

SureStep[®]Pro[™] Linearity Test Kit and Analytical Measurement Range Verification (AMR)

LifeScan developed the SureStep[®]Pro[™] Linearity Solutions to assist institutional customers in meeting regulatory requirements as well as those of accreditation organizations such as the College of American Pathologists (CAP) and Joint Commission on Accreditation of HealthCare Organizations (JCAHO). LifeScan does not require linearity or AMR testing and the decision to perform this testing should be based on current accreditation and regulatory requirements and your institution's policies.

Advantages of SureStep[®]Pro[™] Linearity Solutions

SureStep[®]Pro[™] Linearity solutions are appropriate for SureStep[®]Pro[™] and SureStep[®]Flexx[™] meters in that they have test strip lot specific target values that minimize misinterpretation due to test sample matrix. Additionally, they require no sample preparation, have been manufactured so that the glucose is in a stable matrix, and contain five glucose levels that cover a wide concentration range. In addition to linearity testing, SureStep[®]Pro[™] linearity solutions may be used to verify the AMR. The linearity target values may not cover the entire AMR of the method (e.g., 0 to 500 mg/dL) and it is up to each institution to assess if the target values for the low (Level 1) and high (Level 5) linearity solutions meet your institution's needs. These solutions can also be used, depending on your needs, to assess precision, recovery, and use error (competency testing).

Using SureStep[®]Pro[™] Linearity solutions to interpret and document the AMR

Before using these solutions, assure that the operator performing the test is thoroughly familiar with the correct operation of the system(s) in use and refer to the package insert instructions for limitations and correct handling of these solutions. At least three levels must be used for verifying or validating the AMR (low, mid, and high).

1. Test each level in replicate (a minimum of 2) and calculate the mean value for each meter in use (initial verification) .
2. For DataLink Control users, use the Linearity Report option in DataLink Control if desired. (See Appendix A)
3. For those that prefer to document the results manually, record the results on Form A (Form B at altitudes >2000 feet). Note: Use of this form is optional.
4. Compare the results to the acceptance range. If acceptable, document and sign the form. Retain records. If unacceptable, refer to the package insert for recommended actions to take or contact LifeScan customer support.

Acceptance criteria for LifeScan Linearity Solutions are ± 12 mg/dL for level 1 and $\pm 20\%$ for levels 2-5. The following example provided illustrates how these data may be documented.

SureStep® Pro™ Linearity Test Kit and AMR

Example: Acceptable Performance

All values within acceptable range

Target (mg/dL) (Strip lot specific)	Mean Result (mg/dL)	Acceptance Criteria	Acceptable range (mg/dL) (Target ± Criteria)	Acceptable?
40	42	± 12 mg/dL	28 - 52	Y
93	101	± 20%	74 - 112	Y
238	230	± 20%	190 - 286	Y
380	380	± 20%	304 - 456	Y
450	460	± 20%	360 - 540	Y

Example: Unacceptable Performance

Level 1 value is not within acceptable range

Target (mg/dL) (Strip lot specific)	Mean Result (mg/dL)	Acceptance Criteria	Acceptable range (mg/dL) (Target ± Criteria)	Acceptable?
40	18	± 12 mg/dL	28 - 52	N
93	95	± 20%	74 - 112	Y
238	240	± 20%	190 - 286	Y
380	395	± 20%	304 - 456	Y
450	460	± 20%	360 - 540	Y

For those institutions that require a more robust assessment for testing the linearity of a method, the Clinical Laboratory Standards Institute (CLSI – previously referred to as the National Committee for Clinical Laboratory Standards or NCCLS) has published voluntary guidelines that provide a number of statistical approaches that may be used.

IMPORTANT: While this represents what we believe is the proper interpretation of the requirements, each laboratory is responsible for requirements and checklists specific to its accrediting agency. Individual states may have additional requirements. Local authorities should be consulted as determined by the laboratory director to determine compliance with state/local regulations. This summary reflects information available as of April 2007 and may be superseded by newer regulations and requirements.

SureStep[®]Pro[™] Linearity Test Kit and AMR

References

¹ College of American Pathologists. Commission on Laboratory Accreditation, Point-of-Care-Testing Checklist. 10/2006

² Sidebottom RA et al. Glucose determinations in plasma and serum: Potential error related to increased hematocrit. Clinical Chemistry 1982;28(1):190-192.

³ SureStep[®]Pro[™] Linearity Test Kit Package Insert AW 052-597-02A, 9/02

⁴ LifeScan Technical Bulletin Effect of Altitude on Linearity Testing Using the SureStep[®]Pro[™] Linearity Test Kit, AW 050-590-01, 1999.

⁵ LifeScan Technical Bulletin Linearity AW 054-868A, 6/97

⁶ NCCLS. Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline. NCCLS document EP6-A (ISBN 1-56238-498-8). NCCLS, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 200

