



Linearity Test Kit

Professional Blood Glucose
Management System

Intended Use

SureStepPro Linearity Test Kit is for use with SureStep Brand Blood Glucose Meters and SureStepPro Test Strips for verification of system linearity.

Summary and Principle

The SureStepPro Linearity Test Solutions (Levels 1 through 5) each contain a measured amount of glucose that reacts with chemicals on the SureStepPro Test Strip. The test employs a dry reagent technology based on the glucose oxidase method specific for D-glucose. When you apply a drop of linearity solution to the pink test square on a SureStepPro Test Strip, glucose in the solution reacts with chemicals on the test strip to form a blue color. The intensity of this color directly correlates with the amount of glucose in the solution. This blue color is visible through the confirmation dot on the back of the test strip and is read by the meter – the darker the blue, the higher the glucose level in the solution.

When used according to the same procedure as whole blood, the linearity solutions should provide results near the linearity level value printed on the SureStepPro Test Strip bottle label.

Results may be obtained through the Linearity Report option within the DataLink™ Data Management System (DMS), or compatible DMS, or by manually plotting the test results and drawing the best fit line through the points. When plotted on a graph that displays the test strip lot-specific target values (mg/dL or mmol/L) on the x axis versus the meter results (mg/dL or mmol/L) on the y axis, the data for all five levels should show the appearance of a straight line.

Reagents

Each SureStepPro Linearity Solution is provided as a buffered, stabilized, aqueous solution of D-glucose containing a preservative and other non-reactive ingredients.

The solutions are formulated to react equivalently to a whole blood sample containing the following approximate glucose concentrations:

Level 1	40 mg/dL	2.2 mmol/L
Level 2	106 mg/dL	5.9 mmol/L
Level 3	225 mg/dL	12.5 mmol/L
Level 4	345 mg/dL	19.1 mmol/L
Level 5	450 mg/dL	25.0 mmol/L

Actual lot-specific target values are printed on the SureStepPro Test Strip bottle label.

Precautions

- ◆ For in vitro diagnostic use.
- ◆ Not intended for human consumption.
- ◆ The linearity solutions contain dye that stains clothing.
- ◆ Do not dilute solutions or combine different levels in an attempt to adjust concentrations.

Storage and Handling

- ◆ Store at room temperature below 30°C (86°F). Do not refrigerate or freeze.
- ◆ Shake gently before use. No reconstitution or dilution is necessary.
- ◆ Wipe the vial tip clean and reseal the vial tightly after each use.
- ◆ Do not use linearity solution that has passed the expiration date. Linearity solution expires on the last day of the month indicated on the vial label.

- ◆ Linearity solution can be used for 3 months after opening the vial. Write the opened date on the linearity solution vials when you first open them. Discard any unused portion 3 months after opening.

Instruments

For use with any SureStep Brand Blood Glucose Meter with SureStepPro Test Strips.

Procedure

Materials Provided

- ◆ SureStepPro Linearity Solutions, Levels 1 through 5 (quantity sufficient for approximately 200 tests per vial)

Materials Required but Not Provided

- ◆ SureStep Brand Blood Glucose Meter and applicable operator's guide
- ◆ SureStepPro Test Strips

Optional Materials

- ◆ DataLink DMS software for linearity reporting or compatible DMS.

Test Procedure

To perform a linearity solution test, read the Linearity Test procedure in the appropriate SureStep Brand Meter operator's guide.

Recording Results:

- ◆ If using the SureStepPro Bedside Unit or SureStepFlexx Meter, you may upload the linearity results to the data management system to record and store the data and generate reports as an option.
- ◆ If using the SureStep Hospital Meter, manually record the linearity results according to your institution's policy.

Enter Code:

- ◆ Using the SureStepPro Bedside Unit or SureStepFlexx Meter: enter the correct test strip lot number (and code) in the meter. The lot number and code can be found on the test strip bottle label.
- ◆ Using the SureStep Hospital Meter: set the meter code to match the code printed on the test strip bottle label.

Check the Strip:

- ◆ The Color Chart on the test strip bottle label shows the approximate color of a test strip confirmation dot for 50-mg/dL and 350-mg/dL results. It also shows an off-white shade for a new, unused test strip. DO NOT use the test strip if the confirmation dot is darker than this color.

Apply Linearity Solution:

- ◆ Apply one drop of linearity solution to the center of the pink test square of the test strip.
- ◆ If the entire white pad on the front of the test strip is completely saturated with linearity solution, you have applied too much solution. Repeat the application using a new test strip and apply less solution. Applying too much solution may cause out of range results.
- ◆ After applying the linearity solution, if the confirmation dot on the back of the test strip is not completely blue but shows patches of white, you have not applied enough linearity solution. Repeat the application with a new test strip and apply a larger drop of solution. Applying too little linearity solution may cause out of range results.
- ◆ Perform the test for all five levels. Four replicates are typically suggested for each level with each meter.¹

Expected Values

If using the SureStepPro or SureStepFlexx System, transfer the data to the DMS. Then use the system's Linearity Report Option to plot the data and calculate statistics. Refer to the applicable DMS administrator's guide for details.

