



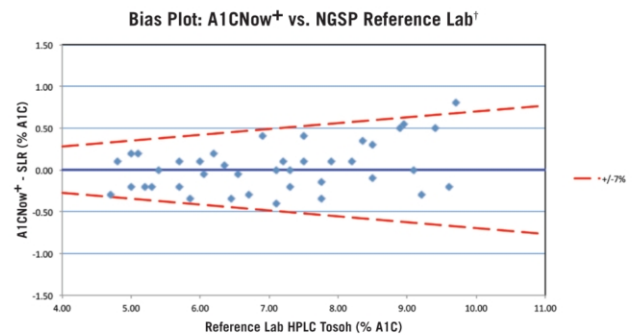
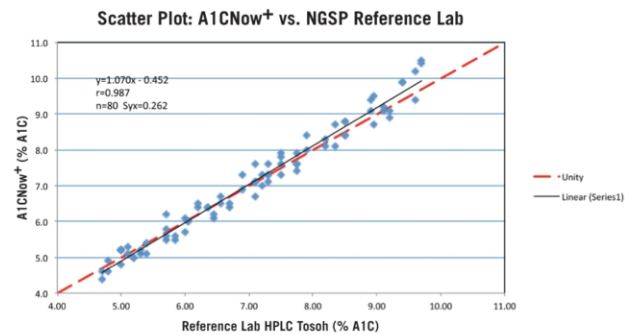
A1CNow+® Accurate Results

NGSP Certification

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



- The purpose of the NGSP is to standardize glycated hemoglobin test results. Standardization allows A1C results to be comparable to those reported in the Diabetes Control and Complications Trial (DCCT) and United Kingdom Prospective Diabetes Study (UKPDS) where relationships between A1C levels and risk for complications have been established.¹
- In order to achieve NGSP certification, an A1C testing method must successfully complete testing requirements annually.¹
- If A1C testing methods pass performance testing criteria, they are awarded a “certificate of traceability to the DCCT reference method”.¹
- A key component of the NGSP 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.¹
- Results*: 95% CI of the differences between the A1CNow+ and the NGSP Reference Lab method were -0.51, 0.59, thus meeting the requirement of +/-0.75% effective for methods certified through 8/31/2012. 39 of 40 results of the A1CNow+ were within +/- 7% (relative bias) of the NGSP Reference Laboratory method, thus meeting the new tighter NGSP manufacturer certification criteria of 37/40.²



†Based on NGSP criteria effective 9/1/2012

NGSP Certification Criteria	Method Results: A1CNow+	Pass (Y/N)
Effective through 8/31/2012: +/- 0.75% A1C, 95% CI	-0.51, 0.59	Y
Effective 9/1/2012: 37 of 40 within +/- 7% (relative)	39 of 40	Y

*Bayer's A1CNow annual NGSP re-certification was received on 8/1/2012, thus certifying under the criteria effective through 8/31/12. Data analysis also demonstrated passing of the tighter NGSP criteria effective 9/1/2012.

Interpreting the Results

As you use A1CNow⁺, you may have questions about the level of performance to expect. The following information will help you answer those questions and interpret differences you may see between results when using A1CNow⁺ and other A1C methods.

Total Error

Total error is a concept that combines both accuracy and precision. Total error is used by the NGSP to describe a test's performance, and it is closely related to the probable error for a single laboratory result. The criteria for NGSP manufacturer certification effective for devices certified through 8/31/2012 require the result be within 0.75% A1C of the Reference Lab (true) value with 95% confidence. As of September 2012, the criteria for certification have been substantially tightened. This criteria applies to methods annually certified after 9/1/2012, and will thus apply to all certified methods by 9/1/2013. Changes in NGSP criteria generally require a 1 year roll over period for currently certified methods. The new NGSP performance requirements for manufacturers and level II laboratories are that 37 of 40 results must be within $\pm 7\%$ (relative bias) of the Reference Lab (true) value.

Difference Between Methods

There will always be differences between multiple test results due to normal variation, time between tests, and differences between methods. In fact, duplicate test results from the same patient will rarely match even when the test is performed using the same method at the same time.

Sources of Variation

There are a variety of methods used to measure A1C, and some methods are susceptible to interference from variant hemoglobins, such as HbAS, HbAC, HbAE, and HbAD. Pathologic conditions that affect red cell half-life can also affect A1C results regardless of the testing method. These conditions may include certain types of anemias, chronic blood loss, or chronic renal failure leading to falsely increased or lowered A1C result. Refer to the NGSP website for additional information at www.ngsp.org.