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Bruna Suellen Breternitz

bruna.breternitz@einstein.br

Hospital Israelita Albert Einstein

Rosimeire Simprini Padula

Hospital Israelita Albert Einstein

Michele Lacerda Pereira Ferrer

Hospital Israelita Albert Einstein

Paula Carvalho Freitas

Ministry of Health

Ellen de Cassia Dutra Pozzetti Gouvea

Ministry of Health

Luiz Menezes-Júnior

Ministry of Health

Oscar Geovanny Enriquez-Martinez

Ministry of Health

Leticia de Oliveira Cardoso

Ministry of Health

Etienne Duim

Hospital Israelita Albert Einstein

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Bruna Suellen Breternitz[1]*, Rosimeire Simprini Padula[1,3], Michele Lacerda Pereira Ferrer[1,4], Paula Carvalho de Freitas[2], Ellen de Cássia Dutra Pozzetti Gouvêa [2], Luiz Menezes-Júnior [2,5,6], Oscar Geovanny Enriquez-Martinez[2], Leticia de Oliveira Cardoso[2], Etienne Duim[1]

[1]Hospital Israelita Albert Einstein, São Paulo, Brazil

[2]Department of Epidemiological Analysis and Surveillance of Non-Communicable Diseases, Secretariat of Health and Environmental Surveillance, Ministry of Health, Brasília, Brazil

[3]Department of Physical Therapy. Masters and Doctoral Program in Physical Therapy, Universidade Cidade de São Paulo, SP, Brazil.

[4]Department of Primary Health Care, Faculdade de Ciências Médicas da Santa Casa de São Paulo, São Paulo, Brazil.

[5]Post-graduate Program in Health and Nutrition, Federal University of Ouro Preto, Ouro Preto, Minas Gerais, Brazil

[6]Department of Preventive Medicine and Public Health, School of Medicine, University of Navarra, 31008 Pamplona, Navarra, Spain

* Correspondence: bruna.breternitz@einstein.br ORCiD 0000-0003-4168-1634

ABSTRACT

Background: Dyslipidemia is a major risk factor for cardiovascular disease. Point-of-care Testing (PoCT) devices provide rapid lipid measurements and may facilitate timely risk assessment and clinical decision-making. However, comparative evidence on their analytical agreement for classification performance, operational feasibility, and acceptability remains limited.

Objective: To evaluate the classification performance, analytical agreement and operational feasibility of the Mission® Cholesterol and CardioChek® Plus Analyzer PoCT devices for lipid profile assessment compared with the reference laboratory method, and to assess participant acceptability, providing evidence to support the implementation of these devices in dyslipidemia screening and monitoring programs within healthcare systems.

Methods: A cross-sectional study was conducted in primary healthcare settings. Paired capillary and venous blood samples were obtained to compare Mission® and CardioChek® with laboratory reference measurements of total cholesterol (TC), HDL-C, LDL-C, and triglycerides (TG). Agreement analysis and clinical classification metrics were calculated, while participant's acceptability of finger-prick sampling was evaluated.

Results: Among the 279 participants with paired measurements, the mean age was 58 ± 12 years, and 79% were female. Both devices showed strong correlations with the laboratory reference method, with ICCs ranging from 0.871 to 0.920 for Mission® and from 0.898 to 0.957 for CardioChek®. CardioChek® showed greater analytical agreement for TC, HDL-C, and TG, whereas Mission® showed greater agreement for LDL-C. Classification performance varied by biomarker, with Mission® showing higher sensitivity for HDL-C and LDL-C abnormalities and CardioChek® showing better classification performance for elevated TG. Finger-prick blood collection was preferred

by 51.3% of participants, compared with 16.1% who preferred venous collection, while 32.6% reported no preference; 94.3% reported no or mild finger-prick pain.

Conclusion: Both devices may support decentralized lipid screening in primary care, provided that biomarker-specific limitations are considered, and laboratory confirmation is recommended when clinically appropriate.

Trial registration: Not applicable.

Keywords: Capillary blood, Dyslipidemia, Screening and Primary health care

INTRODUCTION

Cardiovascular diseases (CVD) are the leading cause of mortality globally, accounting for approximately one-third of all deaths [1]. Dyslipidemia is a major modifiable cardiovascular risk factors, characterized by abnormal levels of total cholesterol, LDL-C, HDL-C, and triglycerides. Elevated LDL-C, in particular, has a well-established causal and dose-dependent relationship with atherosclerotic cardiovascular events [2, 3]. In this context, each 1 mmol/L reduction in LDL-C has been associated with an approximately 20–25% decrease in major cardiovascular events [4].

