Nealact Lactate Control Solution

Intended Use

Nealact Lactate Control Solution is intended for use with Nealact Lactate Test Strips. 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.

About Control Solution

Nealact Lactate Control Solution contains a known amount of lactate that reacts with Nealact Lactate Tes Strips.

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 solution should provide results within an expected range printed on the test strip vial label.

IMPORTANT

The control solution range printed on the test strip vial may differ. Make sure to use the range printed on the current test strip vial label.

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

Nealact Lactate 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		
Lactate	0.01%-0.1%		
Inert ingredients	>99.9%		

Storage and Handling

- ► For in vitro diagnostic use only
- ▶ Use only Nealact Lactate Control Solution with Nealact Lactate Test Strips.
- ► Check the expiration date on the vial. Do not use if expired.
- Tightty 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. Records the date first opened on the control solution vial. Discard after 90 days.

Test Procedure

To do a test with Nealact Lactate Control Solution, follow the instructions printed in the User Manuel that came with the Nealact Lactate Meter.

CAUTION

Each test has 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 **Nealact** Lactate Control Solution:

- It is recommended that the meter, control solution, and test strips come to room temperature (20°C-25°C /68°F-77°F) before testing.
- 2. Shake the control solution well before using.
- 3. Discard the first drop of control solution you squeeze out.
- 4. Squeeze out another drop and touch with the absorbent hole of a test strip.
- 5. Wipe off the dispenser tip to keep it clean.

Expected Results

At room temperature, Nealact 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 User 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.
- ▶ Use of control solution with unmatched test strips.
- Failure to shake the control solution vial vigorously.

If the repeat result is still outside the range, the system may not be working properly. Do not use the system to test your blood. Please contact the dealer for service.

Availability

Nealact Lactate Control Solution is available with the catalog number TD-4924 from your Nealact Lactate Meter and Nealact Test Strips distributor.

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 our product, please contact your distributor for service.

Symbol Information

Symbol	Referent	Symbol	Referent
IVD	In vitro diagnostic medical device	LOT	Batch code
[]i	Consult instructions for use		Manufacturer
X	Temperature limit	EC REP	Authorized representative in the European Community
Σ	Use-by date	CE	CE mark
Λ	Caution	₩ _{RoHS}	RoHS Compliance
REF	Catalogue number		



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