

VivaChek™



VivaChek Biotech (Hangzhou) Co., Ltd.

Level 2, Block 2, 146 East Chaofeng Rd.
Yuhang Economy Development Zone
Hangzhou 311100 Zhejiang P.R. China
Email: info@vivachek.com
www.vivachek.com

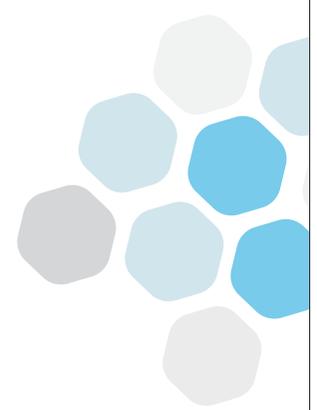
EC REP

Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd,
2595AA, The Hague, Netherlands.
Tel: +31644168999
Email: peter@lotusnl.com

VivaDiag™ POCT Analyzer VIM2000

Fluorescence Immunochromatography

User's Manual



VivaDiag™

POCT Analyzer

Dear VivaDiag™ POCT Analyzer VIM2000 User,

Thank you for choosing the VivaDiag™ Point-of-Care-Testing Analyzer VIM2000! The analyzer has the advantages of easy operation, strong stability, reliable results and simple maintenance. It can be used widely in many areas, such as hospital, medical center, clinic, pharmacy, laboratory, etc.

This User's Manual applies to VivaDiag™ POCT Analyzer VIM2000, it provides detailed descriptions of the analyzer's characteristics, graphical operation steps and other relevant information for your convenience. Please read this User's Manual carefully before you use your analyzer and keep your User's Manual in a safe place, you may want to refer it in the future.

Thank you again for choosing the VivaDiag™ POCT Analyzer VIM2000.

Principle and Intended Use

The VivaDiag™ POCT Analyzer (Model: VIM2000) work with VivaDiag™ POCT Test Kit as a system to measure multiple parameters like hsCRP/CRP, cTnI, HbA1c, T4, SARS-CoV-2, etc. The analyzer is an immunofluorescence detection device that is based on photoelectric detection principle. With the fluorescence immunochromatography technology and tiny sample (whole blood/plasma/serum/urine/hair/nasal swab), the analyzer gives reliable result(s) in just few minutes, which is ideally suitable for professionals to make quick and correct decision at the point of care. It is intended for professional use outside the body (*in vitro* diagnostic use).

TABLE OF CONTENTS

1. Understanding Your Analyzer.....	1
Introduction to Analyzer.....	1
Important Safety Information.....	1
2. Components and Structure.....	2
Components List.....	2
Structure.....	2
3. Installation and Use Conditions.....	4
Analyzer Installation.....	4
Use Conditions.....	4
4. Operation Instructions.....	6
Starting.....	6
Settings.....	6
Testing	12
Quality Control Test.....	17
Record.....	22
5. Maintenance and Troubleshooting.....	26
Maintenance.....	26
Troubleshooting	26
6. Technical Information.....	29
System Specifications.....	29
Limitations.....	30
Index of Symbols.....	31
Warranty.....	32

CHAPTER 1: UNDERSTANDING YOUR ANALYZER

Introduction to Analyzer

1. Model: VIM2000
2. Basic size: 192 mm (Length) x 205 mm (Width) x 161 mm (Height)
3. Total weight: 2.5 kg

Analyzer Use and Precautions

- Keep your analyzer dry and avoid exposing it to extremely temperature or humidity.
- Do not drop the analyzer or get it wet. If you do drop the analyzer or get it wet, check the analyzer by running a quality control test. Refer to **Quality Control Test** for instructions.
- Do not take the analyzer apart. Taking the analyzer apart will void the warranty.
- Refer to the **Maintenance and Troubleshooting** for details on cleaning the analyzer.
- Keep the analyzer and accessories out of reach of children.

Important Safety Information

- It is for *in vitro* diagnostic use by professionals.
- Use only VivaDiag™ POCT Test Kit with your Analyzer. Do not use other brand.
- Use the accessories provided by VivaChek with your VivaDiag™ POCT Analyzer. Do not use other accessories.
- Please read this User's Manual carefully before use your analyzer and keep your User's Manual in a safe place for referring it in the future.
- If the analyzer emits peculiar smell, smoke or the liquid flows into the analyzer, please cut off the power immediately and contact with your local dealer. Continuous use of the analyzer may cause fire, electric shock or personnel injury.
- Please comply with all the national standards for health and safety. This includes (but not limited to) protective cover, gloves, and suitable experimental installation when operating and maintaining the analyzer.
- If the analyzer is used in a manner not specified by the manufacturer, the protection provided by the analyzer will be impaired.



Caution

All products or objects, which come in contact with blood/urine/respiratory secretions, even after cleaning, should be handled as if capable of transmitting viral disease.

CHAPTER 2: COMPONENTS AND STRUCTURE

- Please check whether any component is missing or damaged against the list below after opening the package.
- Note: If some parts are missing or damaged, please contact your local dealer or manufacturer immediately.

Components List

Number	Component	Quantity
1	VivaDiag™ POCT analyzer VIM2000	1
2	Power adapter	1
3	Power line	1
4	Print paper roll	1
5	User's manual	1
6	Packing box	1
7	Quality control test device	2
8	Quality control RFID card	2
9	Pipette (optional)	1

Structure

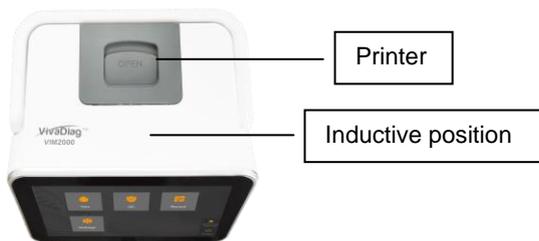
The actual appearance of analyzer and accessories may vary with specific model.

Analyzer

(1) Front Side Structure (Figure 1, 2)



(Figure 1)



(Figure 2)

(2) Back Side Structure (Figure 3)



(Figure 3)

Power Adapter (Figure 4)



(Figure 4)

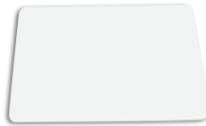
Quality Control Test Device (Figure 5)



(Figure 5)

Quality Control RFID Card (Figure 6)

The quality control RFID card is a specific card with calibration curve, and can be only used with the quality control test device.



(Figure 6)

Test Device (Figure 7)

The test device below is only supplied in VivaDiag™ POCT Test Kit.