If manually evaluating the test results, plot the target (assigned) values on the x axis against the corresponding measured (meter) values on the y axis. Visually inspect the data points to determine if the response appears to be linear and draw the "best fit" straight line through the points. Determine the upper and lower limits of the linear range and their clinical relevance. Examine the data points for outliers and equivalence of scatter at each test level. If necessary, mathematical methods may be used to assess the data for outliers, or goodness of fit.¹

If linearity test results are unacceptable, repeat the test.

NOTE: Each laboratory must establish its own criteria for acceptable linearity results.

Possible causes for out-of-range results may include:

- ◆ procedure error
- ◆ linearity solution is expired, beyond its discard date, contaminated, or inadequately mixed
- ◆ test strip lot number in the meter does not match the lot number on the test strip bottle
- ◆ dirty meter or test strip holder
- ◆ a problem with the test strip (expired, damaged, etc.)
- ◆ Linearity solution outside the 18°–30°C (64°–86°F) system temperature range. (Refer to the appropriate SureStep Brand Meter operator's guide for more information.)
- ◆ applying too much or too little linearity solution
- ◆ Testing linearity solutions at high altitude without applying the correction factors (see below).

If you are unable to resolve the problem, you may have a meter malfunction; call LifeScan for technical help.

IMPORTANT: Higher than expected values may be obtained when linearity solution is tested at altitudes ≥ 2000 ft (≥ 610 m). See Tables 1 and 2 for linearity level altitude adjustments. Correction factors apply only to linearity solutions.

Limitations

- ◆ The linearity target values printed on the test strip bottle label are for SureStepPro Linearity Test Kit Solutions only.
- ◆ The glucose concentrations in these solutions when measured by methods other than SureStep Brand Meters may differ because the amount of glucose added compensates for the different reactivity of glucose in water versus glucose in whole blood.
- ◆ Applying too much or too little linearity solution to the test strip may cause inaccurate results. See *Test Procedure* section.

Altitude Adjustments for Linearity Solutions

A matrix effect² is observed when using SureStepPro Linearity Test solutions when testing at altitudes ≥ 2000 feet (≥ 610 m).

Table 1. Altitude at which adjustment becomes necessary

Linearity Solution	Feet above sea level	Meters above sea level
Level 1	----- no correction necessary -----	
Level 2	≥ 5000 ft	≥ 1524 m
Level 3	≥ 2000 ft	≥ 610 m
Level 4	≥ 3000 ft	≥ 914 m
Level 5	≥ 4000 ft	≥ 1219 m

Table 2. Correction Factors for Adjusting Linearity Target Values

	Testing Altitude (above sea level)				
	2000 ft 610 m	3000 ft 914 m	4000 ft 1219 m	5000 ft 1524 m	6000 ft 1829 m
Level 1	—	—	—	—	—
Level 2	—	—	—	1.02	1.05
Level 3	1.04	1.08	1.13	1.17	1.22
Level 4	—	1.05	1.08	1.11	1.14
Level 5	—	—	1.03	1.05	1.07
	7000 ft 2133 m	8000 ft 2438 m	9000 ft 2743 m	10,000 ft 3048 m	
Level 1	—	—	—	—	
Level 2	1.08	1.1	1.13	1.16	
Level 3	1.26	1.31	1.36	1.4	
Level 4	1.17	1.2	1.23	1.26	
Level 5	1.08	1.1	1.12	1.13	

Adjusting Linearity Target Values for High Altitudes

1. Determine your location altitude and refer to Table 1 to identify the linearity level(s) that require adjustment.
2. Find the corresponding correction factor, if any, listed in Table 2.
3. Adjust the linearity solution target values by multiplying each target value by the appropriate correction factor for that level found in Table 2.

Example: Testing at an elevation of 5200 feet:

Level	1	2	3	4	5
Target Value (from test strip bottle label)	32	107	248	326	446
Multiply by Correction Factor in Table 2	none	1.02	1.17	1.11	1.05
New Target Linearity Value	32	109	290	362	468

NOTE: An adjusted target value is not possible when the adjustment would put the upper limit of the target value above 766-mg/dl (42.5-mmol/L), the highest displayed value with SureStepPro and SureStepFlexx Brand Meters testing in Linearity Special Test Mode, or 500-mg/dL (27.8-mmol/L) for SureStep Hospital Meter. Contact LifeScan Healthcare Professional Line for further assistance:

US: 1 800 524-7226
Canada: 1 888 353-0800



References

1. National Committee for Clinical Laboratory Standards. Evaluation of the linearity of quantitative analytical methods; Proposed Guideline. NCCLS Document EP6-P, 1986.
2. Roberts WR. A tale of two PT materials. *CAP Today*. 1995; 9:65-66.

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