Performance of the GLUCOCARD® Shine by Health Care Professionals against the ISO 15197:2013 Accuracy Criteria

Julie Walker RN BSN PHN, Danielle Maher BS, Patricia Gill BA MLT, and John Gleisner BS PhD
ARKRAY USA, Inc. Minneapolis, MN 55439, USA

**BACKGROUND**

Blood Glucose Monitoring Systems (BGMS) are important tools used in the management of diabetes mellitus. Proper management of diabetes leads to the prevention of micro and macrovascular complications. The ISO (International Organization for Standardization) 15197:2013 is an accepted standard for the accuracy of BGMS. The accuracy boundaries of ISO 15197:2013 require 95% of BGM results to be within ±15mg/dL of the reference analyzer at glucose concentrations <100mg/dL and within ±15% of the reference analyzer at glucose concentrations ≥100mg/dL. In addition, 99% of all results are required to be within the A and B zones of the Consensus Error Grid.

**PURPOSE**

The objective of this study is to determine in ongoing trending studies if the GLUCOCARD® Shine when used by health care professionals continues to provide results that are within the accuracy boundaries of the ISO 15197:2013 Standard.

**METHODS**

Finger stick testing was performed by laboratory professionals on individuals with diabetes (n=24) with one lot of GLUCOCARD® Shine at the ARKRAY Factory, Inc. in Minneapolis, MN. Reference values were obtained by using the YSI Model 2300 Analyzer. The data was analyzed against the accuracy boundaries of the ISO 15197:2013 Standard and the percentage of the results in the A plus B zones of the Consensus Error Grid.

**RESULTS**

100% of the results <100mg/dL (2/2) were within ±15mg/dL of the YSI and 95.5% of the results ≥100mg/dL (21/22) fell within the ±15% of the YSI. All data were within the A and B zones of the Consensus Error Grid. The overall bias to YSI was -3.6%. The correlation coefficient was (r) = 0.99, which demonstrates a strong linear relationship between GLUCOCARD® Shine and the YSI reference method.

**CONCLUSION**

The data acquired on the GLUCOCARD® Shine by laboratory professionals was within the accuracy boundaries of the ISO 15197:2013 Standard.