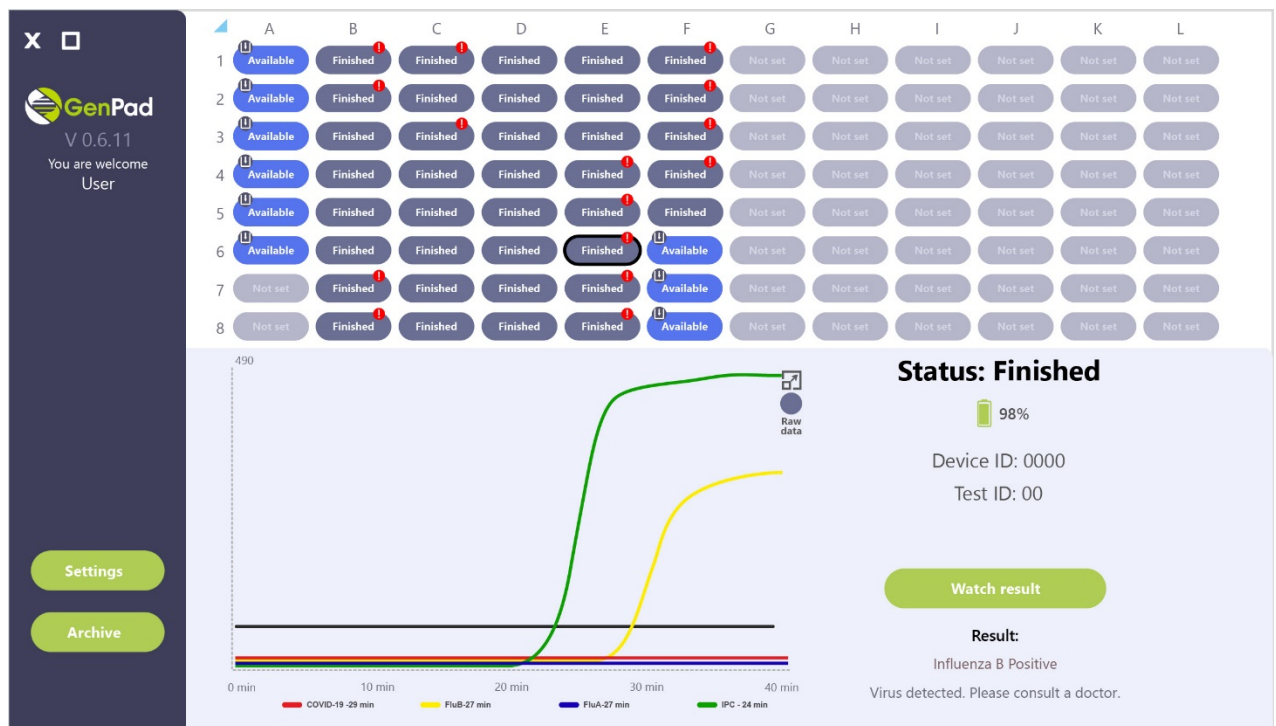


Figure 41. (a) Clinical specimen with detected Influenza B

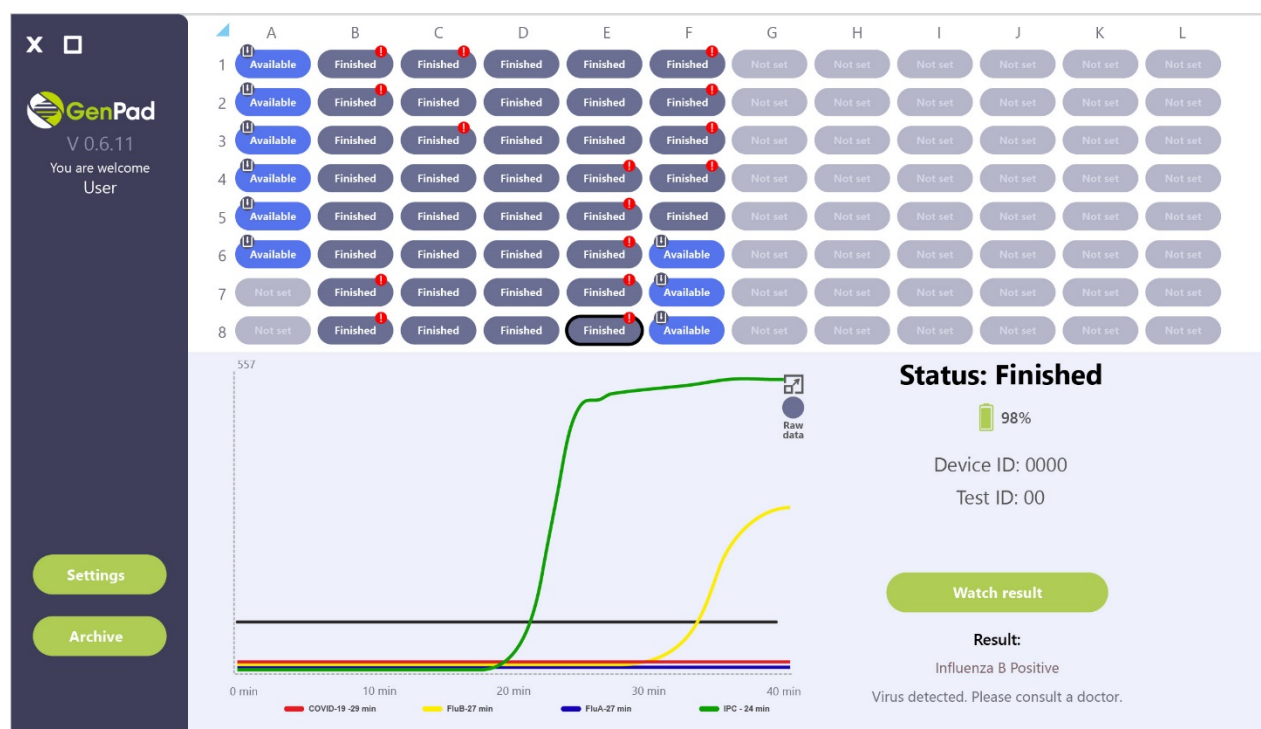


Figure 41. (b) Clinical specimen with detected Influenza B

- The red sigmoid line is specimen with the detected SARS-CoV-2.
- The yellow sigmoid line is specimen with the detected Influenza B.
- The blue sigmoid line is a specimen with the detected Influenza A.
- The green sigmoid line is an internal positive control (IPC).



