

Lactate Pro™ Test Strip

INTENDED USE

Quantitative measurement of lactate in whole blood.
The system can be used in the home or in a clinical setting.

SUMMARY

A colorimetry method with an enzymatic reaction has been a conventional measurement method for lactate. In pursuit of a simpler and more convenient method, ARKRAY, Inc. has developed the Lactate Pro Test Strips (Test Strip) based on an amperometric method using an enzymatic reaction. The Test Strips are designed for exclusive use with the Lactate Pro Test Meter (Test Meter).

Insert the Test Strip into the Test Meter and touch the tip of the Test Strip to a drop of blood. The blood (approximately 5 µL) is drawn automatically into the strip's reaction space and measurement starts automatically. No sample pretreatment, wiping or time control is required. The whole process of measurement is quite easy.

TECHNICAL NOTES

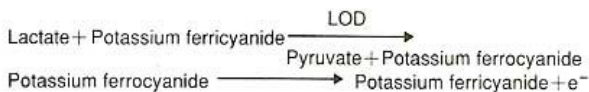
Lactate is mainly produced at muscle cells, erythrocytes and brain cells etc. and metabolized by the liver. Lactate, presented as an anion in blood, is an end product of anaerobic glucose metabolism and plays an important role in acid-base balance in the body. In the critical care, lactate is used as a biochemical indicator of lactic acidosis. As lactate concentration increases in blood during exercises due to lack of oxygen, lactate can be measured to evaluate physical performance or to establish a proper intensity of exercises for athletes. ^{1) 2) 3) 4)}

REAGENT (per strip)

Lactate oxidase (LOD) 1.92 units
Potassium ferricyanide 0.096 mg

PRINCIPLE

When the blood sample drawn from the tip of the Test Strip reaches to the reaction layer, lactate in the sample reacts specifically with lactate oxidase (LOD) in the reaction layer of the Test Strip. Simultaneously, potassium ferricyanide (oxidized form) contained in the reaction layer produces potassium ferrocyanide (reduced form). Potassium ferrocyanide is produced in proportion to the lactate concentration of the sample. The accumulated potassium ferrocyanide is then oxidized to potassium ferricyanide and produces an electrical current which is converted to the lactate concentration.



TEST PROCEDURE

FOR DETAILED DIRECTIONS, SEE THE LACTATE PRO OPERATING MANUAL.

[STARTUP THE TEST METER]

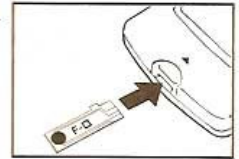
To ensure that you get accurate test results, you must startup the Test Meter using the Calibration Strip whenever you open a new package of Lactate Pro Test Strips. The Calibration Strip is contained in each box with the Lactate Pro Test Strips.

The function number (F-0 through F-12) is printed on each Calibration Strip, on the foil packet of each Test Strip, and on the rear of the Test Strip box. These numbers must match each other.

Items required:

- Lactate Pro Test Meter
- Calibration Strip

1. Insert the Calibration Strip into the Strip Inlet. The function number will appear on the display.
2. Check that the function number matches the number printed on the box.
3. Remove the Calibration Strip from the Strip Inlet and store it in its plastic bag.

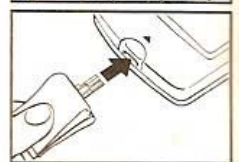


[BLOOD LACTATE MEASUREMENT]

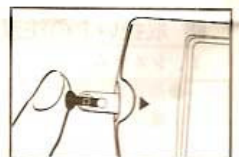
Items required:

- Lactate Pro Test Meter
- Lactate Pro Test Strip (Test Strip)
- Lancing Device and Lancets

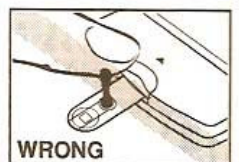
1. Wash your hands with soap and warm water and dry thoroughly.
2. Peel a Test Strip foil packet to the line indicated and insert the Test Strip into the Strip Inlet.
3. The function number and the last measured test result will blink alternately on the display. Make sure the function number matches the number on the Test Strip foil packet.



4. Collect a drop of blood using a lancing device.
5. Touch the tip of the strip to the drop of blood. The measurement will automatically start.



BLOOD SHOULD ONLY BE DRAWN AT THE TIP OF THE TEST STRIP. APPLYING BLOOD ONTO THE SURFACE OF THE TEST STRIP MAY CAUSE INCORRECT TEST RESULTS.

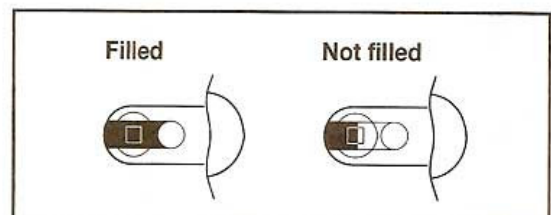


6. The test result will be displayed in 60 seconds. Lo will be displayed when the lactate level is below 0.8 mmol/L, and Hi will be displayed when the lactate level is above 23.3 mmol/L.

If Lo or Hi is displayed, perform the test again. If you still get the same result, contact your doctor.