(Figure 7)

CHAPTER 3: INSTALLATION AND USE CONDITIONS

Analyzer Installation

Please use the analyzer under the proper conditions.

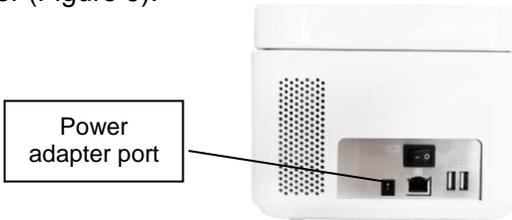
Step 1: Place the analyzer on a stable and level countertop.

Step 2: Connect the structure according to your need (Figure 8).



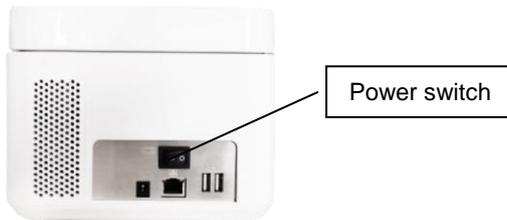
(Figure 8)

Step 3: Connect the power adapter with the power adapter port of the analyzer (Figure 9).



(Figure 9)

Step 4: Turn on the power switch and start the analyzer (Figure 10).



(Figure 10)

Use Conditions

Basic Parameters

- Excitation light source: LED
- Excitation spectrum: 365 nm & 650 nm
- Receiving spectrum: 610 nm & 690 nm
- Connector: Ethernet port RJ-45, USB
- Printer: Built-in thermal printer

Positioning and Placement Requirements

(1) The analyzer should be placed on a stable and level countertop, and in an indoor environment free of dust, direct sunlight or corrosive gases. The countertop must be able to sustain a weight of at least 2.5 kg.

(2) 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.

(3) The place of the analyzer placed should without strong vibration source and electromagnetic fields around.

Storage and Transport Conditions

(1) Storage Conditions

Storage temperature: -10 to 50°C

Relative humidity: 20 to 80%

Atmospheric pressure: 86.0 to 106.0 kPa

(2) Transport Conditions

Avoid moisture, impact and severe vibration.

Power Supply Voltage Requirements



Caution

The power supply of the analyzer varies between 100-240V, 50/60Hz AC depending on countries where the analyzer is used. The input voltage is 12V DC, the power is 60W. Please avoid short circuit and electric shock during use.

CHAPTER 4: OPERATION INSTRUCTIONS

Starting

Turn on the analyzer, the analyzer will initialize and run to self-testing (Figure 11, 12).

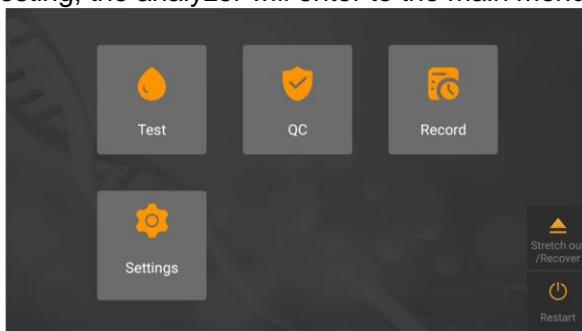


(Figure 11)



(Figure 12)

After the self-testing, the analyzer will enter to the main menu (Figure 13).



(Figure 13)

Settings

Please set up the analyzer according to your requirements before using.

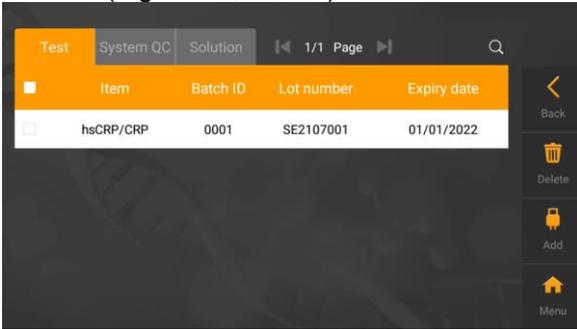
Click “Settings” button to enter the following interface (Figure 14).



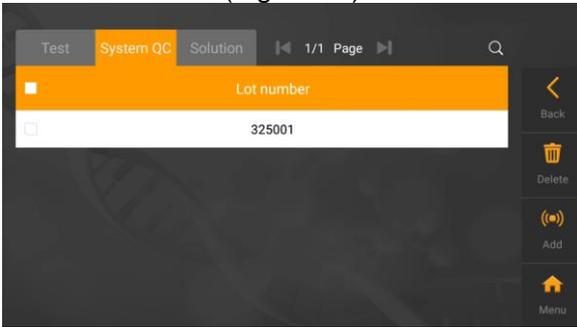
(Figure 14)

Item management

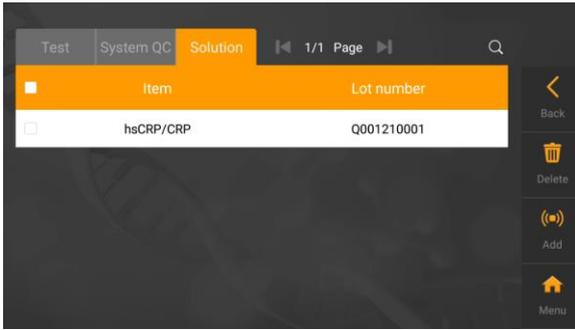
Click “Item management” button to enter the test/system QC/solution item management interface (Figure 15, 16, 17).



(Figure 15)

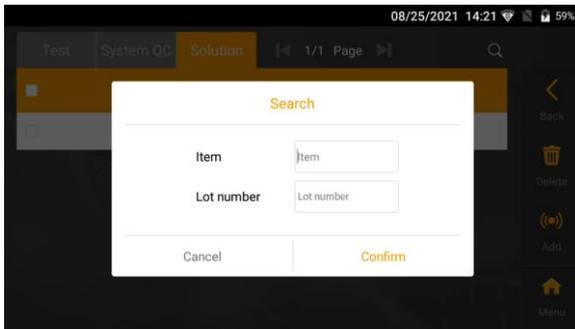


(Figure 16)



(Figure 17)

- (1) Click “◀” or “▶” to browse the saved test items.
- (2) Click “🔍”, input item and lot number to search the saved test items (Figure 18).

