GP Reader NT

User’s Guide

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Biohit Oyj

CE IVD REF 740450

BIOHIT
Innovating for Health

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CONTENTS

1 GENERAL

1.1 ABOUT THIS MANUAL

The purpose of this User's Guide is to provide important information about the GP Reader NT instrument and instructions on setup, operation and maintenance.

Instructions or sections noted as 'admin' are addressed only to users with system administrator access rights, as opposed to regular users (operators). Likewise, screenshots of the GP Reader NT application with the 'admin' indication, show features or functions available only to administrators.

Certain document conventions have been used to make reading and understanding of this manual easier (see section 1.3). Instructions on how to use any specific test kit with the GP Reader NT are out of the scope of this document and for those, the user must refer to the instruction manual of the test kit in use.

1.2 CONTACT INFORMATION

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1.3 CONVENTIONS

1.3.1 Abbreviations

CE	Conformité Européene (European conformity)
SN	Serial Number
IVD	*In vitro* Diagnostics
REF	Reference (Product code)
2D	2-Dimensional
LED	Light Emitting Diode
WEEE	Waste Electrical and Electronic Equipment
USB	Universal Serial Bus
FLFIA	Fluorimetric Lateral Flow Immunoassay
QR	Quick-Response
HL7	Health Level Seven
LIS	Laboratory Information System
MCU	Microcontroller Unit
ADC	Analog-to-Digital Converter
OLS	Ordinary Least Squares
4-PL	4-Parameter Logistic
AC	Alternating Current
DC	Direct Current
BPA	Bisphenol A
IFU	Instructions For Use
LAN	Local Area Network
COM	Communications port
I/O	Input/Output
GUI	Graphical User Interface
QC	Quality Control
SD	Standard Deviation
UV	Ultraviolet
ID	Identification
EU	European Union
CSV	Comma Separated Values
IP	Internet Protocol
MAC	Media Access Control
IT	Information Technology
R&D	Research and Development
IQ	Installation Qualification
OQ	Operational Qualification
PQ	Performance Qualification
RTC	Real-Time Clock
RMA	Return Material Authorization
ISO	International Organization for Standardization
IEC	International Electrotechnical Commission
RoHS	Restriction of Hazardous Substances
IVDR	*In vitro* Diagnostic Regulation
UDI-DI	Unique Device Identification – Device Identifier
RH	Relative Humidity
CV	Coefficient of Variation
LCD	Liquid Crystal Display

1.3.2 Symbols used in this guide

	**Warning!** This icon indicates potential hazards that might result in serious bodily harm.
	**Caution!** This icon indicates potential hazards that might result in minor injury or instrument damage.
	**Do not!** This icon indicates an action that must be avoided or a restriction to the user.
	**Info** This icon calls attention to important information.

1.3.3 Symbols used on the labelling

Symbols	Meaning
	CE mark
	Temperature limit
	Keep dry
	Fragile
	*In vitro* diagnostic medical device
	Catalog number
	Serial number
	Manufacturer
	Manufacturing date
	Consult instructions for use
	This side up
	Separate collection for electrical and electronic equipment
	Corrugated fiberboard PAP 20

1.4 SAFETY AND SECURITY INFORMATION

1.4.1 Warnings, precautions and limitations

Power Rating. The GP Reader NT power supply must be connected to a power receptacle that provides voltage and current within the specified rating for the system. Use of an incompatible power receptacle may produce electrical shock and fire hazards.

Electrical Grounding. Never use a two-prong plug adapter to connect primary power to the GP Reader NT AC adapter. The use of a two-prong adapter disconnects the utility ground, creating a electric shock hazard. Always connect the power cord to a three-prong receptacle with a functional ground.

Internal Voltage. Always turn off the power switch and unplug the power cord from the mains electricity supply before cleaning the outer surface of the instrument.

Electrical Shock. Never touch the power plug, power line or power switch with wet hands.
Never operate the GP Reader NT with wet hands.

Barcode scanner. Avoid direct or reflected light from the 2D barcode scanner entering the eyes.

Liquids. Avoid spilling liquids on the instrument; fluid seepage into internal components creates a potential shock hazard. Disconnect the instrument from the mains power supply and wipe up all spills immediately. Do not operate the instrument if internal components have been exposed to fluid.

Magnetic field. The instrument produces a magnetic field. People with cardiac pacemakers should not use the instrument. The permanent magnetic field may interfere with the functioning of the cardiac pacemaker and result in personal injury.

Installation. Operate the instrument on a flat surface and away from excessive humidity and dust.

Service. The device should be serviced only by Biohit authorized service personnel. Only qualified technical personnel should perform troubleshooting and service procedures on internal components.

Environmental conditions. Always operate the device within the operating environment conditions specified in this guide.

Warranty. Failure to follow preventive maintenance instructions may void the warranty.

Failure. Do not drop or knock the instrument when handling it as it has not been designed to withstand such impacts. Damage caused by such impacts will void the warranty.

Disposal. Dispose of the instrument according to current WEEE (Waste Electrical and Electronic Equipment) directive.

USB devices. Use of infected USB storage devices can pose significant threats to the device.
It is highly recommended to use only trusted USB drives that have been scanned for malware.

Compatible tests. Use only compatible test cassettes. The use of test cassettes that are not designed for use with the instrument could cause damage to the device.

I/O ports. Do not use the USB-B or COM ports of the device. These ports are used for programming and debugging of the instrument by the manufacturer and authorized service technicians.

Operating system settings. Do not modify any of the system-level settings of the device, unless instructed in this manual. Uncontrolled changes of the operating system configuration can cause security vulnerability and data breaches.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

1.4.2 Safety standards

GP Reader NT is compliant with:

- IEC 61326-1:2012 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements,
- IEC 61326-2-6:2012 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - *In vitro* diagnostic (IVD) medical equipment
- IEC 61010-1: 2010/AMD1:2016 Safety requirements for electrical equipment for measurement, control and laboratory use. Part 1, General requirements.
- IEC 61010-2-101:2018 Safety requirements for electrical equipment for measurement, control and laboratory use. Part 2-101, Particular requirements for *in vitro* diagnostic (IVD) medical equipment.

1.4.3 Cybersecurity

To ensure safe and secure operation of GP Reader NT, the application uses user authentication, always starting on the System Login screen. The users can login only with their Account ID and Password. When logged in, the users can change their Password to a new, stronger one or even change passwords regularly, if deemed appropriate. It is crucial to protect your login credentials and avoid sharing them to prevent unauthorized access to the system and protect the data integrity. It is advised to operate the instrument only from your own personal account and logout immediately after completing the tasks on it, following the logout instructions in this guide or simply switching off the instrument. When the device is switched off, any active user account is automatically logged out.

The device's network connectivity is limited to wired local area network from the LAN port and used only for connection to a Laboratory Information System (LIS). This network connection can be configured and controlled by the IT or network administrator of the establishment to ensure safe bidirectional data transfer.

USB devices used for data transfer should always be scanned for malware prior to use with the instrument. Never use a USB storage device that you suspect or has been found to be infected. You should also never keep sensitive data in storage media that could potentially be accessed by unauthorized people.

The instrument should be installed in rooms or areas where physical entry or presence can be controlled, to prevent unauthorized individuals from gaining access to the data on the instrument, in case a user is currently logged in.

The latest compatible software version for the instrument should always be used. Software updates can often include enhancements to the system's safety and security features, helping address potential vulnerabilities.

1.5 REGULATORY COMPLIANCE

GP Reader NT complies with the Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices and is CE marked under the sole responsibility of the manufacturer.

GP Reader NT complies with the Directive 2015/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) and the commission delegated Directive (EU) 2015/863 amending Annex II to Directive 2011/65/EU as regards the list of restricted substances. GP Reader NT complies with the Directive 2012/19/EU on waste electrical and electronic equipment (WEEE).

2 INTRODUCTION

2.1 INTENDED PURPOSE

GP Reader NT is an automated instrument for the quantitative determination of various analytes in human samples, such as whole blood, plasma or fecal samples, by measuring fluorescence signals from lateral flow test cassettes.

GP Reader NT is intended for use with compatible fluorimetric lateral flow immunoassay (FLFIA) test kits, such as GastroPanel® quick test NT (REF 602410 and REF 602420), as an aid in the diagnosis, screening, or monitoring of medical conditions, as specifically defined, along with the characteristics of the testing population, required specimen, and detected analyte, in the intended purpose of the individual test kit it is used with.

GP Reader NT is intended to be used by healthcare professionals, either in a laboratory or near-patient setting. For *in vitro* diagnostic use.

2.2 PREREQUISITES

The instrument is designed for easy operation by healthcare professionals without requiring specialized training. The initial setup and qualification of the device and configuration changes should be performed by an individual with system administration access rights (admin) as outlined in this guide.

A compatible test kit is required for performing tests with the instrument. Materials, reagents, and instructions for specific tests are included with the test kits and not provided with the device.

It's crucial to carefully read and understand the present guide to ensure proper instrument operation.

However, please note that individual test kits may have additional requirements that must be followed.

2.3 DEVICE DESCRIPTION

GP Reader NT is an automated instrument for the quantitative measurement of fluorescence Europium nanoparticle signals from lateral flow test cassettes for the determination of the presence and concentration of target analytes in samples examined with compatible lateral flow test kits. The reader is designed around an embedded Android system as a standalone instrument and controlled through the intuitive graphical user interface of the GP Reader NT application on a touchscreen display.

A motorized cassette tray with slots for 2 different cassette types slides automatically in and out by pressing the "Eject" button for loading and unloading single or multi-strip cassettes. A test is initiated by pressing the "Test" button, and once the test incubation software timer runs out (if activated) the instrument reads the fluorescence intensity from the line(s) on the test strip(s) and analyzes the data using sophisticated algorithms. The conversion of the measured fluorescence intensities into quantitative results is based on test- and lot-specific calibration data read either internally, from a QR code on the test cassette or via an external 2D barcode scanner. The results and an interpretation (where applicable) are displayed on the touchscreen and stored in memory to be retrieved anytime but can also be printed to a paper report using an integrated thermal printer by pressing the "Print" button or exported to a USB flash drive for further analysis or record-keeping purposes. For data management flexibility, GP Reader NT supports connectivity to Laboratory Information Systems (LIS), utilizing the HL7 v2.3.1 protocol.

2.4 OPERATING PRINCIPLE

A fluorescent light detection module is mounted on a platform moving in 2-axes driven by 2 stepper motors attached to linear actuators, controlled by microcontroller unit (MCU). The 2-axis motion of the detection module makes it possible to scan any area of interest within the motion range of the module, allowing the instrument to read single or multichannel fluorimetric lateral flow test cassettes in either of the two slots of the cassette tray.

An ultraviolet light emitting diode LED light source excites the fluorescent particles on the test and control lines of the test strips, which in turn emit fluorescent light that is captured by a light sensor after being filtered and focused by the optical components in the module. The intensity of the fluorescent light is translated by the sensor to an electric signal output, which is amplified and converted to digital, through an analog-to-digital converter (ADC) so that I can be processed as digital data.

The detection module features a 2D barcode scanner that can automatically read lot-specific information, such as the Lot number, expiration date and calibration data, from QR codes printed on the cassette's surface, and a temperature sensor monitoring the temperature of the test cassette. The test's temperature information can be used to scale or "correct" the results in cases where the performance of the immunoassay is influenced by the temperature, and the relationship is known and expressed in a mathematical way that can be implemented in the analysis algorithm.

The GP Reader NT software application receives the fluorescence intensity values, temperature, and lot-specific data in the QR code, from the detection module and together with the user input and test-specific settings on the application's interface, starts analyzing the data to produce results. The data is analyzed using data processing algorithms, which, depending on the test kit used, may include linear or non-linear curve fitting, such as OLS and 4-PL regression, interpolation and extrapolation, and special test-specific result interpretation.

2.5 PACKAGE CONTENTS

The reader is shipped in a cardboard box, including the following items:

1. GP Reader NT instrument (REF 740450)
2. Power supply adapter with mains cord (CEE 7/7)
3. Extra paper roll
4. User's Guide
5. Quality Certificate

Test kits or reagents required for testing purposes are not part of the product and must be purchased separately.

