L1

ver 1.0 2018/08
312-XXXXXXX-XXX

Lactate Test Strips

Use only with L1 Lactate Monitoring System.

Warnings

- For *in vitro* diagnostic use (for use outside of the body only).
- For single use only.
- Healthcare professionals and 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.
- Please read this sheet and your L1 Lactate Monitoring System Owner's Manual before you use this test strip. Use only L1 Lactate Test Strips with L1 Lactate Monitoring System to obtain accurate results, and be covered by the manufacturer's warranty.
- Results may be inaccurate when testing on patients with abnormally low blood pressure, or those who are in shock.
- For patients with impaired peripheral circulation, collection of capillary blood from the approved sample sites is not advised as the results may not be a true reflection of the physiological lactate level.
- Keep test strips and lancets away from small children. If swallowed, consult a doctor immediately for advice.

Intended Use

L1 Lactate Test Strips, when used together with **L1** Lactate Monitoring System, allow your Lactate levels to be measured by yourself at home or by healthcare professionals. It uses fresh capillary whole blood samples from the fingertips. This system is not intended for use in the diagnosis or screening of diseases. The Lactate Monitoring System uses electrochemical methodologies.

Limitations

- Hematocrit: The hematocrit level is limited to between 10% and 65%. Please ask your healthcare professional if you do not know your Hematocrit level.
- *In vitro* paracetamol up to 20 mg/dL, uric acid up to 10 mg/dL and ascorbic acid up to 5.0 mg/dL showed no interference.
- Altitude Effects: Altitudes up to 11,500ft (3,500m) do not affect test results.

Storage and Handling

⚠ Do not use the test strips if they have expired.

- Test strips expire 3 months after first opening. Write the first opening date on the test strip vial when you first opened it. (For strip vial only)
- Store the test strips in a cool, dry place between 2°C and 30°C (35.6°F and 86°F) and between 10% and 85% relative humidity.
- Keep the test strips away from direct sunlight. Do not store the test strips in high humidity.
- Store the test strips in their original vial ONLY. Do not transfer them to a new vial or any other containers. (For strip vial only)
- Do not touch the test strips with wet hands.
- Use each test strip immediately after taking it out of the vial or individual foil packet. Close the vial immediately after taking out a strip. (For strip vial only)
- Keep the vial closed at all times. (For strip vial only)
- Do not bend, cut, or alter the test strip.

Strip Appearance

1. Absorbent Hole
Apply a drop of blood here. The blood will be automatically absorbed.

2. Confirmation Window
This is where you confirm if enough blood has been applied to the absorbent hole in the strip.

3. Test Strip Handle
Hold this part to insert the test strip into the slot.

4. Contact Bars
Insert this end of the test strip into your meter. Push it in firmly until it will go no further.

Code Chip Instructions

Calibration
Calibrate the meter every time whenever begin to use a new box of test strips by setting the meter with the correct code. Test results may be inaccurate if the code number displayed on the meter does not match the number printed on your test strip vial label/packet.

Operation

1. Insert the code chip when the meter is off. Wait until the number appears on the display.

2. Remove the code chip. The display will show "OFF", and then the meter will switch off.

Checking the Code Number
Make sure that the number displayed on the meter matches the number on your test strip vial label/packet before you proceed. If it matches, you can proceed with your test. If the numbers do not match, please stop testing and insert the correct code chip. If the problem persists, contact Customer Service for help.

Testing Your Blood Lactate

PLEASE WASH AND DRY YOUR HANDS BEFORE PERFORMING ANY TESTING.

1. Insert the test strip fully into the slot of your meter until it will go no further. When the strip is fully inserted, the meter will do several self-checks.

2. Collect a blood sample with the test strip. A sufficient quantity of blood is required for the test to provide accurate results. Touch the blood drop with the absorbent hole of the test strip, and wait until the confirmation window is fully covered. The meter will start counting down. **Do NOT** apply a smeared blood sample.

3. After a few seconds, the meter will display your blood lactate level. The last reading will be automatically saved in the meter. Turn it off by removing the test strip and throw away the used test strip.

The used lancet and test strip are potentially biohazardous. Please dispose of them carefully according to your local regulations. Please refer to your Owner's Manual for further information.

Reading Your Result

Your lactate readings deliver plasma equivalent results and are displayed in millimoles of lactate per liter of blood (mmol/L).

Reference values

Lactate*1	0.3 to 2.4 mmol/L

*1: Mary A. Williamson, L. Michael Snyder, 10th ed, 2015. Wallach's interpretation of diagnostic tests : pathways to arriving at a clinical diagnosis. Philadelphia : Wolters Kluwer.

Please consult your doctor to determine a target range that works best for you.

Questionable or inconsistent results
If your test results are unusual or inconsistent with how you are feeling:

- Make sure the confirmation window of the test strip is completely filled with blood.
- Check the expiration date of the test strips.
- Check the performance of your meter and test strip with the control solutions.

Chemical Components

Lactate oxidase (*Microorganism*) ≧ 0.5 U
Mediator 52%
Enzyme protector 6%
Non-reactive ingredients 32%

Quality Control Testing

Our control solutions contain a known amount of lactate that can react with test strips. If you suspect the meter or test strips are not working properly, you can check the performance of meter, test strip and your technique by comparing the control solution results with the range printed on the label of test strip vial or on the box of foil packet. Please refer to the Owner's Manual for complete testing instructions.

⚠ The reference range of the control solutions may vary with each new vial or new box of foil packet of test strips. Make sure you check the range on the label of your current vial or on the current box of foil packet.

Additional Information for Healthcare Professionals

Always wear gloves and follow your facility's biohazard control policy and procedures when performing tests involving patient blood samples. Use fresh whole blood samples only.
Sample Size: 0.8 µL
Reaction Time: 5 seconds
System Measurement Range: 0.3 to 22 mmol/L
Hematocrit Range: 10% to 65%

Accuracy

Lactate	n = 720	
	Capillary samples	Range, mean
Regression	y = 1.002x - 0.0158 R² = 0.9938	Range: 0.89 to 17.82 mmol/L Mean: 1.96 mmol/L

User performance

Lactate	n = 360	
	Capillary samples	Range, mean
Regression	y = 0.9901x - 0.0238 R² = 0.9938	Range: 0.70 to 17.30 mmol/L Mean: 1.91 mmol/L

Precision

Lactate	Concentration		
	1.8 mmol/L	8.5 mmol/L	25 mmol/L
Mean	1.8	8.7	18.4
SD	0.111	0.258	0.882
CV (%)	6.25%	2.97%	4.80

Symbol Information

Symbol	Referent
IVD	*In vitro* diagnostic medical device
	Consult instructions for use
	Temperature limitation
	Use by
LOT	Batch code
	Caution, consult accompanying documents

Symbol	Referent
	Manufacturer
EC REP	Authorized representative in the European Community
	Do not reuse
CE 0123	CE mark
	Humidity limitation
REF	Catalogue number

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

EC REP **MedNet GmbH**
Borkstraße 10, 48163 Münster, Germany

CE 0123 IVD 10% 85% 2°C 30°C REF TD-4261 For self-testing.