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Comparison of test results for several analytes using capillary blood versus venous blood on the Atellica CH and Atellica IM Analyzers

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Background

Capillary blood collection is a minimally invasive method used inside and outside of traditional healthcare settings, especially important for home monitoring, pharmacies, and those with difficult veins, or needle phobia. Capillary blood is suitable for diagnostic testing at the point of care and within core laboratories. This study compared results from capillary* and venous blood samples for common chemistry (CH) and immunoassay (IM) methods on core laboratory Atellica CH and Atellica IM Analyzers.[1-21]

Methods

- An Institutional Review Board-approved clinical study was performed at Babson Diagnostics, Inc. with ambulatory adult subjects recruited with informed consent.
- The specimen equivalence study was designed per CLSI EP35.[22] Matched set samples were collected: venous blood using Vacutainer SST and EDTA (comparators) and capillary blood using Microtainer SST and MAP EDTA tubes. A total of 97–115 matched sets were assayed. Samples were collected on a rolling basis and assayed in duplicate within 4 hours of collection using one reagent lot on one Atellica CH or Atellica IM Analyzer.
- Data were analyzed by regression of the capillary vs venous comparator samples, utilizing the first replicate from each sample for slope, intercept, and correlation coefficient. Relative repeatability was estimated by pooled SD ratio with 95% CI for each parameter.
- Chemistry assays included Enzymatic Hemoglobin A1c (A1c_E), Alanine Aminotransferase (ALT), Albumin (AlbP), Alkaline Phosphatase (ALP_2c), Aspartate Aminotransferase (AST), Calcium (Arsenazo III) (CA_2), Calcium (cresolphthalein) (Ca), Total Cholesterol (Chol_2), electrolytes (A-LYTE IMT Na K Cl), Diazo Direct Bilirubin (D_DBil), Diazo Total Bilirubin (D_TBil), Enzymatic Creatinine (ECre3), Glucose Hexokinase (GluH_3), HDL Cholesterol (HDLC), LDL Cholesterol (LDLC), Total Protein (TP_2), Triglycerides (Trig_2), Urea nitrogen (UN_c).
- Immunoassays included Free T4 (FT4), Total T3 (T3), and Thyroid Stimulating Hormone (TSH3-ULII).

Results

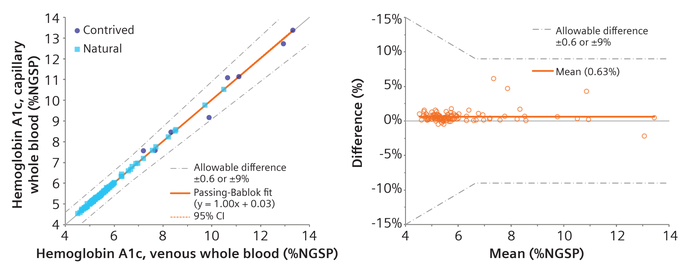
Assay slopes ranged from 0.92–1.04 and correlation coefficients (r) were >0.950, except for Potassium (0.936). Overall, testing covered at least 80% of the entire assay range. The repeatability SD ratio for capillary to venous samples ranged from 0.59–1.33, with ratio 95% CI lower bounds ranging from 0.41–0.92 and upper bounds ranging from 0.86–1.91.

The design requirements for specimen equivalence were met for capillary versus venous samples on the Atellica CH and IM Analyzers. When analyzed by Deming regression, Weighted Deming regression, or Passing Bablok the capillary samples on the Atellica CH and IM Analyzers recovered samples spanning at least 80% of the measuring interval, with slopes of 1.00 ± 0.10 and a correlation coefficient (r) ≥0.950 (except for Potassium) compared to venous samples on the Atellica CH and IM Analyzers. Figure 1 presents Deming, Passing Bablok fit, and difference plots for select assays listed in Table 1, for capillary vs venous samples on the Atellica CH or IM Analyzers.

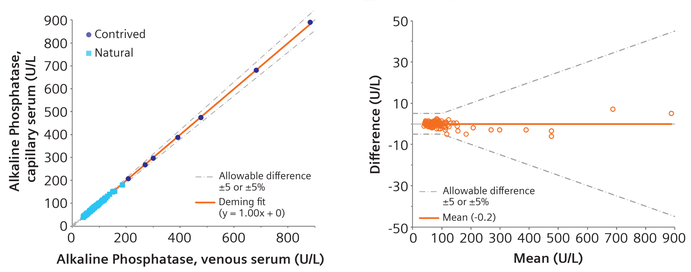
Table 1. Specimen equivalency results for capillary (Y) versus venous (X) serum

