Breaking Barriers in Blood Testing With a Phlebotomy-Free Approach to Near-Patient Diagnostics with Truvian's Multi-Modal Platform Using Microneedle Capillary Collection
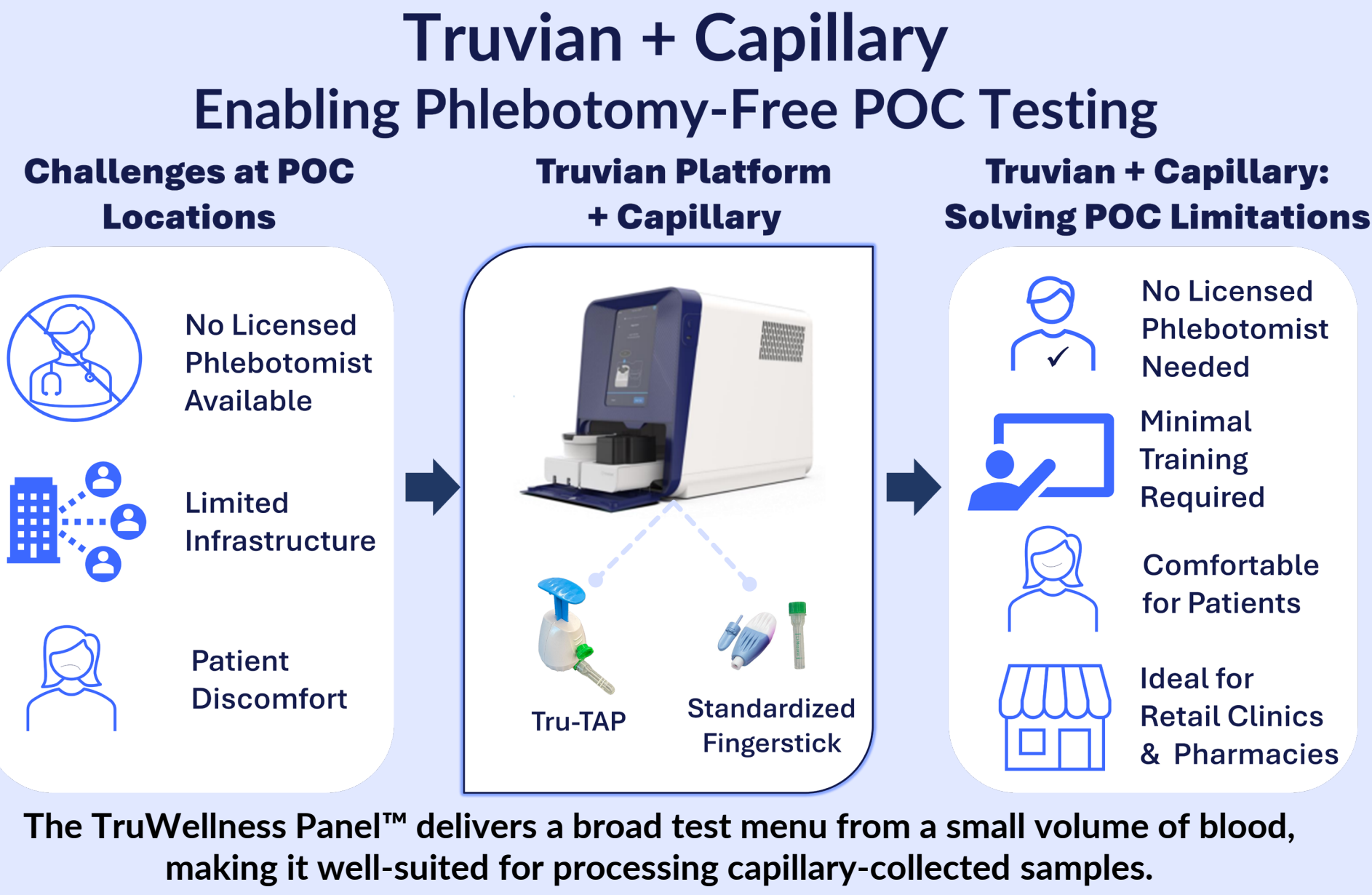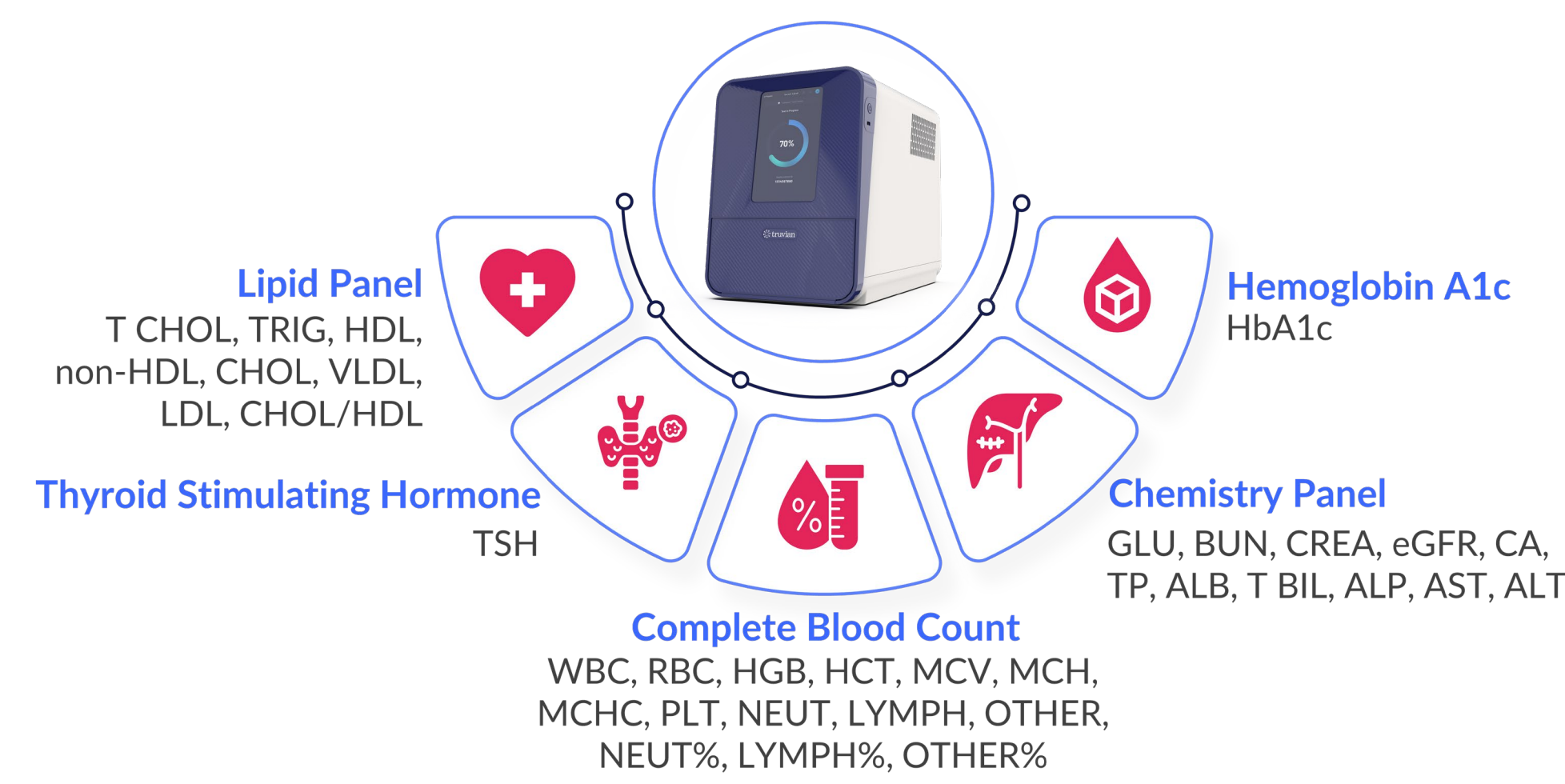
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1. ABSTRACT & METHODS
OPENING THE DOOR TO ACCESSIBLE DIAGNOSTICS

