

CLINICAL EVALUATION OF THE SIDEKICK™ BLOOD GLUCOSE MONITORING SYSTEM



Objective:

To demonstrate the accuracy of the new Sidekick™ blood glucose monitoring system when used by healthcare professionals and diabetes patients.

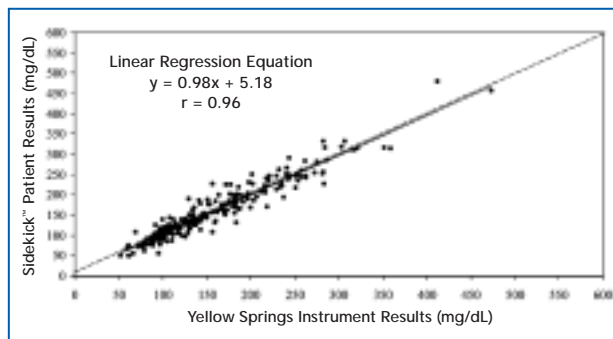
Introduction:

An independent clinical evaluation of the Sidekick™ System was performed at four clinical sites nationwide. Two-hundred and twenty-nine people with diabetes, and experience in self-monitoring of blood glucose, were recruited by healthcare professionals and asked to participate in the study. Participants read the Sidekick™ System instructions for use, including the owner's manual and quick reference guide. Then each participant was asked to perform a fingerstick blood glucose test using the Sidekick™ System. At the same time, trained laboratory professionals obtained fingerstick blood samples from each participant for analysis using the Yellow Springs Instrument (YSI) 2300 STAT blood glucose analyzer. Accuracy was determined by comparing the test results obtained by participants using the Sidekick™ System to the test results obtained by professionals using the YSI blood glucose analyzer.

Healthcare Professional Study Results:

Capillary blood samples ranging from 52-473mg/dL were collected by healthcare professionals from 229 participants. Samples were evaluated using both testing methods, and a linear regression analysis was performed to calculate the correlation between the two test methods. Linear regression analysis of results yielded a slope of 0.98, a y-intercept of 5.18 and an r-value of 0.96.

Sample size	r-Value	Linear Regression Equation
n=229	r=0.96	y=0.98x + 5.18



Patient Study Results:

Sidekick™ System results were obtained from 212 patients and compared to parallel results obtained on the Yellow Springs Instrument Model 2300 STAT. This study shows that patients, when self-testing, and laboratory professionals are able to obtain accurate results when compared to results obtained from a laboratory system.

In addition to fingertip studies, a study was performed to compare forearm and finger stick blood glucose results using the Sidekick™ System. Sidekick™ System blood glucose tests from both the forearm and fingertip, were performed by patients themselves (n=100) and on patients' blood by healthcare professionals (n=108). During a steady glucose state, this study demonstrates substantial equivalence between forearm and finger blood glucose values obtained by patients and healthcare professionals using the Sidekick™ System.

Conclusion:

The Sidekick™ System shows excellent correlation with the YSI laboratory standard over a wide range of blood glucose values (52-473mg/dL). More importantly, study participants successfully used the Sidekick™ System to obtain accurate blood glucose results.

Home Diagnostics, Inc.

Dedicated To Diabetes Management

The Smart Choice™ for Diabetes Monitoring