Evaluation of the "At-Home Lab Testing" (AHLT) Product

AT-HOME LAB TESTING

A Method Comparison between Venous and Capillary Blood Samples

ABSTRACT

The traditional approach to diagnostic procedures often requires patients to visit clinical settings for venous blood collection. The "At Home Lab Testing" (AHLT) product by biosurfit offers a transformative alternative, enabling patients to self-collect capillary blood samples. The primary aim of this study was to investigate the analytical concordance between venous and capillary blood samples collected using the AHLT kit across 26 individual biological parameters. Blood samples from 96 participants were analyzed using Abbott Alinity equipment at two distinct timepoints: immediate testing and after 48 hours of storage at room temperature. Beyond the general guideline of a mean relative bias of less than 10%, each analyte was thoroughly evaluated using Pearson correlation factor and Bland-Altman plots to determine its suitability for the AHLT procedure. The majority of analytes displayed strong analytical similarity with the conventional venous method, with only six not meeting the comprehensive criteria. The findings underscore the feasibility of using capillary blood, with the AHLT product exemplifying the potential advancements in patient-centric diagnostics. This research emphasizes the convenience and reliability of at-home capillary blood collection, highlighting its capability to complement or even replace traditional venous sample collection in specific scenarios.

- **Results at-home made easy and reliable**

The results of this study have shown to be an accurate and reliable method for collecting capillary blood. Results obtained are comparable to the results of venous blood samples.

- **Patient centric solution**

Considered a valuable tool for patients who need to have blood tests but who are unable or unwilling to go to a laboratory.

- **Improve outcomes and reduce long-term costs**

The kit shows to be relevant to be used for remote monitoring of patients who are at risk for chronic diseases.

INTRODUCTION

In the rapidly evolving landscape of medical diagnostics, the emphasis on patient-centric approaches has grown exponentially. The conventional process of venous blood collection, which requires patients to visit clinical facilities, poses not only logistical challenges but also potential barriers to timely healthcare access. As healthcare systems worldwide seek innovative solutions to streamline diagnostic processes, the concept of self-collected capillary blood samples has emerged as a potential game-changer [1].

Tertiary diagnostic centers, which often serve diverse populations, have been burdened by the influx of patients needing regular diagnostic evaluations. Beyond the logistical considerations, such as travel and wait times, there are also significant socioeconomic costs associated with frequent hospital visits. For many patients, especially those with chronic conditions or those living in remote areas, these visits can be both physically and financially taxing [2].

Moreover, primary care infrastructures, which traditionally handle routine phlebotomy and monitoring, are under increasing strain. The disconnect between primary care and specialist facilities often leaves patients in a quandary about where to seek appropriate care and monitoring. This fragmentation in the healthcare journey can lead to inefficiencies, increased costs, and potential delays in treatment adjustments [3].

Ensuring the quality of diagnostic samples is paramount. The German Society for Clinical Chemistry and Laboratory Medicine has emphasized the importance of preanalytical quality in diagnostics, outlining recommendations to ensure the integrity and reliability of samples [4]. Novel self-collection methods have been explored, such as the one proposed for future home-based PrEP monitoring, highlighting the feasibility and acceptability of such approaches [5]. Studies have further evaluated the efficacy of capillary sample collection kits, as seen in the comparative study for HbA1c measurement, emphasizing their reliability [6]. In the context of the recent global pandemic, the value of self-collection systems, especially for SARS-CoV-2 antibody testing, has been underscored [7].

The "At Home Lab Testing" (AHLT) product by biosurfit offers a solution to these challenges. By enabling patients to self-collect capillary blood samples, AHLT has the potential to revolutionize the diagnostic landscape. Such a methodology not only empowers patients, granting them greater control over their health monitoring, but also offers the medical community a more efficient, cost-effective, and scalable diagnostic tool.

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METHODS

STUDY DESIGN

A total of 96 blood collections were performed on different individuals, analyzing 26 biological parameters. Blood samples were analyzed at a central laboratory using the Abbott Alinity equipment. The list of biological parameters evaluated on this study follows below:

FT4 (Free Thyroxine)	Calcium
TSH (Thyroid Stimulating Hormone)	HbA1c (Haemoglobin A1c)
Triglycerides	Albumin
HDL (High-Density Lipoprotein)	ALT (Alanine Transaminase)
LDL (Low-Density Lipoprotein)	Bilirubin
Cholesterol	Creatinine
Testosterone	ALP (Alkaline Phosphatase)
PSA (Prostate-Specific Antigen)	GGT (Gamma-Glutamyl Transferase)
Vitamin D	Urea
VIT B12 (Vitamin B12)	T3 (Triiodothyronine)
Folic Acid	LH (Luteinizing Hormone)
Magnesium	FSH (Follicle Stimulating Hormone)
Total Protein	CRP (C-Reactive Protein)

