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Letter to the Editor

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Accuracy Evaluation of a Blood Glucose Meter System for Self-Testing with Three Strip Lots Following ISO 15197:2013 and EN ISO 15197:2015

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Abbreviations CE: Conformité Européene; ISO: International Organization for Standardization; SMBG: Self-Monitoring of Blood Glucose

Introduction

Standardized verification of blood glucose monitoring systems meeting analytical and clinical accuracy requirements is essential for regulatory, clinical, comparative purchasing and post-launch surveillance purposes. ISO 15197:2013 and the European harmonized version EN ISO 15197:2015 [1] outline acceptable minimum accuracy performance criteria for blood glucose monitoring systems for self-testing (SMBG). For compliance, 95% of the results from each of 3 lots of strips must be within either ± 15 mg/dl of the average measured values of the comparison method at blood glucose concentrations <100 mg/dl or within ± 15% for concentrations ≥ 100 mg/dl. In addition, 99% of the system's blood glucose results must fall within zones A and B of consensus error grid analysis.

The TD-4235B is a CE marked, simple, easy to use, glucose oxidase based blood glucose monitoring system manufactured by TaiDoc (TaiDoc Technology Corp. Taiwan, ROC) and supplied in the UK as the GlucoRx Q (GlucoRx Ltd., Surrey, England).

Accuracy was evaluated in a multicentre study conducted at the diabetes centres of three clinics between August and November 2013. The trial was conducted in accordance with the principles of the Declaration of Helsinki, the applicable guidelines for Good Clinical Practice and informed consent obtained. Meters and 3 lots of strips (TD13A123-BOF, TD13D108-COG and TD13E120-BOD) with expiry dates between July and November 2014 were provided by the manufacturer. The clinical accuracy study was conducted according to the analytical requirements of ISO 15197:2013/15 [1] and consisted of 160 subjects. Samples from subjects meeting the inclusion criteria had haematocrits within the range 30 to 55% and fulfilled defined distribution of blood glucose concentrations.

At each study site, healthcare professionals tested fresh finger stick capillary blood samples in duplicate on meters with 3 different lots of strips and in duplicate on an YSI 2300 analyser (YSI Incorporated, Yellow Springs, OH, USA). The YSI comparison method results were averaged and evaluated to verify sample stability. The calibration accuracy of the YSI analyzer at each study site was validated by testing National Institute of Standards and Technology (NIST) secondary reference material SRM 965a, which consists of four levels of glucose concentrations.

All 3 tested lots of strips of the system met the ISO 15197:2013/15 accuracy criteria: lot 1 311/320 (97.2%), lot 2 316/320 (98.8%) and lot 3 314/320 (98.1%). Overall with the 3 lots combined, 98.0% of the meter system results (941/960) were within ± 15 mg/dl of the comparison measurement at glucose concentrations <100 mg/dl and within ± 15% at glucose concentrations ≥ 100 mg/dl. Consensus error grid [2] analysis (Figure 1) showed 100% (960/960) of test results were within zone A with no results falling in zones B, C, D, or E [3].

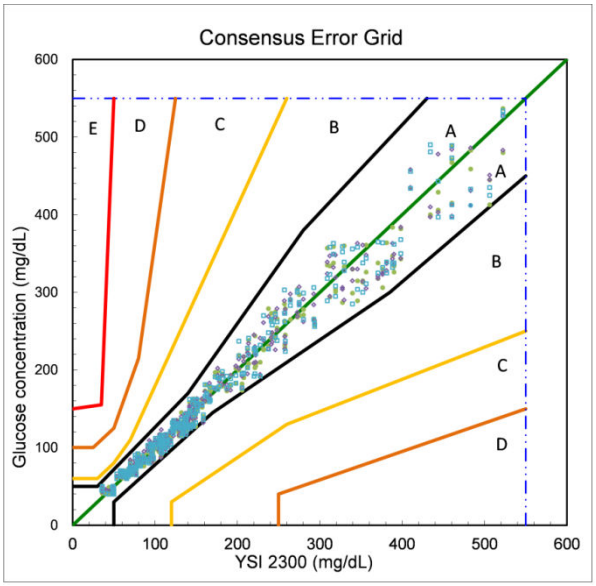

Figure 1: Consensus error grid analysis of the TD-4235B system with 3 lots of strips.

A user trial involving 155 lay people showed similar results with 98.1% (152/155) within ± 15 mg/dl or ± 15%, and 100% within consensus error grid zone A.

In conclusion, this study demonstrates that the TD-4235B SMBG system fulfils and exceeds the minimum analytical and clinical accuracy requirement of ISO 15197: 2013/15.

References

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