To overcome limitations of traditional venipuncture such as requiring a licensed phlebotomist, difficult vein access, fragile skin or needle anxiety, we evaluated capillary sample performance on the Truvian Platform using the TruWellness Panel™. This study aimed to determine whether capillary sampling could maintain analytical integrity while enabling broader patient access to diagnostics. While convenient, traditional capillary collection has faced challenges including interstitial fluid skewing analyte results, hemolysis from finger milking, and clotting at the wound site affecting cell counts. To address these challenges, we assessed two approaches: (1) A standardized fingerstick collection and (2) Tru-TAP, a microneedle-based device. Over 100 matched capillary and venipuncture donor samples were collected under an IRB approved protocol and analyzed on the Truvian Platform. Performance was assessed using regression analysis.

The TruWellness Panel™: A Multi-Modality Solution for Lab-Accurate Point-of-Care Testing

- **Lipid Panel** — T CHOL, TRIG, HDL, non-HDL, CHOL, CA, LDL, CHOL/HDL
- **Hemoglobin A1c** — HbA1c
- **Thyroid Stimulating Hormone** — TSH
- **Chemistry Panel** — GLU, BUN, CREA, eGFR, CA, TP, ALB, T BIL, ALP, AST, ALT
- **Complete Blood Count** — WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT, LYMPH, OTHER, NEUT%, LYMPH%, OTHER%

Truvian + Capillary
Enabling Phlebotomy-Free POC Testing

Challenges at POC Locations:
- No Licensed Phlebotomist Available
- Limited Infrastructure
- Patient Discomfort

Truvian Platform + Capillary:
- Tru-TAP
- Standardized Fingerstick

Truvian + Capillary: Solving POC Limitations
- No Licensed Phlebotomist Needed
- Minimal Training Required
- Comfortable for Patients
- Ideal for Retail Clinics & Pharmacies

The TruWellness Panel™ delivers a broad test menu from a small volume of blood, making it well-suited for processing capillary-collected samples.

Study results support that capillary sampling enables the Truvian Platform to deliver lab-grade diagnostics in point-of-care settings without phlebotomy, expanding access where traditional blood draws are not readily available.
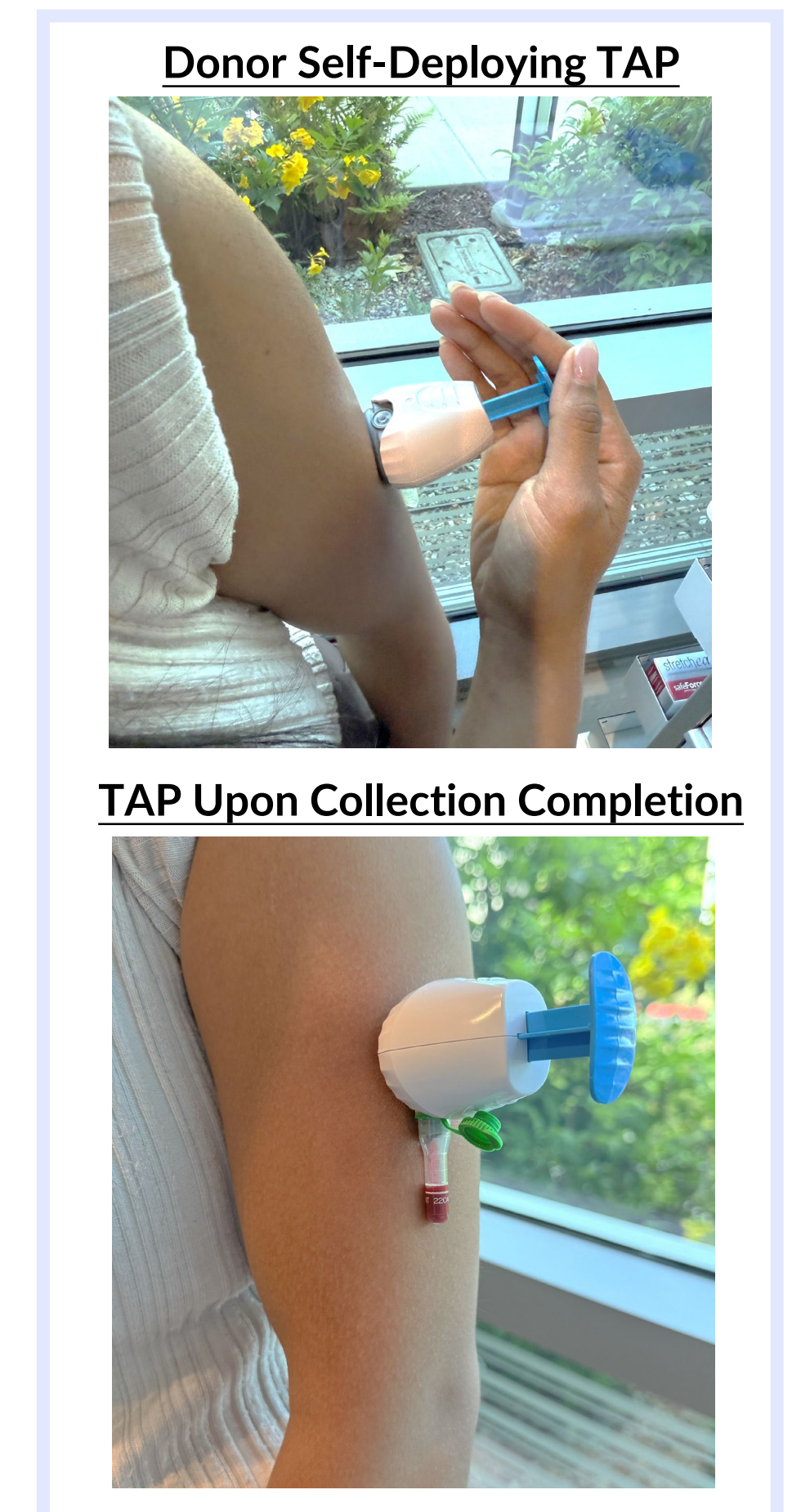
3. MICRONEEDLE DEVICE SHOWS PROMISING CONCORDANCE WITH VENOUS RESULTS

