REF QV-3 Plus

# qLabs<sup>®</sup> Vet User's Manual







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# **1.Introduction**

# 1.1 Before You Start

Before using qLabs<sup>®</sup> Vet, read the User's Manual as well as the package inserts for all relevant consumables carefully.

#### 1.2 Intended Use

The qLabs<sup>®</sup> Vet system, which consists of qLabs<sup>®</sup> Vet instrument and qLabs<sup>®</sup> Vet Test Strips, intended for quantitative determination of Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) in fresh venous blood and citrated whole blood. The qLabs<sup>®</sup> Vet system is only for veterinarian professional use in feline, canine and other animals.

### **1.3 Test Principle**

The qLabs<sup>®</sup> Vet automatically detects the insertion of a qLabs<sup>®</sup> test strip and heats the strip to a preset operating temperature. After a drop of blood is applied to the strip, the sample channel automatically carries the blood sample into the reaction zone through capillary action, where the blood mixes with pre-printed reagent and starts coagulation process. As the blood coagulates, conductivity across the test strip changes. The system measures this electrical change and calculates the development of a clot. The values are then displayed.

# 1.4 Packaging

The qLabs<sup>®</sup> Vet is packed individually.

Upon receipt of the device, please open and remove the packaging materials, then place the qLabs<sup>®</sup> Vet on a flat surface and connect the power adapter to make it ready for testing.

Do not keep the qLabs<sup>®</sup> Vet in direct sunlight, near a high heat source, or near an area with a strong magnetic field.

If you find any damage that may be caused by transportation, please inform your local distributor.

Please pay attention to contents under the symbol "\_\_\_\_\_"appears in the manual.

# **2.Product Overview**



Front View 1. Test Strip Guide 2. Touchscreen



Back View

- 3. Footpad
- 4. Battery Cover with Label
- 5. Magnetic Charging Port





Top View 8. Micro USB Data Port 9. DC 5V Power Supply Jack

# **3.Operation Summary**



# **4.Before Testing**

#### Materials provided

- qLabs<sup>®</sup> Vet
- Power supply
- USB disk (Electronic manual, Data Management Software)

#### Materials required (but not provided)

- qLabs® Vet test strip
- Puncture-resistant container for medical sharps
- Sterile alcohol
- Disposable glove

#### Testing fresh venous blood samples

- 21-gauge needle or larger with 1.0 mL syringe
- Sterile band aid

# Testing citrated whole blood samples:

- qLabs® Re-Calcification Reagent
- 100 uL pipette and pipette tips
- Disposable venous blood lanet
- 1.8 or 2.7 mL 3.2% (w/v) sodium citrate venous collection tube

# 5. Precautions, Limitations and Warnings



The qLabs<sup>®</sup> Vet is for in vitro diagnostic use only. Some environmental factors and incorrect operation may cause the qLabs<sup>®</sup> Vet cannot work effectively or report accurate results. Please read the following warnings carefully before use and strictly follow them.

As with all diagnostic tests, qLabs<sup>®</sup> Vet's test results should be analyzed and interpreted by combining the condition, medical history, current and possible treatment of a specific animal. Any results exhibiting inconsistency with the clinical status should be repeated or supplemented with additional test data or repeated with other testing methods.

# 5.1 Care of Your qLabs® Vet

- DO NOT spill any liquid on the qLabs<sup>®</sup> Vet. In this case, immediately contact the local distributor of Micropoint.
- The qLabs<sup>®</sup> Vet is a delicate instrument and should be handled with care. Dropping or other mishandling may cause malfunction of qLabs<sup>®</sup> Vet.
- The qLabs<sup>®</sup> Vet should be transported in a carrying case or a secure container.
- DO NOT store the qLabs<sup>®</sup> Vet below -10 °C or above 40 °C.
- DO NOT use the qLabs<sup>®</sup> Vet for any other types of test strips not provided by Micropoint.

# 5.2 Test Environment Requirements

- The temperature should be maintained between 10 ° C and 35 ° C.
- This equipment has been tested and found to comply with applicable EMC emission requirements as specified in EN 55032. The emissions of the energy used are low and not likely to cause interference in nearby electronic equipment.
- Do not use this instrument in a dry environment, especially if synthetic materials are present. Synthetic clothes, carpets,etc., may damage static discharges in a dry environment. That may cause incorrect operation or damage to the device. The recommended humidity operating range is 10% to 90%.
- Do not use this instrument near cellular or cordless telephones, walkie talkies, garage door openers, radio transmitters, or other electrical or electronic equipment that are sources of electromag-

netic radiation, as these may interfere with the proper operation of the instrument.

### 5.3 Patient health Status

Current patient health status may cause inaccurate or unexpected test results. It is important to take certain health factors into consideration when interpreting the test results and deciding on a course of action for your patients. Failure to do so may lead to an incorrect interpretation of the test result.

### 5.4 Performing a Test

- The qLabs<sup>®</sup> Vet should be placed on a level surface that is free of vibration. Testing on an uneven or unstable surface may cause inaccurate results. DO NOT hold the qLabs<sup>®</sup> Vet in your hands during the testing.
- Strictly follow the test procedure specified in the manual to perform the test.
- DO NOT move or touch the qLabs<sup>®</sup> Vet during testing.
- After inserting the test strip, please confirm the consistency of the code chip, failure to do may cause inaccurate test result.
- The blood sample must be applied to the test strip immediately after collection. Otherwise, the blood sample may begin clotting and causing inaccurate results.
- Do not add the sample until the system prompts you to start adding sample.
- The sample should be added in one continuous operation, do not reapply additional sample.
- Do not use the device for unintended purposes, failure to do so may cause unexpected test results.

#### 5.5 Collecting Sample

- Use fresh venous whole blood and citrated whole blood. Do not use plasma.
- The drop of blood must be a minimum of 10  $\mu$ L.

# 5.6 Warning Information on Built-in Lithium Battery

• qLabs meter has a built-in lithium battery, which cannot be removed by any user.

