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# LACTATE CONTROL SOLUTION

## Intended Use

Lactate Control Solution is intended for use with Lactate Test Strip made by TaiDoc. It is used to check that the meter and test strips are working together properly. Testing is done outside the body (*in vitro* diagnostic use). It is indicated for use by people with suspecting of having lactic acidosis at home or by health care professionals in clinical settings as an aid to monitoring the effectiveness of acidbase control. It is important to do control solution tests routinely to ensure getting accurate results.

## Summary and Explanation

Lactate Control Solution contains a known amount of lactate that reacts with test strips made by **TaiDoc**.

Operation of the control solution test is similar to **Lactate** test except that you use Lactate Control Solution instead of a drop of blood. The control solutions should provide results within an expected range printed on the test strip vial label.

### IMPORTANT

The control range may change with each new vial of test strips. Always use the control range on the label of your current vial of test strips.

## When should the control solution test be performed?

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

### CAUTION

The control solution range printed on the test strip vial is for control solution only. It is used to test meter and test strip performance. It is not a recommended range for your Lactate levels.

## Chemistry

This control solution is a red solution that contains less than 0.1% Lactate. The solution does not contain any human-derived or biological materials.

Ingredient	Percent
Active ingredient: Lactate	0.01%-0.1%
Inert ingredients	>99.9%

## Storage and Handling

- ► Use only Lactate Control Solution with Lactate Test Strip made by TaiDoc.
- Check the expiration date on the vial. Do not use if expired.
- Tightly close the control solution and store at room temperature between 2°C and 30°C (35.6°F and 86°F). Do not freeze.
- Use only for 90 days after first opening. Record the discard date (date opened plus 90 days) on the control solution vial. Discard after 90 days.

## **Test Procedure**

To do a test with our Lactate Control Solution, follow the instructions printed in the Owner's Manual that came with the system.

#### CAUTION

Blood glucose, total cholesterol and uric acid tests have respective control solutions. Always make sure you have the correct control solution corresponding to your test strip.

Accurate results depend upon following instructions carefully. Follow below technical pointers whenever you test with Lactate Control Solution:

- 1. It is recommended that the meter, control solution, and test strips come to room temperature  $(20^{\circ}C-25^{\circ}C/68^{\circ}F-77^{\circ}F)$  before testing.
- 2. Shake the control solution well before using.
- 3. Discard the first drop of control solution you squeeze out.
- 4. Wipe off the dispenser tip to keep it clean.

## Expected Results

At room temperature, Lactate Control Solution test results should fall within the expected range printed on the test strip vial label.

If test results fall outside the expected range printed on the test strip vial, please check the troubleshooting guide in Owner's Manual and repeat the test. Results that fall outside the expected range may indicate the followings:

- An error in the way you are doing the test.
- Expired test strips and control solutions.
- ► 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 vial. (For models that require coding)
- Failure to shake the control solution vial vigorously.

**PLEASE NOTE:** High Lactate readings can indicate a potentially serious medical condition. If the Lactate readings are unusually high, repeat the test with a new test strip. If the readings are not consistent with any visible symptoms, contact the healthcare professional promptly for advice and assistance.

## Availability

This control solution is available from retail pharmacies.

## OUR COMMITMENT TO YOU

Our goal is to provide you with quality healthcare products and dedicated customer service. If you are not fully satisfied with this product, or if you have questions about the use of any **TaiDoc** product, please contact the dealer for service.

#### **Symbol Information** Referent Symbol Referent Symbol In vitro diagnostic medical IVD Batch code device Consult instructions for use Manufacturer ĺĭ 444 Authorized representative Temperature limitation EC REP in the European Community Caution, consult Use by A accompanying documents **CE**0123 CE mark

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