Tru-TAP offers a low-pain, microneedle-based capillary blood collection alternative. In this study, a research-use-only (RUO) version of the TAP device enhanced with a novel additive to address cell aggregation was evaluated. Results showed all analytes except Platelets and WBC count + Diff aligned with venous sampling on the Truvian Platform.

Donor Demographics	
Age Range (Min - Max)	23yrs - 75yrs
Total Male Samples	35
Total Female Samples	32
Total Samples Collected	67
Collection Metrics	
Mean Volume	531 µL
Mean Collection Time	60 sec
Clot Occurrence	13%
Donor Success Rate*	88%

*Donor Success = % of donors providing sufficient sample volume without visible clots.

Tru-TAP Collection Process

Donor Self-Deploying TAP

TAP Upon Collection Completion

Chemistry Panel, Complete Blood Count, Lipid Panel, TSH & A1c regression plots (Tru-TAP vs Venous):

Glucose r = 0.954; BUN r = 0.975; Creatinine r = 0.974; eGFR (Calc) r = 0.987; Calcium r = 0.074; Protein, Total r = 0.825; Albumin r = 0.774; Bilirubin, Total r = 0.980; Alkaline Phosphatase r = 0.937; AST r = 0.936; ALT r = 0.976

RBC r = 0.905; WBC r = 0.708; Platelets r = 0.669; Hematocrit r = 0.955; Lymphocytes (Absolute) r = 0.916; Neutrophils (Absolute) r = 0.728; Other (Absolute) r = 0.354; Lymphocytes r = 0.638; Neutrophils r = 0.736; Other r = 0.691; Hemoglobin r = 0.645; MCV (Calc) r = 0.828; MCH (Calc) r = 0.582; MCHC (Calc) r = 0.177

Cholesterol, Total r = 0.992; Triglycerides r = 0.977; HDL Cholesterol r = 0.926; Non-HDL Chol (Calc) r = 0.987; TSH r = 0.968; Hemoglobin A1c r = 0.907; VLDL Chol (Calc) r = 0.977; LDL Chol (Calc) r = 0.983; Cholesterol/HDL Ratio r = 0.958