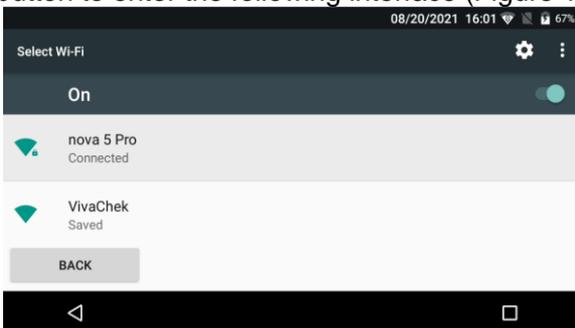


(Figure 18)

- (3) Click “Delete” to delete the item you selected.
- (4) Insert the USB into USB port, and click “Add” to add test item.
- (5) Click “Back” to back to the previous page.
- (6) Click “Menu” to back to the main menu.

WLAN

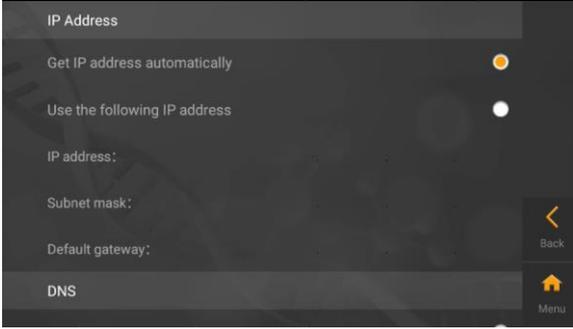
Click “WLAN” button to enter the following interface (Figure 19).



(Figure 19)

LAN

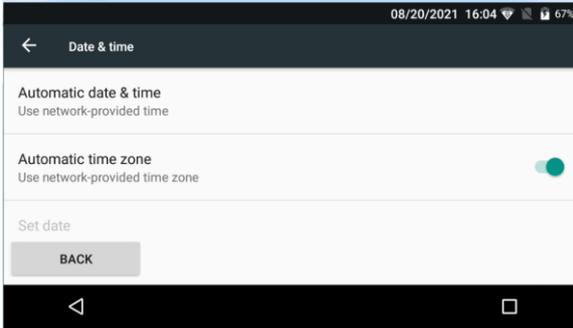
Click “LAN” button to enter the following interface (Figure 20)



(Figure 20)

Date and Time

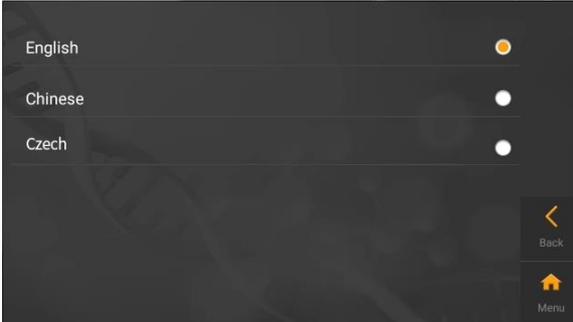
Click “Date & time” button to enter the following interface (Figure 21).



(Figure 21)

Language

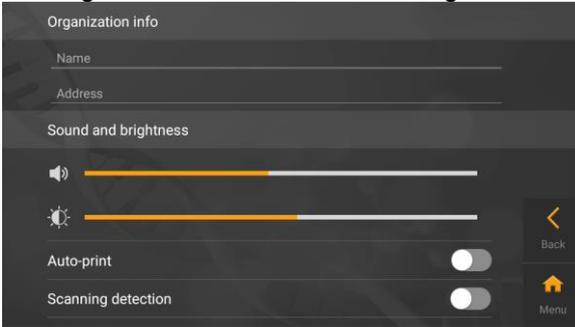
Click “Language” button to enter the following interface (Figure 22).



(Figure 22)

Analyzer setting

Click “Analyzer setting” button to enter the following interface (Figure 23).

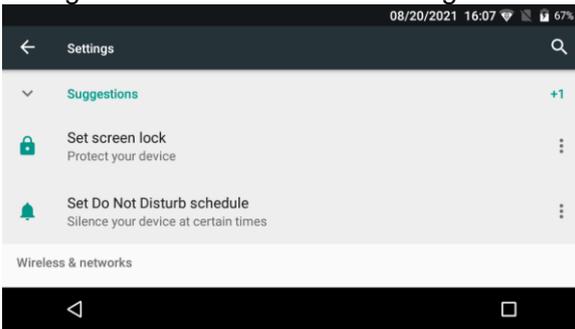


(Figure 23)

In this interface, organization info, sound and brightness, auto-print and scanning detection allowed to being set.

System settings

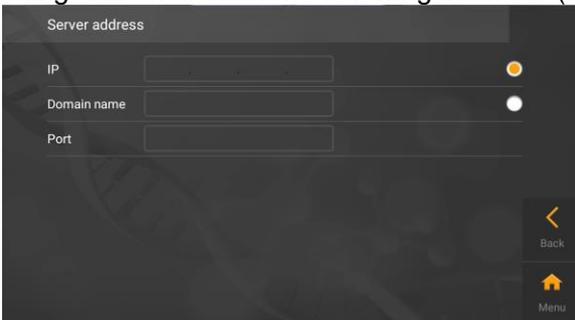
Click “System settings” button to enter the following interface (Figure 24).



(Figure 24)

Server setting

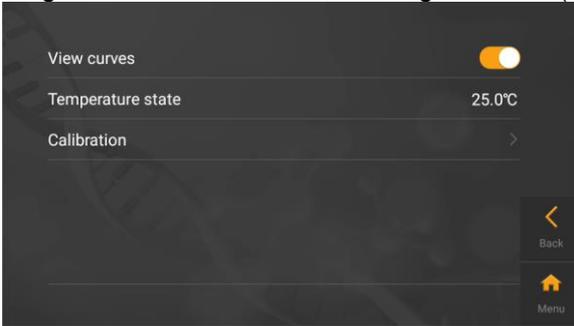
Click “Server setting” button to enter the following interface (Figure 25).



(Figure 25)

Other settings

Click “Other settings” button to enter the following interface (Figure 26).



(Figure 26)

About

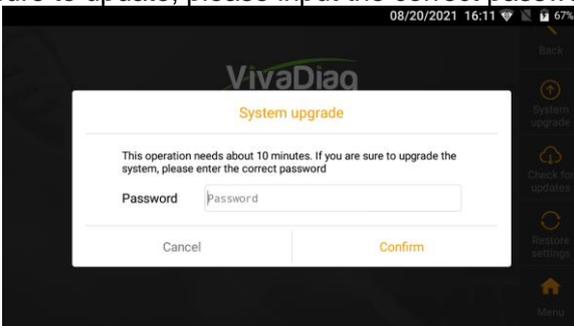
Click “About” button to enter the following interface (Figure 27). Model, system version, software version, hardware version, serial number and storage information of the analyzer will be displayed on the screen.



