

# EDGE Blood Lactate Test Strips

*For the quantitative measurement of lactate in whole blood for use with THE EDGE Blood Lactate Analyzer. THE EDGE Lactate Monitoring System is intended for self-testing by persons and by health care professionals.*

## Intended Use

The EDGE Blood Lactate Test Strips are to be used with THE EDGE Blood Lactate Analyzer to quantitatively measure lactate in capillary whole blood. THE EDGE™ Blood Lactate Monitoring System is plasma-calibrated for easy comparison to lab result. THE EDGE Blood Lactate Monitoring System is intended for self-testing by persons with chronic diseases (diabetes, cardiovascular disease, liver disease, muscular dystrophy) and by health care professionals.

## Before You Begin

- Carefully read this entire insert.
- If you have any question and/or need assistance, please contact our authorized dealer in your country.

## Summary


THE EDGE™ Blood Lactate Monitoring System is designed to provide an easy, accurate method for the determination of capillary whole blood lactate values. This analysis employs the enzyme lactate oxidase which couples with biosensor-based test strip that is specific for lactate measurement. When blood is applied to the reaction zone of the test strip, a signal that correlates with the concentration of lactate in the blood sample is transmit to THE EDGE™ Blood Lactate Analyzer for analysis. The meter analyzes the signal and displays a quantitative result on its large, easy to read LCD screen.



## Reagent Composition

Each cm<sup>2</sup> of test strip contains the following reactive ingredients in the approximate concentrations listed below:



- |                            |         |
|----------------------------|---------|
| • Lactate oxidase          | 0.11 mg |
| • Electron shuttle         | 0.55 mg |
| • Non-reactive ingredients | 0.34 mg |

## Warnings and Precautions

The EDGE Blood Lactate Test Strips are for IN VITRO  diagnostic use only (external use only). The EDGE Blood Lactate Test Strips supplied can be used by healthcare personnel.

- Do not use test strips after their  expiration date.
- Do not use test strips that are wet, bent, scratched, or damaged in any way.
- Do not touch the target area of the test strip.
-  Do not re-use the strips.
- You must calibrate your meter with the code card that is packaged with the test strips for each new package of test strips.
- The screen will show "LO" when the whole blood lactate value is less than 6mg/dL, or "HI" when the value is more than 200 mg/dL.
- After the first opening of the bottle, test strips should be used within 3 months.

## Storage and Handling

1. Store the test strips between 4°C to 30°C  (39°F to 86°F).
2. Keep away from sunlight .
3. Do not freeze.
4. Do not bent, cut, or alter test strips in any way.
5. When stored properly, unopened test strips are stable until the expiration date printed on the vial label.
6. Do not handle the test strips with wet or dirty hands.
7. For vial test strips, always close the vial cap tightly after removing a test strip.

## Sample Collection and Preparation

The EDGE Blood Lactate Test Strips are designed specifically for use with fresh capillary whole blood taken from a fingertip. Plasma or serum samples are not to be used. Testing must be performed immediately after the sample is obtained. Prolong aging of blood will led to in blood and endogenous increase of lactate concentration will cause an incorrect result. Common anticoagulants and preservatives such as heparin and sodium EDTA may be used.

### Materials Needed for Testing

To test your blood lactate, you will need the EDGE Test Strips provided in this package and the following materials:


- THE EDGE™ Blood Lactate Analyzer
- THE EDGE™ User's Guide
- Lancet and/or Lancing Device (puncturer)
- Log Book

## Test Procedure

 Refer to THE EDGE™ User's Guide, "Performing a Test" for testing procedures.

## Quality Control

It is recommended that the performance of THE EDGE™ Blood Lactate Monitoring System be tested:

- When your test result do not agree with how you feel.
- When your test strips have been exposed to temperatures outside the specified storage conditions 4°C to 30°C  (39°F to 86°F).

## Test Results

Blood lactate test results are shown on the monitor display as either mg/dL or mmol/L. Before or during testing, make sure the following:

1. Check if the drop of blood completely filled the reaction zone.
2. Check if the test strip in use is within the expiration date printed on the vial label.
3. Check if the code number of the test strip in use matches the number programmed in the meter.
4. Check meter performance with the monitor checker.
5. Check meter and test strip performance with control solutions when test results are still questionable or inconsistent.

