RAPID BIOTEC™

Fluorescence Immunoassay Analyzer

RL-AFR-300

Rapid Labs Ltd.

Contents

Chapter 1 Introduction

1.1 Intended Use

The Fluorescence Immunoassay Analyzer is an analyzer that based on detection of fluorescence emitted during an immunoassay with antigen-antibody interaction. The analyzer is designed to provide quantitative or qualitative test results by the examination of human samples with specific *in vitro* diagnostic test units including Inflammation Markers, Tumor Markers, Nephrology, Diabetes, Cardiac Markers, Coagulation, Endocrinology, Autoimmunity, Infectious Diseases and etc. The Fluorescence Immunoassay Analyzer offers the advantages of high accuracy, strong stability and fast results. The Fluorescence Immunoassay Analyzer should only be used with *in vitro* diagnostic tests manufactured by Rapid Labs Ltd. as per package insert provided with specific test kits.

For professional *in vitro* diagnostic and point of care use.

Please read this User Manual carefully before operation.

1.2 Scope of Application

The Fluorescence Immunoassay Analyzer works with certain fluorescent reagents. It's for *in vitro* diagnosis professionals and Point of Care Use. It may be used in central laboratories of medical institutions, outpatient or emergency departments, clinical departments or medical services (such as community health centers), or medical center, etc. It can also be used in research laboratories.

1.3 Product Name and Model

Name: Fluorescence Immunoassay Analyzer

Model: RL-AFR-300

1.4 Principle

This analyzer excites the reacted test device which is a based on europium microspheres marked fluorescence immunoassay with a UV LED light source, then collects, analyzes and calculates the signal from the test device and gives the test result.

Chapter 2 Analyzer Components and Parameters

2.1 Standard Equipment List

No.	Description	Model	Quantity
1	Analyzer	RL-AFR-300	1
2	Power Adapter	/	1
3	QC Test Device	/	2
4	User Manual	/	1
5	Print Paper Roll	57*20 mm	1
6	Touch Pen	/	1
7	Carrying bag	/	1
8	Scanner	/	Optional

Upon receipt of the package, please check the accessory list and ensure there is nothing missing or damaged. Scanner is an optional accessory, which is available for specific requirement.

Please keep the analyzer's original box and packing accessories for any future shipping/reference purposes.

Rapid Labs Ltd. strives to provide the right type of power cord suitable for each country. However, in some cases, it may not be possible. In such cases, it is recommended to use the right type of power cord to connect to the power supply.

Attention: If any accessories are missing or damaged, please contact manufacturer or local distributor.

1) Analyzer View

1- Test device slot; 2- Touch screen; 3- Indicator; 4- Built-in thermal printer

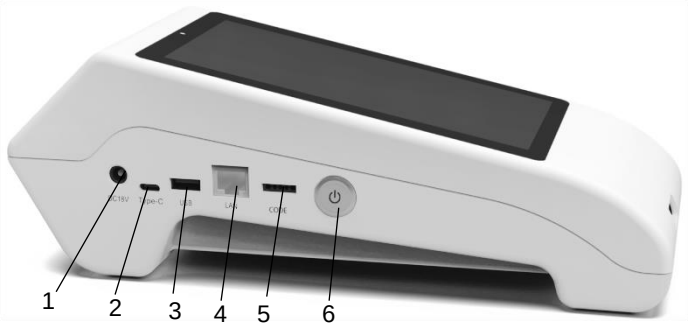
Fig 2.1 (Front view)

Test device slot: Load the test device.

Touch screen: Display analyzer software interface.

Indicator: Indicate the power of the analyzer, please refer to ***section 4.1*** for details.

Built-in thermal printer: Print test results.



1- Power port; 2- Type-C port; 3- USB port; 4- LAN port; 5- ID card slot; 6- Power button

Fig 2.2 (Left view)

Power port: Connect the power adapter, as shown in Fig 2.3.

Type-C port: Used to transmit data.

USB port: To upgrade and export data with a USB disk, or connect a scanner.

LAN port: Connect a network cable.

ID card slot: Insert ID card and import information of the test product.

Power button: Power on or off the analyzer.

Note: The analyzer is tested for immunity to electrostatic discharge and complies with the emission and immunity requirements described in IEC 61326-1 and IEC 61326-2-6. However, when use the analyzer in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets, etc.), it may cause damaging static discharges that may cause erroneous results. Do not use the analyzer in close proximity to sources of strong electromagnetic radiation, as these may interfere with proper operation of the analyzer.

2) Power adapter

Fig 2.3

3) QC test device

Fig 2.4

The QC test device is used to check whether the analyzer works normally.

NOTE: The above pictures are for reference only, subject to your actual purchase.

2.2 Technical Specification

No.	Parameter	Description
1	Principle	Fluorescence Immunoassay
2	Test formats	Device
3	Measurement	Quantitative, Qualitative
4	Read Time	< 20 seconds
5	Test Time	Ref: Analytes
6	Specimen	Ref: Specific Package Insert
7	Power Supply	Lithium battery:14.4V 2500mAh 36Wh; Input:AC 100-240V 50/60Hz; DC 18V 2 A
8	Adapter Input	AC 100-240V 50/60 Hz
9	Dimension	285 mm*130 mm*100 mm (L*W*H)
10	Screen size	7 inches
11	Weight	＜1.5 kg
12	Spectrum	Excitation spectrum: Mean wavelength λ0=365nm Reception spectrum: Mean wavelength λ1=610nm
13	Memory	10,000 records
14	Printer	Built-in thermal printer
15	Ports	LAN×1, USB×1, Type-Cx1

2.3 Transportation and Storage Conditions

2.3.1 Packaging

Packing cases should be reinforced with shockproof liners and moisture-proof packing (plastic bags).

