

Review

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Capillary blood in core laboratories: current and future challenges

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Abstract: Capillary blood sampling is gaining recognition as a patient-centered alternative to traditional venipuncture. Its main advantages are that it is less invasive, reduces patient discomfort, and potentially can be performed without the direct supervision of a healthcare professional. These features could facilitate access to healthcare, particularly for patients with limited access to clinical facilities or those requiring frequent testing, thereby supporting telemedicine, and improving participation in screening programs and clinical trials. However, its integration into routine clinical practice requires the development of standardized traceable processes and user-friendly collection kits that preserve sample quality and have preanalytical error rates comparable to those of venipuncture. Compliance with ISO 15189 and integration into existing laboratory workflows are essential. Moreover, device affordability and compatibility with analyzers will determine accessibility and scalability. Addressing logistical, regulatory, and technical challenges is key to fully realizing its potential as a patient-centric solution in modern healthcare, where the robustness of analytical data derived from capillary blood could be comparable to that obtained from venous blood. In this review, we analyze the potential role of capillary blood in routine clinical practice, highlighting its benefits and challenges and determining the conditions necessary for its successful implementation.

Keywords: core laboratory testing; capillary blood; hemolysis; preanalytical phase

Introduction

Venous blood collection is a well-known and standardized method that has been in use for over 70 years [1] and is well integrated into traceable laboratory processes, obtaining accurate results that support clinical decision-making. However, it is limited by several drawbacks [2, 3]. The process requires the patient to attend a phlebotomy site, entailing additional healthcare infrastructure and trained staff to draw the blood who are at risk of needle-stick injuries and exposure to pathogens transmissible through blood [4]. In certain circumstances, such as during the COVID-19 pandemic, patients may prefer to avoid visiting healthcare facilities [5]. Poor vascular puncture practices can cause hemoconcentration or hemolysis, making samples unsuitable for analysis [3]. The invasive intravascular access with a needle is often painful and may cause complications such as bruising at the site of puncture, infection, nerve damage, iatrogenic anemia or anxiety [2, 6–9]. Furthermore, a substantial volume of the blood obtained by venipuncture is discarded and it has been estimated that approximately 25 million liters of blood are wasted daily in Western countries [10].

The use of capillary blood can be an alternative to venous blood as it involves a minimally invasive extraction. Moreover, capillary blood self-sampling can be carried out without the direct involvement of qualified healthcare personnel [11]. Also, the smaller blood volume drawn may prevent excessive blood extraction to patients [12, 13], thereby minimizing waste and decreasing the risk of iatrogenic anemia in patients undergoing frequent blood sampling or requiring a high volume of venous blood [14].

However, the broader implementation of capillary sampling for clinical decision-making is hindered by variability in concentrations of certain analytes between venous and capillary blood, together with insufficient standardization and quality control of pre-analytical conditions, particularly in self-collected samples. Also, there are differences in the type of collection systems and even in the puncture site [15–17]. In this review, we will discuss the potential use of capillary blood as an alternative to venous

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blood in core laboratories, the pros and cons of its use, the preanalytical and postanalytical challenges that should be addressed, and quality control checks required to considered it a reliable sample to make clinical decisions.

Pros and Cons of using capillary samples

As previously mentioned, the use of capillary sampling as an alternative to venous blood presents different pros and cons that should be considered (Figure 1). A capillary is a tiny blood vessel with a single-cell wall and no muscle or elastic tissue that links arteries and veins, allowing exchange of water, gases, nutrients, and waste between blood and surrounding cells. Capillary blood is a mixture of venous blood, arterial blood and interstitial fluid (Figure 2). Furthermore, if the skin puncture is performed with excessive force or in a traumatic manner, the sample may also contain a high proportion of cell leakage products and intracellular fluid [18]. In addition, strong massage or milking is sometimes performed to obtain larger blood volume but favors hemolysis and excess interstitial fluid with lower protein content into the sample [18, 19]. Therefore, the composition can be different from venous blood, especially in components not equally distributed between these different fluidic compartments [20], or have an important concentration gradient

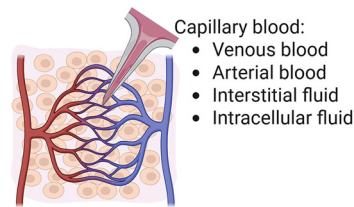


Figure 2: Capillary blood consists of venous blood (blue), arterial blood (red), and interstitial fluid (pink), and possibly intracellular fluid (brown) if cells are damaged during puncture. Created in BioRender. González, A. (2025).

between arterial and venous blood, such as blood gases [21, 22].