Color interpretation may differ from what indicated; compare with the data given in the legend.

The results are interpreted based on the presence (or absence) of a rise in the fluorescence curve and the cycle threshold (Cq) value in minutes.

The performance of the analytical system is verified using an internal control sample (IPC).

The operation of the device as part of the analytical system is considered correct if the fluorescence accumulation curve for the positive control sample has a characteristic “sigmoid” shape and crosses the threshold line. The value of the reaction time at the moment of exit should not exceed 38 minutes, the amplitude of the signal does not matter (Figure 42). If the reaction time at the time of release of the positive control sample exceeds 38 minutes, the result is considered doubtful. In this case, stop using the product and contact an authorized service center.

Table 11. Results interpretation

Result	SARS-CoV-2 RNA, Influenza A, Influenza B virus is DETECTED	SARS-CoV-2 RNA, Influenza A, Influenza B virus is NOT DETECTED	Invalid¹
IPC	Positive* or negative	Positive	Negative Positive**
Test specimen (SARS-CoV-2, Influenza A and Influenza B	Positive	Negative	Negative

* IPC is positive, time to cross the threshold is in the range from 15 to 35 minutes, while the curve has a characteristic sigmoid shape.

** IPC is positive, but time to cross the threshold exceeds 35 minutes, or curve crosses threshold in the specified time range (15-35 minutes) but has an uncharacteristic (other than sigmoid) shape.

Each Test Kit for SARS-CoV-2 and Influenza A/B RNA PCR Detection in Biological Material and 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.

¹ The result is not interpreted. Please retest the specimen.

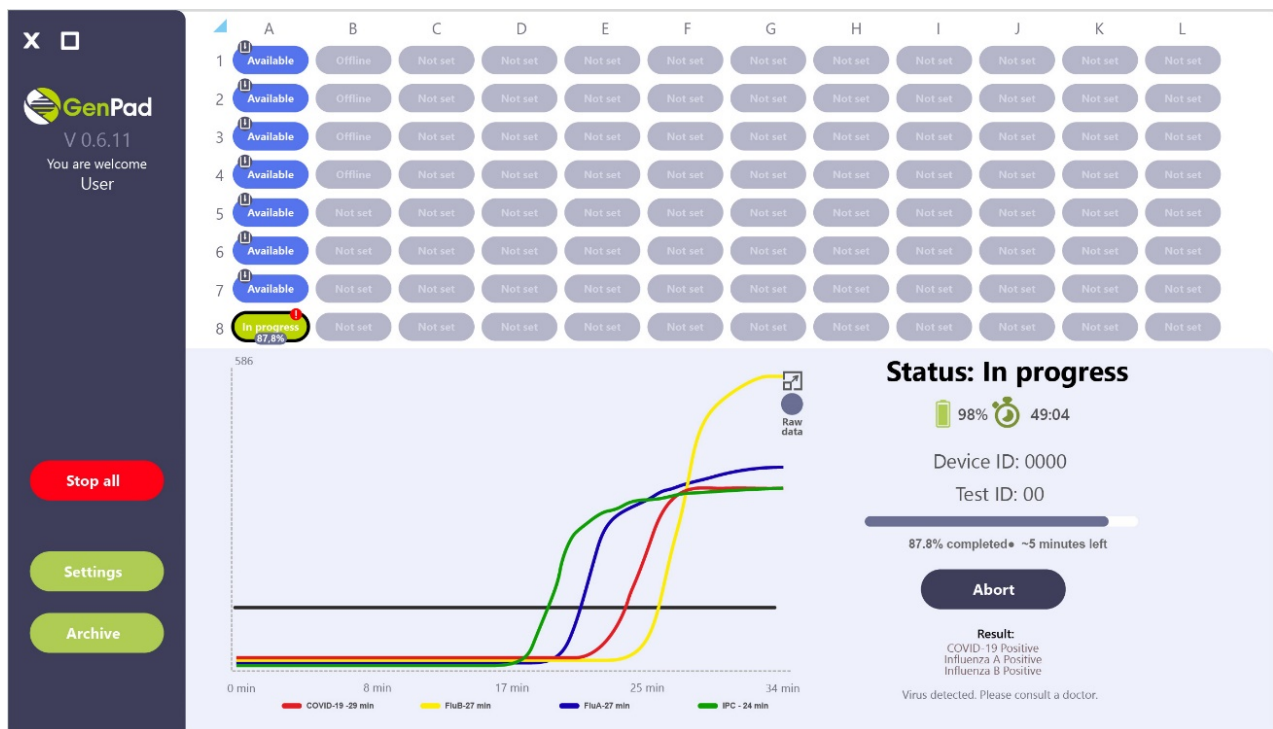


Figure 42. Positive Control Sample and IPC Interpretation.

The result is considered negative if there is no the Cq value (Figure 43).

