

INTENDED USE

The control solution is a desired aqueous glucose solution with small amounts of non-reactive ingredients and food coloring for verifying the accuracy of the entire blood glucose monitoring system. The control solution test examines the performance of the glucose meter, test strip, and your operating techniques.

WHEN TO PERFORM A CONTROL SOLUTION TEST

1. Daily or per facility protocol.
2. When you are using your system for the first time.
3. When you are using a new batch of test strips.
4. Anytime you question the performance of the system, or when the blood glucose test results are lower or higher than patients normal level.

CONTROL SOLUTION CONTENTS

Each control solution is provided as a buffered, stabilized, aqueous solution of desired D(+)-glucose containing a preservative and other non-reactive ingredients. The solutions are formulated to react equivalently to a whole blood sample containing approximate 50, 110 or 300 mg/dL glucose concentrations. Actual lot-specific ranges are printed on the test strip bottle label.

Control Solution	mg/dL	mmol/L
Level 1	50	2.8
Level 2	110	6.1
Level 3	300	16.7

CAUTION: Control solution is for in vitro use only. It is not to be swallowed or injected. The use of the control solution is recommended to verify proper system performance and should not be considered as a substitution of actual capillary whole blood testing for blood glucose level.

MATERIALS REQUIRED

1. Glucose Meter
2. Test Strip
3. Control Solution

Note: Please make sure you are using the same model of test strip and glucose meter.

TEST PROCEDURE

Note: Make sure the solution is at room temperature(59°F to 82°F or 15°C to 28°C) prior to testing.

PREPARATION

Make sure that you have set the glucose meter in the control solution test “” mode, so the result will not be stored in the memory and not be incorporated into the average. Please read your blood glucose monitoring system user manual.

TESTING

1. Insert a test strip, contact bar's end first, into the test port. The meter will automatically turn on. A beep will sound and moving dotted lines will appear followed by a flashing "●" symbol.
2. After the "●" symbol appears, press the M button for 4 sec to switch control solution mode. The "☒" symbol indicates that the meter will mark your current test as a control solution test. Now you are ready to apply the control solution.
3. Gently swirl or invert control solution bottle a few times. DO NOT SHAKE. Discard the first drop of control solution and squeeze a small drop of control solution on a clean nonabsorbent surface (such as a clean piece of wax paper). Do not apply control solution to the test strip directly from the bottle.
4. Bring the tip of the test strip to lightly touch the drop of control solution. Control solution is automatically pulled into the strip through the tip. Hold until the meter beeps. The meter will now be counting down from 5 to 1 and the control solution test result will appear.

CAUTION:

- Use the same model of control solution, test strip and glucose meter.
- DO NOT apply control solution to the test strip directly from the bottle, such operation could be leaded to contaminate and decrease the concentration of control solution. You MUST place a drop of control solution on a clean nonabsorbent surface first.

5. Compare the results with the control solution range printed on the test strip vial. The results should fall within the specified range listed on the test strip vial.

COMPARING CONTROL SOLUTION RESULTS

If the test result falls outside the specified range printed on the Test Strip vial, repeat the test.

RESULTS FALLING OUTSIDE THE SPECIFIED RANGE MAY BE CAUSED BY:

- Error in performing the test
- Control solution temperature is lower than 59°F(15°C) or higher than 82°F(28°C)
- Expired or contaminated control solution
- Expired or contaminated test strips
- Meter malfunction

If the problem persists, the system may not be working properly. DO NOT continue to use the system to test your blood glucose level. If you continue to get results that fall outside the specified range, please call Tyson Bioresearch, Inc. customer service or e-mail : service@tysonbio.com

STORAGE AND STABILITY

For best results, store control solution at room temperature; do not refrigerate. Refer to the expiration date for stability. The solution should NOT be used after the expiration date or 3 months after opening.

For in vitro diagnostic use

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