2.3.2 Transportation

- Temperature: -30 °C ~ 55 °C;
- Relative humidity: ≤ 85%.

Note: No toxic gases, flammable, explosive substances and corrosive gases are allowed. Attention should be paid to moistureproof, shock and severe vibration during transportation.

2.3.3 Storage

- Storage temperature: 5 °C~45 °C;
- Relative humidity: ≤ 85%;
- Atmospheric pressure: 86 kPa ~106 kPa, no corrosive gas.

2.4 Operating Conditions

- Adapter input: 100-240 V AC, 50/60 Hz;
- Power: 36 VA;
- Environment temperature: 10 °C ~30 °C;
- Relative humidity: ≤ 85%;
- Atmospheric pressure: 86 kPa~106 kPa.

Chapter 3 Analyzer Installation

3.1 Installation Requirements

The Fluorescence Immunoassay Analyzer should be placed indoors on a flat work surface that meets the following requirements:

- The analyzer should be placed in an indoor environment free of dust, direct sunlight or corrosive gases. The countertop must be able to sustain a weight of 1.5 kg.
- No strong vibration source and strong electromagnetic fields around.
- The analyzer should be placed in a well-ventilated place. There should be at least 10 cm space around the analyzer to ensure the necessary space for operation and maintenance.
- The power supply of the analyzer varies between 100-240V/50/60 Hz AC depending on countries where the analyzer is used. The input voltage is 18 V DC. The power is 36 VA. Avoid short circuit and electric shock during the using. The analyzer is grounded through power adapter.

3.2 Loading Printer Paper

Install or replace the print paper roll in the order as shown below, the size of the paper roll is 57*20 mm.

Step 1: Pull out the buckle under the printer indicator (Fig 3.1), press the buckle slightly downward and pull out the printer cover (Fig 3.2).

Step 2: Take the printer paper roll along with the analyzer, remove the wrapping paper and insert the paper roll under the printer roll. Make sure the paper is placed flat against the printer roll in the directions shown in Fig 3.3.

Step 3: Close the printer cover and reset the buckle (Fig 3.4).

Fig 3.1

Fig 3.2

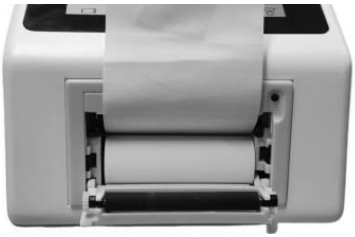


Fig 3.3

Fig 3.4

Note: Heat-sensitive paper must be placed flat in the center to prevent the paper from skewing or jamming, pull out approximate 3-5 cm of paper from the roll, and then close the cover of the printer. The printer will only print on the outside surface of the roll. If it is placed incorrectly, it will not be print.

Chapter 4 Instructions for Use

Please use the analyzer under the proper conditions mentioned in ***2.4 Operating Conditions***.

Prior to testing, read the user manual carefully and learn about all the components of the Fluorescence Immunoassay Analyzer.

4.1 Power on/off

- Analyzer charging

Connect the analyzer to a socket with the power adapter provided with the analyzer for charging, and the power level is displayed at the top right of the screen.

Note: Before turning on the analyzer, the batteries should be fully charged and the charging time should be 2-3 hours. Be careful not to overcharge or over discharge, otherwise batteries will be damaged and the analyzer will not work properly.

- Turn on the analyzer

Press the power button  to turn on the analyzer and enter the initialization interface.

- Turn off the analyzer

Long press the power button  to turn off the analyzer.

- Awake the sleep mode

The default time for entering a sleep mode is 5 minutes, user can change the time according to ***4.5 Settings-Dormant***.

Indicator Description

No.	Analyzer Status	Indicator Status
1	Power on	Green light on, after entering the login interface, the green light is off indicating that battery power is sufficient for normal use.
		Red and green lights blink alternately and the touch screen is black indicating that battery power is very low, please charge the battery.
2	Power on and no operation within 5 minutes.	Green breathing light is on, indicating the screen enter a sleep mode.
3	Power on and charge	No lights on

4	Power off	Red light is on, indicating that the turn-off procedure has been started.
5	Power off and charge	The indicator flashes in different colors depending on the battery power level (Green/Yellow/Red), the light will be off when the battery is fully charged.

Note: The indicator is used to indicate whether the analyzer is turned on/off successfully, it also indicates the battery status when charging in the off state. If the analyzer cannot be turned on and the indicator light does not light up, please try to charge the battery, if the problem persists, please contact the manufacturer or local distributor.

4.2 Login

Press the power button  to turn on the analyzer, the login interface will appear after analyzer initialization (Fig 4.1).

