Table S1. A summary of subject demographic statistics

Demographic Parameters		Sample size (n)	Percent (%)
Age	Mean +/- SD	50.76 +/- 16.25	N/A
	Median	54.50	N/A
	Min	18	N/A
	Max	79	N/A
Gender	Male	27	20.15
	Female	105	78.36
	Declined to answer	2	1.49
Race	White	93	69.40
	Hispanic or Latino	20	14.93
	Black or African American	15	11.19
	Native American or American Indian	0	0.00
	Asian or Pacific Islander	1	0.75
	Others	5	3.73
Total		1**34**	N/A

Table S2. Extreme MDLs used for mean percent bias analysis tested with common pathophysiology associated with extreme MDL values.

Analyte	Extreme MDL	Common Pathophysiology of Extreme MDL
K	≥ 7 mmol/L	Severe hyperkalemia in the case of renal failure or blood transfusion
Na	≤ 115 mmol/L	Severe hyponatremia in the case of burns or hypotonic IV use
AST	≥ 300 U/L	Infectious hepatitis, primary or metastatic carcinoma of the liver and other inflammatory conditions affecting the liver
ALT	≥ 250 U/L	Infectious hepatitis, primary or metastatic carcinoma of the liver and other inflammatory conditions affecting the liver
ALP	≥ 300 U/L	Extra/intrahepatic obstruction (e.g. by stone or cancer)

Table S3. A summary of performance comparison results for potassium (K)

Site	Sample Size (n)	Analyzer	Slope (95% CI)	Intercept (95% CI)	Pearson's coefficient	Mean % Bias

Site 1	**47**	**Analyzer 1**	1.025 (0.960 – 1.163)	-0.075 (-0.614 - 0.195)	0.954	-0.648
	47	**Analyzer 2**	1.062 (0.981 - 1.273)	-0.181 (-1.061 - 0.147)	0.940	-1.866
	94	**Analyzer Pooled**	1.047 (0.992 – 1.162)	-0.145 (-0.618 – 0.086)	0.946	-1.257
Site 2	**48**	**Analyzer 1**	0.960 (0.846 - 1.053)	0.170 (-0.199 - 0.612)	0.929	-0.339
	48	**Analyzer 2**	0.956 (0.870 - 1.112)	0.211 (-0.407 - 0.547)	0.924	-0.870
	96	**Analyzer Pooled**	0.963 (0.894 – 1.046)	0.170 (-0.169 – 0.435)	0.927	-0.604
Site 3	**39**	**Analyzer 1**	0.993 (0.870 - 1.142)	0.096 (-0.509 - 0.587)	0.910	-1.748
	39	**Analyzer 2**	0.929 (0.811 - 1.071)	0.316 (-0.241 - 0.798)	0.909	-0.728
	78	**Analyzer Pooled**	0.949 (0.864 – 1.050)	0.254 (-0.150 – 0.598)	0.908	-1.238
Pooled (n=134)			1.027 (0.982 - 1.102)	-0.069 (-0.355 - 0.111)	0.944	-1.018

Table S4. A summary of performance comparison results for sodium (Na)

Site	Sample Size (n)	Analyzer	Slope (95% CI)	Intercept (95% CI)	Pearson's coefficient	Mean % Bias
Site 1	**47**	**Analyzer 1**	0.881 (0.739 – 0.949)	14.971 (5.892 – 35.446)	0.946	1.264
	47	**Analyzer 2**	0.984 (0.923 – 1.046)	2.290 (-6.298 – 10.864)	0.981	-0.082
	94	**Analyzer Pooled**	0.916 (0.842 – 0.963)	10.975 (4.384 – 21.169)	0.956	0.591
Site 2	**48**	**Analyzer 1**	0.606 (0.441 – 0.854)	54.527 (19.674 – 77.674)	0.835	0.449
	48	**Analyzer 2**	0.984	1.919	0.859	0.206

			(0.837 - 1.147)	(-21.100 – 22.980)		
	96	**Analyzer Pooled**	0.799 (0.651 – 0.976)	27.824 (2.932 – 48.503)	0.837	0.328
Site 3	**39**	**Analyzer 1**	1.083 (0.902 - 1.286)	-11.599 (-39.832 – 13.630)	0.898	0.002
	39	**Analyzer 2**	0.925 (0.738 – 1.112)	10.169 (-15.819 – 36.126)	0.844	0.256
	78	**Analyzer Pooled**	1.015 (0.891 – 1.149)	-2.324 (-20.934 – 15.017)	0.869	0.129
	Pooled (n=134)		0.911 (0.840 – 0.960)	11.934 (5.226 – 21.825)	0.937	0.362

Table S5. A summary of performance comparison results for chloride (Cl)

Site	Sample Size (n)	Analyzer	Slope (95% CI)	Intercept (95% CI)	Pearson's coefficient	Mean % Bias
Site 1	**47**	**Analyzer 1**	0.944 (0.838 – 1.006)	4.848 (-1.512 – 15.437)	0.970	0.991
	47	**Analyzer 2**	0.993 (0.947 – 1.045)	1.081 (-4.159 – 5.873)	0.986	-0.379
	94	**Analyzer Pooled**	0.957 (0.902 – 0.996)	4.117 (0.348 – 9.696)	0.975	0.306
Site 2	**48**	**Analyzer 1**	0.896 (0.783 – 1.019)	10.322 (-2.514 – 22.123)	0.881	0.477
	48	**Analyzer 2**	0.974 (0.856 – 1.124)	2.408 (-13.141 – 14.750)	0.906	0.320
	96	**Analyzer Pooled**	0.937 (0.854 – 1.029)	6.110 (-3.310 – 14.654)	0.893	0.399
Site 3	**39**	**Analyzer 1**	1.027 (0.946 – 1.125)	-2.982 (-13.217 – 5.495)	0.948	0.175
	39	**Analyzer 2**	0.977 (0.786 – 1.123)	1.869 (-12.927 – 21.573)	0.889	0.451
	78	**Analyzer Pooled**	1.017 (0.930 – 1.096)	-2.020 (-10.167 – 6.832)	0.920	0.313