(Figure 27)

(1) Check for updates

Click the “Check for updates” button to enter the following interface (Figure 28). If you are sure to update, please input the correct password.



(Figure 28)

(2) Restore settings

Click the “Restore settings” button to enter the following interface (Figure 29). This operation will clear the data in the analyzer, if you are sure to restore the factory settings, please input the correct password.



(Figure 29)

Testing

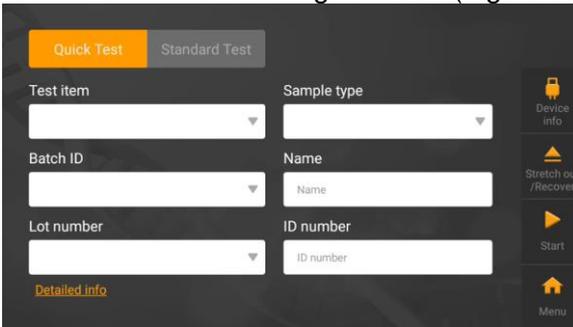
Before you perform the test, you need to prepare the VivaDiag™ POCT Analyzer VIM2000 and VivaDiag™ POCT Test Kit.

Operation Steps for Quick Test

Step 1: Connect the power adapter and turn on the power switch to start the analyzer and wait for 20 minutes.

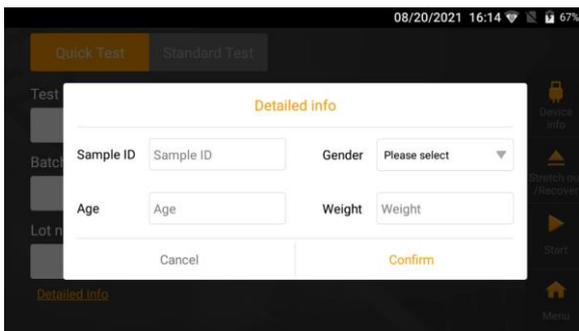
Note: 20 minutes is the preheating time for analyzer to complete the temperature control with built-in incubator.

Step 2: Click “Test” to enter the following interface (Figure 30).



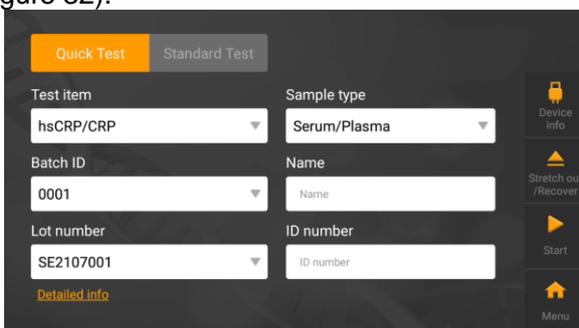
(Figure 30)

You can click “Detailed info” to input the sample ID, gender, age and weight (Figure 31).



(Figure 31)

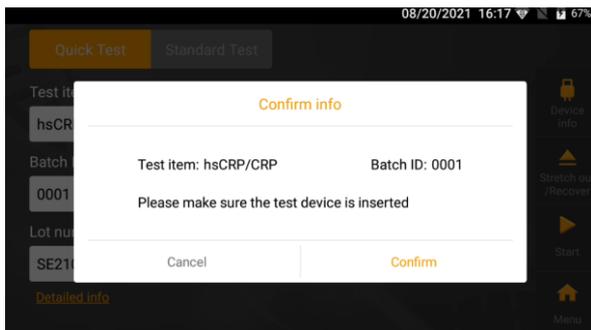
Step 3: Remove the USB from VivaDiag™ POCT test kit, insert the USB into USB port, and click “Device info”, the analyzer will read the item’s information (Figure 32).



(Figure 32)

Step 4: Remove the test device from foil pouch in VivaDiag™ POCT test kit of the item you need to test, refer to the package insert to add the sample and wait for the corresponding reaction time.

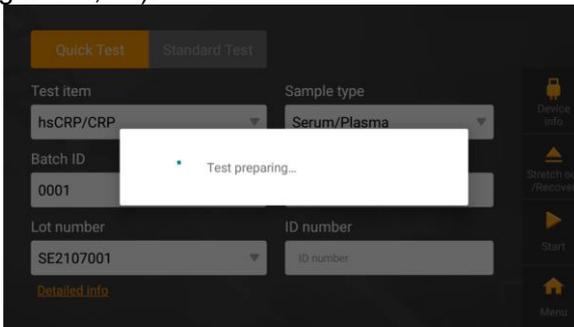
Step 5: Insert the test device into the test device slot after the reaction time completed, click “Start”, the analyzer will remind you of the item’s information (Figure 33).



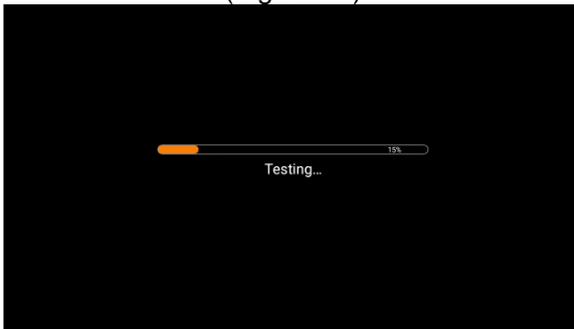
(Figure 33)

Step 6: The analyzer will prepare and start the test after confirming the

information (Figure 34, 35).



(Figure 34)



(Figure 35)

Step 7: The analyzer will display the test result (Figure 36).

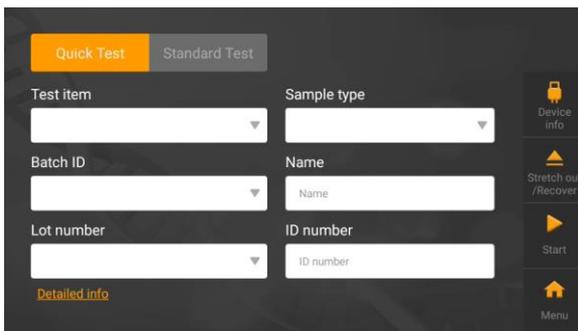


(Figure 36)

Operation Steps for Standard Test

Step 1: Connect the power adapter and turn on the power switch to start the analyzer and wait for 20 minutes.

Step 2: Click "Test" to enter the following interface (Figure 37).



