Advancing Point-of-Care Testing: Independent Evaluation of the Truvian Platform

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Abstract & Methods

Abstract

Truvian's Platform is a benchtop blood testing analyzer that can generate 34 test results, including a Chemistry Panel, Lipid Panel, HbA1c, TSH, and CBC in under 30 minutes with 300 µL whole blood from a single Lithium Heparin sample. This study focused on the rigorous evaluation of the accuracy, reliability, and usability of Truvian's platform in a point-of-care clinical setting run by untrained operators. The performance of the Truvian Platform was evaluated by the UC San Diego Anti-Viral Research Center (AVRC) and focused on recruitment of patients with chronic medical conditions along with apparently health donors. Matched samples were tested on Truvian's platform and compared to central laboratory results. The findings of this independent study demonstrate that **the accuracy of Truvian's device, currently in late-stage development, is highly comparable to centralized testing and the instrument is reliable and easy to use.**

Methods:

For **accuracy evaluation,** a total of **105 unique donors** representing various **chronic disease** states along with apparently healthy donors were consented and enrolled in an IRB approved study. Matched blood samples were collected from each donor and run on the Truvian System and on FDA cleared central laboratory analyzers (Roche Cobas and Sysmex XN). Concordance to the central laboratory analyzers was assessed via relative difference plots and regression analyses. **Reliability** was assessed by calculating the number of runs that reached completion out of the total number of runs attempted. Operators also filled out a survey on the usability and their experience operating the Truvian Platform.
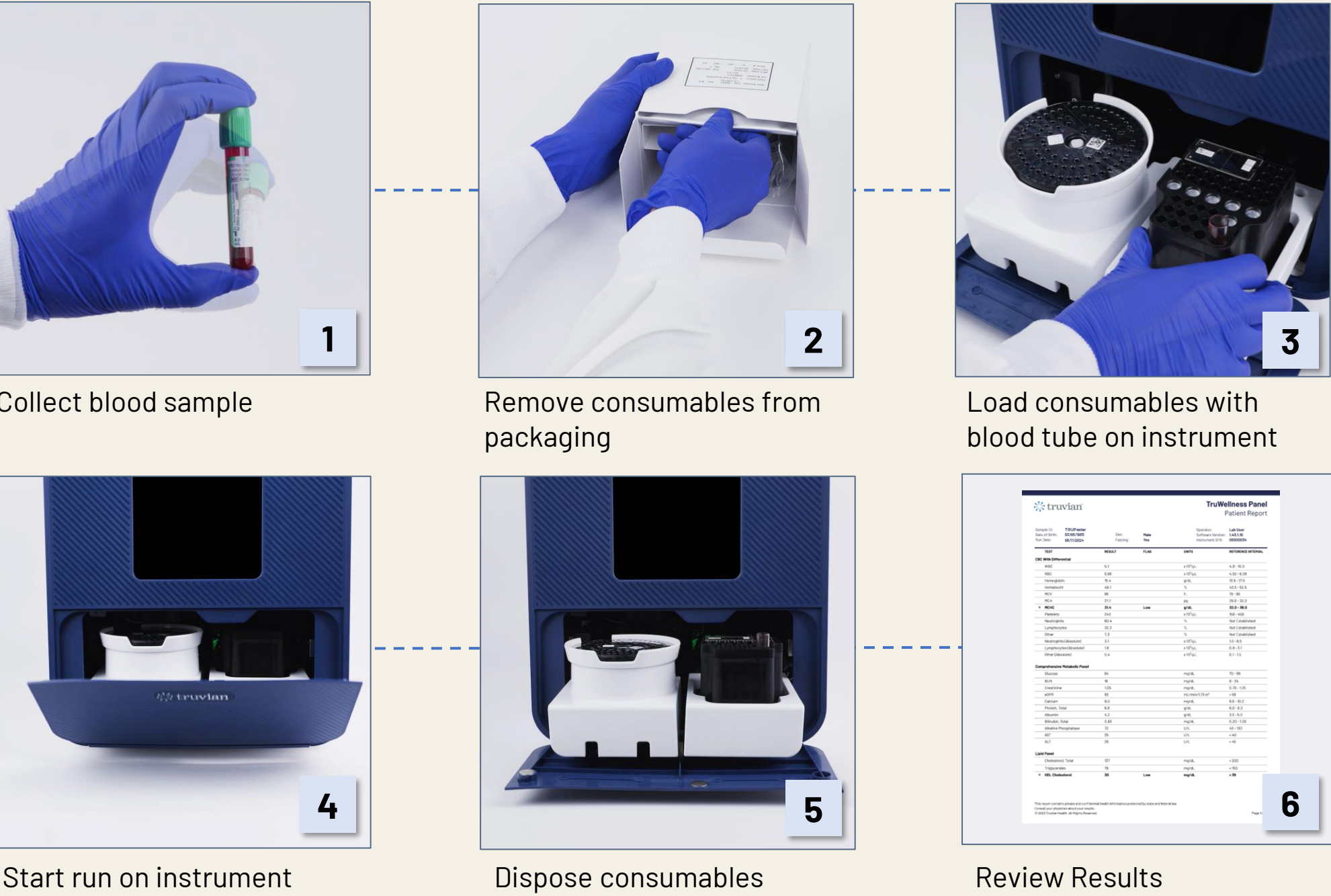
Method Comparison Study Overview
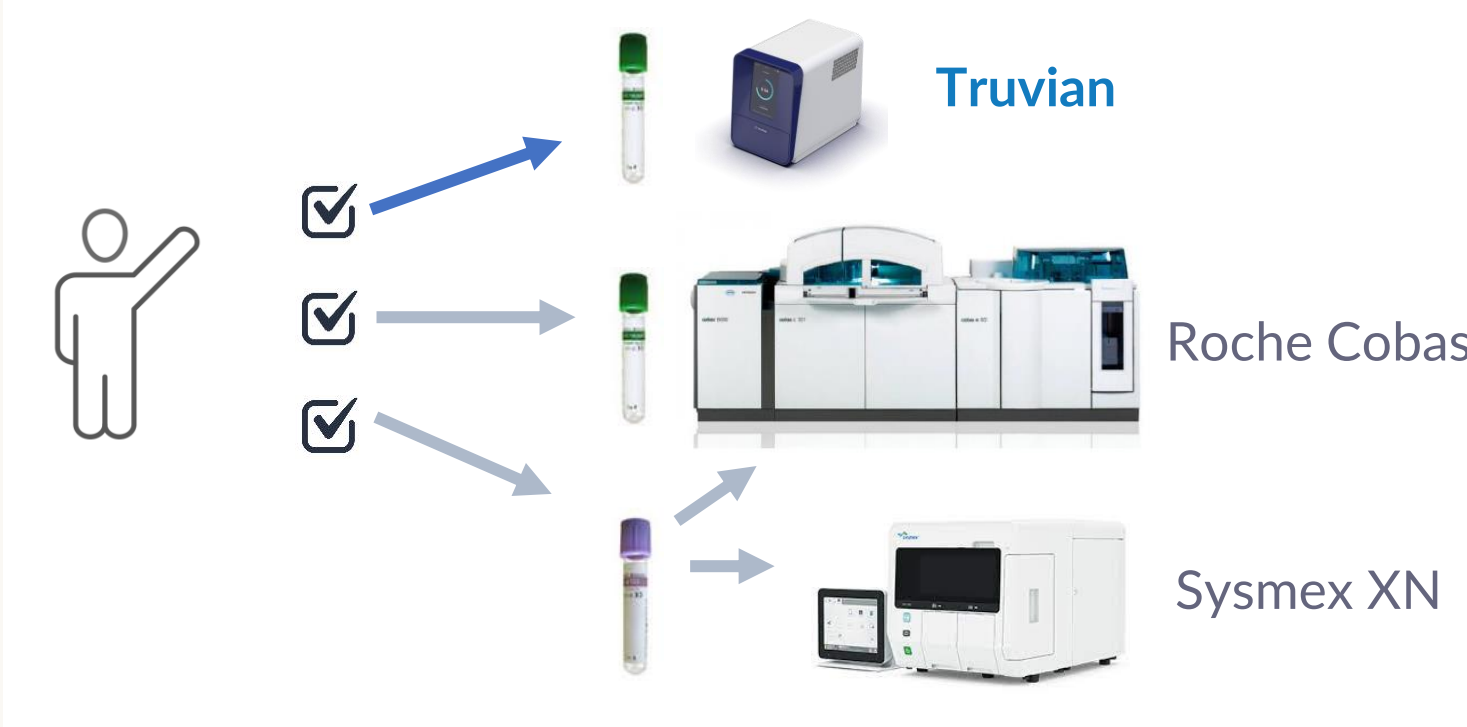
Patient Demographics

