VivaDiag

POCT Multifunction Meter

Dear VivaDiag POCT Multifunction Meter User,

Thank you for choosing the VivaDiag POCT Multifunction Meter! The meter 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 Multifunction Meter, it provides detailed descriptions of the meter's characteristics, graphical operation steps and other relevant information for your convenience. Please read this User's Manual carefully before you use your meter 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 Multifunction Meter VIM220H.

Principle and Intended Use

The VivaDiag POCT Multifunction Meter (Model: VIM220H) work with VivaDiag POCT Test Kit as a system for quantitative or qualitative measurement of multiple parameters. The meter is an immunofluorescence detection device that is based on photoelectric detection principle. With the fluorescence immunochromatography technology and tiny sample, the meter 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).

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Introduction

1. Model: VIM220H
2. Dimensions: 124.5 mm (Length) x 72.5 mm (Width) x 40 mm (Height)
3. Weight: 165 g

Meter Use and Precautions

• Keep your meter in the temperature rang 14°F to 131°F (-10 to 50°C) and relative humidity range 10 to 90%.
• Meter will shut off by itself after 10 minutes of inactivity.
• Do not drop the meter or get it wet. If you do drop the meter or get it wet, check the meter by running a quality control test.
• Do not use the meter if it drops into water or other liquids or splashing water on to it.
• Use only VivaDiag POCT FIA Test Kit with your meter. Do not use other brand, otherwise it will not guarantee the reliability of the result.
• Do not take the meter apart. Taking the meter apart will void the warranty.
• Refer to the **Caring and Maintenance** for details on cleaning the meter.
• Keep the meter and accessories parts out of reach of children.

Important Safety Information

• It is for *in vitro* diagnostic use by professionals.
• Use the accessories provided by VivaChek with your VivaDiag POCT Multifunction Meter. Do not use other accessories.
• Please read this User's Manual carefully before use and keep your User's Manual in a safe place for referring it in the future.
• If the meter emits peculiar smell, smoke or the liquid flows into the meter, please turn off the power immediately and contact with your local dealer. Continuous use of the meter 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 meter.
• If the meter is used in a manner not specified by the manufacturer, the protection provided by the meter 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 Multifunction Meter VIM220H	1
2	Type C & USB 2 in 1 cable	1
3	User's manual	1
4	Quality control test device	1
5	Quality control code chip	1

Structure

The actual appearance of meter and accessories may vary with specific model (Figure 1).
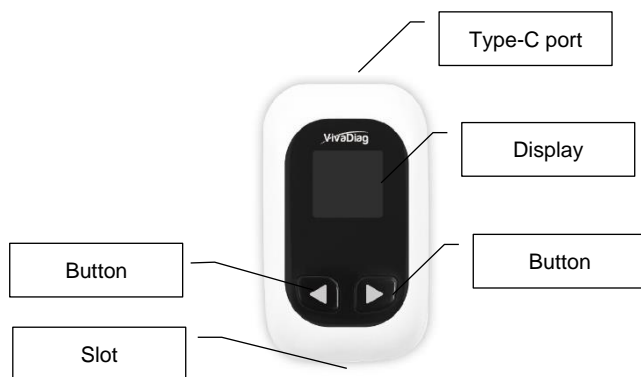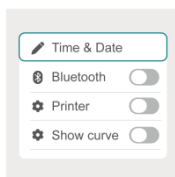

(Figure 1)

CHAPTER 3: SETTING UP YOUR METER

Before you first time using your meter, you should check and update your meter settings.

Setting

Press the "▶" button for 3 seconds to turn on the meter. Press the "◀" button for 3 seconds to enter the "Menu".
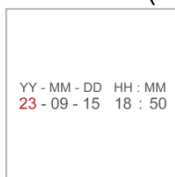Press the "▶" button to select "Setting", and press the "◀" button to enter the interface of "Setting" (Figure 2).

(Figure 2)

Set the Time and Date

Press the "◀" button to enter the interface (Figure 3).

(Figure 3)

Press the "◀" button to adjust the digit. Press the "▶" button to remove to the next digit. Repeat the above action until the date and time setting is completed. Press the "◀" button for 3 seconds to keep the set.
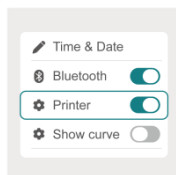
Bluetooth Connection

Press the "▶" button to select "Bluetooth", and press the "◀" button to turn on the Bluetooth (Figure 4).
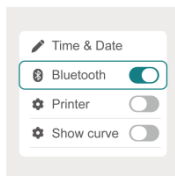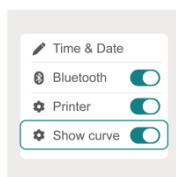

(Figure 4)

Print

Press the "▶" button to select "Printer", and press the "◀" button to connect the printer (Figure 5).

(Figure 5)

More Details
Press the "▶" button to select "Show curve", and press the "◀" button to open the function (Figure 6). Then, you can check more detailed information in test record interface.

