

Professionals - A1CNow+® Overview

Clinical Performance

Bayer's A1CNow+® is annually certified by the National Glycohemoglobin Standardization Program (NGSP).

- The purpose of the NGSP is to standardize glycosylated hemoglobin test results so that A1C 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.
- In order to achieve NGSP certification, an A1C testing method must successfully complete rigorous testing requirements annually.
- A key component of the certification process 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.
- A1C test methods are awarded a 'certificate of traceability to the DCCT reference method' if they pass rigorous accuracy-testing criteria.[1]

About IFCC

The relationship between the National Glycohemoglobin Standardization Program (NGSP) A1C calibration (expressed as % A1C) and the International Federation of Clinical Chemistry (IFCC) network calibration (expressed as mmol/mol) has been shown to be stable and is given by the master equation: $(\text{NGSP} = [0.0915 * \text{IFCC}] + 2.15)$. For further details and additional references see the NGSP website at <http://www.ngsp.org/>.

The A1CNow+® is NGSP certified (DCCT-traceable) and results can be converted to IFCC units with the master equation. Demonstrating IFCC traceability is a formal process during which A1C blood samples are assigned values by the IFCC network. Manufacturers use these samples to verify alignment of their assay with the IFCC network. Bayer's A1CNow+ is now IFCC-traceable, while continuing to maintain NGSP certification (DCCT-traceable).

A1CNow+® Literature

The studies were supported in whole or in part by Bayer's Diabetes Care.

1. Study published in Journal of Diabetes Science and Technology demonstrates that the A1CNow+® has improved performance and is accessible, accurate, and affordable for both primary and specialist practices. Bode, B.W. et al. "[Advances in Hemoglobin A1C Point of Care Technology](#)," *Journal of Diabetes Science and Technology*, 1, 2007, pp. 319-325. [2]
2. Study presented at American Diabetes Association 69th Scientific Sessions finds In-office A1CNow+® monitor demonstrates precision & accuracy in A1C testing. Lemke, Christian & Matthaei, Stephan. "[The Point-of-Care \(POC\) A1CNow+ Device: Precision and Accuracy of an Improved Version](#)," *Diabetes: A Journal of the American Diabetes Association*. June 2009. Vol. 58, Supp 1. Poster presentation at the American Diabetes Association 69th Scientific Sessions (418-P) [3]
3. Study presented at ADA finds in-office A1CNow+® monitor reliable, accurate in the pediatric endocrine clinical setting. Less, Joane et. al. "Reliability of A1CNow+ in a Pediatric Clinical Endocrine Setting." [Poster presentation at the American Diabetes Association \(ADA\) 67th Scientific Session](#), June 2007.[4]
4. The A1CNow+® provides an accurate and precise result when compared to a standardized NGSP certified laboratory method. Knaebel, J., McKiernan, W., Xie, C., Irvin, B. "[Correlation of A1CNow+ Glycated Hemoglobin \(A1C\) Assay to an NGSP Standardized Laboratory](#)," 2008. [5]