

Read this entire insert thoroughly before you start using the CERA-CHEK™ Lactate Test Strips. Only use CERA-CHEK™ Lactate Test Strips with CERA-CHEK™ Lactate Test Meter. Keep this insert for future reference. If you have any inquiries, please contact your local distributor.

Introduction

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 of athletes.

Intended Use

The CERA-CHEK™ Lactate Test Strip is intended to help people manage their lactate level. It also provides professional healthcare personnel with helpful information by measuring Lactate in fresh capillary whole blood as well as venous blood. The CERA-CHEK™ Lactate Test Strip is intended for in vitro diagnostic use.

Principle of Measurement

The test is based on the measurement of electrical current generated by the reaction of lactate with the reagent of the test strip. The test meter measures the current and displays the corresponding blood lactate level. The strength of the current produced by the reaction depends on the amount of lactate in the blood sample.

Reagent Composition

- Each CERA-CHEK™ Lactate Test Strip contains:
 - Lactate Oxidase (Microorganism) 2.2 unit
 - Potassium ferricyanide 0.05 mg
- * Each vial cap contains a desiccant.

Calibration

When using the CERA-CHEK™ Lactate Test Strip for the first time, or before using a new box of test strips, you will need to calibrate the test meter. There is a code key in each box of test strips. Calibration is done by simply inserting the code key into the test meter. Remember to use the code key that is packaged with the box of test strips that you are presently using.


1. Press the ON/OFF button to turn the test meter on.
2. Insert the code key completely into the code key port with the code number facing up. The code number will appear on the LCD display. Make sure that the code numbers on the display, on the code key, and on the test strip vial match.
3. Remove the code key. The test meter is now ready for a test. Store the code key with the test strip box. Do not discard the code key until you have used all of the test strips in the box.

Testing your Lactate

IMPORTANT

Do not handle the test strips with wet or dirty hands. Wash and dry your hands before testing.

1. Remove the test strip from the vial and immediately close the cap.
2. Insert the test strip to the test strip port to turn the test meter on.
3. A code number will appear on the display.
4. Verify that the code number on the LCD display matches the code number on the test strip vial. If they are not identical, remove the test strip from the test meter and do the calibration again.
5. Obtain a drop of blood.

- Wash and dry your hands before the test.
- Use the lancing device to get a drop of blood from a fingertip.
6. Apply blood to the test strip.
- When the 'blood' symbol  is flashing on the display, apply a drop of blood to the absorbent hole until blood has completely filled the confirmation window.
- The test meter will automatically shut down after 2 minutes not used.
7. The test meter will countdown for 9 seconds and then display a result. The reading is automatically stored in the test meter memory.
8. Remove the test strip from the test meter and discard it.

Test result

1. Measurement Range : 0.5~25.0 mmol/L (4.5~225 mg/dL)
2. Analyzing interval: 0.1 mmol/L
3. Result display

Measurements below as a result of the CERA-CHEK™ Lactate Meter, Test date and the Lactate level in the sample is automatically quantify the results are displayed.

Measurements result	Display
Range	0.5~ 25.0 mmol/L
<0.5 mmol/L	'Lo'
>25.0mmol/L	'HI'

4. Normal Lactate Range

Whole Blood (capillary blood, venous whole blood) : (0.7~2.1 mmol/L*)

Storage and handling

1. Store the test strips at 1°C~32°C (34°F~90°F).
2. Keep the test strips away from direct sunlight.
3. Store the test strips below 85% relative humidity
4. Do not use the test strips after expiration date. Results will be inaccurate.
5. Test strips expire 4 months after first opening. Do not use the test strips after expiration date.
6. Do not handle the test strips with wet or dirty hands.
7. After removing a CERA-CHEK™ Lactate Test Strip from the vial, close the vial cap tightly.
8. Test strips are single use only. Do not reuse.
9. Store the test strips in the original vial. Do not transfer them to a new vial or another container.
10. Keep away from children. In case a vial cap or a test strip is swallowed, consult a doctor immediately.