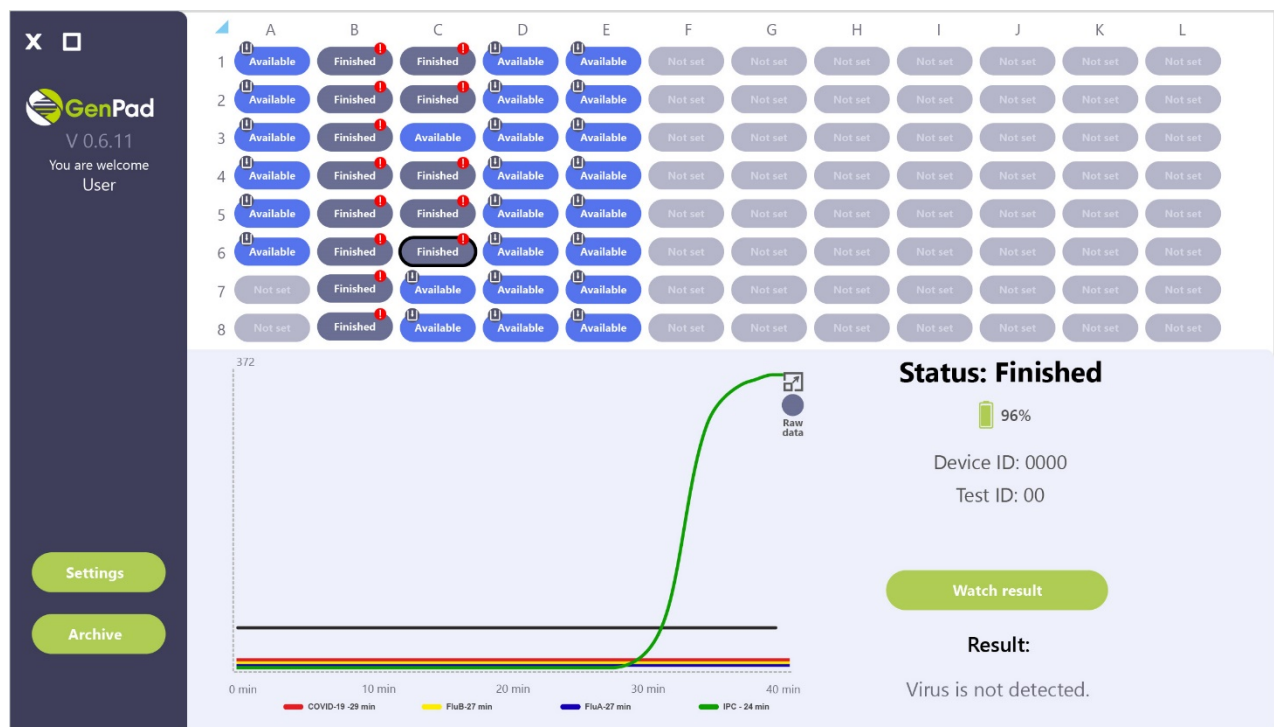


Figure 43. Negative Control Sample Interpretation.

The report can be uploaded as a document in .xlsx by clicking the *Save* button.

12. TURNING ON THE DEVICE AND RUNNING THE GENPAD SOFTWARE ON A SMARTPHONE



Figure 44. QR code for Application Downloading

For Android OS

Enter *GenPad* in the search bar: in the app store:

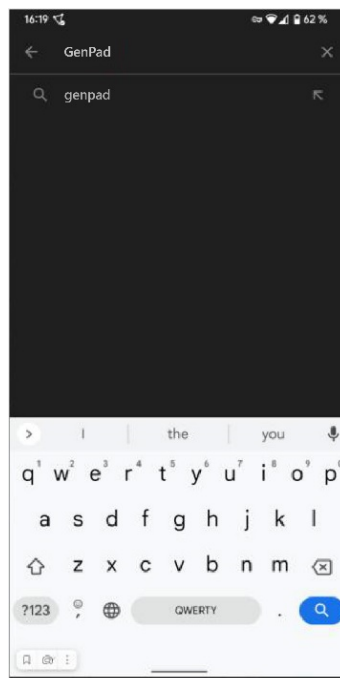


Figure 45. Apps Search Bar.

In the list provided, select the *GenPad* application.

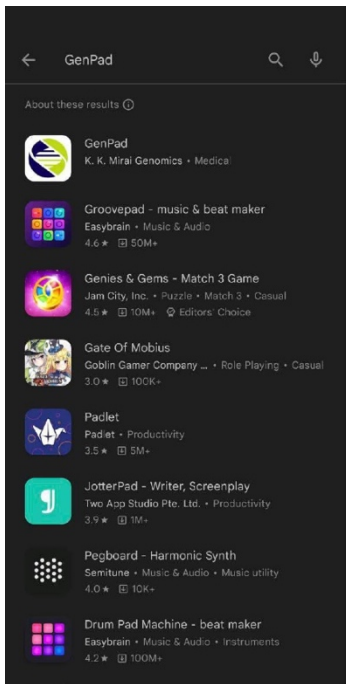


Figure 46. Application Search Results.

Click the *Install* button. The software will then be downloaded and installed.