- The user must use the matching 5V special charger provided by Micropoint to charge.
- Do not bring the meter close to a high-temperature heat source.
- Do not allow the meter to be hit or exert heavy pressure on the meter.
- If it is found that there is leakage from the battery cover on the back of the meter, direct skin contact should be avoided as much as possible. In case of accidental contact with skin due to battery leakage, please rinse with water. If your eyes come into contact with battery liquid, you should also seek medical care.
- The battery should be disposed with the meter in accordance with local regulations.

# 6.Power ON/OFF

# 6.1 Battery and Charging

When turning on the meter for the first time after unpacking, please connect the adapter for power supply and turn off the transportation mode. You do not need to repeat this operation for subsequent reboot.

Ensure the meter is fully charged before using for the first time. Approximately 3.5 hours to fully charge.

When the screen displays E001, the adapter should be connected immediately for charging. If the battery charge display shows only one bar, it is recommended that the user connect the power adapter to charge as soon as possible.

When the meter automatically shuts down due to insufficient power, the user should charge the meter within 7 days. Otherwise the time and date will require a reset.

The test results and all settings of the meter will be permanently stored in the memory except the time and date.

# 6.2 Power On

When the instrument is turned on for the first time, the battery must be fully charged. If the battery is low, do not turn on the instrument until the power adapter provided with the instrument is inserted into the power jack and connected to the external power supply. If the instrument is in power off mode, short press the Power button and wait 2 seconds to power on. If the instrument is in sleep mode, short press the Power button or insert a test strip and wait 2 seconds to wake it up.

	12:12 AM Logi		* 💷
Operator	ID		
Passwor	d		
Rememb	er passw	ord	
1	2	3	<b>1</b>
	-		<<-
4	5	6	<<-
4 7	5 8	6 9	
4 7 ABC	5 8 0	6 9 space	
4 7 ABC	5 8 0	6 9 space	· ·

If Operator ID is set to On, the meter automatically enters Operator ID menu (see figure 1-1) after it is turned on. Manually input Operator ID and Password or obtain by scanning (The default Operator ID is "admin" and all must be lower case. The default password is "123456".) and touch "√" to enter Main menu.

Please set Operator ID function according to Section 7.8 of this manual.



Once Operator ID is On, the Log out icon in Main screen will be enabled and displayed in brown (see figure 1-2). To switch between the operators, please return to the screen for inputting the operator ID by pressing the Log out icon, and then re-enter the operator ID.

If Operator ID is Off, the Log out icon in Main screen will be disabled and grayed out (see figure 1-3), and the meter then directly enters the Main screen after it is turned on.

#### 6.3 Sleep mode

Settinas

Logout

Results

After a short press and release of the Power button, the screen will be off and enter sleep mode. The sleep mode is a low power mode to save battery power. Short press the Power button or insert a test strip and wait 2 seconds for device start-up.

If auto sleep function is enabled, the meter will automatically shut down after the idle time reaches the sleep waiting time.

#### 6.4 Power OFF



1-4

After a press of the Power button for 3 seconds, the system will deliver a message to select. Press " I to power off the instrument, or press " I to cancel the operation (see figure 1-4). When the battery power of the meter is exhausted, it will automatically shut down.

# 7.Setting

#### 7.1 Enter setting screen

2020-04-15 02:19 PM Settings	-
Language	>
WIFI	>
Bluetooth	>
Test Parameter	>
System Parameter	>
Operator ID	>
About the Device	>
<b>←</b>	A
2-1	

Click the "Settings" icon from the main menu screen (Figure 1-2) to enter the Settings screen (Figure 2-1).

# 7.2 Language

2020-12-17 09:42 AM * 🕮					
English		~			
中文					
Français					
Deutsch					
Italiano					
Español					
Protuguês					
Polski					
K < 1/	1 >	К			
-					
2-2	)				

#### 7.3 WIFI

WIFI connectivity allows the meter to connect with Data Management System (DMS) or other software system without connecting to eStation II. This function can be used for data transmission.

2020-06-28 02.01 PM WIFI		2020-04-15 02-20 PM WIFI	≈
WIFI	Ð	WIFI	
		Server	
		Micropoint	~
		YFB_GUEST	
		YFB_2.4G	
		MCL	
		FQC	
+	•	<b>(</b>	Ĥ

Click "WIFI" from Settings menu (see Figure 2-1) to enter the WIFI menu (see Figure 2-3). When the WIF button is displayed in blue, it means WIFI is turned on; when the WIFI button is grayed out, it means WIFI is turned off. Once WIFI is turned on and connected successfully, the WIFI icon on the upper right corner of the menu is highlighted. However, if WIFI is turned on but fails to connect, the WIFI icon is grayed out. Click "—" to return to the previous screen and click "**^**" to return to the main menu.



The system will search nearby hotspot list automatically. Click the hotspot name to enter the password to connect successfully. The system will remember the password and connect to the last connected hotspot automatically.



The server is used for wireless data transmission with the specific Data Management System. Click "Server" to enter the server IP address and port number, and click "✓" to save. Please set the instrument's IP address and port number to be consistent with DMS.

The loss of signal or access to bandwidth of one particular client may vary depending on one or more of the following situations: the type and number of other clients, the performance of the Access Point, the presence of electromagnetic disturbances, and other potential interfering factors, e.g., concrete walls.

# 7.4 Bluetooth



Click "Bluetooth" from Settings menu (see Figure 2-1) to enter the Bluetooth menu (see figure 2-6). When the Bluetooth button is displayed in blue, it means Bluetooth is turned on; when the Bluetooth button is graved out, it means Bluetooth is turned off. Once Bluetooth is turned on and connected successfully, the Bluetooth icon on the upper right corner of the menu is highlighted. However, if Bluetooth is turned on but fails to connect. the Bluetooth icon is graved out.Click " return to the previous screen and click " 🛖" to return to the main menu.