The leading pre-analytical problem in clinical laboratories is hemolysis, responsible for rejecting more than 60 % of venous blood specimens [23]. Hemolysis is more predominant in capillary serum or plasma samples compared to venous serum or plasma samples, while lipemia and icterus levels remain comparable between the two [24–26]. However, hemolysis rejection criteria should be considered in the context of the specific analytes being tested. Most routine analytes can be measured without relevant bias, but aspartate aminotransferase and potassium, which have hemolysis thresholds of ≤ 0.4 g/L in many analytical methods are particularly susceptible to positive interference in many samples [24, 27, 28]. The increase of potassium in capillary serum or plasma is not only attributable to hemolysis but

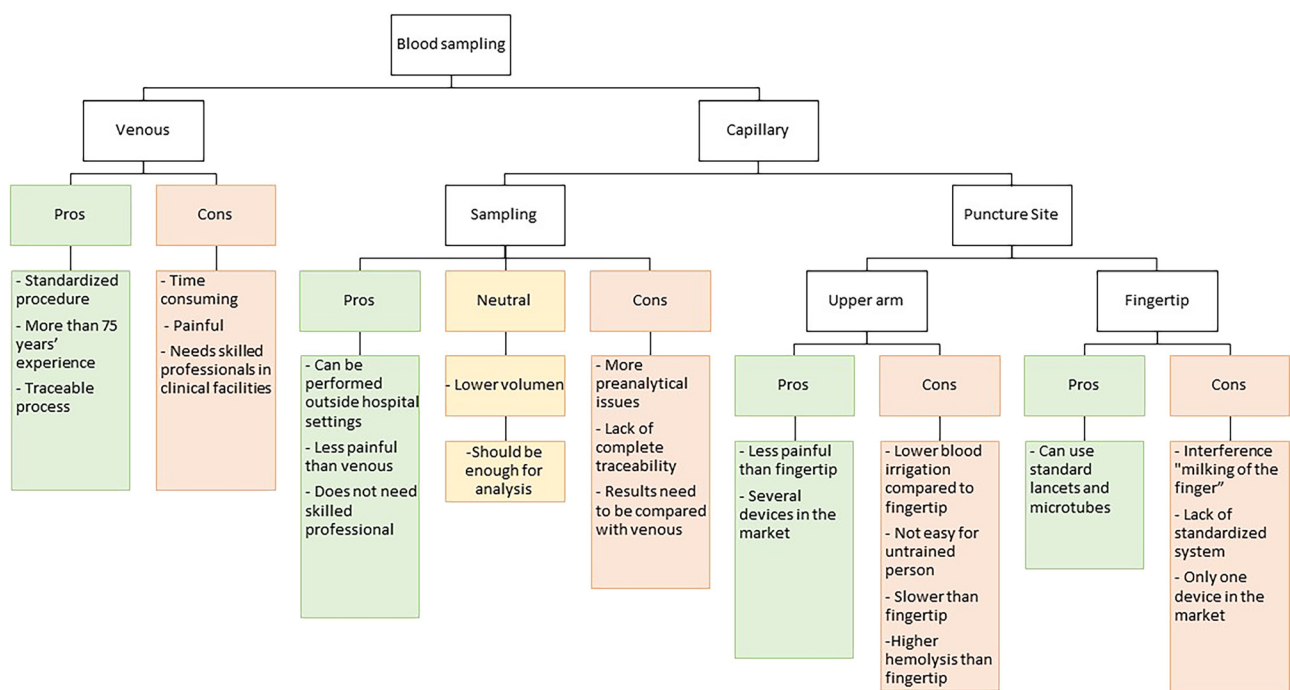


Figure 1: Pros and cons of venous and capillary blood sampling.

also to leakage from cells as it exceeds lactate dehydrogenase increase [29]. Collier et al. [27] observed that hemolysis indexes were higher using an arm blood collection device compared to fingertip sampling. Currently, there are no studies directly comparing phlebotomist assisted and self-sampling in relation to hemolysis.

Collecting a sufficient volume for concentration-based analyses is an important issue that can be specially challenging in capillary liquid blood sampling. Self-collection of blood samples is usually performed by individuals without training so it is necessary to ensure that patients fully understand the self-sampling procedure and are capable of following it correctly to collect an adequate blood volume [30]. Rejection rates vary significantly across studies, but remain consistently higher than those observed with venous blood collection [31] which limits widespread clinical use [28]. For instance, rejection rates due to insufficient volume have been reported as low as 3.2 % following fingerprick blood collection when performed in adults by qualified personnel [24]. Likewise, capillary self-collection using the Tasso-SST device in the upper arm of both adults and children showed a device failure rate (less than 100 μL of blood) of 4.4 % [32]. Another study using Tasso+ from the upper arm in athletes reported that the device failed to collect sufficient blood volume (500 μL) in 3.4 % of the participants [33]. However, another study investigating fingerprick self-sampling by adolescents at home, has reported a rejection rate of 72 % due to insufficient volume, probably related to the poor comprehension of the instructions for use [34]. There were notable differences in how instructions were understood across devices and only 47 % rated the instructions for liquid blood samples as clear, which was lower compared to the ratings for dried blood spots (DBS) instructions. Similarly, capillary fingerstick sampling in hospitalized patients yielded enough volume in only 70 % of patients [28]. A study involving self-collection of fingerprick blood samples using a topper and pediatric tubes reported an overall success rate of 86.7 % [35]. The success rate of collecting blood from the fingertip was lower for men older than 80 years old (25 % success rate) than for men under 60 years old (100 % success rate). Collier et al. [27] using the TAP-II device (YourBio Health) for upper-arm blood collection reported collection volume success (>350 μL) in 86.8 % of participants.