2.6 ACCESSORIES

Accessory	Specifications
Printer paper roll	Thermal, size 57 × 30 × 12 mm, BPA-free
Euro plug	CEE 7/7 - C13, (250 V, 16 A)
Power Supply Adapter	Voltage: 100 ~ 240 V AC to 12 V DC Frequency: 50/60 ± 1 Hz, Rated power: 30 W

2.7 TEST KIT COMPATIBILITY

The device is intended to be used only with test cassettes from compatible test kits. A test kit is considered compatible with GP Reader NT only when this is clearly stated in the kit's Instruction for User (IFU) and its intended purpose does not override the intended purpose of the instrument.

Test kit compatibility. Do not use a test cassette before confirming it is compatible with the reader by consulting the test kit's instructions.

2.8 HARDWARE

The reader is designed around an embedded Android system (Android mainboard), to operate as a standalone instrument, allowing user interaction through a touchscreen display. The main measuring module of the system is the detection module incorporating the fluorescence measurement module, an internal 2D barcode scanner and an infrared temperature sensor.

The motion control module is responsible for the mechanical parts of the system, driving 2-axis motion of the detection module and in/out sliding of the cassette tray. The motion control module is a metallic assembly equipped with 2 stepper motors with linear actuators and 2 limit sensor switches for setting the home position of the module during initialization. The detection and motion control modules are powered by the Motion control and detection power and data routing board, which also handles the data transfer from and to the main processing board. The Power and I/O board provides connection ports (USB, LAN, COM) and includes the power switch (On/Off) and the DC power input socket and the data interface needed for the thermal printer mounted in the housing of the device. The external 2D barcode scanner and the physical buttons for printing, test initialization, and ejecting the cassette tray, are directly interfaced to the Android mainboard. A block diagram of the hardware structure of the system is shown in Figure 1.

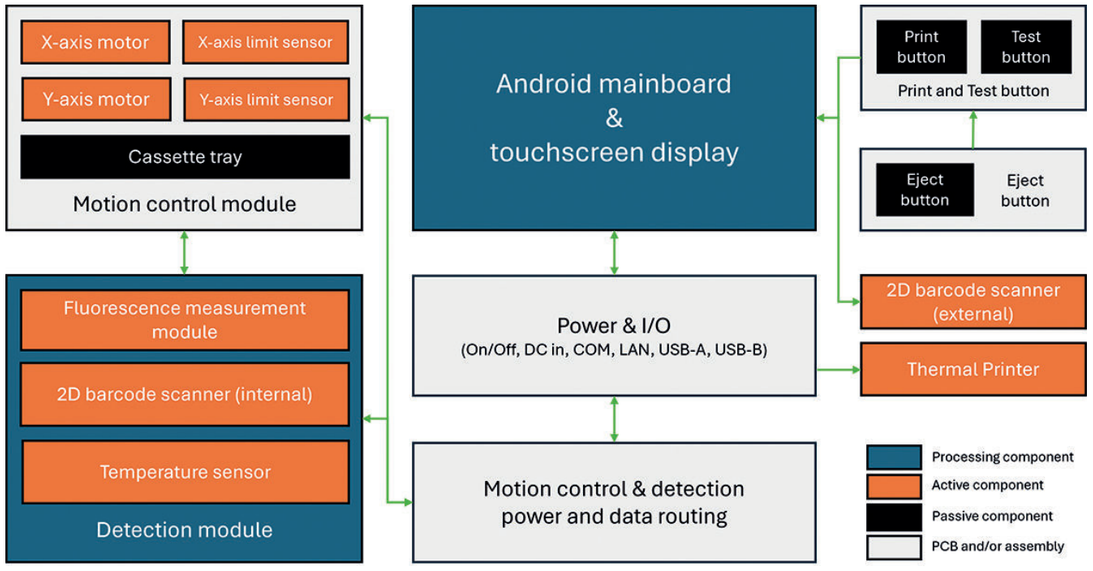

Figure 1. *Hardware block diagram of the system.*

2.9 SOFTWARE

The graphical user interface (GUI) of the reader has been designed to be intuitive, simple to use, and to minimize the steps needed for basic operations, making new test reading and result browsing easy and fast. The hierarchical structure of the of the software GUI is shown in Figure 2.

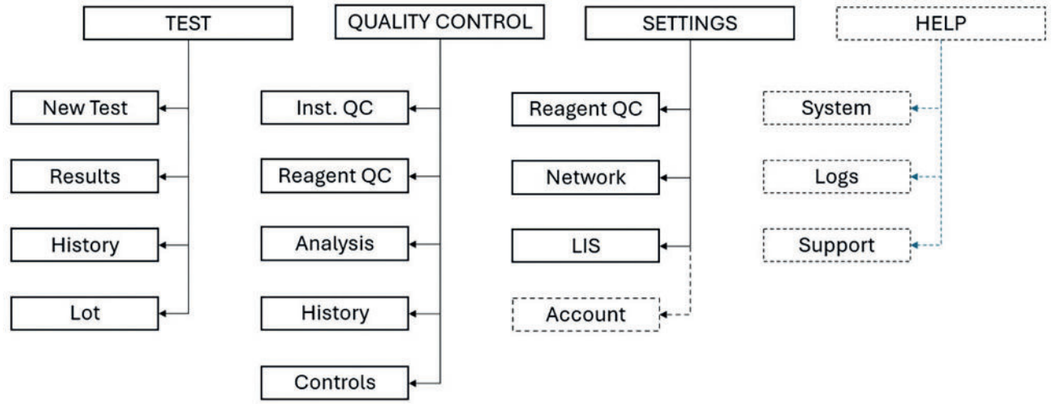

Figure 2. *Hierarchical structure of the GP Reader NT app interface. Dashed borders indicate admin access only.*

TEST menu is used to carry out new analyses and review, print, or export results stored in memory.

QUALITY CONTROL menu is used to check the instrument's measuring performance or perform quality control of reagents.

SETTINGS menu is used to configure and establish the connection to LIS and Reagent QC. This is also where the user accounts are created, deleted, or modified by an operator with admin permissions.

HELP is only accessible to admin users and shows information such as the hardware and software version and serial number of the device. In the help menu, the admin can also set the time and language, update the software, clear all the stored data and reset the instrument.

2.10 INTERFACE

The main functional and I/O interface features are illustrated and described below:

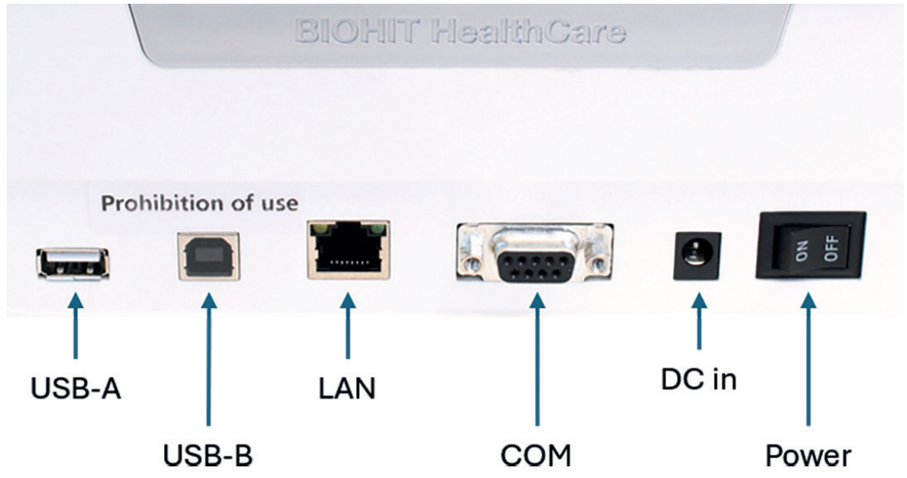

Figure 3. *Back side panel of GP Reader NT with I/O ports.*

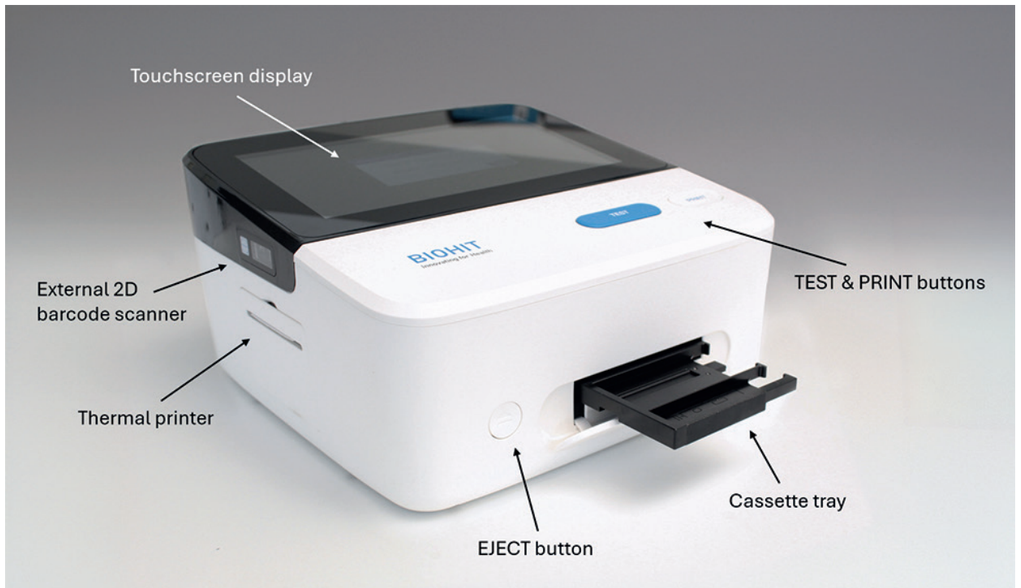

Figure 4. *GP Reader NT main external features.*

Feature	Description
Touchscreen	User control of the instrument software
External 2D barcode scanner	Reads QR codes to import Lot files (if provided with the test kit)
Test and Print buttons	Buttons to start the testing or print the test results
Eject button	Button to Slide the cassette tray in/out to load/unload a test cassette
Thermal printer	Prints a paper report of the results
Cassette tray	Holds the cassettes to be tested by the instrument
USB-A	Connection of USB memory devices for data export and software updates
USB-B	Not used; reserved for programming and debugging
LAN	Port for local network connection to LIS
COM	Not used; reserved for programming and debugging
DC in	12 V DC input socket
Power	Switches on and off the instrument

2.11 BASIC FUNCTIONS AND FEATURES

GP Reader NT has the following features:

1. Operation through a touchscreen display
2. Intuitive Graphical User Interface (GUI)
3. 2-way QR code scanning (internal, external) of the Lot-specific parameters, from the test cassette or sticker inside the kit box
4. Conversion of fluorescence intensity measurements to concentrations, display of the results on the screen
5. Instant result printing to a paper report on the integrated thermal printer
6. Data storage to internal memory and easy test history browsing (over 100,000 single strip results)
7. LIS connectivity (HL7 protocol)
8. Export of stored data to USB memory device
9. Automated tray with 2 slots for different test cassette sizes

3 SETUP

3.1 OPERATING ENVIRONMENT

The GP Reader NT is designed to operate optimally at normal room temperatures. Although the instrument withstands wide operating temperatures, the tests used with it can have their own specific operating tolerances which must be adhered to. The ranges of the operating conditions of GP Reader NT are shown below:

Operating conditions	Ambient temperature: 5 to 40°C Relative humidity: < 80% Atmospheric pressure: 86–106 kPa

The reader is intended to be used indoors and placed on a dry, clean, flat, horizontal, and stable surface such as a table or laboratory bench, away from any major heat sources. The room must be free of excessive dust, vibration, strong magnetic fields, UV radiation and high humidity. Leave enough space on each side of the instrument (10 cm at least).

3.2 UNPACKING

GP Reader NT and its accessories are securely shipped inside packaging that protects them from damage during transportation. Upon delivery, inspect the shipping box, packaging, instrument, and accessories for signs of any damage.

To unpack the instrument and its accessories:

1. Carefully open the top of the box, and remove the power supply, documents supplied, and accessories.
2. Check that all the listed package contents are included in the box and the delivery is complete.
3. Lift the reader out of the box and remove the left and right foam end caps. Place the reader on a flat table or bench.
4. Connect the power cord to the power adapter and connect the power supply to the DC-in socket at the rear of the instrument. Finally, connect the power cord to the mains.
5. Remove transport support from the cassette slot.

Damaged packaging. If the product has been shipped to you in a condition that might indicate damage to the contents, please notify the carrier and your manufacturer's representative before using the instrument.

