

XPER L1 Technology

Lactate Monitoring System

Owner's Manual

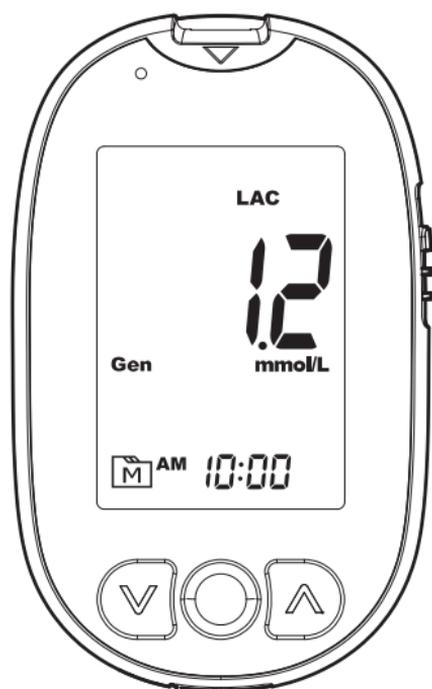


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Dear XPER Technology L1 System Owner

Thank you for choosing the XPER Technology L1 Lactate Monitoring System. This manual provides important information to help you to use the system properly. Before you begin, please read the following contents thoroughly and carefully. If you have other questions regarding this product, please contact the local customer service or place of purchase.

Intended Purpose

The XPER Technology L1 Lactate Monitoring System consists of the XPER Technology L1 Lactate Meter, the XPER Technology L1 Lactate Test Strips, and the Control Solutions.

The system is intended for use outside the body (*in vitro* diagnostic use) to quantitatively measure lactate in fresh capillary whole blood. It is for self-testing or for near-patient testing by healthcare professionals. It is intended for *in vitro* diagnostic use by healthcare professionals in clinical settings.

Near-patient testing may also use the test strips for lactate measurement in venous whole blood. Self-testing is limited to testing with fresh capillary whole blood.

Lactate measurements are indicated to monitor metabolic disorders.

Lancing Device and Lancet

The lancing device and the sterile lancet are intended to obtain capillary blood for testing purposes from the sides of the fingertips. The sterile lancet is to be disposed of and is for single use only. The sterile lancet and the lancing device are for use only on a single patient by healthcare professionals and lay users.

Control Solution

The lactate control solutions are intended for checking that the meter and lactate test strips are respectively working together properly. It is for self-testing or near-patient testing by healthcare professionals. It is intended for *in vitro* diagnostic use by healthcare professionals in clinical settings and by people at home.

Contraindications

There are no known contraindications for the meter, although care should be taken when considering using the meter according to the

warnings, precautions, and limitation of use.

The lancing device should be used only on a single patient, not on multiple patients. Use on multiple patients may cause infections from residual blood.

Test Principle

The test is based on the measurement of electrical current generated by the reaction of the Lactate with the reagent of the strip.

Warnings and Precautions

Please read the following carefully before use:

1. Use this device only for the intended use described in this manual.
2. Do not use accessories that are not specified by the manufacturer.
3. The XPER Technology L1 Lactate Monitoring System should only be used with XPER Technology L1 test strips. Using other test strips with this meter can produce inaccurate results.
4. Do not use the device if it is not working properly or is damaged.
5. This device does not serve as a cure for any symptoms or diseases. The data measured is for reference only. Always consult your doctor to have the results interpreted.
6. Keep the device and testing equipment away from children. Small parts such as the battery cover, batteries, test strips, lancets, and vial caps are choking hazards.
7. The presence of synthetic materials (synthetic clothing, carpet, etc.) may cause damaging static discharges that lead to erroneous results.
8. Do not use this device in close proximity to sources of strong electromagnetic radiation, as these may interfere with the accurate operation.
9. Remove the battery from the unused meter to avoid battery leakage.
10. Proper maintenance and control solution tests are essential to the longevity of your device. If you are concerned about your accuracy of measurement, please contact local customer service or place of purchase for assistance.
11. We do not recommend using this product on severely hypotensive

individuals or patients in shock. Severe dehydration and excessive water loss may also cause inaccurate readings. Please consult a healthcare professional before use.