(Figure 6)

About
Press the "◀" button to enter the interface (Figure 7). You can check the serial number and software version.
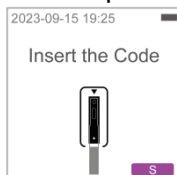

(Figure 7)

Set up your meter correctly and have all the materials you will need ready before you begin testing. It includes your VivaDiag POCT Multifunction Meter and VivaDiag POCT FIA Test Kit.

Start
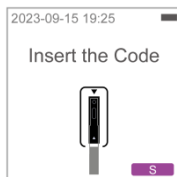Press the "▶" button for 3 seconds to open the meter (Figure 8).

(Figure 8)

Choose Test Mode
Standard Test Mode
Press the "◀" button twice to change the test mode to standard test. When the test mode is changed successfully, the Meter will display "S" in the right corner (Figure 9).
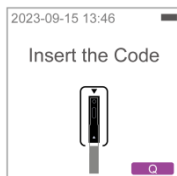

(Figure 9)

In the standard test mode, you need insert the test device immediately after adding the sample, and the meter will display the test result when the countdown is finished.

Quick Test Mode
Press the "◀" button twice to change the test mode to Quick test. When the test mode is changed successfully, the Meter will display "Q" in the right corner (Figure 10).

(Figure 10)

In the quick test mode, you need insert the test device after the reaction time completed, and the meter will display the test result in seconds.

Standard Test

Step 1: Insert the code chip into the slot of the Meter. When the Meter displays the lot number and item name, remove the code chip (Figure 11).

```
2023-09-15 19:14        ▬
          FYL

      SE2303053
```
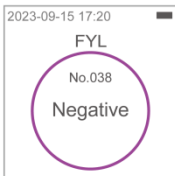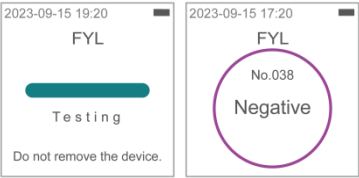
(Figure 11)

Step 2: Take the test device out of the foil pouch and place it on a clean, dust-free and flat surface. Refer to the package insert to add the sample.

Step 3: Insert the test device into the slot immediately. The Meter will start a countdown (Figure 12).

```
2023-09-15 17:14        ▬
          FYL


      ▬▬▬▬▬▬

        3 0 0

Do not remove the device.
```

(Figure 12)

Step 4: The Meter will display the test result after the countdown is finished (Figure 13). Do not remove the test device when testing.

```
2023-09-15 17:20        ▬
          FYL
        No.038
       Negative
```

(Figure 13)

Quick Test

Step 1: Insert the code chip into the slot of the Meter. When the Meter displays the lot number and item name, remove the code chip (Figure 14).

```
2023-09-15 19:14        ▬
          FYL

      SE2303053
```

(Figure 14)

Step 2: Take the test device out of the foil pouch and place it on a clean, dust-free and flat surface. Refer to the package insert to add the sample wait for the reaction time

Step 3: Insert the test device into the slot after the reaction time. The Meter

will display the test result in seconds (Figure 15, 16). Do not remove the test device when testing.

(Figure 15, 16)

QC Test

Step 1: Insert the QC code chip into the slot of the Meter. When the Meter displays the lot number and "QC", remove the code chip (Figure 17).

(Figure 17)

Step 2: Insert the QC test device into the slot.
Step 3: The Meter will display the QC test result in seconds (Figure 18). Do not remove the QC test device when testing.

(Figure 18)

Viewing Your Test Results

Press the "◀" button for 3 seconds to enter the "Menu".

Test Record

Press the "◀" button to enter the interface of "Test Record" (Figure 19).

(Figure 19)

Press the "◀" or "▶" button to view the previous or next test results.

QC Record

Press the "►" button to select "QC Record". Press the "◄" button to enter the interface of "QC Record" (Figure 20).

2023-09-15 19:25

QC

No.002

Pass

Record

(Figure 20)

Press the "◄" or "►" button to view the previous or next QC test results.

Meter Turn Off

Press the "►" button for 3 seconds to shut down the Meter.

# CHAPTER 5: MAINTENANCE AND PRECAUTIONS

Charging Instructions

Indications on the meter displayed for when the meter is properly connected, actively charging, and adequately recharged:

When the meter is properly connected and actively charging, the meter displays the battery icon and repeats the charging status from through ▇ , ▇ , ▇. When the meter is fully charged, the meter displays the battery icon ▇.

