

EasyTouch® HealthPro™ Glucose Control Solution

Intended Use

The EasyTouch® HealthPro™ Glucose Control Solution is for use with the EasyTouch® HealthPro™ Glucose Meter and Test Strips. The control solution is used to verify the accuracy of the EasyTouch® HealthPro™ meter and strips.

Quality Control

Acceptable performance is assured when the control test results falls within the appropriate range listed on the vial of your test strips.

Summary

The control solution contains a known amount of sugar that reacts with the test strip. A test with control solution is similar to that of a blood test. All you will do is use your control solution instead of a drop of blood. The control solution result should fall within the appropriate range printed on the side of the test strip vial.

CAUTION:

If the glucose control solution test is not in range, DO NOT proceed with a blood glucose test. Please contact MHC Customer Support at (877) 358-4342 Monday thru Friday, 9 to 5pm Eastern Time.

When to Perform a Glucose Control Solution Test

- Before using a new box of strips.
- Whenever you feel that your sugar levels are inaccurate.
- If you feel the meter or test strips have been compromised in anyway.
- When your test results are inconsistent with your symptoms.

Note: The EasyTouch® HealthPro™ Glucose Monitoring System does not include Test Strips and Control Solution and can be purchased separately.

Storage and Handling

- Make sure the control solution bottle is tightly closed and stored between 46-86°F (8-30°C). Keep out of direct sunlight. Do not Refrigerate. Do not Freeze.
- Shake well before use. If the control solution is too warm or cold, do not use until the solution has remained at room temperature for at least 30 minutes.
- Use before the expiration date shown on the bottle.
- Once opened, use within three months. Record the discard date on the control solution bottle. Discard 3 months after opening.
- Discard according to local regulations.
- Do not use if the expiration date has passed.

Test Procedure

For accurate results, please follow the instructions carefully.

1. It is recommended that the meter, control solution, and test strips are at room temperature (68-77°F) before testing.
2. Prior to use, gently shake the bottle.
3. Discard first couple drops of control solution.
4. Wipe the tip clean.
5. Make sure the test strip is fully inserted into the test strip port of the meter.
6. The meter will automatically turn on and display the code number. Make sure the code number matches the code number on the test strip vial.
7. Specify that it's a control solution test and not a regular blood sugar test by pressing the up or down button. A control solution icon (Ⓐ) will appear on the screen.

8. Place a drop of solution on a clean, dry surface (For example: the lid of your test strip vial). Pick up the meter and touch the end of the test strip to the drop. Be sure to hold the test strip to the drop until you hear a 'beep' sound.
9. A result will appear in 5 seconds.
10. Repeat steps with both Low (Level 1) and High (Level 3) control solution.

Expected Results

At room temperature, control solution test results will fall within the expected range printed on the test strip bottle. If the test result falls outside the expected range, repeat the test. DO NOT continue with your blood sugar test if the control solution test result is out of range. Results that fall outside the expected range may indicate:

1. Test performed was not in room temperature.
2. Expired or contaminated control solution.
3. Control solution is too warm or cold.
4. Failure to discard the first drop of control solution and to wipe the bottle tip clean.
5. Failure to shake the control solution adequately.
6. A problem with the meter or test strip.
7. An error in the way you are doing the test.

Range of Expected Values:

Testing of blood glucose levels provides a way to control and manage diabetes. Consult with your physician to determine the best range for your expected blood glucose values.

Expected Values for Nondiabetic Adults:

Before eating < 100 mg/dL (5.6 mmol/L)
One to Two hours after meals < 140 mg/dL (7.8 mmol/L)

Reagents

Each EasyTouch® HealthPro™ Glucose Control Solution is provided as a buffered, stabilized, aqueous solution of D-glucose containing a preservative and other non-reactive ingredient.

High (Level 3): 0.20 wt% glucose 99.80 wt% non-reactive ingredients

Low (Level 1): 0.04 wt% glucose 99.96 wt% non-reactive ingredients

Precautions

The EasyTouch® HealthPro™ Control Solution is for In-Vitro Diagnostic use only. This means that it is only used for testing outside of the body.

- The EasyTouch® HealthPro™ Control Solution is made for the EasyTouch® HealthPro™ systems. Do not use any other brand of control solutions.
- Check the expiration date on the bottle. Do not use if expired.
- Do not swallow. Not for human or animal consumption.

Reference:

American Diabetes Association: Clinical Practice Recommendations(2013) Diabetes Care, Vol 36, Supplement 1, p. S1-S100.

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