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Home Diagnostics, Inc.
Dedicated To Diabetes Management



Prestige IQ™ Blood Glucose Monitoring System Shows Excellent Correlation With Laboratory Standard

CLINICAL SITE EVALUATION OF THE PRESTIGE IQ™ BLOOD GLUCOSE MONITOR

OBJECTIVE

To demonstrate the accuracy of the Prestige IQ Blood Glucose Monitor results when compared to the Yellow Springs Instrument 2300 STAT PLUS Blood Glucose Analyzer as the standard laboratory reference instrument.

INTRODUCTION

A clinical evaluation of the Prestige IQ Blood Glucose Monitor was performed by Home Diagnostics, Inc. at a large, metropolitan Diabetes Care Center in Atlanta, Georgia. Trained healthcare professionals collected duplicate fingerstick blood samples from 145 adult diabetic patients. Blood samples were tested congruently on the Prestige IQ and the YSI Glucose Analyzer laboratory instrument. Accuracy was verified by comparing the Prestige IQ results to the YSI laboratory standard using linear regression analysis.

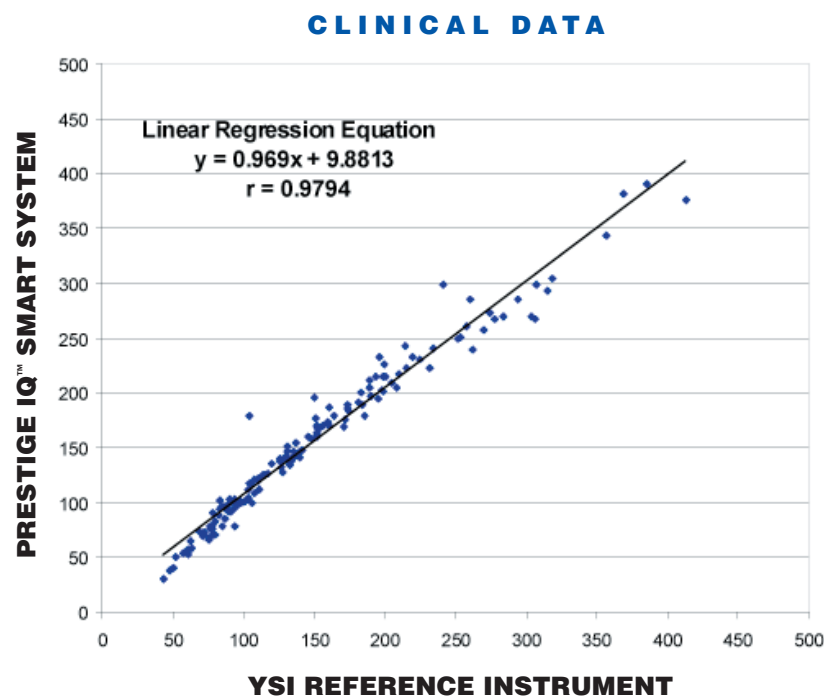
STATISTICAL ANALYSIS OF PERFORMANCE

Using linear regression analysis, the Prestige IQ test results, when compared to the YSI blood glucose results, generated an r-value or correlation of 0.9794. This shows that there is an excellent correlation between the Prestige IQ and the YSI laboratory standard. Results show that the Prestige IQ meets the performance criteria for this industry standard.

Glucose concentrations vary from patient to patient, and the Prestige IQ accurately measures a wide range of glucose concentrations. The linear regression slope measures how well the Prestige IQ responds to varying blood glucose concentrations as compared to the YSI laboratory standard. The Prestige IQ generated a slope of 0.969, which is near an ideal slope of 1.000.

CONCLUSION

Over a wide range of blood glucose values (43-413mg/dL), Prestige IQ Blood Glucose Monitor results show an excellent correlation with YSI laboratory standard results.



In a clinical evaluation comparing the Prestige IQ Blood Glucose Monitor versus the YSI laboratory standard, the Prestige IQ meets the National Committee for Clinical Laboratory Standards criteria.

Patients Confirm the Prestige IQ Blood Glucose Monitoring System is Easy to Use

PATIENT EVALUATION ON EASE OF USE OF THE PRESTIGE IQ™ BLOOD GLUCOSE MONITORING SYSTEM

INTRODUCTION

A patient evaluation of the Prestige IQ Blood Glucose Monitoring System was performed by Home Diagnostics, Inc. at a large metropolitan Diabetes Care Center in Dallas, TX. The purpose of the study was to evaluate the feedback from patients with diabetes regarding ease of use of the Prestige IQ Blood Glucose Monitor and Prestige Smart System Test Strips.

PROCEDURE

All participants attending a diabetes education class were asked to participate in the study by filling out an initial questionnaire relating to demographics and specific diabetes self-management practices.

After completing the initial questionnaire, participants were instructed in the use of the Prestige IQ Blood Glucose Monitor by either a Certified Diabetes Educator or a Registered Nurse. The participants were asked to demonstrate specific tasks including coding the meter, performing quality control testing using the standard strip and glucose control solution, and performing a finger-stick blood glucose test. The participants evaluated the skill level necessary to perform the task by completing a 5-7 statement questionnaire. A final evaluation form was given to each participant to determine an overall rating of the Prestige IQ.

BACKGROUND

Twenty-two female and fourteen male adults with diabetes ranging in age from 29-84 years participated in the study. Eighty-one percent of the participants completed a high school level of education or higher. The participants had a mean diabetic history of 5.2 years. The majority of participants (83%) had a diagnosis of Type 2 diabetes and 64% of all participants received diabetes education at the time of diagnosis. All of the subjects had been monitoring their blood glucose levels at home, and thus were familiar with self-testing. Sixty-nine percent of the participants tested their blood glucose level two or more times per day. The majority of the participants had been instructed on blood glucose monitoring by either a diabetes educator (40%) or by reading the instructional materials enclosed with the meter (29%). Seventy-nine percent of the participants selected "ease of use" as the most important feature in selecting a monitor.

PATIENT EVALUATION

All 36 participants successfully performed the tasks of coding the meter, performing a standard strip test, and performing a glucose control test. The patient evaluation on coding the monitor and performing a finger-stick blood glucose test is included in the diagrams below. The overall evaluation of the Prestige IQ is located in the diagrams below.

CONCLUSION

All participants rated the Prestige IQ Blood Glucose Monitor as very easy to code. In addition, 90% of participants rated the overall finger-stick blood glucose test as very easy/easy to perform. Ninety-nine percent of participants strongly agree/agree that they would use the Prestige IQ to monitor their daily blood glucose levels. Overall, 100% of the participants rated the Prestige IQ as excellent or good.