Table 1: *List of biological parameters evaluated.*

Blood collection and sample processing

Venous blood was collected using standard laboratory procedures and material. Capillary blood samples were taken using Becton Dickinson tubes (BD365968/BD365975). Venous and capillary samples were tested immediately (t=0h) and after a 48 hours storage (t = 48h; capillary samples only). When necessary, the capillary tubes were centrifuged to separate serum, yielding approximately 300 µL from the maximum 600 µL of the capillary blood collected.

Data Analysis

Relative Mean Bias, Pearson Coefficient and Bland Altman plots for each analyte, sample collection method and capillary sample storage time were evaluated. Results are presented on the next chapter.

RESULTS

The results section will present findings from the method comparison. Relative Mean Bias, Pearson Coefficient (R), and Bland Altman plots for each timepoint and analyte tested.

Venous collection results vs AHLT capillary collection result | t = 0h

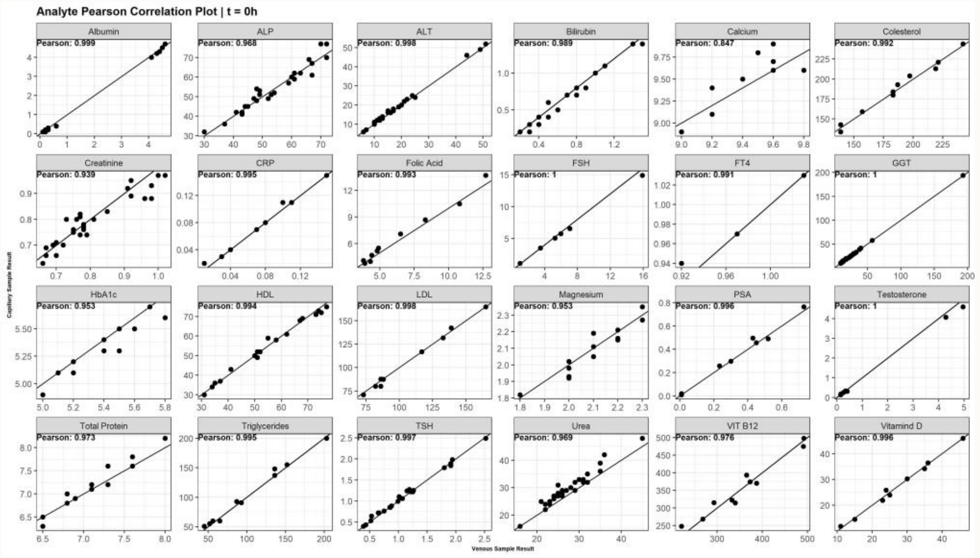

Figure 1: *Scatter plot and Pearson correlation data per analyte (t=0h) for venous collection (reference method) vs AHLT capillary collection.*

