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Performance comparison of the Assure® Platinum and EvenCare® G2® blood glucose monitoring systems against the ISO 15197:2013 accuracy criteria

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Background: Blood Glucose Monitoring Systems (BGMS) are used in the management of diabetes. ISO 15197:2013 is an accepted standard for measuring the accuracy of BGMS which requires 95% of results within ± 15 mg/dL of the reference analyzer at glucose concentrations < 100 mg/dL and within $\pm 15\%$ of reference analyzer at glucose concentrations ≥ 100 mg/dL. Furthermore, 99% of results need to be within the A and B zones of the Consensus Error Grid.

Objective: This study compared the performance of the Assure® Platinum and EvenCare® G2®.

Methods: Two lots of test strips for each BGMS were evaluated side-by-side at ARKRAY Factory with the same study participants. Blood samples were drawn from the fingertip of confirmed diabetics ($n=120$) by laboratory professionals. Reference values were obtained using the YSI Model 2300 Analyzer. Data was evaluated against the accuracy boundaries of the ISO 15197:2013 Standard and Consensus Error Grid.

Results: Assure® Platinum demonstrated 100.0% of < 100 mg/dL samples (8/8) were within ± 15 mg/dL and 97.3% of ≥ 100 mg/dL samples (109/112) fell within $\pm 15\%$. Overall bias was -2.8% and correlation coefficient (r)=0.98. For EvenCare® G2®, 87.5% of < 100 mg/dL samples (7/8) gave values ± 15 mg/dL and 92.0% of ≥ 100 mg/dL samples (103/112) fell within $\pm 15\%$. Overall bias was 2.2% and correlation coefficient (r)=0.98. All data for the Assure® Platinum and EvenCare® G2® were within the A and B zones of the Consensus Error Grid.

Conclusion: Assure® Platinum results fell within ISO 15197:2013 accuracy boundaries while EvenCare® G2® results did not meet the accuracy boundaries of the ISO 15197:2013 Standard.

Biography

Julie Walker 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 this time she has been responsible for the submission of more than 50 publications. Currently, she is the Manager of Market Development for ARKRAY USA—a leader in the diabetes care market. Julie 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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