

ABSTRACT 580

**Clinical evaluation of SureStep[®] Pro Test Strips
with capillary, venous, arterial, and neonatal blood**

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Abstract

SureStep[®]Pro (LifeScan, Inc.) Test Strips are used with the following blood glucose monitoring systems: SureStep[®]Flex, SureStep[®]Pro, and SureStep[®]Hospital. These hospital systems use glucose oxidase/reflectance technology and report plasma-equivalent glucose concentrations. This multi-site study evaluated the performance of two different formulations of SureStep[®]Pro Test Strip lots (lot 1: reformulation*, lot 2: current formulation) using capillary, arterial, venous, and neonatal blood. SureStep[®]Pro glucose concentrations were compared to those from the YSI 2700 Biochemistry Analyzer (Yellow Springs Instrument Co, Inc., Yellow Springs, OH) and several laboratory reference analyzers. Data was analyzed by linear regression, bias plots, and error grids. Over a wide range of glucose concentrations, results from two SureStep[®]Pro test strip lots compared well with those measured by the reference methods. Bias analysis (YSI plasma reference) for capillary, venous, and arterial results within ± 15 mg/dL (glucose concentrations < 100 mg/dL) or $\pm 15\%$ (glucose concentrations ≥ 100 mg/dL) showed the following:

	<i>n</i> total	<i>n</i> within range	% within range
Capillary (glucose range: 67–367 mg/dL)			
Lot 1	114	104	91.2
Lot 2	115	108	93.9

	<i>n</i> total	<i>n</i> within range	% within range
Venous (glucose range: 0–453 mg/dL)			
Lot 1	112	100	89.3
Lot 2	112	107	95.5

	<i>n</i> total	<i>n</i> within range	% within range
Arterial (glucose range: 55–464 mg/dL)			
Lot 1	101	97	96.0
Lot 2	100	97	97.0

Bias analysis (YSI plasma reference) for neonatal results within ± 10 mg/dL (glucose concentrations < 75 mg/dL) or $\pm 10\%$ (glucose concentrations ≥ 75 mg/dL) showed the following:

	<i>n</i> total	<i>n</i> within range	% within range
Neonatal (glucose range: 17–244.5 mg/dL)			
Lot 1	111	101	91.0
Lot 2	108	101	93.5

Over a wide range of hematocrit levels (15.9–66.5%; manufacturer's claim is 25–60% for non-neonatal and 25–65% for neonatal having glucose levels less than 200 mg/dL), a slightly negative to no obvious trend was demonstrated. This data indicates that both SureStep[®]Pro Test Strip lots provide accurate plasma-equivalent glucose values for capillary, venous, arterial, and neonatal blood.

* Reformulation lot is for investigational use only.

Introduction

- Monitoring blood glucose concentrations at the point of care has become a fundamental element in the clinical management of hospitalized patients.
- Blood glucose monitoring systems need to provide a high level of performance.
- The performance of two formulations for SureStep[®]Pro Test Strips were evaluated in the clinical laboratory.

Materials and Methods

Blood glucose monitoring systems

Meters

- SureStep Hospital (LifeScan, Inc., Milpitas, CA)

Test strips (single lot)

- Lot 1: reformulated
- Lot 2: SureStepPro

Reagents

- SureStep[®]Pro Control Solutions (LOW, HIGH)

Study samples (whole blood)

- Adult capillary
- Adult venous
- Adult arterial
- Neonatal

Materials and Methods

Reference method

- YSI 2700 Select Biochemistry Analyzers (Yellow Springs Instrument, Yellow Springs, OH)

Hematocrit

- STAT-CRIT (Wampole Laboratories, Cranbury, NJ)

Procedure

Venous, arterial, and neonatal

- Quality control was performed daily on all analyzers before testing began.
- Adult arterial, adult venous, and neonatal whole blood samples were obtained from patients with existing physician's orders for laboratory testing.
- Samples were analyzed once with both test strip lots using the SureStep meters. Meters and test strips were randomized.
- Hematocrit levels were determined on the samples using the STAT-CRIT.
- Plasma glucose results were obtained using the YSI.

Capillary

- Quality control was performed daily on all analyzers before testing began.
- Capillary whole blood samples were obtained from fingers of adults with diabetes using a lancet device.
- Samples were analyzed once with both test strip lots using the SureStep meters. Meters and test strips were randomized.
- Hematocrit levels were determined on the samples using the STAT-CRIT.
- Plasma glucose results were obtained using the YSI.

Results

Linear regression analysis

Both test strip lots correlated well with plasma values measured by the YSI reference method over a wide range of glucose values. All regression parameters demonstrated that a high level of accuracy was achieved for capillary, venous, arterial, and neonatal blood.