NOTE: AN INSUFFICIENT VOLUME OF BLOOD SAMPLE MAY CAUSE ABNORMALLY LOWER VALUE. BE SURE THAT A NEEDED VOLUME OF BLOOD IS DRAWN INTO THE STRIP AS SHOWN.



PERFORMANCE CHARACTERISTICS

Measuring range 0.8-23.3 mmol/L

Precision

When two different blood samples containing normal and abnormal level of lactate were evaluated 15 times, the following results were obtained:

	Sample I	Sample II
Mean	2.2 mmol/L	11.6 mmol/L
S.D. (Standard Deviation)	0.07 mmol/L	0.30 mmol/L
C.V. (Coefficient of Variation)	3.2%	2.6%

Accuracy

Lactate Pro system (y) was compared to the enzymatic method (x), using LOD (Determiner LA, Kyowa Medex Co., Ltd.). Fifty nine blood samples gave the following correlation:

Number of samples $n = 59$
Correlation coefficient $r = 0.9988$
Regression equation $y = 0.9964 x - 0.01$

INTERFERING SUBSTANCES

- Reducing Substances: A sample with a large amount of reducing substances such as ascorbic acid and uric acid cause results higher than the actual lactate value.
- Hematocrit: Measurement value tends to become lower as hematocrit value increases.
- Antiglycolysis: It shows higher lactate value when antiglycolysis is used.
- Perspiration: It shows higher value when perspiration is mixed with blood sample.

PRECAUTIONS FOR USE

System

- Inappropriate handling of the Test Meter may cause incorrect test results. Prior to operation, read the Lactate Pro Operating Manual carefully.

Test Strips

- The Lactate Pro Test Strips are designed for use only with the Lactate Pro Test Meter. Do NOT use the Test Strips with any other analyzers or testing devices.
- Confirm that the displayed function number corresponds to the number on the foil packet before measuring. Mismatching numbers will cause incorrect test results.
- Do NOT reuse the used Test Strips. The Test Strips are for one-time disposable use only. If reused, it will not provide correct test results.
- Do NOT use expired Test Strips. If used, incorrect results will be obtained. The expiration date of Test Strip is printed on both the foil packet and box.
- Use the Test Strip immediately after opening the foil packet. Leaving it exposed for a long time may cause incorrect test results.
- Do NOT handle the Test Strip with wet hands or hold it for a long time in your palm. This may cause incorrect test results.
- After measurement, wrap the used Test Strips in the foil packets and discard them according to local regulations.

Calibration Strip

- Once the Test Meter has been setup with the Calibration Strip, additional procedure is not necessary until a new box of Test Strips is used. However, keep the Calibration Strip until you finish using them all.

Sample

- Use fresh whole blood. Serum or plasma will cause higher lactate results.
- A sample with a high hematocrit such as neonatal blood cause results lower than the actual lactate value.

- Make sure that the puncture site is clean before obtaining a drop of blood because perspiration significantly interferes test results. We recommend the following procedures for blood collection during exercises:

1. Clean the puncture site (i.e. the fingertip) with an alcohol pad.
2. Allow the skin to dry well.
3. Prick the site using a lancing device.
4. Apply pressure to the surrounding site to obtain a drop of blood.
5. Wipe the blood with a tissue because the first drop of blood contains perspiration.
6. Apply pressure to the surrounding site again to obtain a drop of blood and touch the tip of the Test Strip. See the instructions of the Operating Manual.

- Testing should be performed immediately after blood collection. Test result may be falsely elevated if a blood sample is left for a long period because lactate will be produced in blood as the time elapses.

- Make sure to dry the skin thoroughly to avoid hemolysis* condition. *Hemolysis: When blood is mixed with alcohol or perspiration, red blood cell breaks, and substances such as hemoglobin start dissolving into whole blood. This condition will lead incorrect test results.

STORAGE AND HANDLING

- Store at temperatures between 1° and 30° C (33.8° and 86° F). Excessive heat or cold may damage the Test Strips.
- Do NOT freeze the Test Strips. Frozen and thawed reagents may cause incorrect test results.
- Keep the Test Strips and other accessories away from the reach of children. If a strip is swallowed, contact your physician immediately.

EXPIRATION

The expiration date is printed on both the foil packet and box.

CONTENTS

Lactate Pro Test Strips in aluminum-foil packet	25
Calibration Strip	1

REFERENCES

- 1) Kawachi M, et al: Lactate. Jpn J Clin Med 1989; 47: 439-495
- 2) Kinoshita K, et al: The measurements of blood lactate concentration and its age change in days on healthy infant. Jpn J Clin Pathol 1995; 43: 1071-1076
- 3) Westgren M, et al: Routine measurements of umbilical artery lactate levels in the prediction of perinatal outcome. Am J Obstet Gynecol 1995; 173: 1416-1422
- 4) Shimojo N, et al: Electrochemical assay system with single-use electrode strip for measuring lactate in whole blood. Clin Chem 1993; 39: 2312-2314

WARNING

HANDLING BLOOD CAN BE DANGEROUS. Incorrect or imprecise procedures may result in the death of you or others. **USE EXTREME CAUTION** when handling blood, blood products and equipment that comes into contact with blood.

Lactate Pro test system is waived.

If the laboratory modifies the waived test system instructions, the test is considered high complexity and subject to applicable CLIA requirements, CLIA certificate, fees and survey.

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