Control Solution

IB BGM Control Solution EN 4520 Revision Date: 2020-11-04



IVD

Instructions for use

Intended use:

Microlife Control Solution is for use with all models of Microlife Blood Glucose Monitoring System as a quality control check to verify if the meter is working properly or if your test results are accurate.

- For use in self-testing outside the body only.
- For in vitro diagnostic use only

When to do the control solution test:

It is recommended that you use the control solution to test in the following conditions:

- 1. When you use your meter for the first time or after replacing the battery.
- 2. When opening a new lot of test strips.
- 3. Whenever you question the test result.
- When the performance of the Microlife Blood Glucose Meter or Test Strips are suspected.
- 5.If you drop your meter.
- 6. For training or practicing without using any blood
- 7.On the advice of your doctor or healthcare professional.

Control solution use warnings:

- 1.Use before the expiration date printed on the vial.
- 2.Use within 90 days after first opening. Write the «Discard Date» on the space provided on the bottle label when you first open it.
- 3.Do not add any liquid to the Microlife control solution.
- 4.Do not take internally or inject.

Material required but not supplied:

- Blood Glucose Test Strips
- Blood Glucose Meter

Contents of package:

1 Bottle: 4.0 ml

Chemical composition:

The control solution contents:

- 1.D-Glucose
- 2. Polyvinyl acetate (aqueous emulsion): 10%
- 3.Fumed silica: 0.2%
- 4. Sodium Benzoate: 0.2%
- 5.Disodium EDTA: 0.1%
- 6.Food Pigment Red No.6: 0.05%
- 7. Antifoaming agent (Polyethylene Glycol 4000): 0.02%

Storage and handling:

- 1.Store at room temperature between 4°C (39°F) and 30°C (86°F).
- 2.Do not freeze, heat or expose to direct sunlight.
- 3. Recap the bottle after use

Control test procedure:

- Insert a test strip to turn the meter on.
- Open the bottle cap and hold the control solution bottle by gently squeezing it, a small drop of control solution appears at the tip.
- Discard the first drop, and squeeze again for second drop on a clean non-absorbent surface.
- 4.Apply the absorbent channel of the test strip to the drop of control solution until the meter makes a «beep» sound.
- 5. Within seconds, the test result will be shown. Compare the test result to the range printed on the test strip vial.

What to expect with the control solution test?

When a control solution test is done, you should get results within the range printed on the test strip vial label. Repeat the test if the control solution result falls outside the range. Consult your user's manual for more information. Results that fall outside of the range may be caused hy:

- 1. Error in performing the test.
- 2. Expired or contaminated control solution.
- 3.Blood glucose test strip is not working.
- Blood glucose meter is not working.

If the control solution test result falls outside the range printed on the test strip vial, first repeat the test. If the second control measurement still falls outside the range, your meter and test strip may not be working properly. DO NOT use the system to test your blood, please contact us for help.

Notes on control solution testing:

- The control solution test result should fall within the range printed on the test strip vial.
- Results from Microlife control solution tests do not reflect your blood glucose level.



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