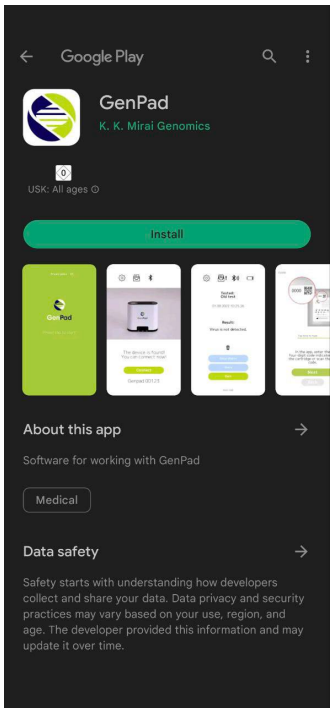
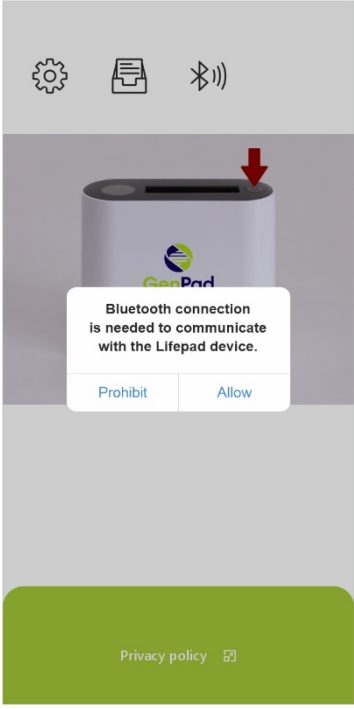
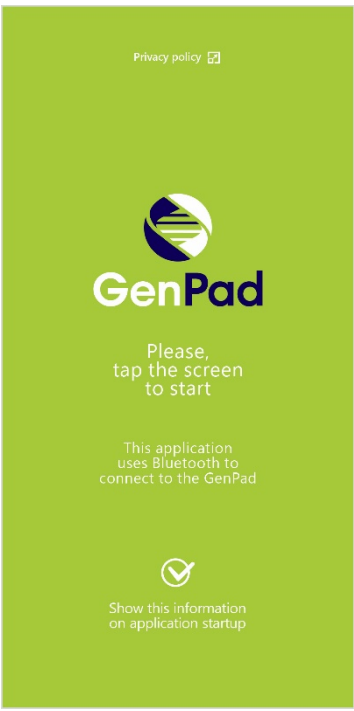
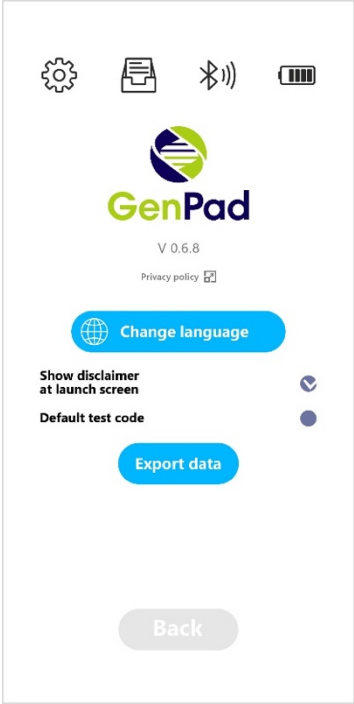




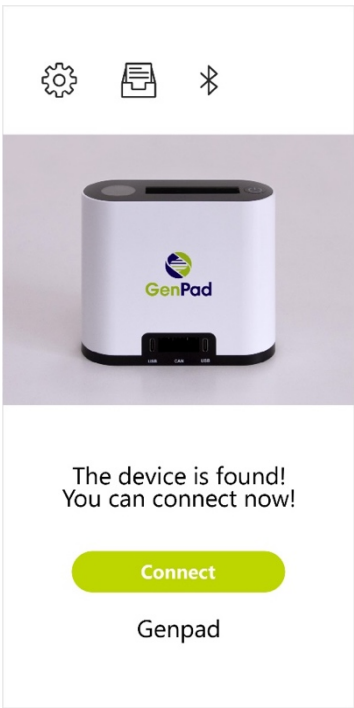
Figure 47. Application Page.

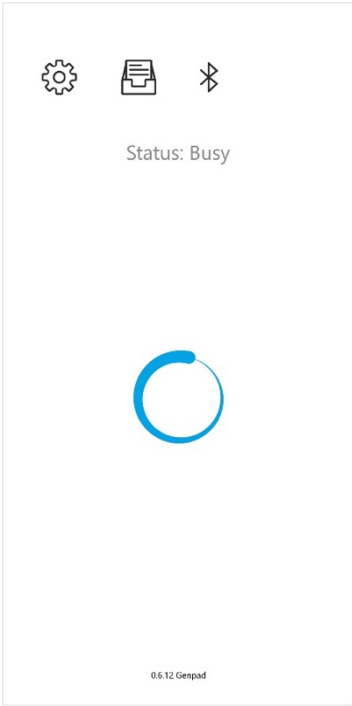

Connect the Analyzer to a smartphone using Bluetooth wireless personal area networks and follow the instructions step by step:

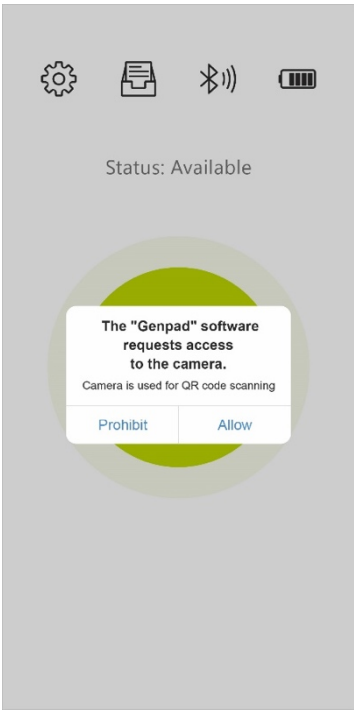
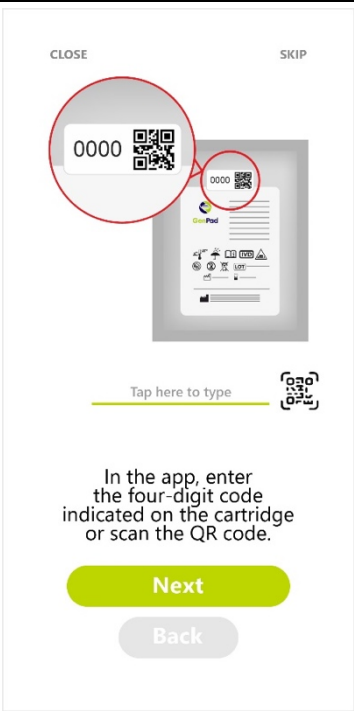
Test Step	Screenshot	Description

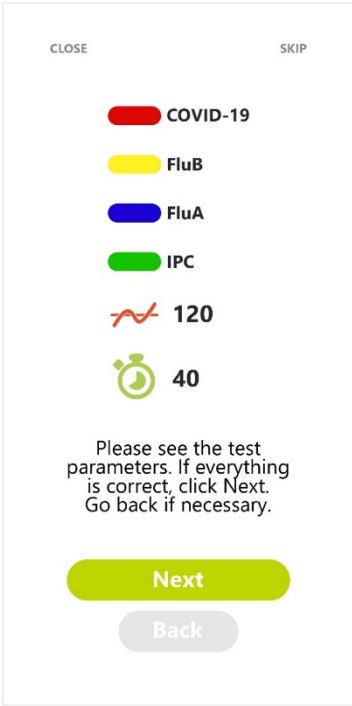

1.		<p>When launching the <i>GenPad</i> app for the first time, grant access to your geolocation data.</p> <p>Click <i>Allow</i> to continue.</p>
2.		<p>Tap the screen to start test.</p>