12. Only use fresh whole blood sample. Using any body substances other than blood will lead to incorrect results.
13. If your test results are significantly different from what you expect, inconsistent with your symptoms, or at unusually high or low levels, please repeat the test with a new test strip or contact your healthcare professional.
14. If the device is used in a manner not specified within this manual, the protection provided by the device may be impaired.
15. Other users testing multiple patients with this system should handle everything that comes into contact with human blood carefully to prevent transmitting infectious diseases, including sanitized objects.
16. If any serious incident has occurred in relation to the device, it should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Lancing Device and Lancet

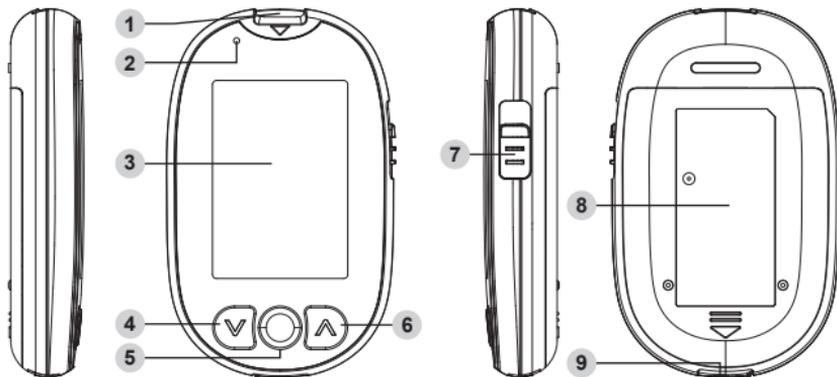
1. Possible skin infection present at the sample site.
2. Never share a lancet and the lancing device.
3. Do not reuse lancets. Always use a new, sterile lancet for testing. The used lancet may potentially be biohazardous. Discard it according to your local regulations.
4. If the lancing device is being operated by a second person who is providing testing assistance to the user, the lancing device should be cleaned and disinfected prior to use by the second person. The second person must wear protective gloves for all the steps when providing testing assistance.
5. Always keep the lancing device and the lancet with all its components away from children.
6. Do not use if the sterile lancet package is damaged.

KEEP THESE INSTRUCTIONS AT A SAFE PLACE

Product Overview

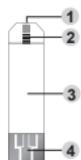
The contents included in the kit depend on the package. Check the components in the kit and quantity of each item. Test strips, control solution, sterile lancets, safety lancets and lancing device may be purchased separately. Please make sure you have those items needed for a test beforehand. If any item is missing or damaged, contact customer service for assistance.

Meter



- 1 Test Strip Slot**
Insert test strip here to turn the meter on for testing.
- 2 Bluetooth Indication Light**
Bluetooth is available for data transmission.
- 3 Display Screen**
- 4 Down Button (▼)**
Adjust value decrement.
- 5 Main Button (M)**
Enter the meter memory.
- 6 Up Button (▲)**
Enter Bluetooth function, adjust value increment.
- 7 Test Strip Ejector**
Eject the used strip by pressing this ejector.
- 8 Battery Compartment**
- 9 Data Port**
Insert the cable for data transmission.

Test Strip



- 1 Absorbent Hole
- 2 Confirmation Window
- 3 Test Strip Handle
- 4 Contact Bars

Control Solution

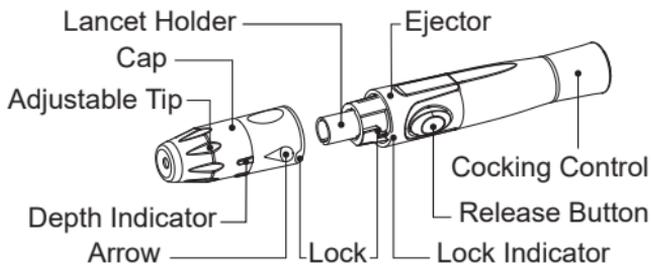


Safety Lancet

(For professional use)



Lancing Device and Lancet (For self-testing)

