

## Accuracy and Precision of the Axis-Shield Afinion Hemoglobin A1c Measurement Device

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### Abstract

#### *Background:*

The Afinion HbA1c (Axis-Shield) is a newer point-of-care device for measurement of hemoglobin A1c (A1C) using a boronate affinity method unlike the more commonly used DCA immunoassay method (Siemens Medical Solutions Diagnostics). The Afinion's accuracy and precision, when compared with high-performance liquid chromatography (HPLC) and DCA methods, have not been established in pediatric practice settings.

#### *Methods:*

Capillary blood was collected from 700 subjects with diabetes mellitus at seven Pediatric Diabetes Consortium sites. Each subject's A1C was measured locally using Afinion and DCA devices, and by a central laboratory (University of Minnesota) using a Tosoh HPLC method. In addition, repeated measurements on six whole blood samples provided by the National Glycohemoglobin Standardization Program (NGSP) were taken at three clinical centers using the Afinion and DCA methods and centrally using the Tosoh HPLC method to assess the precision of each device.

#### *Results:*

The coefficient of variation for measurements of whole blood samples for precision analysis was 2% for Afinion, 3% for DCA, and 1% for HPLC. In the patient samples measured at the seven clinic sites, the Afinion generated higher A1C results than the HPLC (mean difference = +0.15;  $p < 0.001$ ), while the DCA produced lower values (mean difference = -0.19;  $p < 0.001$ ). The absolute differences with HPLC were similar for the Afinion and DCA (median 0.2%) with a slight advantage for the Afinion when compared with DCA ( $p < 0.001$  by rank test). The DCA tended to read lower than HPLC, particularly at high A1C levels ( $p < 0.001$ ), while the Afinion's accuracy did not vary by A1C.

*continued* →

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**Abbreviations:** (A1C) hemoglobin A1c, (CI) confidence interval, (CV) coefficient of variation, (DirecNet) Diabetes Research in Children Network, (HPLC) high-performance liquid chromatography, (NGSP) National Glycohemoglobin Standardization Program, (PDC) Pediatric Diabetes Consortium, (POC) point of care, (RAD) relative absolute difference, (SD) standard deviation

**Keywords:** accuracy, diabetes mellitus, glycated hemoglobin, HbA1c, point-of-care testing, precision

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**Abstract cont.****Conclusions:**

When compared to the central laboratory HPLC method, the differences between the results of the Afinion and DCA devices are clinically insignificant, and the Afinion and DCA have similar accuracy and precision when used in pediatric practice settings.

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