	<i>n</i>	slope	<i>y</i> -intercept	<i>r</i>	Se
Capillary					
Lot 1	114	1.04	0.59	0.975	17.15
Lot 2	115	1.00	-5.63	0.979	15.38
Venous					
Lot 1	112	1.12	-4.77	0.991	10.59
Lot 2	112	1.03	-3.50	0.993	8.47
Arterial					
Lot 1	101	1.03	3.80	0.992	8.07
Lot 2	100	1.01	-4.74	0.986	10.51
Neonatal					
Lot 1	111	0.934	9.28	0.986	5.06
Lot 2	108	0.868	9.26	0.988	4.46

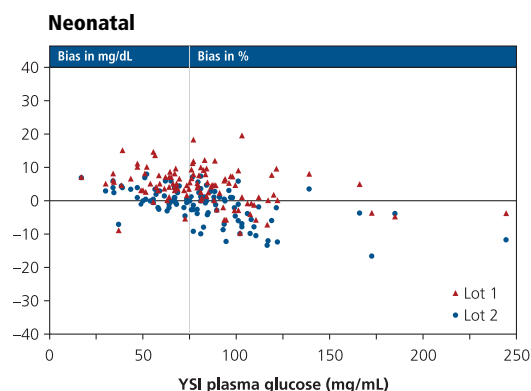
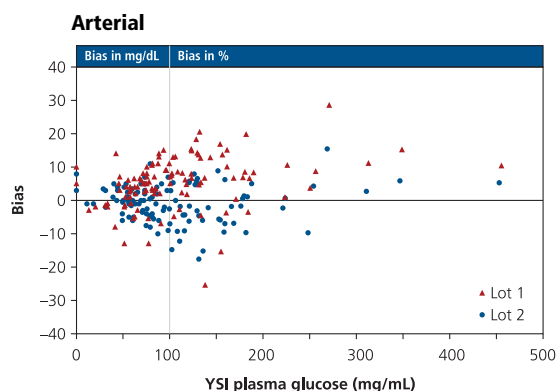
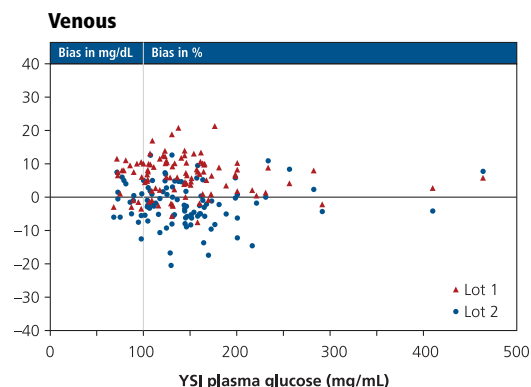
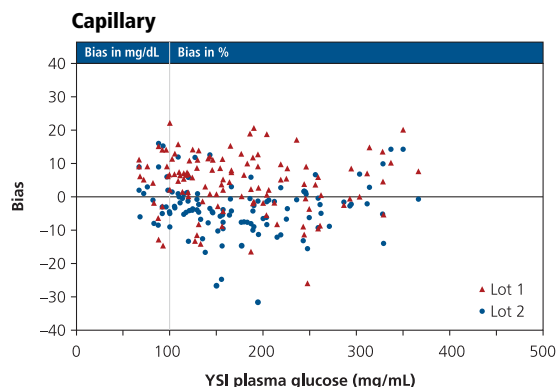
Results (continued)

Bias plots

- Both test strip lots produced clinically accurate results using capillary, venous, and arterial blood. Over a wide glucose range, $\geq 89.3\%$ of the glucose results fell within ± 15 mg/dL (glucose levels < 100 mg/dL) or $\pm 15\%$ (glucose levels ≥ 100 mg/dL) of their corresponding YSI reference results.
- Both test strip lots produced clinically accurate results using neonatal blood. Over a wide glucose range, $\geq 91.0\%$ glucose results fell within ± 10 mg/dL (glucose levels < 75 mg/dL) or $\pm 10\%$ (glucose levels ≥ 75 mg/dL) of their corresponding YSI reference results.

See Abstract for a table of bias results.

NOTE: SureStepPro labeling indicates that the reportable range for neonatal samples is 0–200 mg/dL glucose with a hematocrit range of 25–65%. Results outside these glucose and hematocrit ranges may be inaccurate.



