Clinical Performance

Study Design

This clinical study was specifically designed to determine the accuracy and reliability of the Prodigy AutoCode®, Abbott Precision®, Abbott Freestyle®, Bayer Contour®, OneTouch Ultra®, and Accu-Chek Aviva® blood glucose monitoring systems and compare their levels of accuracy to a calibrated YSI glucose analyzer.

Study Approach

Duke University performed an independent study in April 2012 testing the accuracy of six different glucose meter models. Two of each model performed a total of 100 tests each with blood spiked to seven different glucose levels: 32.65, 66.8, 92.2, 185.5, 271, 371.5, and 503.5 mg/dL. Each of the readings was compared to a YSI glucose analyzer using the FDA required ISO 15197:2003 standard for accuracy (95% of results should be within ± 15 mg/dL of the YSI reading at glucose concentrations < 75 mg/dL and within ± 20% at glucose concentrations ≥ 75 mg/dL).

Results

The study was conducted by Duke University. The principal investigators were Mark Feinglos, M.D. and Bruce Lobaugh, Ph.D. Prodigy Diabetes Care, LLC provided financial support for the study.

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