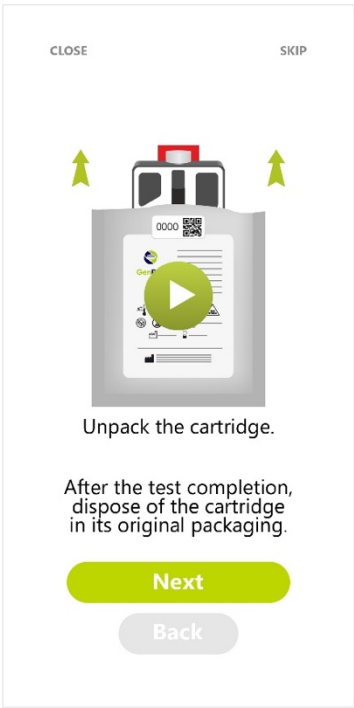

3.		<p>App language setting.</p> <p>Go to the settings screen and click on the <i>Change Language</i> button.</p>
4.		<p>Select the desired language from the menu that appears.</p>


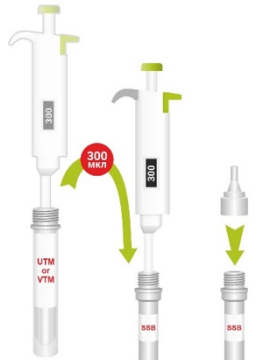
5.	 <p>Turn on by pressing the button on the device</p> <p>Searching for device...</p>	To connect the software, the Analyzer must be enabled.
6.	 <p>The device is found! You can connect now!</p> <p>Connect</p> <p>Genpad</p>	Click <i>Connect</i> to continue.


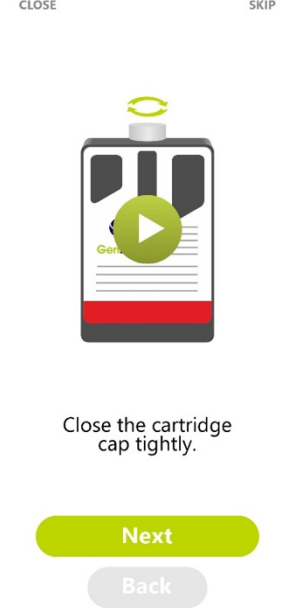
7.	 <p>The screenshot shows the Genpad software interface. At the top, there are three icons: a gear (settings), a document (file), and a Bluetooth symbol. Below these icons, the text 'Status: Busy' is displayed. In the center, there is a large blue circular progress indicator that is partially filled. At the bottom, the text '0.6.12 Genpad' is visible.</p>	<p>The software will then connect to the Analyzer.</p>
8.	 <p>The screenshot shows the Genpad software interface. At the top, there are four icons: a gear (settings), a document (file), a Bluetooth symbol, and a battery level indicator. Below these icons, the text 'Status: Available' is displayed. In the center, there is a large green circular button with the text 'TAP HERE TO START PREPARING TO TEST'. At the bottom, the text '0.6.8 Genpad 00001003 243 c0120 10120' is visible.</p>	<p>To prepare for the test start, click on the green area on the and follow the instructions.</p>

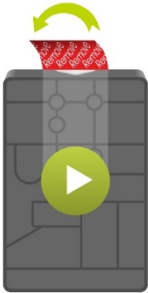

9.		For further actions for cartridge scanning, permit the software to use the <i>Camera</i> function.
10.		Scan the QR code on the Cartridge foil packaging using the <i>Camera</i> function, or enter four digits manually into the highlighted area on the screen.

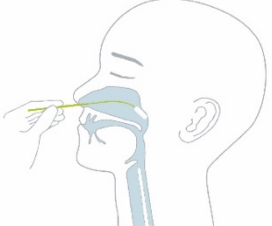

11.		<p>Review the test information.</p> <p>Click <i>Next</i> to continue.</p>
12.		<p>Manually enter test patient data.</p> <p>Click <i>Save</i> to continue.</p>

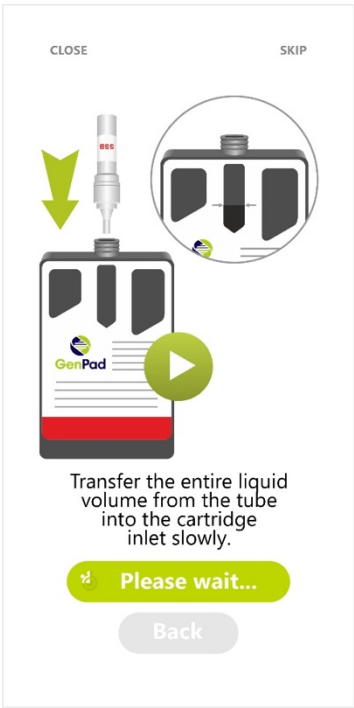
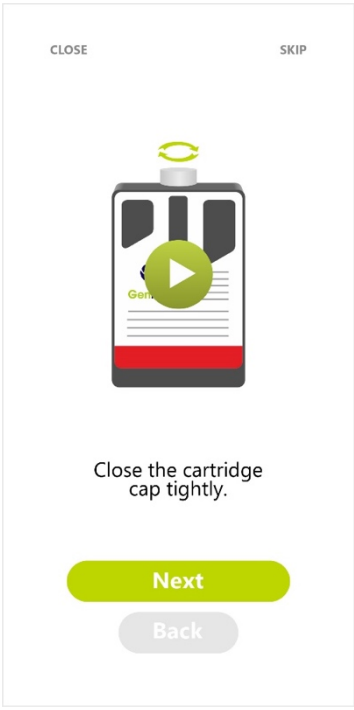
13.		<p>Unpack the Cartridge following the prompts in the software.</p> <p>Click <i>Next</i> to continue.</p>
14.		<p>Select the tested specimen type:</p> <p><i>UTM/VTM</i> for clinical specimen in transport medium (not included in the Kit).</p> <p><i>Swab</i> for a clinical specimen swabbed according to the Kit IFU.</p>

