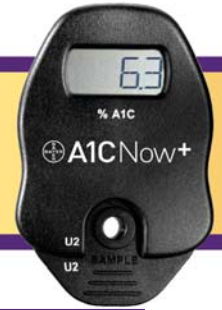


Correlation of A1CNow+® Glycated Hemoglobin (A1C) Assay to an NGSP Standardized Laboratory

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Summary

Objective: A correlation study was conducted to primarily examine the accuracy and precision of the Bayer A1CNow+® point-of-care A1C test compared to an National Glycohemoglobin Standardization Program (NGSP) Certified Laboratory (TOSOH 2.2) in July of 2008. **Methods:** Paired fingerstick and venous blood samples were obtained from 53 (diabetic and non-diabetic) volunteers. Fingerstick specimens were analyzed on the A1CNow+® device and venous samples were analyzed at an NGSP Certified Laboratory on the TOSOH 2.2. Blood samples were run in duplicate on each device. **Results:** Least squares linear regression yielded the slope and intercept values of 0.952 and 0.278 respectively, with a correlation coefficient (r^2) of 0.951. The estimated coefficient of variation (CV) was 3.7% and the average bias %A1C was -0.03. The 95% confidence limits for the bias of individual test results relative to NGSP values were -0.63 to 0.56. **Conclusion: The A1CNow+® provides an accurate and precise result when compared to a standardized NGSP laboratory method.**

Background

Immediate feedback of glycated hemoglobin (A1C) test results to patients with diabetes has been shown to decrease A1C levels.² Point-of-care A1C testing provides rapid turn-around-time from sampling to result, allowing immediate feedback and intervention to better enable disease management.³ A1CNow+® is a multi-use, portable, disposable, CLIA-waived, point-of-care A1C test that requires no capital equipment purchase. Lab-accurate results are available to providers in five minutes, allowing for immediate feedback to patients. Accurate A1C results are essential for appropriate diabetes care and management. Variation occurs between different A1C methods and is dependent upon the calibration and testing methodology of each device. The National Glycohemoglobin Standardization Program (NGSP) was established in 1996 to minimize the variation seen between different glycated hemoglobin methods and standardize A1C test results so that they are comparable to those reported in the Diabetes Control and Complications Trial (DCCT), where relationships to mean blood glucose and risk for vascular complications have been established.⁴ A1CNow+® is annually certified by the NGSP.⁵

Objectives

The primary objective of this study was to assess the accuracy and precision of the A1CNow+® device compared to an NGSP Certified Laboratory (TOSOH 2.2). A secondary objective was to examine the correlation of this NGSP Certified Laboratory (TOSOH 2.2) compared to two other NGSP Certified Laboratories, Fairview University Medical Center (TOSOH G7) and the University of Missouri School of Medicine (TOSOH G7).

Methods

A total of 53 blood samples (fingerstick and venous) were obtained by a laboratory technician from diabetic and non-diabetic volunteers at the Bayer Diabetes Care site in Mishawaka, Indiana from June 23rd to July 3rd, 2008. A1CNow+® fingerstick testing was performed at the Bayer Mishawaka site and venous (heparin) blood samples were sent to an NGSP Level II Certified Laboratory in Sunnyvale, CA for comparative testing on the TOSOH 2.2 by a clinical chemist. Venous blood samples were tested on the NGSP Laboratory (TOSOH 2.2) method within 5 days of the day of blood draw. Three blood samples were dropped from the analysis. Sample #1 was identified as a hemoglobin variant and thus excluded from all analysis due to reported inaccuracies of A1C results associated with variants.⁶ Samples #27 & #42 were excluded from analysis of the A1CNow+® because A1C reported values were >13%. A1CNow+® reports numeric values within the range of 4%-12% and blood samples greater than this range are reported as >13%. This range (4%-12%) is congruent with the blood samples used for NGSP Certification.⁷ Single lot (LN A805018), replicate testing (double) generated a total of 100 data points (50 pairs). Venous blood samples were also sent for testing at the NGSP Certified Laboratories at Fairview University Medical Center (TOSOH G7) and the University of Missouri School of Medicine (TOSOH G7).

Results

Least squares linear regression was performed on the data. A1CNow+® vs. NGSP TOSOH 2.2: The slope and intercept values were 0.952 and 0.278 respectively, with a correlation coefficient (r^2) of 0.951. The estimated coefficient of variation (CV)⁸ was 3.7% and the average bias %A1C was -0.03. The 95% confidence limits for the bias of individual test results relative to NGSP values were -0.63 to 0.56 (Table 1). NGSP TOSOH 2.2 vs. University of Missouri and Fairview University (TOSOH G7): The slope and intercept values were 0.903, 0.554 and 0.937, 0.23 respectively. Correlation coefficients were >0.99, demonstrating a strong correlation between NGSP methods (Table 3, Table 4).

