

ABRA

CONTROL SOLUTION

NORMAL

USE ONLY WITH ABRA GLUCOSE METER
AND ABRA BLOOD GLUCOSE TEST STRIPS

SELF-TESTING DEVICE

- Do not take any decision of medical relevance without first consulting your doctor.
- For diagnostic in vitro use only.
- Only for external use.

INSTRUCTIONS FOR USE

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. When you are using your Blood Glucose Monitoring System for the first time.
2. When you are using a new batch of Test Strips.
3. Anytime you question the performance of the system, or on a regular basis to ensure accuracy, e.g. once a week.
4. When you adjust your diabetic medication plans.
5. When your blood glucose test result is lower or higher than your 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. Actual lot-specific ranges are printed on the Test Strip bottle label.

Control Solution	mg/dL	mmol/l	Caution! This is an example. Ranges on your test strips vial should be considered.
Poziom 1 (LOW)	28-58	1,6-3,2	
Poziom 2 (NORMAL)	92-152	5,1-8,4	
Poziom 3 (HIGH)	261-351	14,5-19,5	

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 use the correct test strip for your specific blood glucose meter model.

TEST PROCEDURE

Note: Make sure the solution is at room temperature(15°C to 35°C or 59°F to 95°F) prior to testing.

PREPARATION

Make sure that you have set the Glucose Meter in the Control Solution test "ctl" mode, so the result will not be stored in the memory and not be incorporated into the average.

NOTE: Please read your blood glucose monitoring system user manual.

TESTING

1. Insert a Test Strip, 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 „●" On the ABRA blood glucose meter, press and hold the button **S** for 3 seconds to enter the control solution mode. The "ctl" 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. Discard the first drop of Control Solution and squeeze a small drop of Control Solution on a clean nonabsorbent surface (such as a ceramic plate). 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 15°C (59°F) or higher than 35°C (95°F)
- 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 Diagnosis Customer Service +48 800 70 30 11 or +48 858 746 928 (Polish language only).

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.

 Storage temperature	 Keep away from the sunlight
 Consult instructions for use	 Keep dry
 Use-by Date	IVD In vitro diagnostic medical device
 Manufacturer	LOT Batch code
Rev. Last revision of the instruction for use	REF Catalogue number
 Do not use if package is damaged	UDI Unique Device Identifier

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