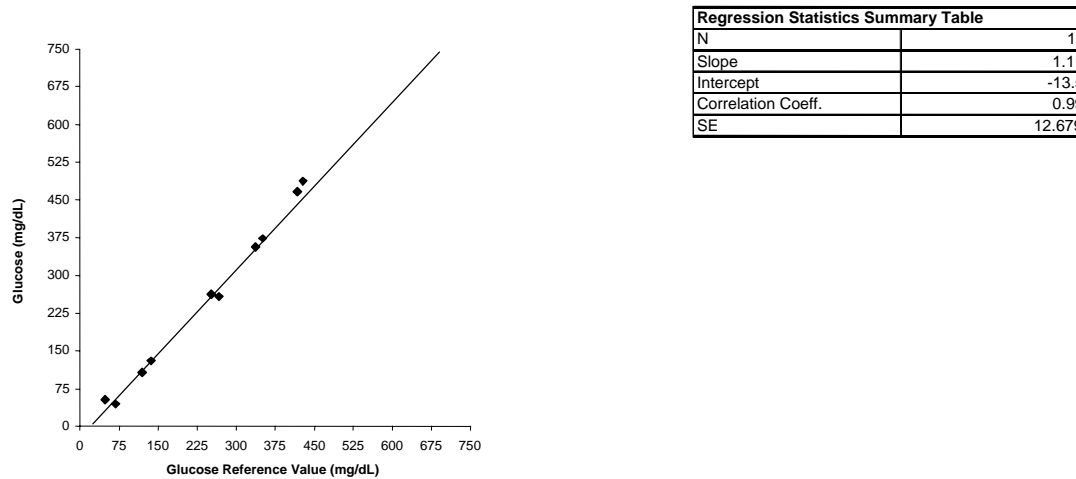
SureStep® Pro™ Linearity Test Kit and AMR

Appendix A - Interpretive Guidelines for AMR Verification using the DataLink Linearity Report

When using the DataLink Linearity report for interpreting the Analytical Measurement Range (AMR), refer to the last column in the bottom table. Acceptable criteria for SureStep®Pro™ Linearity Test solutions are ± 12 mg/dL for level 1 and $\pm 20\%$ for level 2 – 5 when compared to lot-specific reference (target) values.

Example: Acceptable Performance

Linearity Report



Linearity Level	Test Strip Lot Number	Test Strip Exp. Date	Reference Value	N	Mean	SD	%CV	% Difference From Reference Values
1	246418A002	12/2005	48	2	53.7	1.5	2.8%	+11.8%
2	246418A002	12/2005	120	2	107.2	5.2	4.9%	-10.7%
3	246418A002	12/2005	252	2	261.5	2	8.0%	3.8%
4	246418A002	12/2005	337	2	354.5	12.2	3.4%	5.2%
5	246418A002	12/2005	418	2	466.9	8.1	1.7%	11.7%

Level 1: mean within ± 12 mg/dL of Ref. value
 +5.7 mg/dL (Note: Manually calculate mg/dL difference for Level 1)
 Levels 2-5: mean within $\pm 20\%$ of Ref. value

SureStep[®] Pro[™] Linearity Test Kit and AMR

SureStep[®] Pro[™] AMR and Calibration Verification Record Form A

Meter Serial Number: _____

Test Strip Lot #: _____
Test Strip Exp. Date: _____

Target (mg/dL) (Strip lot specific)	Mean Result (mg/dL)	Acceptance Criteria	Acceptable range (mg/dL) (Target ± Criteria)	Acceptable?
		± 12 mg/dL		
		± 20%		
		± 20%		
		± 20%		
		± 20%		

AMR and Calibration
Verification Confirmed: _____

Reviewed By: _____

Date: _____

Meter Serial Number: _____

Test Strip Lot #: _____
Test Strip Exp. Date: _____

Target (mg/dL) (Strip lot specific)	Mean Result (mg/dL)	Acceptance Criteria	Acceptable range (mg/dL) (Target ± Criteria)	Acceptable?
		± 12 mg/dL		
		± 20%		
		± 20%		
		± 20%		
		± 20%		

AMR and Calibration
Verification Confirmed: _____

Reviewed By: _____

Date: _____

Meter Serial Number: _____

Test Strip Lot #: _____
Test Strip Exp. Date: _____

Target (mg/dL) (Strip lot specific)	Mean Result (mg/dL)	Acceptance Criteria	Acceptable range (mg/dL) (Target ± Criteria)	Acceptable?
		± 12 mg/dL		
		± 20%		
		± 20%		
		± 20%		
		± 20%		

AMR and Calibration
Verification Confirmed: _____

Reviewed By: _____

Date: _____

Please make copies before use.

SureStep[®] Pro[™] Linearity Test Kit and AMR

SureStep[®] Pro[™] AMR and Calibration Verification Record

(For use at altitudes > 2000 feet above sea level ONLY)

Form B

Meter Serial Number: _____

Test Strip Lot #: _____

Test Strip Exp. Date: _____

Target (mg/dL) (Strip lot specific)	Correction Factor	New Target	Mean Result (mg/dL)	Acceptance Criteria	Acceptable range (mg/dL) (Target ± Criteria)	Acceptable?
				± 12 mg/dL		
				± 20%		
				± 20%		
				± 20%		
				± 20%		

AMR and Calibration
Verification Confirmed: _____

Reviewed By: _____

Date: _____

Meter Serial Number: _____

Test Strip Lot #: _____

Test Strip Exp. Date: _____

Target (mg/dL) (Strip lot specific)	Correction Factor	New Target	Mean Result (mg/dL)	Acceptance Criteria	Acceptable range (mg/dL) (Target ± Criteria)	Acceptable?
				± 12 mg/dL		
				± 20%		
				± 20%		
				± 20%		
				± 20%		

AMR and Calibration
Verification Confirmed: _____

Reviewed By: _____

Date: _____

Meter Serial Number: _____

Test Strip Lot #: _____

Test Strip Exp. Date: _____

Target (mg/dL) (Strip lot specific)	Correction Factor	New Target	Mean Result (mg/dL)	Acceptance Criteria	Acceptable range (mg/dL) (Target ± Criteria)	Acceptable?
				± 12 mg/dL		
				± 20%		
				± 20%		
				± 20%		
				± 20%		

AMR and Calibration
Verification Confirmed: _____

Reviewed By: _____

Date: _____

Please make copies before use.