Total Count	105	
Mean Age		**Range**
43yrs		(20 - 82yrs)
Gender	**Count**	**Percentage**
Male	50	47.6%
Female	51	48.6%
Unknown	4	3.8%
Primary Diagnosis	**Count**	**Percentage**
Liver Disease	7	6.7%
Diabetes	4	3.8%
Thyroid Disorders	4	3.8%
Blood Disorders	40	38.1%
Heart Disease	2	1.9%
Apparently Healthy	48	45.7%

Truvian Platform Offers a Reliable, Easy To Use Point-of-Care Solution

Patient Workflow

1. Collect blood sample
2. Remove consumables from packaging
3. Load consumables with blood tube on instrument
4. Start run on instrument
5. Dispose consumables
6. Review Results

- **Run Reliability =** % of runs that go to completion and produce a result report was assessed over the course of the study

- Evaluation of the Truvian instrument resulted a run reliability of **98%** (105 successful runs out of 107 attempted)

Operator Satisfaction Survey

11 operators were surveyed regarding their experience operating the Truvian Platform

Operator Experience Level Using Point-of-Care Devices

Minimal experience
Somewhat experienced
Experienced
Moderately experienced
Highly Experienced

# of Operators
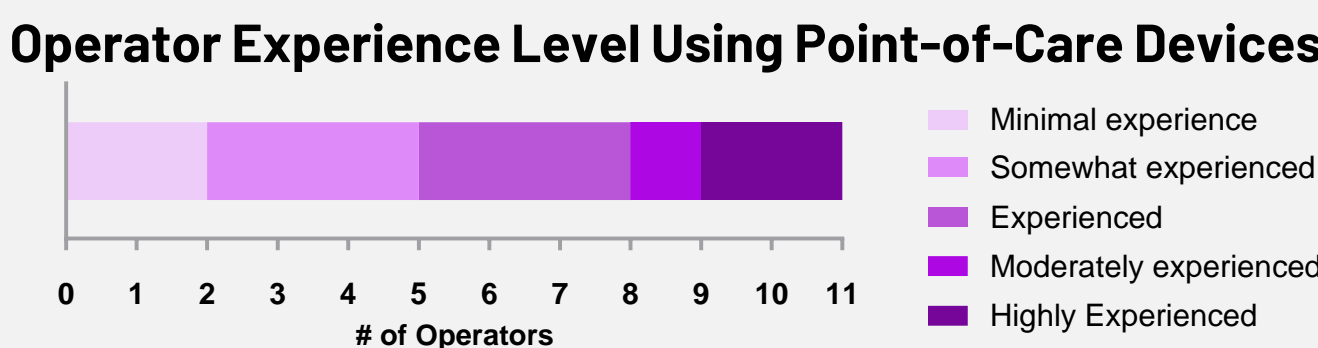
| Survey Question	Survey Response		
	Disagree	Neutral	Agree
System was intuitive and straightforward to use	0	1	10
System interface and prompts were easy to follow	0	0	11
Most people would learn to use the system quickly	0	1	10
Quick start guide was helpful in operating the system	0	3	8
I feel confident using the system	0	1	10
This system will be easy for most people to learn	0	1	10

Usability Summary

✓ Truvian platform exhibited **98% run reliability**

✓ 100% of operators found the system interface and prompts easy to follow

✓ 90% of operators found the system intuitive and straightforward to use

✓ 90% of operators felt the Truvian Platform will be easy for most people to learn

Truvian's Blood Testing Platform Produces Accurate Results in Independent Study

- 57 chronic disease and 48 apparently healthy donor samples were evaluated
- Matched samples were run on Truvian's platform and sent to the central laboratory
- Passing-Bablok regression was performed across 34 tests to determine concordance to central lab
  - Truvian values on Y-axis & corresponding predicate values on X-axis. Regression equation with y-intercept, slope and r value above plot

