

Evaluation of the Analytical Performance of the Coulometry-Based Optium Omega Blood Glucose Meter: What Do Such Evaluations Show?

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Abstract

The article entitled "Evaluation of the Analytical Performance of the Coulometry-Based Optium Omega Blood Glucose Meter", by Solnica and colleagues in this issue of *Journal of Diabetes Science and Technology* demonstrates that the Optium Omega blood glucose meter meets the analytical requirements for glucose meter performance and it is stated that the results are clinically useful. The authors studied precision, bias, and reagent lot-to-lot error sources. The ultimate goal of an evaluation is to estimate the distribution of errors (from any source) that will be experienced in routine use. The data collection and analysis methods to achieve this are discussed, as are the standards used to compare the results. Claiming clinical usefulness is almost a boilerplate statement in evaluations but meeting standards does not prove clinical usefulness.

J Diabetes Sci Technol 2011;5(6):1618-1620

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Abbreviations: (FDA) Food and Drug Administration, (GUM) Guide to the Expression of Uncertainty in Measurement, (ISO) International Organization for Standardization

Keywords: error grids, ISO 15197:2003, self-monitoring blood glucose devices, pre-analytical and post-analytical error

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