3.3 REPACKING

To repack the instrument and its accessories:

1. Before repacking the reader, please make sure to decontaminate the instrument as instructed in section 6.2.

2. Repack the reader to its original packaging in the reverse order of the unpacking instructions. Other forms of commercially available packaging are not recommended and can void the warranty. If the original packing materials have been damaged or lost, contact Biohit Oyj for replacement packaging.
3. Always contact a Biohit Oyj representative and follow the support instructions in section 9.1 before sending an instrument for return or repair.

3.4 ELECTRICAL CONNECTIONS

To provide electrical power to the instrument:

1. Connect the mains power cord to the external power adapter.

2. Plug the round end of the power adapter cable into the power supply socket on the rear of the instrument.

3. Plug the 3-prong end of the mains power cord into an appropriate power receptacle.

4. Use the **ON/OFF** switch, at the rear of the instrument, to power on the instrument.

Power Supply. Only use the specified power adapter provided with the GP Reader NT to ensure proper operation of the unit. The GP Reader NT has a universal 12 V DC, 30 W power supply that functions from 100 to 240 V AC (± 10.0%) at 50/60 Hz (± 1 Hz) without external switching.

Electrical shock. The GP Reader NT power supply must be connected to a power receptacle that provides voltage and current within the specified rating for the system. Use of an incompatible power receptacle may produce electrical shock and fire hazards.

Grounding. Never use a two-prong plug adapter to connect primary power to the GP Reader NT power supply. Use of a two-prong adapter disconnects the utility ground, creating a severe shock hazard. Always connect the power supply cord directly to a three-prong receptacle with a functional ground.

Power Supply. Only use the specified power adapter provided with the GP Reader NT to ensure proper operation of the unit. The GP Reader NT has a universal 12 V DC, 30 W power supply that functions from 100 to 240 V AC (± 10.0%) at 50/60 Hz (± 1 Hz) without external switching.

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4 OPERATION

4.1 STARTING THE INSTRUMENT

Switch on the instrument using the **ON/OFF** switch at the back of the device. The system will boot up and the Biohit logo screen (Figure 5) will appear on the display.

Figure 5. *Biohit logo screen is shown during the boot up.*

During this process, the operating system boots, automatic hardware self-checks are performed, and the GP Reader NT app is started. When the booting process is completed the System Login screen appears on the display.

4.2 LOGIN

4.2.1 Login as regular user (operator)

In the System Login screen (Figure 6), enter your credentials (Account ID and Password) and tap **Login**. If the credentials are correct and the login is successful, the Main Menu screen will be displayed.

Do not operate the device from an account that does not belong to you. In case another user is logged in, first logout and login again with your own credentials.

Make sure that the operator's Account ID, date and time displayed in the top right corner of the screen are correct, so as not to hamper the traceability of the analysis. If the date and/or time are not correct, ask the system administrator to adjust them.

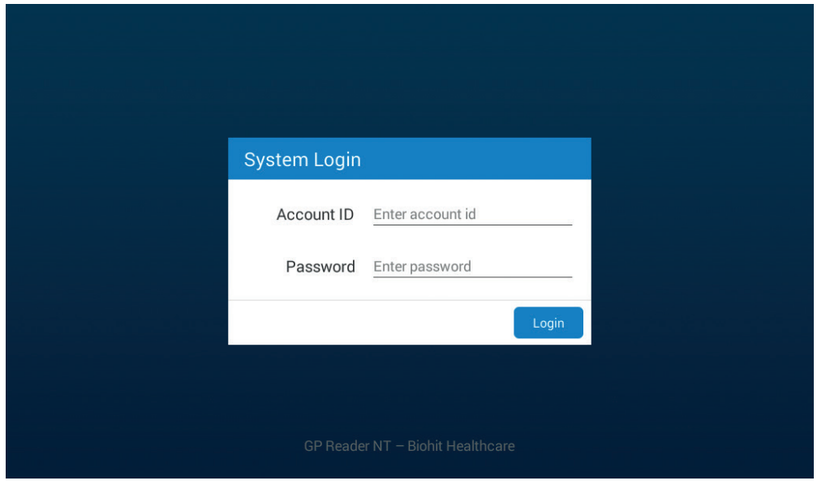

Figure 6. *System Login screen.*

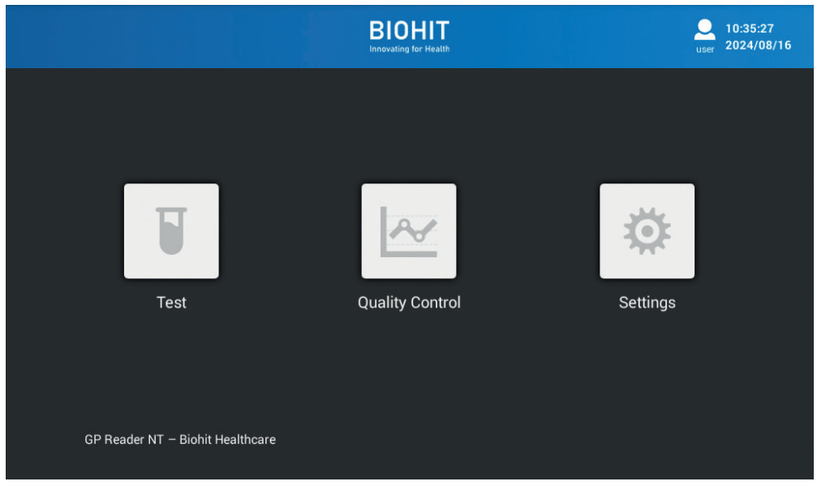

Figure 7. *Main menu screen.*

4.2.2 Login as system administrator (admin)

The administrator of the system (or admin) is a user with elevated control rights and responsibility over the instrument's settings and operation. The admin initially obtains the login credentials from the distributor or the manufacturer but can change the password once logged in for the first time. Use your administrator credentials to login as admin. When logged in as administrator, the Main menu includes an additional Help icon and a **QUIT** button.

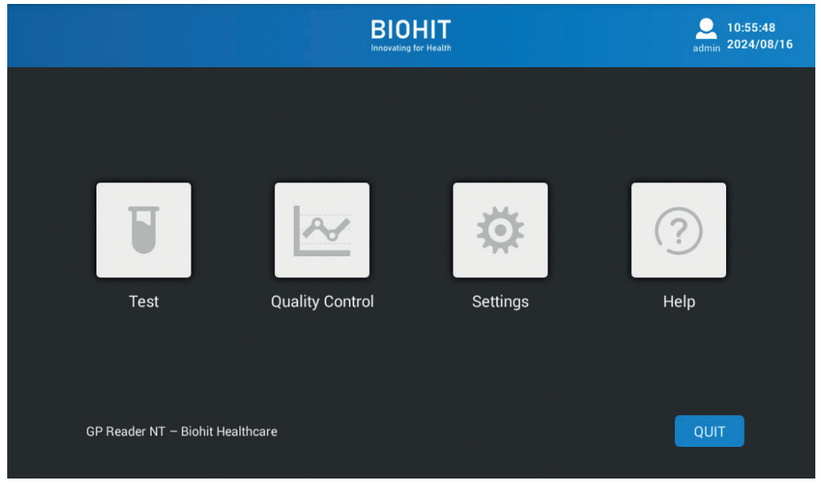

Figure 8. *Main menu when logged in as administrator (admin).*

QUIT Exits the application and shows the home screen of Android the operating system

Do not use the 'admin' account to run any clinical samples. Instead, always use a specific 'operator' account to run new tests. If you don't have credentials, ask the system administrator to create a user account for you.

4.3 TEST

Some of the figures used in this guide present a use case of GP Reader NT in conjunction with Biohit's GastroPanel® quick test NT (GPQT NT) test kit (REF 602410, REF 602420), as an example. The interface of the application is dynamic and may vary depending on the product selected. For settings, texts, or input and output data that are specific to the product used, refer to the instructions provided with the test kit.

Measurement initiation, cassette tray opening/closing, and report printing functions of GP Reader NT can be started in two, equally effective ways, either by pressing the **TEST**, **EJECT**, and **PRINT** physical buttons on the external surface of the instrument or tapping **START**, **IN/OUT**, and **PRINT** software buttons of the app interface on the touchscreen display, respectively. In the context of this document, wherever the software button is mentioned, for any of the above functions, the corresponding physical button could be used as well, and vice versa, according to the user's preference.

4.3.1 New Test

To perform a new test, tap on the **Test** icon of the Main menu to enter the New Test screen (Figure 19).

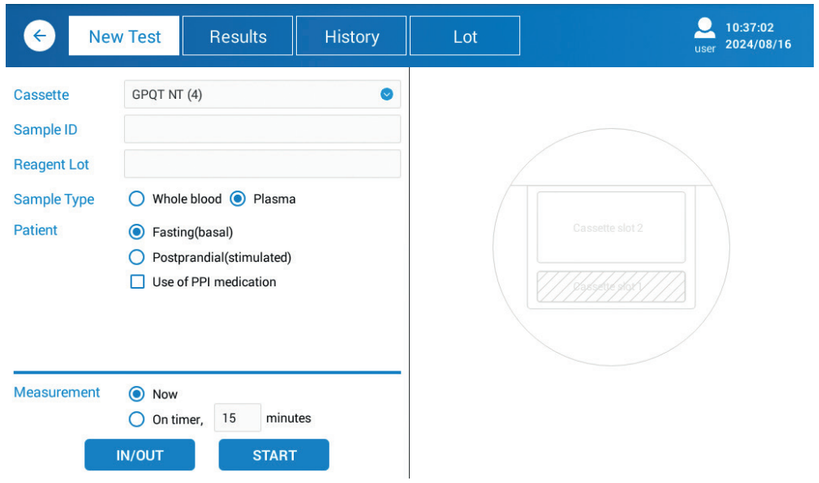

Figure 9. *New Test tab of Test menu.*

The New Test screen is entered by default when selecting Test from the main menu. To carry out a new test, the test-specific parameters (if any) need to be entered. Refer to the instructions of the test kit used with the instrument.

Cassette
The Cassette dropdown menu is used to select the test kit product to be used with the instrument.

Sample ID
Enter the ID of the sample to be analyzed. When the field is selected, a pop-up keyboard will be displayed.
Please follow local and national regulations in using sample/patient identification. Make sure you follow EU General Data Protection Regulation 2016/679 when processing the data of EU citizens.

Reagent Lot
The Reagent Lot dropdown menu is used to select the lot number of the test kit to be used with the instrument. In most cases it can be left blank as the lot number and the lot-specific data needed for analyzing the test are automatically read from a QR code printed on the test cassette. In case the QR code on the test cassette does not exist or is unreadable for any reason, a QR code containing the necessary lot-specific information, which can be either printed on the kit box or found inside it as a sticker, must be read using the external 2D barcode scanner. This is achieved with the functions in the Lot tab of the Test menu. As soon as the Lot QR code has been read successfully or if the same lot has been used before and stored in memory, the lot number can be selected from the Reagent lot dropdown menu.

Using an incorrect QR code may lead to incorrect test results, so be careful when feeding the QR code manually.

Inaccurate test-specific settings may lead to incorrect results.

Measurement

The measurement of the test cassette can be initiated in two ways:

Option 1: Now
With this option, the measurement and analysis of the test starts immediately after pressing **TEST** or tapping **START**. If incubation time is needed for the test, an external timer can be used, following the instructions of the kit in use. In this case, the test cassette may be placed into the cassette tray slot for the incubation time. The measurement must be started when the timer expires. Upon pressing **TEST** or tapping **START** the cassette tray slides in automatically.

Option 2: On timer
With this option, no external incubation timer is needed. If incubation time is needed for the test, the GP Reader NT's dedicated timer can be used. The user sets the incubation time according to the instructions of the test kit in use. The timer is activated, and the countdown starts as soon as **TEST** is pressed. The remaining time before the measurement starts is displayed on the screen, as shown in Figure 10. The test cassette can be placed into the slot of the tray for the incubation time. When the timer expires, the cassette tray automatically slides into the reader, and the measurement starts. The default time for the software timer depends on the product selected.