Pooled (n=134)	0.959 (0.913 – 0.992)	3.869 (0.565 – 8.567)	0.964	0.341

Table S6. A summary of performance comparison results for calcium (Ca)

Site	Sample Size (n)	Analyzer	Slope (95% CI)	Intercept (95% CI)	Pearson's coefficient	Mean % Bias
Site 1	**44**	**Analyzer 1**	0.931 (0.866 - 1.005)	0.508 (-0.165 – 1.094)	0.962	1.445
	44	**Analyzer 2**	1.007 (0.960 - 1.082)	-0.024 (-0.731 – 0.404)	0.986	-0.445
	88	**Analyzer Pooled**	0.958 (0.914 – 1.001)	0.338 (-0.026 – 0.721)	0.966	0.500
Site 2	**45**	**Analyzer 1**	0.963 (0.823 – 1.147)	0.248 (-1.455 – 1.562)	0.871	0.957
	45	**Analyzer 2**	0.955 (0.869 - 1.031)	0.415 (-0.296 – 1.243)	0.945	0.042
	90	**Analyzer Pooled**	0.995 (0.896 – 1.096)	0.001 (-0.951– 0.926)	0.903	0.499
Site 3	**38**	**Analyzer 1**	0.880 (0.759 – 0.980)	1.174 (0.249 – 2.296)	0.922	-0.406
	38	**Analyzer 2**	1.116 (0.966 – 1.243)	-1.070 (-2.263 – 0.342)	0.917	-0.241
	76	**Analyzer Pooled**	0.978 (0.880 – 1.072)	0.234 (-0.647 – 1.151)	0.914	-0.323
	Pooled (n=127)		0.974 (0.935 – 1.010)	0.218 (-0.118 – 0.573)	0.951	0.257

Table S7. A summary of performance comparison results for Aspartate Aminotransferase (AST)

Site	Sample Size (n)	Analyzer	Slope (95% CI)	Intercept (95% CI)	Pearson's coefficient	Mean % Bias
Site 1	**47**	**Analyzer 1**	1.009	-0.179	0.999	-0.386

			(0.868 - 1.030)	(-0.745 – 2.356)		
	47	**Analyzer 2**	1.002 (0.972 - 1.044)	0.027 (-0.844 – 0.680)	1.000	-0.387
	94	**Analyzer Pooled**	1.005 (0.977 – 1.023)	-0.066 (-0.462 – 0.462)	1.000	-0.387
	48	**Analyzer 1**	0.942 (0.869 – 0.974)	1.354 (0.463 – 2.730)	0.965	-1.286
Site 2	**48**	**Analyzer 2**	0.979 (0.887 - 1.016)	0.800 (-0.358 – 2.806)	0.962	-1.582
	96	**Analyzer Pooled**	0.965 (0.909 – 0.993)	0.998 (0.212 – 2.179)	0.965	-1.434
	38	**Analyzer 1**	0.992 (0.980 - 1.121)	0.964 (-1.114 – 1.511)	0.996	-4.234
Site 3	**38**	**Analyzer 2**	0.994 (0.982 - 1.065)	0.849 (-0.746 – 1.374)	0.998	-3.182
	76	**Analyzer Pooled**	0.993 (0.984 – 1.052)	0.908 (-0.250 – 1.254)	0.997	-3.708
	Pooled (n=133)		1.003 (0.982 – 1.018)	0.236 (-0.140 – 0.726)	0.999	-1.714

Table S8. A summary of performance comparison results for Alanine Aminotransferase (ALT)

Site	Sample Size (n)	Analyzer	Slope (95% CI)	Intercept (95% CI)	Pearson's coefficient	Mean % Bias
	46	**Analyzer 1**	0.997 (0.968 – 0.998)	-0.437 (-0.629 – -0.034)	1.000	3.870
Site 1	**46**	**Analyzer 2**	0.987 (0.977 - 1.063)	0.424 (-0.742 – 1.032)	0.999	-1.811
	92	**Analyzer Pooled**	0.992 (0.982 – 1.001)	0.002 (-0.423 – 0.365)	0.999	1.029
	48	**Analyzer 1**	0.975 (0.930 – 1.016)	-0.241 (-0.821 – 0.347)	0.991	4.356
Site 2	**48**	**Analyzer 2**	1.002 (0.972 - 1.037)	-0.294 (-0.777 – 0.097)	0.995	2.444

	96	**Analyzer Pooled**	0.985 (0.957 – 1.013)	-0.229 (-0.599– 0.136)	0.992	3.400
Site 3	**36**	**Analyzer 1**	0.876 (0.823 – 0.967)	0.887 (-0.215 – 1.500)	0.994	4.875
	36	**Analyzer 2**	0.918 (0.771 – 0.971)	0.769 (0.097 – 2.313)	0.982	-0.180
	72	**Analyzer Pooled**	0.896 (0.834 – 0.959)	0.839 (0.125 – 1.559)	0.987	2.348
	Pooled (n=130)		0.987 (0.967 – 0.996)	-0.197 (-0.400 – 0.107)	0.998	2.270

Table S9. A summary of performance comparison results for Alkaline Phosphatase (ALP)

Site	**Sample Size (n)**	**Analyzer**	**Slope (95% CI)**	**Intercept (95% CI)**	**Pearson's coefficient**	**Mean % Bias**
Site 1	**47**	**Analyzer 1**	0.983 (0.948 - 1.008)	-0.850 (-3.020 – 1.701)	0.999	2.783
	47	**Analyzer 2**	0.993 (0.970 - 1.004)	0.074 (-0.865 – 1.848)	1.000	0.517
	94	**Analyzer Pooled**	0.988 (0.975 – 1.003)	-0.320 (-1.722 – 0.804)	0.999	1.650
Site 2	**48**	**Analyzer 1**	0.963 (0.935 – 1.015)	1.096 (-2.387 – 3.193)	0.995	2.195
	48	**Analyzer 2**	0.994 (0.980 - 1.020)	-0.059 (-1.741 – 0.899)	0.999	0.752
	96	**Analyzer Pooled**	0.982 (0.957 – 1.010)	0.331 (-1.667– 2.031)	0.996	1.474
Site 3	**39**	**Analyzer 1**	0.994 (0.961 - 1.021)	0.332 (-1.442 – 2.491)	0.997	0.147
	39	**Analyzer 2**	0.966 (0.928 – 0.998)	1.954 (-0.190 – 4.505)	0.996	0.501
	78	**Analyzer Pooled**	0.978 (0.951 – 1.000)	1.259 (-0.248 – 3.039)	0.996	0.324
	Pooled (N=134)		0.984	0.299	0.998	1.201

