

Clinical Evaluation of the TRUEtrack® Blood Glucose Monitoring System



Objective:

To demonstrate the accuracy of the TRUEtrack® Blood Glucose Monitoring System when used for the first time by diabetes patients.

Introduction:

A clinical evaluation of the TRUEtrack® System was performed at four clinical sites nationwide. Two hundred 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 TRUEtrack® 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 TRUEtrack® 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 using the TRUEtrack® System to the test results obtained by professionals using the YSI blood glucose analyzer.

Analysis of Results:

Capillary blood samples ranging from 52-473mg/dL were collected from the 229 participants. Samples were evaluated 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 |

Conclusion:

The TRUEtrack® 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 TRUEtrack® System to obtain accurate blood glucose results.

