



Suresign Resure Glucose Control Solution

Important:

Please read the Suresign Resure User's Manual before using Suresign Resure Glucose Control Solutions.

Intended Use

The Suresign Resure Self Monitoring Blood Glucose Test System (BGMS) is intended for the quantitative measurement of glucose in venous whole blood or fresh capillary whole blood from fingertip, palm and forearm. Testing is done outside the body (In Vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

Summary and Description

Glucose control solution allow you to perform quality control checks to ensure that your Suresign Resure BGMS is working properly and your blood glucose test results are reliable.

The control solution contains a known amount of glucose, which reacts with Suresign Resure Blood Glucose Test Strips. If the result is within the acceptable range, you know that your system is working right. Acceptable control ranges for control tests with Suresign BGMS are shown on the test strip vial label.

When You should Use the Control Solution

- ◆ When using the Suresign Resure blood glucose meter for the first time.
- ◆ When you open a new vial of test strips.
- ◆ When you think the meter or test strips may be working incorrectly.
- ◆ If your test results do not reflect how you feel.
- ◆ If you drop the meter.
- ◆ If you have repeated a test, and the test results are still lower or higher than expected.
- ◆ For teaching or learning how to use the system.

Reagent Composition

Glucose Normal Control Solution:

- 0.12(w/w)% D-glucose
- 99.88(w/w)% Non-reactive ingredients

Glucose High Control Solution:

- 0.35(w/w)% D-glucose
- 99.65(w/w)% Non-reactive ingredients

Glucose Low Control Solution:

- 0.05(w/w)% D-glucose
- 99.95(w/w)% Non-reactive ingredients

Materials Provided

- Normal Control Solution Volume: 4.0 mL.
- High Control Solution Volume: 4.0 mL.
- Low Control Solution Volume: 4.0 mL.

Warnings and Precautions

- ◆ Suresign Resure Glucose Control Solution is for in vitro diagnostic use only.
- ◆ Suresign Resure Glucose Control Solution is not intended for human consumption or injection.
- ◆ Use the Suresign Resure Glucose Control Solution only for testing with Suresign BGMS and Suresign Resure Test Strips.
- ◆ Shake the control solution gently before each use.

Storage and Handling

- ◆ Store the Suresign Resure Glucose Control Solution at temperatures between 2°C to 30°C (36°F to 86°F).
- ◆ DO NOT freeze.
- ◆ Indicate the first opening date on the control solution vials.
- ◆ Discard any unused portion 3 months after first opening date.
- ◆ Use before the expiration date shown on the vial.

Procedures

Please follow the test procedures for using the control solution.

Step 1: Insert Test Strip. Remove a test strip from the vial and immediately replace the vial cap. Insert the test strip into the slot of the meter, and then the meter will turn on automatically.

Step 2: Apply Sample. When the "◆" symbol is displayed, shake the glucose control solution gently. Holding the glucose control solution vial, discard the first drop of control solution. Then squeeze a drop of control solution slowly onto a plastic plate, remove the control solution vial and recap immediately. Let the control solution on the plastic plate touch the blood collection area at the tip of the test strip. The control solution will be drawn into the strip automatically. Remove the control solution when the reaction zone is full. The meter will begin counting.

Step 3: The reading will appear on the display after 5 seconds.

Step 4: Check if the reading falls within the range printed on the test strips vial.

Interpreting the Readings

If the reading of your test falls within the expected range printed on the test strips vial label, then the test strip and the glucose meter are working together correctly. The results of your blood glucose tests are reliable.

If the reading falls outside the expected range, your meter may not be working properly. Check the following :

- ◆ Have the control solution or test strips been used after their expiration date? Has the control solution been contaminated?
- ◆ Did you forget to replace the cap on the vial of control solutions or test strips?
- ◆ Did you follow the test procedures correctly?

Please repeat the test. In addition, if the reading is still not acceptable, contact your local EPS authorized distributor.

Labeling and Information

	Consult instructions for use		Caution
	Batch code		Do not reuse
	In vitro diagnostic medical device		Temperature limitation 2 - 30°C
	Use by		Catalogue number
	Manufacturer		Control
	Serial number		Authorised representative in the European Community
	Sufficient for		This product meets the requirements of Directive 98/79/EC in vitro diagnostic medical devices



EPS Bio Technology Corp.

No.8, R&D RD III, Hsinchu Science Park Hsinchu, Taiwan 30077
TEL : +886-3-6686868 FAX : +886-3-6686866

E-mail: info@epsbio.com.tw Website: <http://www.epsbio.com>



Obelis s.a.

Boulevard Général Wahis 53, B-1030 Brussels, Belgium
Tel: +(32) 2.732.59 54 Fax: +(32) 2.732.60 03
E-Mail : mail@obelis.net

Distributor:

CIGA Healthcare Ltd.
Kilcran House, Kildowney Road, Ballymena, UK BT44 9EY
E-mail: info@suresign.com Website: www.suresign.com

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