A key factor influencing the rate of sample rejection due to insufficient volume is the type of analytical system employed for measurement. In a study involving 1,535 participants, a single fingerprick provided an adequate sample in 47.1 % of cases, while up to two were required in 86.9 % of cases to perform analyses of five metabolites for a metabolic panel and six autoantibodies for an autoimmune panel [36].

Notably, the implementation of point-of-care platforms and the Luciferase Immunoprecipitation System enabled the complete panel of measurements using only 50.6 μL of capillary blood, which is lower than those use in many analyzers in a core laboratory [15].

All these data suggest that device systems should be improved to achieve enough blood volume and hemolysis rates similar to those of venous blood, thereby enabling the generation of samples with sufficient quality for use in routine laboratory workflows.

Potential target population for capillary sampling

Capillary blood has been used for many years in some specific areas in clinical laboratories. For example, capillary blood is widely used as DBS for neonatal screening [37] and liquid in point-of-care testing (POCT) such as to monitor glucose and glycosylated hemoglobin in diabetic patients or to obtain the International Normalized Ratio to monitor anticoagulant therapy [38]. The increasing concern for health and well-being, along with the increased utilization of remote health care following the onset of the coronavirus pandemic [32, 39], has led to a renewed interest in the utilization of capillary blood self-collection with the purpose of facilitating blood sampling from patients' homes.

Capillary blood would be particularly useful for pediatric and elderly patients, or in those with difficult venous access or fragile veins, chronic or cancer patients who undergo frequent testing and frequently visit hospital centers, patients with fear of venous blood collection, with difficult access to medical facilities or among vulnerable groups such as people experiencing homelessness [40], improving patient care and follow-up. It would also be valuable for dynamic and longitudinal studies, and could support telemedicine services [41–43]. In addition, self-sampling reduces clinic visits mitigating infection risk during outbreaks such as seasonal influenza [44]. In any case, the target population varies across countries depending on culture, healthcare structure, medical costs, hospital revenues and national regulations.

The use of capillary blood for biochemical analyses can be performed either for routine healthcare monitoring or as direct-to-consumer tests [45] (Figure 3). In both cases, blood collection could be carried out either in a hospital collection unit by qualified personnel or through patient self-sampling at home. In direct-to-consumer tests, the clinician plays no role in selecting or interpreting the test, and as such, it is regarded to fall outside the healthcare system. Thus,

allowing patients to choose between venous or capillary blood collection without the clinician supervision may pose risks [47]. However, it is in this latter scenario that capillary blood collection has gained significant interest and achieved widespread use.

The International Consortium for Innovation and Quality in Pharmaceutical Development published a position paper on the benefits of patient-centric sampling in clinical trials development, highlighting its value to patients and trial sponsors by enriching the datasets generated and improving efficiency and diversity [48]. Capillary blood has been proposed as a sample for general population assessment aiming at early detection of chronic autoimmune, metabolic and cardiovascular diseases [49, 50]. For example, a screening study inviting 19,593 Swedish schoolchildren to test for type 1 diabetes, celiac disease, and autoimmune thyroid disease used home capillary sampling and detected autoimmunity in 9.3 % of the population and undiagnosed disease in a further 1.5 % [50]. Also, the World Health Organization recommends the use of DBS testing for the screening of infectious diseases, such as hepatitis B and C and human immunodeficiency virus, in regions with limited healthcare infrastructure [51, 52]. Other potential target population is athletes, where the Athlete Biological Passport (ABP) may require frequent venous blood draws in which venipuncture needles may cause discomfort and may be perceived as a potential health risk [53].

However, it should be noted that capillary blood collection is not a simple process and has associated risks, such as pain, possible infections or calcifications at the puncture site, scarring problems and bruising [32, 54, 55]. Therefore, this collection is not recommended in patients

with circulatory problems, inflammation at the puncture site, peripheral edema, thrombocytopenia or platelet disorders, severe dehydration, skin ulceration or blisters at the puncture site or when analytical determinations require high blood volume [18].

Comparison between venous and capillary blood concentrations

Different studies have addressed the comparison between capillary and venous blood concentrations of different biochemical magnitudes and in most cases with a significant agreement which can facilitate the transference of reference values [14]. Maroto-García et al. [24] performed the analysis of 22 common biochemical measurands in capillary plasma from 296 patients showing that there were no bias for all studied parameters. Doeleman et al. [25] carried out a study in 167 patients studying 34 routine analytes and observed that mean relative differences between venous and capillary measurements met the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) desirable total error criteria. These and other studies [26, 27] demonstrated that hepatic, metabolic and lipid panels show very good agreement between venous and capillary serum. Similarly, high correlations have been observed for the tumor markers carcinoembryonic antigen [56] and prostate-specific antigen [35, 57], small dense low-density lipoprotein [58], and antibodies such as islet autoantibodies [11]. On the contrary, lower correlations have been observed for glucose, CO₂ and the electrolytes calcium, chloride, potassium and sodium [25, 27, 59]. These differences may be attributed to the different