Analyte	Assay	Slope	Intercept	Sample Interval	R value	n	SD, Y/X (95% CI)
Whole Blood							
Hemoglobin A1c	A1c_E	1.00	+0.03 %NGSP	4.5–13.32 %NGSP	0.998	109	0.79 (0.54,1.15)
Serum							
Alanine Aminotransferase	ALT	0.99	+0 U/L	7–871 U/L	1.000	114	1.00 (0.69,1.45)
Albumin	AlbP	1.00	+0.0 g/dL	3.1–7.5 g/dL	0.992	114	1.00 (0.69,1.45)
Alkaline Phosphatase	ALP_2c	1.00	+0 U/L	40–883 U/L	1.000	114	0.71 (0.49,1.03)
Aspartate Aminotransferase	AST	0.99	+2 U/L	11–847 U/L	1.000	109	0.78 (0.53,1.13)
Calcium	CA_2 (Arsenazo III)	1.00	+0.0 mg/dL	4.5–13.4 mg/dL	0.983	114	0.86 (0.59,1.24)
Calcium	Ca	1.00	+0.0 mg/dL	4.2–14.1 mg/dL	0.983	114	0.63 (0.43,0.9)
Total Cholesterol	Chol_2	1.00	+0 mg/dL	74–581 mg/dL	0.999	115	1.00 (0.69,1.44)
Chloride	A-LYTE IMT Cl	1.00	+2.00 mEq/L	78.0–166 mEq/L	0.990	114	1.09 (0.75,1.58)
Potassium	A-LYTE IMT K	0.92	+0.49 mEq/L	2.01–8.98 mEq/L	0.936	99	1.00 (0.67,1.49)
Sodium	A-LYTE IMT Na	1.00	+0 mEq/L	70.0–197 mEq/L	0.991	115	1.04 (0.72,1.51)
Direct Bilirubin	D_DBil (Diazo)	0.93	-0.01 mg/dL	0.10–10.71 mg/dL	1.000	97	0.91 (0.61,1.36)
Total Bilirubin	D_TBil (Diazo)	0.98	-0.01 mg/dL	0.14–19.86 mg/dL	1.000	115	0.67 (0.46,0.96)
Creatinine	ECre3 (Enzymatic)	0.98	-0.03 mg/dL	0.34–25.88 mg/dL	1.000	114	0.90 (0.62,1.30)
Glucose	GluH_3 (Hexokinase)	1.03	+3 mg/dL	48–649 mg/dL	0.995	114	1.00 (0.69,1.45)
HDL Cholesterol	HDLC	1.00	-0.0 mg/dL	29.0–178.9 mg/dL	0.999	115	1.33 (0.92,1.91)
LDL Cholesterol	LDLC	0.99	+1 mg/dL	32–359 mg/dL	0.998	115	0.84 (0.58,1.21)
Total Protein	TP_2	1.03	-0.2 g/dL	3.9–10.6 g/dL	0.990	115	1.00 (0.69,1.44)
Triglycerides	Trig_2	1.00	+3 mg/dL	27–904 mg/dL	0.999	115	0.91 (0.63,1.31)
Urea Nitrogen	UN_c	1.00	+0 mg/dL	7–134 mg/dL	0.999	115	1.20 (0.83,1.73)
Free Thyroxine (Free T4)	FT4	1.04	+0.0 ng/dL	0.8–10.6 ng/dL	0.999	115	1.00 (0.69,1.44)
Total Triiodothyronine (Total T3)	T3	0.98	+0.02 ng/mL	0.50–7.20 ng/mL	0.993	115	1.02 (0.70,1.47)
Thyroid Stimulating Hormone (TSH)	TSH3-ULII	1.00	-0.002 mIU/L	0.128–135.638 mIU/L	1.000	111	0.59 (0.41,0.86)

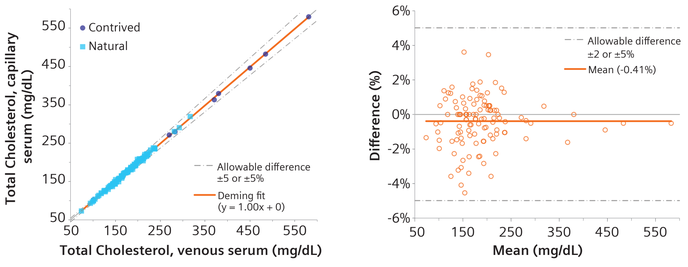
A. Atellica CH Enzymatic Hemoglobin A1c (A1c_E) assay



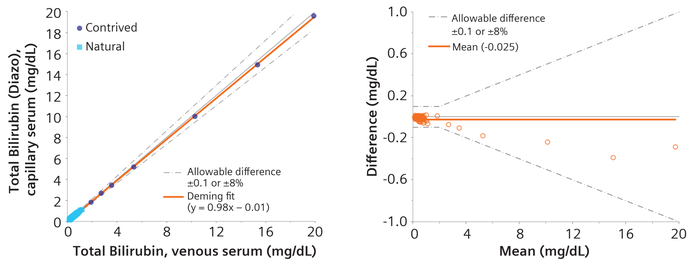
B. Atellica CH Alkaline Phosphatase (ALP_2c) assay



