Evaluation of the Analytical Performance of the Coulometry-Based Optium Omega Blood Glucose Meter

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Abstract

Background:
The goal of diabetes treatment is maintaining near normoglycemia based on self-monitoring of blood glucose (SMBG). In this study, an evaluation of the analytical performance of the coulometry-based Optium Omega™ glucose meter designed for SMBG has been carried out.

Methods:
The assessment of precision and between-lot variability was based on glucose measurements in ethylenediaminetetraacetic acid venous blood samples. Glucose concentrations measured in 289 fresh capillary blood samples using the Omega glucose meter and the Biosen C_line analyzer were compared.

Results:
Within-run imprecision coefficient of variation for the lower and higher glucose concentrations amounted to 5.09 and 2.1%, respectively. The relative lot-dependent differences found for the lower and higher glucose concentrations were equal to 6.8 and 2.6%, respectively. The glucose meter error calculated for various concentration ranges amounted from 2.22 to 4.48%. The glucose meter error met the accuracy criteria recommended by the International Organization for Standardization and the American Diabetes Association. The Passing-Bablok agreement test and error grid analysis with 96% of results in zone A indicated good concordance of results, including glucose concentrations below 100 mg/dl.

Conclusions:
The evaluated Optium Omega glucose meter fits the analytical requirements for its use in blood glucose monitoring in diabetes patients.


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Abbreviations: (ADA) American Diabetes Associations, (CI) confidence interval, (CV) coefficient of variation, (EDTA) ethylenediaminetetraacetic acid, (ISO) International Organization for Standardization, (SD) standard deviation, (SMBG) self-monitoring of blood glucose

Keywords: diabetes mellitus, glucose meter, glucose meter error, self-monitoring of blood glucose

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