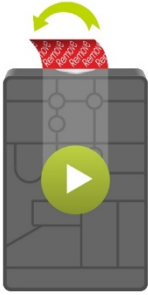

<i>UTM/VTM</i>		
1.	<div> <div>CLOSE</div> <div>SKIP</div>  <p>Unscrew the cartridge cap.</p> <p>IMPORTANT! Keep the cap until the test ends.</p> <div>Next</div> <div>Back</div> </div>	<p>Unscrew the Cartridge lid as prompted by the software.</p> <p>Click <i>Next</i> to continue.</p>
2.	<div> <div>CLOSE</div> <div>SKIP</div>  <p>Transfer 300 µl of the liquid from the transport medium tube to the SSB solution tube.</p> <p>Close the SSB tube with the cap with a dropper nozzle.</p> <div>Next</div> <div>Back</div> </div>	<p>Transfer 300 µl of the specimen with transport medium using a pipette into a tube with SSB solution.</p> <p>Screw the dropper nozzle tightly onto the SSB solution tube.</p> <p>Click <i>Next</i> to continue.</p>

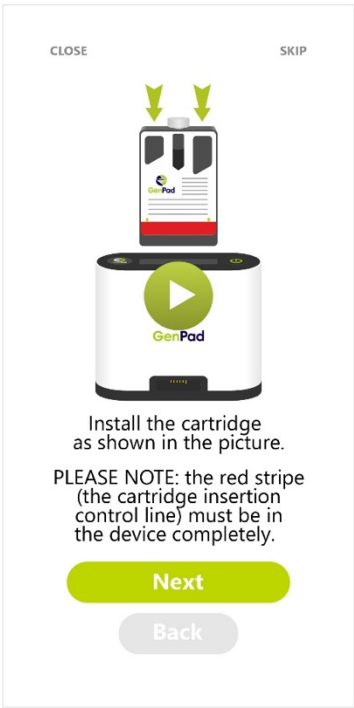
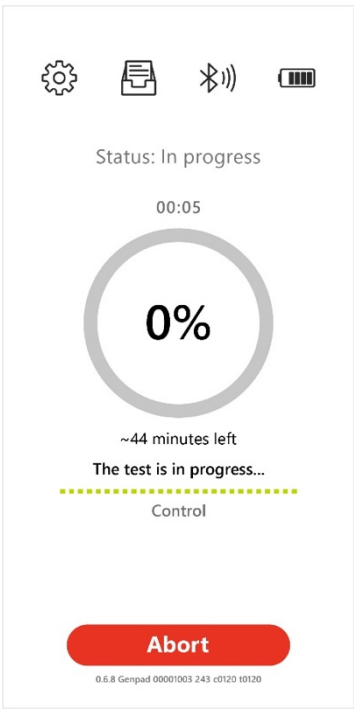
3.	<div data-bbox="475 159 831 860"> <div>CLOSE SKIP</div>  <p>Transfer the entire liquid volume from the tube into the cartridge inlet slowly.</p> <p>Please wait...</p> <p>Back</p> </div>	<p>Transfer the resulting solution to the Cartridge inlet, filling to the level indicated by the gray arrows.</p> <p>When transferring the resulting solution, squeeze the walls of the test tube with the SSB solution.</p> <p>Please watch the video below before starting work.</p> <p>Click <i>Next</i> to continue.</p>
4.	<div data-bbox="475 887 831 1588"> <div>CLOSE SKIP</div>  <p>Close the cartridge cap tightly.</p> <p>Next</p> <p>Back</p> </div>	<p>Screw the Cartridge lid tightly.</p> <p>Please watch the video below before starting work.</p> <p>Click <i>Next</i> to continue.</p>

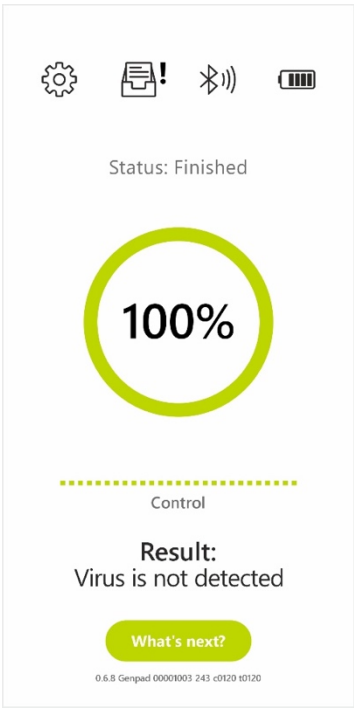

5.	<div data-bbox="475 159 831 862"> <div> CLOSE SKIP </div>  <p>Gently pull on the red tab of the sticker and remove the transparent film from the back of the cartridge. Make sure the film is completely removed.</p> <div> Next Back </div> </div>	<p>Tear off the protective film with the red sticker as prompted by the software.</p> <p>Click <i>Next</i> to continue.</p>
6.	<div data-bbox="475 880 831 1583"> <div> CLOSE SKIP </div>  <p>Install the cartridge as shown in the picture.</p> <p>PLEASE NOTE: the red stripe (the cartridge insertion control line) must be in the device completely.</p> <div> Next Back </div> </div>	<p>Correctly install the Cartridge into the Analyzer as prompted by the software until the Cartridge insertion control line is fully seated in the device.</p> <p>Please watch the video below before starting work.</p> <p>Click <i>Next</i> to continue.</p>