Screening for dyslipidemia is an important component of cardiovascular prevention, particularly in primary healthcare settings. However, reliance on laboratory testing limits its large-scale implementation due to costs, infrastructure requirements, and turnaround time [5]. In this scenario, Point-of-Care Testing (PoCT) technologies enable rapid lipid measurements from capillary blood samples and may facilitate screening and clinical assessment at the point of care [6]. Nevertheless, these devices exhibit variability in performance, particularly in agreement with laboratory methods and precision across different biomarkers [7—9]

Previous studies evaluating devices such as CardioChek® and Mission® have reported strong correlations with laboratory methods; however, correlation alone does not establish analytical agreement or interchangeability between measurement methods. Two methods may be highly correlated while still exhibiting systematic differences in their measurements. Therefore, the assessment of agreement, including the magnitude and direction of measurement bias, is essential when determining whether point-of-care measurements are comparable to laboratory reference methods. Previous evaluations have demonstrated variability in agreement and bias across lipid biomarkers and devices, which may affect cardiovascular risk stratification and clinical decision-making [7, 10]. In addition, substantial heterogeneity has been reported across PoCT technologies in their ability to identify abnormal lipid levels [5, 8, 11].

The heterogeneity in performance across PoCT devices, together with the scarcity of comparative evaluations under real-world conditions, limits understanding of their applicability across healthcare contexts, including population screening, primary care settings, and clinical monitoring. Furthermore, evidence integrating classification performance and operational feasibility remains limited. Operational costs and implementation of feasibility are also key determinants for the large-scale adoption of these technologies, particularly in resource-limited health systems.

Limited access to laboratory testing remains an important barrier to cardiometabolic screening, particularly in remote and resource-limited primary care settings. In this context, portable lipid analyzers may provide timely results at the point of care and represent a potential strategy for expanding access to lipid assessment in populations with limited access to conventional laboratory testing [12, 13]. Therefore, it is important to evaluate these devices in real-world settings to identify those that strike

the best balance among accuracy and applicability, thereby supporting their incorporation into healthcare systems.

This study aimed to evaluate the analytical agreement and classification performance of two PoCT devices (Mission® and CardioChek®) for lipid profile testing compared with a laboratory reference method under real-world primary healthcare conditions. Additionally, the study aimed to assess participant acceptability of capillary blood collection and discuss the potential applicability of these devices as tools for decentralized dyslipidemia screening.

MATERIAL AND METHODS

Ethical statement

The study was approved by the Research Ethics Committee of Hospital Israelita Albert Einstein (approval number 7,541,989; CAAE: 87471725.4.0000.0071). All participants provided written informed consent before enrollment. Participant information was kept confidential and analyzed using de-identified data.

Study design and population

This cross-sectional study used a non-probability convenience sampling approach and was conducted between November 2025 and February 2026. A total of 300 participants aged 35 years or older were recruited. The minimum age criterion was established due to the prevalence of dyslipidemia and other cardiovascular risk factors increases with age, thereby increasing the likelihood of observing a broader range of lipid values and abnormal lipid profiles. In addition, the sample was intentionally enriched with individuals presenting previously diagnosed non-communicable diseases (NCDs) to increase the prevalence of lipid abnormalities and ensure an adequate distribution of

abnormal lipid values for agreement and classification performance analyses. Approximately 80% of the sample comprised individuals with at least one self-reported NCD and 20% without reported NCDs. All participants were registered at a public Primary Health Care service in the capital of São Paulo, Brazil.

Participant recruitment was supported by Community Health Workers and Family Health Strategy nurses, who assisted in disseminating information about the study and inviting potential participants. Additional recruitment was conducted by researchers, who approached and invited individuals awaiting care at the primary health care unit. Eligibility criteria were predefined and are described in figure 1. After eligibility assessment, participants were classified into two groups: (1) individuals reporting at least one previously diagnosed non-communicable disease (NCD), and (2) a control group consisting of individuals reporting no prior diagnosis of NCDs.

