

## PRINCIPLE AND INTENDED USE

The TeleRPM Control Solution contains a known concentration of glucose. The TeleRPM Blood Glucose Control Solution is for use with the TeleRPM Blood Glucose Meter and TeleRPM Blood Glucose Test Strips as a quality control check to verify that the meter and test strip are working together properly, and that the test is performing correctly.

For self-testing use only.

You should perform a quality control test:

- Once a week.
- Before using a new box of test strip.
- When you suspect that the meter and test strips are not working together properly.
- If you suspect your meter is damaged.
- After cleaning your meter.
- You dropped the meter.
- Always perform a quality control test if you suspect your results are inaccurate or do not match how you are feeling.

Three levels of control solutions are available. Control Solution 1 (level 1), Control Solution 2 (level 2) and Control Solution 3 (level 3). Control Solution 2 (level 2) is sufficient for most of all self-testing needs. If you think your meter or strips are not working correctly, you may perform a Level 1 and Level 3 test. If you want to purchase control solution kit, contact 24/7 Customer Support at (833)445-5666.

## COMPOSITION

Control Solution 1 contains less than 0.1% glucose (active ingredient). Control Solution 2 contains less than 0.2% glucose (active ingredient). Control Solution 3 contains less than 0.3% glucose (active ingredient). Three levels control solution have preservatives in an aqueous based mixture.

## STORAGE AND HANDLING

- Store between 36-86°F. Store at 10-90% RH.
  - If the control solution is cold, do not use until it has warmed to room temperature.
  - Use before the expiration date. The date is shown on the vial.
- Note: All expiration dates are printed in Year-Month-Day format. 2023-01-01 indicates 1st January, 2023.
- Use the control solution only for 6 months after you first open it. The control solution will expire 6 months after the vial is opened for the first time. Record the expiration date on the control solution label immediately after opening.

## PRECAUTIONS

- For in vitro diagnostic use. The control solution is for testing only outside the body. Do not swallow or inject. For self-testing use.
- Shake well before using.
- To obtain accurate results complete all control testing between 50-104°F.
- The control ranges are shown on the test strip vial. The control ranges are not a recommended range for your blood glucose level. Figure out your personal blood glucose target ranges with your doctor.
- Do not touch the end of the test strip to the control solution vial. This could cause contaminants to enter the control solution vial.
- Do not use the control solution if the package is damaged.
- Use only TeleRPM brand control solution with your TeleRPM meter and TeleRPM brand test strips.
- Always wash your hands well with soap and water before and after testing.

## MATERIALS PROVIDED

- Control Solution
  - Package Insert
- If you want to purchase control solution kit, or want to know more information, contact 24/7 Customer Support at (833)445-5666.

## MATERIALS REQUIRED BUT NOT PROVIDED

- Meter
- Test Strips

## INSTRUCTIONS FOR USE

1. Insert a new test strip. The meter turns on. Refer to your meter's User Manual details on how to record the result as a quality control test, and more details on operating the meter.
  2. Shake the control solution vial thoroughly.
  3. Squeeze the control solution vial gently. 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 tip of the test strip to the control solution drop until the meter beeps.
- Notes:
- Test immediately after the control solution has squeezed.
  - Do not apply control solution to the test strip directly from the vial.
  - If the control solution sample does not 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 after a beep.

## EXPECTED RESULTS

Control solution test results should be within the control range. The ranges for three levels (Level 1, Level 2 and Level 3) are displayed on the test strip vial label. For confirmation of results, Control Solution 1 tests should fall within the level 1 range, Control Solution 2 tests should fall within the level 2 range, and Control Solution 3 tests should fall within the level 3 range. If the test results are in the correct ranges provided, this means that your Blood Glucose Monitoring system is working properly.

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

- Check the expiration date of the test strip and control solution. Discard any expired test strips or control solution.
- Make sure you are testing at a temperature between 50 and 104°F (10-40°C).
- Make sure that the test strip vial and the control solution vial have been tightly capped.
- Confirm that you are using TeleRPM brand control solution with your TeleRPM brand test strips.
- Make sure that you follow the test procedure correctly.

After checking everything 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, your meter may not be working properly. DO NOT use the system to test your blood glucose. Contact Customer Support for help. For complete instructions, please refer to the User Manual included with your meter. Please contact 24/7 Customer Support at (833)445-5666 for technical support or questions.

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