

## Advances in Hemoglobin A1c Point of Care Technology

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### Abstract

Measurement of hemoglobin A1c (A1C) has long been accepted as the best indicator of glucose control over time. Assays for A1C use technologies based on either charge differences (high-pressure liquid chromatography) or structure (boronate affinity or immunoassay combined with general chemistry). These technologies are generally employed in expensive laboratory instruments. More recently, A1C technology has been incorporated into point of care (POC) devices, allowing for immediate availability of A1C measurements, greatly facilitating diabetes care in both specialist and general practices. POC A1C tests should have acceptable performance, standardization to national reference, National Glycohemoglobin Standardization Program (NGSP) certification, simple operation without need for costly instrumentation, and Clinical Laboratory Improvement Amendments (CLIA) waiver. CLIA-waived POC technology includes Bio-Rad MicroMat™ II (distributed by Cholestech as GDX™) and the Axis-Shield Afinion,™ both of which utilize boronate affinity. The DCA 2000®+ utilizes combined immunoassay and general chemistry. These instruments cost \$1000 to \$3000 and require regular maintenance, making them appropriate only for high-volume physician offices. The newly improved A1CNow+™ also utilizes combined immunoassay and general chemistry, but the small, inexpensive, disposable monitor can be used by patients as well as by health care professionals. The new version of A1CNow+ has improved performance through recent introduction of automated solid state chemistry manufacturing, improved fluidics and automated assembly of the test cartridge, error-correcting software, and unitary meter calibration with factory calibration directly to the NGSP reference standard.

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**Abbreviations:** (A1C) hemoglobin A1c, (ADA) American Diabetes Association, (CLIA) Clinical Laboratory Improvement Amendments, (DCCT) Diabetes Control and Complications Trial, (FDA) Food and Drug Administration, (HPLC) high-pressure liquid chromatography, (NGSP) National Glycohemoglobin Standardization Program, (POC) point of care, (SDK) sample dilution kit, (SRLs) Secondary Reference Laboratories

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