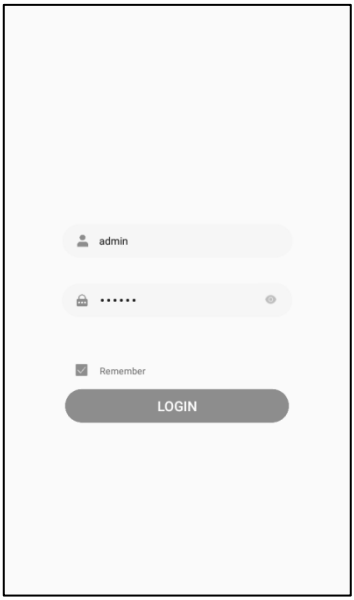


Fig 4.1

Enter the main account: **admin**; the default password is **123456.**

Tap “**LOGIN**” to enter the main interface, as shown in Fig. 4.2.

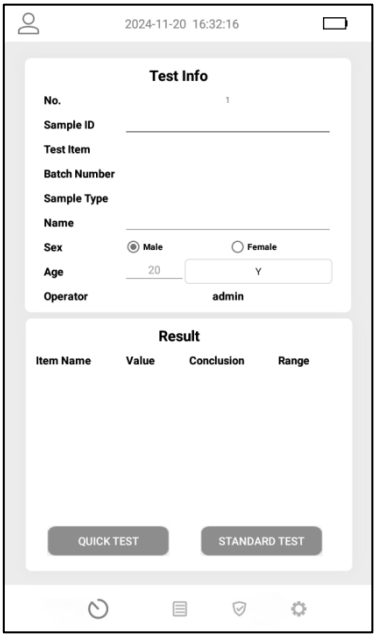


Fig 4.2

NOTE 1: Admin is the main account, user can change the password of the account. The **admin** account can create a sub-account, please refer to the ***Section 4.5***.

The sub-account can only have access to: **Test**, **History** and **QC** functions, but cannot enter the **Settings** function. The admin account can view the historical data of all accounts.

NOTE 2: User can tap icon on the upper left of any interface to exit the current account and return to the login interface.

4.3 QC Test

Tap icon on the main interface to enter the QC test interface, as shown in Fig 4.3.

Fig 4.3

Insert the QC test device provided with the analyzer into the end of the test device slot as the arrow direction, with the sample well outward (Fig 4.4, Fig 4.5).

Fig 4.4

Fig 4.5

Tap “**QC TEST**” to start QC test, after finishing the QC test, the result will be shown as Fig 4.6 and Fig 4.7.

Fig 4.6

Fig 4.7

If the QC test fail message is displayed, please check whether the QC test device used is correct, restart the analyzer and test the QC device again.

If the error still exists, do not use the analyzer for any test and contact manufacturer or local distributor.

Users are advised to perform the QC test when the analyzer is in the following conditions:

1) The analyzer is used for the first time.

2) The analyzer is placed for a long time without operation.

3) The analyzer is transported from one place to another.

4) The analyzer is accidentally dropped from a surface or hit by a strong impact.

NOTE: It is recommended that the QC test should be performed every 3 months under normal circumstances.

QC interface button definition:

Button	Operation
SELECT ALL	Select all QC records
DELETE	Delete the selected QC test record
PRINT	Print the selected QC record

4.4 History

Tap button to enter test result records interface.

1) Search test record

Enter the Name/Sample ID/Item/No. in the search bar and tap icon to query the target test result, as shown in Fig 4.8.

Fig 4.8

2) View history details

- To view the details of a historical record, user can press and hold the target historical record to go to the details page (Fig 4.9). On the details page, user can view Sample ID/Name/Sex/Age/Test Item/Sample Type/Operator /Test Time and test results.
- User can modify the Sample ID/Name/Sex/Age information on the history details page. After modification, tap "**SAVE**" button on the details page to save the modified result.
- Tap "**PRINT**" button to print the selected record if the automatic print is off.
- If the LIS system is connected, tap "**UPLOAD**" button to transfer the history information to LIS. When upload successfully, "**Upload succeeded**" will be displayed. If the upload fails, "**Upload failed**" will be displayed, please contact manufacturer and/or local distributor.

NOTE: The admin account can view the test records of all accounts and sub-account can only view the test records of itself.

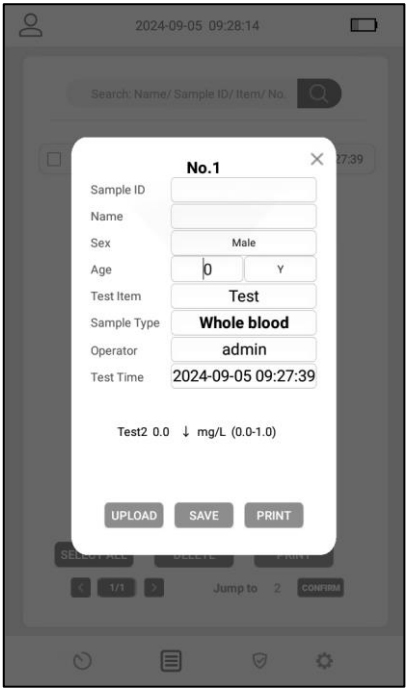


Fig 4.9

3) History interface button definition:

Button	Operation
SELECT ALL	Select all test records
DELETE	Delete the selected test record
PRINT	Print the currently selected test record
<	Page back
>	Page forward
CONFIRM	Input the page number and tap "**CONFIRM**" to show the test records on the target page.
🔍	Search the test records

4.5 Settings

Tap Settings icon, “**About**”, “**System**”, “**Time**”, “**User**” and “**Debug**” can be operated in this interface, as shown in Fig 4.10.