x – denotes samples with PLT flag, indicating potential presence of cell aggregation or abnormalities that may compromise count accuracy; flagged samples tracked but excluded from regression analysis.
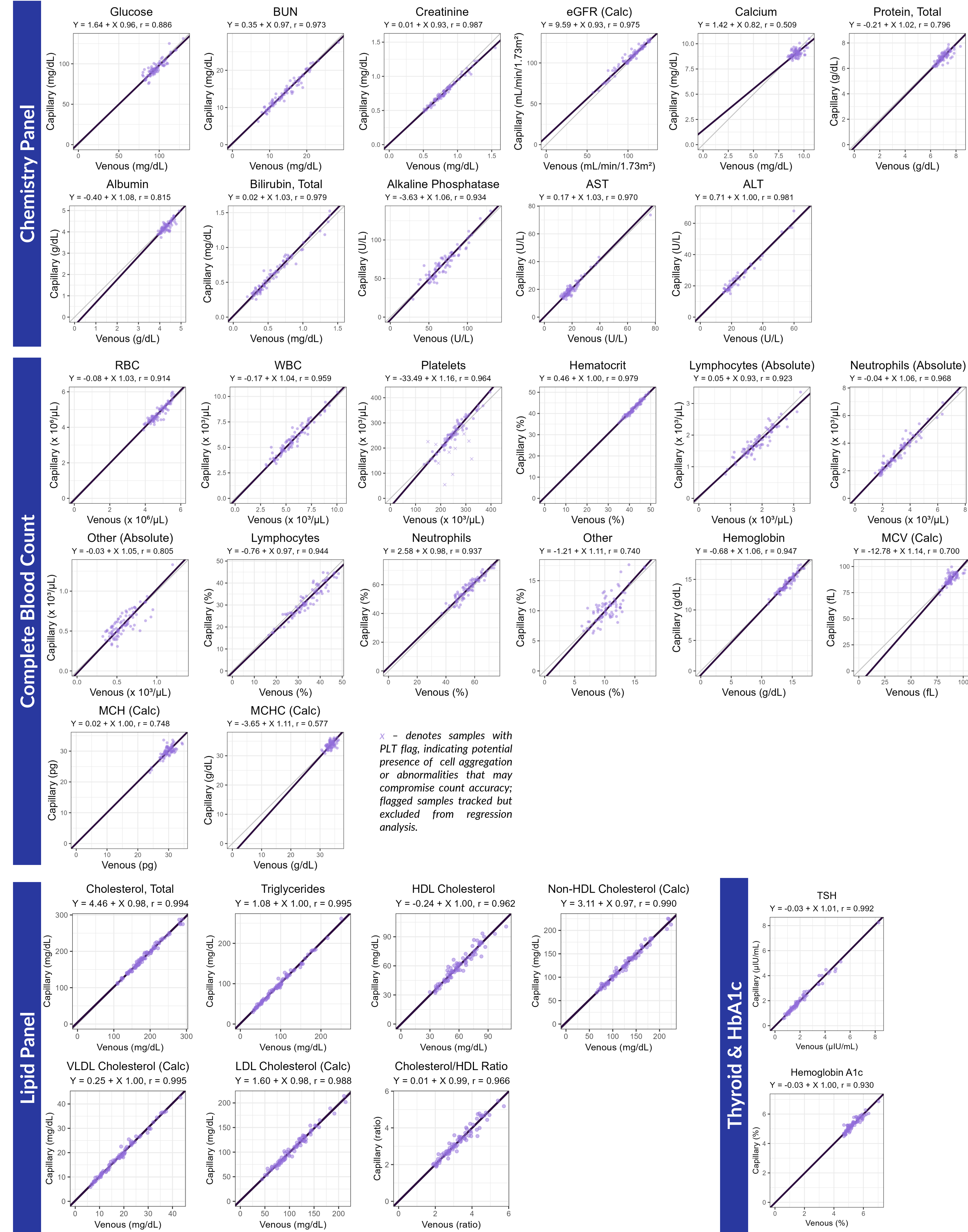
◆ Chemistry, Lipid, TSH & HbA1c panels showed Tru-TAP sample results comparable to venous
◆ Platelet flags observed in 53% of Tru-TAP samples, potentially affecting count and diff accuracy; further work underway to reduce cell aggregation

2. FINGERSTICK RESULTS COMPARABLE TO VENOUS ON TRUVIAN PLATFORM

A standardized method for fingerstick capillary collections was developed and utilized to collect 89 donor samples. Matched venous and capillary samples were analyzed on the Truvian Platform, demonstrating strong concordance across all analytes. These findings support the suitability of fingerstick-based capillary sampling as a viable alternative to venous collection for multi-analyte testing on the Truvian system.

