



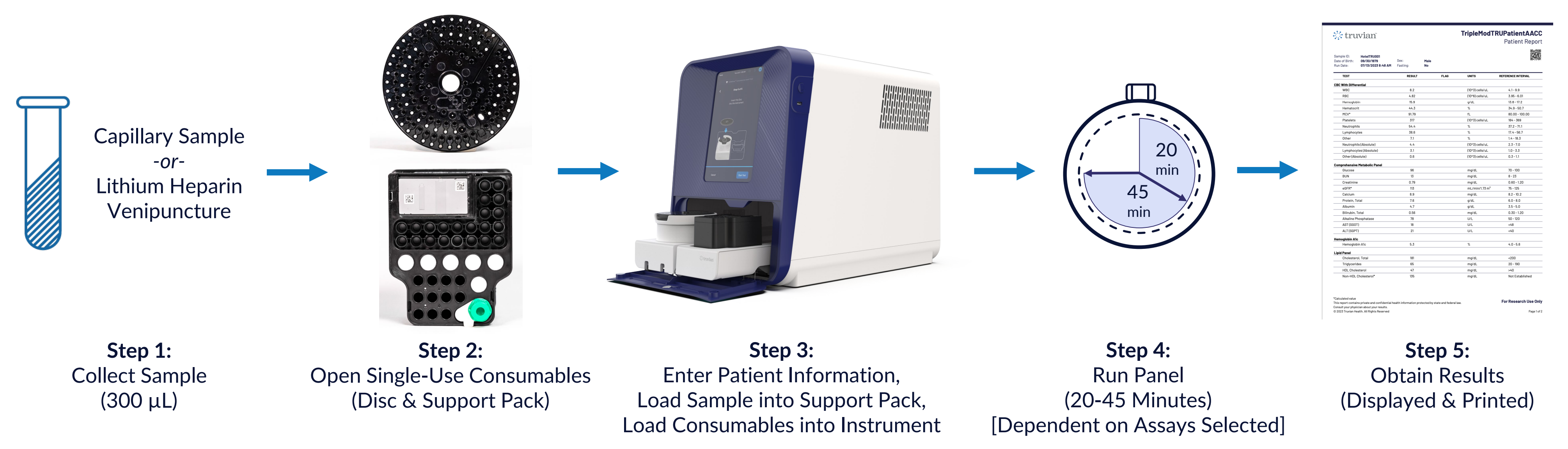
# Concordance of Truvian's Point-of-Care Blood Testing Analyzer to Central Laboratory Testing

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## Truvian is Bringing the Central Lab to the Point-of-Action

Truvian has integrated and miniaturized proven technologies into a benchtop device that can simultaneously execute immunoassay, clinical chemistry, and hematology assays from a single, small sample of blood. The *TruWellness Panel™* includes Complete Blood Count with 3-part differential, Comprehensive Metabolic, Lipid, Thyroid, and Diabetes subpanels.

In late-stage development, the *TruWellness Panel™* was evaluated in a multi-site study for performance and reliability.



## Precision Performance Meets Acceptance Criteria

### Reproducibility Study Design:

- 180 total runs with low, normal, and high controls
- Each assay level = 60 Runs
  - 4 Replicates/Level/Day
  - 5 days
  - 3 Instruments (single site)
- CV represents the sum of repeatability (within-run), between-day and between-instrument variances