Limitations

1. Hematocrit below 20% and hematocrit above 60% may cause inaccurate result. Please consult your healthcare professional if you do not know your hematocrit level.
2. The venous whole blood collected in anticoagulant Sodium Fluoride (NaF) is used.
3. This product is designed and manufactured to use fresh whole blood from capillary and venous to measure lactate. Do not use serum or plasma.
4. Do not use the product at altitudes above 13,200 feet (4,000m)
5. Do not use the product at a temperature below 4°C (39.2°F) or above 40°C (104°F).
6. Reducing substances: A sample with a large amount of reducing substances such as ascorbic acid and uric acid infarct cause results higher than the actual lactate value
7. If the high levels of blood mixed with sweat can be measured, so please be careful.

Quality Control Testing

CERA-CHEK™ Lactate Control Solutions contain a known amount of Lactate that reacts with a CERA-CHEK™ Lactate Test Strips. By

comparing your Lactate Control Solution test results with the expected range printed on the test strip vial label, it is able to check that the test meter and the test strips are working properly together and that you are performing the test correctly. It is very important that you do this simple check routinely to make sure you get correct results. Read the CERA-CHEK™ Lactate User Manual for detail.

IMPORTANT

Use the CERA-CHEK™ Lactate Control Solution ONLY.

It is recommended to run a control test if:

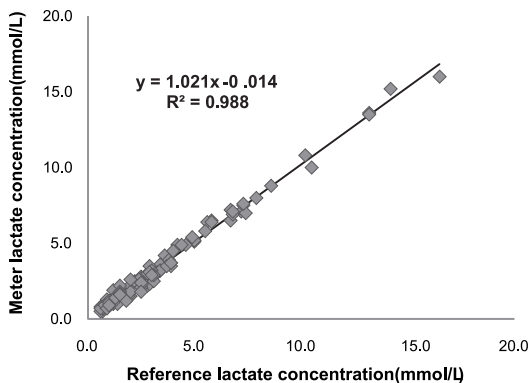
- You would like to test your system without using a blood sample.
- You suspect the test meter or test strips may not be functioning properly.
- Test results appear to be abnormally high or low, or are not consistent with how you feel.
- The test strip vial was left open.
- You are using a new vial of test strips.
- You use the test meter for the first time.
- You dropped the test meter.

The control range may change with each new vial of test strips. Always use the control range on your current vial of test strips. If the quality control test result falls outside the specified range printed on the test strip vial, repeat the quality control test. If you still have a problem, please contact your local distributor.

Performance Characteristics

1. Accuracy

The accuracy of the CERA-CHEK™ Lactate Test Strip was evaluated by comparing blood lactate results obtained from 100 people with replicate measurement. Readings obtained with the CERA-CHEK™ Lactate Test Strip was compared to those obtained using an YSI Model 2300 Lactate Analyzer. The correlation obtained between the CERA-CHEK™ Lactate Measuring System results and reference device results was $R^2=0.988$, therefore CERA-CHEK™ Lactate Test Strip has shown high accuracy.



2. Precision

The precision of CERA-CHEK™ Lactate Test Strip was estimated with venous blood samples in the laboratory.

Lactate concentration (mmol/L)	STD (mmol/L)	CV (%)	n
3.1	0.16	5.1	60
9.1	0.23	2.5	60
16.1	0.22	1.3	60
22.2	0.37	1.7	60

Symbol Information

	In vitro diagnostic medical device
	Do not reuse
	Consult instructions for use
	Temperature limitation
	Use by
	Date of manufacture
	Batch code
	Manufacturer
	This product fulfills the requirements for directive on in vitro diagnostic medical devices.
	Authorized representative in the European community
	Caution, consult accompanying documents

Reference

- 1) Wallach, J. Interpretation of Diagnostic Tests 7th ed., p13, Brown and Company, Boston MA (2000)

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