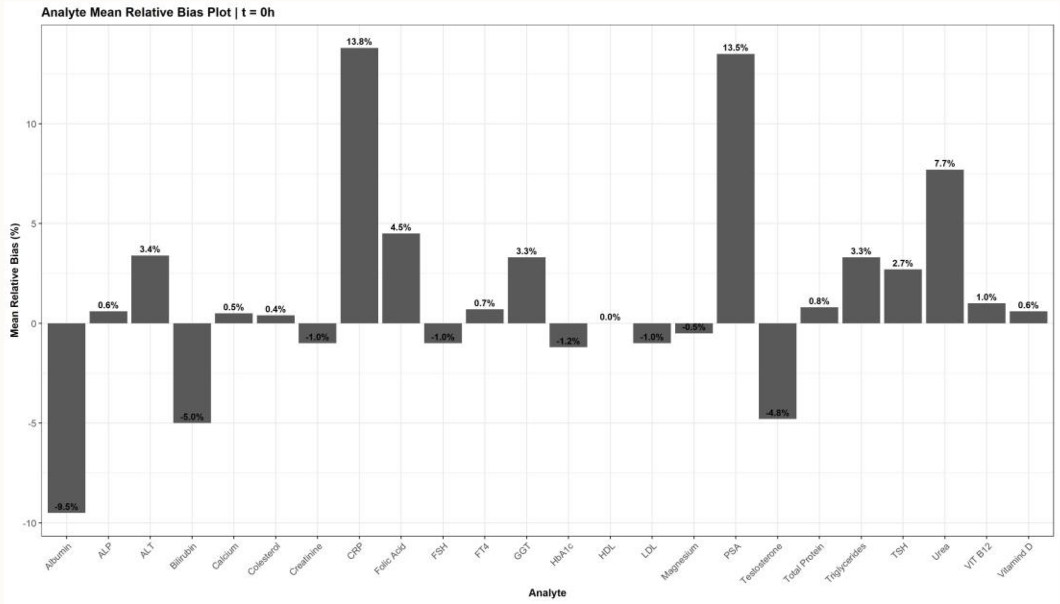

Figure 2: *Mean relative bias (%) data per analyte (t=0h) for venous collection (reference method) vs AHLT capillary collection.*

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Venous collection results vs AHLT capillary collection result | t = 0h

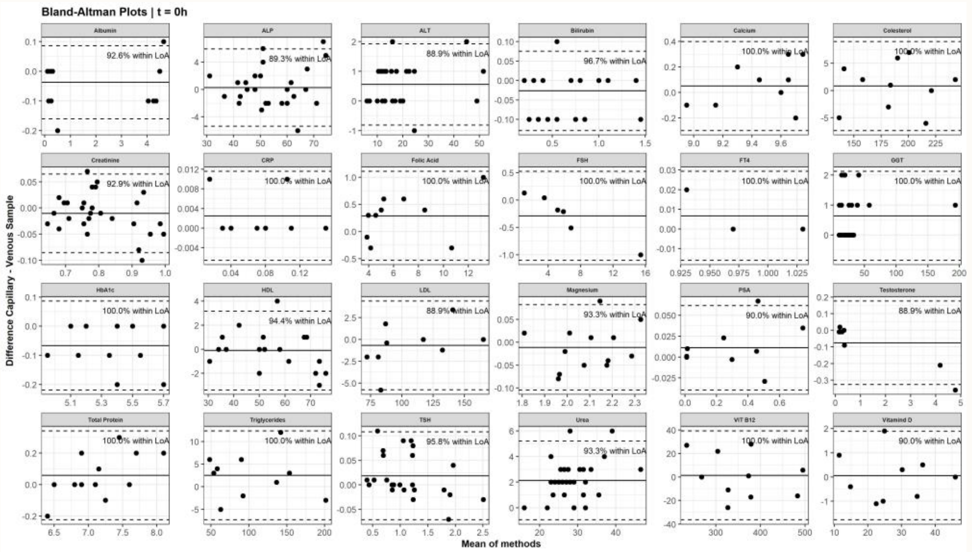

Figure 3: *Bland Altman data per analyte (t=0h) for venous collection (reference method) vs AHLT capillary collection.*

Analyte	Assay Count	Pearson Correlation Factor (R)	Mean Relative Bias (%)	% within Limits Agreement (%)
Albumin	27	0.999	-9.5	92.6
ALP	28	0.968	0.6	89.3
ALT	27	0.998	3.4	88.9
Bilirubin	30	0.989	-5.0	96.7
Calcium	10	0.847	0.5	100.0
Cholesterol	11	0.992	0.4	100.0
Creatinine	28	0.939	-1.0	92.9
CRP	8	0.995	13.8	100.0
Folic Acid	10	0.993	4.5	100.0
FSH	6	1.000	-1.0	100.0
FT4	3	0.991	0.7	100.0
GGT	25	1.000	3.3	100.0
HbA1c	12	0.953	-1.2	100.0
HDL	18	0.994	0.0	94.4
LDL	9	0.998	-1.0	88.9
Magnesium	15	0.953	-0.5	93.3
PSA	10	0.996	13.5	90.0
Testosterone	9	1.000	-4.8	88.9
Total Protein	12	0.973	0.8	100.0
Triglycerides	10	0.995	3.3	100.0
TSH	24	0.997	2.7	95.8
Urea	30	0.969	7.7	93.3
VIT B12	10	0.976	1.0	100.0
Vitamin D	10	0.996	0.6	90.0

Table 2: *Performance metrics summary table (Timepoint: t = 0h) venous collection (reference method) vs AHLT capillary collection*

