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Accuracy of the Assure® Prism multi as it relates to the ISO 15197:2013 Requirements in the Monitoring of Diabetes Mellitus

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BACKGROUND

Blood Glucose Monitoring Systems (BGMS) are used to monitor and regulate blood glucose levels in diabetes mellitus. The gold standard in measuring the accuracy of BGMS is the ISO 15197:2013. System accuracy performance criteria are defined as 95% of BGMS values at <100 mg/dL must be within ±15 mg/dL of the reference analyzer results, and for samples with glucose concentrations ≥100 mg/dL, 95% of BGMS values need to be within 15% of the reference analyzer results. In addition, 99% of all results are required to fall within A and B zones of the Consensus Error Grid.

PURPOSE

Demonstrate that the Assure® Prism multi meets the ISO 15197:2013 accuracy performance requirements.

METHOD

Three lots of Assure® Prism multi test strips were evaluated for performance and bias comparison (n=600 data points). Reference values were obtained using the YSI Model 2300 Analyzer. Data was analyzed using the minimum system accuracy performance criteria published in the ISO 15197:2013.

RESULT

99.5% of the <100 mg/dL samples (n=191/192) were within ±15 mg/dL thus meeting the 95% accuracy criteria. 99.0% of the ≥100 mg/dL samples (n=403/408) fell within the pre-determined 15% which met the 95% performance criteria. All data were within the A and B zones of the Consensus Error Grid. Overall bias was 0.16% (average of all three lots) demonstrating strong agreement between the Assure Prism multi and YSI reference analyzer results. Good linear regression was demonstrated.

CONCLUSION

Data acquired on the Assure® Prism multi met the ISO 15197:2013 system accuracy performance criteria.

Table 1:
Assure® Prism multi
ISO 15197:2013 guidelines

<100 mg/dL	≤15 mg
n = 192	191
	99.5%
≥100 mg/dL	≤15%
n = 408	403
	99.0%