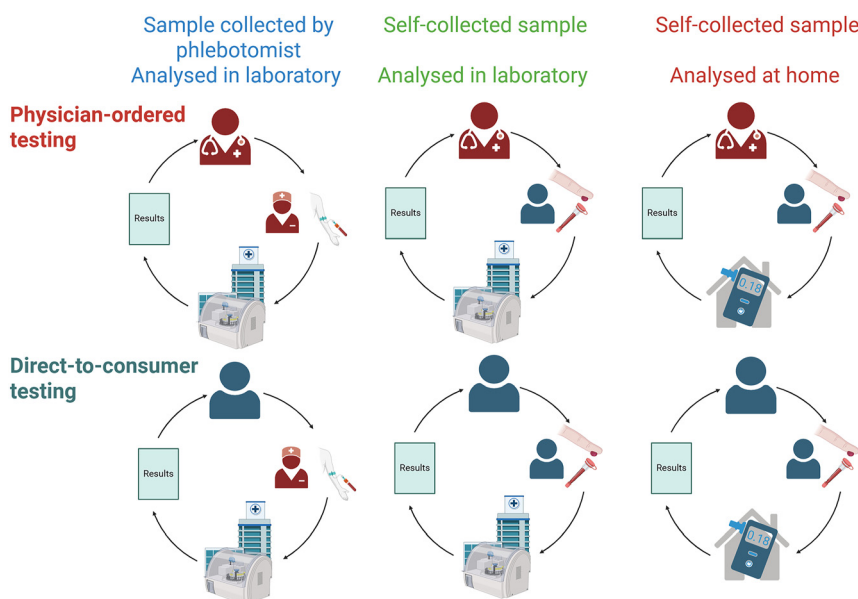


Figure 3: Options for capillary blood tests: Physician-ordered testing (initiated by a clinician, interpreted in a medical context) vs. direct-to-consumer testing (initiated and interpreted by the consumer). Based on [46] with modifications. Created in BioRender. González, A. (2025).

characteristics of capillary and venous fluids in the case of glucose and CO₂, the lower calcium concentration in interstitial fluid relative to that in plasma [60], as well as to ion leakage from cells.

Many comparative studies involving drug monitoring have been performed using DBS or volumetric absorptive microsampling (VAMS) with very good correlations [61–63]. However, the influence of the hematocrit should be taken into account when employing DBS, as it affects sample flow across the paper altering spot homogeneity and, consequently, decreasing reproducibility [64]. In this regard, the International Association of Therapeutic Drug Monitoring and Clinical Toxicology has published a guideline on the development, validation and evaluation of DBS-based methods for therapeutic drug monitoring [65].

In relation to hematological parameters, Maroto-García et al. [24] did not observe differences between capillary and venous blood in 15 common hematological magnitudes, except for mean corpuscular volume. Also, Goodrum et al. [53] showed an excellent agreement, except for mean corpuscular volume, platelets, red cell distribution width, and mean corpuscular hemoglobin concentration. The high agreement in cell blood count supports the use of capillary blood sampling as a viable alternative to collect the hematological data hemoglobin, percentage of reticulocytes and, based on these, calculating the OFF-Score included in the Athlete Biological Passport [33]. The use of low capillary blood volumes, of only a few microliters, may lead to differences in the concentration of certain hematological parameters requiring cautious interpretation of the results [66]. There is high variability in hematological measurements in successive blood drops, with coefficients of variation up to 7.7 times higher than those observed in venous samples. However, the fluctuations are within instrument variability for volumes equal to or greater than 60–100 µL of fingerprick blood.

A different situation occurs when comparing results of cytokines or inflammatory molecules. The analysis of some cytokines, such as IL-1Ra, IL-5, IL-6Ra, and IL-1B showed a poor correlation between venous and at-home self-collected capillary liquid sample with delayed processing [39, 67]. This may be related to the traumatic nature of the procedure where capillary blood flows through a damaged tissue producing local inflammatory reaction. Also, these magnitudes are usually more unstable and sensitive to prolonged delay in measurement. Interestingly, the inflammatory biomarkers C-reactive protein and ferritin, as well as the proinflammatory cytokine IL-6 show strong correlations between venous and capillary serum/plasma [39, 62].

Capillary samples stability

In many situations, capillary blood samples are collected externally and shipped to the laboratory. Sample transportation is a critical aspect in the pre-analytical phase [68], and monitoring this process is a requirement of ISO 15189. The transport process must be carefully checked to avoid important temperature fluctuations, delays, or other factors that could compromise the requested analyses [69]. A transport audit trail, incorporating data loggers for monitoring, is required to ensure sample integrity [68]. There are several low-cost, single-use, irreversible temperature indicators available for tracking samples, such as the RS PRO Temperature Label Indicator (www.es.rs-online.com) and the Varcode SmartTag™ (www.varcode.com), which permanently record when samples are exposed to unsafe temperatures. The laboratory is responsible for ensuring that transport managed by third parties is appropriately controlled and that potential delivery delays are considered, and that appropriate corrective actions are taken when they occur. As these materials are biological samples, both packaging and transport must comply with applicable regulations governing the shipment of dangerous goods.