			(0.974 – 0.995)	(-0.529 – 1.018)		

Table S10. A summary of performance comparison results for total bilirubin (T.Bili)

Site	Sample Size (n)	Analyzer	Slope (95% CI)	Intercept (95% CI)	Pearson's coefficient	Mean % Bias
Site 1	**45**	**Analyzer 1**	1.045 (0.940 – 1.089)	-0.015 (-0.053 - 0.014)	0.946	2.206
	45	**Analyzer 2**	1.027 (0.981 - 1.073)	-0.010 (-0.024 - 0.007)	0.988	0.593
	90	**Analyzer Pooled**	1.021 (0.971 – 1.051)	-0.010 (-0.026 – 0.006)	0.969	1.400
Site 2	**47**	**Analyzer 1**	0.907 (0.823 – 0.991)	0.022 (-0.012 - 0.053)	0.971	3.971
	47	**Analyzer 2**	0.993 (0.966 - 1.015)	0.003 (-0.008 - 0.015)	0.996	-0.299
	94	**Analyzer Pooled**	0.946 (0.892 – 0.992)	0.013 (-0.005 – 0.032)	0.983	1.836
Site 3	**37**	**Analyzer 1**	1.030 (0.964 - 1.136)	-0.002 (-0.039 - 0.027)	0.963	-2.452
	37	**Analyzer 2**	1.055 (1.005 - 1.094)	-0.010 (-0.027 - 0.008)	0.989	-2.488
	74	**Analyzer Pooled**	1.004 (1.000 – 1.093)	-0.006 (-0.024 – 0.011)	0.977	-2.470
Pooled (n=129)			0.978 (0.944 - 1.010)	0.007 (-0.005 - 0.018)	0.976	0.449

Table S11. A summary of performance comparison results for albumin (Alb)

Site	Sample Size (n)	Analyzer	Slope (95% CI)	Intercept (95% CI)	Pearson's coefficient	Mean % Bias
Site 1	46	Analyzer 1	0.917 (0.820 - 1.040)	0.232 (-0.309 – 0.639)	0.910	2.878
	46	Analyzer 2	0.952 (0.883 - 1.038)	0.152 (-0.221 – 0.452)	0.961	1.290
	92	Analyzer Pooled	0.941 (0.882 – 1.010)	0.162 (-0.136 – 0.422)	0.930	2.084
Site 2	48	Analyzer 1	1.021 (0.827 – 1.278)	-0.177 (-1.230 – 0.634)	0.821	2.166
	48	Analyzer 2	1.025 (0.934 - 1.177)	-0.167 (-0.823 – 0.225)	0.948	1.296
	96	Analyzer Pooled	1.047 (0.951 – 1.174)	-0.276 (-0.819 – 0.145)	0.903	1.731
Site 3	38	Analyzer 1	0.890 (0.776 - 1.006)	0.420 (-0.067 – 0.894)	0.899	1.141
	38	Analyzer 2	1.000 (0.870 - 1.208)	-0.057 (-0.988 – 0.528)	0.905	1.297
	76	Analyzer Pooled	0.949 (0.880 – 1.041)	0.171 (-0.242 – 0.466)	0.916	1.219
Pooled (n=132)			0.978 (0.934 – 1.023)	0.021 (-0.179 – 0.214)	0.919	1.706

Table S12. A summary of performance comparison results for total protein (TP)

Site	Sample Size (n)	Analyzer	Slope (95% CI)	Intercept (95% CI)	Pearson's coefficient	Mean % Bias
Site 1	46	Analyzer 1	0.874 (0.774 – 0.951)	0.760 (0.224 – 1.467)	0.927	1.979
	46	Analyzer 2	1.031 (0.966 – 1.101)	-0.264 (-0.744 – 0.193)	0.973	0.541
	92	Analyzer Pooled	0.962 (0.911 – 1.014)	0.179 (-0.179 – 0.526)	0.943	1.260
Site 2	48	Analyzer 1	0.962	0.180	0.892	1.187

			(0.792 – 1.104)	(-0.789 – 1.363)		
	48	**Analyzer 2**	0.996 (0.920 - 1.075)	0.050 (-0.520 – 0.585)	0.962	-0.326
	96	**Analyzer Pooled**	0.999 (0.907 – 1.085)	-0.024 (-0.634 – 0.613)	0.923	0.431
Site 3	**39**	**Analyzer 1**	0.981 (0.840 - 1.089)	0.130 (-0.629 – 1.160)	0.907	0.137
	39	**Analyzer 2**	1.123 (0.997 – 1.290)	-0.896 (-2.162 – 0.057)	0.913	-0.249
	78	**Analyzer Pooled**	1.056 (0.964 – 1.141)	-0.407 (-1.038 – 0.266)	0.909	-0.056
	Pooled (n=133)		1,003 (0.964 – 1.045)	-0.063 (-0.368 – 0.225)	0.933	0.575

Table S13. A summary of performance comparison results for blood urea nitrogen (BUN)

Site	Sample Size (n)	Analyzer	Slope (95% CI)	Intercept (95% CI)	Pearson's coefficient	Mean % Bias
	47	**Analyzer 1**	1.011 (0.966 - 1.058)	-0.233 (-0.838 – 0.353)	0.992	0.665
Site 1	**47**	**Analyzer 2**	0.999 (0.973 - 1.021)	-0.044 (-0.379 – 0.301)	0.995	0.525
	94	**Analyzer Pooled**	1.005 (0.979 – 1.028)	-0.140 (-0.460 – 0.189)	0.994	0.595
	48	**Analyzer 1**	0.984 (0.959 – 1.016)	0.317 (-0.134 – 0.689)	0.995	-0.730
Site 2	**48**	**Analyzer 2**	0.998 (0.985 - 1.012)	0.008 (-0.208 – 0.217)	0.997	0.093
	96	**Analyzer Pooled**	0.991 (0.977 – 1.007)	0.156 (-0.080 – 0.389)	0.996	-0.319
Site 3	**39**	**Analyzer 1**	1.032 (0.975 - 1.084)	-0.277 (-0.998 – 0.501)	0.991	-0.999
	39	**Analyzer 2**	0.996 (0.964 - 1.032)	0.033 (-0.412 – 0.423)	0.996	0.245