Venous collection results vs AHLT capillary collection result | t = 48h

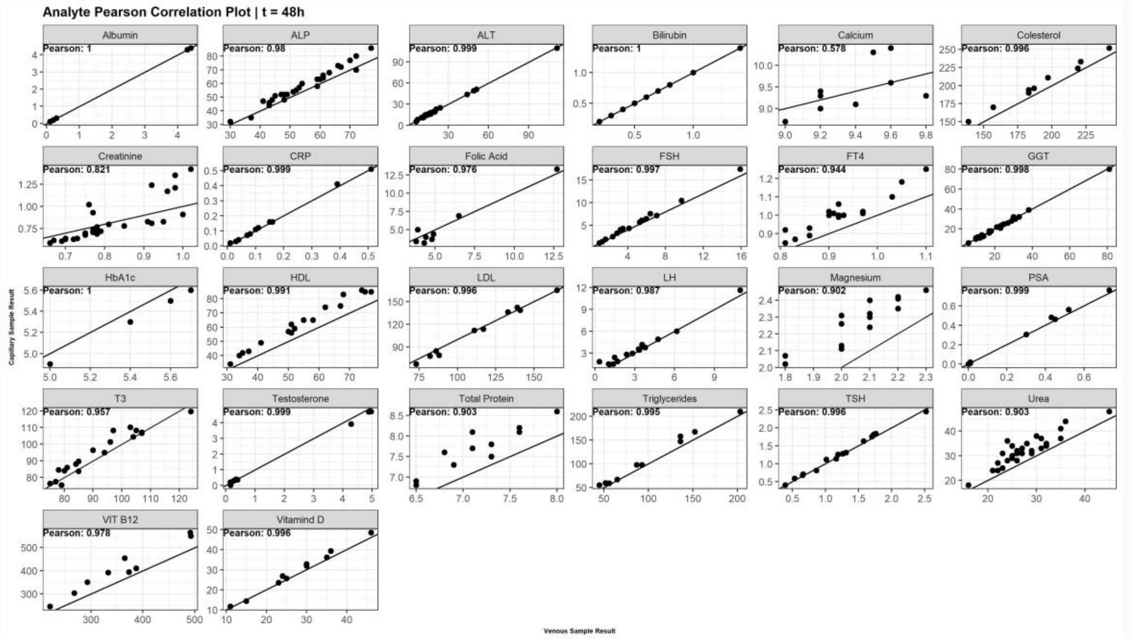

Figure 4: *Scatter plot and Pearson correlation data (t = 48h) for venous collection (reference method) vs AHLT capillary collection*