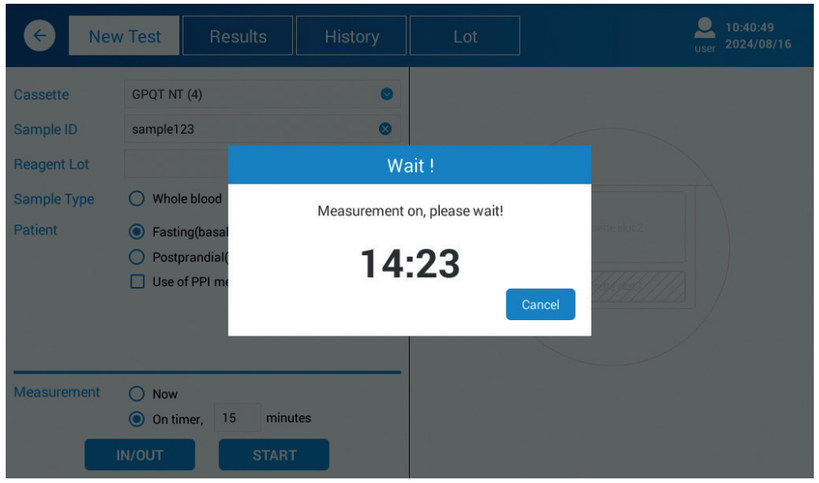

Figure 10. *The remaining time before measurement starts is displayed on the screen.*

For most tests, it is critical to measure the cassette at exactly the defined time after pipetting the sample onto the test strips. If, for some reason, the activation of the timer is delayed, the user can compensate for the time missed by setting the timer accordingly.

Open the tray by pressing **EJECT** or tapping **IN/OUT**.

Make sure to place your test cassette in the correct orientation in the cassette tray slot. The arrow on the cassette should be pointing to the left, as shown in Figure 11.

Figure 11. *Correct orientation of the test cassette in the tray slot.*

Pay attention to the correct orientation of the test cassette on the slide-in cassette holder.

Do not hinder the cassette holder from moving as it may fail to find the correct position when preparing for scanning.

As soon as the measurement has been completed and data processed, the test results will be displayed on the right side of the screen, as illustrated in Figure 12. Results are automatically stored in the memory of the reader.

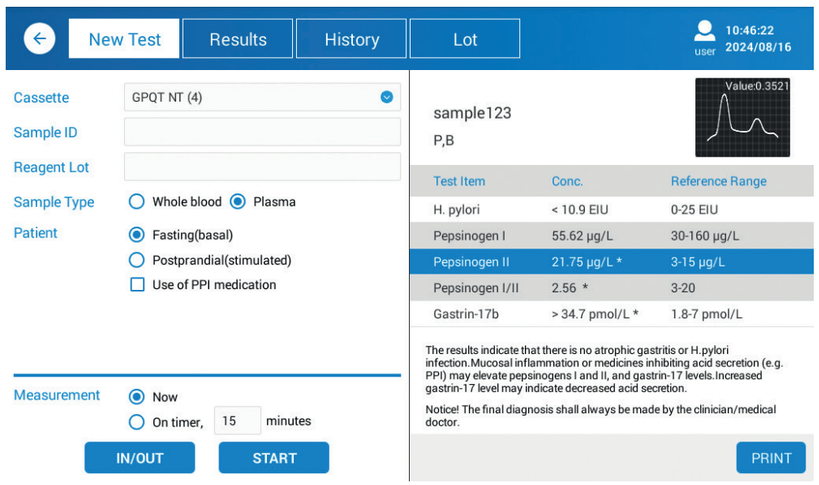

Figure 12. *Test results displayed on the screen.*

Tap **PRINT** to print a test report, including the date/time, user, sample information, test-specific settings, results, and instrument information on a paper report, using the integrated thermal printer.

IN/OUT Slide the cassette tray in/out to load/unload a test cassette into the instrument

STARTS Start the measurement (Now) or activate the timer (On timer) for the measurement

PRINT Print a paper report of the results.

4.3.2 Results

To view, print, or export previous results, select the Results tab from the Test menu.

On the Results screen, a list of recent results is displayed. The results shown on the list can be filtered by Date range, Sample ID or by Operator on the filtering ribbon right under the top bar. When a specific result is selected from the list on the left side of the screen, the results are displayed on the right panel of the screen.

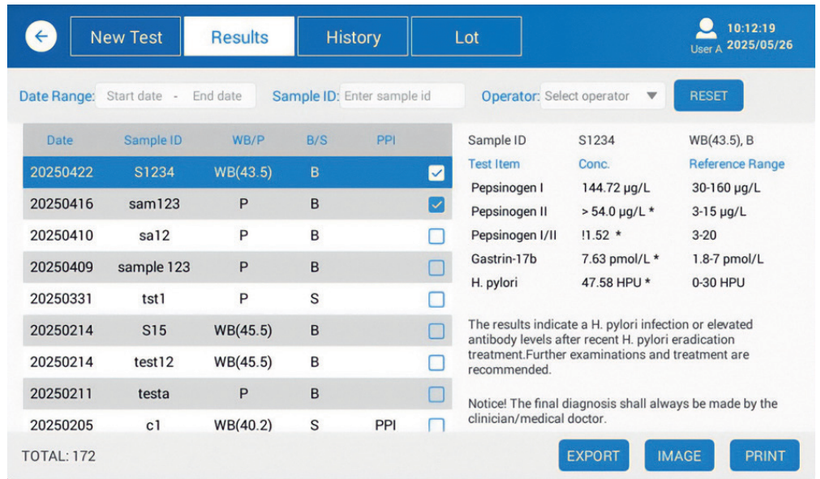

Figure 13. *Results tab of Test menu.*

RESET Reset the filter settings

PRINT Print the selected result (high-lighted with a blue background) to a paper report, using the integrated thermal printer

IMAGE Export the selected reports (tick box checked) to a USB memory device connected to the USB-A port on the back panel of the instrument in jpeg format.

EXPORT Export the results to a USB memory device connected to the USB-A port on the back panel of the instrument in a CSV format file for further processing or storage.

Follow local and national regulations in using patient name or other identification of the sample. As the reader contains patient laboratory results, make sure that the reader is kept in a safe and secure place, which is not accessible by any unauthorized user. If you print or export data on any media, make sure that patient rights and consent are obeyed, and the EU General Data Protection Regulation 2016/679 is followed when processing data of EU citizens.

4.3.3 History

The History tab is similar to the Results tab in that both show test results stored in the internal memory of the instrument (Figure 14). The filtering of the results also works in the same way. The difference is that in the History tab the results of multistrip tests are shown as separate entries on the list, so that a specific analyte or marker measure can be isolated and deleted or sent to LIS on its own.

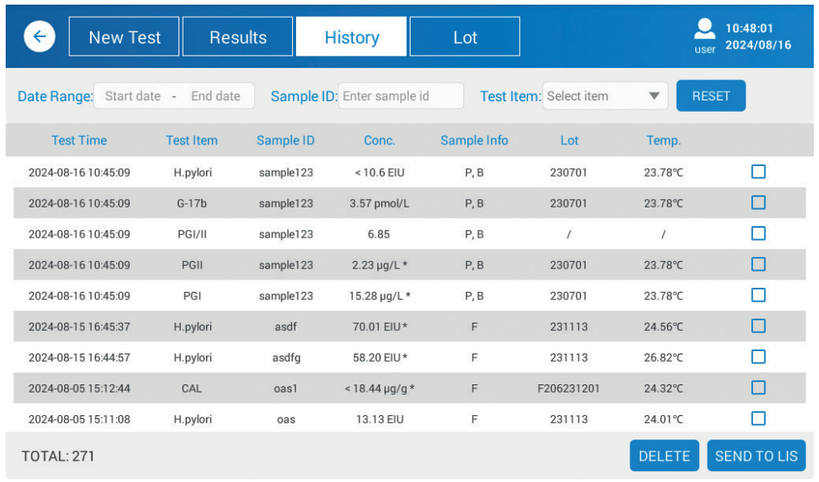

Figure 14. *History tab of Test menu.*

RESET Reset the filter settings

DELETE Delete the selected results from memory permanently

SEND TO LIS Send the selected results to a connected Laboratory Information System (LIS). The LIS connection must be configured and enabled before data transmission. Please contact Biohit Oyj for more information about the LIS connectivity and the supported protocol

Be careful when deleting data from the instrument. These actions cannot be reversed, and the data will be erased permanently.

4.3.4 Lot

This tab of the Test menu is used to import the lot-specific data needed when reading and analyzing a new test cassette. Most tests cassettes have the QR code printed on their surface, and it is read automatically by the internal 2D barcode reader. For cases where the test cassette does not have the QR code printed on it, the necessary lot-specific information can be read from a sticker or insert that comes with the test kit box using the external 2D barcode scanner by tapping **CODE SCAN**. Alternatively, the data can be imported as a file titled (batch_info.txt) from the root directory of a USB memory device by tapping **FROM USB**. This file should be provided by the manufacturer or distributor of the test kit to be used, upon request.

The imported lot files are stored in memory and can be selected from the Reagent Lot dropdown menu of the New Test tab when configuring a new test. When a Lot file is no longer needed, it can be deleted from memory by tapping **DELETE**.

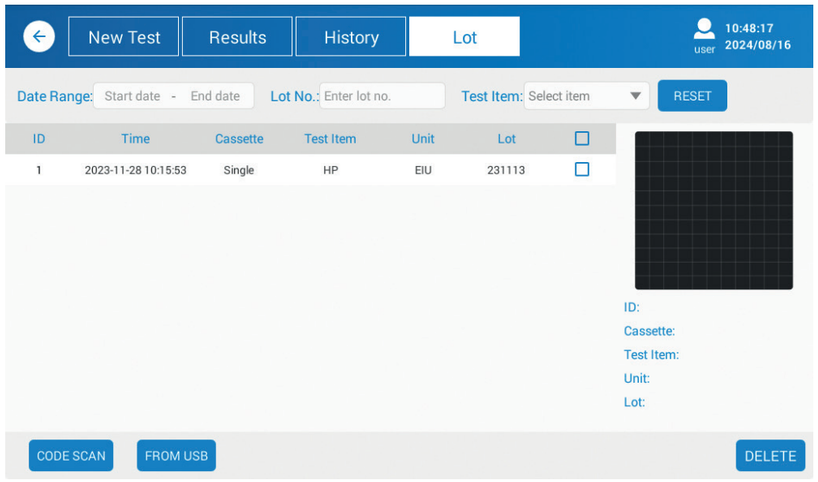

Figure 15. *Lot tab of Test menu.*

The list of Lot files can also be filtered by Date, lot number or Test Item.

RESET Reset the filter settings

CODE SCAN Activate the external 2D barcode scanner to read a QR code containing the Lot-specific information.

FROM USB Import the data from a file titled batch_info.txt which is stored in the root directory of a USB memory device connected to the USB-A port of the instrument.

DELETE Delete the selected lot file

4.4 QUALITY CONTROL

4.4.1 Instrument QC (Inst. QC)

The Instrument QC function can be used to test the instrument's fluorescence measurement function performance with the help of a single-strip QC Cassette (not provided). The High Limit and Low Limit values set the range within which the result needs to be for the QC test to be considered successful.

To start the Instrument QC process, tap **IN/OUT** to open the cassette tray, insert the single-strip QC cassette into the single cassette slot of the cassette tray and tap **START** to start the measurement. The results will be displayed on the right side of the display. The results of the Instrument QC can be printed on paper using the integrated printer.