Site	Sample Size (n)	Analyzer	Slope (95% CI)	Intercept (95% CI)	Pearson's coefficient	Mean % Bias
	78	**Analyzer Pooled**	1.015 (0.979 – 1.051)	-0.132 (-0.577 – 0.315)	0.993	-0.377
	Pooled (n=134)		1.001 (0.990 – 1.016)	-0.014 (-0.209 – 0.152)	0.995	-0.015

Table S14. A summary of performance comparison results for creatinine (Cre)

Site	Sample Size (n)	Analyzer	Slope (95% CI)	Intercept (95% CI)	Pearson's coefficient	Mean % Bias
Site 1	**46**	**Analyzer 1**	0.939 (0.905 – 0.977)	0.030 (0.001 – 0.055)	0.989	1.875
	46	**Analyzer 2**	0.980 (0.919 - 1.047)	0.001 (-0.046 – 0.043)	0.988	1.808
	92	**Analyzer Pooled**	0.960 (0.926 – 1.001)	0.014 (-0.012 – 0.039)	0.988	1.841
Site 2	**48**	**Analyzer 1**	0.973 (0.953 – 1.008)	0.007 (-0.026 – 0.027)	0.994	1.929
	48	**Analyzer 2**	0.997 (0.956 - 1.026)	-0.012 (-0.035 – 0.019)	0.997	1.821
	96	**Analyzer Pooled**	0.985 (0.961 – 1.011)	-0.003 (-0.024– 0.017)	0.995	1.875
Site 3	**39**	**Analyzer 1**	0.993 (0.923 – 1.051)	-0.001 (-0.046 – 0.053)	0.984	0.787
	39	**Analyzer 2**	1.011 (0.941 – 1.080)	-0.019 (-0.073 – 0.033)	0.981	1.504
	78	**Analyzer Pooled**	0.969 (0.949 – 0.991)	0.012 (-0.005 – 0.027)	0.982	1.146
	Pooled (n=133)		0.982 (0.964 – 1.001)	0.001 (-0.012 – 0.015)	0.992	1.649

Table S15. A summary of performance comparison results for cholesterol (Chol)

Site	Sample Size (n)	Analyzer	Slope (95% CI)	Intercept (95% CI)	Pearson's coefficient	Mean % Bias
Site 1	**47**	**Analyzer 2**	0.963 (0.934 - 1.005)	5.876 (-1.651 – 11.038)	0.996	-0.719
Site 2	**48**	**Analyzer 2**	0.998 (0.983 - 1.010)	-0.365 (-2.943 – 2.395)	0.999	-0.401
Site 3	**39**	**Analyzer 2**	0.999 (0.960 – 1.037)	-0.399 (-7.485 – 6.518)	0.994	-0.260
Pooled (n=133)			0.988 (0.972 – 1.004)	1.426 (-1.336 – 4.287)	0.997	-0.438

Table S16. A summary of performance comparison results for triglycerides (TRIG)

Site	Sample Size (n)	Analyzer	Slope (95% CI)	Intercept (95% CI)	Pearson's coefficient	Mean % Bias
Site 1	**47**	**Analyzer 2**	0.995 (0.972 – 1.015)	-0.857 (-2.751 – 1.154)	0.997	-1.057
Site 2	**48**	**Analyzer 2**	0.997 (0.978 – 1.020)	0.200 (-2.349 – 2.289)	0.998	-0.121
Site 3	**39**	**Analyzer 2**	1.064 (0.970 – 1.105)	-7.902 (-12.417 – 1.805)	0.997	1.160
Pooled (n=133)			1.017 (0.986 – 1.050)	-2.856 (-6.932 – 0.676)	0.997	-0.251

Table S17. Total percent (%) CV and components of variance between lots and within lots based on site and analyte for electrolytes.

		Mean % CV		
Analyte (Unit)	**Variance Component**	**Site 1**	**Site 2**	**Site 3**
K (mmol/L)	Between Lot	0.00 *	0.64	0.25
	Within Lot	4.23	1.93	1.83

	Total	4.23	2.03	1.84
	Mean (sample size)	4.47 (n = 56)	4.71 (n = 55)	4.41 (n = 60)
Na (mmol/L)	Between Lot	0.42	0.00 *	0.00 *
	Within Lot	0.65	0.66	0.76
	Total	0.77	0.66	0.76
	Mean (sample size)	138.80 (n = 56)	139.04 (n = 55)	136.37 (n = 60)
Cl (mmol/L)	Between Lot	0.56	0.00 *	0.00 *
	Within Lot	0.94	0.60	0.73
	Total	1.09	0.60	0.73
	Mean (sample size)	104.21 (n = 56)	105.00 (n = 55)	103.38 (n = 60)
Ca (mg/dL)	Between Lot	0.24	0.00 *	0.37
	Within Lot	0.94	0.85	0.91
	Total	0.97	0.85	0.98
	Mean (sample size)	8.37 (n = 53)	8.58 (n = 51)	8.70 (n = 62)

Table S18. Total percent (%) CV and components of variance between lots and within lots based on site and analyte for liver function tests.

