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Performance comparison of the Glucocard® shine and Fora® G30 against the ISO 15197:2013 accuracy criteria

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Background: Blood Glucose Monitoring Systems (BGMS) are a critical component to managing diabetes and are instrumental in preventing microvascular complications. ISO 15197:2013 is an accepted standard for assessing the accuracy of BGMS. The accuracy boundaries of this standard require 95% of BGM results to be within ±15 mg/dL of the reference analyzer at glucose concentrations <100 mg/dL and within ±15% of the reference analyzer at glucose concentrations ≥100 mg/dL. Furthermore, 99% of all results are required to be within the A and B zones of the Consensus Error Grid.

Objective: This study compared the performance of the Glucocard® shine to the Fora® G30.

Methods: Three lots of test strips were evaluated for performance for each BGMS at ARKRAY Factory, Inc. All testing was conducted under the same IRB approved protocol and used the same group of participants. To further reduce variables samples were drawn directly from the fingertip of confirmed diabetics (n=104) by laboratory professionals. Reference values were obtained using the YSI Model 2300 Analyzer. The data was analyzed against the accuracy boundaries of the ISO 15197:2013 standard and the consensus error grid.

Results: For Glucocard® shine 100.0% of the results <100 mg/dL (6/6) were within ±15 mg/dL and 99.0% of the results ≥100 mg/dL (97/98) fell within ±15%. Overall bias was 1.3% and the correlation coefficient was r=0.99. For Fora® G30 only 85.7% of the results <100 mg/dL (6/7) were within ±15 mg/dL and 95.9% of the results ≥100 mg/dL (93/97) fell within ±15%. Overall bias was 0.5% and the correlation coefficient was r=0.97. All Data for both BGMS were within the A and B zones of the consensus error grid. Glucocard® shine had only one result outside the 2013 accuracy boundaries while Fora® G30 had 5 outside of the boundaries.

Conclusion: Glucocard® shine had better performance than Fora® G30 when assessed against the ISO 15197:2013 accuracy boundaries.

Biography

Julie Walker has completed her Bachelor of Science in Nursing from the University of North Dakota, Grand Forks and is a Member of Sigma Theta Tau International Honor Society of Nursing. She has more than 15 years of experience in the medical device and pharmaceutical industries as an Educator and a Marketer; during which she has more than 50 publications. Currently, she is the Manager of Market Development for ARKRAY USA; a leader in the diabetes care market. She is also on the Executive Council at the Minnesota based American Diabetes Association and is Co-Captain for the ARKRAY USA Step Out and Walk team.

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