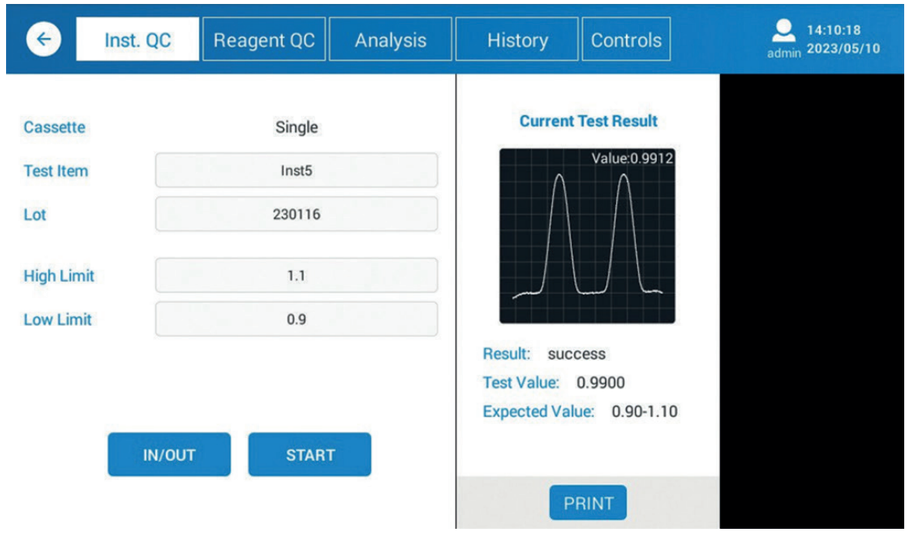

Figure 16. *Instrument QC.*

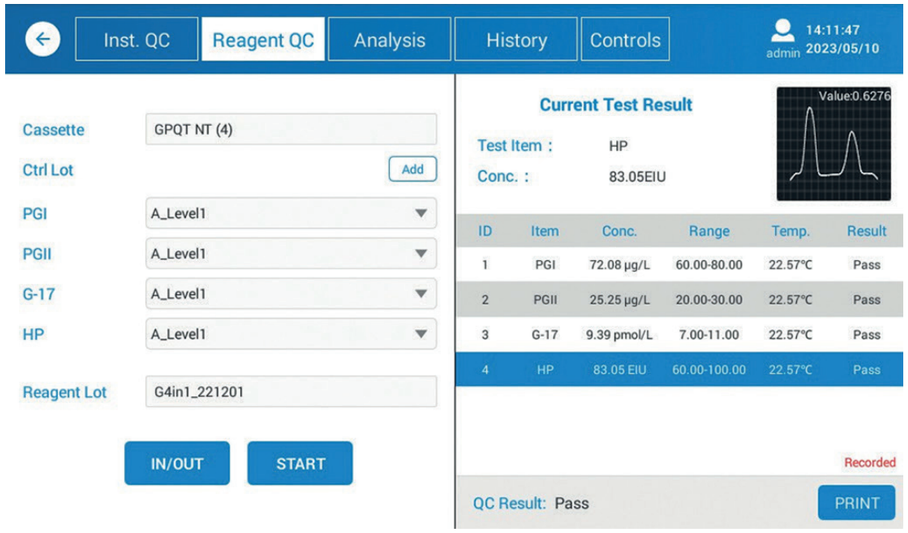

Figure 17. *Reagent QC.*

IN/OUT Slide the cassette tray in/out to load/unload a test cassette into the instrument.

START Start the measurement process of the QC cassette

PRINT Print the results of the Instrument QC to a paper report

4.4.2 Reagent QC

The Reagent QC feature can be used to control the performance of the combination of the instrument with a test kit and control samples used for the quality control of the kit (not provided).

The product (test kit name) used can be selected from the **Cassette** dropdown menu and the control sample values for the markers or analytes detected by the test can be selected from their own dropdown menus. The values of the control samples shown in the dropdown menus must have previously been set using the **Control LOT** dialog window (Figure 18) that is displayed by tapping the **Add** button and stored in memory. The Lot number of the test kit used is selected from the Reagent Lot dropdown menu and must have been stored in memory or printed on the test cassette used for the Reagent QC testing.

When everything has been set, tap **IN/OUT** to open the cassette tray, insert the test cassette into the correct cassette slot of the cassette tray and tap **START** to start the measurement. The details and the results of the Reagent QC test will be displayed on the right side of the screen. The last column to the right of the table will be showing the Pass or Fail result, separately for each one of the markers or analytes. The results of the Reagent QC can be printed on paper using the integrated printer, by tapping **PRINT**.

Add Add values and ranges for a new lot of control samples

IN/OUT Slide the cassette tray in/out to load/unload a test cassette into the instrument

START Start the measurement process

PRINT Print the results of the Reagent QC to a paper report

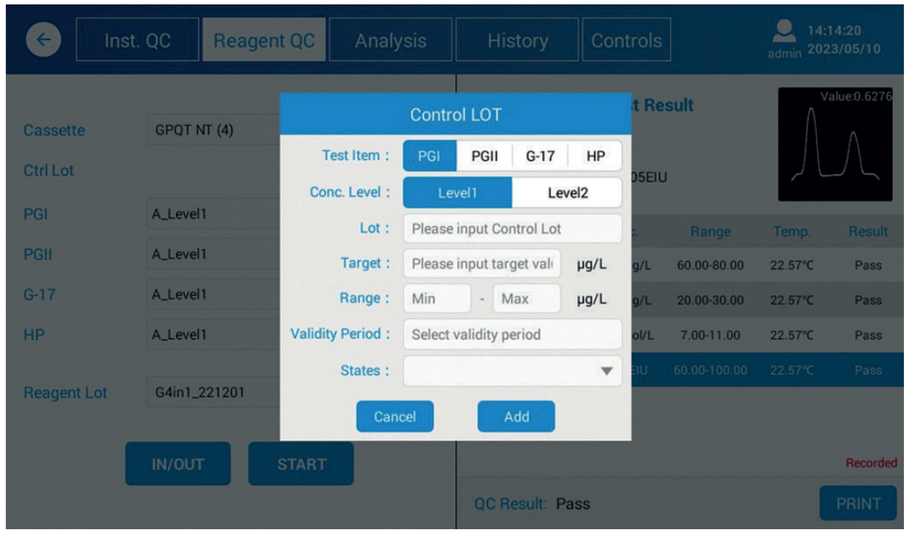

Figure 18. *Control Lot Dialog window.*

In the Control LOT, the user can configure up to two values for control samples for each marker for a new Lot. The fields that must be filled for each control sample are the control **Lot** number, **Target** concentration value, acceptance **Range**, date **Validity Period** and the state can be set to Enabled or Invalid from the **States** dropdown menu. When all fields are set, tap Add to store the Control Lot or Cancel to abort the process.

4.4.3 Analysis

The Analysis page is used to display statistical information of the results of the Reagent QC data and a graph of the resulting value against the QC test points. The results can be filtered by marker (**Test Item**), product (**Cassette**), control sample value **Level**, **Date**, and Control Lot (**Ctrl Lot**).

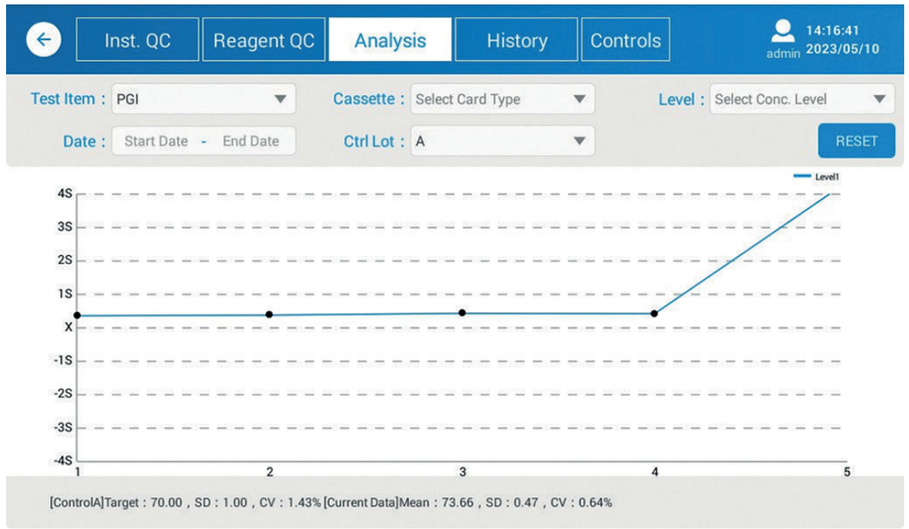

Figure 19. *Analysis of the Reagent QC.*

RESET Reset all filters that have been applied

4.4.4 History

The **History** page displays all the QC data measurement results and can be filtered by **Date Range**, marker (**Test Item**), control sample value level 1 or 2 (**Ctrl Level**), Control Lot (**Ctrl Lot**), success or fail (**Result**) and **Status** of the control sample. The user can choose to display only Instrument QC or Reagent QC data from the radio buttons at the bottom-left part of the screen. The results are selectable using the checkboxes on the last column of the result table. The selected results can then be sent to LIS, exported as a CSV file to USB, processed, deleted or printed on paper.

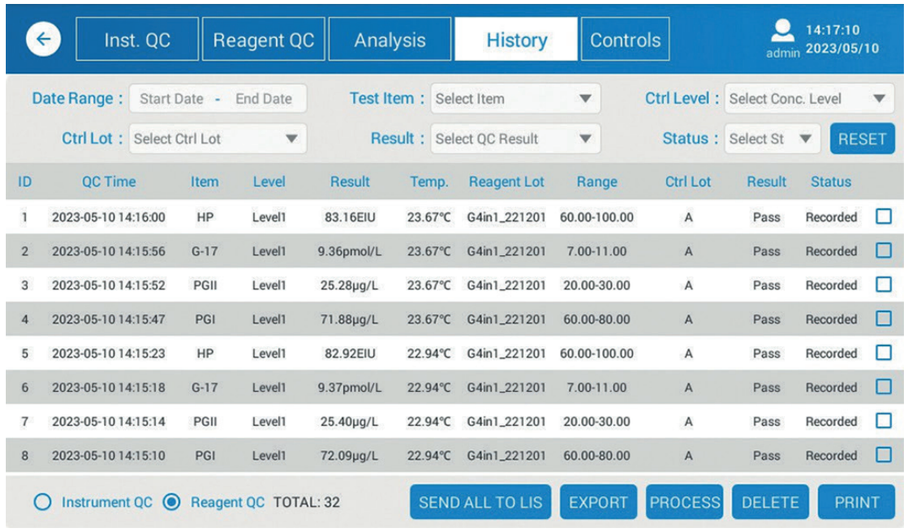

Figure 20. *History of QC tests.*

RESET Reset the filter settings

SEND ALL TO LIS Send the selected QC results to a connected and enabled LIS over LAN

EXPORT Export the selected QC results to a connected USB storage device

PROCESS Add short informative text to the selected result for identification

DELETE Delete the selected QC results

PRINT Print the selected QC results to a paper report

Be careful when deleting data from the instrument. These actions cannot be reversed, and the data will be erased permanently.

4.4.5 Controls

The Controls tab displays all the control samples used and stored in the device´s memory (Figure 21). The controls can be filtered by **Date**, marker (**Test Item**), and Control Lot (**Ctrl Lot**), control sample value level 1 or 2 (**Level**), and **Status**.

The status of the controls can be changed to Enabled or Invalid from the Using Status column of the table (change to Invalid when a specific control sample has expired or is unavailable, for example), and entries can be deleted by selecting them using the checkbox and tapping **DELETE**.

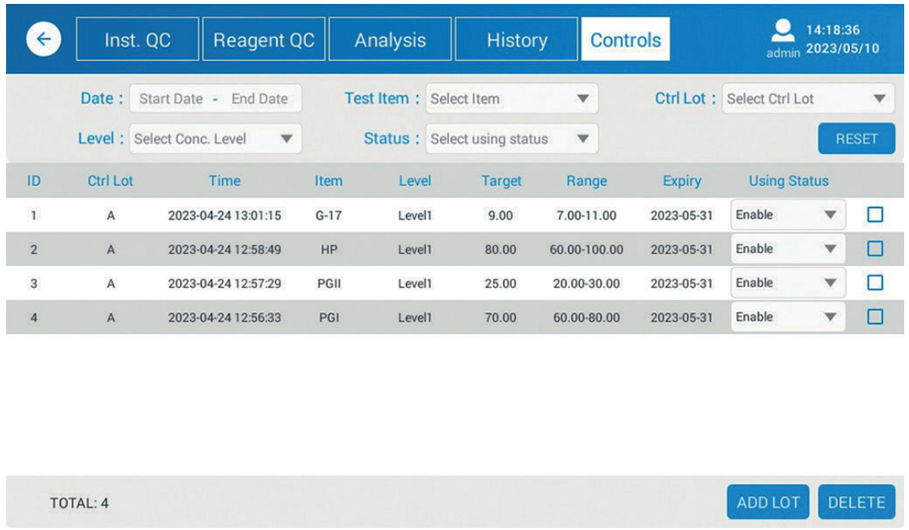

Figure 21. *Controls tab of Quality Control menu.*

RESET Reset the filter settings

ADD LOT Add a new Control Lot with the Control LOT dialog window (Figure 18)

DELETE Delete the selected QC control sample entries

4.5 SETTINGS

4.5.1 Reagent QC

The Reagent QC tab of the Settings menu offers some customization options for the configuration of the Reagent QC function described in 4.4.2.