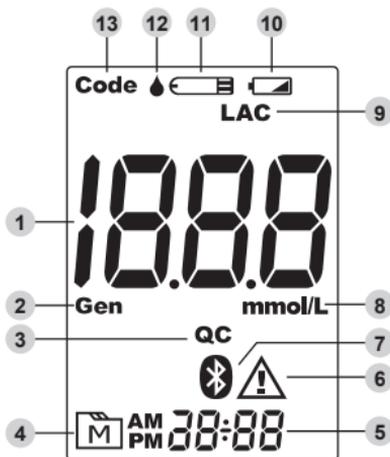


Protective Disk



Sterile Lancet

Display Screen



- 1 Test Result
- 2 Measuring Mode
Gen – any time of day
- 3 QC Mode
QC – control solution test
- 4 Memory Mode
- 5 Date / Time
- 6 Error Message

7 Bluetooth Symbol

9 Lactate Symbol

11 Test Strip Symbol

13 Code

8 Measurement Unit

10 Low Battery Symbol

12 Blood Drop Symbol

Before Testing

Get all accessories ready and follow the preparation steps below before testing.

Setting the Meter

Setting up your meter to the correct date, time, desired measurement unit, personal target range, etc. for better health management. Date and time could be synced with the paired device by data transmission.

Entering the Setting Mode

Start with the meter off (no test strip inserted). Press and hold ▲ and ▼ at the same time for 3 seconds. The following settings could be set up in sequence:

1. Date

With the YEAR / MONTH / DAY flashing in sequence, press ▲ or ▼ to select the number. Press **M**.

2. Time format and time

Press ▲ or ▼ to select the desired time format (12h or 24h). Press **M**. With the HOUR / MINUTE flashing in sequence, press ▲ or ▼ to select the number. Press **M**.

3. Buzzer

With the buzzer displays, press ▲ or ▼ to switch between “On” and “OFF”. Press **M**.

4. Memory clearing

With “dEL” and “” on the display, press ▲ select “no” then press **M** to keep all the results in memory. To delete all the results, press ▼ to select “yES”, and press **M**.

5. Bluetooth function

This function is referring to the Bluetooth data transmission. With “BLE” on display, press ▲ or ▼ to select “On” or “OFF”. Press **M**. If “On” is

selected, your result will be transmitted automatically right after the test.

NOTE

The date and time setting of the meter are synchronized by the paired device with each data transmission.

Calibration

Each time you start testing with a new package of lactate test strips, you must calibrate the meter with correct code. Please refer to calibration instructions in the test strip manual.

Prepare the Lancing Device for Blood Tests

To set up the lancing device, you need: lancing device and lancet.

1. Twist and pull off the cap of the lancing device.
2. Insert a lancet into the lancet holder of lancing device and push down firmly until it is fully secured.
3. Twist off the protective disk of the lancet.
4. Replace the cap onto the lancing device.
5. Hold the cap and select the depth of penetration by turning the adjustable tip. The longer the length of indicator line, the greater the depth of penetration.
6. Pull the cocking control back until it clicks. You will see a color change inside the release button when it is ready. If it does not click, the device may have been cocked when the lancet was inserted.

Perform Blood Tests

Before collecting a drop of blood

- ◆ Wash and dry your hands before you start.
 - ◆ Rub the puncture site for about 20 seconds before penetration.
 - ◆ Clean the site by using a cotton swab moistened with 70% alcohol and let it air dry.
-

To perform a blood test for self-testing, you need: meter, test strip, lancing device and lancet. For professional use, you need: meter, test strip and safety lancet.

1. Turn on the meter by inserting a test strip: Wait for the meter to display the flashing “”.

2. Prick the puncture site: Hold the pre-set lancing device's tip or safety lancet firmly against the lower side of your fingertip. Press the release button to prick the puncture site.

3. Obtaining a blood sample: Gently squeeze the punctured site to obtain a drop of blood for the test. Be careful not to smear the blood sample.

4. Apply the sample: Gently apply the drop of blood to the absorbent hole of the test strip at a tilted angle. Make sure the absorbent hole of the test strip comes into contact with the blood sample but not the skin. Hold the meter still until the confirmation window of the test strip is completely filled. Confirmation window should be completely filled if enough blood has been applied.