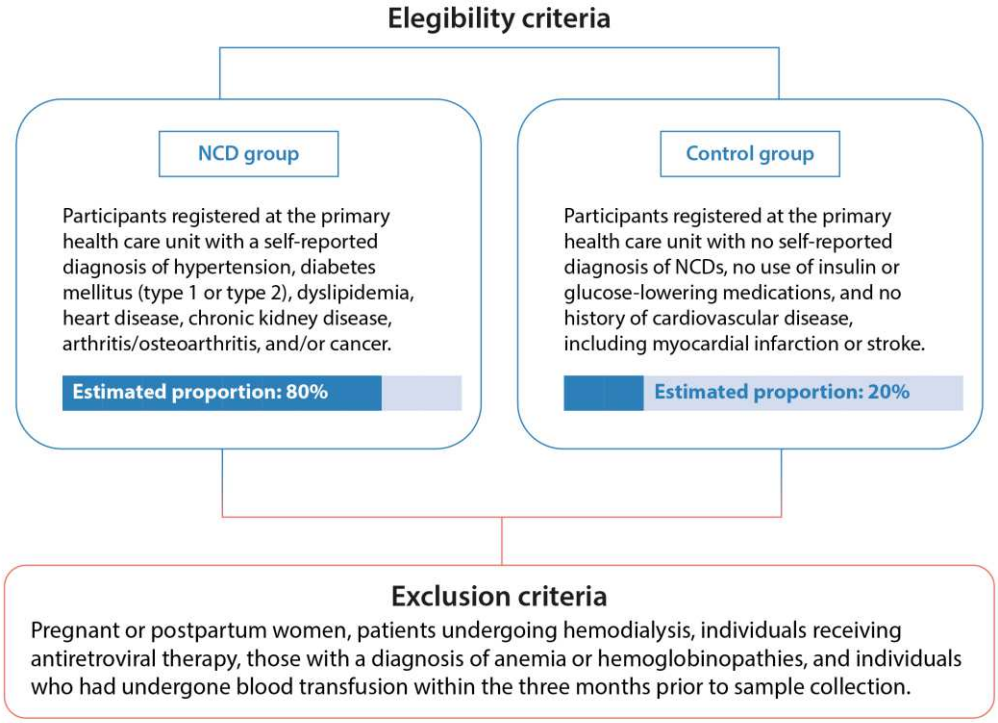


Figure 1. Sample selection criteria and classification into chronic disease and control groups.

Data collection

Eligible participants completed a structured questionnaire to collect sociodemographic information (age, sex, and self-reported color or race) and self-reported non-communicable diseases (NCDs) (Supplementary Material 1). NCD status was based on participants' self-report of a previous diagnosis of hypertension, diabetes mellitus, dyslipidemia, cardiovascular disease, chronic kidney disease, arthritis/osteoarthritis, or cancer. Color or race was self-reported according to the categories adopted by the Brazilian Institute of Geography and Statistics (IBGE): White, Black, Brown (Pardo), Asian (Yellow), and Indigenous. To ensure confidentiality, each participant was assigned a unique identification code. Data were collected electronically using secure digital forms and stored in a protected database with access restricted to authorized members of the research team.

PoCT lipid devices

Lipid profile measurements were performed using the Mission® Cholesterol Meter (ACON Laboratories Inc., San Diego, CA, USA) and the CardioChek® Plus Analyzer (PTS Diagnostics, Whitestown, IN, USA). Both portable PoCT devices use reflectance photometry and reagent strips for lipid assessment in capillary whole blood. Total Cholesterol (TC), High-Density Lipoprotein Cholesterol (HDL-C), and Triglycerides (TG) are measured by the devices, whereas Low-Density Lipoprotein Cholesterol (LDL-C) is calculated from the measured lipid parameters.

For the CardioChek® Plus Analyzer, LDL-C is calculated using the Friedewald equation [LDL-C = TC − HDL-C − (TG/5), in mg/dL], when TG concentrations are ≤400 mg/dL. For the Mission® Cholesterol Meter, LDL-C is also calculated by the analyzer; however, the equation used for this calculation is not specified in the manufacturer's user

169 manual. Therefore, LDL-C comparisons in this study represent agreement between
170 calculated estimates rather than agreement between direct LDL-C measurements.
171 Measurements were performed by a trained nurse who received specific training
172 from the manufacturers' representatives and followed standardized procedures and
173 manufacturers' instructions. Before participant testing each day, device functionality was
174 verified using the control devices provided by the manufacturers, and participant
175 measurements were initiated only after verification.
176
177 **Capillary and venous blood sample collection for lipid profile analysis**
178 Participants were not required to fast before blood collection. Capillary and
179 venous samples were obtained during the same study visit to allow comparison between
180 the PoCT devices and the reference laboratory method. For capillary sampling, the
181 puncture site was disinfected, and a sterile lancet was used for the finger-prick. The first
182 drop of blood was discarded, and subsequent drops were collected using the device-
183 specific capillary collection systems. A total of 40 µL of capillary blood was collected for
184 CardioChek® Plus and 35 µL for Mission®, according to the manufacturers' instructions.
185 PoCT measurements were performed immediately after collection, and the results were
186 recorded in the electronic case report form.
187 For the reference laboratory analysis, approximately 4.9 mL of venous blood was
188 collected into S-Monovette® Gel Z (Sarstedt) tubes. The samples were centrifuged at
189 4,000 rpm for 10 minutes, stored and transported ate 2—8ºC to the reference laboratory.
190 TC and TG were measured using enzymatic colorimetric assays, HDL-C using a
191 homogeneous enzymatic colorimetric assay, and LDL-C was calculated using the Martin–
192 Hopkins algorithm. Laboratory analyses were performed using the cobas® c 502 analyzer
193 (Roche Diagnostics, Mannheim, Germany).