Fig 4.10

NOTE: Only the “**admin**” account has the access to **Settings** interface.

1) About

Tap “**About**” to view the software version, as shown in Fig 4.10. Scan the QR code on the interface to view the analyzer operation video.

NOTE: The software version and QR code shown in Fig 4.10 are for reference only. Please refer to the software version and QR code displayed on the analyzer in use.

2) System

Tap “**System**” to enter the system interface, as shown in Fig 4.11.

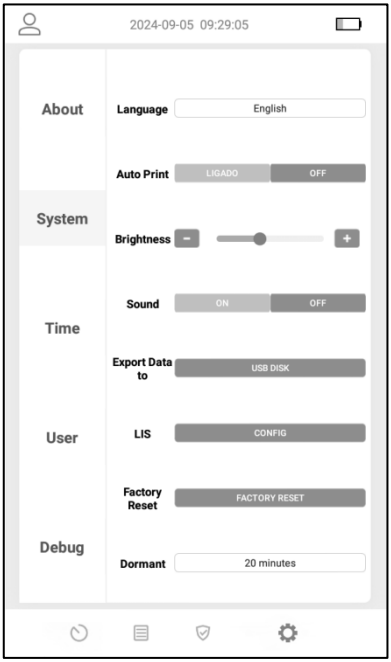


Fig 4.11

➢ **Language**

Tap “**Language**” to select the targeted language.

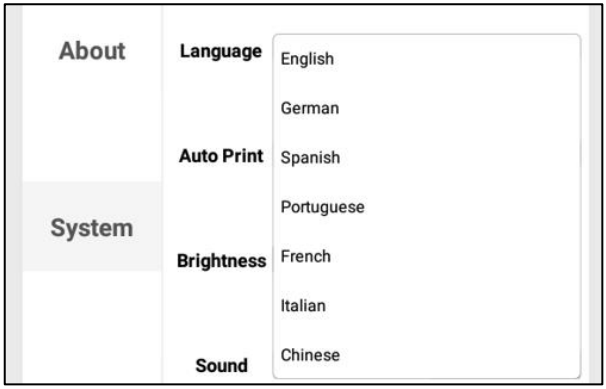


Fig 4.12

➢ **Auto Print**

Tap “**On**” or “**Off**” to turn automatic printing on/off. If the button **turns blue**, this option is selected.

Fig 4.13

➢ **Brightness**

Tap "+" button to increase screen brightness;

Tap "-" button to reduce screen brightness.

NOTE: User can change the screen brightness by dragging the slider on the progress bar left and right to quickly change the screen brightness.

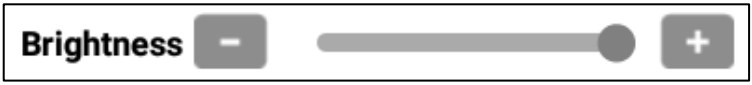


Fig 4.14

➢ **Sound**

Tap "**On**" or "**Off**" to turn on or off the analyzer beeps. After this function turning on, the analyzer will emit a "**beep**" prompt tone at the end of each test.

Fig 4.15

➢ **Export Data to**

The function is used for data export. Export Data to a USB disk as below:

- Insert a USB disk into the USB port.
- Tap "**USB DISK**" button (Fig 4.16) and the historical data will be exported. If the USB disk is not inserted, the interface prompts "**Please insert USB disk**", as shown in Fig 4.17.

Fig 4.16

Fig 4.17

- During the data export process, the button “**Export Data to**” turns gray. When the export is completed, the color of the button will turn blue and a message indicating that the data export is successful will display, as shown in Fig 4.18. If it fails to export the data, please contact manufacturer and/or local distributor.

Fig 4.18

➢ **LIS**

Before using LIS function, user needs to contact technician for requirements, and enter in the configuration information under the guidance of technician. After configuring the LIS function, the test data can be uploaded to the LIS system.

Tap “**CONFIG**” (Fig 4.19) to enter the LIS configuration interface.

Fig 4.19

➢ **Factory Reset**

Tap “**Factory Reset**” button to enter the restore factory settings interface, as shown in Fig 4.20.

Fig 4.20

In the pop-up interface, tap the “**Factory Reset**” option, tap “**Confirm**” to clear all data and restore the initial settings; tap “**Cancel**” to cancel the factory reset.

Fig 4.21

➢ **Dormant**

Tap "**Dormant**" to select the targeted sleep time, there are three options: 5 min/15 min/20 min.

If the sleep time is set to 5 minutes, the analyzer will enter the sleep mode if there is no operation within 5 minutes, the analyzer can be awakened by pressing the power button . If analyzer keeps in sleep mode for 10 minutes, it will automatically turn off.

Fig 4.22

3) Time

Tap the **Time** to change the current time.

Set the year, month, day, hour and minute based on the current time zone. After setting, tap "**Set**" to save settings. Tap "**Clear**" will clear the settings and restore the current time (Fig 4.23).

4) User

Tap the "**User**" button to view all user accounts of the analyzer (Fig 4.24).

The Admin User can add, delete and change user account in this interface.

