

Lot-to-Lot Variability of Test Strips and Accuracy Assessment of Systems for Self-Monitoring of Blood Glucose according to ISO 15197

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Abstract

Background:

Accurate and reliable blood glucose (BG) measurements require that different test strip lots of the same BG monitoring system provide comparable measurement results. Only a small number of studies addressing this question have been published.

Methods:

In this study, four test strip lots for each of five different BG systems [Accu-Chek® Aviva (system A), FreeStyle Lite® (system B), GlucoCheck XL (system C), Pura™/mylife™ Pura (system D), and OneTouch® Verio™ Pro (system E)] were evaluated with procedures according to DIN EN ISO 15197:2003. The BG system measurement results were compared with the manufacturer's measurement procedure (glucose oxidase or hexokinase method). Relative bias according to Bland and Altman and system accuracy according to ISO 15197 were analyzed. A BG system consists of the BG meter itself and the test strips.

Results:

The maximum lot-to-lot difference between any two of the four evaluated test strip lots per BG system was 1.0% for system E, 2.1% for system A, 3.1% for system C, 6.9% for system B, and 13.0% for system D. Only two systems (systems A and B) fulfill the criteria of DIN EN ISO 15197:2003 with each test strip lot.

Conclusions:

Considerable lot-to-lot variability between test strip lots of the same BG system was found. These variations add to other sources of inaccuracy with the specific BG system. Manufacturers should regularly and effectively check the accuracy of their BG meters and test strips even between different test strip lots to minimize risk of false treatment decisions.

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Abbreviations: (BG) blood glucose, (CE) Conformité Européenne, (GOx) glucose oxidase, (ISO) International Organization for Standardization, (SMBG) self-monitoring of blood glucose

Keywords: blood glucose monitoring systems, Conformité Européenne mark, DIN EN ISO 15197:2003, lot-to-lot variability, self-monitoring of blood glucose, system accuracy

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