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SYMPOSIUM

Hemoglobin A1c Point-of-Care Assays; a New World with a Lot of Consequences!

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Abstract

Background:

Point-of-care instruments for the measurement of hemoglobin A1c (HbA1c) may improve the glycemic control of people with diabetes by providing a rapid result if the performance of the instruments used is acceptable. A 0.5% HbA1c difference between successive results is considered a clinically relevant change. With this in mind, the In2it from Bio-Rad and the DCA Vantage from Siemens were evaluated according to Clinical and Laboratory Standards Institute (CLSI) protocols.

Methods:

The CLSI protocols EP-5 and EP-9 were applied to investigate precision, accuracy, and bias. The bias was compared with three certified secondary reference measurement procedures. Differences between capillary and venous blood were investigated by an end-user group consisting of nurse practitioners at a diabetes care center.

Results:

At HbA1c levels of 5.1 and 11.2%, total coefficients of variation (CV) for the In2it were 4.9 and 3.3%, respectively, and for the DCA Vantage were 1.7 to 1.8% and 3.7 to 5.5% depending on the lot number of the cartridges. Method comparisons showed significant lot number-dependent results for the In2it and the DCA Vantage compared with the three reference methods. No overall difference was observed between capillary and venous blood for both methods.

Conclusion:

Performance results of the In2it and the DCA Vantage showed variable and lot number-dependent results. To maintain the interlaboratory CV of 5% for HbA1c, the Clinical Laboratory Improvement Amendments rules for waived point-of-care instruments should be revised. An obligation for participating in external quality schemes and taking adequate action should be considered for POC instruments that perform poorly.

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Abbreviations: (CAP) College of American Pathologists, (CI) confidence intervals, (CLIA) Clinical Laboratory Improvement Amendments, (CLSI) Clinical and Laboratory Standards Institute, (CV) coefficients of variation, (HbA1c) hemoglobin A1c, (HPLC) high-performance liquid chromatography, (IFCC) International Federation of Clinical Chemistry, (MDP) medical decision points, (NGSP) National Glycohemoglobin Standardization Program, (POC) point of care

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