"Discoverable" option pops up automatically when Bluetooth is set to On. When "Discoverable" option is displayed in blue, it means Discoverable Mode is opened, and the meter can be searched by other Bluetooth devices. However, the meter cannot search other Bluetooth devices actively in the mode. If "Discoverable" option is grayed out, it means Discoverable Mode is closed.



When Bluetooth is set to On and Discoverable Mode is closed, the meter automatically searches for the connectable base. Touch one of the bases in the search result list after completing the search, the screen then displays "connecting ... ", and the meter displays "connected" after the connection is completed. Touch " Q " to manually search for the connectable Bluetooth devices. Touch the connected Bluetooth device, and the system prompts whether to disconnect, then touch OK to disconnect the current connection.

Bluetooth can be used to connect the meter to eStation II and a specific mobile APP. Once connected to eStation II, the test results can be transferred to eStation II for printing. The test results can also be transferred to DMS, LIS or HIS system via eStation II.

When Bluetooth is disconnected or failed to connect during operation, the system pops up a box and prompts the user to reconnect. In such case, please turn on Bluetooth again and then reconnect.

#### 7.5 Test Parameter



Click "Test Parameter" from the Setting screen (Figure 2-1) to enter the screen (Figure 2-10) that prompts the user to set the parameters.

# 7.5.1 Sample NO.

2020-09-23-03-99 PM Sample No.		2020-09-22-09-41 AM Sample No.	
Sample No.	Ø	Sample No.	€
		Auto	~
		Manual	
<b>4</b>		<b>←</b>	
	2-	11	

Click "Sample No." from the Test Parameter screen (Figure 2-10) to enter the screen (Figure 2-11) that prompts the user to set the sample No. If the sample No. button is grayed out, then the sample does not need to be numbered. If the sample No. button is blue, the sample can be numbered manually or automatically.Click "—" to return to the previous screen and click " " to return to the main menu.

# 7.5.2 Codeship Strip



Click "Codechip" from Test Parameter menu (see figure 2-10) to enter Codechip menu (see figure 2-12). Touch "Q" to search and view the corresponding Codechip information displayed based on the search criteria.Click "I" to return to the previous screen and click "I" " to return to the main menu.

Test Strip           No.         Item         Expiry Date           AAAA         PT         2022/08/27           YYY         PT         2022/02/1           NNNN         PT         2022/10/21	2020-12-17	09:38 AM	* 💷
No.         Item         Explry Date           AAAA         PT         202208/27           YYYY         PT         202208/27           NNNN         PT         20220/21		Test S	trip
AAAA PT 202208/27 YYYY PT 202208/27 NNNN PT 2022/10/21 K < 1/1 > >	No.	Item	Expiry Date
YYYY PT 202206/27 NNNN PT 2022/10/21 K < 1/1 > >  ← ♠	AAAA	PT	2022/08/27
NNNN PT 2022/10/21	YYYY	PT	2022/08/27
K < 1/1 > > ← ♠	NNNN	PT	2022/10/21
	K	< 1/1	х х

2020-12-17 09:36 AM * 💷						
No.	lte	m	Expir	y Date		
AAAA	Ρ	т	2022	2/10/21		
AAAA PT 2022/10/21						
+						

2-14

Click "Test Strip" from Codechip menu (see figure 2-12) to enter Test Strip menu (see figure 2-13). The Codechip information of the installed strip then displayed in this menu. A new strip Codechip can also be installed by inserting the strip Codechip into the Codechip slot (see the right figure on Section 2 Product Overview). Please make sure the side with the arrow is facing up and the Codechip is inserted into the end. If the Codechip has not been installed, the Codechip is automatically installed into the meter and displayed in the list.Click " " to return to the previous screen and click "A " to return to the main menu.

Click "Control" from Codechip menu (see figure 2-12) to enter Control menu (see figure 2-14). The Codechip information of the installed control then displayed in this menu. A new control Codechip can also be installed by inserting the control Codechip into the Codechip slot (see the right figure on Section 2 Product Overview). Please make sure the side with the arrow is facing up and the Codechip is inserted into the end. If the Codechip has not been installed, the Codechip is automatically installed into the meter and displayed in the list.Click " " to return to the previous screen and click "A " to return to the main menu.

In addition to being installed from Codechip menu, a Codechip can also be installed during the test. When testing with a test strip or control with a Codechip installed, the installation operation is no longer required during the test; otherwise, the system enter the prompt menu which enables the user to install the desired Codechip accordingly.

The Codechip provides the meter with important information that it needs to perform the coagulation test. The chip contains information about the test strip code, the lot number, and the expiration date. The Codechip is required, whenever a new test strip lot is used, so that the meter can read and store the lot information about that particular lot of test strips.

- Do not forget to use the test strip Codechip that is supplied with each pack of test strips before you perform the first test with these strips. We recommend that you leave the Codechip in the meter to protect the electrical contacts in the meter from becoming dirty.
- Each Codechip belongs to a particular lot of test strips. Only remove the Codechip when you are testing with test strips taken from a new pack.
- Protect the Codechip from moisture and equipment that produces magnetic fields.Reference Range

Reference Range		2020-12-13 R	eferenc	e Rang	*≡⊃ je		
Refere	nce Ran	ge	Ð	Reference Range			
ltem	Lower	Upper	Units	Item	Lower	Upper	Units
PT			s	PT	13.0	20.0	s
APTT	96.0	124.0	s	APTT	96.0	124.0	s
FIB	2.0	4.0	g/L	FIB	2.0	4.0	g/L
TT		24.0	s	TT	10.0	24.0	ŝ
Feline			~	Feline			~
Canine				Canine			
Other	Other						
-			<b>A</b>	-			<b>A</b>
2-15							

# 7.5.3 Refrence range

Click "Reference Range" from Test Parameter screen (Figure 2-10) to enter the screen (Figure 2-15) that prompts the user to set the reference range switch. Grey button indicates the reference range function is disabled and blue button indicates the reference range is enabled.