NOTE

- ◆ In case of sweaty hands, alcohol residue, incomplete cleaning or other personal operational factors that may affect the blood test procedure, wipe off the first blood drop before measurement.
 - ◆ Do not put blood on top of the test strip.
 - ◆ Always apply a blood sample after the test strip is inserted into the meter.
 - ◆ Do not hold the test strip parallel to the finger for absorption.
 - ◆ If you do not apply a blood sample to the test strip within 2 minutes, the meter will automatically turn off. You must remove and reinsert the test strip to start a new test.
 - ◆ The confirmation window should be filled with blood before the meter starts counting down. Never try to add more blood to the test strip. Discard the used test strip and retest with a new one.
-

5. Read your result: Place the meter flat on the table and wait for the test result display. Do not move the meter during the countdown.

6. Eject the used test strip: Eject the test strip by pushing the eject button on the side, and dispose of them carefully according to your local regulations.

7. Remove the used lancet: Remove the sterile lancet by twisting the lancing device cap off first. Safely dispose of the used lancet by placing the protective disk on a hard surface and pushing the exposed tip into

the protective disk. Slide the ejector forward to remove the used lancet and dispose of the lancet according to your local regulations.

Result Reading with Display Messages

Lo: test result is below the measurement range.

Hi: test result is above the measurement range.

Quality Control Tests

If you are concerned that the meter or test strips are not working properly, you can check the performance of the meter, test strips and your technique by comparing the control solution results with the range printed on the test strip package.

Perform a Control Solution Test when:

- it is mandatory following the local regulations in your country;
- you suspect the meter or test strips are not working properly;
- your test results are not consistent with how you feel, or if you think the results are not accurate;
- to practice the testing process; or
- you have dropped or think you may have damaged the meter.

To perform a control solution test, you will need: meter, test strip and control solution.

1. Insert the test strip to turn on the meter

Insert the test strip into the meter. Wait for the meter to display a flashing “”.

2. Apply the control solution

Shake the control solution vial thoroughly before use. Squeeze out the first drop and wipe it off, then squeeze out another drop and place it on the tip of the vial cap. Hold the meter to move the test strip absorbent hole to the droplet. Once the confirmation window fills completely, the meter will start counting down.

3. Read and compare the result

Compare the displayed number with the range printed on the test strip vial or foil packet and it should fall within range. If not, please read the instructions again and repeat the control solution test.

NOTE

- ◆ The control solution range printed on the test strip vial or foil packet is for control solution use only. It is not a recommended range for your blood test levels.
 - ◆ For the lactate control solution test, your device will tag this measurement as QC test automatically.
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Out-of-range Result

Results that fall outside the expected range may indicate:

- An error in the way you are doing the test.
- Expired test strips and control solution.
- A problem with the meter.
- Control solution that is too warm or too cool.
- The meter code does not match the code printed on the test strip package.
- Failure to shake the control solution vial vigorously.

If you are still unsure of the problem, please contact customer service for assistance.

Review Test Results

To enter memory mode, start with the meter switched off.

1. Press and release **M**. “**M**” will display with the latest result.
2. Press **▲** or **▼** to scroll through all the test results stored in the meter.

Data Transmission

Data Transfer to a Computer

You can use the Health Care Management System to view test results on a **Windows 10 (or above)** computer. Connect to a computer via, USB Type-C cable or Bluetooth and visit TaiDoc website at <https://taidoc.com/> to find the appropriate Health Care Management System for this meter. Follow the instructions in the system for pairing.

Data Transfer to a Mobile Device

You can transfer testing results from the meter to **ProCheck app** on your mobile device via Bluetooth. For the requirement of OS version, please find it on App Store or Google Play when you download the app. Follow the Quick Start Guide (For Bluetooth Pairing) and instructions in the app for pairing.

Bluetooth Indicator on the Meter

Flashing Blue: The Bluetooth function is on and waiting for connection.

Solid Blue: The Bluetooth connection is established.

NOTE

- ◆ The cable can be purchased separately, please contact local customer service or the place of purchase for more information.
 - ◆ The meter will be unable to perform a test while it is in transfer mode.
 - ◆ Please make sure your device supports Bluetooth Smart Technology, the Bluetooth setting on your device is turned on, and the meter is within the receiving range before transferring the data.
 - ◆ The Bluetooth functionality is implemented in different ways by various mobile device manufacturers; compatibility issue between your mobile device and the meter may occur. The additional connection with other equipment to IT-network may cause previously unidentified risks to patients, operators, or third parties. These risks should be identified, analyzed, evaluated, and controlled.
 - ◆ The changes of IT-network include configuration, the connection of additional items, disconnection items, and the update and upgrade of the monitor, which could introduce risks and require additional analysis.
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Maintenance

Meter Storage and handling

- Always store or transport the meter in its original storage case.
- Avoid dropping the meter or heavy impact.
- Avoid direct sunlight or high humidity.
- Store the meter at -20°C to 60°C (-4°F to 140°F), 10% to 93% R.H. (non-condensing).

