

Date: 11/7/10
From: Marek Wojciechowski, PhD, Timothy O'Brien, MSc, Charles Humble, PhD
To: Dr. Randall Best and Ms. Lisa Weeks
Re: Prodigy Report

Methods

All supplies, instruments, and materials were provided by Prodigy, under the watchful eyes of independent evaluators. Blood samples were spiked with glucose targeted at 3 glucose ranges: 30-50, 110-150, and 250-400 mg/dL. Totals of 10 meters representing 3 different Prodigy models and 300 test strips from 3 separate lots were provided. The 3 levels of spiked blood were run on a YSI Stat 2300 reference analyzer provided by Prodigy before and after the testing of the Prodigy meters. Thirty strips, 10 at each glucose level, were tested per meter by a convenience sample of lab technicians, students and fellows at NC Memorial Hospital who served as operators. Data were delivered in an Excel spreadsheet to Dr. Humble. Analyses by the authors of this report were conducted using Excel and Stata statistical packages.

Conclusion

The data obtained in this study indicates with strong confidence that the Prodigy Diabetes Care blood glucose testing system performs reliably when operated under controlled conditions. The statistical analysis shows that the results are not dependent on the operator or the sensor lot used.

Comments

- Two of the ten machines failed at one point in the testing. They were restarted after moving the batteries in their containers.
- There is weak evidence that the Prodigy Autocode meter produces less precise results compared to other types, i.e., the Pocket and the Voice.
- One could conclude that the significant discrepancies in reported test results obtained using the Prodigy glucometers at some pediatric clinics were unlikely the result of deficiencies of the Prodigy system. Operator errors should be considered as a most likely cause of those discrepancies. The Prodigy meters tested meet current FDA standards for accuracy. There were no outliers at any level of blood glucose tested using current FDA standards. Indeed, the meters would also comfortably meet proposed more-restrictive standards of +/- 15% around the average above the 75 mg/dL level.

Limitation

We did not test capillary samples from live patients.

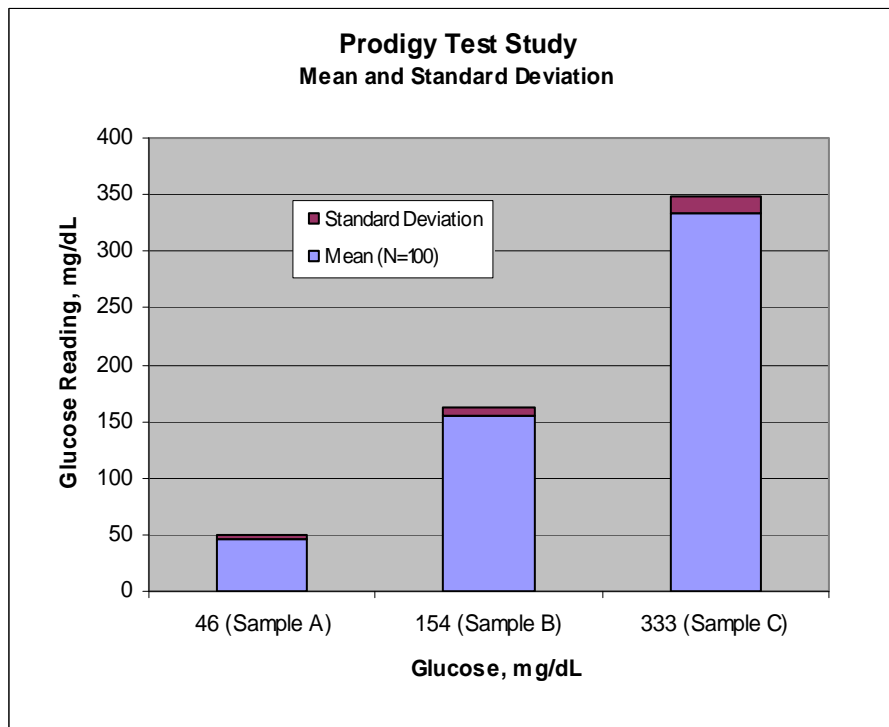
Assessment of the Prodigy Diabetes Care Blood Glucose Testing System

Experimental Setup:

