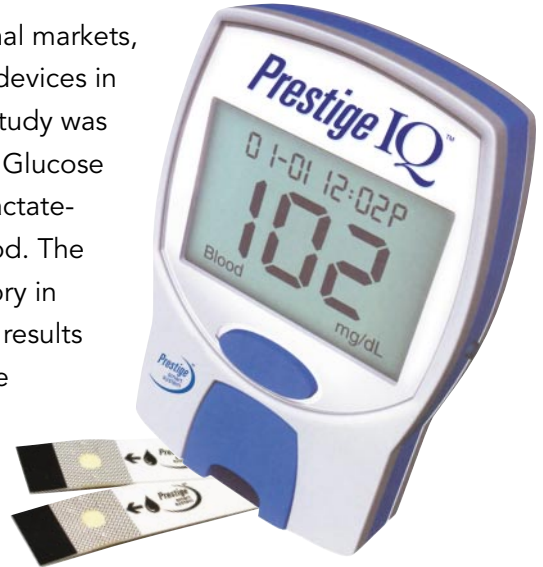


Clinical Study Confirms Prestige IQ™ Blood Glucose Monitor Offers Outstanding Accuracy

Abstract:

As new blood glucose monitors are introduced into international markets, it is necessary to evaluate the accuracy and reliability of these devices in comparison to standard laboratory methods. The goal of this study was to assess the accuracy and reliability of the Prestige IQ™ Blood Glucose Monitoring System in comparison to the Super GL Glucose-/Lactate-Analyzer, a standard for measurement of glucose in whole blood. The study was performed by IKFE, an independent clinical laboratory in Mainz, Germany. Prestige IQ™ meter results were compared to results obtained using the Super GL, an accepted laboratory reference instrument. Data analysis showed that the Prestige IQ™ Blood Glucose Monitoring System demonstrated excellent correlation with the Super GL laboratory reference instrument. In conclusion, the performance of the Prestige IQ™ Blood Glucose Monitoring System is accurate for measuring whole blood glucose levels.



Study Objectives:

The main objective of the clinical study was to evaluate the accuracy of the Prestige IQ™ Blood Glucose Monitoring System in comparison to an established laboratory reference instrument, the Super GL Glucose-/Lactate-Analyzer.

Methodology:

Sixty patients with diabetes were recruited from the inpatient and outpatient group of the investigative site, IKFE. Each patient underwent a brief physical examination, medical history and medication history. Patients were scheduled to visit the clinic two times. On the first visit, clinic healthcare professionals collected and analyzed fingertip capillary blood samples from 60 adult diabetic patients using the Prestige IQ™ Blood Glucose Monitoring System and the Super GL Glucose-/Lactate-Analyzer. Duplicate samples were analyzed using the Super GL and the mean of the results was used in the data analysis. On the second visit, 14+/- 7 days, blood glucose values were obtained again by measuring capillary blood from the fingertip with the Prestige IQ™ Blood Glucose Monitoring System and the Super GL laboratory reference instrument.

As in the first visit, duplicate samples were tested on the Super GL laboratory reference instrument and the mean of the results was used for data analysis.

Results:

All blood glucose measurement data was analyzed using the Clarke Error Grid Analysis. The Clarke Error Grid Analysis is a means of interpreting laboratory comparisons as they relate to therapeutic decisions¹. The assumption upon which the error grid is constructed is that glucose values should be kept within an ideal range of 70-180 mg/dL. If glucose levels fall below 70 mg/dL, then the treatment of choice is ingestion of a carbohydrate. If blood glucose levels are above 180 mg/dL, then the treatment should include administration of insulin. Using this method, the results of the Prestige IQ™ Blood Glucose System are plotted on a graph in comparison to the results using the laboratory reference method. The graph is divided into four zones which represent the error as it relates to the therapeutic decisions made, based on the results. The zones of the error grid are defined as follows:

- Zone A** – Clinically accurate, within +/-20% of the laboratory
- Zone B** – Error greater than +/- 20%, but would lead to benign or no treatment
- Zone C** – Errors would lead to unnecessary corrective treatment
- Zone D** – Potentially dangerous failure to detect hypo- or hyperglycemia
- Zone E** – Erroneous treatment of hypo- or hyperglycemia

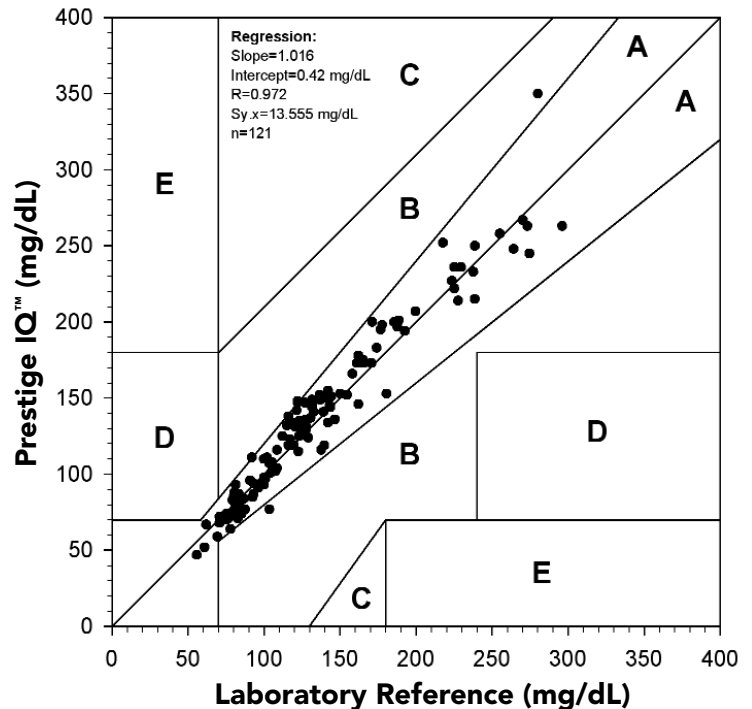
Figure 1: The results of the Prestige IQ™ Blood Glucose Monitoring System showed excellent correlation with the results of the Super GL laboratory method. Zone A of the error grid contains 96% of the measurements, and the other 4% are located in Zone B.

The regression statistics give us a slope of 1.016, an intercept of .42 mg/dL and a correlation coefficient of 0.972.

Conclusions:

The Prestige IQ™ Blood Glucose Monitoring System accurately measures blood glucose levels over a wide range of glucose values. Our findings suggest that the Prestige IQ™ Blood Glucose Monitor is an accurate system for patients to use in the self management of diabetes.

Figure 1
Error Grid Analysis
Prestige IQ™ vs. Super GL



Distribution

Zone	A	B	C	D	E
n	116	5	0	0	0