* indicates calculated values
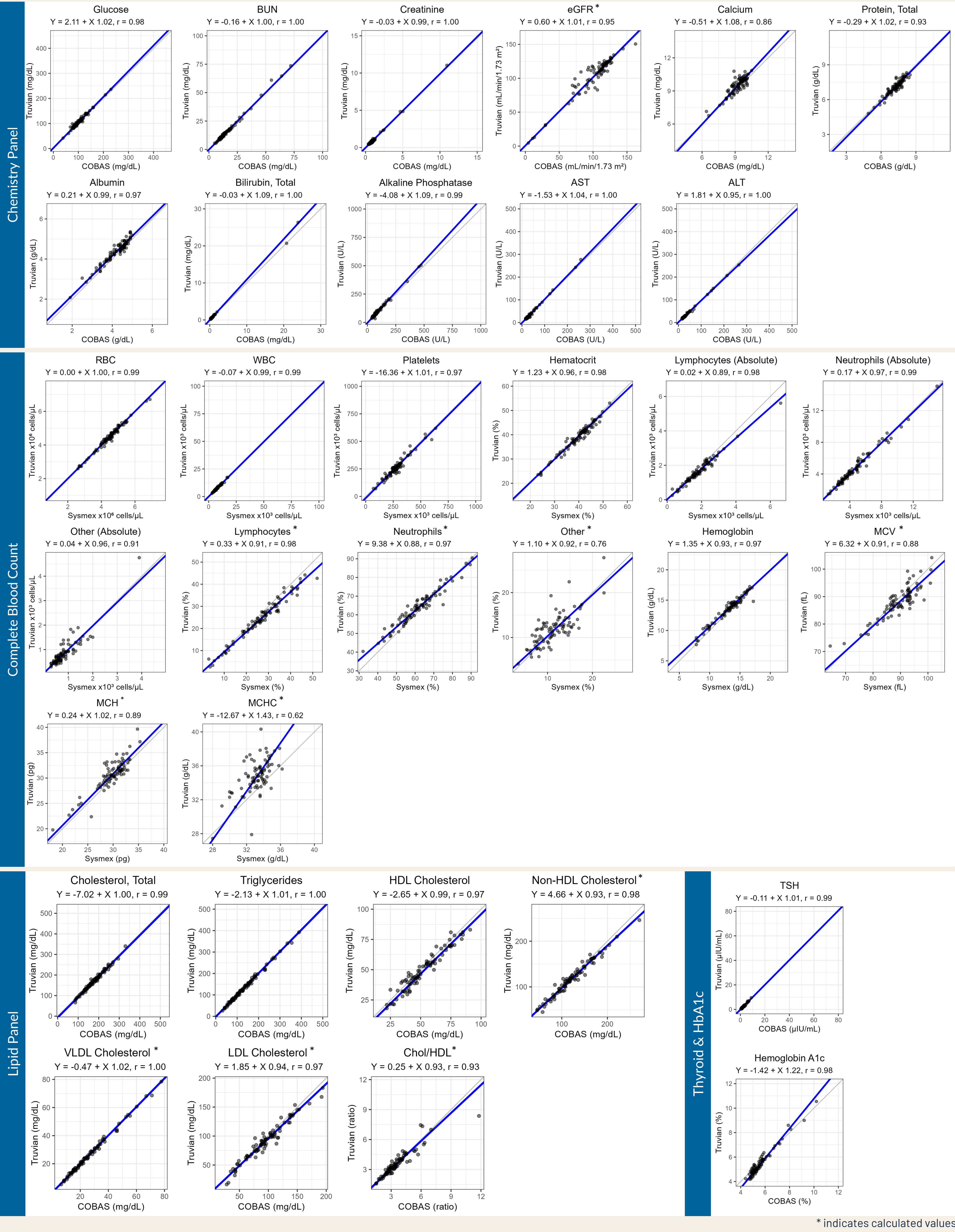
Method Comparison Summary

✓ Truvian's platform is concordant to central lab analyzers in patients with chronic disease and apparently healthy donors

✓ Lithium heparin samples run on Truvian's device produce concordant results to EDTA samples ran on Sysmex XN for CBC

Key Takeaways

Routine blood testing remains inconvenient, complicated and opaque for patients and providers resulting in a lack of adherence, prolonged turnaround times, and delayed medical intervention. Truvian's benchtop blood testing platform is purpose-built to address these pain points, making blood testing simple and convenient for all. This independent assessment of the platform involved untrained operators from UCSD AVRC conducting studies using **chronic disease patient samples** and apparently healthy donor samples to scrutinize its performance. The operators found the platform to be **user-friendly** and **easy to operate**. The outcomes of this evaluation confirm the platform's **reliability** and ability to deliver **accurate results**.