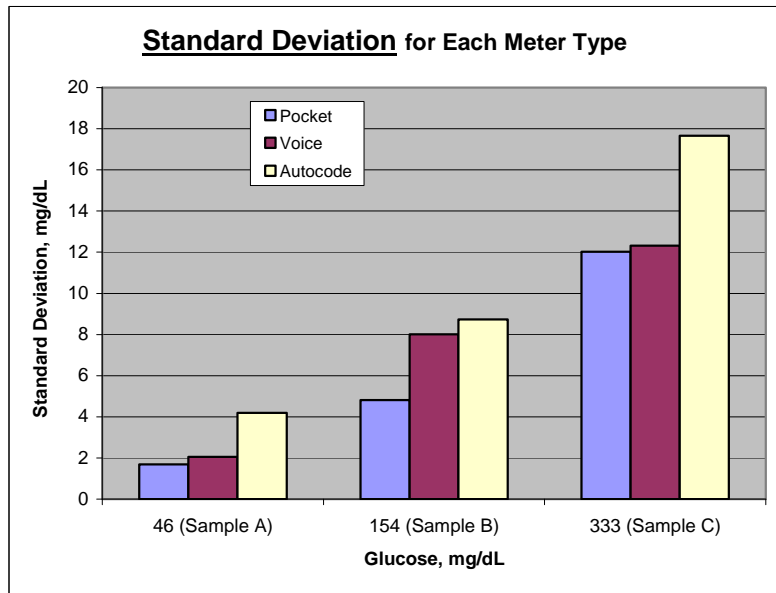
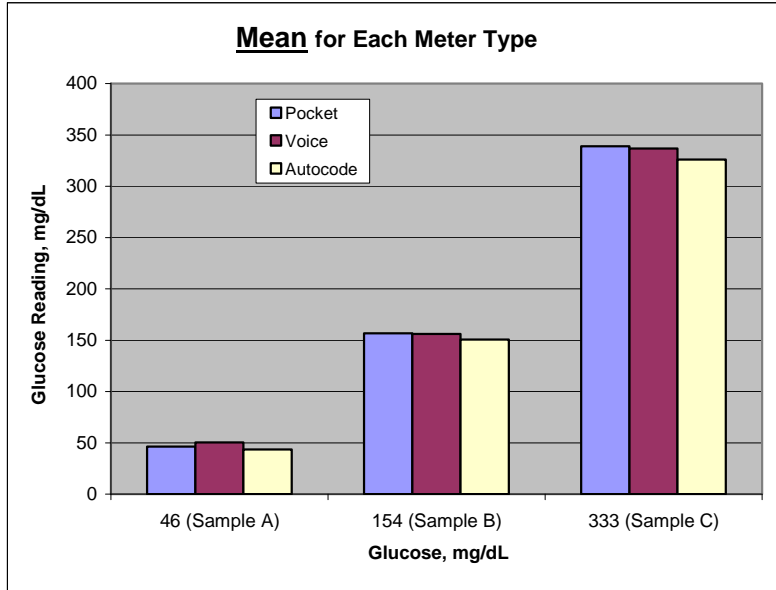
- Tested Variables:
 - Operator
 - Meter type
 - Level of blood glucose
 - Production lot of test strips
- Non-clinical (office) and non-sterile setting was used.
- Ten (10) operators were used none with prior experience in blood glucose measurement
- Ten (10) Prodigy glucometers were used
 - Three (3) Pocket Prodigy meters
 - Three (3) Voice Prodigy meters
 - Three (4) Autocode Prodigy meters
- Three (3) lots of Prodigy blood glucose test strips were used
- Three (3) blood glucose standards were used – human blood spiked with three (3) levels of glucose using glucose standard solutions. Each of these standards was tested using the industry benchmark, a YSI blood glucose analyzer immediately before testing using Prodigy meters.
- All series of measurements were conducted by all operators simultaneously working in the same room.

Summary of Results:

- Total number of measurements: **300**
- The number of failed measurements: **2** (battery had to be re-inserted)
- Relative Standard Deviation (RSD) for the entire data set: **4%**



- RSD for individual operators ranged:
 - from 2% to 8% for Sample A (46 mg/dL)
 - from 2% to 6% for Sample B (154 mg/dL)
 - from 2% to 6% for Sample C (333 mg/dL)
- RSD for individual sensor lots ranged:
 - from 1% to 5% for Sensor Lot #1
 - from 1% to 6% for Sensor Lot #2
 - from 3% to 5% for Sensor Lot #3
- Average RSD for individual meter types was:
 - 3% for the Pocket Prodigy meter (average Relative Spread: 15%)
 - 4% for the Voice Prodigy meter (average Relative Spread: 17%)
 - 7% for the Autocode Prodigy meter (average Relative Spread: 29%)



- Mean results and confidence ranges for each of the 3 Samples were:
 - Sample A: 46 ± 4 mg/dL, RSD = 9%
 - Sample B: 154 ± 8 mg/dL, RSD = 5%
 - Sample C: 333 ± 16 mg/dL, RSD = 5%
- Relative Spread for the entire data set: 6%