2020-12-17	* 💷			
(Range 5.0-75.0)				
	Illegal Ir	nput		
			L	
	×		:<-	
4	5	б		
7	8	9		
Abc	0	space		
← ✓				
2-16				

# 7.5.4 PT units



# 7.5.5 APTT units



Click any value in the Reference Range table to automatically enter the menu which allow the user to modify the value, and the user can re-modify the upper and lower limits (see figure 2-16) within the given setting range. After the value range is modified, if the test result is below the lower limit, then will popup prompt"Input is illegal".Click "Implication" to return to the previous screen.

Click "PT Units" from Test Parameter menu (see figure 2-10) to enter the PT Units menu (see figure 2-17). Default format is PT,the display format of the PT test result can be set as required. The available display formats are: PT,PT//QC.After selecting a format, PT test result is displayed accordingly.Click " " to return to the previous screen and click " " to return to the main menu.

Click "APTT Units" from Test Parameter menu (see figure 2-10) to enter the APTT Units menu (see figure 2-18). Default format is APTT. the display format of the APTT test result can be set as required. The available display formats are: APTT and APTT/QC. After selecting a format, APTT test result is displayed accordingly.Click "In to return to the previous screen and click "In " to return to the main menu.

#### 7.6 System Parameter

2020-09-22 09:55 AM System Paramet	er 🚥
Date/Time	>
Beeper	>
Screen Rotation	>
Brightness	>
Auto Sleep	>
Auto Print/Upload	>
Transport Mode	>
+	ŵ
2-19	

#### 7.6.1 Date/Time

2020-09-22 10:00 AM Date/Time	
Date	>
Time	>
Format	>
<b>←</b>	•
2-20	

Click "Date/Time" from the System Parameter screen (Figure 2-19) to enter the screen (Figure 2-20) that prompts the user to set the date and time. The user can set the date, time, and even their display format respectively.Click "—" to return to the previous screen and click " to return to the main menu.

#### 7.6.2 Beeper



Click "Beeper" from the System Parameter screen (Figure 2-19) to enter the screen (Figure 2-21) that prompts the user to set the beeper. The beeper is turned off when the beeper button is graved out. The beeper is turned on when the beeper button is blue, and the user can set different volume: high. medium and low. After the beeper is turned on, it will "beep" in any of the following circumstance: the instrument is turned on, the test strip is inserted successfully, scan is performed successfully, the heating is completed, the sample is added. the test is completed, and the instrument enters sleep mode.

#### 7.6.3 Screen Rotation



Press the "Screen Rotation" from the System Parameter screen (Figure 2-19) to enter the screen for selecting screen rotation (Figure 2-22). Change the settings and rotate the screen for 180°, then the text direction is adjusted automatically. The test strip is inserted from the lower part by default.Click "—" to return to the previous screen and click "

#### 7.6.4 Brightness Adjustment



Click "Brightness" from the System Parameter screen (Figure 2-19) to enter the brightness adjustment screen (Figure 2-23). The adjustment range is between 1 and 10. Click " to return to the previous screen and click " " to return to the main menu.

# 7.6.5 Sleep setting

Auto Sleep		Auto Sleep	
Auto Sleep	Ð	Auto Sleep 🔍	
		⊖ 5 min ⊕	
<b>—</b>	2	-24	

Click "Auto Sleep" from the System Parameter screen (Figure 2-19) to enter the sleep setting screen (Figure 2-24). The auto sleep function is turned off when the button is grayed out. The auto sleep function is turned on when the button is blue, and the user can set the idle time value before the instrument enters auto sleep mode. Insert the test strip or re-power the instrument to wake it up from the sleep mode.

#### 7.6.6 Print and Upload

Auto Print/Upload		Auto Print/Upload	
Auto Upload	Ð	Auto Upload	
Auto Print	Ð	Auto Print	•
4			
		25	

7.6.7 Transport Mode



Click "Auto Print/Upload" from the System Parameter screen (Figure 2-19) to enter the print upload setting screen (Figure 2-25). The auto print/upload function is disabled when the button is graved out. The auto print/upload function is enabled when the button is blue. Click "
 to return to the previous screen and click "A " to return to the main menu. Auto Print function can be worked when the meter is connecting with eStation II. Auto Upload function can be worked when the meter is connecting DMS software.

Click "Transport Mode" from System Parameter menu (see figure 2-19) to enter Transport Mode menu (see figure 2-26). When the button is in blue. Transport Mode is turned on; when the button is graved out, Transport Mode is turned off. Transport Mode is set to On by default to extend the storage period of the battery. When using the meter for the first time, please connect the external power supply, and the transport mode then turns off automatically after booting. After Transport Mode is turned on and the power is turned off. the system time will be reset. Please set the correct system time after the next boot.Click "- to return to the previous screen and click "A " to return to the main menu.

#### 7.7 About the Device



Click "About the Device" from Settings screen (Figure 2-1) to enter the screen that displays the system information (Figure 2-27). The user can check the version and log information.Click " To return to the previous screen and click " " " to return to the main menu.

# 7.8 Operator ID

* 00	2019-12:00 09:09 PM Operator ID	* 000
$\odot$	admin	
	User Management	
	Remember password	
	Auto Sign-In	
		Anno Socie de Marine     Coperator ID     admin     User Management     Remember password     Auto Sign-in

Touch "Operator ID" from Settings screen (Figure 2-1) to enter the screen for setting the Operator ID (Figure 2-28). The operator ID is enabled when displayed in blue and it is disabled when displayed in grey. There is no limit on operator ID under the status of "Disabled". Touch " " to return to the previous screen, and touch " " to return to the main menu.

When enable Operator ID, need use administrator account "admin" which all must be lower case, and input administrator password. The initial password is "123456" if not change password.

Administrator account is allowed to create and manage ordinary accounts, and set all function of Operator ID. The meter can remember the password. After the function is enable, the user can check "Remember Password" checkbox to save the password. Automatic login is also supported. Once the function is enabled, the user can automatically login with the last used account number and password.



