



Blood Glucose Control Solution

Package Insert

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| REF | C902095 | English |
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PRINCIPLE AND INTENDED USE

The Blood Glucose Control Solution contains a known concentration of glucose. It is used to confirm that your C902005 Blood Glucose Test Strips and your Blood Glucose Test Meter are working together properly and that you are performing the test correctly. The control solution acts like blood when you apply it to an *Acuteck* Blood Glucose Test Strips. Performing a control test lets you know the meter and test strips are working properly.

Blood Glucose Monitoring System is an automatic *in vitro* monitoring system for quantitative detection of glucose concentration in fresh capillary whole blood or venous whole blood. The system is intended for self-testing by people with diabetes or people suspected of having diabetes at home, and for near-patient testing by healthcare professionals in clinical settings.

The system is only used for the monitoring of blood glucose levels and the preliminary screening of blood glucose abnormalities, and is not suitable for the diagnosis of diabetes.

You should perform a quality control test:

- Before you first use your meter to familiarize yourself with its operation.
- Before using a new box of test strips.
- When you suspect your meter or test strips are not working properly.
- When you suspect your test results are inaccurate, or if they are inconsistent with how you feel.
- If you suspect your meter is damaged.
- After cleaning your meter.

Two levels of control solution are available labeled Control solution 1 and Control solution 2. Control solution 1 is sufficient for most all self-testing needs. If you think your meter or strips may not be working correctly, you may also want to do a level 2 at least.

COMPONENTS

Control solution 1 contains less than 0.1% glucose(active ingredient)and Control solution 2 contains less than 0.2% glucose(active ingredient),both with preservatives in an aqueous based mixture.

STORAGE AND HANDING

- Store the control solution at temperature between 2-30°C and ≤90% relative humidity.
- Shelf life: 24 months.
- Do not freeze.
- If the control solution is cold, do not use until it has warmed to room temperature.
- Use before the unopened expiration date that is shown on the bottle.
- The control solution will expire 3 month after the bottle is opened for the first time. Record this opened expiration date on the bottle label.

PRECAUTIONS

- For *in vitro* diagnostic use. The control solution is for testing only outside the body. Do not swallow or inject. For self-testing and near-patient testing.
- Shake well before using.
- Control solution tests are specified to be accurate only when tested at temperature between 20 - 25°C.
- The control ranges shown on the test strip canister are not a recommended range for your blood glucose level. Your personal blood glucose target ranges should be determined by your diabetes healthcare professional.
- Do not touch the end of the test strip to the control solution could contaminants to enter the control solution bottle.
- Use only control solution with your C902005 Blood Glucose Test Strips and your GOH-101Pro Blood Glucose Test Meter or GHP-101ProSK Blood Glucose Monitoring System.
- Please dispose of the relevant waste in accordance with local standards and regulations.
- If the outer packaging is seriously damaged or solution leaks during transportation, please contact your local dealer. Please check the completeness of the product. Check the use by date on the control solution container. Do not use the control solution after that date

MATERIALS

MATERIALS REQUIRED

- Blood Glucose Control Solution
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

• Blood Glucose Test Meter

• Blood Glucose Test Strips

INSTRUCTIONS FOR USE

Before testing, the control liquid should be gently reversed to mix well for at least 2 minutes. Do not shake vigorously.

1. Power on the meter by inserting a new test strip. Refer to your meter's User's Manual details on how to record the result as a quality control test and for further details on operating the meter.
2. Shake the control solution bottle thoroughly.
3. Squeeze the control solution bottle gently and discard the first drop. If the tip clogs, tap the tip gently on a clean, hard surface, shake again, and then use.
4. Squeeze out a second small drop on a clean nonabsorbent surface. Touch the sample tip of the test strip to the control solution drop. If the audio option is turned on, the meter will beep to indicate a sufficient sample has been applied.

Notes: Do not apply control solution to the test strip directly from the bottle.

If the control solution sample does not completely fill the check window, Do not add a second drop. Discard the test strip and start over with a new test strip.

5. Read the result from the meter display.

EXPECTED RESULTS

Control solution test results should be within the control range. The ranges for both (CTRL 1 and CTRL 2) are displayed on the test strip vial (or on the foil pouch). For confirmation of results, Control Solution 1 test should fall within the CTRL 1 range, and Control Solution 2 test should fall within the CTRL 2 range. If the test results with control solution fall within the specified control range, it indicates your meter is working properly and you are performing the procedure correctly.

If the control solution test results do not fall within the respective ranges:

- Check the expiration date of the test strip and control solution. Make sure that neither the test strip vial nor the control solution bottle has been opened for more than 3 months. Discard any expired test strips or control solution.
- Confirm the temperature in which you are testing is between 20 and 25°C.
- Make sure that the test strip vial and the control solution bottle have been tightly capped.
- Make sure the code number on the vial (or on the foil pouch) of test strips you are using matches the code number stored in the meter memory.
- Check that the control solution you are using is applied to your testing system.
- Make sure that you followed the test procedure correctly.

After checking all of the conditions listed above, repeat the control solution test with a new test strip. If your results still fall outside the range indicated on the test strip vial label (or on the foil pouch), your meter may not be working properly.

DO NOT use the system to test blood. Control your dealer for help.













For complete instructions, please refer to the User's Manual included with your meter.

SUMMARY OF SAFETY AND PERFORMANCE

Intended users and patients can log in to the European database on medical devices (Eudamed) to request the summary of safety and performance (SSP) of the device or contact the manufacturer to obtain it.

For more ordering information, please contact 400-853-5577 or email 'contact@diareagent.com'.

INDEX OF SYMBOLS

| | | | |
|---|---|---|---|
|  | Catalog number |  | Batch code |
|  | Date of manufacture |  | Use by |
|  | Manufacturer |  | Unique device identifier |
|  | For near patient testing |  | For self-testing |
|  | In vitro diagnostic medical device |  | CE marking |
|  | Authorized representative in the European Community |  | Consult instructions for use or consult electronic instructions for use |

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