Meter Cleaning and Disinfecting

Wipe the meter exterior with soft damp cloth or mild cleaning agent, then dry the device with soft dry cloth. Do not use organic solvents (except isopropanol and ethyl alcohol) to clean the meter. Do not rinse or immerse in water or other liquids. Always disinfect the surfaces of the meter with cotton moistened with 70% isopropanol or ethyl alcohol after taking a test. Avoid getting any moisture into any openings (e.g. test strip port, battery compartment).

Meter Disposal

The used meter should be treated as a contaminated item that may carry a risk of infection during measurement. This device does not belong to household waste and must be returned to a collection point for recycling electric and electronic devices according to local laws. If it contains batteries, the batteries should be removed and disposed in accordance with locations for separate collection of spent batteries.



Battery

The meter will display the messages below to alert you when the meter power is getting low.

1. When the “” symbol appears along with display messages: The meter is functioning properly and the result remains accurate, but it is time to change the battery.
2. When E-b display: The power is too low to perform a test. Please change the battery immediately.

Properly dispose of the battery according to your local environmental regulations.

Lancing Device, Lancet Storage and Handling

- Avoid getting hand lotion, oils, dirt, or debris in or on the lancets and the lancing device.
- Store the lancing device only without a lancet inserted.
- Store the lancing device at -20°C to 60°C (-4°F to 140°F), 10% to 93% R.H.
- Store the sterile lancet at -10°C to 50°C (14°F to 122°F), 0% to 80% R.H.
- Store the safety lancet at -20°C to 50°C (-4°F to 122°F), 0% to 80% R.H.

Lancing Device and Cap Cleaning and Disinfecting

The disposable lancet is intended for single use only. The lancing device is reusable. To clean the lancing device and the cap, use mild soap and water to wipe and clean the lancing device. Do not rinse the device under water.

Disinfect the cap by placing it in 70% alcohol for 10 minutes and then allow it to air dry. Do not place the device in a dishwasher or use detergents.

Control Solution Storage and Handling

- Check the expiry date on the vial. Do not use it if expired.
- Refer to the period after opening on the control solution vial. Record the first opening date on the vial.
- Tightly close the control solution and store at room temperature at 2°C to 30°C (36°F to 86°F), 10 to 90% R.H. Do not freeze.

System Troubleshooting

If you follow the recommended action but the problem persists, please call your local customer service.

Error Messages

MESSAGE	WHAT IT MEANS	WHAT TO DO
E-b	The battery is too low.	Replace the battery immediately.
E-U	A used test strip is inserted.	Repeat with a new test strip.
E-t	Ambient temperature is above or below system operation range.	Repeat the test after the meter and test strip are within the operation temperature range.
E-0, E-A E-E, E-C	Problem with the meter.	Repeat the test with a new test strip. If the meter still does not work, please contact customer service for assistance.

E-F	Test strip is removed while counting down, or insufficient blood volume.	Review the instructions and repeat test with a new strip. If the problem persists, please contact customer service for assistance.
E-2	The code chip or test strip is expired.	Make sure the date you set on the meter is correct and check the expiry date shown on the packaging. If the problem persists, repeat with a new code chip or test strip.

Troubleshooting

1. If the meter does not display a message after inserting a test strip:

POSSIBLE CAUSE	WHAT TO DO
Battery exhausted.	Replace the battery.
Test strip inserted upside down or incompletely.	Insert the test strip with contact bars end first and facing up.
Defective meter or test strips.	Please contact customer service.

2. If the test does not start after applying the sample:

POSSIBLE CAUSE	WHAT TO DO
Insufficient blood sample.	Repeat the test using a new test strip with larger volume of blood sample.
Defective test strip.	Repeat the test with a new test strip.
Sample applied after automatic switch-off.	Repeat the test with a new test strip. Apply sample only when flashing “  ” appears on the display.
Defective meter.	Please contact customer service.