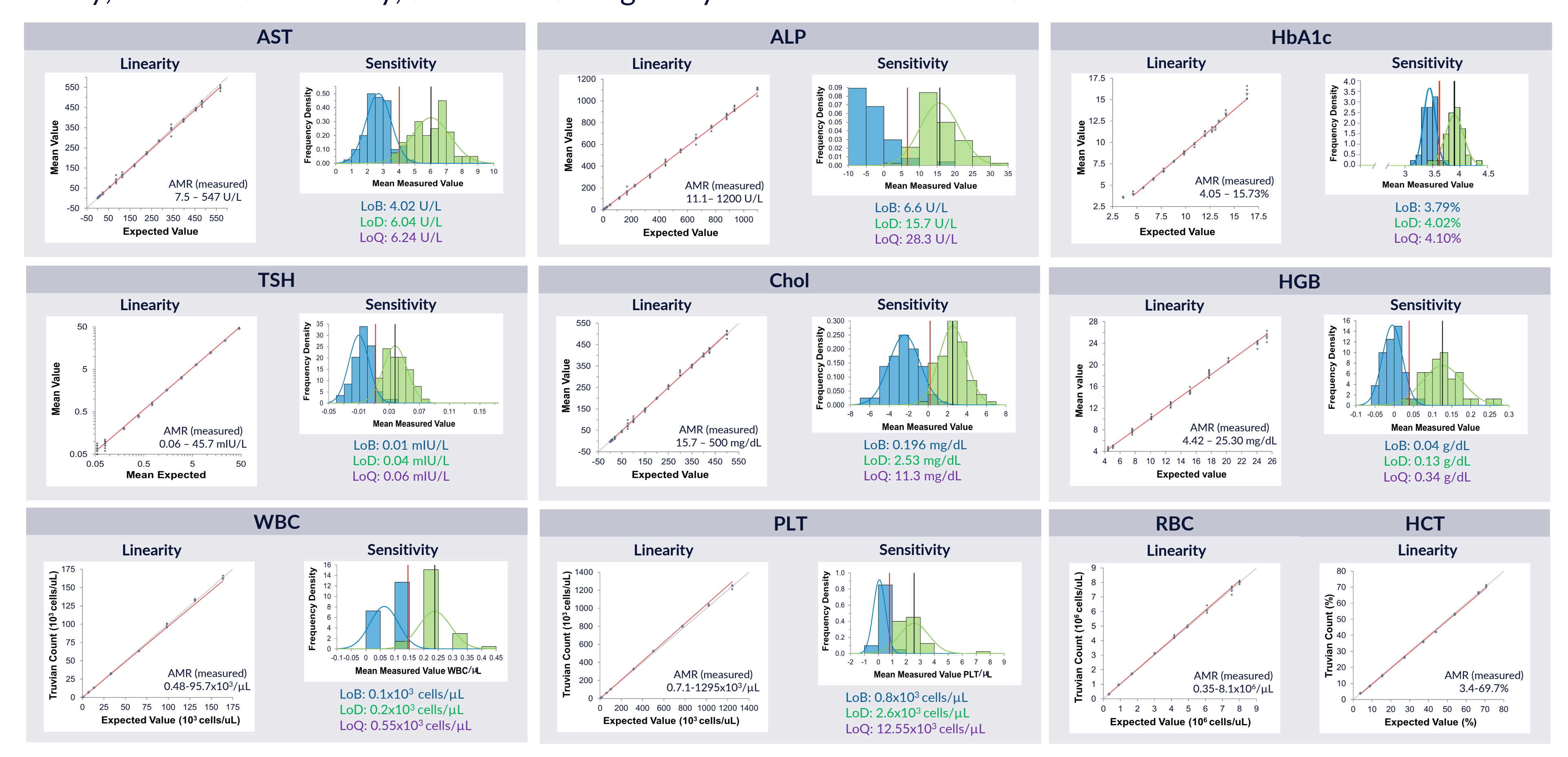
### Reproducibility Summary:

- ✓ *TruWellness Panel™* is performing well across all levels on multiple machines over multiple days
- ✓ Met CV acceptance criteria for 74/75 (99%) of all levels
- ✓ 100% of all levels meet the CV acceptance criteria if single RBC normal level outlier is excluded from analysis
- ✓ An updated QC metric in development suppresses reporting this type of outlier