Especially for those samples collected at home or in out-of-hospital settings, there is no prior centrifugation step and transport to the laboratory is usually carried out using mail or standard courier systems, which may take 24–48 h and, in many cases, occurs at ambient temperature. Therefore, it is essential to ensure that the magnitudes of interest are stable in these conditions [70]. Shipping conditions during transport can vary significantly, with temperatures and humidity reaching extreme levels; for example, inside a mailbox during summer or in desert regions where ambient temperatures often exceed 30 °C [65]. For instance, capillary blood samples used for monitoring Infliximab have demonstrated stability across a wide temperature range, from 1.7 to 37 °C, under external environmental conditions [62]. One study demonstrated that capillary blood shipped by air under cold conditions to the laboratory prior to antidoping analysis maintained its integrity [33].

Some studies have assessed the stability of biochemical and hematological parameters for up to one or two days at room temperature; however, longer evaluation periods are needed to account for potential delays in sample delivery [24, 58, 70, 71]. Considering common biochemical analytes, many of them, such as enzymes (aspartate aminotransferase, alanine aminotransferase, creatine kinase), hormones (antimüllerian hormone, testosterone, cortisol, thyroid-stimulating hormone, free thyroxine), tumor markers (PSA), lipids (triglycerides, cholesterol, high-density

lipoprotein), or vitamin B12 remain stable after 24 h delay in processing [24]. However, others such as ferritin, vitamin D, hematocrit, mean corpuscular volume, mean corpuscular hemoglobin concentration, platelets distribution width, mean platelet volume and basophils are less stable. When the delay time increases up to 5 days, the number of stable magnitudes decreases noticeably [72]. If samples are transported refrigerated, parameters such as hemoglobin or reticulocytes percentage are stable for up to 72 h [53]. A study that conducted a proteomic analysis observed that only a small subset of 384 proteins (11.3 %) showed high correlation between capillary blood self-collection with Tasso+ with delayed centrifugation (24 or 48 h) and the venipuncture gold standard [67]. This suggests that remote capillary blood self-collection, followed by delayed laboratory processing, may be an unreliable approach for large-scale plasma proteomic discovery. All of this indicates that courier transport is especially critical in this process and must guarantee timely delivery.

Capillary blood collection

Anatomical considerations for specimen collection

Before choosing the location, it is important to consider patient's special situations, such as burns or inflammation. The heel is the usual puncture site used in newborns for inborn error of metabolism screening [73], as their fingers are too small for finger-stick sampling [2, 73, 74]. Although the earlobe has been used for capillary blood sampling [75], CLSI GP42-ED7:2020 guidelines [54] recommend avoiding it due to the increased risk of complications and patient apprehension, while studies also report potential differences in results compared to fingertip samples [76]. The most common site to collect capillary blood is the fingertip, as it has high irrigation and anastomoses that favor heat exchange [77]. The puncture should be performed on the side of the middle or ring fingertip, as it is deep enough not to cause bone lesions, avoiding the other three fingers [54]. Lowering the arm and the finger helps the gravity drip process. The arm is another site used for blood collection, although it has less irrigation than the finger, since there are no anastomoses, making extraction slower and more complicated for patients or untrained personnel, and producing more hemolysis [77, 78]. Capillary blood extraction can be increased by massaging the site or applying external heat to the puncture area [54, 79], and several commercial devices already include a pad to provide local heat to the extraction zone.

Devices for capillary blood collection

The skin vascular bed ranges from 0.35 to 1.6 mm, but from that depth pain receptors are also located [19]. So, lancets of 1.5–2 mm can provide adequate blood but may cause greater pain [80]. Also, the blade type produces more pain than the needle version [81]. Although the pain produced is generally mild, the use of topic analgesia has been proposed to reduce pain without affecting the volume of blood collected [32].

Different manufacturers have developed devices for capillary blood collection, which have been recently reviewed [15, 17] and summarized in Table 1. These devices are designed to collect either DBS or liquid blood, in both cases as whole blood or serum/plasma. The collected volume varies from a few microliters for devices for DBS to 300–1,000 μL for those that obtain liquid blood. The use of liquid blood has some advantages over DBS, making it more suitable for routine clinical laboratories in most situations:

- It is possible to perform a broader range of analyses, particularly hematological ones.
- The utilization of collection tubes compatible with automated analyzers facilitates integration within central laboratory workflows.
- There are no concerns with spot homogeneity and hematocrit interference [15, 96]. Additionally, some devices for dried blood sampling have been developed to overcome these issues, such as VAMS [96, 97].
- The use of liquid provides a cleaner matrix (e.g., less hemolyzed) to perform analyses. For example, a study that longitudinally monitored androstenedione, testosterone and insulin-like growth factor-1 in four different blood matrices reported a bias higher than 20 % in IFG-1 in capillary plasma compared with DBS [98]. Also, immunoglobulin G measured by turbidimetry produced comparable result in venous plasma and capillary plasma samples, but not in DBS samples [99].