3. If the control solution testing result is out of range:

POSSIBLE CAUSE	WHAT TO DO
Error in performing the test.	Read instructions thoroughly and repeat the test again.
Control solution vial was poorly shaken.	Shake the control solution thoroughly and repeat the test again.

Expired or contaminated control solution.	Check the expiry date of the control solution.
Control solution that is too warm or too cold.	Perform the test with a proper stored control solution.
Defective test strip.	Repeat the test with a new test strip.
Meter malfunction.	Please contact customer service.
Improper working of meter and test strip.	Please contact customer service.

Symbol Information

SYMBOL	REFERENT	SYMBOL	REFERENT
	<i>In vitro</i> diagnostic medical device		Manufacturer
	Serial number		Date of manufacture
	Consult instructions for use or consult electronic instructions for use		Authorized representative in the European Community
	Temperature limit		Humidity limitation
	Caution		RoHS compliance
	Unique device identifier		Sterilized using irradiation
	Medical device		Batch code
	CE mark		Use-by date
	Do not reuse		Do not use if package is damaged and consult instructions for use
	Model number		Importer
	Direct current		



This device does not belong to household waste and must be returned to a collection point for recycling electric and electronic devices according to local laws. If it contains batteries, the batteries should be removed and disposed in accordance with locations for separate collection of spent batteries.

Specifications

Dimension: 93.4 (L) x 57.5 (W) x 18.5 (H) mm

Weight: 52.5 g (without batteries)

Power Source: Two 1.5V AAA alkaline batteries

Display: LCD with backlight

Memory: 1000 measurement results

External Output: USB Type-C cable, Bluetooth

Operating Conditions: 10°C to 40°C (50°F to 104°F), 10% to 85% R.H. (non-condensing)

For indoor use. Refer to the strip manual for operating altitude.

Sample Size and Reaction Time: 0.8 μ L, 5 seconds

Measurement Units: Fixed mmol/L

Measurement Range: 0.3 to 22 mmol/L

Shelf Life: 5 years

Degree of Pollution: Pollution degree 2

This device has been tested to meet the electrical and safety requirements of: IEC/EN 61010-1, IEC/EN 61010-2-101, IEC/EN 61326-1, IEC/EN 61326-2-6, EN 300 328, EN 301 489-1, EN 301 489-17, EN 62479.

Control Solution Chemical Component & Precision

Lactate: 0.01% to 0.1% and inert ingredients > 99.9%.

	Overall SD	Overall CV
L1	0.033 mmol/L	2.51%
L2	0.106 mmol/L	2.20%

*The control solution does not contain any human-derived or biological materials.

Clinical Performance

Accuracy

The prepared samples were then tested on this meter and compared to the readings from the Cobas C311 analyzer.

Lactate	n = 480	
	Capillary samples	Range, mean
Regression	$y = 0.9657x - 0.0735$ $R^2 = 0.9936$	Range: 0.45 to 21.0 mmol/L Mean: 3.21 mmol/L

Lactate	n = 480	
	Venous samples	Range, mean
Regression	$y = 0.9644x + 0.0753$ $R^2 = 0.9926$	Range: 0.45 to 21.0 mmol/L Mean: 3.21 mmol/L

User performance

Lactate	n = 160	
	Capillary samples	Range, mean
Regression	$y = 1.0073x - 0.0475$ $R^2 = 0.9804$	Range: 0.52 to 10.63 mmol/L Mean: 2.16 mmol/L

Precision

Interval	Mean (mmol/L)	Repeatability	
		SD	%CV
Interval 1	1.82	0.07	3.94%
Interval 2	8.74	0.18	2.04%
Interval 3	18.20	0.38	2.10%

*The contents included in the kit depend on the sale packaging.

Model No. of Meter:	TD-4261
Model No. of Lancing Device:	TD-5010
Model No. of Sterile Lancet:	TD-5084
Model No. of Control Solution:	TD-4923 / TD-4924



TaiDoc Technology Corporation

B1-7F, No.127, Wugong 2nd Rd.,
Wugu Dist., 24888 New Taipei City, Taiwan
www.taidoc.com



MedNet EC-REP GmbH

Borkstraße 10, 48163 Münster, Germany

For self-testing.
For near-patient testing.

