

# Clinical Performance

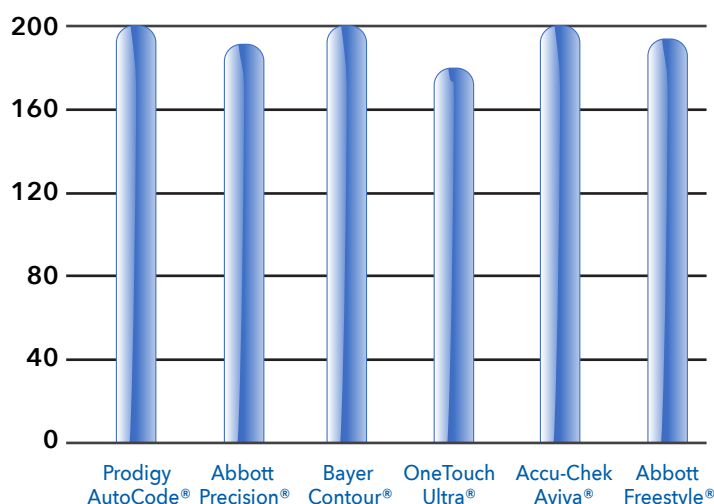
## Study Design

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  $\pm 15$  mg/dL of the YSI reading at glucose concentrations < 75 mg/dL and within  $\pm 20\%$  at glucose concentrations  $\geq 75$  mg/dL).

## Results



### Percentage of results within FDA standard:

Prodigy AutoCode®	<b>100%</b>
Abbott Precision®	<b>97.5%</b>
Abbott Freestyle®	<b>98.5%</b>
Bayer Contour®	<b>100%</b>
OneTouch Ultra®	<b>87%</b>
Accu-Chek Aviva®	<b>100%</b>

## Test Results

100% of the Prodigy AutoCode® results were within the FDA required Standard.

## Conclusion

The Prodigy AutoCode® system's results were within the FDA required ISO 15197:2003 guidelines on 100% of the tests performed.