Upper and lower limit rule allows users to set up upper and lower limits as the acceptance range for the control sample QC results.

1_3S rule corresponds to the 1_{3S} in a Levey-Jennings chart where the control limits are set as ±3 s (3 × SD) from the mean value of the measurements. A single data point is rejected when it falls outside the ±3 s control limit.

The data set from which the mean value and the standard deviation are calculated can also be chosen to include the first 20 plus last month's data points, the first 20 plus previous month's data points, or all mean target values and Standard deviation be explicitly set by the user for each marker.

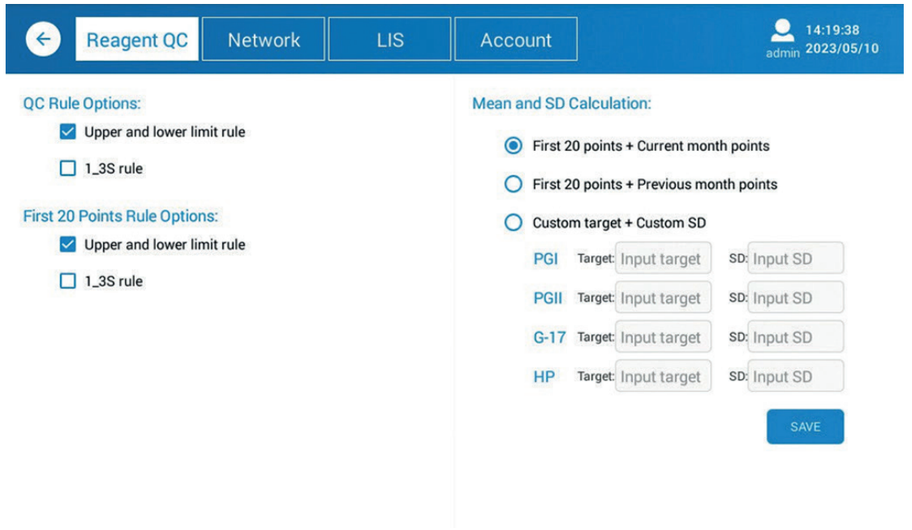

Figure 22. *Reagent QC settings.*

SAVE Save the selected options for the Reagent QC

4.5.2 Network

In the Network tab of the Settings menu, tap **SETTINGS** to open the system network settings. From there, select Ethernet and configure the IP Address and MAC Adress of the network adapter of the system to connect to LIS over a local area network (LAN). If you are not familiar with LAN and LIS protocols and configurations, it is advised that these settings are modified only by or after consulting IT personnel or the LIS administrator of the establishment.

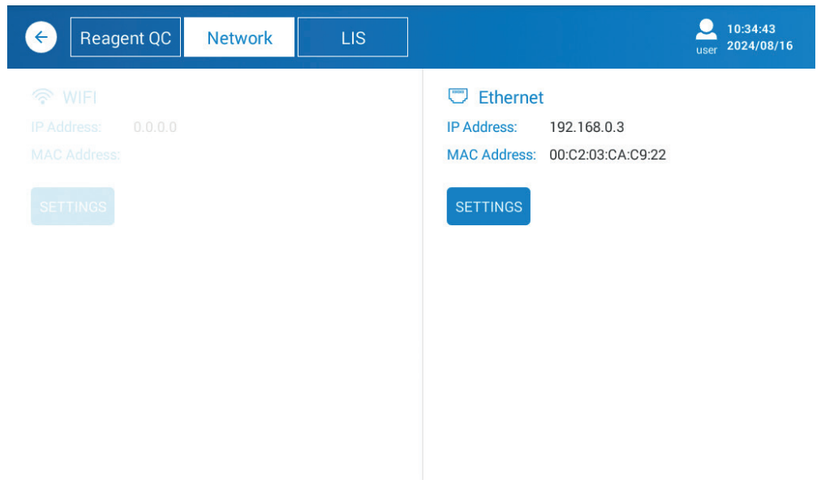

Figure 23. *Network settings tab*

SETTINGS Open the system local network connection settings.

4.5.3 LIS

GP Reader NT supports integration with LIS systems via the HL7 protocol (v. 2.3.1). As soon as the network parameters have been set and communication enabled, you can set up LIS parameters to connect to the host system.

Lis Enabled is used to enable or disable the connection to LIS.

Local IP shows the IP of the instrument on the local network, when connected. Otherwise, it shows that the network is not connected.

LIS IP is used to set the IP of the LIS host system.

LIS Port is used to set the Port of the LIS system. Enter the host system LIS IP address and the LIS Port.

LOCAL IP SETTINGS Open the Network settings tab

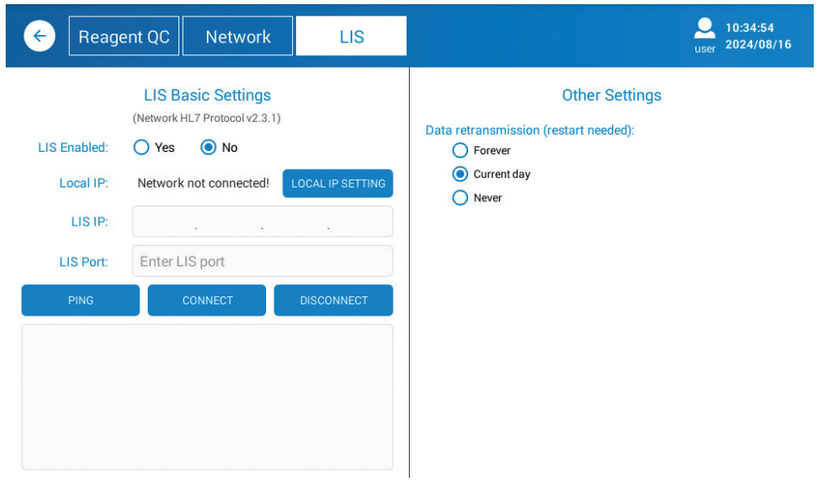

Figure 24. *LIS settings tab.*

PING Test the connection between the instrument and the LIS host
CONNECT Try to establish a connection between the instrument and the LIS server
DISCONNECT Close the connection

Please contact Biohit Oyj for more information about LIS connectivity and the HL7 protocol messages supported by the instrument.

4.5.4 Account (admin)

On this tab, the system administrator can create new user accounts, delete accounts or modify the passwords of the existing ones.

Change Password Change the password of an existing user account
Delete Delete a user account from the system
ADD Add a new user account to the system

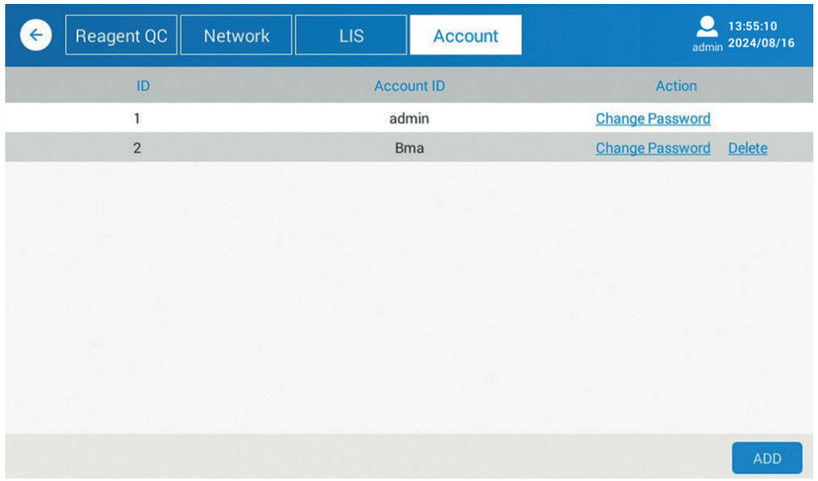

Figure 25. *Account settings tab (admin).*

4.6 HELP (admin)

Tap Help to enter the Help menu screen. On the System tab the administrator can see important traceability and reference information about the device:

Instrument Displays the name of the reader
Hardware Displays the firmware version of the device
Serial Number Displays the unique serial number of the device
Software Version Displays the version of the software currently installed on the instrument

The admin can also clear all stored data, reset the device to the factory defaults, adjust date and time, change the display language, and update the software version running on the device from a USB storage device. When clearing all data or resetting the device, a confirmation window will appear, asking to confirm the operation with a warning message that all data will be deleted permanently and cannot be restored if **OK** is pressed. Click **Cancel** to abandon the operation and return to the Help screen keeping the data intact.

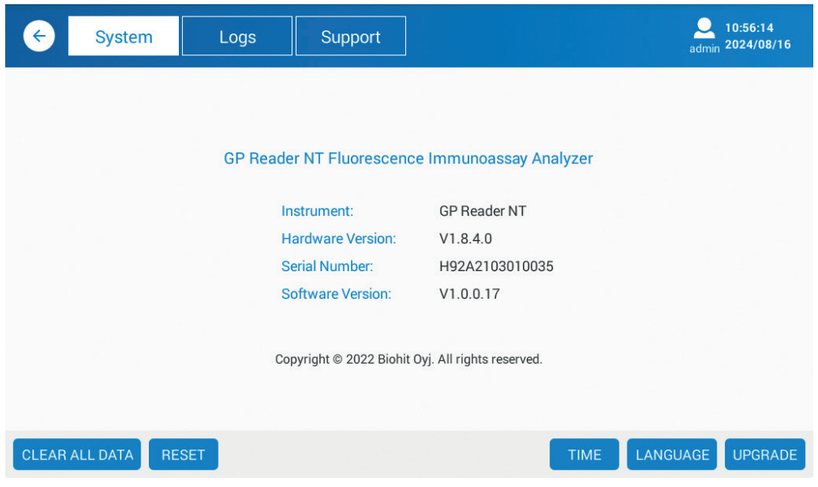

Figure 26. *Help screen (admin).*

CLEAR ALL DATA Delete all test, quality control and history data from the device

RESET Reset the device to its factory default settings

TIME Adjust the time and date settings (see 4.6.3)

LANGUAGE Select the preferred language for the user interface (see 4.6.1)

UPGRADE Update the software version of the instrument (see 4.6.2)

Be careful when using the functions and modifying the settings available in the Help menu as they affect the instrument's operation for all user accounts.

Be careful when clearing data from the instrument or resetting the device. These actions cannot be reversed, and the data will be erased permanently.

4.6.1 Language (admin)

The admin user can change the language in which the user interface of the application is displayed. The available languages to choose from are English, Spanish, German, French, Italian, Finnish, and Romanian.
Tap **LANGUAGE** and select a language from the popup list menu.

4.6.2 Software update (admin)

The GP Reader NT application can be updated from a USB storage device, such as a USB flash drive. Your distributor will provide you with the correct installation package file (.apk file extension). Copy this file to the root directory of a USB storage device and connect it to the USB-A port of the instrument. When you tap **UPGRADE**, the system will automatically find the update file from the USB drive and open an installation dialog box. Tap Install, wait for the installation to finish and tap **Open** to open the updated application. In case an update file is not found on the root of the USB drive, a USB device is not connected or is not working, you will see the *"No update on USB flash drive or wrong file location"* message on the display.

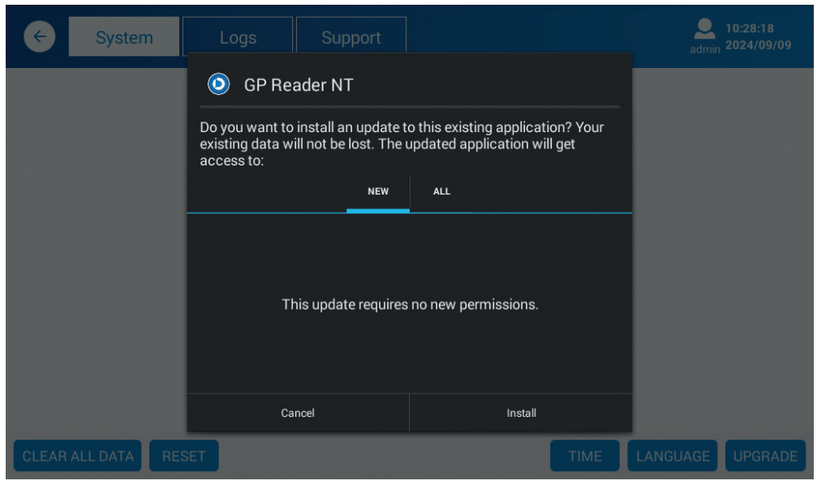

Figure 27. *GP Reader NT application update (admin)*

4.6.3 Date/Time (admin)

If the date and time need to be adjusted, tapping **TIME** will open the Date & Time system-level settings window. Uncheck Automatic date & time if it's checked and then tap **Set date** or/and **Set time** to adjust the date and time respectively. When the correct time or date has been set, tap **Done** to return to the Date & Time stings screen. Tap the ⮌ button on the bottom navigation bar to return to the GP Reader NT application.

