WHITE PAPER

SureStepPro® and OneTouch® SureStep® Test Strip blood volume

Clinical accuracy of SureStep Test Strips at 5 µL blood sample volume

INTRODUCTION

Clinical studies conducted by LifeScan have shown that SureStep Test Strips provide accurate blood glucose results at blood sample volumes lower than 10 µL. In response to customer inquiries, additional testing was conducted to verify the performance at a blood sample volume of 5 µL.

METHOD

Six (6) lots of SureStep Test Strips (3 SureStepPro and 3 OneTouch SureStep) were tested with hematocrit-unadjusted whole bloods, using a 5 µL sample size placed on the center of the pink test square on the test strip. Blood samples were collected from 30 donors; the hematocrits ranged from 38% to 54%. Plasma glucose was adjusted to 50, 100, 250, 350, and 450 mg/dL.

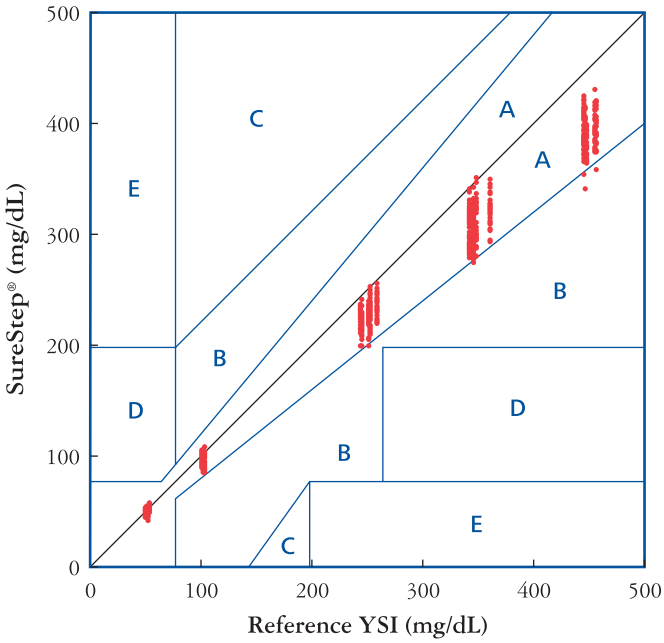
RESULTS

At blood sample volume of 5 µL and normal hematocrit levels, the study showed that all 6 lots of SureStepPro and OneTouch SureStep Test Strips had 99.55% of the blood data in the A zone of the Clarke error grid, and 100% in the A or B zones.

CONCLUSION

SureStepPro and OneTouch SureStep Test Strips produced accurate blood glucose results at 5 µL blood sample volume, if the blood drop is applied to the center of the pink test square and if the adult patient's hematocrit is below 50%. A larger drop of blood is required if the blood drop is not applied to the center of the pink test square, or if the adult patient's hematocrit is greater than or equal to 50%, or if the patient is a neonate.

Clarke Error Grid: 5 µL blood samples



Error grid zone	Percent of results
A	99.55
B	0.45
C	0
D	0
E	0

Zone definitions

Zone A:	Clinically accurate.
Zone B:	Deviating from the reference method by more than 20% but would lead to benign or no treatment error.
Zone C:	Deviating from the reference method by more than 20% and would lead to unnecessary corrective treatment errors.
Zone D:	Potentially dangerous failure to detect and treat blood glucose levels outside of desired target range.
Zone E:	Would result in erroneous treatment.

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