Technical Bulletin

Hemoglobin A1c, DBS

Self-Collection Capillary Blood Microsample Method.

Performance Characteristics

● Within-Run Precision

Within-run precision was determined by testing microsamples containing two concentrations of Hemoglobin A1c. Each of the microsamples was tested ten times:

Mean HbA1c (%)	Standard Deviation	Coefficient of Variation (%)
4.6 9.7	0.1 0.1	2.2 1.0

● Clinical Sensitivity and Specificity

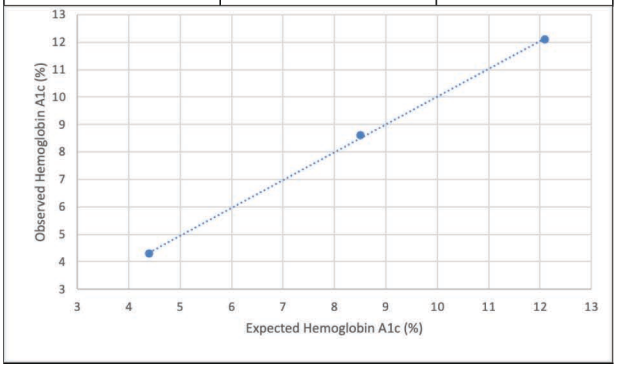
Clinical sensitivity and specificity were determined by testing paired venous samples and capillary blood microsamples from 50 donors and the results evaluated at a cut-off value of 6.0 %:

N=50	Capillary HbA1c ≥ 6.0 %	Capillary HbA1c < 6.0 %
Venous HbA1c ≥ 6.0 % < 6.0 %	10 4	0 36

● Linearity

Capillary blood samples containing different levels of HbA1c, expanding throughout the reportable range, were selected and the assay was performed in triplicate:

Observed HbA1c (%)	Expected HbA1c (%)	Recovery (%)
4.3 8.6 12.1	4.4 8.5 12.1	97.7 101.2 100.0



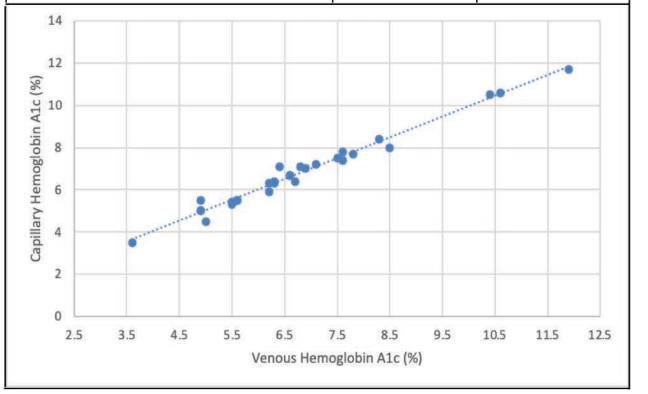
● Microsample Stability

Hemoglobin A1c dried blood microsamples are stable for two weeks when stored at ambient temperature during regular shipping and handling conditions.

● Accuracy

Paired venous samples, and capillary blood microsamples containing varying concentrations of Hemoglobin A1c (HbA1c), were tested. HbA1c concentrations observed for the dried blood microsamples versus venous (immunoturbidimetric method) were statistically analyzed by simple regression.

N=25		
Correlation Coefficient		0.9796
Slope		0.9875
Intercept		0.0850
	Microsample	Comparable Standard Method
Mean Value of HbA1c	6.78	6.78
Standard Deviation of Range	1.80	1.81



● Sample Requirements

The HbA1c dried blood microsample test requires capillary blood placed into a Microcollection device. The device is then placed in the return box and mailed to the laboratory for analysis.

● Convenience and Simplicity

Simple stepwise instructions are provided to health awareness participants for collection of a Microsample using a finger lancet:

1. The collection kit is provided
2. Participant deposits 5 blood drops into transport device
3. The Microsample is mailed to the laboratory

● Interpretation

Hemoglobin A1c is a biomarker for diabetes risk assessment. Results higher than 6.0 % are associated with abnormal glycemia over the past 2 or 3 months.