Swab		
1.	<div> <div>CLOSE</div> <div>SKIP</div>  <p>Take a nasopharyngeal swab.</p> <div>Next</div> <div>Back</div> </div>	<p>To take biological material, Use a nasopharyngeal swab for swabbing.</p> <p>Click <i>Next</i> to continue.</p>
2.	<div> <div>CLOSE</div> <div>SKIP</div>  <p>Place the swab into the tube with the SSB solution.</p> <p>Rotate the swab 10 times around the test tube walls.</p> <p>Squeeze the tube walls when taking the swab out of the tube.</p> <p>Close the tube with the cap with a dropper nozzle.</p> <div>Next</div> <div>Back</div> </div>	<p>Prepare a specimen by immersing the swab in the tube with the SSB solution, rotating the swab around the tube walls.</p> <p>Screw the dropper nozzle tightly onto the SSB solution tube.</p> <p>Please watch the video below before starting work.</p> <p>Click <i>Next</i> to continue.</p>

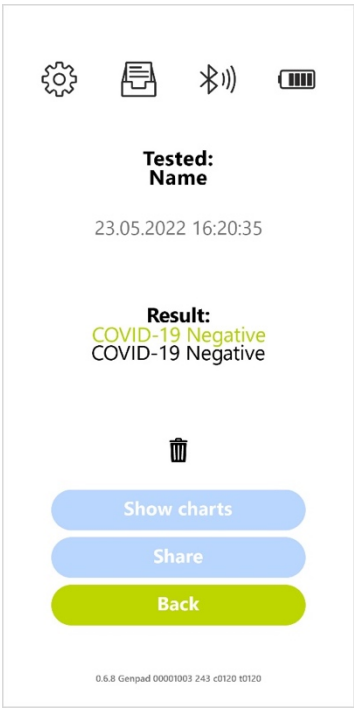
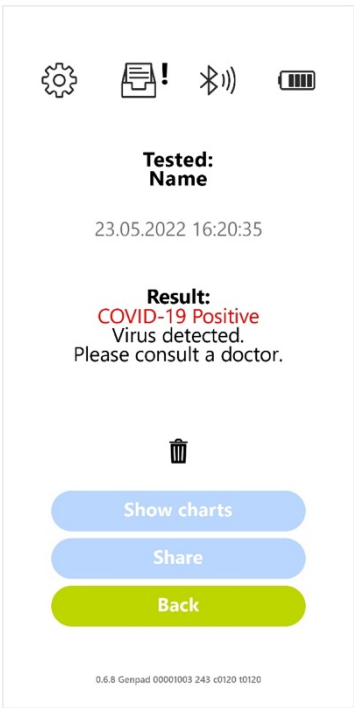
3.	 <p>CLOSE SKIP</p> <p>Transfer the entire liquid volume from the tube into the cartridge inlet slowly.</p> <p>Please wait...</p> <p>Back</p>	<p>Transfer the resulting solution to the Cartridge inlet, filling to the level indicated by the gray arrows.</p> <p>When transferring the resulting solution, squeeze the walls of the test tube with the SSB solution.</p> <p>Please watch the video below before starting work.</p> <p>Click <i>Next</i> to continue.</p>
4.	 <p>CLOSE SKIP</p> <p>Close the cartridge cap tightly.</p> <p>Next</p> <p>Back</p>	<p>Screw the Cartridge lid tightly.</p> <p>Please watch the video below before starting work.</p> <p>Click <i>Next</i> to continue.</p>

5.	<div data-bbox="475 161 829 864"> <div> CLOSE SKIP </div>  <p>Gently pull on the red tab of the sticker and remove the transparent film from the back of the cartridge. Make sure the film is completely removed.</p> <div> Next Back </div> </div>	<p>Tear off the protective film with the red sticker as prompted by the software.</p> <p>Click <i>Next</i> to continue.</p>
6.	<div data-bbox="475 907 829 1610"> <p>Warning!</p>  <p>Close the cartridge cap tightly .</p> <div> Next Cancel </div> </div>	<p>Warning informing about the presence of a tear-off sticker. Visually check the presence of a tear-off sticker and remove it completely.</p> <p>Click <i>Next</i> to continue.</p>

7.	 <p>Install the cartridge as shown in the picture. PLEASE NOTE: the red stripe (the cartridge insertion control line) must be in the device completely.</p> <p>Next</p> <p>Back</p>	<p>Correctly install the Cartridge into the Analyzer as prompted by the software until the Cartridge insertion control line is fully seated in the device.</p> <p>Please watch the video below before starting work.</p> <p>Click <i>Next</i> to continue.</p>
8.	 <p>Status: In progress</p> <p>00:05</p> <p>0%</p> <p>~44 minutes left</p> <p>The test is in progress...</p> <p>Control</p> <p>Abort</p> <p>0.6.8 Genpad 00001003 243 c0120 10120</p>	<p>The test has started.</p>

9.		The test is finished.
10.		After the test is finished, take the Cartridge out of the Analyzer and disposed of it.

11.		The test results are stored in the <i>Archive</i> tab.
12.		From the <i>Archive</i> tab, the test results can be shared on social networks and messengers.

13.		Negative test result.
14.		Positive test result.

The test result is interpreted in accordance with the used Cartridge purpose.

13. STEP-BY-STEP PROCEDURE FOR RNA EXTRACTION AND MASTER MIX PREPARATION USING THE ANALYZER

The Analyzer is an automatic device with microprocessor control, a pneumatic system with a pressure sensor for creating vacuum pressure in order to ensure the conditions for filtration of solutions, an

automatic mixing system for extraction solutions, an automatic dosing system for reagents, and automatic heating.

The principle of operation of the system is aimed at automating the process of RNA extraction and preparation of the reaction mixture for further studies. The method used is based on the gradual creation of a vacuum in order to pass the solution from the filter column through the glass filter in the corresponding channel of the Cartridge.