Comprehensive Metabolic Panel (CMP)					Complete Blood Count (CBC)					Lipid Panel				
Measurand	Level	Mean	CV (%)		Measurand	Level	Mean	CV (%)		Measurand	Level	Mean	CV (%)	
Glucose (mg/dL)	Low	56	3.0		RBC (10 <sup>6</sup> cells/µL)	Normal*	4.11	3.6		Chol (mg/dL)	Normal	176	2.5	
	High	950	1.9			High	5.24	2.5			High	259	2.3	
	Low	14	5.1			Low	4.6	5.0			Low	92	2.3	
BUN (mg/dL)	Normal	41	2.9		WBC (10 <sup>3</sup> cells/µL)	Normal	8.8	2.0		Trig (mg/dL)	Normal	129	2.0	
	High	79	3.2			High	26.6	2.2			High	191	2.0	
	Low	0.89	3.0			Low	5.3	4.4			Low	17	9.9	
CRE (mg/dL)	Normal	1.87	2.3		PLT (10 <sup>3</sup> cells/µL)	Normal	215	2.8		HDL (mg/dL)	Normal	44	4.5	
	High	6.49	1.5			High	413	3.4			High	75	4.3	
	Low	5.3	4.4			Low	15.3	3.3			Normal	132	2.8	
Calcium (mg/dL)	Normal	9.5	3.1		HCT (%)	Normal	35.0	1.9		non-HDL (mg/dL)	Normal	179	2.0	
	High	11.6	2.4			High	47.0	1.0			High	184	2.7	
	Low	3.9	3.4			Low	5.8	2.9			Low	19	3.0	
Total Protein (g/dL)	Low	5.6	2.7		HGB (g/dL)	Normal	13.4	2.6		VLDL (mg/dL)	Normal	26	2.7	
	High	6.8	1.9			High	17.9	1.4			High	38	2.3	
	Low	2.7	4.5			Low	77	3.6			Low	66	4.2	
ALB (mg/dL)	Normal	3.7	3.4		MCV (fL)	Normal	85	4.6		LDL (mg/dL)	Normal	106	3.3	
	High	0.6	7.3			High	90	2.5			High	146	3.2	
	Low	3.3	2.8			Low	6	7.8			Low	6	7.8	
TBIL (mg/dL)	Normal	7.7	1.9							Chol/HDL (ratio)	Normal	4	3.6	
	High	25	10.7								High	3	3.8	
	Low	129	4.7								Low	6	7.8	
ALP (U/L)	Normal	129	4.7											
	High	277	2.6											
	Low	43	2.4											
AST (U/L)	Normal	107	1.9											
	High	246	1.3											
	Low	28	4.3											
ALT (U/L)	Normal	81	2.4											
	High	173	2.0											
	Low	43	2.4											

## Linearity and Sensitivity Achieved Across Clinically Relevant Ranges

Representative data below demonstrates various detection methods including immunoassay, endpoint and kinetic clinical chemistry, immunoturbidimetry, and cell counting assays within the *TruWellness Panel™*.



## Suitable Thresholds for HIL Interferences Established

H Index : Hemolysis (mg/dL)				I Index : Icterus Conjugated / Unconjugated (mg/dL)				L Index : Lipemia (mg/dL)			
CMP	CBC	Lipid Panel	Thyroid & HbA1c	CMP	CBC	Lipid Panel	Thyroid & HbA1c	CMP	CBC	Lipid Panel	Thyroid & HbA1c
Glucose >500	RBC >250	Chol >175	TSH >800	Glucose >10 / >20	RBC >40 / >36	Chol >5 / >10	TSH >45 / >45	Glucose >500	RBC >720	Chol >1000	TSH >1000
BUN >800	WBC >1000	Trig >100	HbA1c >800	BUN >45 / >45	WBC >40 / >40	Trig >5 / >7.5	HbA1c >45 / >45	BUN >1000	WBC >800	Trig >N/A	HbA1c >1000
CRE >500	PLT >1000	HDL >400	N/A	CRE >10 / >10	PLT >40 / >18	HDL >20 / >20	N/A	CRE >1000	PLT >800	HDL >1000	N/A
Calcium >800	HCT >900	Thyroid & HbA1c	N/A	Calcium >30 / >30	HCT >40 / >20	Thyroid & HbA1c	N/A	Calcium >750	HCT >800	Thyroid & HbA1c	N/A
Total Protein >800	HGB >NA	TSH >800	N/A	Total Protein >15 / >10	HGB >45 / >45	TSH >45 / >45	N/A	Total Protein >1000	HGB >1000	TSH >1000	N/A
ALB >800	Lymphocytes >1000	HbA1c >N/A	N/A	ALB >45 / >45	Lymphocytes >40 / >40	HbA1c >45 / >45	N/A	ALB >1000	Lymphocytes >800	HbA1c >1000	N/A
TBIL >50	Neutrophils >1000	N/A	N/A	TBIL >45 / >45	Neutrophils >40 / >40	N/A	N/A	TBIL >750	Neutrophils >800	N/A	N/A
ALP >50	Other >1000	N/A	N/A	ALP >45 / >45	Other >40 / >40	N/A	N/A	ALP >1000	Other >800	N/A	N/A
AST >50				AST >45 / >20				AST >300			
HIL >400				ALT >45 / >20				ALT >300			

