

Evaluation of an Over-the-Counter Glycated Hemoglobin (A1C) Test Kit

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Abstract

Background:

Glycated hemoglobin (A1C) monitoring is an integral component of diabetes management. This study was conducted to evaluate the performance of the A1CNow[®] SELFCHECK device when used by lay users and health care professionals (HCPs) to measure A1C.

Methods:

Subjects performed two A1CNow SELFCHECK finger-stick self-tests followed by a finger-stick test of the subject's blood by a HCP. The primary endpoint assessed accuracy of the subject and HCP A1CNow SELFCHECK readings. Secondary endpoints included precision, comprehension of instructional material (written material \pm DVD), and product satisfaction. For accuracy comparison, a venous blood sample was drawn from each subject and tested by laboratory (TOSOH) analysis. Subject comprehension of product instructional material was evaluated via first-time failure (FTF) rate as recorded by the HCP, and subject satisfaction was assessed through written survey.

Results:

A total of 110 subjects with ($n = 93$) and without ($n = 17$) diabetes participated. Of 177 subject A1C values, 165 (93.2%) were within the acceptable range of $\pm 13.5\%$ of the laboratory reference value and considered accurate. Regression analysis showed good correlation of subject values to laboratory and HCP results ($R^2 = 0.93$ for both). The average within-subject coefficient of variation was 4.57% ($n = 74$). The FTF rates with and without instructional DVD were 11.3% ($n = 56$) and 39.6% ($n = 54$), respectively. Subjects with diabetes/prediabetes overwhelmingly indicated that they were "very" to "extremely" likely (93.5%) to discuss their home A1C results with their HCP.

Conclusions:

Lay users found the A1CNow SELFCHECK easy to use, and both lay users and HCPs were able to measure A1C accurately.

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Abbreviations: (A1C) glycated hemoglobin, (CLSI) Clinical and Laboratory Standards Institute, (CV) coefficient of variation, (FTF) first-time failure, (HCP) health care professional, (HPLC) high-performance liquid chromatography, (NGSP) National Glycohemoglobin Standardization Program, (OTC) over-the-counter, (POC) point-of-care, (SD) standard deviation

Keywords: A1CNow, diabetes, glycated hemoglobin A1c, *in vitro* diagnostic for home use, over-the-counter diagnostic kit, point of care

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