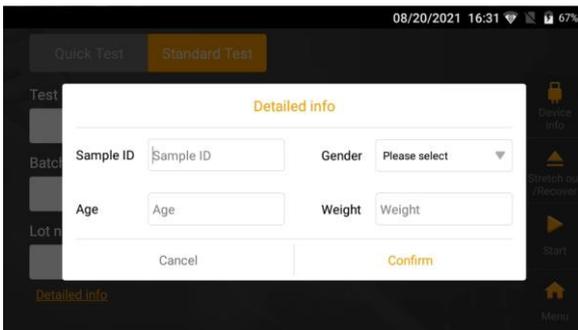
(Figure 37)

Step 3: Click “Standard Test” to enter the following interface (Figure 38).



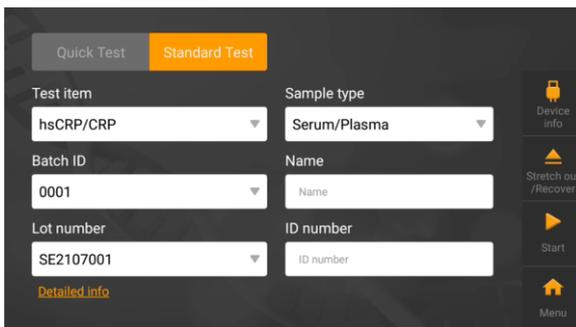
(Figure 38)

You can click “Detailed info” to input the sample ID, gender, age and weight (Figure 39).



(Figure 39)

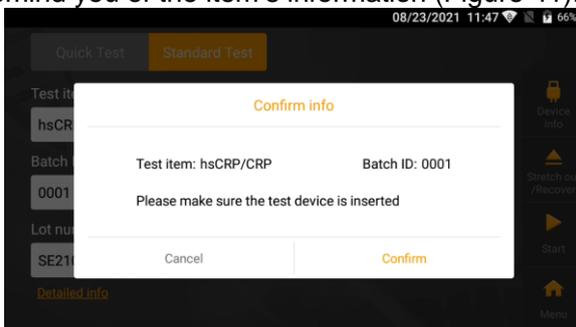
Step 4: Remove the USB from VivaDiag™ POCT test kit of the item you need to test, insert the USB into USB port, and click “Device info”, the analyzer will read the item’s information (Figure 40).



(Figure 40)

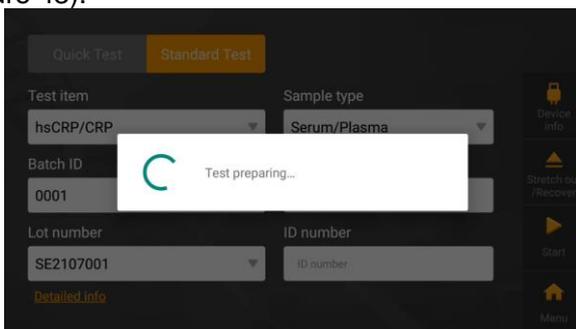
Step 5: Remove the test device from foil pouch in VivaDiag™ POCT test kit of the item you need to test, refer to the package insert to add the sample.

Step 6: Insert the test device into the test device slot, click “Start”, the analyzer will remind you of the item’s information (Figure 41).



(Figure 41)

Step 7: The analyzer will prepare the test after confirming the information (Figure 42), and start to count down, the count down time is the reaction time of the item you test. Please wait for the pre-determined incubation time for each test (Figure 43).

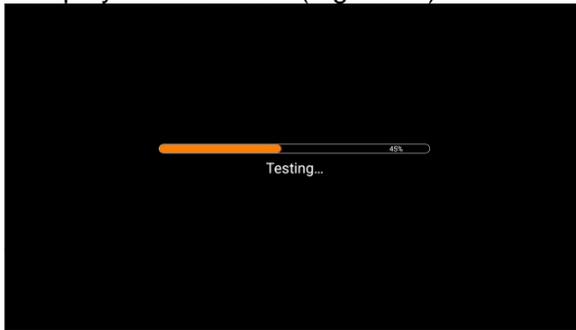


(Figure 42)



(Figure 43)

Step 8: The analyzer will start to test after the count down time is ending (Figure 44), and display the test result (Figure 45).



(Figure 44)



(Figure 45)

Quality Control Test

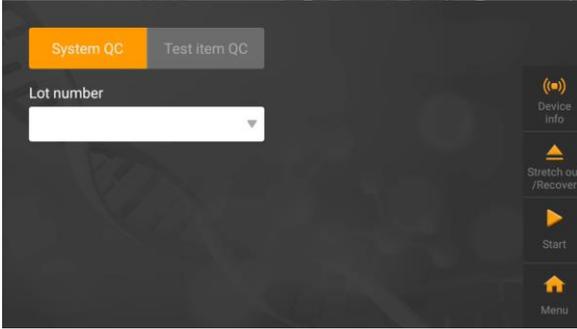
Before you perform the quality control test, you need to prepare the VivaDiag™ POCT quality control RFID card and its test device.

Operation Steps for System QC

Step 1: Connect the power adapter and turn on the power switch to start the

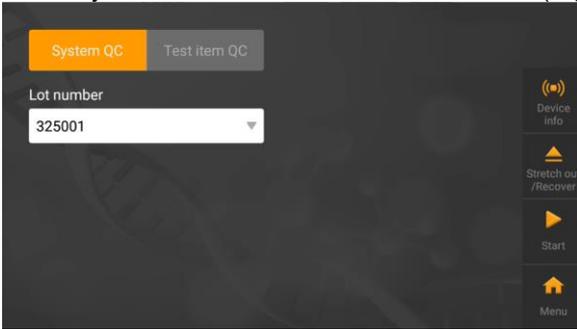
analyzer and wait for 20 minutes.

Step 2: Click “QC” to enter the following interface (Figure 46).



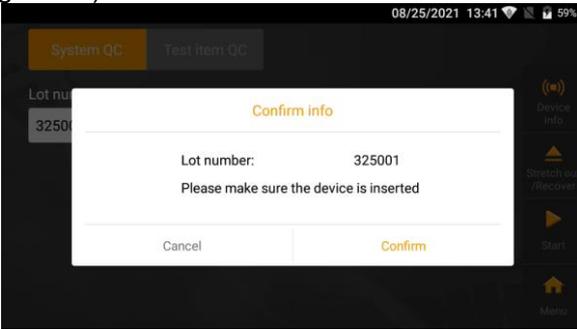
(Figure 46)

Step 3: Remove the QC RFID card, put it in inductive position, and click “Device info”, the analyzer will read the card’s information (Figure 47).