The extraction method is based on the selective adsorption of the nucleic acids to the column filter material. The extraction of the SARS-CoV-2, Influenza A and B RNA from nasopharyngeal, oropharyngeal, and combined oro- and nasopharyngeal swabs using the Kit and the Analyzer includes 5 consecutive stages and consists of:

1. Virus inactivation and
2. lysing of the specimen in the SSB (swab suspension buffer) solution
3. Collecting the RNA on the filter column.
4. Purifying and 5) collecting the eluate containing purified target RNA.

The resulting specimen is then used for PCR.

The stages of the RNA extraction using the Kit and the Analyzer are as follows:

- During the first stage of the sample preparation, the specimen and Internal Positive Control (IPC) are suspended in the SSB lysis buffer. The lysis buffer is composed of ethanol and a chaotropic agent (guanidine thiocyanate) giving the buffer its protein denaturation properties and allowing effective viral particle lysis.
- As a result, viral capsid proteins lose their structure, viral particles are disintegrated, and viral genetic material (a single-stranded RNA that includes highly conserved sequence targeted for the detection) is released into solution.
- During the second stage, the SSB lysis buffer, that already contains lysed viral particles, and IPC pass through a filter. The viral RNA is retained in the filter, while remaining specimens together with the SSB lysis buffer that could interfere with the reaction pass through the filter.
- Two successive washing stages are performed to ensure complete removal of all interfering substances using the WS1 washing solution and the ethanol-based WS2 washing solution.
- During the next stage, the filter membrane has to be dried completely to ensure no ethanol residue remains. Ethyl alcohol may interfere with the reaction by inhibiting nucleic acid amplification. During both washing and drying stages, the target RNA and IPC are retained with the filter.
- During the fifth stage, RNase free ultra-pure water (EB solution) passes through the filter to elute the target RNA and IPC.

The stages of the master mix preparation are as follows:

- At the sixth stage, the eluate is automatically dosed and mixed with reagent E (Enzymes) and IPC.
- At the seventh stage, automatic dosing and mixing with reagent P (Primers) takes place.

The method is based on the detection of specific viral RNA fragments by obtaining a DNA copy (cDNA) from the RNA matrix using a reverse transcription reaction and its accumulation (amplification) using PCR method.

14. 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. The list of errors, their codes, and actions to eliminate the errors is shown in Table 12 and Table 13.

Table 12. Malfunctions and troubleshooting

MALFUNCTION	POSSIBLE REASON	HOW TO FIX
After turning on the Analyzer, there is no light indication of the thermal block wells.	Battery is off.	Check the battery switch condition on the device bottom.
	Battery is low.	Connect charger and try again later.
The Analyzer is not recognized in the software status line or on the display when the device is turned on.	Poor contact or break in the communication cable with the PC.	Check the Analyzer's communication cable.
	The Analyzer driver is not installed.	Install the Analyzer Driver.
	Windows system crash.	Restart the PC.
During the testing, an error message appeared in the program window.	The software indicates the error possible cause.	Contact service center.
During the testing, the device heats up.	Device malfunction.	Turn off the Analyzer, turn off the battery using the toggle switch. Contact service center.
When the device is turned on without the Cartridge, the software recognizes the Cartridge presence.		If the status is <i>ERROR</i> , take out the Cartridge and / or restart the device.
Errors occur when reading the Cartridge.		Take out the Cartridge and repeat the process from the beginning. If it doesn't lead to a positive result, use another Cartridge. This Cartridge is considered unsuitable for further testing.
Errors occur when writing information to the Cartridge.		
When the device is connected to the AC mains through the charger, the <i>Power</i> icon on the device display does not respond or the	No voltage.	Check the voltage and the socket.
	The socket is faulty.	

battery charge level has not changed after the time has elapsed.	Poor contact or break in the power cable and the Analyzer.	Check the contact of the power cable and the Analyzer
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Table 13. List of errors on the display

Error Code	Reason/Source	Where	How to Fix
01 01	No connection	Servo	Contact service center.
01 02		Heating module	
01 03		Optics module	
01 04		RFID antenna	
01 05		Battery	
01 06		Pressure sensor	
01 07		Charge scheme	
01 08		Power Delivery Port Controller (LP2)	
01 0D		Power Delivery Port Controller #1 (LP3)	
01 0E		Power Delivery Port Controller #2 (LP3)	
01 09		Accelerometer	
01 0A		Display (LP2)	
01 0B		Non-volatile memory	
01 0C		BLE communication module (LP2)	
01 0F		CAN communication module (LP3)	
02 01	Insufficient supply voltage/current	Servo	
02 02		Battery	

02 03		Common line	
03 01	Overheating	Servo	
03 02		Heating module	
03 03		Heating module	
04 01	Incorrect homing position	Servo	Contact service center.
04 02		Device position according to the accelerometer	Install the device on a horizontal surface.
04 03	Inserted Cartridge was detected when the device was turned on	Cartridge presence sensor	If ERROR status is displayed, take out the Cartridge and/or restart the Analyzer.
05 01	Inability to achieve the correct position (value) during the test	Servo	Contact service center.
05 02	Device incorrect position	Device position according to the accelerometer	
05 03	The Cartridge was taken out during the test		
06 01	The pressure doesn't change	Pressure sensor	Contact service center.
06 02	The pressure level is insufficient		
07 01	Heater low temperature on one or all channels	Heating module	Contact service center.
08 01	Incorrect values of the optical module sensors	Optics module	
09 01	Errors when recognizing the Cartridge	NFC module	Take out the Cartridge and re-insert it.
09 02	Errors when writing information to the Test Cartridge		Take out the Cartridge and re-insert it.

0A 01	System update error	Main board	Contact service center.
0B 01	Battery	Voltage level is exceeded	Contact service center.
0B 02		Voltage level is reduced	Contact service center.
0B 03		Battery error	Contact service center.



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

15. ANALYZER MAINTENANCE

15.1. 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.

15.2. Maintenance procedure

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

- Perform external inspection of the Device for any damage to its surface.
- 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.
- Remove dust and dirt from the surface of the Device in a timely manner using a dry wipe.
- 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.

15.3. 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.

16. 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 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.