		Mean % CV		
Analyte (Unit)	**Variance Component**	**Site 1**	**Site 2**	**Site 3**
AST (U/L)	Between Lot	3.94	2.12	1.03
	Within Lot	4.77	9.00	2.97
	Total	6.19	9.25	3.15

	Mean (sample size)	17.75 (n = 56)	20.05 (n = 55)	21.87 (n = 62)
ALT (U/L	Between Lot	1.41	0.00 *	1.94
	Within Lot	6.35	5.30	7.49
	Total	6.50	5.30	7.73
	Mean (sample size)	11.59 (n = 56)	12.49 (n = 55)	16.20 (n = 61)
ALP (U/L)	Between Lot	0.37	0.00 *	0.75
	Within Lot	1.64	2.09	1.50
	Total	1.69	2.09	1.68
	Mean (sample size)	86.34 (n = 56)	70.93 (n = 56)	68.81 (n = 62)
Total Bilirubin (mg/dL)	Between Lot	2.10	0.00 *	0.22
	Within Lot	4.71	3.68	3.92
	Total	5.16	3.68	3.93
	Mean (sample size)	0.30 (n = 53)	0.35 (n = 50)	0.31 (n = 60)
Albumin (mg/dL)	Between Lot	0.61	0.38	1.11
	Within Lot	2.34	2.15	1.81
	Total	2.42	2.19	2.12
	Mean (sample size)	4.01 (n = 56)	3.88 (n = 52)	4.16 (n = 62)
Total Protein (mg/dL)	Between Lot	0.81	0.00 *	0.81
	Within Lot	1.80	1.14	1.42
	Total	1.97	1.14	1.63
	Mean (n)	6.74 (n = 56)	6.50 (n = 51)	6.75 (n = 62)

Table S19. Total percent (%) CV and components of variance between lots and within lots based

on site and analyte for kidney function tests.

Analyte (Unit)	Variance Component	Mean % CV		
		Site 1	Site 2	Site 3
BUN (mg/dL)	Between Lot	0.00 *	0.13	0.00 *
	Within Lot	2.94	2.04	2.60
	Total	2.94	2.04	2.60
	Mean (sample size)	11.56 (n = 55)	17.04 (n = 51)	13.01 (n = 62)
Creatinine (mg/dL)	Between Lot	0.17	0.00 *	0.79
	Within Lot	2.79	2.64	2.76
	Total	2.79	2.64	2.87
	Mean (sample size)	0.82 (n = 55)	0.83 (n = 50)	0.69 (n = 60)

Table S20. Total percent (%) CV and components of variance between lots and within lots based on site and analyte for lipid tests.

Analyte (Unit)	Variance Component	Mean % CV		
		Site 1	Site 2	Site 3
Cholesterol (mg/dL)	Between Lot	0.46	0.10	0.79
	Within Lot	2.03	1.85	1.59
	Total	2.98	1.85	1.77
	Mean (sample size)	151.80 (n = 56)	149.83 (n = 52)	185.19 (n = 62)
Triglycerides (mg/dL)	Between Lot	0.00 *	0.00 *	0.00 *
	Within Lot	1.44	1.83	2.77
	Total	1.44	1.83	2.77

	Mean (sample size)	137.80 (n = 56)	108.92 (n = 52)	141.05 (n = 62)

Table S21. Total percent (%) CV and components of variance between operators and within operators based on site and analyte for electrolytes.

		Mean % CV		
Analyte (Unit)	**Variance Component**	**Site 1**	**Site 2**	**Site 3**
K (mmol/L)	Between Operator	1.48	0.00 *	0.39
	Within Operator	4.14	2.08	1.48
	Total	4.39	2.08	1.54
	Mean (sample size)	4.38 (n = 60)	4.70 (n = 60)	4.50 (n = 63)
Na (mmol/L)	Between Operator	0.00 *	0.17	0.00 *
	Within Operator	0.66	0.75	0.59
	Total	0.66	0.77	0.59
	Mean (sample size)	137.87 (n = 60)	139.28 (n = 60)	136.73 (n = 63)
Cl (mmol/L)	Between Operator	0.06	0.21	0.00 *
	Within Operator	0.82	0.83	0.97
	Total	0.82	0.86	0.97
	Mean (sample size)	103.15 (n = 60)	104.97 (n = 60)	103.95 (n = 63)
Ca (mg/dL)	Between Operator	0.17	0.00 *	0.23
	Within Operator	0.94	2.70	1.01
	Total	0.95	2.70	1.03
	Mean (sample size)	8.31 (n = 56)	8.52 (n = 51)	8.64 (n = 65)

Table S22. Total percent (%) CV and components of variance between operators and within operators based on site and analyte for liver function tests.

Analyte (Unit)	Variance Component	Mean % CV		
		Site 1	**Site 2**	**Site 3**
AST (U/L)	Between Operator	2.27	1.57	1.81
	Within Operator	7.29	8.16	2.72
	Total	7.63	8.31	3.26
	Mean (sample size)	18.02 (n = 60)	20.05 (n = 60)	21.61 (n = 66)
ALT (U/L)	Between Operator	2.74	0.00 *	0.00 *
	Within Operator	5.48	4.21	7.27
	Total	6.13	4.21	7.27
	Mean (sample size)	11.82 (n = 60)	12.73 (n = 60)	15.50 (n = 64)
ALP (U/L)	Between Operator	0.82	0.15	0.94
	Within Operator	1.50	1.24	1.65
	Total	1.71	1.25	1.90
	Mean (sample size)	86.22 (n = 60)	72.13 (n = 60)	68.14 (n = 66)
Total Bilirubin (mg/dL)	Between Operator	0.75	0.00 *	0.76
	Within Operator	5.20	4.09	3.14
	Total	5.25	4.09	3.23
	Mean (sample size)	0.29 (n = 57)	0.35 (n = 51)	0.31 (n = 62)
Albumin (mg/dL)	Between Operator	0.73	0.42	0.91
	Within Operator	2.13	1.68	1.78
	Total	2.25	1.73	2.00

Total Protein (g/dL)	Mean (sample size)	4.00 (n = 60)	3.89 (n = 54)	4.11 (n = 66)
	Between Operator	1.08	0.31	0.77
	Within Operator	1.71	1.22	1.42
	Total	2.02	1.26	1.62
	Mean (sample size)	6.78 (n = 60)	6.51 (n = 54)	6.70 (n = 65)

Table S23. Total percent (%) CV and components of variance between operators and within operators based on site and analyte for kidney function tests.