Acceptability assessment

Acceptability of capillary blood collection was assessed using a structured questionnaire administered after the blood collection procedures. Participants were asked which blood collection method they would prefer if given a choice, with four response options: venous blood collection, finger-prick blood collection, no preference, or prefer not to answer. Perceived pain during finger-prick blood collection was assessed using four response categories: no pain, mild pain, moderate pain, or severe pain.

Statistical analysis

Statistical analyses were performed using R version 4.5.0. Descriptive statistics were used to summarize laboratory and PoCT lipid measurements, including mean ± standard deviation (SD), minimum, and maximum values. Analyses comparing the PoCT devices with the reference laboratory method were restricted to participants with complete paired measurements for the laboratory, Mission®, and CardioChek® Plus methods. Correlations between PoCT devices and the reference laboratory method were assessed using Pearson's correlation coefficient (r). Agreement between methods was evaluated using the intraclass correlation coefficient (ICC) with a two-way, single-measure, absolute-agreement model, accompanied by 95% confidence intervals (95% CIs), and by Bland–Altman analysis, including estimation of the mean bias and 95% limits of agreement (LoA). For Bland–Altman analyses, differences were calculated as PoCT minus the reference laboratory measurement (PoCT − laboratory); therefore, negative bias indicates underestimation and positive bias indicates overestimation by the PoCT device relative to the reference method. Proportional bias was assessed by regressing the differences between methods on their mean measurements.

Classification performance was evaluated using the reference laboratory method as the reference standard. For method-comparison purposes, altered lipid levels were defined as TC ≥190 mg/dL, HDL-C <40 mg/dL, LDL-C ≥115 mg/dL, and TG ≥175 mg/dL. The same thresholds were applied to the laboratory and PoCT measurements. The non-fasting threshold was adopted for TG because fasting was not required by the study protocol. These thresholds were used as standardized classification criteria and were not intended to represent individualized therapeutic targets or cardiovascular risk categories; in particular, LDL-C therapeutic targets vary according to cardiovascular risk stratification [14]. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy were calculated with exact binomial 95% CIs. Classification agreement was assessed using the unweighted Cohen's kappa coefficient, with 95% CIs estimated using percentile bootstrap with 2,000 resamples.

Acceptability outcomes were summarized using absolute and relative frequencies. The association between finger-prick pain intensity and preferred blood collection method was assessed using Fisher's exact test. Statistical significance was defined as $p < 0.05$.

RESULTS

Population characteristics

A total of 300 participants were enrolled in the study. Of these, 279 (93.0%) had complete paired lipid measurements from the reference laboratory and both PoCT devices and comprised the analytical sample. The remaining 21 participants (7.0%) were excluded from the paired analyses because complete measurements from all three methods were unavailable. Among the 279 participants included in the paired analyses, the mean age was 58 ± 12 years, and most were female (79%). Self-reported race/ethnicity was

predominantly Brown (44%), followed by White (33%) and Black (19%). Hypertension was the most frequently reported non-communicable disease (62%), followed by diabetes mellitus (42%), whereas dyslipidemia and cardiovascular disease were each reported by 13% of participants (Table 1).

Table 1 Demographic and clinical characteristics of participants included in the paired analytical sample (n = 279).

Characteristic	Overall (n = 279)
Demographic characteristics	
[1]Age, years	58 ± 12
Sex	
Female	220 (79%)
Male	59 (21%)
Race/ethnicity	
White	91 (33%)
Black	54 (19%)
Brown	123 (44%)
Asian	9 (3.2%)
Indigenous	2 (0.8%)
Clinical characteristics (self-reported)	
Dyslipidemia	36 (13%)
Cardiovascular disease	36 (13%)
Diabetes mellitus	117 (42%)
Hypertension	174 (62%)

[1]Mean ± SD; n (%)

Note: Self-reported NCDs were not mutually exclusive; participants could report more than one condition.