After touching "User Management" from the operator ID screen (Figure 2-28), the administrator can enter the screen and view the created user list (Figure 2-29). To create a new user account, please touch "(+)" at the bottom of the screen. The number of user accounts should not exceed 50. If the upper limit is exceeded. "Maximum number of account exceeded" will be prompted. An account must be removed before creating a new account. The historical results of the old account will be retained. The character length of the operator ID and password is between 1 and 16 digits. The Operator ID can be input manually or by scanning the barcode or QR code.



The password reset screen will be appeared when the administrator touches the created account (Figure 2-30). The password of an user account can be reset from the screen, please touch " ✓" to save the settings after the password is reset. The user account can be removed by touching the " 📺 " at the bottom of the password reset screen (Figure 2-30). Users can only change the passwords of their own ordinary accounts.



To change the password, the user needs to provide the current password, the new password, and confirm the new password (Figure 2-31). If a user forgets their password, contact the administrator to reset the user password. If the administrator forgets the password, please contact the local distributor or relevant technicians of Micropoint.



The user can log in to any existing account from the Login screen. Enter the correct password and log into the screen to perform the relevant operation. After entering the ID and password, please touch " ✓ ". If it is prompted that the user does not exist or the password is incorrect, please use the administrator account to log in and create a new account and reset the password.

# 8.Sample Test

#### 8.1 Choosing test type

2020-12-16 04:05 PM	* 🎟
Feline	~
Canine	
Other	
←	$\checkmark$
3	3-1

#### 8.2 Input Sample NO.

When the sample No. switch is turned off, skip the step of inputting the sample No. and insert the test strip directly. When the sample number switch is turned on, the sample can be numbered manually or automatically. If auto numbering is selected, please enter the screen for inserting the test strip directly after entering the sample test channel, the system then generates a sample No. automatically; if manual numbering is selected, please input the sample No. manually and save it after entering the sample test channel (as shown in Figure 3-2), then enter the strip insertion screen.



Click the "Sample Test" icon from the main menu (Figure 1-1) to enter the sample information screen (Figure 3-2), and manually enter the sample number, which consists of numbers, uppercases and lowercases, and space. The character length should be between 1-20, Click"  $\checkmark$ " to save.

#### 8.3 Insert a Test Strip



Save the sample No. and enter the strip insertion screen, then insert the test strip in the direction shown in Figure 3-3. Keep inserting the strip from the right direction until the sample well on it is align with the dot on the instrument. If the test strip is already inserted, please skip the strip insertion screen and enter the next screen to input the test strip information.

#### 8.4 Input Test Strip Information



After the test strip is inserted, please enter the test strip information screen (Figure 3-4), and input the Codechip number of the test strip, the Codechip number can be inputted through manually input and click "</ " to save, or by scanning the barcode on the package of the test strip. The package of the test strip bears the Codechip number of the test strip. The Codechip number of the test strip must be input, or the system will deliver a warning message indicating that the input is invalid when you click Save. When Meter scans, the indicator will be automatically lights up first. The white area in the rectangular light field is the sensing area. When scanning, the scan port should be aligned with the barcode, and the position, distance and angle between the barcode and scan port should be adjusted according to the light field.

Location: The barcode should be placed in the white sensing area with the barcode direction align with the long axis of the white sensing area.

Distance: Adjust the distance between the barcode and meter scan port to make sure the barcode fits completely within the white sensing area.

Angle: The light field should be as perpendicular to the barcode plane as possible, and the vertical deviation should have the highest recognition rate within  $\pm 5^{\circ}$ .



#### 8.5 Install Codeship

Insert the test strip Codechip into the chip slot (see Section 1.3 for position details), then the specific Codechip information will display (Figure 3-5). Codechip number and arrow side should be face up.



When the input Codechip number of the test strip does not match the Codechip information, the system will deliver a warning message indicating that the Codechip information does not match.



When the input Codechip number of the test strip has expired, the system will deliver a warning message indicating that the Codechip has expired.

# 8.6 Heating





After the test strip is inserted and its Codechip is installed, the instrument will enter the heating state, and the screen will display the heating progress (Figure 3-6).

# 8.7 Add sample



3-7

The system will count down and prompt the user to add sample (Figure 3-7) upon the completion of heating, and the sample must be added within 10 minutes. Do not move the instrument or your fingers during sample adding. If the sample is not added properly within 10 minutes, the system will deliver an error message indicating sample adding is timeout.

### 8.8 Collecting a sample

After the heating is complete, collect whole blood samples and run test. Refer to the test strip insert for detailed sample collecting procedures. **NOTE:** 

- To avoid mechanical hemolysis of the blood sample, nonheparinized syringe with 21 gauge needle or larger is highly recommended.
- Since the interstitial fluid (thromboplastin) will accelerate the clotting process, vascular puncture action is preferably a one-time action so as to minimize the interstitial fluid from entering into the blood sample.
- Excitement of the patient should be minimized when collecting the sample. The clotting reaction and test results will be affected when the patient is extremely exciting. Sedatives and analgesics can also affect the blood clotting process.
- When collecting the sample, follow the guidelines and procedures for blood collection as instructed by the veterinary clinic.

### 8.9 Peforming the Test

Disuse the first drop of blood needle disuse, then apply a total of about 10-20 microliter blood sample to sample well of the strip.Make sure to apply the blood sample directly on the sample well of the strip. DO NOT move the qLabs<sup>®</sup> Vet while adding the blood to the strip.



After the sample is added properly, the system will start the test automatically and display the test progress (Figure 3-8). Do not perform other operations during testing.

#### 8.10 Test Results

Please check the strip insert for the results and explanation.



The system will display the test results after the test is completed (Figure 3-9). The test results can be printed or uploaded, provided that the instrument is properly connected to the printer or server. When the result is out of the normal range, the system will prompt that the result is  $\uparrow$  (high) or  $\downarrow$  (low), if Reference Range function is enable."