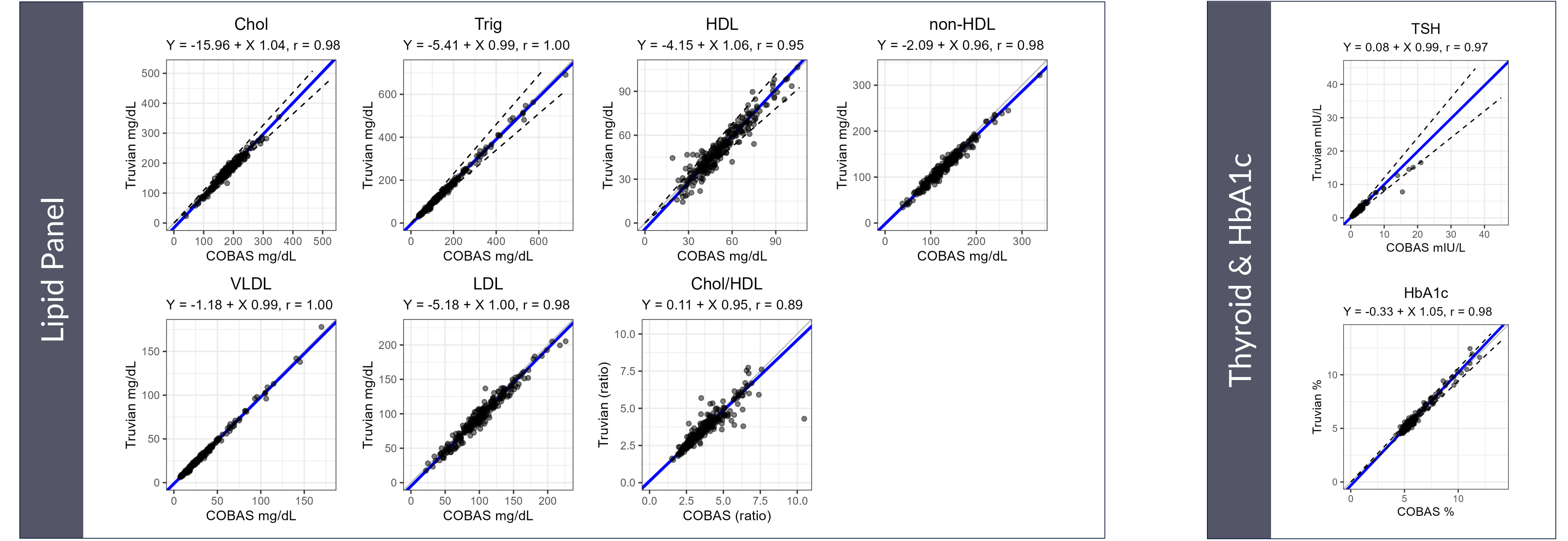
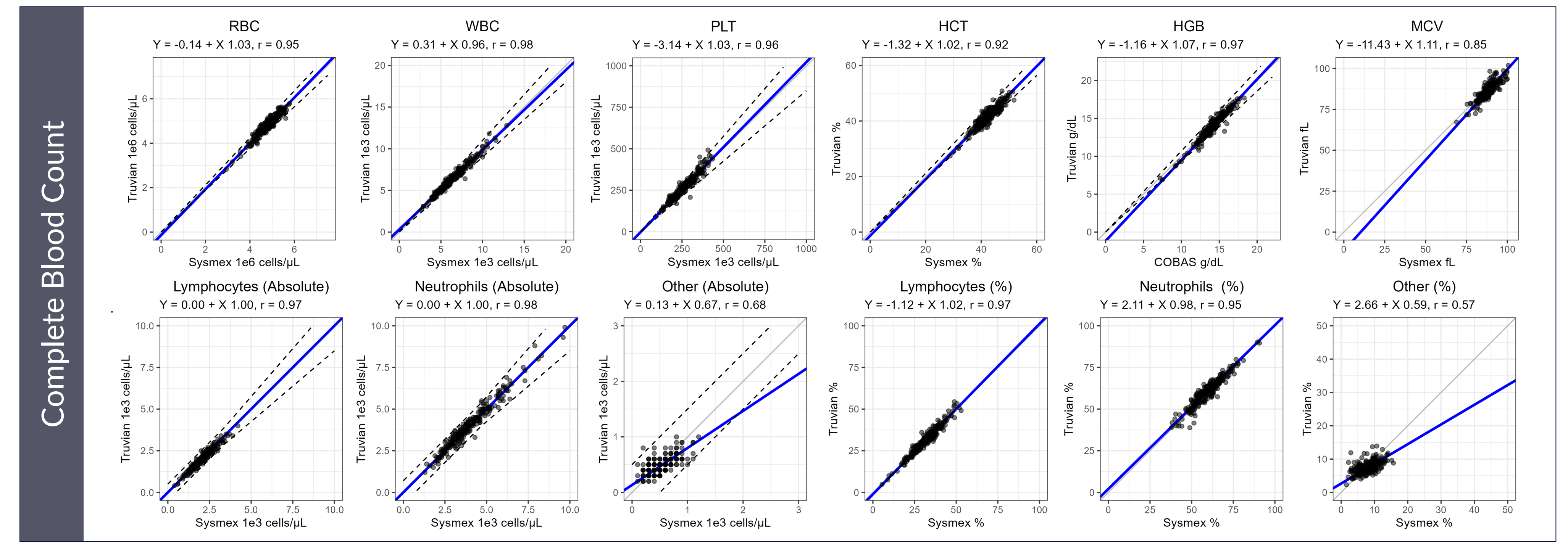
