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 ± 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 ±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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