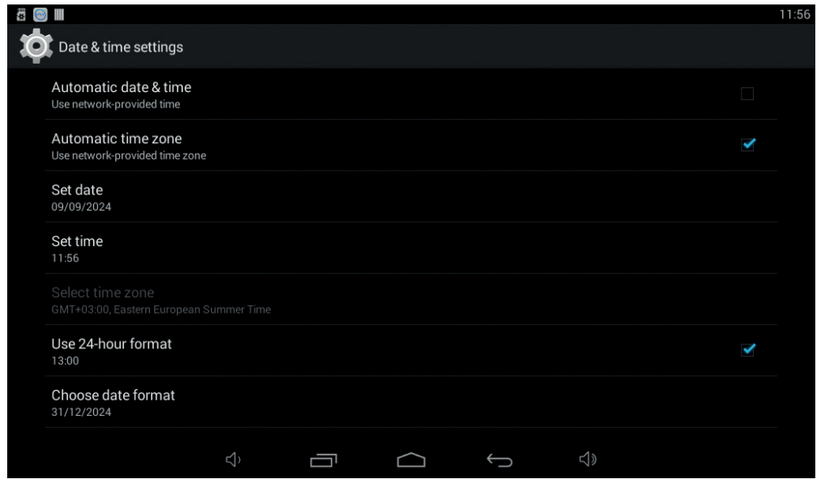

Figure 28. *Date & Time settings (admin).*

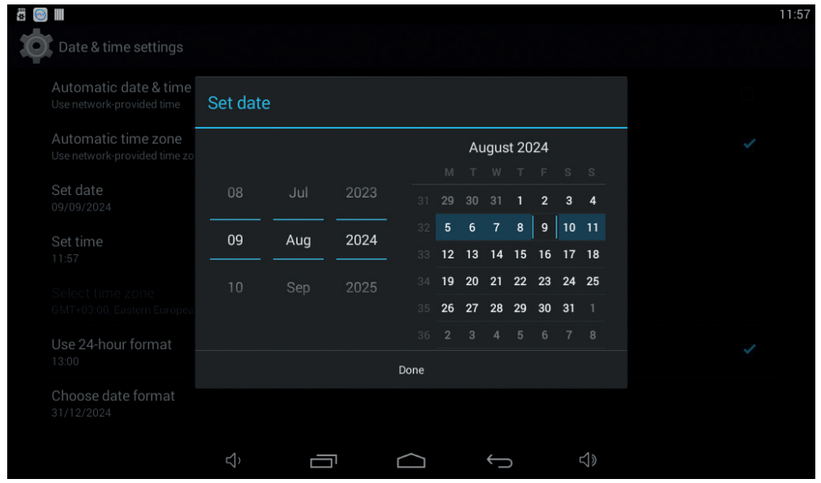

Figure 29. *Setting the date (admin).*

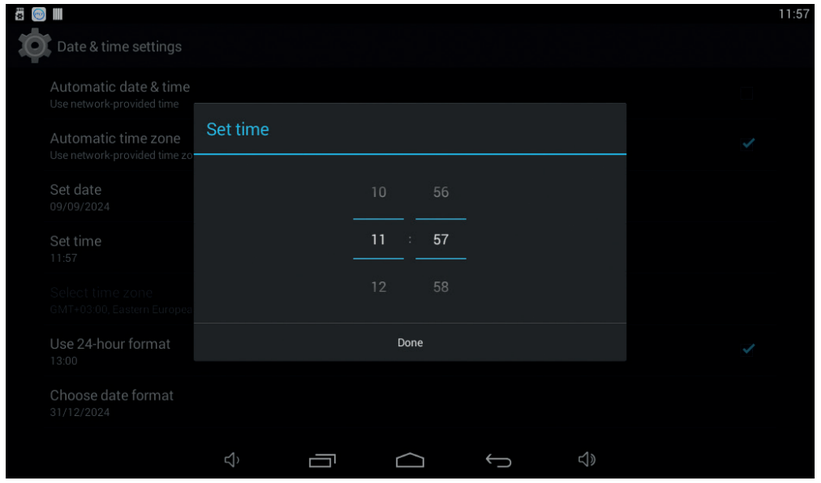

Figure 30. *Setting the time (admin).*

Figure 31. *Logs tab (admin).*

It is important to keep the clock on time, as it is stored as a timestamp in analyses and file references.

4.6.4 Logs

Log files contain important information about the processes running on the system and can be accessed from the Logs tab of the Help menu. Although the log file may not contain interpretable information for the user of the instrument, it can be helpful for troubleshooting by the manufacturer or authorized service technicians. The log file can be browsed through and viewed, using the buttons at the bottom of the screen and exported to a text file to be sent to Biohit Oyj to check whether the instrument is performing properly. The manufacturer or your distributor may request the log file for solving problems with the device. The log file to be displayed can be selected by date from the bottom-left corner of the screen and depending on the nature of the issue, the user can choose between **Instrument** or **LIS** log file to be displayed. Finally, the log files can be exported to a connected USB storage drive by tapping **EXPORT**. The files will be stored in the following path of the USB drive:

HIT92A / <serial number of the instrument> / <date_time> / Log

where: **<serial number of the instrument>** is the serial number of the device and
<date_time> is the timestamp of the date and time the files were exported
(path example: HIT92A/H92A2306010015/20240222_163640/Log)

|<	First page of the log file
<	Previous page of the log file
>	Next page of the log file
>|	Last page of the log file
EXPORT	Export the log file to a connected USB storage drive

4.6.5 Support

The support tab is password protected and contains some settings accessible and reserved only for the manufacturer.

4.7 CHANGE PASSWORD

To change your account's password, tap the user icon at the top right corner of the display, select **Change Password** from the popup menu that appears, and complete the fields that are shown on the display. Please note that the Account ID can be changed only by the administrator.

4.8 LOGOUT

After completing the tasks or if you will be away from the instrument, logout of the instrument to prevent unauthorized access and ensure data security. To logout, tap the user icon at the top right corner of the display and select Logout from the popup menu that appears. After successful logout, the System Login screen is displayed. Another way to logout is switch off the instrument.

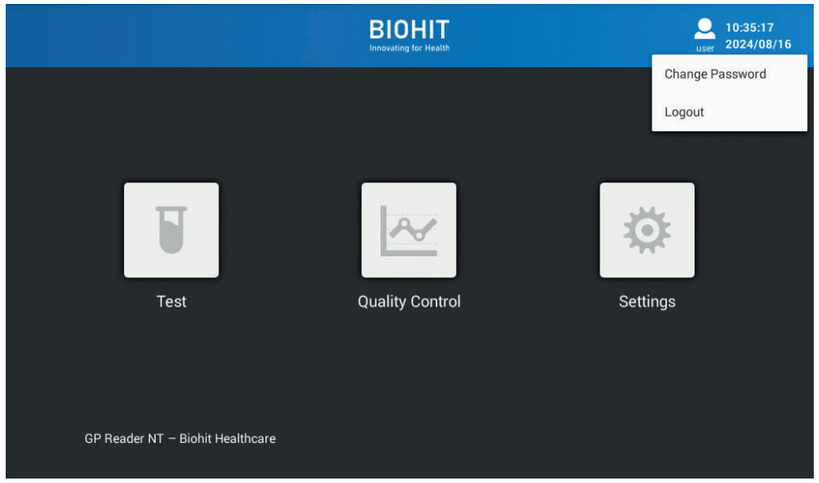

Figure 32. *User logout.*

5 INSTRUMENT QUALIFICATION (admin)

5.1 INSTALLATION QUALIFICATION (IQ)

The IQ is conducted when unpacking and setting up the GP Reader NT, following these steps:

1. Ensure that the shipment has arrived free from damage and that it contains all the items listed in section 2.5.
2. Unpack the contents and place the GP Reader NT on a clean flat surface away from dust and direct sunlight.
3. Connect the power adapter to mains and the power supply to the reader. Switch on the instrument. The reader will boot up displaying Biohit logo, and after a while the System Login screen will be displayed.

5.2 OPERATIONAL QUALIFICATION (OQ)

Make sure that the following basic functions work as expected:

1. Login
At the System Login screen, login as administrator. Please contact Biohit Oyj for the administrator **Account ID** and **Password**, if needed. At this point, you can also create accounts for the operators from **Settings > Account**, as described in section 4.5.4.

2. Time/Date
Check the current time and date displayed on the top right corner of the screen. If the time/date is incorrect, follow the time/date adjustment instructions in section 4.6.3. It is important to keep the clock on time, as it is stored as a timestamp in analyses and file references.

3. Access the functions
Make sure that as an administrator you have access to all screens of the app's navigation map as shown in section 2.9.

4. QR code scanner
Test that the external QR code scanner is functioning (lights up) when activated by browsing to **Test > Lot** and tapping **CODE SCAN**. At this stage it is not necessary to have a valid QR code to scan.

5. Measurement
To perform this step, you will need a test cassette, used or new. Carry out a new test on **Test > New Test** tab, following the instructions of both the test kit and section 4.3.1 of this guide. Follow the measurement process and check that all information about the results, such as sample information, analyte concentrations, reference ranges and interpretation (depending on the test kit used), are all displayed as expected.

6. Printing
Open the side cover of the thermal printer module. Make sure that a printer paper roll has been installed in the printer and press the small form feed button to check that the form feeding is working. Print a sample test report by tapping **PRINT** on the results screen. Check that all information on the printed test report is in agreement with that shown on the display.

5.3 PERFORMANCE QUALIFICATION (PQ)

GP Reader NT has been factory calibrated but also features an internal optoelectronic monitoring function to adjust the luminescence of the excitation light source in real-time so that the measurement module produces consistent output. Therefore, calibration is needed only in very special cases and is performed by the manufacturer.

If you suspect that the reader's performance has deteriorated, please contact Biohit Oyj.

6 MAINTENANCE

6.1 PREVENTIVE MAINTENANCE

The instrument requires little maintenance when operating in a clean environment at normal temperature and humidity conditions. It should be kept free of dust and debris to ensure safe and error-free operation.

- Follow these guidelines to maintain the instrument in good condition:
- Switch off the instrument and disconnect the power supply before cleaning the instrument.
- For daily maintenance, keep the instrument clean and free from dust, debris and moisture.
- Clean the enclosure, screen and cassette tray on a regular basis with a soft microfiber or other lint-free dry or damp cloth. Mild detergent or a solution of up to 70% isopropyl alcohol can be applied to the cloth, if needed. Do not apply detergent or isopropyl alcohol directly onto the instrument.
- Do not use strong detergent/acid/alkali, organic solvents or alcohols other than isopropyl alcohol (max. 70%) for cleaning, as these solutions may damage the cover and display of the instrument.
- In case there is any salt, acid, alkali solution or organic solvents spilled on the instrument, clean immediately to protect the instrument.
- In case the instrument will not be used for a long time, unplug its power cord, and cover the device with a piece of soft cloth or a plastic bag to prevent dust from entering.
- If the instrument is used infrequently, it is recommended to power on the reader and run a dummy test cassette every 30 days.

Do not place any heavy objects on top of the instrument.

Do not clean the instrument while it is running or when it is connected to the power supply.

Do not spray or pour any liquid directly on the surface of the device.