Hematocrit effect

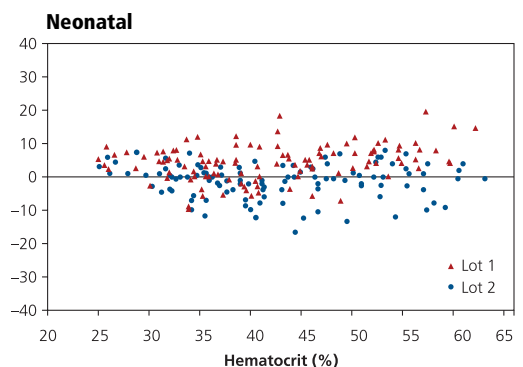
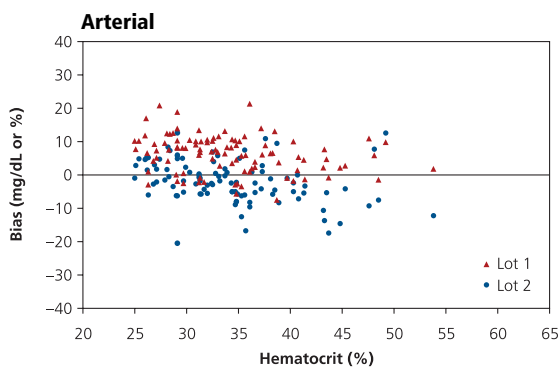
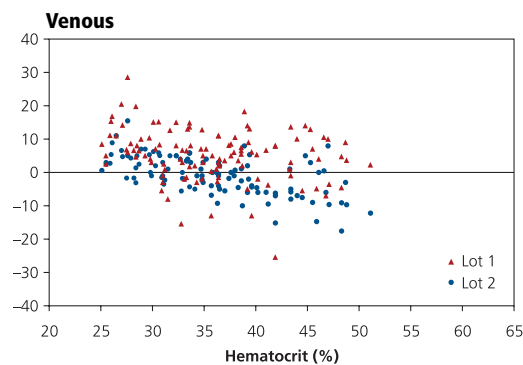
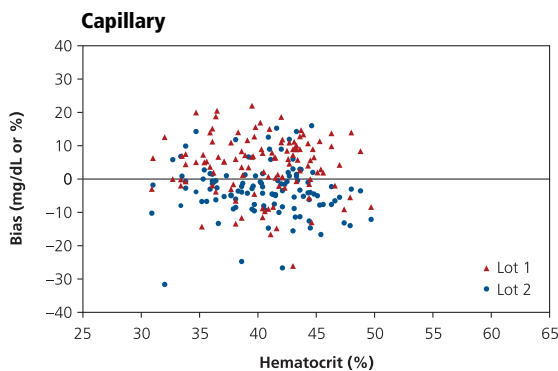
Capillary (range 30.9%–49.7%)
Both test strip lots demonstrated no obvious trend as a function of hematocrit.

Venous (range 25.0%–51.1%)
Lot 2 demonstrated an increasingly negative bias with increasing hematocrit. Lot 1 demonstrated no obvious trend as a function of hematocrit.

Arterial (range 25.0%–53.8%)
Both test strip lots demonstrated no obvious trend as a function of hematocrit.

Neonatal (range 25.0%–62.2%)
Both test strip lots demonstrated no obvious trend as a function of hematocrit.

Test strip manufacturers' claims for hematocrit:
SureStepPro test strips: 25%–60% (non-neonatal samples); 25%–65% (neonatal samples < 200 mg/dL)



Results (continued)

Linear regression analysis

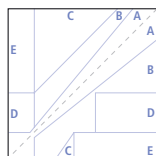
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Error grid analysis

All the results fell within Zone A and Zone B of the error grid. A high level of clinical accuracy was demonstrated for both test strips using capillary, venous, and arterial blood.

	A	B	C	D	E
Capillary					
Lot 1	97.4% (111 of 114)	2.6% (3 of 114)	0%	0%	0%
Lot 2	97.4% (112 of 115)	2.6% (3 of 115)	0%	0%	0%
Venous					
Lot 1	97.3% (109 of 112)	2.7% (3 of 112)	0%	0%	0%
Lot 2	100% (112 of 112)	0%	0%	0%	0%
Arterial					
Lot 1	98.0% (99 of 101)	2.0% (2 of 101)	0%	0%	0%
Lot 2	99.0% (99 of 100)	1.0% (1 of 100)	0%	0%	0%



Error zone definitions¹

- Zone A: clinically accurate.
- Zone B: deviating from the reference method by more than 20%, but would lead to benign or no treatment.
- Zone C: deviating from the reference method by more than 20% and would lead to unnecessary corrective treatment.
- Zone D: potentially dangerous failure to detect and treat blood glucose levels outside of desired target range.
- Zone E: resulting in erroneous treatment.

Conclusions

- Both test strip lots produced clinically accurate results as indicated by bias plots, linear regression analysis, and error grid analysis.
- Both test strip lots showed no obvious trend as a function of hematocrit using capillary, arterial, and neonatal blood.

References

1. Clarke WL, Cox D, Gonder-Fedrick LA, Carter W, and Pohl SL. Evaluating clinical accuracy of systems for self-monitoring of blood glucose. *Diabetes Care*. 1987;10(5):622-628.