Descriptive statistics of laboratory and PoCT lipid measurements

Descriptive statistics for laboratory and PoCT lipid measurements are presented in Table 2. For TC, the reference laboratory showed the highest mean concentration (200.6 ± 42.6 mg/dL), whereas the Mission® (194.1 ± 46.1 mg/dL) and CardioChek® Plus (194.0 ± 46.2 mg/dL) showed similar lower mean values. Similar results were

observed for HDL-C and LDL-C, with the highest mean concentrations obtained by the reference laboratory (53.9 ± 13.1 mg/dL and 121.6 ± 35.8 mg/dL, respectively), followed by the CardioChek® Plus (52.0 ± 13.0 mg/dL) and Mission® (51.4 ± 15.6 mg/dL) for HDL-C, and by the Mission® (118.9 ± 39.6 mg/dL) and CardioChek® Plus (113.1 ± 39.3 mg/dL) for LDL-C. In contrast, for triglycerides, the CardioChek® Plus showed the highest mean concentration (144.4 ± 66.8 mg/dL), exceeding both the reference laboratory (139.2 ± 64.7 mg/dL) and the Mission® (120.9 ± 55.7 mg/dL), which presented the lowest mean value.

Table 2 Descriptive statistics of reference laboratory and PoCT lipid measurements obtained from paired samples (n = 279).

Biomarker	Method	Mean ± SD	Minimum	Maximum
Total Cholesterol	Laboratory	200.6 ± 42.6	114	328
	Mission®	194.1 ± 46.1	101	321
	CardioChek® Plus	194 ± 46.2	100	324
HDL Cholesterol	Laboratory	53.9 ± 13.1	26	94
	Mission®	51.4 ± 15.6	18	93
	CardioChek® Plus	52 ± 13.0	28	98
LDL Cholesterol	Laboratory	121.6 ± 35.8	42	217
	Mission®	118.9 ± 39.6	30	230
	CardioChek® Plus	113.1 ± 39.3	32	222
Triglycerides	Laboratory	139.2 ± 64.7	44	377
	Mission®	120.9 ± 55.7	46	364
	CardioChek® Plus	144.4 ± 66.8	53	363

Note Values are presented as mean ± Standard Deviation (SD), minimum and maximum.

Correlation analysis

Pearson correlation analyses showed strong positive linear correlations between the reference laboratory method and both PoCT devices for all lipid biomarkers (Figure 1). All correlation coefficients were statistically significant ($p < 0.001$). For Mission®,

the correlation coefficients were $r = 0.922$ for TC, $r = 0.898$ for HDL-C, $r = 0.927$ for LDL-C, and $r = 0.961$ for TG (Figure 1A–D). For CardioChek® Plus, the corresponding coefficients were $r = 0.949$, $r = 0.920$, $r = 0.925$, and $r = 0.960$, respectively (Figure 1E–H). TG showed the highest correlation coefficient for both devices, whereas HDL-C showed the lowest