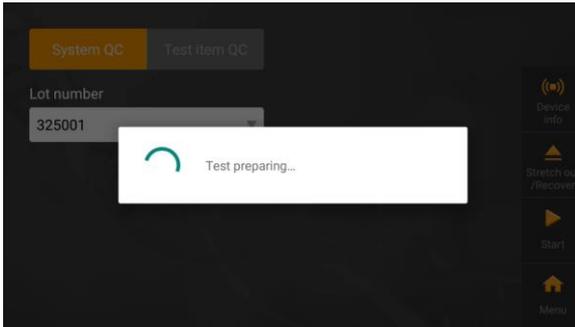
(Figure 47)

Step 4: Remove the QC test device, and insert the QC test device into the test device slot, click “Start”, the analyzer will remind you of the item’s information (Figure 48).

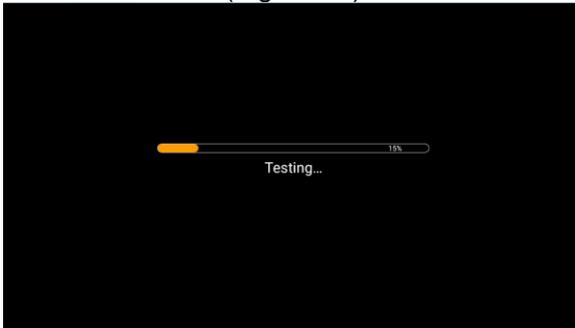


(Figure 48)

Step 5: The analyzer will prepare and start the test after confirming the information (Figure 49, 50).



(Figure 49)



(Figure 50)

Step 6: The analyzer will display the test result (Figure 51).

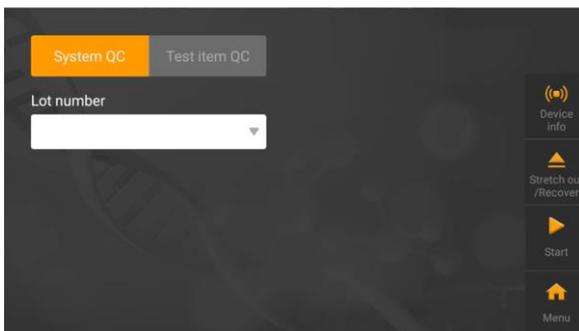


(Figure 51)

Operation Steps for Test Item QC

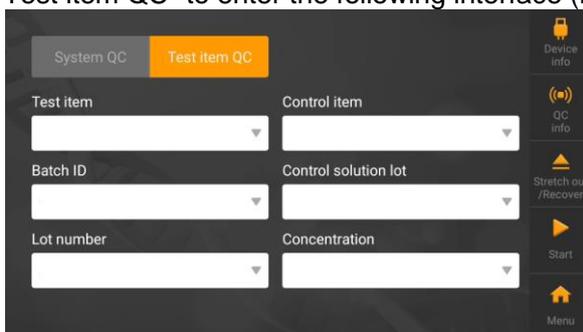
Step 1: Connect the power adapter and turn on the power switch to start the analyzer and wait for 20 minutes.

Step 2: Click "QC" to enter the following interface (Figure 52).



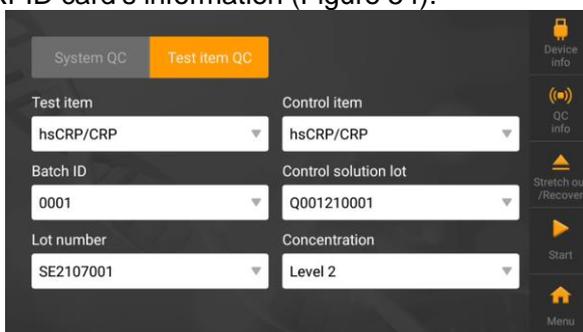
(Figure 52)

Step 3: Click “Test item QC” to enter the following interface (Figure 53).



(Figure 53)

Step 4: Remove the USB from VivaDiag™ POCT test kit of the item you need to test, insert the USB into USB port, and click “Device info”, the analyzer will read the item’s information. Remove the test item QC RFID card, put it in inductive position, and click “QC info”, the analyzer will read the test item QC RFID card’s information (Figure 54).

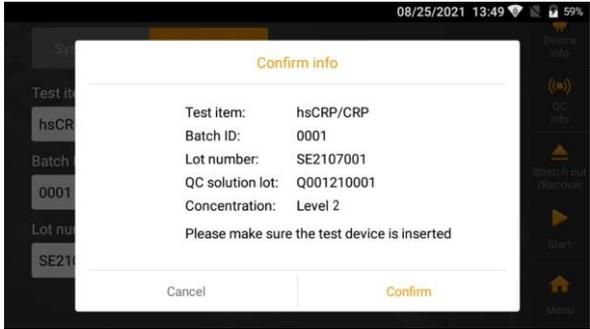


(Figure 54)

Step 5: Remove the test device from foil pouch in VivaDiag™ POCT test kit of the item you need to test, refer to the control solution package insert to add control solution and wait for the corresponding reaction time.

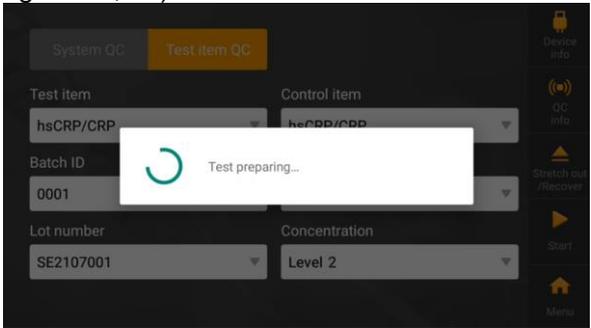
Step 6: Insert the test device into the test device slot after the reaction time

completed, click “Start”, the analyzer will remind you of the item’s information (Figure 55).

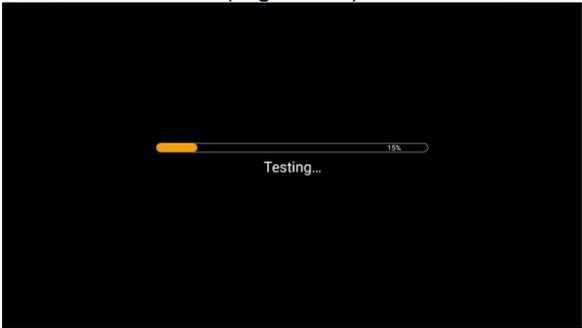


(Figure 55)

Step 7: The analyzer will prepare and start the test after confirming the information (Figure 56, 57).