Fig 4.23

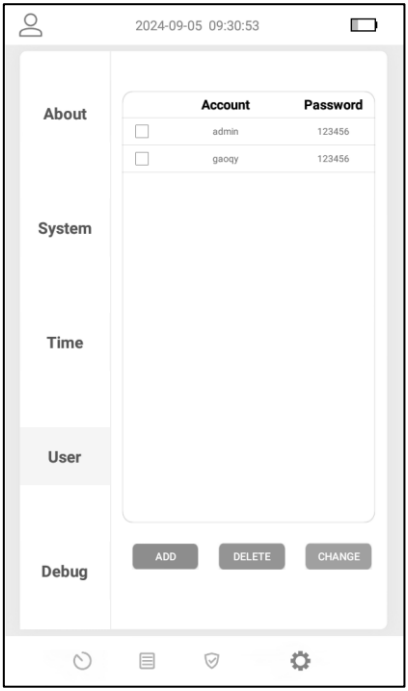


Fig 4.24

NOTE: The **admin** account cannot be deleted. After deleting the user account, the test records related to the account will be deleted. Please use this function with caution!

➢ **Add a User**

Step 1: Tap "**ADD**" in Fig 4.24 to enter the **Add User** interface (Fig 4.25).

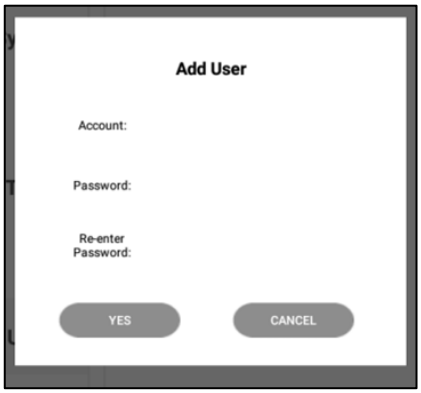


Fig 4.25

Step 2: Fill in the new user name in "**Account**", enter the password of the new user in "**Password**", and enter the password again in "**Re-enter Password**". Tap "**YES**" to complete the adding of a new user account. Tap "**CNACEL**" on the interface to clear the current content and return to the user interface. The user name and password can contain a maximum of 18 characters.

NOTE 1: When "The two passwords entered are not the same. Please re-enter the password." is displayed, please input **Re-enter Password** as same as **Password** again.

➢ **Delete a User**

Tap "**DELETE**" in Fig 4.24 to delete the selected user account.

➢ **Change user account information**

Step 1: Tap the account that information needs to be changed in the **User** interface, and tap "**CHANGE**" to enter the **Change User** interface to change user account information (Fig 4.26).

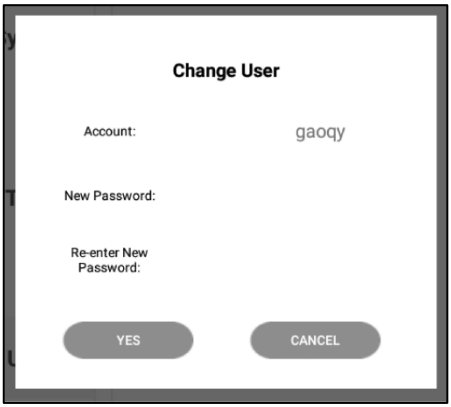


Fig 4.26

Step 2: Fill in the New Password in "**New Password**" and "**Re-enter New Password**", and then tap "**YES**" to save the change.

NOTE: The user name cannot be changed. Only the password can be changed.

5) Debug

The debug function is used to handle after-sales problems only under the guidance of the after-sales technician. This function does not affect the normal use of the analyzer.

4.6 Test

1) Item information Import

Step 1 Take out the ID card (Fig 4.27) provided with test kit from the specific test package, insert the ID card into the ID Card Slot, as shown in Fig.4.28.

Fig 4.27

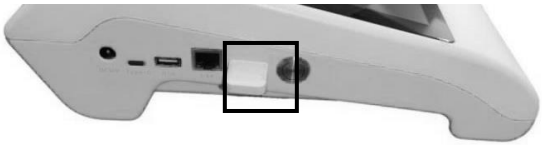


Fig 4.28

Step 2 The ID card information import interface will be displayed, as shown in Fig 4.29. Tap “**OK**”.

Fig 4.29

NOTE: The pop-up window displays the project name and Curve Code, indicating that the ID information has been successfully imported.

Step 3 Remove the ID card after the information is imported successfully.

NOTE 1: ID card information for 1 batch of product should only be imported once.

If **Factory Reset** were operated, user needs to import ID card information again.

NOTE 2: If a message indicating that the ID card information fails to be imported, reinsert the ID card.

If the information import still fails, do not use the analyzer for any testing and contact manufacturer and/or local distributor.

2) Testing Procedures

There are two modes for testing: **Quick Test** and **Standard Test**.

Quick Test Mode: Incubation of the test device is done outside the analyzer.

Standard Test Mode: Incubation of the test device is done inside the analyzer.

Mode 1: Quick Test Mode

Step 1: Fill in the Test Information

Tap icon to enter test interface, fill in the sample ID, Name, Sex and Age as shown in Fig 4.30.