3-10

If the test strip has not been removed after the test is completed, please click " " from the test result screen to go to the strip removal screen (Figure 3-10), and remove the test strip in the direction shown in the figure. If the test strip is removed from the test result screen after the test is finished, the screen will directly jump to the Main screen.

# 9. Quality Control

Onboard QC Test

The qLabs<sup>®</sup> system utilizes a number of internal quality methods to ensure proper operation. The built-in quality control of instrument automatically monitors critical conditions before and during the testing period. The onboard quality control of strip detects the signal characteristics of two channels. By identifying possible problems such as test strip defects and operational issues, to ensure the accuracy of the test results.

Failure of Quality Control test will result in the instrument displaying an error code. Please repeat the test utilizing a new test strip.

Liquid QC Test

Micropoint Biotechnologies Co., Ltd. has optional liquid controls for qLa bs<sup>®</sup> Vet system. The qLabs<sup>®</sup> liquid controls are used with qLabs<sup>®</sup> test strips to verify the qLabs<sup>®</sup> system performance, respectively. It is recommended that two levels of liquid controls are used to perform the test.

# Only use qualified qLabs<sup>®</sup> Controls for QC test. The specific procedure for external QC test are as follows.

# 9.1 Insert a Test Strip



Click the "QC Test" icon from the main menu screen (Figure 1-1) to start the QC test, and insert the test strip in the direction as indicated by the figure (Figure 4-1). Keep inserting the strip from the right direction until the sample well on it is align with the dot on the instrument. If the test strip is already inserted, please skip the strip insertion screen and enter the next screen to input the test strip information.

#### 9.2 Input Test Strip Information



After the test strip is inserted, please enter the test strip information screen (Figure 4-2), and input the Codechip number of the test strip, the Codechip number can be inputted through manually input and click "✓" to save, or by scanning the barcode on the package of the test strip. The package of the test strip bears the Codechip number of the test strip. The Codechip number of the test strip. The Codechip number of the test strip must be input, or the system will deliver a warning message indicating that the input is invalid when you click Save.

#### 9.3 Install Test Strip Codechip



Insert the test strip Codechip into the chip slot (see Section 1.3 for position details), then the specific Codechip information will display (Figure 4-3).



When the input Codechip number of the test strip does not match the Codechip information, the system will provide a warning message indicating that the Codechip information does not match.



When the input Codechip number of the test strip has expired, the system will provide a warning message indicating that the Codechip has expired.

### 9.4 Input QC Information



After the Codechip is installed, please enter the QC information screen (Figure 4-4), and input the Codechip number of the QC liquid (see the outer package for details), The Codechip number can be inputted through manually input and click "✓" to save, or by scanning the barcode on the package of the test strip. The Codechip number of the QC liquid cannot be empty, or the system will provide a warning message indicating that the input is invalid when you click Save.

#### 9.5 Install QC Liquid Codechip



The screen will display the specific Codechip information of the QC liquid (Figure 4-5) after inputting the Codechip information of the QC liquid.

2020-06-28	02:01 PM	
	Codechip Information Does Not Match	
	Confirm	

2020-06-28 02:01 PM	
Codechip Has Expired	

When the input Codechip number of QC liquid does not match the Codechip information, the system will provide a warning message indicating that the Codechip information does not match.

When the input Codechip number of QC liquid has expired, the system will provide a warning message indicating that the Codechip has expired.

#### 9.6 Heating



After the test strip is inserted and Codechip is installed, the instrument will enter the heating state, and the screen will display the heating progress (Figure 4-6).

# 9.7 Add Sample



The system will count down and prompt the user to add sample (Figure 4-7) upon the completion of heating, and the sample must be added within 10 minutes. Please strictly follow the requirements of the QC liquid insert during sample adding. Do not move the instrument or your fingers during sample adding. If the sample is not added properly within 10 minutes, the system will deliver an error message indicating sample adding is timeout.

# 9.8 QC Test



After the QC liquid is added, the system will start the QC test automatically and display the test progress (Figure 4-8).

#### 9.9 QC Test Results



The system will display the QC test results after the test is completed (Figure 4-9). The test results can be printed or uploaded, provided that the instrument is properly connected to the printer or server.



4-10

If the test strip has not been removed after the QC test is completed, please click "A" from the test result screen to go to the strip removal screen (Figure 4-10), and remove the test strip in the direction shown in the figure. If the test strip is removed from the test result screen after the QC test is finished, the screen will directly jump to the Main screen.

# **10. Results**

When the storage amount of the sample result reaches 80% of the total amount of the meter, the user will be prompted to upload data. If the user does not upload the data, the sample results will automatically overwrite the oldest records after the total amount exceeds the limit.

#### **10.1 Results Channel**

2020-09-22 10.56 / R	™ esults	
Test Results	;	>
QC Results		>
←	Q	<b>A</b>
	5-1	

Click the "Result" icon from the main menu screen (Figure 1-1) to enter the result query screen (Figure 5-1).

2020-09-22 11:02 AM Results	
Туре	>
Item	>
Sample No.	>
Start Time	>
End Time	>
<b>←</b>	~
5-2	

From Query Result screen, touch "Q" to view the information by specific criterion. Both test results and QC results can be viewed by Type, Item, Sample No., Start Time or End Time.

#### **10.2 Test Results**

2020-09-2	2 11:03 / Tes	™ t Res	ults	
0001		2020	/09/18	16:56 >
0001		2020	/09/18	16:56 >
K	,	1/4		N
K	<	1/1	>	N
-		亩		
		5-3	;	

Click "Test Result" from the result screen (Figure 5-1) to enter the test result query screen (Figure 5-3). If there are multiple test results, please scroll through the display for all results. Click """" in the test result screen to clear all test results.

2020-12-17 09:11 AM	∗≡⊃
Test Resu	Ilts
Operator ID	admin
Sample No.	0001
Item	Feline PT
Strip Codechip No.	AAAA
PT 12	2.3 ₅
QC Pass	ed
← = ;	t 🔒

To view the detailed test result information (Figure 5-3), please click a result from the test result query screen (Figure 5-4), the result can be uploaded and printed.