(Figure 56)



(Figure 57)

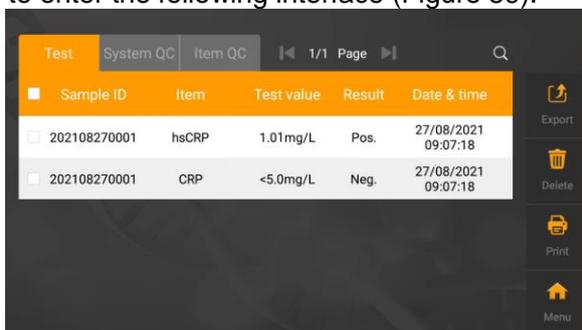
Step 7: The analyzer will display the test result (Figure 58).



(Figure 58)

Record

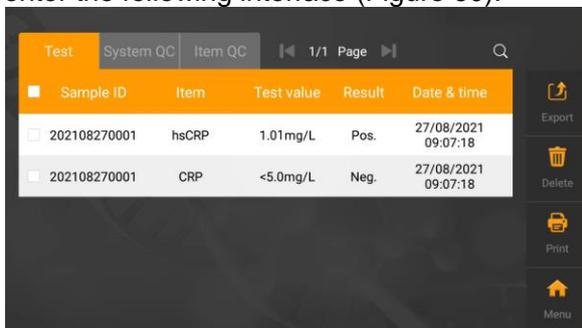
Click "Record" to enter the following interface (Figure 59).



(Figure 59)

Test

Click "Test" to enter the following interface (Figure 60).



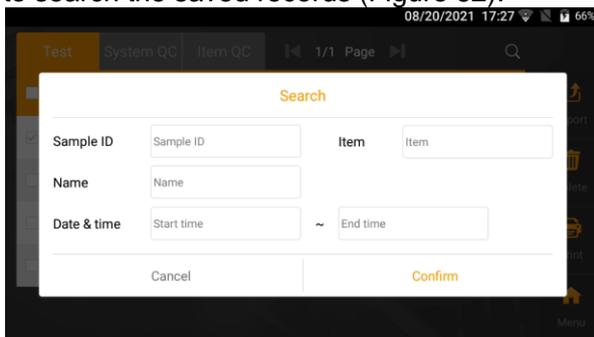
(Figure 60)

- (1) Click "◀" or "▶" to browse the saved records.
- (2) Click the corresponding item to browse the detailed information (Figure 61).



(Figure 61)

(3) Click “” to search the saved records (Figure 62).

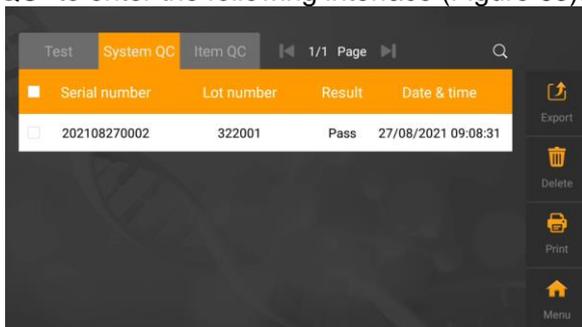


(Figure 62)

- (4) Click “Export” to export the saved records.
- (5) Click “Delete” to delete the record you selected.
- (6) Click “Print” to print the record you selected.
- (7) Click “Menu” to back to the main menu.

System QC

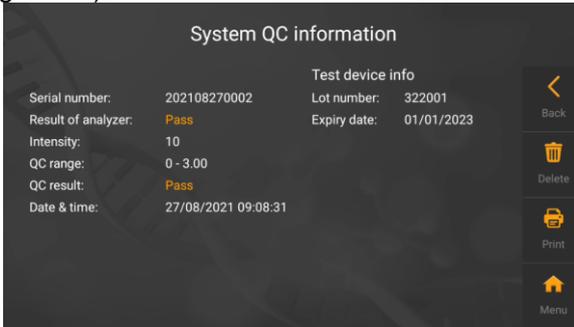
Click “System QC” to enter the following interface (Figure 63).



(Figure 63)

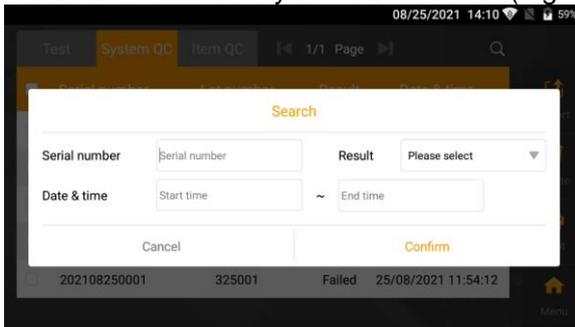
- (1) Click “” or “” to browse the saved system QC records.
- (2) Click the corresponding item to browse the detailed system QC records

information (Figure 64).



(Figure 64)

(3) Click “” to search the saved system QC records (Figure 65).

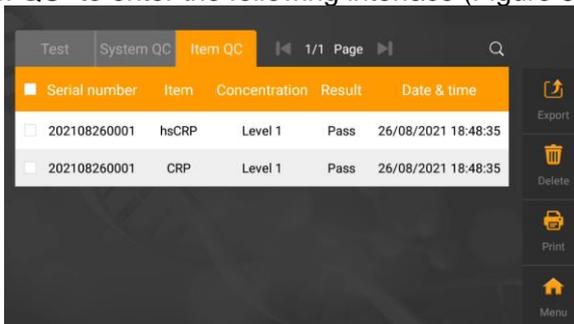


(Figure 65)

- (4) Click “Export” to export the saved system QC records.
- (5) Click “Delete” to delete the system QC records you selected.
- (6) Click “Print” to print the system QC records you selected.
- (7) Click “Menu” to back to the main menu.

Test Item QC

Click “Test item QC” to enter the following interface (Figure 66).



(Figure 66)

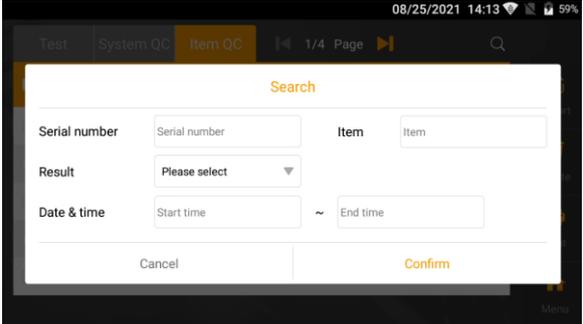
(1) Click “” or “” to browse the saved test item QC records.

