DTI Laboratories, Inc.

Technical Bulletin

Capillary Hemoglobin A1c
Performance Characteristics

Within-Run Precision Within-run was determined by assaying capillary collected samples containing various concentrations of Hemoglobin A1c. Each sample was assayed in replicates of two in twenty different runs. Both whole blood (WB) and capillary data are presented for comparison below.

Mean %A1c	Standard Deviation	% Coefficient of Variation (CV)
3.2 (CB)	0.02	.051%
6.0 (CB)	0.01	0.059%
14.6 (CB)	0.08	0.091%
4.0 (WB)	0.02	0.065%
7.6 (WB)	0.011	1.000%
15.0 (WB)	0.085	0.069%

Between-Run Precision Between-run precision was determined by performing a series of duplicate measurements of two different samples over a series of twenty different runs (n=20). Both whole blood (WB) and capillary blood (CB) are presented.

Mean %A1c	Standard Deviation	% Coefficient of Variation (CV)
3.2 (CB)	0.01	1.3%
6.0 (CB)	0.02	1.2%
14.6 (CB)	0.02	1.4%
4.0 (WB)	0.05	1.1%
7.6 (WB)	0.06	1.2%
15.0 (WB)	0.05	1.3%

Accuracy Paired whole blood (venous/vein) and EDTA capillary samples containing a variety of concentrations of HbA1c were analyzed. Percent (%) HbA1c concentrations observed for capillary samples versus EDTA whole blood (vein) samples were analyzed by linear regression.

Correlation Coefficient	0.992
Slope	0.980
Intercept	0.988

WB/CB Comparison		
	Capillary Blood	***Venous Blood***
Mean %A1c	6.0	6.0
% A1c Range	3.2-19.4	3.2-20.1
Standard Deviation A1c	1.2	1.0

Total Error Determination Total error is a measurement of the overall analytical performance of an assay and combines both accuracy and precision. Total error is equal to the % Bias of the DTI Laboratories Hemoglobin Capillary A1c assay was calculated using the linear regression formula, derived from the comparison of the capillary % HbA1c assay versus the comparable whole blood methodology. Total CV = 0.09 (CVC 2 + CV WB 2)½.The results of the total error analysis for the DTI capillary % A1c assay at both normal and highly elevated % A1c levels are presented below.

%A1c Concentration	% Bias	Total %CV	Total Error % (HbA1c)
3.2 %	0.2	1.4%	± 0.12%
6.0%	0.1	1.3%	± 0.11%
7.6%	0.1	0.8%	± 0.09%
14.6%	0.2	1.6%	± 0.15%

Expected Values A population of 165 non-diabetic individuals were analyzed using the capillary % A1c methodology. The expected values generated utilizing these values are presented below.

	Lower Limit of %A1c	*Upper Limit of %A1c*
Expected Values	4.2%	5.9%

Linearity of procedure/methodology
(HPLC-IE Linearity range of assay: 3.2% - 19.2%. Specimen Requirements Capillary blood collection requires 10 µl drop of capillary blood. The blood is placed in a 1 ml vial of EDTA/.025KCN,

Specimen Stability Capillary A1c blood samples are stable for 30 days or more. Samples were tested at a following number of days in transit and thresholds of environmental temperatures.

Days	*Mean Capillary % A1c*	*Bias (%)*
1	4.2%	0.0%
5-6	9.0	0.0
7-14	9.0	0.0
15-21	9.1	+ 0.1
22-30	9.1	+ 0.1

Temperature Threshold Study
Temperature indicator failure strips were applied to sample containers containing two levels of A1c capillary samples. The following demonstrates the results of temperature variation.

Temperature Indicator Strips	%A1c	Observed Results	Variance
130° F	6	5.0	-1.00
25° F	6.0	5.9	-0.10
130° F	14.0	12.0	-2.00
125° F	14.0	13.8	0.200
-20° F	6.0	5.3	-0.70
-10° F	6.0	5.8	-0.200
-20° F	14.0	13.2	0.800
-10° F	14.0	13.8	0.20

% A1c values. Known values at 6.0% and 14.0% were applied.