		Mean % CV		
Analyte (Unit)	**Variance Component**	**Site 1**	**Site 2**	**Site 3**
BUN (mg/dL)	Between Operator	0.00 *	0.34	0.40
	Within Operator	2.35	1.58	2.72
	Total	2.35	1.61	2.75
	Mean (sample size)	11.85 (n = 60)	16.96 (n = 54)	13.15 (n = 65)
Creatinine (mg/dL)	Between Operator	0.00 *	0.00 *	0.41
	Within Operator	3.16	2.47	2.72
	Total	3.16	2.47	2.75
	Mean (sample size)	0.81 (n = 59)	0.83 (n = 54)	0.68 (n = 62)

Table S24. Total percent (%) CV and components of variance between operators and within operators based on site and analyte for lipid tests.

		Mean % CV		
Analyte (Unit)	**Variance Component**	**Site 1**	**Site 2**	**Site 3**

Cholesterol (mg/dL)	Between Operator	0.93	0.00 *	0.97
	Within Operator	1.89	1.25	1.57
	Total	2.11	1.25	1.85
	Mean (sample size)	152.33 (n = 60)	149.17 (n = 54)	185.36 (n = 66)
Triglycerides (mg/dL)	Between Operator	0.36	0.00 *	0.12
	Within Operator	1.30	1.57	2.58
	Total	1.35	1.57	2.58
	Mean (sample size)	137.28 (n = 60)	109.17 (n = 54)	137.91 (n = 66)

Sample Contriving Method Validation Study

In the performance comparison study and precision study, select samples were modified in order to achieve extreme values for analytes' concentration. Briefly, blood samples from a single subject are collected into 10mL lithium heparin BCTs (Blood Collection Tubes) and transferred to a sterile 50mL conical tube. The blood samples are slightly diluted to modify the analyte concentration, and then drawn into lithium heparin ZDiscs or PSTs by butterfly tubing, similar to conventional blood draw as shown in the Supplementary Figure S1.

In order to validate the sample contriving method, analytes' concentrations in the double-heparinized blood samples, which were drawn from the test apparatus as shown in Figure S1, were compared to directly drawn whole blood for both ZDiscs and PSTs.

Blood samples were collected from 10 subjects. Each subject had blood directly drawn into one ZDisc as well as one PST (i.e. direct draw group) and two 10 mL Li-Heparin PSTs. The blood in Li-Heparin tubes were subject to the contriving method: blood samples were drawn into one ZDisc

and one PST (i.e. contrived group). No dilution was performed here in order to compare analyte concentration in the double-heparinized group (i.e. contrived group) vs the direct draw group. Blood samples in ZDiscs were separated using the ZDrive while samples in the PSTs were separated using a conventional centrifuge and tested for the concentration of analytes. Analyte concentration in plasma from both ZDisc and PST were measured using a chemistry analyzer, Piccolo Xpress Chemistry Analyzer (Abaxis, Union City, CA, USA). Note that 12 analytes excluding lipid analytes (i.e. cholesterol and triglycerides) were assessed in this study due to the limitation in the panel configuration of the chemistry analyzer.

Table S25 shows the grand mean and SD of analyte concentration across ZDiscs and PSTs, and mean % differences between the direct draw vs the contrived method for both ZDisc and PST. Notably, several analytes (Creatinine, ALT) showed the mean % difference close to or greater than 5%. Mean % difference between the direct draw vs the contrived method for creatinine was -12.37% for ZDisc and 9.76% for PST, however the paired t-test showed that the difference is not significant (p-value: 0.14 for ZDisc and 0.38 for PST). Similarly, mean % difference between the direct draw vs the contrived method for ALT is 4.39% and 8.99% for ZDisc and PST, respectively, but no significance determined in the paired t-test (p-value: 0.87 for ZDisc and 0.11 for PST). All other analytes showed less than 5% in the mean % difference for the direct draw and the contrived method.

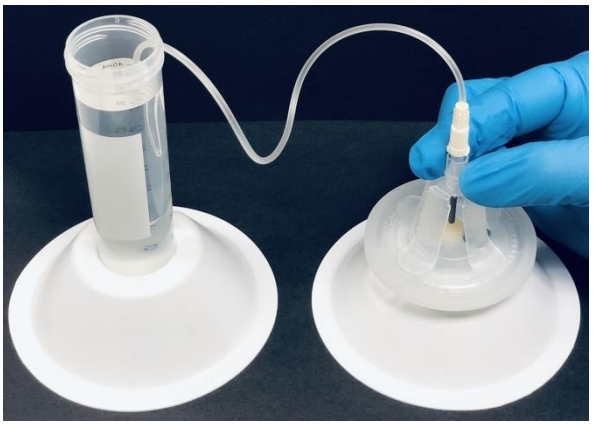

Figure S1. Modified blood collection set including 21G butterfly 12-inch tubing to transfer the modified samples in a 50mL conical tube into a ZDisc.

Table S25. Grand mean with SD and mean % difference between the direct draw group vs the contrived group for each analyte

		K	Na	Cl	Ca	BUN	Cre
Total Mean (± SD)		4.08 ± 0.26	141.48 ± 1.99	103.35 ± 1.96	2.39 ± 0.09	5.20 ± 1.37	78.80 ± 18.25
Mean condition analyte concentration (± SD)	**ZDisc (Contrived)**	4.1±0.2	141.4±2.0	103.2±1.8	2.4±0.1	5.2±1.4	72.5±20.9
	ZDisc (Direct draw)	4.2±0.4	142.1±2.1	103.4±2.3	2.4±0.1	5.2±1.4	84.4±16.9
	PST (Contrived)	4.0±0.2	141.2±2.3	103.6±2.0	2.4±0.1	5.2±1.4	81.8±18.3
	PST (Direct draw)	4.0±0.2	141.2±1.5	103.2±1.9	2.4±0.1	5.2±1.4	76.5±17.1
Mean % difference	**ZDisc**	-3.08	-0.49	-0.17	1.09	-0.02	-12.37
	PST	-0.37	0.00	0.40	0.74	0.95	9.76
		AST	**ALT**	**ALP**	**T.Bili**	**Alb**	**TP**
Total Mean (± SD)		30.38 ± 6.13	33.13 ± 15.20	62.48 ± 7.47	17.35 ± 3.75	41.20 ± 3.34	75.00 ± 7.05
Mean condition analyte concentration (± SD)	**ZDisc (Contrived)**	31±6.6	33.1±15.5	63.4±7.0	17.2±3.9	41.7±3.1	75.3±7.4
	ZDisc (Direct draw)	30.2±6.6	32.9±17.0	61.9±8.9	17.4±3.8	40.5±3.7	75.4±7.9