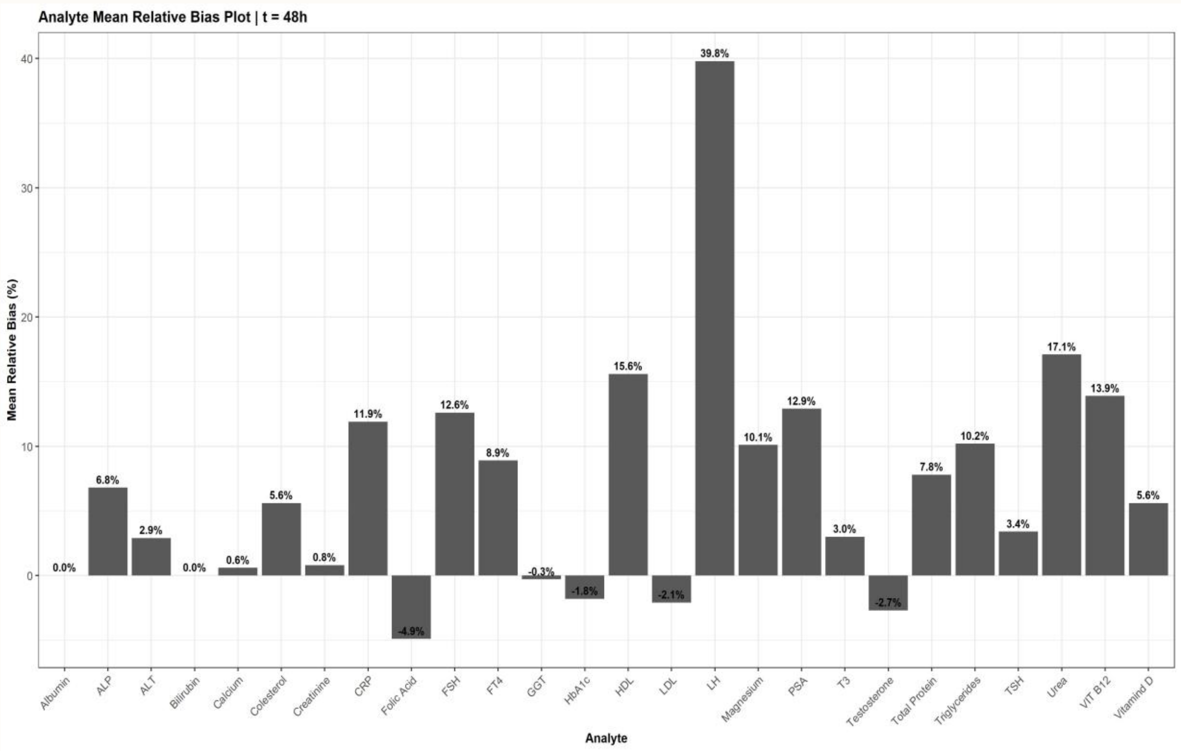

Figure 5: *Mean relative bias (%) data per analyte (t=48h) for venous collection (reference method) vs AHLT capillary collection*

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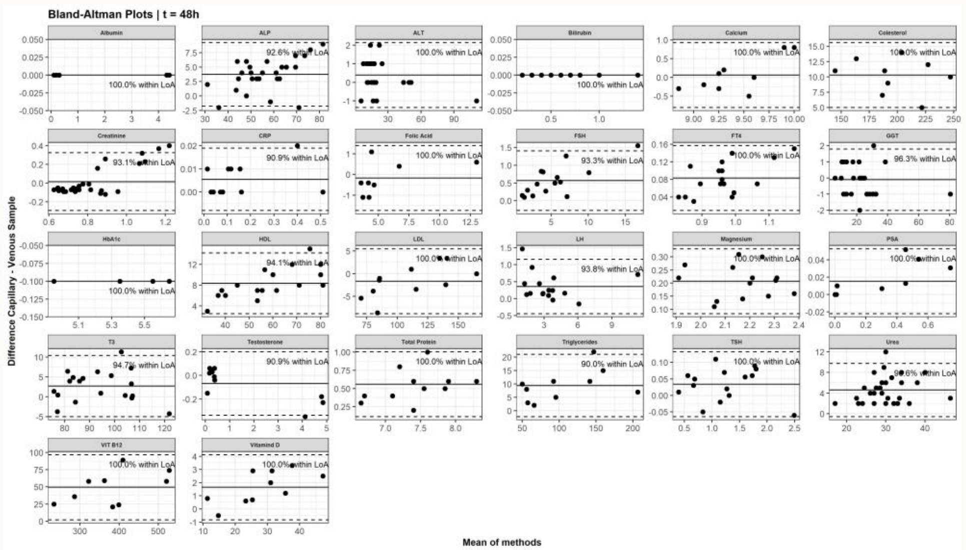

Figure 6: *Bland Altman data per analyte (t=48h) for venous collection (reference method) vs AHLT capillary collection*

ANALYTE	ASSAY COUNT	PEARSON CORRELATION FACTOR (R)	MEAN RELATIVE BIAS (%)	PERCENTAGE WITHIN LIMITS OF AGREEMENT (%)
Albumin	16	1.000	0.0	100.0
ALP	27	0.980	6.8	92.6
ALT	23	0.999	2.9	100.0
Bilirubin	22	1.000	0.0	100.0
Calcium	10	0.578	0.6	100.0
Cholesterol	10	0.996	5.6	100.0
Creatinine	29	0.821	0.8	93.1
CRP	11	0.999	11.9	90.9
Folic Acid	8	0.976	-4.9	100.0
FSH	15	0.997	12.6	93.3
FT4	17	0.944	8.9	100.0
GGT	27	0.998	-0.3	96.3
HbA1c	5	1.000	-1.8	100.0
HDL	17	0.991	15.6	94.1
LDL	11	0.996	-2.1	100.0
LH	16	0.987	39.8	93.8
Magnesium	14	0.902	10.1	100.0
PSA	10	0.999	12.9	100.0
T3	19	0.957	3.0	94.7
Testosterone	11	0.999	-2.7	90.9
Total Protein	12	0.903	7.8	100.0
Triglycerides	10	0.995	10.2	90.0
TSH	15	0.996	3.4	100.0
Urea	29	0.903	17.1	96.6
VIT B12	9	0.978	13.9	100.0
Vitamin D	10	0.996	5.6	100.0

Table 3: *Performance metrics summary table (Timepoint: t = 48h) venous collection (reference method) vs AHLT capillary collection*

DISCUSSION

The results of this study showed that the AHLT kit is an accurate and reliable method for collecting capillary blood. It provides results that are comparable to the results of venous blood samples. The AHLT kit can be a valuable tool for patients who need to have blood tests but who are unable or unwilling to go to a laboratory. The kit can also be used for remote monitoring of patients who are at risk for chronic diseases.

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Acknowledgements

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