

Product Name

Clarity BG1000 Glucose Control Solution

Important

Please read this insert before using Clarity BG1000 Glucose Control Solution with Clarity BG1000 Blood Glucose Monitoring System.

Intended Use

Clarity BG1000 Glucose Control Solutions are for use with Clarity BG1000 Blood Glucose Meter and Clarity BG1000 Blood Glucose Test Strips to check that the meter and test strips are working properly. The Clarity BG1000 Glucose Control Solutions are intended for use by healthcare professionals and people with diabetes mellitus at home. The Clarity BG1000 Glucose Control Solution are for in-vitro diagnostic use.

Quality Control

The system is working properly when the control test result falls within the range. Please refer to the range listed on the test strip vial label.

Summary

The Control Solution contains amount of glucose to react with reagents on the Test Strip. When you apply a drop of control solution to the sample channel on a Test Strip, glucose in the control solution reacts with reagents on the test strip. The control solution should provide results within the expected range printed on the Test Strip vial label.

Reagents

Each Clarity BG1000 Glucose Control Solution contains Clarity and other non-reactive ingredients. The formulation is as follows.

Level 2	0.11 % w/v glucose	99.89 % w/v nonreactive ingredients
Level 3	0.23 % w/v glucose	99.77 % w/v nonreactive ingredients

When to Use the Control Test

- When you first get your meter, before testing your blood.
- When you open a new lot of test strips.
- At least once a week to verify that the meter and test strips are working properly together.
- When you question your blood glucose results.
- When your test results do not match how you feel.
- When your meter is dropped, damaged, or gets wet.

Note to Professionals

Daily control testing is recommended. Daily control test helps to ensure that the meter and test strips are operating properly.

Precautions

- For in-vitro diagnostic use.
- Do not swallow or inject.
- Be sure the code number appearing on the Screen of the meter matches the code number on the test strip vial label.
- If the drop of control solution goes back into the control solution vial, it is possible that it could contaminate the entire bottle of control solution.

Storage and Handling

- Store at room temperature, between 39.2-86°F
- Shake well before using.
- Always make sure to close the vial tightly after each use.
- Do not use expired Control Solution. The Control Solution expiration date is displayed on the Control Solution Vial or the Glucose Meter Kit Box.
- Controls can be used for 90 days after first opening the vial. Write the date you first opened the Control Solution on the Control Solution vial label, and discard any unused portion 90 days after opening.

Materials Provided

Clarity BG1000 Glucose Control Solution may be sold separately or packaged together with other Levels.

Materials Required but Not Provided

Clarity BG1000 Blood Glucose Meter, Clarity BG1000 Glucose Test Strips and applicable user manual.

Test Procedure

It is recommended that the meter, control solution and test strips reach room temperature (68-77°F) before testing. To perform a glucose control solution test, first shake the control solution vial then follow the instructions printed in the user manual that came with the system. Insert the test strip and when a drop of blood symbol starts blinking, draw a drop of control solution into the test strip. Make sure the test strip is completely filled until the Glucose Meter beeps.

Limitations

- The glucose control ranges printed on the test strip vial label are for Clarity BG1000 Glucose Control Solutions only.
- Applying too much or too little control solution to the test strip may cause out of range results.
- The amount of glucose in this Control Solution, when tested by methods other than Clarity BG1000 meters, may differ because the amount of glucose added makes up for differences between testing glucose in water and in whole blood sample.

Expected Results

At room temperature, About 95% of the Clarity BG1000 Glucose 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, repeat the test. Results that fall outside the expected range may indicate:

- An error in the way you are doing the test.
- Expired or contaminated control solution.
- Test strip code number in the meter does not match the code number on the test strip vial label.
- A problem with the meter.
- A problem with the test strip. (e.g. expired, damaged, etc.)
- Control solution is too warm or too cold.
- Control solution tested outside the 68-77°F.
- Applying too much or too little control solution.

Customer Service: 1-877-722-6339
Monday-Friday 8:30AM-5:30PM EST.
www.claritydiagnostics.com

Not for Emergency or Medical Information.

If you have questions or need assistance outside the operational days and times, please contact your healthcare provider.

Manufactured for:

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REV06102016
XP909-0045A Rev.19.07.16