	PST (Contrived)	30.7±5.9	34.4±15.5	62.2±6.8	17.5±4.0	42.1±3.3	75.1±6.4
	PST (Direct draw)	29.6±6.3	32.1±15.1	62.4±8.1	17.3±3.9	40.5±3.3	74.2±7.5
Mean % difference	**ZDisc**	3.05	4.39	1.75	-1.21	3.15	0.00
	PST	4.25	8.99	0.91	1.04	4.04	1.40

Lowest Quartile Performance Comparison Analysis

In order to assess whether use of the ZDisc might impact analytical limit of detection, as secondary analysis the bottom quartile of reference sample results was analyzed separately. Performance comparison fit and bias for this sub-set were generally comparable to those found for analysis of all samples for each of the 14 analytes.

Table S26. Mean percent bias for all analytes at each site and for each chemistry analyzer for the lowest quartile subgroup

Site/Analyzer		**K**	**Na**	**Cl**	**Ca**	**AST**	**ALT**	**ALP**
Site 1	**Analyzer 1**	1.279	0.503	0.057	0.133	-0.730	3.590	2.482
	Analyzer 2	0.042	-0.356	-0.090	-0.268	-0.338	1.873	-0.410
	Analyzer Pooled	0.661	0.073	-0.017	-0.067	-0.534	2.726	1.036
Site 2	**Analyzer 1**	0.043	-0.275	-0.472	0.436	-0.110	0.071	1.209
	Analyzer 2	-0.648	0.265	0.498	0.559	-2.765	1.382	1.537
	Analyzer Pooled	-0.685	-0.005	0.431	-0.144	-4.124	1.037	3.032
Site 3	**Analyzer 1**	0.066	0.094	0.133	0.178	-0.449	-0.201	-0.202
	Analyzer 2	-1.934	0.181	0.461	0.559	-2.192	-5.221	0.076
	Analyzer Pooled	-2.672	0.137	0.365	-0.144	-3.125	-2.034	0.366
3 sites pooled / Analyzer 1		-1.193	0.109	0.198	0.603	-2.848	1.618	2.392
3 sites pooled / Analyzer 2		-0.930	0.015	0.226	-0.107	-1.471	-1.387	0.420
Total		-1.062	0.062	0.212	0.248	-2.159	0.116	1.406

Site/Analyzer	**Total Bilirubin**	**Albumin**	**Total Protein**	**BUN**	**Creatinine**	**Cholesterol**	**Triglycerides**
Analyzer 1	0.000	1.559	0.899	1.111	0.077	N/A	N/A
Analyzer 2	7.043	1.329	1.318	0.256	2.161	-0.938	-0.026
Analyzer Pooled	3.522	1.444	1.109	0.683	1.119	-0.938	-0.026
Analyzer 1	0.000	3.428	0.913	-2.872	-0.255	N/A	N/A
Analyzer 2	-0.170	1.717	-0.529	0.000	2.534	0.221	-0.675
Analyzer Pooled	-0.085	2.573	0.192	-1.436	1.140	0.221	-0.675
Analyzer 1	0.000	0.412	0.606	0.386	-0.282	N/A	N/A
Analyzer 2	-3.756	1.969	0.863	0.980	2.277	-0.709	0.883
Analyzer Pooled	-1.878	1.190	0.735	0.683	0.997	-0.709	0.883

3 sites pooled / Analyzer 1	0.000	2.143	0.862	-0.316	-0.102	N/A	N/A
3 sites pooled / Analyzer 2	0.401	1.610	0.298	0.436	2.279	-0.412	0.131
Total	0.200	1.877	0.580	0.060	1.088	-0.412	0.131

