

Multi-center accuracy assessment of a1cnow+: a disposable system for monitoring hemoglobin a1c

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Abstract:

Background: HbA_{1c} is indicated for diagnoses (Dx) of diabetes using central laboratory (CL) analyzers. Point of Care (POC) Hb A_{1c} analyzers offer advantages such as real time consultation, but are not indicated for screening or Dx due to perceived inaccuracy. CAP criteria allow +/- 6 % bias and WHO allows POC when it is the only option or when a quality assurance (QA) program exists. POC instruments are often CLIA waived thus not subject to QA proficiency testing. Accordingly, the accuracy of PTS Diagnostics A1CNow+ POC Hb A_{1c} test was evaluated relative to CL Hb A_{1c} systems.

Methods: Blood from 94 subjects was taken from three US wellness centers: Finger stick blood was used to test A1CNow+. EDTA venous blood was used for the Roche Cobas Integra and Abbott Architect. Heparin venous blood was used for the Tosoh G8 comparator. Correlation regression analyses were performed to determine accuracy and % difference to assess bias. Clinical risk stratification was assessed using Hb A_{1c} category (cat) cut points of < 5.7; 5.7-6.4; and ≥ 6.5 and if differences resulted in 0, 1, or 2 cat change. Fisher's exact test was used to assess differences associated with risk.

Results: In total, slopes were 1.020 and 0.986 for CL and A1cNow+ relative to Tosoh (p = 0.63); r of 0.99 and 0.96, and intercept 0.24 and 0.13, respectively (p = 0.64). Bias was 0.3% for A1cNow+ and 3.8% for CL. Risk was unchanged in 81.7% of CL and 77.7% of A1CNow+ measures, resulting in non-statistical (p= 0.54) cat 1 differences between the POC and CL methods. There were no cat 2 risk differences regardless of method.

Conclusions: A1CNow+ was at least as accurate in measuring Hb A_{1c} relative to three CL analyzers and well within the 6% CAP guideline for bias. Risk stratification revealed no differences between the CL and A1CNow+ in classifying the patient state. Ease of use and disposability of A1CNow+ should help assess Hb A_{1c} in situations where CL analyzers are unavailable and to provide physicians with real time information to better manage diabetes.

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Author Disclosure Information:

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