Devices for collecting capillary blood from liquid samples have been developed for both the fingertip and upper arm. However, the differences between blood obtained from these two sites have not been thoroughly investigated [27]. Variations may exist due to the differing blood supply to each area, as previously mentioned, and the effectiveness of capillary blood collection largely depends on maintaining adequate blood flow and circulation at the puncture site. A recent clinical trial (Trial ID: RD006798; approved by the Spanish Agency of Medicines and Medical Devices) has addressed potential differences, in both the quality of blood collection and analyte concentrations.

Table 1: Examples of capillary blood self-sampling collecting devices.

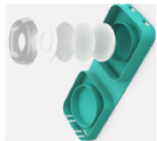
Device	Company	Website	Collection site	FDA	CE-IVD	Capillary blood sample	Sample volume	Prenanalytical processing	Picture	References
Capitainer (B10, B50)	Capitainer	capitainer.com	Finger	Class I listing	Yes	Volumetric dried blood spot	B10: 2 × 10 µL B50: 2 × 50 µL	Elution		[34, 82]
Capitainer SEP10	Capitainer	capitainer.com	Finger	Class I listing	Yes	Dried plasma-like spot	10 µL	Elution		
Cobas plasma separation card	Roche diagnostics	Roche.com	Finger	Not broadly cleared	Yes	Dried heparinized plasma spot	40 µL plasma (140 µL blood input)	Elution		[83, 84]
EzDraw	PreciHealth	prechealth.com	Upper arm	No	Yes (CE-marked only)	Liquid blood: Serum/anticoagulant (EDTA, heparin)	1,500–3,000 µL	Centrifugation for serum/plasma		
HemaPEN	Trajan/ Neoteryx	trajanscimed.com neoteryx.com	Finger	Class I listing	Yes	Volumetric dried whole blood spot	4 × 2.74 µL (10.96 µL/device)	Elution		[85, 86]
HemaSpot HF	Spot on sciences	spotonsciences.com	Finger	No	Yes	Dried blood spot in sealed cartridge	10–20 µL	Elution		[87, 88]
HemaSpot SE	Spot on sciences	spotonsciences.com	Finger	No	Yes	Dry serum spot	10–20 µL	Extraction (reconstitution)		
HemaSpot HD	Spot on sciences	spotonsciences.com	Finger	No	No	Dried blood spot in sealed cartridge	160 µL	Elution		[89]

Table 1: (continued)

Device	Company	Website	Collection site	FDA	CE-IVD	Capillary blood sample	Sample volume	Prenalytical processing	Picture	References
HemaXis DB10	DBS system SA	hemaxis.com	Finger	Class I listing	Yes	Volumetric dried blood spot	10 µL/spot	Elution		[82, 90]
Hem-col	Labonovum	labonovum.nl	Finger	No	Yes	Liquid capillary blood: Serum/anticoagulant (EDTA, heparin) with stabilizer	100–200 µL (6 drops)	Centrifugation/Extraction		[72, 91]
BD MiniDraw	Becton dickinson	bd.com	Finger	510(k) cleared	Yes	Liquid blood: Serum/anticoagulant (EDTA, heparin)	435–635 µL	Centrifugation for serum/plasma		[71, 92]
Mitra (VAMS)	Neoteryx	neoteryx.com	Finger	RUO	Yes	Volumetric absorptive microsampling (dry blood spot)	Tips size: 10, 20, 30 µL	Elution		[34]
Onflow	Loop medical	Loop-medical.com	Upper arm	No	Yes	Liquid blood: Serum/anticoagulant (EDTA, heparin)	1,200–1,500 µL	Centrifugation for serum/plasma		[93]
RedDrop ONE	RedDrop DX	reddropdx.com	Upper arm	510(k) cleared	No	Liquid blood: Serum/anticoagulant (EDTA, heparin)	500–800 µL	Centrifugation for serum/plasma		[94]
TAP micro	YourBio health	yourbiohealth.com	Upper arm	510(k) cleared	Yes	Liquid blood: Serum/anticoagulant (EDTA, heparin)	280–900 µL	Centrifugation for serum/plasma		[27, 43, 56, 95]

Table 1: (continued)

Device	Company	Website	Collection site	FDA	CE-IVD	Capillary blood sample	Sample volume	Prenanalytical processing	Picture	References
Tasso+	Tasso inc.	tassoinc.com	Upper arm	510(k) cleared	Yes	Liquid blood: Serum/anticoagulant (EDTA, heparin)	500–700 µL	Centrifugation for serum/plasma		[26, 67, 94, 95]
TASSO M-20	Tasso inc.	tassoinc.com	Upper arm	510(k) cleared	Yes	Volumetric dried blood spot	4 × 17.5 µL (70 µL)	Elution		[34, 89]

