

Assessing the Analytical Performance of Systems for Self-Monitoring of Blood Glucose: Concepts of Performance Evaluation and Definition of Metrological Key Terms

Oliver Schnell, M.D.,¹ Rolf Hinzmann, M.D., Ph.D.,² Bernd Kulzer, Ph.D.,³ Guido Freckmann, M.D.,⁴ Michael Erbach, M.D.,⁵ Volker Lodwig, Ph.D.,² and Lutz Heinemann, Ph.D.⁶

Abstract

Reliability of blood glucose (BG) measurements is a prerequisite for successful diabetes management. Publications on the evaluation of self-monitored glucose values, however, are frequently characterized by a confusion in terminology. We provide an inventory of key terms such as accuracy, trueness, precision, traceability, calibration, and matrix effect to avoid future misunderstanding. Definitions are taken from the metrological literature and international norms and explained in a language intended for nonspecialists in metrology. The terms are presented in light of the need to apply generally accepted definitions. In addition, a description of requirements and components for a sound evaluation of BG measurement systems is presented. These factors will also enable improvement in future comparisons of study results.

J Diabetes Sci Technol 2013;7(6):1585–1594

Author Affiliations: ¹Forscherguppe Diabetes e.V., Helmholtz Center Munich, Munich-Neuherberg, Germany; ²Roche Diagnostics GmbH, Mannheim, Germany; ³Research Institute of the Diabetes Academy Mergentheim, Bad Mergentheim, Germany; ⁴Institute for Diabetes-Technology GmbH, University of Ulm, Ulm, Germany; ⁵Sciarc GmbH, Baierbrunn, Germany; and ⁶Science & Co GmbH, Düsseldorf, Germany

Abbreviations: (BG) blood glucose, (ID-GC/MS) isotope dilution gas chromatography mass spectrometry, (ISO) International Organization for Standardization, (SMBG) self-monitoring of blood glucose

Keywords: accuracy, blood glucose meter evaluation, diabetes, self-monitoring of blood glucose, trueness

Corresponding Author: Oliver Schnell, M.D., Forscherguppe Diabetes e.V., Helmholtz Center Munich, Ingolstaedter Landstrasse 1, 85764 Munich-Neuherberg, Germany; email address oliver.schnell@lrz.uni-muenchen.de