Limitations

- The EDGE Test Strips are designed for use with fresh capillary whole blood samples. DO NOT use serum or plasma samples.
- Hematocrit variation in sample hematocrit between 35% to 50% have no significant effect on test results. Very high (above 50%) and very low (below 35%) hematocrit can cause inaccurate results.
  - Neonates: Do not use THE EDGE™ Test Strips to test neonates. The performance of this system has not been validated with neonatal samples.
  - Abnormal blood specimens (i.e., high, ascorbic acid, uric acid and hemolysis, etc.) may affect the results. Blood lactate readings from these cases should be interpreted with caution.
  - Altitudes up to 2,000 meters (6,562 feet) do not affect test results.

Expected Values

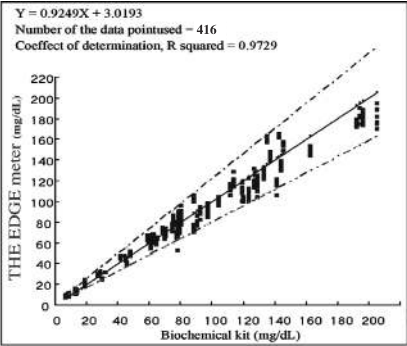
- Expected blood lactate levels for:
- Normal Range: 9-45 mg/dL (1-5 mmol/L).
  - Higher Range: 45 mg/dL to 89.1 mg/dL (5-9.9 mmol/L) Should be considered as severe hyperlactatemia.
- If the result is higher than 45 mg/dL, please contact your physician or healthcare professional immediately.
- Anaerobic threshold (IAT): 22.5-54 mg/dL about muscle training.

Performance Characteristics

The performance characteristics of THE EDGE™ Analyzer, used with the EDGE Test Strips, have been determined in both clinical and laboratory evaluations.

Accuracy:

Accuracy describes how well the readings from a testing system (meter and test strips) agree with the readings from an accepted reference system. The accuracy of THE EDGE™ Blood Lactate Monitoring System was assessed in studies using biochemical lactate oxidase-peroxidase method. The data are presented in the figure below.



Precision:

Precision describes the variation between readings in the test system. A test system with little variation is defined as being precise. A laboratory study was conducted with THE EDGE™ Blood Lactate Monitoring System using fresh heparin-venous blood which was adjusted to a broad range of lactate levels. Ten strip readings were obtained with each blood sample. In order to thoroughly verify the precision performance of THE EDGE™ Blood Lactate Monitoring System, this study was repeated several times.

The results from a single typical run of this study, shown in the table, exhibit excellent precision characteristics for the THE EDGE™ Blood Lactate Monitoring System. From all the studies taken together, estimates of mean system precision were calculated to be:

Within run precision ,2.5%.

Between run precision ,2.6%.

Reagent Lot LS 001B				
Number of Readings:	10	10	10	10
Average (mg/dL):	20.0	69.2	101.2	154.2
S.D. (mg/dL):	1.0	1.1	1.5	2.5
CV%:	5.1	1.6	1.5	1.6

Reference

- 1.Brooks, G.A. (1985) Anaerobic threshold: review of the concept and directions for future research. Medicine Science for Sports and Exercise. 17(1), 6-21. Review.
- 2.Smith, E.W., Skelton, M. S., Kremer, D. E., Pascoe, D. D., & Gladden, L. B. (1998). Lactate distribution in the blood during steady-state exercise. Medicine and Science in Sports and Exercise, 30(9), 1424-1429.
- 3.Mader, A., & Heck, H. (1986). A theory of the metabolic origin of "anaerobic threshold". International Journal of Sports Medicine, 7(Sup), 45-65.

Symbols

- Use-by date
- In vitro diagnostic medical device
- Batch code
- Consult instructions for use
- Temperature limit
- Catalogue number
- Do not re -use
- Manufacturer
- Keep away from sunlight
- Caution
- Authorised representative in the European Community
- This product complies with the EC directives and bears the CE mark. 0197 indicates the number of notified body involved in production quality module

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**IVD**

**REF** S54108 S5638025  
S5638053

**CE** 0197

Suitable for self-testing

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