Patient acceptability

Self-collection of capillary blood requires patient acceptability and participation. Several studies have examined the degree of acceptance and satisfaction of patients regarding this procedure [24, 34, 92, 95, 100, 101]. Usually, the data were collected through a questionnaire that included the level of agreement with the instructions provided for correct collection, perceived pain using a numerical pain rating scale, the usability perceived by the patient and the overall acceptability of the collection to assess the possibility of performing the collection at home. These questionnaires have not been previously validated so the results should be interpreted with caution. However, all these studies reported that patients experienced less pain compared to venous blood collection, and perceived usability was rated as excellent. Children groups also preferred capillary blood self-sampling to venous sampling [32, 36]. Interestingly, patients who frequently visited hospital centers or regularly underwent venous blood draws found this method more convenient [24]. However, individuals with lower school education stated reduced perceived usability [101]. Some studies reported that capillary blood collection from the arm using TAP-II [56] or Tasso [34] was preferred over fingertip collection with a lancet, probably because these devices are specifically designed for this purpose. In relation to this, another study analyzing fingertip blood collection with the BD MiniDraw (Becton Dickinson) collection system in 107 volunteers reported a positive experience in 90 % of the cases [92].

Integration of the capillary blood samples into the clinical laboratory

For the widespread use of capillary blood samples, integration into a fully automated laboratory workflow is essential, which implies fulfilling some requirements for the device and system:

- a) Liquid capillary samples should have sufficient volume to perform all assays required. Liquid capillary blood can yield a sample volume typically ranging between 200 and 1,000 µL, with potential integration in the core laboratory [42]. Using modern laboratory automated systems, the volume of sample required for most routine analyses is usually just a few microliters, often less than 10 µL [15], and can be further reduced without compromising technical performance [102]. However, most analyzers require a dead volume in the sample tubes, usually higher than 100 µL [15]. This

represents a high excess for this type of microsamples and therefore manufacturers should explore new adaptations to reduce the dead volume to a minimum [42]. An optimized serum or plasma separator system could increase the liquid volume obtained and decrease the dead volume [103, 104]. For example, BD MiniDraw includes serum separator tubes designed for reverse centrifugation, which displace gel and cells into the cap to maximize serum recovery for analysis [71].

- b) In the case of using dried sample, a matrix unfamiliar to most laboratories, it is necessary to implement time-consuming additional preanalytical processes, such as analyte extraction, to accurately measure the concentrations [48]. Due to the nature of this type of sample, some analyses, such as cell count or potassium quantification, cannot be performed.
- c) The liquid capillary sample collecting tube should be designed to avoid special handling or pipetting. It should be compatible with most analyzers, have a shape that minimizes dead volume, and allow barcode labeling.
- d) Due to the characteristics of the self-sampling, a short turnaround time is not a priority, so the laboratory workflow can be adapted to these samples without interfering with other processes. An example could be to analyze samples in periods of less activity of the laboratories, without affecting the other urgent work dynamics.
- e) Analysis performed on capillary blood collected in clinical centers by healthcare professionals should achieve turnaround times that meet clinical demands and be comparable to those of venous sampling [38]. Timely processing is particularly important for emergency situations.

Quality control checks for capillary blood samples

It is well known that the preanalytical process is the main cause of laboratory errors, that could lead to altered interpretation of results and clinical decision-making [46]. Much effort has been exerted to develop indicators as a mean to control and improve the quality of this process [105]. This has made venous blood sampling highly traceable, with pre-analytical quality improved over the years [31, 106]. Capillary blood sampling involves a complex preanalytical procedure which could become even more challenging in the case of self-sampling. Different organizations have published guidelines and recommendations regarding capillary blood sampling [2, 18, 54]. It is necessary that all steps within this phase be controlled, traceable and meet the requirements of ISO 15189. For self-collected capillary blood samples, additional checks beyond the usual preanalytical controls should be implemented, since much of the process is out of the direct control of health professionals [105] (Figure 4). These should include:

- a) Patient identification: It is important to guarantee correct patient identification for samples collected at home or out of hospital settings [18, 107]. There are applications based on code identification or face recognition that can be used for a proper and unequivocal identification to guarantee patient's safety [48]. Patient identification and sample labeling must be performed in accordance with General Data Protection Regulations [68].
- b) Understanding of self-collection instructions: Self-sampling is usually performed by lay people thus, procedures, such as a questionnaire with comprehension

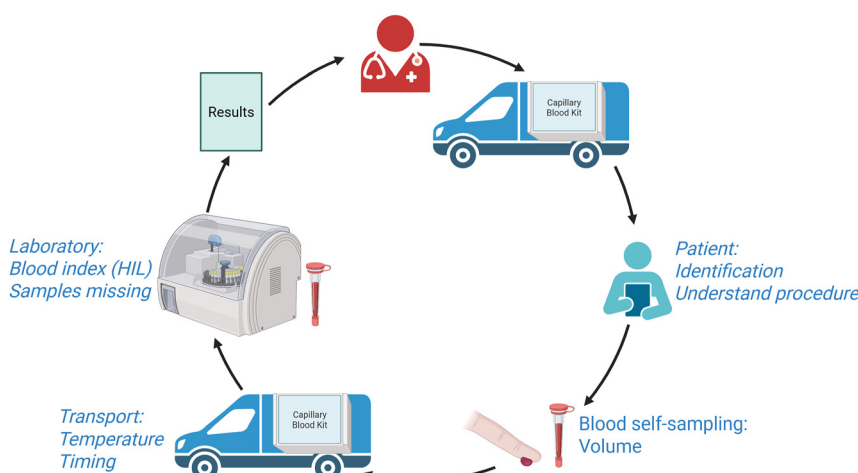


Figure 4: Preanalytical quality checks for capillary liquid blood samples should include correct patient identification, confirmation of instruction comprehension, collection of sufficient sample volume, safe and compliant transport, monitoring of temperature and timing during shipment, tracking of delayed or missing samples, and quality assessment of received samples. HIL: hemolysis, icterus, lipemia. Created in BioRender. González, A. (2025).