Table 1. Linear Regression Statistics: NGSP TOSOH 2.2 vs. A1CNow+®

n	95 % CI % HbA1C	Slope	Intercept	" r ² "	Average Bias % A1C	CV
100	-0.63, 0.56	0.952	0.278	0.951	-0.03	3.7 %

Table 2. Estimated Bias: NGSP TOSOH 2.2 vs. A1CNow+®

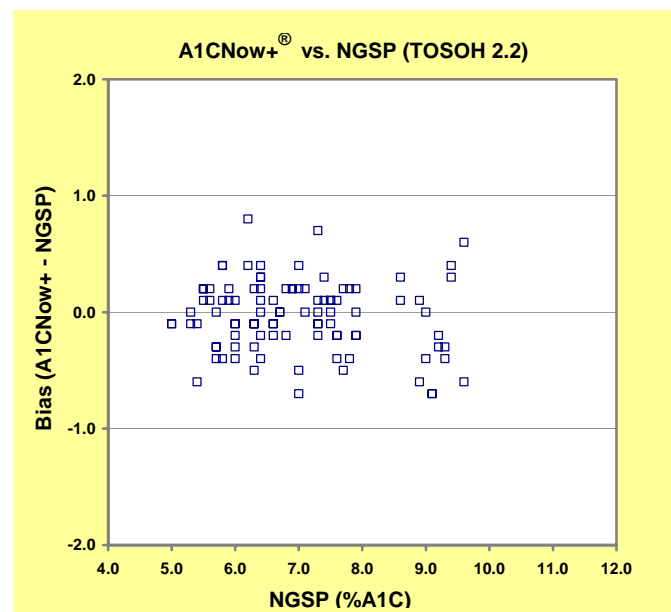
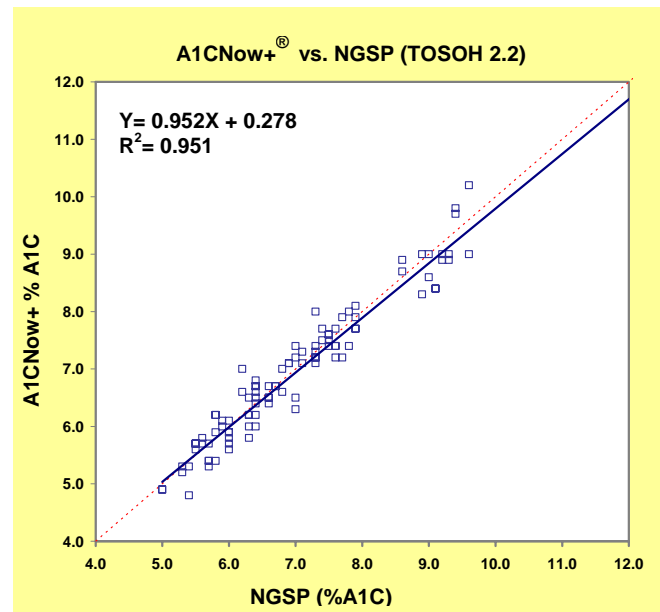
Actual "True" % A1C	Calculated A1CNow+® % A1C ⁹
6	5.99
7	6.94
8	7.89

Table 3. NGSP (TOSOH 2.2) vs. University of Missouri School of Medicine (TOSOH G7)

n	Slope	Intercept	" r ² "
52	0.903	0.554	0.996

Table 4. NGSP (TOSOH 2.2) vs. Fairview University Medical Center (TOSOH G7)

n	Slope	Intercept	" r ² "
52	0.937	0.23	0.998



Conclusion

The A1CNow+® provides an accurate and precise result when compared to a standardized NGSP laboratory method.

Reference

- 1 Bayer HealthCare LLC, Diabetes Care- A1CNow+
- 2 Miller CD et al., Rapid A1C availability improves clinical decision-making in an urban primary care clinic. Diabetes Care 2003; 26:1158-1163.
- 3 Cagliero E et al., Immediate feedback of HbA1C levels improves Glycemic control in type 1 and insulin-treated type 2 diabetic patients. Diabetes Care 1999; 22: 1785-1789.
- 4 NGSP. Background and Rationale. www.ngsp.org/prog/index.html. Accessed 10/1/2008.
- 5 NGSP Certificate of Traceability, Manufacturer Certification. Bayer Healthcare, LLC- A1CNow+. Date of Certification: July 1, 2008. Certificate Expiration: July 1, 2009.
- 6 National Institutes of Health. National Diabetes Information Clearing Houses. <http://diabetes.niddk.nih.gov/dm/pubs/hemovari-A1C/index.htm>. Accessed 10/10/2008.
- 7 NGSP Manufacturer's Information Packet (Protocol). 11/07/2007.
- 8 The calculated A1CNow+ %A1C value represents the expected result based on the data generated in this study, when compared to a "true" NGSP reference result.
- 9 Estimated CV % calculated by analyzing the difference between the duplicate samples.