Donor Demographics	
Age Range (Min - Max)	19yrs – 71yrs
Total Male Samples	47
Total Female Samples	42
Total Samples Collected	89
Collection Metrics	
Mean Volume	584 µL
Mean Collection Time	70 sec
Clot Occurrence	0%
Donor Success Rate*	98%

*Donor Success = % of donors providing sufficient sample volume without visible clots.

Chemistry Panel regression plots (Capillary vs Venous):

Glucose: Y = 1.64 + X 0.96, r = 0.886
BUN: Y = 0.35 + X 0.97, r = 0.973
Creatinine: Y = 0.01 + X 0.93, r = 0.987
eGFR (Calc): Y = 9.59 + X 0.93, r = 0.975
Calcium: Y = 1.42 + X 0.82, r = 0.509
Protein, Total: Y = -0.21 + X 1.02, r = 0.796
Albumin: Y = -0.40 + X 1.08, r = 0.815
Bilirubin, Total: Y = 0.02 + X 1.03, r = 0.979
Alkaline Phosphatase: Y = -3.63 + X 1.06, r = 0.934
AST: Y = 0.17 + X 1.03, r = 0.970
ALT: Y = 0.71 + X 1.00, r = 0.981

Complete Blood Count regression plots:

RBC: Y = -0.08 + X 1.03, r = 0.914
WBC: Y = -0.17 + X 1.04, r = 0.959
Platelets: Y = -33.49 + X 1.16, r = 0.964
Hematocrit: Y = 0.46 + X 1.00, r = 0.979
Lymphocytes (Absolute): Y = 0.05 + X 0.93, r = 0.923
Neutrophils (Absolute): Y = -0.04 + X 1.06, r = 0.968
Other (Absolute): Y = -0.03 + X 1.05, r = 0.805
Lymphocytes: Y = -0.76 + X 0.97, r = 0.944
Neutrophils: Y = 2.58 + X 0.98, r = 0.937
Other: Y = -1.21 + X 1.11, r = 0.740
Hemoglobin: Y = -0.68 + X 1.06, r = 0.947
MCV (Calc): Y = -12.78 + X 1.14, r = 0.700
MCH (Calc): Y = 0.02 + X 1.00, r = 0.748
MCHC (Calc): Y = -3.65 + X 1.11, r = 0.577

x – denotes samples with PLT flag, indicating potential presence of cell aggregation or abnormalities that may compromise count accuracy; flagged samples tracked but excluded from regression analysis.

Lipid Panel regression plots:

Cholesterol, Total: Y = 4.46 + X 0.98, r = 0.994
Triglycerides: Y = 1.08 + X 1.00, r = 0.995
HDL Cholesterol: Y = -0.24 + X 1.00, r = 0.962
Non-HDL Cholesterol (Calc): Y = 3.11 + X 0.97, r = 0.990
VLDL Cholesterol (Calc): Y = 0.25 + X 1.00, r = 0.995
LDL Cholesterol (Calc): Y = 1.60 + X 0.98, r = 0.988
Cholesterol/HDL Ratio: Y = 0.01 + X 0.99, r = 0.966

Thyroid & HbA1c regression plots:

TSH: Y = -0.03 + X 1.01, r = 0.992
Hemoglobin A1c: Y = -0.03 + X 1.00, r = 0.930

◆ Standardized fingerstick results concordant to venous for all analytes
◆ Platelet flags observed in 14% of standardized fingerstick samples

KEY FINDINGS

◆ Capillary samples collected via standardized fingerstick showed strong concordance with venous samples across all analytes on the Truvian Platform.

◆ Tru-TAP improves sample quality over previously evaluated capillary methods by reducing cell aggregation (historical data not shown); refinements are ongoing to resolve residual platelet flags.

◆ By leveraging the low sample volume requirements of the TruWellness Panel™, capillary-collected blood can be used to deliver an expansive test menu with lab-comparable performance.

◆ When paired with phlebotomy-free collection methods, the Truvian Platform supports improved access to diagnostics at the point of care.