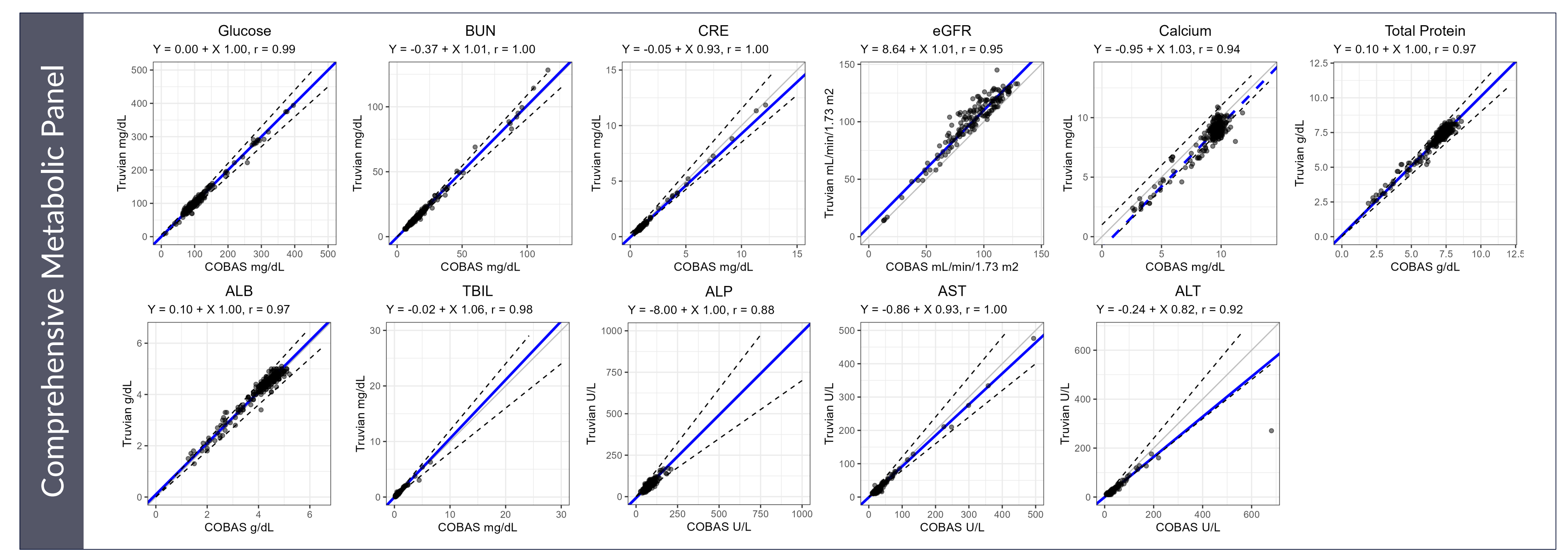
### HIL Interference Summary:

- ✓ *TruWellness Panel™* features integrated sample quality assessment (SQA) to determine levels of HIL in samples
- ✓ Tolerance to HIL interferences is established for all assays and is comparable to FDA-cleared predicate methods

## Multi-Site Method Comparison Study Demonstrates Truvian Results are Concordant with Central Lab Testing

### Method Comparison Study Design:

- Matched samples from 237 donors run on Truvian platform vs central laboratory analyzers
- Estimated 49% apparently healthy donors, 43% donors with chronic disease, and 8% contrived samples
- Samples were run across 5 Truvian instruments at 2 sites
- Regression analysis (Passing Bablok or Deming) was used to determine concordance for each assay



Measurand	Results Range	Correlation Coefficient (r)	Slope (95% CI)	Intercept (95% CI)	Median Relative Bias	Median Bias
Glucose	10.0 - 396 mg/dL	0.99	1.00 (0.97, 1.01)	0.00 (-1.00, 3.50)	0.0%	0.00 mg/dL
BUN	5.63 - 128 mg/dL	1.00	1.01 (0.99, 1.03)	-0.37 (-0.62, -0.07)	0.0%	0.00 mg/dL
CRE	0.29 - 12.2 mg/dL	1.00	0.93 (0.89, 0.96)	-0.05 (-0.09, -0.02)	-13.0%	0.00 mg/dL
eGFR	12.9 - 145 mL/min/1.73 m <sup>2</sup>	0.95	1.01 (0.96, 1.06)	8.64 (4.27, 14.10)	11.0%	9.90 mL/min/1.73 m <sup>2</sup>
Calcium	2.20 - 11.8 mg/dL	0.94	1.03 (0.99, 1.08)	-0.95 (-1.39, -0.52)	-7.0%	-0.60 mg/dL
Total Protein	1.90 - 8.60 g/dL	0.97	1.00 (0.97, 1.00)	0.10 (0.10, 0.38)	2.5%	0.10 g/dL
ALB	1.26 - 5.20 g/dL	0.97	1.00 (0.91, 1.00)	0.10 (0.10, 0.47)	2.3%	0.10 g/dL
TBIL	0.01 - 6.48 mg/dL	0.98	1.06 (1.01, 1.10)	-0.02 (-0.05, 0.00)	0.4%	0.00 mg/dL
ALP	21.0 - 210 U/L	0.88	1.00 (0.91, 1.05)	-8.00 (-11.8, -2.15)	-12.0%	-8.00 U/L
AST	10.0 - 494 U/L	1.00	0.93 (0.88, 0.96)	-0.86 (-2.07, 0.17)	-11.0%	-3.00 U/L
ALT	6.00 - 681 U/L	0.92	0.82 (0.77, 0.87)	-0.24 (-1.56, 1.33)	-19.0%	-5.00 U/L

