Evaluation of Accuracy, Precision and Consensus of Four Laboratory Glucose Measurement Kits with Reference Method

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Abstract

Background and Objective: According to recent changes in diagnostic criteria for diabetes, the harmonization of results obtained from various methods and systems by considering their accuracy and precision is essential. This study aimed to evaluate the accuracy, precision and consensus of some routine laboratory glucose kits in comparison with Hexokinase reference method.

Material and Methods: The participants were 38 diabetic patients with fasting blood sugar (FBS) ≥126 mg/dl, nine prediabetic patients with FBS of 100-125 mg/dl, 15 non-diabetic people with FBS of 60-100 mg/dl and 9 hypoglycemic patients with FBS of ≤60 mg/dl. Their FBS were measured by four routine laboratory glucose kits: Glucose oxidase on BT3000 analyzer with an open system and Hexokinase reference method on a close system (COBAS INTEGRA®400plus analyzer, Roche kit). Accuracy and precision were determined and compared with reference method.

Results: Glucose oxidase methods showed a good agreement with the reference method, in Correlation Coefficient>0.99. Based on regression analysis, the slope of 1.114 for Pars Azmoon, 1.105 for Bionik, 1.121 for Elitech and 1.087 for Human were reported (P<0.05). Error of the mean for ParsAzmoon was 12.79, for Bionik 10.86, for Elitech 12.58 and for Human were 8.46. Coefficient of Variation showed more imprecision for Bionik and Human kits.

Conclusion: Given the same almost standard errors, standard deviations and regression analysis, the precision in four methods is the same but in comparison with Hexokinase, reference method has not the accuracy.

Keywords: Blood Glucose, Glucose Oxidase, Hexokinase, Methods, Consensus