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Multi-Center Accuracy Assessment of A1CNow®+: A Disposable System for Monitoring Hemoglobin A1c

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BACKGROUND

Hemoglobin A1c (HbA1c) is indicated for diagnosis of diabetes using clinical laboratory (CL) analyzers. Point-of-Care (POC) HbA1c analyzers provide an advantage in fast turn-around-time which leads to immediate feedback of results, provider/patient discussion, and better disease management. POC HbA1c analyzers are not indicated for diabetes screening due to perceived inaccuracy. College of American Pathologists (CAP) criteria allow ±6% bias and the World Health Organization (WHO) allows POC when it is the only option or when a quality assurance (QA) program exists. The PTS Diagnostics A1CNow+ system is FDA cleared and CLIA waived, thus not subject to mandatory laboratory QA and proficiency testing. The A1CNow+ system is intended to monitor glycemic control for people with diabetes. Accordingly, the accuracy of PTS Diagnostics A1CNow+ system was evaluated relative to three clinical laboratory HbA1c analyzers.

The A1CNow+ system combines microelectronics, optics, and dry-reagent chemistry strips within a reusable, self-contained, integrated handheld monitor and single-use test cartridge. The A1CNow+ system is calibrated to an NGSP-certified reference analyzer and performs over 50 internal quality control checks when performing a test.

METHODS

The study was conducted at three U.S. wellness centers with three clinical laboratory analyzers:

- Roche Cobas® 6000
- Roche Cobas Integra 800
- Abbott ARCHITECT

For reference, the comparative measurements were performed on the Tosoh G8 analyzer.

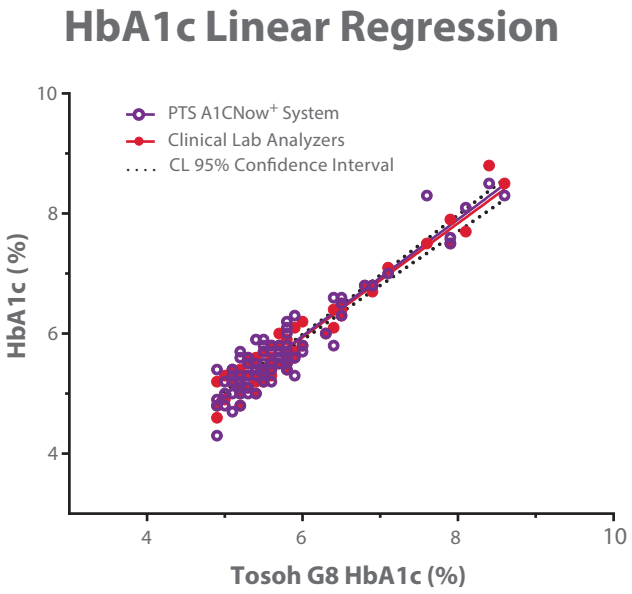
For this study, blood from 94 subjects was obtained and analyzed on the A1CNow+ system (fingerstick), clinical laboratory analyzers (EDTA venous blood), and the Tosoh (heparin venous blood). Correlation regression analysis was performed to determine accuracy and percent difference to assess bias.

Clinical risk stratification was assessed using HbA1c clinical category cut points of <5.7%, 5.7-6.4%, and ≥6.5%. Fisher's exact test was used to assess differences associated with risk.

LINEAR REGRESSION

PTS A1CNow+ system
y = 0.986 (±0.036) x + 0.13 (±0.203)

Clinical Lab analyzers
y = 1.020 (±0.019) x + 0.24 (±0.17)

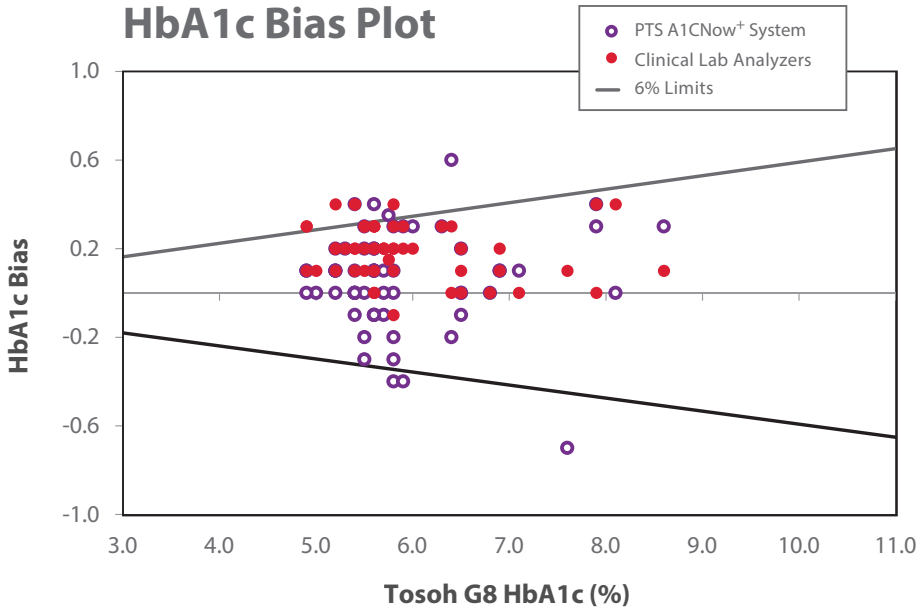


BIAS

Both the A1CNow+ system and CL analyzer results are within acceptable ±6% bias

PTS A1CNow+ system
Average Bias +0.3%

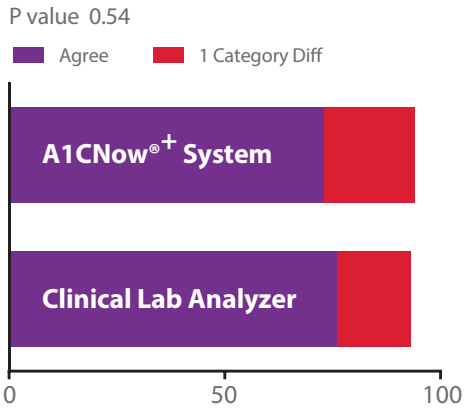
Clinical Lab analyzers
Average Bias +3.8%



CLINICAL RISK

The A1CNow+ system and CL analyzers are both able to accurately assess patient risk.

HbA1c Clinical Risk



Tosoh G8 Risk Stratification

PTS A1CNow+ system
77.7% risk agreement

Clinical Lab analyzers
81.7% risk agreement

RESULTS SUMMARY

In total, slopes were 1.020 and 0.986 for CL and the A1CNow+ system 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 3.8% for CL analyzers and 0.3% for the A1CNow+ system. Risk classification was unchanged in 81.7% of CL analyzers and 77.7% of A1CNow+ system measurements, resulting in non-statistical ($p = 0.54$) category 1 differences between the POC and CL methods. There were no category 2 risk differences regardless of method.

CONCLUSIONS

Based on the results of this study, the PTS Diagnostics A1CNow+ system is as accurate in measuring HbA1c relative to three clinical laboratory analyzers and well within the ±6% CAP guideline for bias. Risk stratification revealed no differences between the clinical laboratory and A1CNow+ system in classifying the patient state.

Ease of use and disposability of the A1CNow+ system provides an advantage in measuring HbA1c in situations where clinical laboratory analyzers are unavailable to provide physicians with real-time information to better manage diabetes.

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