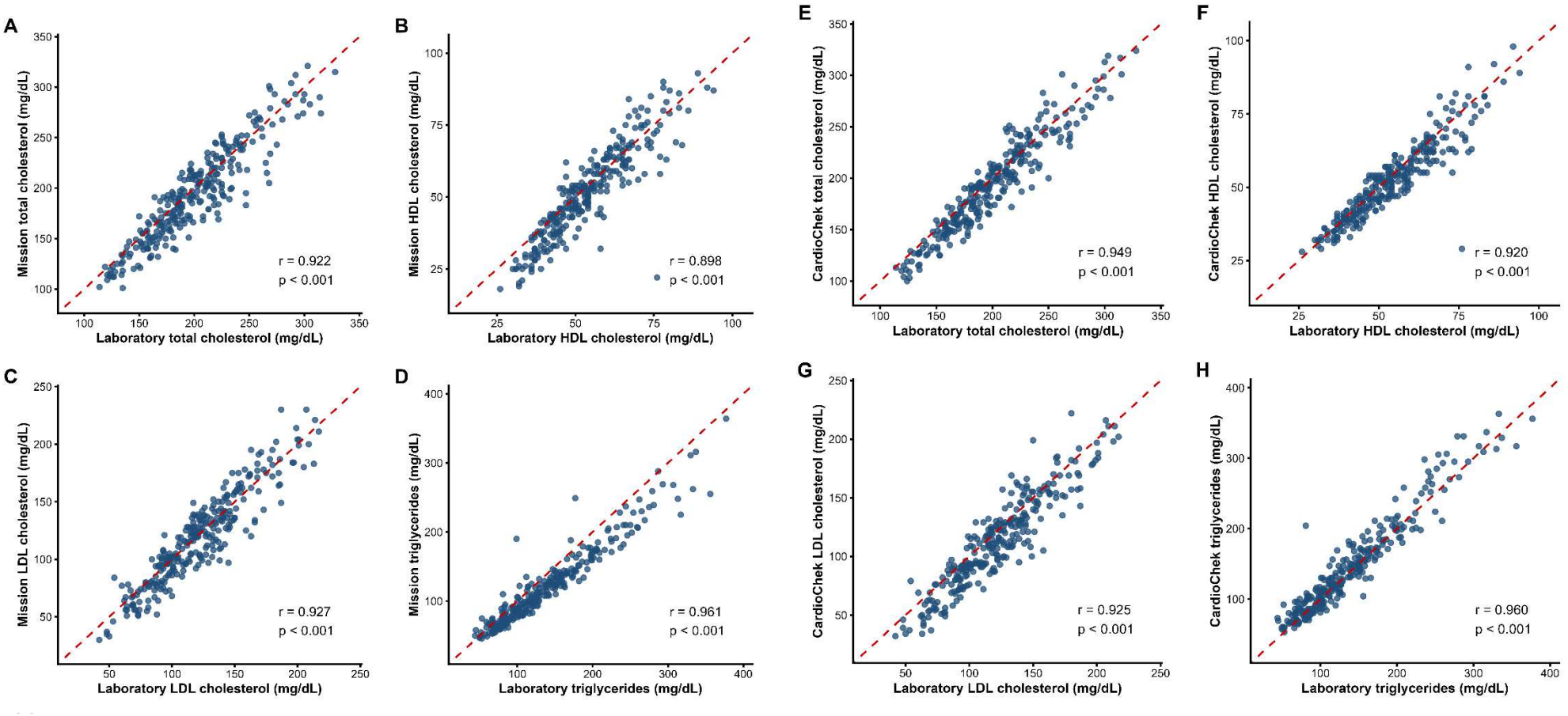


Figure 1 Pearson correlation between laboratory and PoCT measurements for lipid biomarkers. Panels **A–D** represent comparisons between Mission® and laboratory measurements for total cholesterol, HDL cholesterol, LDL cholesterol, and triglycerides, respectively. Panels **E–H** represent the corresponding comparisons between CardioChek® Plus and laboratory measurements. Pearson correlation coefficients (*r*) and *p*-values are shown in each panel.

Analytical agreement

Intraclass correlation coefficients between the PoCT devices and the reference laboratory method ranged from 0.871 to 0.957 across lipid biomarkers (Table 3). ICC estimates ranged from 0.871 to 0.920 for Mission® and from 0.898 to 0.957 for CardioChek® Plus, with the corresponding 95% confidence intervals presented in Table 3.

Table 3 Analytical agreement between PoCT devices and the reference laboratory *(n* = 279).

Biomarker	Device	ICC (95% CI)	Mean bias (mg/dL)	95% limits of agreement (mg/dL)
Total Cholesterol	Mission®	0.910 (0.868–0.936)	-6.5	-41.4 to 28.4
	CardioChek® Plus	0.936 (0.891–0.959)	-6.6	-35.1 to 22.0
HDL Cholesterol	Mission®	0.871 (0.812–0.908)	-2.6	-16.1 to 11.0
	CardioChek® Plus	0.910 (0.867–0.937)	-1.9	-12.2 to 8.3
LDL Cholesterol	Mission®	0.920 (0.899–0.937)	-2.6	-31.8 to 26.5
	CardioChek® Plus	0.898 (0.791–0.942)	-8.4	-37.8 to 20.9
Triglycerides	Mission®	0.909 (0.544–0.965)	-18.3	-55.5 to 18.8
	CardioChek® Plus	0.957 (0.941–0.968)	5.2	-31.4 to 41.9

Note: Agreement was assessed using the intraclass correlation coefficient (ICC), mean bias, and 95% limits of agreement (LoA) obtained from Bland–Altman analysis. Bland–Altman differences were calculated as PoCT − laboratory; therefore, negative bias indicates underestimation, and positive bias indicates overestimation by the PoCT device relative to the reference laboratory method.