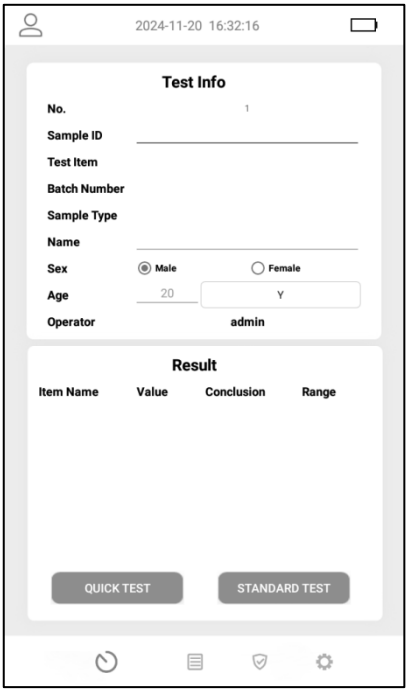


Fig 4.30

NOTE 1: No. is automatically continued for each test and cannot be modified or customized. After the Factory Settings are restored, the number is restored to 1.

NOTE 2: The age options are Y, M and D, where Y indicates the year, M indicates the month and D indicates the day.

Step 2: Add the sample to the sample well, insert the test device into the analyzer after incubation.

Add the sample and/or buffer to the test device as per package insert and place the test device on a clean and flat surface by the side of the analyzer for incubating, the incubation time is mentioned in the package insert.

After incubation, insert the test device into the end of the test device slot **with the sample well facing outward**, as shown in Fig 4.4, Fig 4.5.

NOTE: Do not use excessive force when inserting the test device, otherwise the analyzer alarm may be triggered during the test. When the analyzer alarm is triggered, take out the test device and restart the analyzer. After the restart, if the alarm still appears in the operation, please contact manufacturer and/ or local distributor. (Standard Test mode is also applicable.)

Step 3: Tap "**Quick Test**", the analyzer reads the QR code information on the test device and displays the Test Item, Batch number and Sample Type information on the interface, at the same time, the analyzer reads the reaction result of the test device. After reading, the test results will be displayed on the interface (Fig 4.31), and then the test device will automatically pop up.

NOTE: If the test item supports more than one sample type, a window will pop up to confirm the required sample type. User can select sample type accordingly (Fig 4.32) and tap "**YES**". (Standard Test mode is also applicable.)

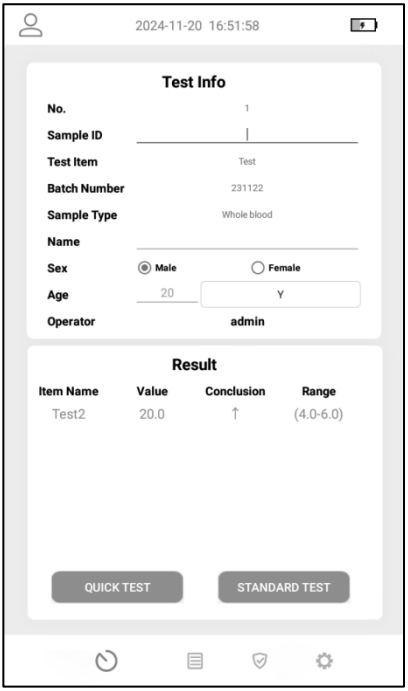


Fig 4.31

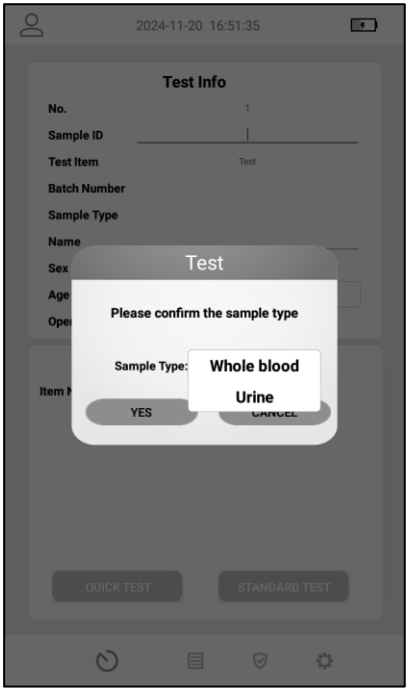


Fig 4.32

Mode 2: Standard Test Mode

Step 1: Fill in the Test Information

Tap button to enter test interface, fill in the sample ID, Name, Sex and Age as shown in Fig 4.29.

Step 2: Add the sample to the sample well, and insert it into the analyzer for incubation.

Add the sample and/or buffer to the sample well as per package insert, then immediately insert the test device into the test device slot **with the sample well facing outward**, as shown in Fig 4.4, Fig 4.5.

Step 3: Tap "**Standard Test**", the analyzer starts to count down for incubation, it reads the QR code information on the test device and displays the Test Item, Batch number and Sample Type information on the interface (Fig 4.33).

