

Accuracy of the Prestige Smart System™ Blood Glucose Monitoring Products



Introduction

In association with nationally acclaimed Emory University in Atlanta, Georgia, HDI conducted a clinical evaluation of the Prestige Smart System™ Meter and Test Strips at the Grady Center for Diabetes. The results indicate that the Prestige Smart System™ provides a superb measure of blood glucose values when compared to a laboratory instrument.

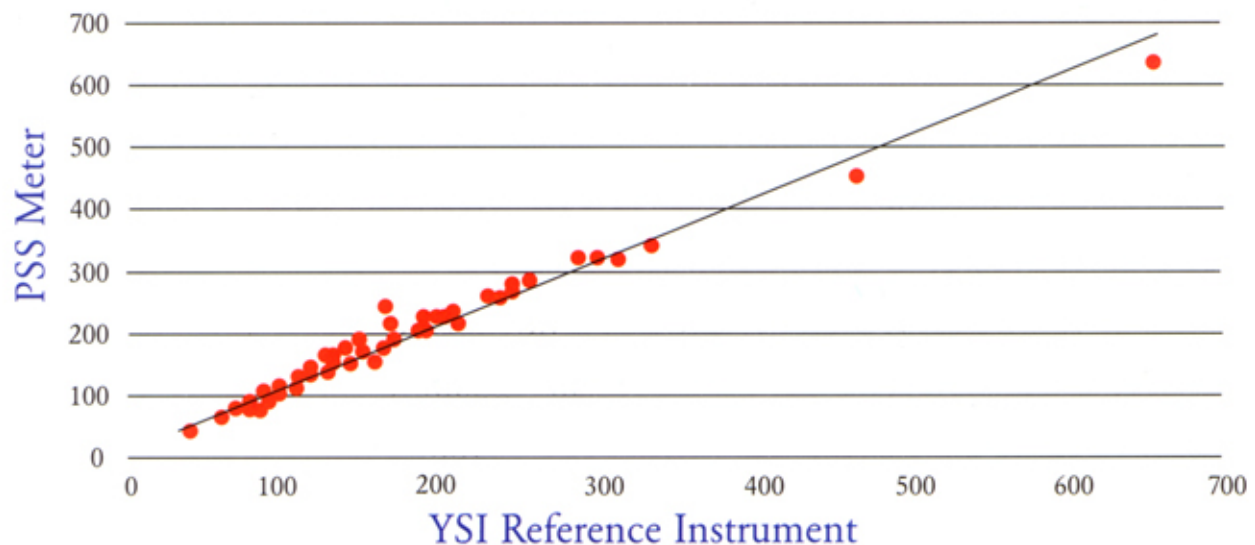


Background

Ninety-nine patients participated in the study. Trained professionals collected blood samples from the fingers of each patient, and tested the samples concurrently using both the Prestige Smart System™ and the YSI 2300 Stat PLUS Glucose Analyzer – a laboratory blood glucose instrument – as a reference. This methodology allowed for an indication of the accuracy of the Prestige Smart System™ when compared to a sophisticated laboratory benchmark.

Prestige Smart System™ Meter results were compared to the YSI Glucose Analyzer results using linear regression analysis. The results are summarized below. The Prestige Smart System™ showed an excellent correlation with the YSI Glucose Analyzer for the entire range of blood glucose values.

Professional Testing Data



N=99 $y=1.013x + 15.65$ slope = 1.013 intercept = 15.65 $r=0.9847$

Discussion

The r-value, or correlation, indicates the overall variation of the Prestige Smart System™ Meter against the YSI Glucose Analyzer laboratory reference with both systems testing the identified patient samples concurrently. A perfect correlation with laboratory values would be 1.00. In the study, the Prestige Smart System™ result was .9847 which is within 1.5% of a perfect correlation. The slope indicates how far the Prestige Smart System™ Meter deviates from the laboratory reference instrument overall. No deviation, or a perfect result, would be 1.0. The slope from the Grady study is near 1.0; which shows very little deviation from the YSI Glucose Analyzer reference laboratory instrument.

In addition to the study conducted at the Grady Center for Diabetes, an internal study was performed. The trained laboratory technician who performed the internal study obtained results, which support the Grady study findings. The results are summarized below.

Meter	r- value	Slope	Linear Regression Equation	No. of Samples
Prestige Smart System™	0.9967	1.009	$y = 1.009x + 3.45$	70

The performance data published within the directions for use of leading commercially available systems, including Prestige Smart System™, are compiled below.

Meter	r- value	Slope	Linear Regression Equation
Prestige Smart System™ ¹	0.995	1.007	$y = 1.007x - 0.24$
Precision QID ²	0.980	0.996	$y = 0.996x + 14.2$
Glucometer Elite ³	0.995	0.95	$y = 0.95x - 0.47$
One Touch Basic ⁴	0.981	1.02	$y = 1.02x - 0.1$
Accu-Chek ⁵	0.977	0.986	$y = 0.986x - 0.4$

Conclusions

The data compiled from the Grady Center for Diabetes study, Home Diagnostics' internal study, and the Prestige Smart System™ directions for use all demonstrate that the Prestige Smart System™ is accurate when compared to a laboratory instrument.

¹ Prestige Smart System™ test strips directions for use, Home Diagnostics, Inc., 2000. Prestige Smart System™ is a trademark of Home Diagnostics, Inc.

² Precision QID blood glucose test strips directions for use, Abbott Corporation, February 1998. Precision QID is a trademark of Abbott Corporation.

³ Glucometer Elite test strips directions for use, Bayer Corporation, September 1998. Glucometer Elite is a trademark of Bayer Corporation.

⁴ One Touch test strips directions for use, Lifescan Inc, a Johnson & Johnson Company, 1996.

One Touch is a trademark of Johnson & Johnson.

⁵ Accu-Chek Advantage test strips directions for use, Roche Diagnostics, 1999. Accu-Chek Advantage is a trademark of Roche Diagnostics.



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