

Gluco Spark Control Solution

Intended Use

Gluco Spark Control Solutions are for use only with the *Gluco Spark* Meter and *Gluco Spark* Test Strips. They allow you to check that the meter and test strips are working correctly and that you are testing correctly. You should do control solution tests routinely to check that you are getting accurate results.

Summary

Gluco Spark Control Solutions contain a known amount of glucose. A test with a *Gluco Spark* Control Solution is like a blood test except that you use a Control Solution instead of blood. The test result using a Control Solution should fall within the range of results printed on your vial of strips.

CAUTION: The control solution range printed on the test strip vial is only for control solution. It is not a recommended range for your blood glucose level. This should be discussed with your doctor.

WHEN SHOULD YOU RUN A CONTROL SOLUTION TEST?

The *Gluco Spark* meter should be tested using the control solution during the following situations:

- Before you first use your new *Gluco Spark* meter, practice with a control. When you can do three tests in a row correctly, you will be able to use the meter successfully.
- When you begin using a new vial of strips.
- At least once a week.
- When you think that the meter or strips are not working correctly.
- When your test results are not consistent with your symptoms, or when you think your results are not accurate.
- If the meter is dropped.

A test result that is within the expected range shows that the meter and strips are working correctly and that you are testing correctly.

Chemistry

Gluco Spark Control Solution 1 is red aqueous solutions containing a range of approximately a 70-100 mg/dL D-glucose for normal values.

Gluco Spark Control Solution 2 is red aqueous solutions containing a range of approximately a 70-100 mg/dL D-glucose for normal values.

Precautions & Limitations

Gluco Spark Control Solutions must only be used outside of the body (in vitro diagnostic use).

- *Gluco Spark* Control Solutions are made only for the *Gluco Spark* Blood Glucose Monitoring System. Do not use any other brand of control solutions for testing your *Gluco Spark* system.
- Check the expiry date on the vials. Do not use after the expiry date.
- Shake the vials before use. Discard the first drop of *Gluco Spark* Control Solution, and wipe off the tip to ensure a good sample and an accurate result.
- Use only for three months after first opening. Record the discard date (date opened plus three months) on the control solution vials.
- Storage and Handling.

Store the control solution at room temperature between 50 and 86°F (10 and 30°C). Do not refrigerate. Do not freeze. Do not use beyond expiration date or beyond 90 days after opening

Test Procedure

To perform a test with *Gluco Spark* Control Solution, follow the instructions printed in your Gluco Spark User Manual that came with the system. In addition, follow these instructions when you test with Control Solution:

1. Before using control solutions wash your hands thoroughly.
2. The meter, Control Solution, and strips must be at room temperature (66-77°F /20-25°C) before testing. If they have been stored outside room temperature, be sure to give them time to adjust to room temperature before using.
3. Shake the Control Solution well before using.
4. Discard the first drop of Control Solution you squeeze out.
5. Apply the drop of Control Solution to the top edge of the strip. You may also apply a drop to your finger and test as if it were a drop of blood (See test strip instructions.)

Unexpected Results

At room temperature, the Control Solution results should fall within the range printed on the test strip vial label. If test results fall outside the expected range, repeat the test. Results that fall outside the expected range may indicate:

- An error in your method.
- Premature withdrawal of strip from the Control Solution site.
- Expired or contaminated Control Solution.
- Damaged or outdated strips.
- A problem with the meter.
- Control Solution that is too warm or too cool.
- Failure to discard the first drop of Control Solution and to wipe the vial tip clean.
- Failure to shake the Control Solution vial well.

IMPORTANT :

DO NOT test your blood until you obtain control results that fall within the expected range.

Availability:

Gluco Spark Control Solutions are available from authorized distributors. See your System User Manual for the details of your customer service.



For in vitro diagnostic use



Lot Number



Expiry Date