Bland–Altman analyses showed differences in the magnitude and direction of bias across biomarkers and devices (Figures 2–5; Table 3). For TC, both devices showed similar negative mean biases (Mission®: −6.5 mg/dL; CardioChek® Plus: −6.6 mg/dL). For HDL-C, mean biases were −2.6 mg/dL for Mission® and −1.9 mg/dL for CardioChek® Plus. For LDL-C, the mean biases were −2.6 mg/dL and −8.4 mg/dL, respectively. The largest difference in the direction and magnitude of bias between

devices was observed for TG, with a mean bias of −18.3 mg/dL for Mission® and 5.2 mg/dL for CardioChek® Plus. Regression of the differences against the mean measurements indicated significant proportional bias for TC with both devices, HDL-C with Mission®, LDL-C with both devices, and TG with Mission® (all $p < 0.001$). For TG with Mission®, the regression slope was −0.153 (95% CI −0.186 to −0.120; $R^2 = 0.231$), indicating greater underestimation at higher TG concentrations. No significant proportional bias was observed for HDL-C with CardioChek® Plus ($p = 0.839$) or TG with CardioChek® Plus ($p = 0.052$). The corresponding 95% limits of agreement are presented in Table 3 and Figures 2–5.

Classification performance

Classification performance varied across lipid biomarker and between PoCT devices when laboratory-based thresholds were used as the reference standard (Table 4). For TC, classification performance was highly comparable between devices across all evaluated metrics. Greater differences between the Mission® and CardioChek® Plus were observed for HDL-C, LDL-C, and TG.

Sensitivity and specificity showed distinct patterns according to both the biomarker and device. For HDL-C, the Mission® demonstrated higher sensitivity than the CardioChek® Plus (97.4% vs. 86.8%), whereas CardioChek Plus showed higher specificity (92.5% vs. 88.0%). A similar pattern was observed for TG, with the Mission® presenting the lowest sensitivity (60.6%) but the highest specificity (99.1%), while the CardioChek® Plus achieved a more balanced combination of sensitivity (95.5%) and specificity (95.3%). For LDL-C, the Mission® showed higher sensitivity (87.0% vs. 75.3%), whereas specificity was similar between devices.

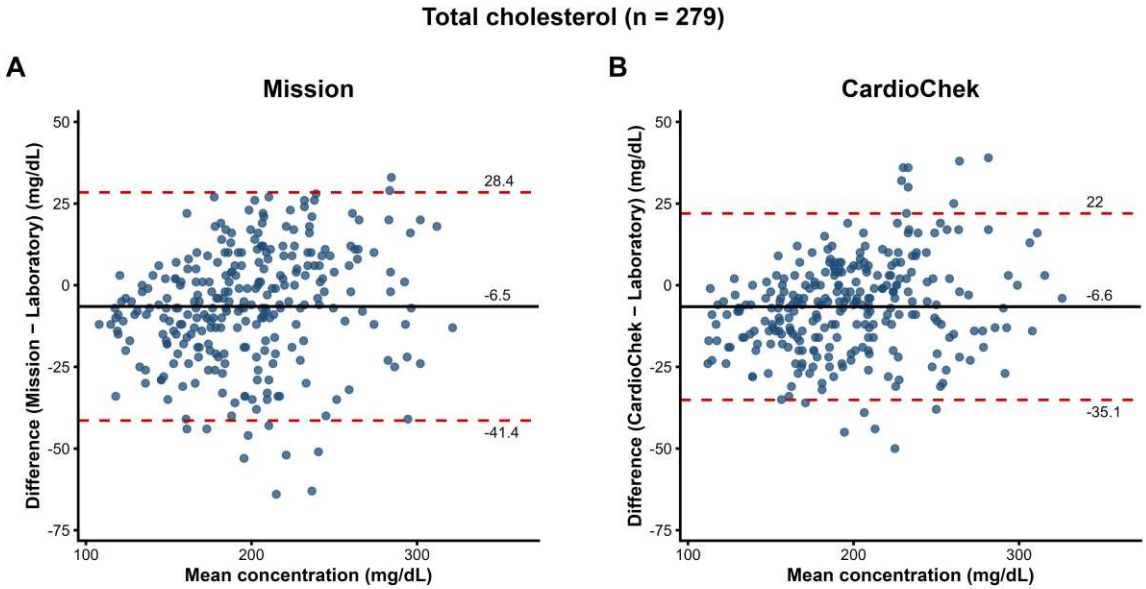


Figure 2. Bland–Altman plots comparing total cholesterol measurements obtained using the Mission® (**A**) and CardioChek® Plus (**B**) PoCT devices with the reference laboratory (n = 279). The black line represents the mean bias, and the dashed red lines indicate the 95% limits of agreement.