Recommendations for Recharging Battery:

The meter battery may be charged using one of the following options:
• Type C & USB 2 in 1 cable (computer charging)
• Type C & USB 2 in 1 cable with the AC adapter (wall charging)

To optimize battery life, it is recommended to recharge the battery when the critical battery level (running out of battery) (▇) appears. When using the USB port on your computer to recharge the battery, be sure the computer is turned on and not in standby mode. If the meter is not recharged, try using another USB port on your computer. Contact seller to confirm whether the AC adapter meets following specifications before purchasing it:
Input: 100-240V~, 50/60Hz, 0.2A Max; Output: 5.0V⎓, 1.0A;
Standard ANSI/AAMI ES

Warnings for Recharging Battery:

• Do not disassemble the meter and take battery out for recharging.
• Do not use the Type C & USB 2 in 1 cable, AC adapter or meter if it is damaged, discolored or deformed.
• Do not put the meter on the thermally insulating materials such as clothing, carpet, blanket, or plastic surface for recharging.
• Do not recharge the meter in outdoors, sunlight, a wet area or a heating area.
• Do not place the meter in environmental temperature above 131°F (50°C), such as outdoors for recharging to avoid overheating, smoking, and catching fire; the meter can be safely recharged at normal indoor temperatures.
• Do not allow unsupervised children to recharge the meter battery

Recommended Procedures for Recharging Battery:

Step 1): Select a recharging method from the options below:
Option A: Using a Type C & USB 2 in 1 cable by connecting computer, the computer should be turned on during recharging;
Option B: Using a Type C & USB 2 in 1 cable by connecting AC adapter, the AC adapter should meet the specifications in the section "Recommendations for Recharging Battery" in the User's Manual.

Step 2): Check and ensure the contents in the section "Recommendations for Recharging Battery" are followed.

Step 3): Check and ensure that the applicable contents in the section "Warnings for Recharging Battery" are followed.

Step 4): After connecting the meter, check that the main button flashes with green color during recharging.

Step 5): Check that the meter displays the battery icon and repeats the recharging status from through ▬ , ▮ , ▬ ;

Step 6): Check whether the meter displays battery icon ▬ , this means that the battery is fully charged. If not, please continue to recharge.

Step 7): Recommend recharging the meter for two hours.

Step 8): Remove the Type C & USB 2 in 1 cable from the meter after recharging.

Step 9): Your meter is now ready to use.

Caring and Maintenance

(1) Please keep VivaDiag POCT Multifunction Meter clean. There is no other special maintenance required.

(2) The internal hardware and software of VivaDiag POCT Multifunction Meter can only be repaired, replaced or upgraded by manufacturer. Please contact your local dealer or manufacturer for support.

Maintenance Method and Plan

Your VivaDiag POCT Multifunction Meter does not require special maintenance or cleaning.

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

Caution
Before cleaning, please make sure the meter is turned off and the charging cable is pulled out to avoid short circuit and electric shock danger!

Maintenance Plan

Maintenance item	Every week	When needed
External cleaning	X	

Precautions for Meter Use

1. Please use the meter in strict accordance with the User's Manual provided by the manufacturer, otherwise, the protection provided by the meter will be damaged.

2. Meter data preservation and recovery procedures: the meter can save the user test records. The test results during the normal use of the user will be automatically saved to the meter in the form of records. The meter can save up to 99 records. The saved data can be recovered automatically after power failure and will not be lost.

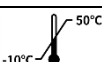# CHAPTER 6: TECHNICAL INFORMATION

System Specifications
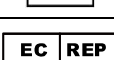
Feature	Specification
Principle	Fluorescence Immunochromatography
Measurement	Quantitative or Qualitative
Dimensions	124.5 mm (Length) x 72.5 mm (Width) x 40 mm (Height)
Weight	165 g
Display size	1.54'' LCD
Sample type	Nose swabs/nasopharyngeal swabs/oropharyngeal swabs/urine/whole blood/etc
Operating temperature	50°F ~ 86°F (10 ~ 30°C)
Storage temperature	14°F ~ 131°F (-10 ~ 50°C)
Relative humidity	10 ~ 90%
Atmospheric pressure	86.0 ~ 106.0 kPa
Connectivity	Bluetooth
Battery	Lithium battery
Memory	1000 test results

Limitations

- Do not use any other brands' components or test devices with this meter.
- Please use the meter strictly according to the User's Manual provided by manufacturer.
- Do not insert anything else into the test device slot except 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 Meter 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
-10°C / 50°C	Temperature limitations
	Contains sufficient for <n> tests
	Use by
LOT	Lot Number
EC REP	Authorized representative
REF	Catalog number
#	Model number
SN	Serial Number
	Do not re-use
	Caution, consult accompanying documents
IVD	*In vitro* diagnose
	Dispose items according to local relevant laws regarding disposal and recycle
	Keep away from sunlight and heat
	Biological Hazard

Warranty

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

If the meter fails to work for any reason other than obvious abuse within the first three (3) years from purchase, we will repair or 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 meter in the original purchase, and does not apply to the battery supplied with the meter.

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 meter does not work for any reason other than obvious abuse in the first 3 years after purchase, we will repair or replace it with a new or equivalent meter free of charge.

Date of purchase _____ / _____ / _____

meter serial number (e.g. 601A0000001) _____

Where purchased _____

Telephone number _____

Email address _____

Suggestion/Comments _____

VivaChek™