6.2 DECONTAMINATION

Disinfect the instrument in case of liquid spill or contamination in the cassette tray or other parts of the reader or before moving it to another location or shipping it to the manufacturer, following these steps:

1. Make sure to perform the disinfection in a clean and well-ventilated area.
2. Wear protective clothing and medical disposable gloves.
3. Leave the cassette tray open and switch off the reader. Remove any test cassette and disconnect the power supply.
4. Prepare the disinfectant in advance (such as Mikrozid® 70 or comparable product).
5. Moisten an absorbent cloth with the prepared disinfectant.
6. Gently clean the cassette tray with the cloth.
7. Wait until the cassette tray is completely dry and repeat the process.
8. Wipe all instrument surfaces with mild detergent and clean immediately with a cloth dampened with clean water.
9. Wait until the cassette tray and the instrument surfaces are completely dry before packing or reconnecting power for use.
10. Optionally, short exposure to UV-light disinfection can be used.

6.3 PRINTER PAPER REPLACEMENT

If the paper roll is not in place, or if you need to replace printing paper, do as follows:

1. Open the printer cover.
2. Release the lock (at the center of the cover).
3. Take away the paper roll core and replace it with a new paper roll (57 × 30 mm thermal paper roll is used).
4. Be sure to release the end of the paper before putting it in place and closing the cover. Pay attention to the direction of the paper roll: the paper is released 'over the top' of the roll.
5. Close the lock.
6. Close the printer cover.
7. After powering on the instrument, use the small feed button to make sure that paper emerges smoothly from the printer.

A flashing green light on the paper feed button indicates the paper roll needs replacing.

6.4 RTC BATTERY

The Real-time clock (RTC) keeps track of the current time and date, even when the instrument is powered off and is powered by a 3 V, 230 mAh, Lithium-manganese dioxide (Li-MnO2) CR2032 type coin battery, compliant with EC 1907/2006 (REACH) regulation and directives 2011/65/EU (RoHS) and 2006/66/EC (Batteries). The battery should last for at least 5 years from the manufacturing date before needing replacement and could potentially last for the whole expected lifespan of the instrument. Due to the device's design, the battery is not user-replaceable and can be replaced only by a service technician authorized by Biohit Oyj and disposed of according to local regulations. Improper disposal can harm the environment. In the case of battery depletion, contact your distributor or the manufacturer for instructions on the battery replacement procedure.

Do not try to replace the RTC battery on your own. The replacement should be carried out only by authorized service personnel. Any problems caused by attempts to open, disassemble, or modify GP Reader NT will void the warranty.

The real-time clock (RTC) of the reader is powered by a small Lithium coin battery. Should you need to replace or remove the battery, please contact a Biohit Oyj representative for assistance.

7 STORAGE & HANDLING

7.1 STORAGE AND TRANSPORTATION

GP Reader NT can be safely stored and transported in its original packaging, at conditions within the ranges specified below:

Transportation and storage conditions	Ambient temperature: -40 to 55°C Relative humidity: < 93% Atmospheric pressure: 86–106 kPa

During transportation and storage, the device should be well protected from excess humidity, direct sunlight, rain, and strong vibrations.

7.2 DISPOSAL

During its operating time, the device may come into contact with potentially infectious material, such as blood, and hence a used device can constitute a possible source of infection. Decontaminate the device according to instructions in section 6.2 before disposal.

Before disposal, all data stored in the memory of the device should be deleted following the instructions in section 4.6.

This instrument contains electrical and electronic waste, such as printed circuit boards, electronic components and wiring.

When the device reaches the end of its lifespan, please contact our technical support team for proper disposal instructions.

It's important to dispose of the device and its components, including the battery, in accordance with local environmental regulations. Improper disposal can harm the environment.

For specific disposal guidelines, please consult your local waste management authorities.

The coin battery powering the real-time clock on the instrument must be removed and disposed of separately, according to local regulations about battery disposal.

According to EU General Data Protection Regulation, personal data must be removed prior to disposing of the reader.

8 TROUBLESHOOTING

The tables below describe problematic situations and messages that may occur during the operation of GP Reader NT, their possible causes and solutions or actions to be taken. If unable to solve a problem after troubleshooting, please contact your local distributor.

Error	Possible reason	Solution
Unable to start the device	Power supply is not properly connected to device	Check and reconnect power
	Power cord not connected to mains	Connect the power cord to the mains
	Power cord not connected to adapter input	Connect the power cord to the adapter input
	Power adapter failure	Contact supplier or manufacturer
Operating system boot failure	Hardware error	Contact supplier or manufacturer
Application does not start successfully	Hardware error	Restart the instrument and recheck. If problem persists, contact supplier or manufacturer.
	Missing application	Reinstall application from USB
Display is not responding	Display frozen or application crash	Restart the instrument and recheck
	Display broken	Contact supplier or manufacturer
Product used not shown in the Cassette dropdown menu	Incompatible software version	Contact supplier for the correct software version
Unable to complete test	Instrument heated up / environmental temperature is too high	Turn off the device, wait for the device to cool down, then restart
	Other reasons	Contact supplier or manufacturer
Beep	GP Reader NT is not operated in accordance with the instructions specified in this manual	Follow the Error prompt on the screen
	Power supply is damaged	Contact supplier or manufacturer
QR code scan failure	Distance and angle between the scanner and the QR code may be wrong	Rescan by adjusting the bar code or QR code distance, angle, or orientation
	Incompatible QR code	Use only QR codes from test kits compatible with the device
	2D barcode scanner failure	Contact supplier or manufacturer
Data exception	Undetectable QR code, wrong orientation or false cassette	Retest cassette
	Other reasons	Contact supplier or manufacturer
Cassette jam	Cassette is not in correct position on the tray	Make sure that cassette is placed in the tray correctly
	Incompatible cassette	Use a compatible test kit
Printing failure	The printer is out of paper	Replace paper roll
	Printing queue is full	Wait for printer to handle requests
	Paper jam	Check whether the print paper output slot is jammed
	System error	Restart the instrument
Unable to update the software	Wrong or no installation file	Get the correct installation file and follow the software update instructions
	Corrupted installation file	Request the installation file again from your distributor and carefully copy it to the USB drive
	Faulty USB drive	Try again with a different USB drive
	Wrong file location	Copy the installation file to the root directory of the USB drive

Message	Possible reason	Solution
“Enter account password”	Account password missing	Enter your account’s password.
“Wrong password”	Wrong account password entered	Enter the correct password.
“Please insert flash drive”	USB device not present	Insert a USB storage device into USB-A port.
	USB device or not recognized	Try a different USB storage device.
“Data exporting…”	USB data transfer in process	Wait for the file transfer to complete.
“!” displayed in Sample ID field	Sample ID is missing	Enter a Sample ID.
“Measurement on, please wait!”	Measurement is in process	Wait until the measurement finishes.
“Existing sample ID, overwrite?”	A test result with the same Sample ID exists in memory.	Enter a different Sample ID or choose to overwrite the old one.
“Test cassette not found”	Missing or misplaced test cassette	Open the cassette tray and place a cassette onto the tray according to the instructions.
“CMD_MOVE_TO_TARGET”	Actuator positioning error	Restart the instrument. If the problem persists, contact your distributor.
“CMD_TEMP_ERROR”	Temperature sensor error	Restart the instrument. If the problem persists, contact your distributor.
“The system time is wrong, is the time calibrated?”	RTC failure	Restart the instrument. If the problem persists, contact your distributor.
	RTC battery empty	Device needs to be serviced. Contact your distributor.

Do not make any changes to the GP Reader NT. The instrument is not user serviceable. Any problems caused by attempts to open, disassemble, or modify GP Reader NT will void the warranty.

If you experience a problem that is not included in the troubleshooting lists or the problem cannot be resolved following the suggested solutions, please contact your distributor or the manufacturer.

9 SUPPORT & WARRANTY

9.1 SUPPORT

If your instrument or software fails to function properly, or you have questions about how to use or maintain your product, or if you need to return an instrument to Biohit Oyj for service or repair, please contact Biohit Oyj:

Phone: +358 8 773 861
Email: info@biohit.fi
Web: www.biohithealthcare.com

Please be prepared to provide the following information:

- Your name and company information
- A phone number, and/or an e-mail address
- The product name, model, and serial number; found on the sticker at the bottom of the reader.
- The current software version (found in Help > System)
- For troubleshooting assistance or instruments needing repair, the specific steps that produce the issue

Returning Instruments for Service/Repair:

If you need to return an instrument to Biohit Oyj, please contact Biohit Oyj for a Return Materials Authorization (RMA) number and the shipping address. Repack the instrument according to the instructions in section 3.3.

Any laboratory instrument that has been used for research or clinical analysis is considered a biohazard and requires decontamination prior to handling (see section 6.2, Decontamination). Decontamination minimizes the risk to all who come into contact with the instrument during shipping, handling, and servicing. Make sure that the reader has been decontaminated before shipping the reader to Biohit Oyj.

As the instrument may contain patient results, please export the results out of the instrument to avoid data loss and/or transfer of patient data, which may contravene Regulation (EU) 2016/679.

If you need to ship the instrument to Biohit Oyj for service or repair, contact Biohit Oyj for a Return Materials Authorization (RMA) number, and be sure to use the original packaging. Other forms of commercially available packaging are not recommended and can void the warranty. If the original packaging materials have been damaged or lost, contact Biohit for replacement packaging.

9.2 WARRANTY

The warranty time for GP Reader NT is a period of 12 months and will commence from the date the product is shipped by Biohit.

Biohit Oyj shall remedy all defects discovered in any Product (the “Defective Product”) that result from unsuitable materials or negligent workmanship which prevent the mechanical functioning or intended use of the Products including, but not limited to, the functions specified in Biohit’s specifications for the Product.

ANY WARRANTY WILL, HOWEVER, BE DEEMED AS VOID IF FAULT IS FOUND TO HAVE BEEN CAUSED BY ACTS OF NATURE, MALTREATMENT, MISUSE, ABUSE, LACK OF ROUTINE MAINTENANCE, ACCIDENTAL DAMAGE, INCORRECT STORAGE OR USE OF THE PRODUCTS FOR OPERATIONS OUTSIDE THEIR SPECIFIED LIMITATIONS OR OUTSIDE THEIR SPECIFICATIONS, CONTRARY TO THE INSTRUCTIONS GIVEN IN THE INSTRUCTION MANUAL. IF THE PRODUCT IS MODIFIED IN ANY WAY, OR DISASSEMBLED BY ANYONE OTHER THAN BIOHIT, ALL TERMS OF THIS WARRANTY ARE VOID.

In accordance with the terms of the warranty Biohit Oyj shall be obligated to replace any defective product returned by the end- user, distributor or agent of Biohit Oyj, within a reasonable time.

The product has been manufactured according to ISO 9001/ISO 13485 quality management protocols and has passed all relevant Quality Assurance procedures related to these products.

In case of interpretation disputes the English text applies.

10 SPECIFICATIONS

INSTRUMENT	
Name	GP Reader NT
Model	HIT-92A
Type	Fluorescence Immunoanalyzer
Dimensions (L × W × H)	291 mm × 290 mm × 150 mm
Weight	4.0 kg
Lifespan	10 years
SYSTEM	
Operating system	Android 4.4.2
CPU	Quad-Core ARM Cortex-A7, 1.5 GHz
RAM	1 GB DDR3
Software version (at date of issue)	2.0.0.28
Firmware version (Hardware version)	1.8.4.0
INTERFACE	
Display type	10” LCD touchscreen (1024 × 600 resolution)
QR code scanners	2 × 2D barcode scanner (internal, external)
Printer	Thermal printer (57 × 30 mm paper roll)
Ethernet	Wired 10/100
I/O ports	1 × USB-A, 1 × USB-B, 1 × COM, 1 × LAN
POWER	
AC adapter	INPUT 100–240 V AC ~50/60 Hz, 1.1 A OUTPUT: 12 V DC, 2.5 A, 30 W
Operating voltage	12 V DC
Date/Time keeping	Lithium CR2032 battery (3 V, 230 mAh)
PACKAGING (with contents)	
Dimensions (L × W × H)	350 mm × 330 mm × 220 mm
Weight	4.9 kg
ENVIRONMENT	
Operating conditions	5 to 40°C, < 80% RH, 86 - 106 kPa
Storage & Transport conditions	-40 to 55°C, < 93% RH, 86–106 kPa
PERFORMANCE	
Detection limit	≤ 1 µg/ml (fluorescent microspheres)
Within-day precision (Stability)	≤ ± 5%
Linearity	r > 0.99
Repeatability	CV < 1.5%
Reading speed	18–32 seconds (1–4 channels), Speeds can vary depending on the test cassette and kit used

NOTES

GP Reader NT

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