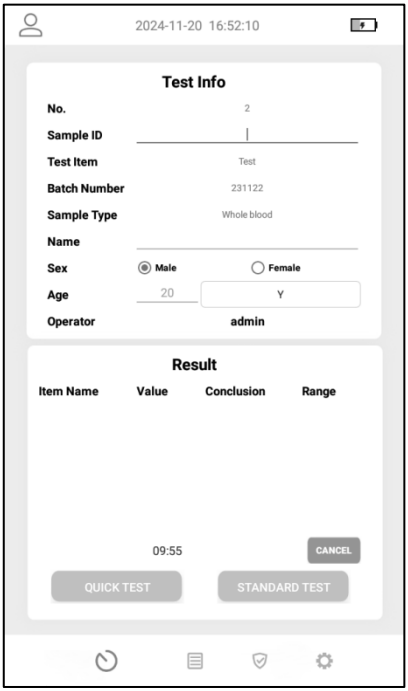


Fig 4.33

Step 4: After the incubation countdown, the test result will be displayed (Fig 4.31) and the test device will pop up automatically.

NOTE: If user wants to stop the standard test, tap "**CANCEL**" button shown in Fig 4.33, the analyzer will cancel the test and pop up the test device automatically.

NOTE: After test, the analyzer will automatically print the results if "**Auto Print**" is on. If "**Auto Print**" is off, manually tap "**PRINT**" to print the test results on the History interface (Fig 4.8).

Chapter 5 Maintenance and Cleaning

5.1 Attention

1) Ensure that the power socket is reliably grounded. If not, replace the power socket.
2) Visually check whether the power adapter is deformed or broken. If yes, it may cause fire due to electric leakage. Contact technical support immediately to replace the power adapter.

5.2 Analyzer Maintenance and Cleaning

1) The analyzer only needs external cleaning and dust removal, no special maintenance items.
2) Before cleaning the analyzer, turn it off and ensure that the power cord plug is disconnected to prevent short circuit and electric shock. Do not clean and disinfect the analyzer while charging
3) When cleaning the analyzer, use a wet cloth and 70% ethanol to clean the outer surface of the analyzer. Do not use strong bleach (≥0.5% solution), as oxidants and solvents may damage the analyzer casing and touch screen. Be careful not to clean any internal parts or internal surfaces.
4) Check the printer daily for paper shortage to ensure that the report can be printed smoothly after a test.
5) If the customer uses the method other than the instructions in this manual to clean the analyzer, please consult the technical service personnel first.
6) If the analyzer is not used for a long time, it must be thoroughly disinfected and stored in the original packaging in accordance with the storage conditions in ***2.3.3 Storage***.

Chapter 6 Precautions and Safe Use

1) For professional use only.

NOTE: Persons other than those specified above should not operate the analyzer and the company will not be responsible for the malfunction of the analyzer caused by this.

2) Use test kits manufactured by **Rapid Labs Ltd.** and supplied by authorized distributors of **Rapid Labs** only. The customer should prepare for the analyzer installation according to the instructions.
3) Analyzer installation, maintenance and cleaning, after-sales service and repairing work should only be done by professionals.
4) Improper operation of the analyzer under electric condition will cause damage to the analyzer. It is not allowed to interfere with the normal movement of the analyzer.
5) If there is liquid inside the analyzer, please turn off the analyzer and cut off the power in time and ask a professional technician to deal with it.
6) Operations specified in the User Manual to be performed by technical service personnel must be performed by authorized technical engineers.
7) Materials from human or animal sources, as well as tissue or in vitro cultures, must be handled in accordance with the principle of potential risk of infection. Always wear appropriate protective equipment such as approved disposable gloves, waterproof laboratory coats and safety goggles when handling biohazardous materials. Dispose of biohazardous materials according to equipment biohazard procedure.
8) The following items must be treated as potential biohazards: all in vitro diagnostic device, pretreatment equipment, samples, serum-based calibration reagents, QC products and waste materials.
9) Waste disposal must comply with local laws and regulations.
10) Always wear approved protective equipment when operating or maintaining the system. Protective equipment must include (but not limited to) approved protective gloves, waterproof lab coat, protective masks and goggles.
11) If biohazardous material spills onto the analyzer, it should be cleaned immediately, washed with residual material and disinfected with disinfectant.
12) If any biohazard comes into contact the skin, wash immediately, disinfect with

disinfectant in accordance with laboratory practice and consult a doctor.

13) Fire regulations in the medical field must be strictly observed and enforced and fire extinguishers for both electrical and non-electrical fires must be provided.
14) For electrical fires, use only specific extinguishers. Water or other liquid extinguishers can cause serious injury. For the sake of safety, the power supply should be cut off before extinguishing the fire to eliminate the danger of electric shock.
15) Keep flammable materials away from the analyzer when using alcohol for repair or inspection. When using ethanol on or around the analyzer, do not exceed 20 mL at a time. Isopropyl alcohol and ethanol (70%) are flammable substances and present combustion, explosion and burn hazards.
16) When using the analyzer, the electrical equipment associated with the analyzer should comply with local standards.
17) The company will no longer be responsible for the safety, reliability and performance of the products in the following cases:
    - The analyzer use date is not within the expiration date;
    - Without the authorization of the company, the analyzer is disassembled, repaired and so on;
    - The analyzer is not used correctly in accordance with this instruction.
18) Any serious incident that has occurred in relation to the analyzer shall be reported to the manufacturer and the competent authority.

Chapter 7 Troubleshooting, Service and Disposal

This chapter lists the possible faults that may occur during the use of the analyzer and the solutions to these faults. If the analyzer fails, the user can troubleshoot the fault according to the methods given in this chapter according to the type of fault. If there is a problem that cannot be handled, please contact the manufacturer or local distributor in time.