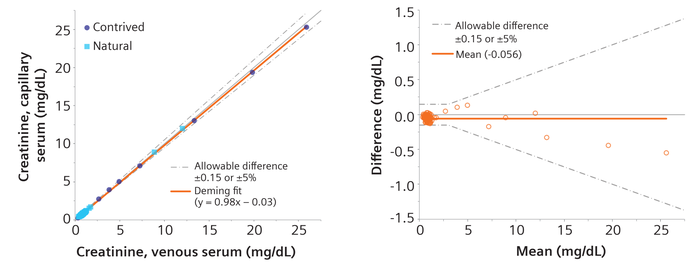
C. Atellica CH Total Cholesterol (Chol_2) assay



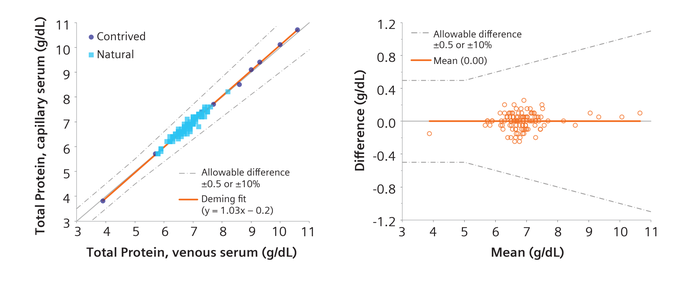
D. Atellica CH Diazo Total Bilirubin (D_TBil) assay



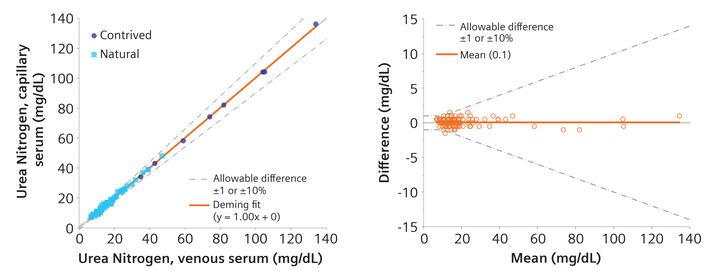
E. Atellica CH Enzymatic Creatinine (ECre3) assay



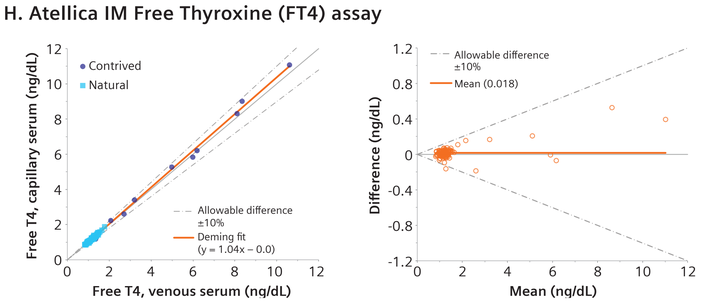
F. Atellica CH Total Protein (TP_2) assay



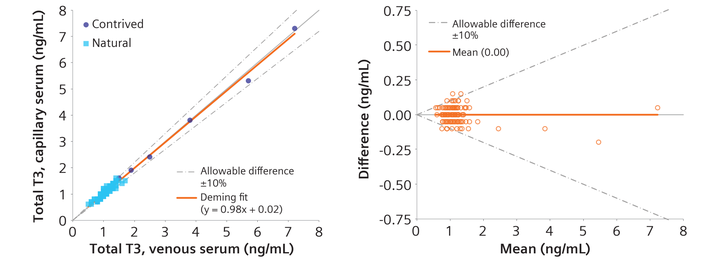
G. Atellica CH Urea Nitrogen (UN_c) assay



H. Atellica IM Free Thyroxine (FT4) assay



I. Atellica IM Total Triiodothyronine (T3) assay



J. Atellica IM Thyroid Stimulating Hormone (TSH3-ULII) assay

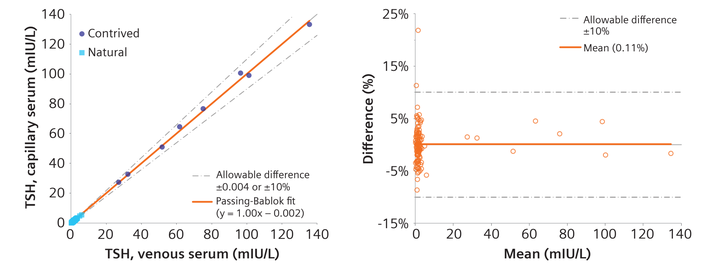


Figure 1. Representative Deming and Passing Bablok regression and difference plots for capillary serum compared to venous serum specimen equivalence on the Atellica CH and IM analyzers for several of the assays in Table 1.

Conclusion

Results for routinely tested Atellica CH and Atellica IM assays were equivalent between capillary and venous samples across the assay range measured.

References

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