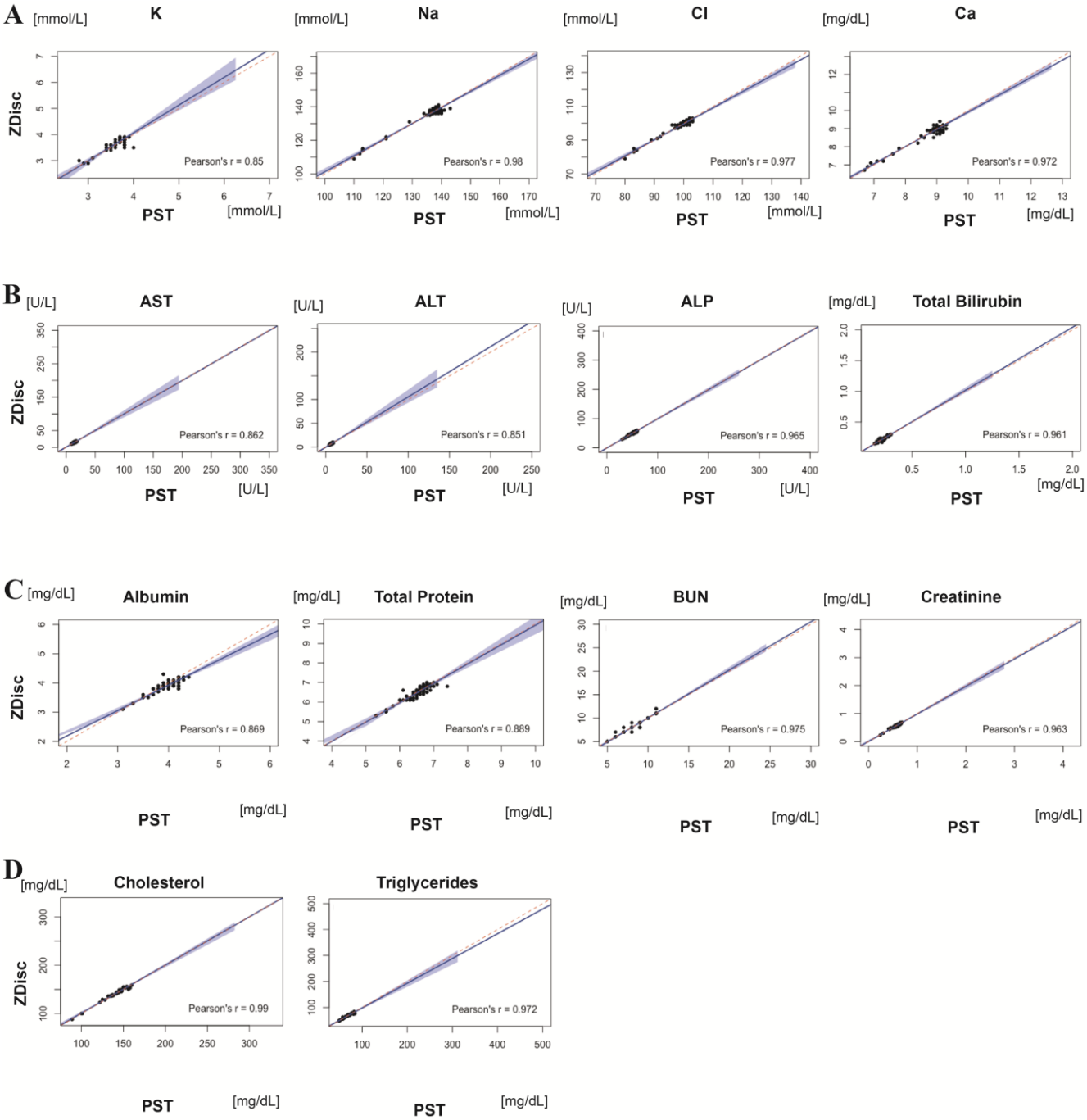

Figure S2. Scatter plots of the lowest quartile subgroup representing all 14 analytes results for ZDisc vs. vacutainer PST with Deming regression line with 95% CI (blue), reference interval for each analyte (orange), and identity line (red dots) across all sites and analyzers (A thru D); Bland-Altman plots with mean (red solid line) and +/- 2*SD (red dotted line) (E thru H).

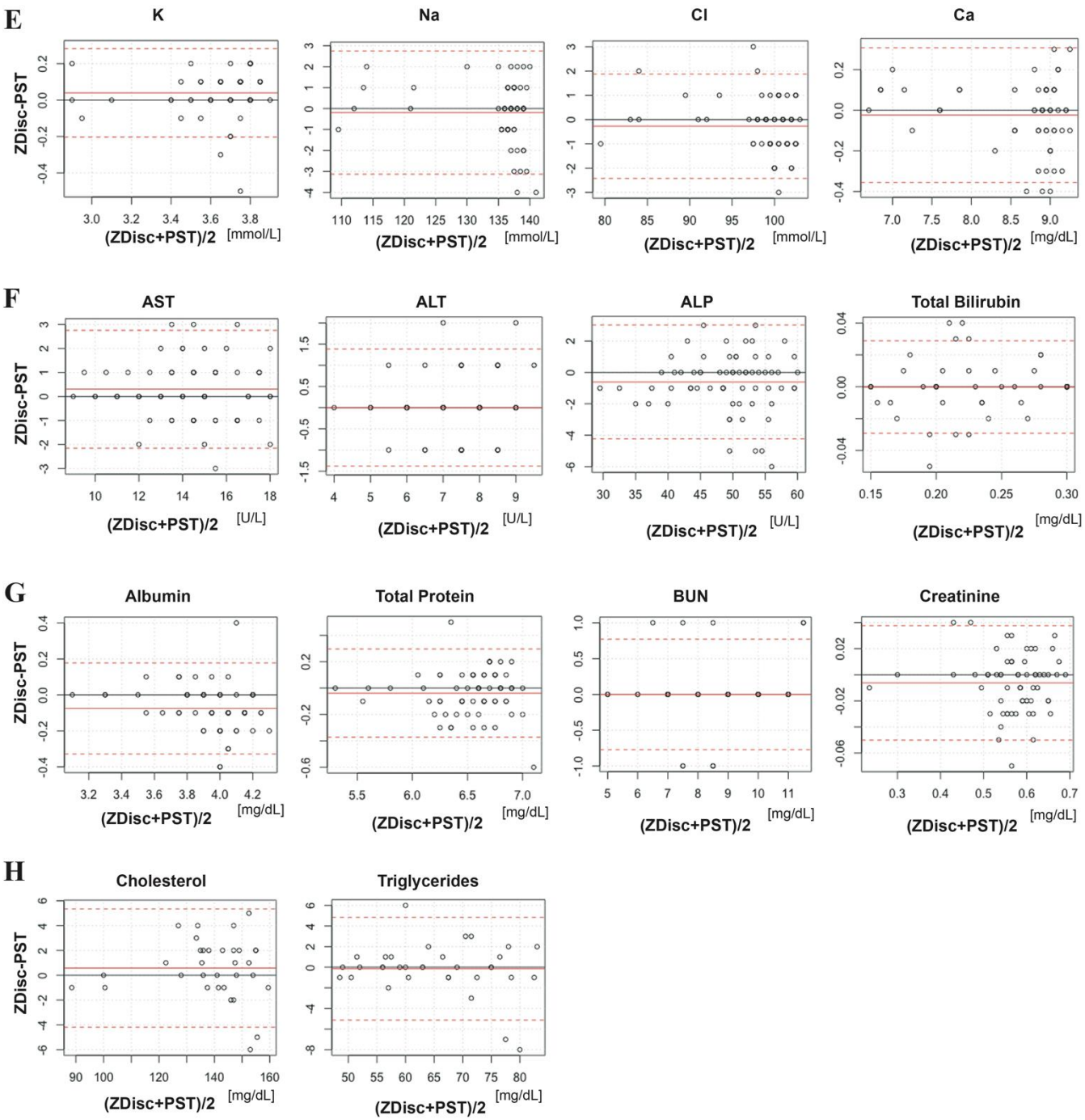

Figure S2. (continued) Scatter plots of the lowest quartile subgroup representing all 14 analytes results for ZDisc vs. vacutainer PST with Deming regression line with 95% CI (blue), reference interval for each analyte (orange), and identity line (red dots) across all sites and analyzers (A thru D); Bland-Altman plots with mean (red solid line) and +/- 2*SD (red dotted line) (E thru H).