Measurand	Results Range	Correlation Coefficient (r)	Slope (95% CI)	Intercept (95% CI)	Median Relative Bias	Median Bias
RBC	2.83 - 5.79 x 10 <sup>6</sup> cells/µL	0.95	1.03 (0.99, 1.07)	-0.14 (-0.33, 0.04)	0.3%	0.00 x 10 <sup>6</sup> cells/µL
WBC	2.70 - 12.9 x 10 <sup>3</sup> cells/µL	0.98	0.96 (0.93, 1.00)	0.31 (0.00, 0.46)	0.0%	0.00 x 10 <sup>3</sup> cells/µL
PLT	113 - 492 x 10 <sup>3</sup> cells/µL	0.96	1.03 (0.99, 1.07)	-3.14 (-12.60, 5.02)	1.1%	2.80 x 10 <sup>3</sup> cells/µL
HCT	27.4 - 51.8 %	0.92	1.02 (0.97, 1.07)	-1.32 (-3.58, 0.65)	-1.0%	0.00 %
HGB	6.90 - 18.3 g/dL	0.97	1.07 (1.04, 1.10)	-1.16 (-1.68, -0.78)	-1.5%	-0.20 g/dL
MCV	67.1 - 102 fL	0.85	1.11 (1.02, 1.22)	-11.4 (-21.1, -3.26)	-1.9%	-1.70 fL
Lymphocytes (Absolute)	0.40 - 4.20 x 10 <sup>3</sup> cells/µL	0.97	1.00 (1.00, 1.00)	0.00 (-0.10, 0.00)	0.0%	0.00 x 10 <sup>3</sup> cells/µL
Neutrophils (Absolute)	1.20 - 9.90 x 10 <sup>3</sup> cells/µL	0.98	1.00 (1.00, 1.04)	0.00 (-0.10, 0.10)	0.0%	0.00 x 10 <sup>3</sup> cells/µL
Other (Absolute)	0.10 - 1.20 x 10 <sup>3</sup> cells/µL	0.68	0.67 (0.60, 1.00)	0.13 (0.00, 0.16)	0.0%	0.00 x 10 <sup>3</sup> cells/µL
Lymphocytes (%)	4.80 - 54.4 %	0.97	1.02 (0.99, 1.05)	-1.12 (-2.02, -0.10)	-1.0%	0.00 %
Neutrophils (%)	38.0 - 90.7 %	0.95	0.98 (0.94, 1.03)	2.11 (-0.78, 4.55)	1.6%	1.00 %
Other (%)	1.60 - 15.7 %	0.57	0.59 (0.52, 0.67)	2.66 (1.97, 3.42)	-9.1%	-0.70 %

Measurand	Results Range	Correlation Coefficient (r)	Slope (95% CI)	Intercept (95% CI)	Median Relative Bias	Median Bias
Chol	23.0 - 354 mg/dL	0.98	1.04 (1.02, 1.07)	-16.0 (-20.2, -11.3)	-4.8%	-9.00 mg/dL
Trig	29.0 - 726 mg/dL	1.00	0.99 (0.97, 1.00)	-5.41 (-7.00, -3.85)	-5.0%	-7.00 mg/dL
HDL	14.4 - 106 mg/dL	0.95	1.06 (1.02, 1.11)	-4.15 (-6.94, -1.95)	-2.1%	-1.10 mg/dL
non-HDL	34.0 - 339 mg/dL	0.98	0.96 (0.94, 0.99)	-2.09 (-4.99, 1.27)	-5.0%	-6.80 mg/dL
VLDL	6.00 - 178 mg/dL	1.00	0.99 (0.98, 1.00)	-1.18 (-1.60, -0.84)	-5.0%	-1.40 mg/dL
LDL	17.3 - 226 mg/dL	0.98	1.00 (0.97, 1.03)	-5.18 (-8.26, -2.60)	-5.0%	-5.20 mg/dL
Chol/HDL	1.52 - 10.5 (ratio)	0.89	0.95 (0.91, 0.98)	0.11 (0.00, 0.23)	-1.6%	0.00 (ratio)

Measurand	Results Range	Correlation Coefficient (r)	Slope (95% CI)	Intercept (95% CI)	Median Relative Bias	Median Bias
TSH	0.34 - 21.0 mIU/L	0.97	0.99 (0.94, 1.03)	0.08 (0.02, 0.15)	4.1%	0.06 mIU/L
HbA1c	4.20 - 12.4 %	0.98	1.05 (1.01, 1.10)	-0.33 (-0.56, -0.10)	-0.6%	0.00 %

### Method Comparison Summary:

- ✓ Results from *TruWellness Panel™* demonstrates central laboratory quality results are possible at the point-of-action
- ✓ Performance improvements (formulation, algorithm, workflow) will be included in upcoming planned studies