7.1 Common Faults and Troubleshooting

Fault code	Fault phenomenon	Possible cause	Solutions
ERR 3	Command is Error	Test invalid	Replace the test device. If the problem persists, contact manufacturer or local distributor.
		Analyzer detects component failure	Restart the analyzer. If the problem persists, contact manufacturer or local distributor.
ERR 6	Motor is not Initialized	Mechanical motion failure	Restart the analyzer. If the problem persists, contact manufacturer or local distributor.
ERR 7	Motor exceeds the software limitation	Config error	Contact manufacturer or local distributor.
ERR 8	Motor meets the Limit Sensor	Mechanical movement failure or operation error	Restart the analyzer. If the problem persists, contact manufacturer or local distributor.
ERR 11	Motor is out-of-step	Other fault	Contact manufacturer or local distributor.
ERR 12	Motor driver is error		Contact manufacturer or local distributor.
ERR 27	The original sensor is not found		Contact manufacturer or local distributor.

7.2 Service and Disposal

The internal structure of the analyzer, including the circuit board, optical detection module, touch screen, printer, camera and other important parts, can only be replaced and checked by Rapid Labs, no third party allowed.

If the product runs abnormally due to a fault and user cannot solve the problem, please contact manufacturer or local distributor. We will provide remote technical support to help user troubleshoot.

If for any reason, the user needs to destroy the product, it is recommended that the user do so in accordance with the Regulations for Class B electronic Analyzers.

During use, the user should maintain and repair the analyzer in accordance with the requirements of the analyzer user manual.

The Analyzer that confirmed to maintain the essential safety and effectiveness after maintaining and repair can be used normally. Rapid Labs declares that the above service guarantee can only be obtained under the condition of complete compliance with the instructions in this manual. Otherwise, Rapid Labs will not take any responsible.

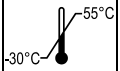
This product is required to comply with the European Unions' Waste Electrical & Electronic Equipment (WEEE) Directive. If you wish to discard electrical and electronic equipment (EEE), please contact your dealer or supplier for further information.

Chapter 8 Manufacturer Information

Name: Rapid Labs Ltd.

Address: Unit 2 & 2A, Hall Farm Business Centre Church Road, Little Bentley, Colchester Essex CO7 8SD, United Kingdom

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		*In vitro* diagnostic medical analyzer
	Temperature limit		Catalogue number		Keep dry
	Manufacturer		Keep away from sunlight		Protect from heat and radioactive sources
	Fragile, handle with care		Biological risks		Dispose items according to local relevant laws regarding disposal and recycle
	Caution		Serial number		Date of manufacture
	Batch code		Authorized representative in the European Community/ European Union		CE Mark
	Unique analyzer identifier				

Advena Ltd.
Tower Business Centre, 2nd Flr.,
Tower Street, Swatar, BKR 4013 Malta

Rapid Labs Ltd.
Unit 2 & 2A, Hall Farm Business Centre
Church Road, Little Bentley, Colchester
Essex CO7 8SD, United Kingdom

Revision 1 05/08/2025

Appendix

A. Warranty

Please complete the warranty card included in the packaging. Mail it to your local distributor to register your purchase within one year of purchase.

For your records, write the purchase date of your starter kit here:

_____

Note: This warranty applies only to the analyzer in the original purchase. It does not apply to the other materials included with the analyzer.

Rapid Labs Ltd. warrants to the original purchaser that this analyzer will be free from defects in materials and workmanship for a period of one year (12 months). The one year starts from the later of the date of original purchase or installation (except as noted below). During the stated one year period, **Rapid Labs** shall replace the unit under warranty with a reconditioned unit or, at its option, repair at no charge a unit that is found to be defective. **Rapid Labs** shall not be responsible for shipping charges incurred in the repair of such an analyzer.

This Warranty is subject to the following exceptions and limitations:

This warranty is limited to repair or replacement due to defects in parts or workmanship. Parts required which were not defective shall be replaced at additional cost. **Rapid Labs** shall not be required to make any repairs or replace any parts that are necessitated by abuse, accidents, alteration, misuse, neglect, failure to operate the analyzer in accordance with the operations manual, or maintenance by anyone other than **Rapid Labs.**

Furthermore, **Rapid Labs** assumes no liability from malfunction or damage to analyzers caused by the use of products other than products manufactured by **Rapid Labs. Rapid Labs** reserves the right to make changes in the design of this analyzer without obligation to incorporate such changes into previously manufactured analyzers.

Disclaimer of Warranties

This warranty is expressly made in lieu of any and all other warranties express or implied (either in fact or by operation of law) including the warranties of merchantability and fitness for use, which are expressly excluded, and is the only warranty given by **Rapid Labs**.

Limitations of Liability

In no event shall ***Rapid Labs*** be liable for indirect, special or consequential damages, even if ***Rapid Labs*** has been advised of the possibility of such damages.

For warranty service, please contact your local distributor.

B. Warranty Card

Please complete this warranty card and mail it to your local distributor to register your purchase within one year of purchase.

Purchaser	
Model	
Serial Number	
Date of Purchase	
Address	
Telephone Number	
E-Mail Address	

RAPID BIOTEC™

Rapid Labs Ltd.

Address: Unit 2 & 2A, Hall Farm Business Centre
Church Road, Little Bentley, Colchester
Essex CO7 8SD, United Kingdom