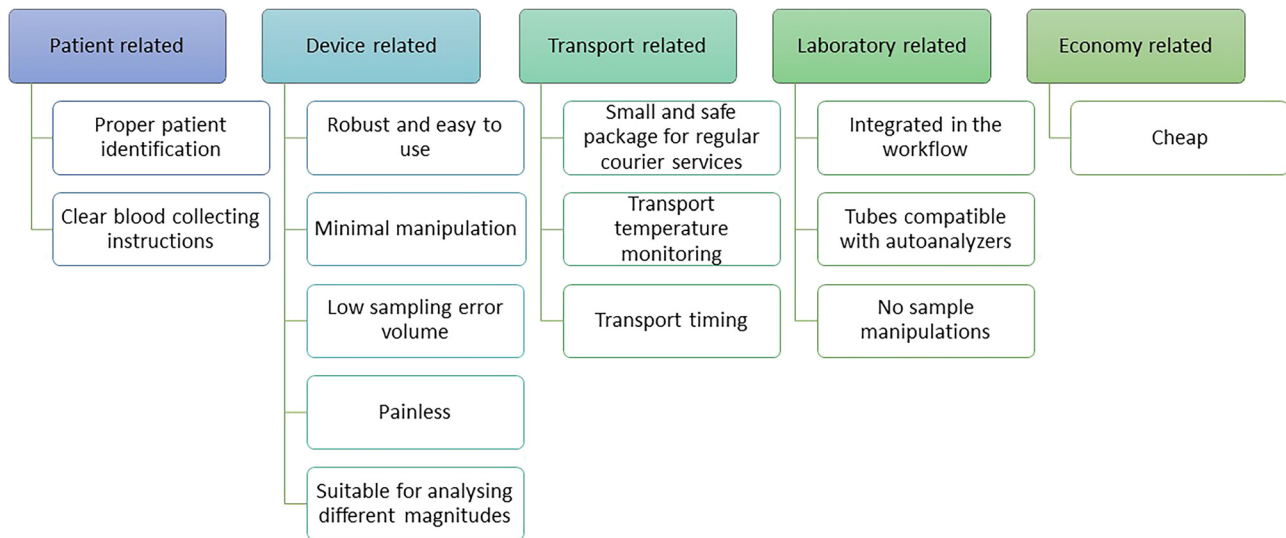


Figure 5: Key attributes of an optimal capillary blood self-collection procedure.

checks should be implemented to ensure correctly understanding of the instructions provided [34, 35].

- c) Enough volume collection: Particularly in the case of liquid blood, target volume should be objectively indicated on the collection device, as patient's perception will not always be accurate, and insufficient volumes may compromise analytical performance [24, 27, 34].
- d) Courier transport: The transportation of biological samples to clinical laboratories must be safe, preferably in a small box, and comply with legislation [15, 68].
- e) Temperature monitoring during transport: Packages containing samples shipped to the laboratory should include a temperature-sensitive labels or other suitable devices to monitor the temperature individually during transport [15, 69].
- f) Sample tracking: Some samples may arrive late or not at all, so the laboratory should implement procedures to track samples and confirm transit and collection.

Based on these conditions, the ideal capillary blood collection kit should include access to an informatics platform for proper patient identification, courier request, and reporting to the laboratory that the sample is being delivered.

Conclusions

Capillary blood sampling is emerging as a valuable alternative to venous blood collection in healthcare, though further development is still needed. Its growing potential is driving increased research and innovation aimed at creating optimal collection devices. However, ensuring high sample quality

also requires attention to other preanalytical factors, which must be integrated into commercial kits (Figure 5). An ideal home capillary blood collection kit should ensure proper patient identification for full traceability, with a collection device designed to reduce handling and sample errors, be user-friendly by lay people, and painless. It must support the analysis of a wide range of biochemical markers and be compatible with courier transport, including temperature monitoring. The aim would be to decrease the percentage of rejections similar to those observed with venous blood, which is 2.1 % [106]. Another important aspect is its integration into the clinical laboratory and the compatibility of the blood collection tubes with the analyzers currently in use. In addition, to be accessible to the majority of the target population, it must be inexpensive. Also, comparative studies evaluating the concentration between capillary and venous samples should be undertaken prior to clinical implementation, and, where necessary, novel reference ranges should be established. Achieving this objective would bring home self-sampling and telemedicine closer to patients who face difficulties in undergoing a conventional venous blood collection or accessing hospital centers. Certainly, it would become a new paradigm of patient care in the future.

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