(2) Click the corresponding item to browse the detailed system QC records information (Figure 67).



(Figure 67)

(3) Click "Q" to search the saved test item QC records (Figure 68).



(Figure 68)

- (4) Click "Export" to export the saved test item QC records.
- (5) Click "Delete" to delete the test item QC records you selected.
- (6) Click "Print" to print the test item QC records you selected.
- (7) Click "Menu" to back to the main menu.

CHAPTER 5: MAINTENANCE AND TROUBLESHOOTING

Maintenance

- Your VivaDiag™ POCT analyzer VIM2000 does not require special maintenance or cleaning. Basic maintenance is to keep the external clean of the analyzer.

External cleaning and maintenance method: A cloth dampened with 70% alcohol can be used to wipe the outside of the analyzer. Do not use strong bleach ($\geq 0.5\%$ bleach solution), because oxidizing substances and solvents may damage the analyzer's parts and touch screen. Take care to avoid getting liquids, dirt, blood or buffer into the analyzer through the slot or data port.

- Except for external cleaning, your VivaDiag™ POCT analyzer VIM2000 also requires thermal printing paper replacement when needed.

Caution

Turn off the power switch before cleaning! Ensure the power line is disconnected to avoid the risk of short circuit and electric shock!

Replacing printing paper method: VivaDiag™ POCT analyzer VIM2000 uses the built-in thermal printer, it does not require changes the cartridge, just require replace the thermal printing paper when needed. After the thermal printing paper is run out, open the built-in thermal printer's cover of the analyzer, and replace the thermal printing paper with a new one (Figure 69), then close the cover.



(Figure 69)

Note: Recommended paper size: 57/30/12 mm

Troubleshooting

Appearance	Description	Actions
Power failure	Power switch is unopened	Turn on the power switch.
	Power plug or power adapter is damaged	Contact your local dealer or manufacturer.
	Bad wire contact between the analyzer and power adapter	Pull off the power line and reconnect, If the problem continues, contact your local dealer or manufacturer.
No response	The analyzer is crashed	Turn off the power switch, replug the power line, and then turn on the power switch again, if the problem continues, contact your local dealer or manufacturer.
Abnormal display	Electrostatic effect	Ground and release the static electricity or reopen the analyzer.
	Circuit fault	Contact your local dealer or manufacturer.
Unable to test	Internal structure, technical or software is damaged	Contact your local dealer or manufacturer.
	Interface error	Contact your local dealer or manufacturer.
	The USB does not match the analyzer or the USB is damaged	Repeat the test with a new one. Make sure that it is not damaged and you are using a USB from VivaChek Biotech (Hangzhou) Co., Ltd.

	<p>The test device does not match the analyzer or the test device is over the expiration date</p>	<p>Discard the test device and repeat the test with a new one. Make sure that it is not over the expiration date and you are using a test device from VivaChek Biotech (Hangzhou) Co., Ltd.</p>
	<p>The USB and test device are not match</p>	<p>Make sure that the USB and test device you are using is match and gain from VivaChek Biotech (Hangzhou) Co., Ltd.</p>

CHAPTER 6: TECHNICAL INFORMATION

System Specifications

Feature	Specification
Principle	Fluorescence immunochromatography
Dimensions	192 mm (Length) x 205 mm (Width) x 161 mm (Height)
Weight	2.5 kg
Display size	7" LCD
Sample type	Whole blood/serum/plasma/urine/hair /nasal swab
Test items	30+
Barcode identification	2D
Operating temperature	10-30°C
Storage temperature	-10-50°C
Relative humidity	20-80%
Atmospheric pressure	86.0-106.0 kPa
Connectivity	Ethernet port RJ-45, USB
Battery	AC/DC adapter & UPS (optional)
Printer	Built-in thermal printer
Memory	50000 test results

Limitations

- Do not place the analyzer in a position that is difficult to operate or inconvenient to disconnect.
- Please use the analyzer strictly according to the User's Manual provided by manufacturer.
- Do not insert anything into the test device slot except for the test device provided by or purchased from manufacturer.
- If the tested samples are potentially contagious, please take protective measures such as wear protective gloves to avoid skin contacting with sample.
- Please dispose the analyzer that no longer use according to the procedures and rules of destruction for Class B electric devices.
- Please dispose the used test device according to "Medical Waste Management Regulations" to avoid biohazards.
- Dispose the tested samples and materials carefully. Treat them as if they are infectious materials. Follow proper precautions and obey all local regulations when dispose them.

Index of Symbols

These symbols may appear on the packaging and in the instructions for the VivaDiag™ POCT system.

Symbols	Explanation
	Consult instructions for use
	Manufacturer
	Date of manufacture
	Temperature limitations
	Contains sufficient for <n> tests
	Use by
	Lot Number
	Authorized representative
	Catalog number
	Model number
	Serial Number
	Do not re-use
	Caution, consult accompanying documents
	Direct current
	Alternating current
	<i>In vitro</i> diagnose
	Dispose items according to local relevant laws regarding disposal and recycle
	Keep away from sunlight and heat

Warranty

Please complete the warranty card that came with the product and mail it to your dealer to register your purchase.

If the analyzer fails to work for any reason other than obvious abuse within the first five (5) years from purchase, we will replace it with a new one free of charge. For your records, also write the purchase date of your product here.

Date of purchase: _____

Note:

This warranty applies only to the analyzer in the original purchase, and does not apply to the battery supplied with the analyzer.

Warranty Card

Please complete this warranty card to validate your warranty. Mail it within 30 days of purchase to the local dealer address labeled on the product.

If the analyzer does not work for any reason other than obvious abuse in the first 5 years after purchase, we will replace it with a new or equivalent analyzer free of charge.

Date of purchase _____ / _____ / _____

Analyzer serial number (e.g.501C0000001) _____

Where purchased _____

Telephone number _____

Email address _____

Suggestion/Comments _____



VivaChek Biotech (Hangzhou) Co., Ltd.

Level 2, Block 2, 146 East Chaofeng Rd..

Yuhang Economy Development Zone,

Hangzhou, 311100, Zhejiang P.R. China

Email: info@vivachek.com

www.vivachek.com

© 2021 VivaChek Biotech (Hangzhou) Co., Ltd.