#### 10.3 QC result



Click "QC Test" Result from the result screen (Figure 5-1) to enter the QC test result query screen (Figure 5-5). If there are multiple QC test results, please scroll through the display to list all results. Click " $\hat{\mathbf{m}}$ " in the test result screen to clear all test results.

2020-12-17 10:03 AM QC Results	* 💷
ltem Strip Codechip No. Control Codechip No.	PT AAAA AAAA
Passed Level2 PT 33.5	
<b>← ≜ 1</b>	A

To view the detailed QC test result information (Figure 5-5), please click a result from the QC test result query screen (Figure 5-6), the result can be uploaded and printed.

# 11. Maintenance

# 11.1 Care and Cleaning of Your Screen

Follow these steps for cleaning the qLabs® Vet:

#### 11.1.1 Cleaning Frequency

- Clean the meter after every patient and when there are signs of visible soil and/or organic material prior to disinfecting. Also follow any facility disinfection SOPs.
- 2. The exterior of the meter and test strip guide area should be cleaned and disinfected before being used between each patient.
- 3. The exterior of the meter and test strip guide area should be cleaned and disinfected if too much blood (> 20 uL) has been applied to the strip in the case of sampling the same patient.
- 4. Disinfect the meter when it is soiled, and per your facility's guidelines.
- 5. Routine cleaning should be performed a minimum of once a month when the meter is in regular use or per any facility SOP.

#### 11.1.2 Areas to be cleaned and/or disinfected

- 1. The area around the test strip insert port
- 2. The meter display
- 3. The meter housing (front and back)
- 4. The button area on the face of the meter

#### 11.1.3 Precautions to avoid moisture

- 1. Make sure that no liquid enters the meter. If moisture enters the meter it may cause a malfunction of the meter.
  - 1.1. Ensure the meter is turned off
  - 1.2. Never spray anything onto the meter
  - 1.3. Never immerse the meter in liquid
  - 1.4. Do not use cloths or swabs that are saturated. Remove any excess solution before wiping the surface of the meter.

#### 11.1.4 Recommended cleaning/disinfecting solutions

- 1. Disposable wipes containing a quaternary ammonium compound up to 0.5% (single compound or mixture) in isopropyl alcohol up to 55%.
- 2. Do not use other disinfectants or cleaning solutions on the meter.

- 3. Recommended cleaning cloths are listed in table 1
- 4. The button area on the face of the meter

#### Table 1. Recommended Cleaning cloths.

Name	Disinfectant	Size
PDI SaniCloth Plus®	Quaternary/low-alcohol formula (14.85% IPA).	8" x 14", or 6" x 6.75
Cavi Wipes®	Quaternary/low-alcohol formula (17.2% IPA).	9" x 12 ", or 6" x 6.75"

### 11.1.5 Cleaning and disinfecting the meter housing

- 1. Use the recommended cloth in table 1 to clean and disinfect the meter exterior.
- 2. Remember to apply the solutions and allow a contact time of 2 minutes.
- 3. Turn the meter off.
- 4. Pre-clean: Using a clean cloth, gently remove any gross debris and wipe the entire surface of the meter.
- 5. Disinfecting: Using a new cloth, gently wipe the meter housing surfaces. Wipe the entire meter housing including the LCD screen, sample, and button areas.
  - 5.1. Wipe the meter twice top to bottom, then twice left to right. With the cleaning cloth in the palm of your hand, hold the meter with the LCD screen side up (battery side on the cloth) and wipe the meter twice top to bottom, then left to right. Wipe each of the sides of the meter twice from top to bottom then from left to right.
  - 5.2. Next wipe the sample area in an up and down motion, and repeat. Do not insert or press the cloth into the Test Strip Guide, Data Port or Power Supply Jack areas.
  - 5.3. Do not let liquid accumulate near any opening, make sure no liquid enters the meter.
  - 5.4. Leave meter "wet" for 2 minutes or the recommended time.
  - 5.5. With a fresh dry cloth (like a Kimwipe®) remove any residual moisture.
  - 5.6. Once the meter is dried with the Kimwipe it is ready for use.

11.1.6 Visually verify that no residual moisture is on the meter or sample area.

### **11.2 Precautions for Lithium-ion Battery**

qLabs<sup>®</sup> ElectroMeter has a built-in lithium battery, which cannot be removed by any user. For battery replacement, please contact your local distributor or dealer.

If you plan not to use the meter for more than one month, please fully charge the meter. Turn on the transportation mode in the Settings screen, and then turn off for storage. Please charge the meter for 3.5 hours before using.

When stored for more than 3 months, it is recommended to turn on the transportation mode after charging every 3 months to avoid battery discharge and capacity attenuation.

### **11.3 Servicing**

No user serviceable components. All service and adjustment must be performed by Micropoint Biotechnologies Co., Ltd.

# **12. Troubleshooting**



When you receive an error code, please retest. If you receive a second error code, then contact your local distributor and test the patient with a laboratory method. Do not interpret an error code as a patient result in any case.

Error Code	Description	Corrective Actions
E001	Low battery.	Please use power adapter or the base as a power source.
E001.1	Battery failure.	Please turn off the meter and restart it. If the problem recurs, please contact the relevant technicians.
E002	Heating has timed out.	Please adjust the ambient temperature to 10 C - 35 C , and turn off the meter for 5 minutes, then turn on the meter and restart the test. If the problem recurs, please contact the relevant technical staff.
E003	The ambient temperature is too high or too low.	Please ensure that the meter is used in an environment of $10^{\circ}$ - $35^{\circ}$ .
E004	The added sample is insufficient.	Please retest with a new test strip and ensure that the added blood is sufficient for the test.
E005	Internal QC failed.	Please use an unexpired test strip and enter the correct test strip Codechip number.

