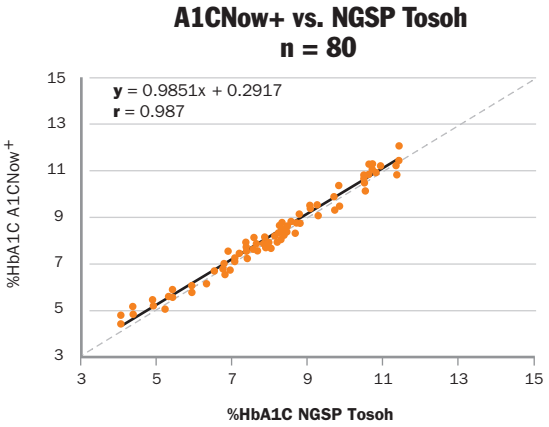
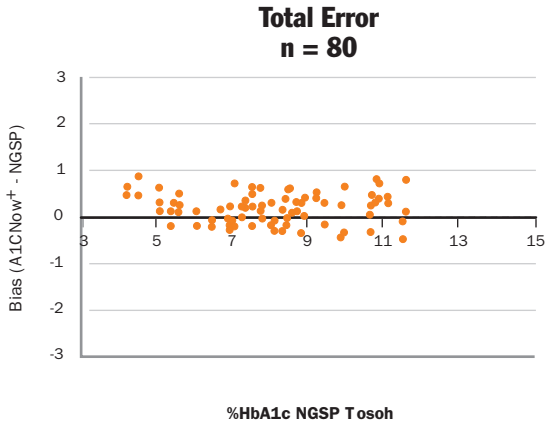
A1CNow+ Accurate Results

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 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.[1]
- In order to achieve NGSP certification, an A1c testing method must successfully complete rigorous testing requirements annually.[1]
- 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.
- A1c test methods are awarded a 'certificate of traceability to the DCCT reference method' if they pass rigorous accuracy testing criteria.[1]





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A1CNow+ MULTI-TEST A1C SYSTEM

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Accurate 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 accuracy, and it is closely related to the probable error for a single laboratory result. A NGSP certification is granted when 95% of the results from a testing method are within ±0.85% of the reference (true) value.[2]

» 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 by the same method at the same time. Within the NGSP's "95% confidence interval of differences" of ±0.85%, differences can sometimes appear greater because one result could be slightly higher and the other could be slightly lower than the reference (true) value.[2]

» Sources of Variation

There are a variety of methods used to measure A1c and all methods are susceptible to interference from variant hemoglobins such as Hb S and Hb C. Pathologic conditions that affect red cell half-life can also affect A1c results regardless of the testing method. These conditions may include iron deficiency anemia (pro-longed red cell survival, leading to increased A1c results), chronic blood loss, or chronic renal failure (shortened red cell survival, leading to lowered A1c results).

1 www.ngsp.org/prog/index.html
2 The 95% confidence interval of the differences is defined by NGSP to be the average difference +/- 1.96 x the standard deviation of the differences under a special protocol that defines the distribution and number of samples. See www.ngsp.org/prog/protocol/prot.html for details.

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