Professionals - A1CNow+® Overview

Clinical Performance FAQs

1. Is the A1CNow+® accurate?

Accuracy refers to the closeness of agreement between the measured value and the "true" value. Accuracy studies were conducted with 189 diabetic and non-diabetic subjects across three US sites. Fingerstick sampling was performed on each subject for testing with A1CNow+, and venous blood was collected from each subject for comparative testing using an NGSP-certified method. A1CNow+ results were compared to the NGSP reference results. The A1C results ranged from 5.0 %A1C to 12.8 %A1C, with a mean of 7.3 %A1C (reference results). Data analysis consisted of least squares linear regression (x = reference results), bias calculation, and Bland Altman limits. The data are provided below.[1]

A1CNow+ Fingerstick Comparative Testing

(NGSP-certified method is the Tosoh A1C 2.2 Plus)

n	189	Bias at 6% A1C (% difference)	5.89 (- 1.83%)
Slope	1.02	Bias at 7% A1C (% difference)	6.91 (-1.29%)
y-intercept	-0.23	Bias at 9% A1C (% difference)	8.95 (- 0.56%)
"r"	0.95	Avg. % diff	- 1.23%

The results showed that the accuracy of A1CNow+, with fingerstick samples was, on average, 99%. This means that, on average, a true 7 %A1C could read approximately 6.9 %A1C. An individual A1CNow+ result may differ by as much as -1.0 %A1C to +0.8 %A1C from the true result. This represents the 95% confidence limits of a Bland-Altman plot. [2]

A1CNow+ Venous Comparative Testing

(NGSP-Certified method is the Tosoh A1C 2.2 Plus)

Venous blood was collected from 110 diabetic subjects, and each sample was tested on one of three different lots. Aliquots of the venous samples were also tested by the NGSP-certified method, providing comparative results. Data analysis again consisted of least squares linear regression (x = reference results), bias calculation and Bland-Altman limits. The data are provided below.

n	110	Bias at 6% A1C (% difference)	5.95 (-0.8%)
Slope	1.03	Bias at 7% A1C (% difference)	6.98 (-0.3%)
y-intercept	-0.237	Bias at 9% A1C (% difference)	8.01 (+0.1%)
"r"	0.97	Avg. % diff	-0.3%

The results showed that the accuracy with venous sampling was, on average, 99.7%. An individual result may differ by -0.8 %A1C to +0.7 %A1C from the true result. This represents the 95% confidence limits of the Bland-Altman plot. A1CNow+ may be used with either fingerstick (capillary) or venous (heparin-anticoagulated) whole blood samples.[1]

2. Is the A1CNow+ precise?

Precision is the quality of being repeatable in amount or performance. Precision of a test is observed when measurement of a sample has nearly the same value each time it is measured. Precision testing was done under a specialized protocol. Following this protocol, two whole blood samples, one of approximately 6 %A1C (low), and one of approximately 9 %A1C (high), were tested over 20 days and four runs per day, for a total of 80 assays per level. The overall imprecision (including within-day and between-day) was 3.00% CV at the low level and 4.02% CV at the high level.[1]

3. What is the National Glycohemoglobin Standardization Program (NGSP) certification?

The NGSP standardizes glycated hemoglobin test results so that clinical laboratory results 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. A key component of the program is the Reference Laboratory Network. The network interacts with manufacturers of glycohemoglobin methods to assist them first in standardizing their methods and then in providing comparison data for certification of traceability to the DCCT.

4. How does an A1C testing method become NGSP certified?

The NGSP certification process includes the exchange of 40 patient blood samples and a method comparison analysis. A certificate of traceability to the Diabetes Control and Complications Trial (DCCT) Reference Method is issued to any manufacturer or laboratory that successfully completes the certification process. The certificate is effective for 1 year and is specific to the reagents and instrumentation used during certification. The process consists of a 40 sample comparison with a Secondary Reference Laboratory (SRL). In order for a commercial method to be considered traceable to the Central Primary Reference Laboratory, the 95% CI of the differences between methods (test method and SRL method) must fall within the limits of ±0.75%