Error Code	Description	Corrective Actions
E006	External QC failed.	Please ensure that the test strip and control are within the expiry period, and enter the correct test strip Codechip number and control Codechip number.
E008	Scanning error.	Please turn off the meter and reboot it again. If the problem recurs, please contact the relevant technical staff.
E010	The operation of sample adding has timed out.	Make sure the sample adding is completed before the end of the countdown.
E011	The sample is added too early or the strip is a used one.	Please use the new test strip to re-test and add the sample after the meter prompts the user to add sample.
E012	APTT calculation error.	Please retest with a new test strip. If the problem recurs, please contact your local dealer and use the laboratory method to perform the test.
E013	The strip is defective or the sample is added improperly.	Please retest with a new test strip and add the sample strictly as specified in the insert.
E014	The HCT of the sample is out of range.	Please ensure that the HCT value of the sample is within specification of strip insert.

Error Code	Description	Corrective Actions
E015	Bluetooth error.	Please turn off the meter and reboot it. If the problem recurs, please contact the relevant technical staff.
E016	FIB calculation error.	Please retest with a new test strip. If the problem recurs, please contact your local dealer and use the laboratory method to perform the test.
E017	TT calculator error.	Please retest with a new test strip. If the problem recurs, please contact your local dealer and use the laboratory method to perform the test.
E018	The strip is placed improperly.	Do not remove the test strip during the test.
E019	The temperature of the meter is too high.	Please adjust the ambient temperature to 10°C - 35°C , and turn off the meter for 5 minutes, then turn on the meter and restart the test. If the problem recurs, please contact the relevant technical staff.
E020	The coagulation reaction of PT and/or APTT is not activated.	Please retest with a new test strip. If the problem recurs, please contact your local dealer and use the laboratory method to perform the test.

Error Code	Description	Corrective Actions
E021	PT calculation error.	Please retest with a new test strip. If the problem recurs, please contact your local dealer and use the laboratory method to perform the test.
E022	No sample coagulation of APTT is detected.	Please retest with a new test strip. If the problem recurs, please contact your local dealer and use the laboratory method to perform the test.
E023	APTT result extremely high and unreliable.	Please retest with a new test strip. If the problem recurs, please contact your local dealer and use the laboratory method to perform the test.
E024	PT result extremely high and unreliable.	Please retest with a new test strip. If the problem recurs, please contact your local dealer and use the laboratory method to perform the test.
E025	PT result is above reportable range.	Please retest with a new test strip. If the problem recurs, please contact your local dealer and use the laboratory method to perform the test.
E026	PT result is below reportable range.	Please retest with a new test strip. If the problem recurs, please contact your local dealer and use the laboratory method to perform the test.

Error Code	Description	Corrective Actions
E032	Print error.	Make sure that the meter is properly communicating with the base and that printing paper at the base is installed correctly and that there is sufficient paper.
NO COAG	No sample coagulation of PT is detected.	Please retest with a new test strip. If the problem recurs, please contact your local dealer and use the laboratory method to perform the test.

# 13. Symbols

SYMBOLS	EXPLANATION	SYMBOLS	EXPLANATION
ī	Consult Instructions For Use	$\sum$	Expiry Date
	Caution. Read Carefully		Fragile
Ť	Keep Dry	₿ B	Biological Risk
X	Separate Collection	$\otimes$	Do Not Reuse
	Temperature Limitation		Manufacturer
REF	Catalogue Number	SN	Serial Number
	Laser Radiation Risk	LOT	Lot Number
CE	CE Marking		

# 14. Operating Condition and Product Specifications

# 14.1 Operating Condition

Temperature	10°C ~ 35°C / 50°F ~ 95°F
Humidity	10% ~ 90% (No condensation)
Altitude	4300 m (14,000 feet)

# **14.2 Product Specifications**

Processor	32-Bits V2 ARM Cortex-M4
Display	320×480 LCD
Touch screen	Capacitive touch screen
Bar code module	QR code scanning module (QR code, Code 39, Code 128, UPC, PDF417, Data Matrix)
Memory	Stores up to 2,000 patient records and 500 raw data
Power	External power supply: 100-240V~50/60Hz±5Hz, 0.4A Max Internal power supply: DC3.7V (lithium polymer)
Size	148mm×70mm×26mm(L*W*H)
Weight	203g
Warranty period	2 years

# 15. Special storage conditions and methods

- 1). Environment temperature:  $-10^{\circ}C \sim 40^{\circ}C$ ;
- 2). Relative humidity:  $\leq 90\%$  (no coagulation).

# 16. Warranty

#### Use of the qLabs® Vet

Proper adherence to the instructions in the User's Manual and package insert is critical to proper operation.

WARNING: Failure to comply with the user manual could lead to inaccurate results and incorrect medication dosing which could result in injury or death.

#### Limited Warranty

Micropoint Biotechnologies Co., Ltd. guarantees to the original purchaser of the Meter that the Meter is free from material defects in material and workmanship for two years from the date of purchase. This warranty does not guarantee the uninterrupted operation of the meter.

Micropoint Biotechnologies Co., Ltd.'s only liability and purchaser's only remedy under this warranty is that during the warranty period Micropoint Biotechnologies Co., Ltd. shall replace or repair, at no charge, any Meter component with defects in material or workmanship. MICROPOINT BIOTECHNOLOGIES CO., LTD. MAKES NO OTHER WARRANTIES AND EXPRESSLY EXCLUDES ANY IMPLIED WARRANTY OF MERCHANTABILITY, NONINFRINGEMENT OR FITNESS FOR A PARTICULAR USE.

Tampering with any other portion of the Meter, abusing the Meter or using the Meter in a manner inconsistent with its user manual will void this warranty. This warranty does not apply to any component that is damaged by improper storage or accident or that is subject to alteration, misuse, tampering or abuse. Before returning any defective components, you must obtain a "Return Material Authorization" number and return instructions from Micropoint Biotechnologies Co., Ltd. Technical Support and emailing customerservice@micropointbio.com or calling +86 755 21600849.

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