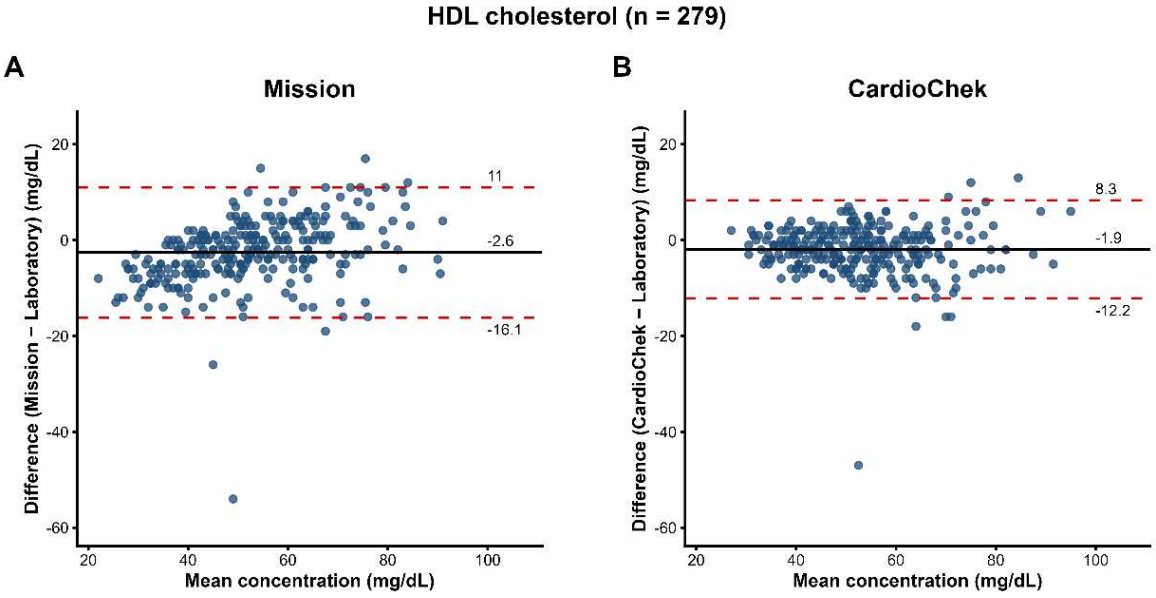
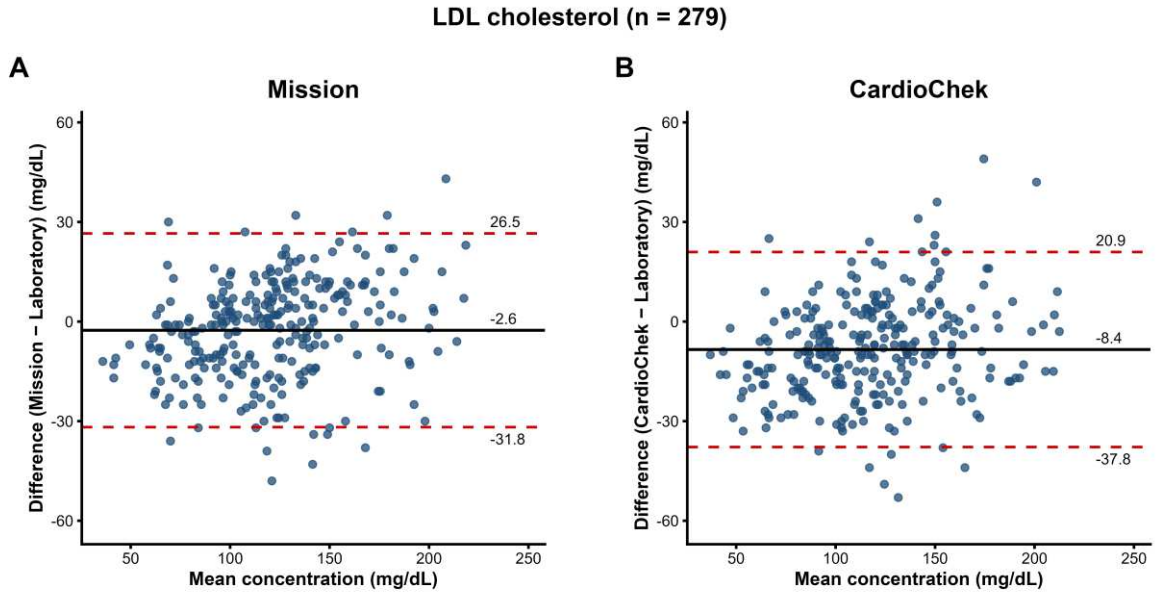


Figure 3. Bland–Altman plots comparing HDL cholesterol measurements obtained using the Mission® (**A**) and CardioChek® Plus (**B**) PoCT devices with the reference laboratory (n = 279). The black line represents the mean bias, and the dashed red lines indicate the 95% limits of agreement.



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343 **Figure 4.** Bland–Altman plots comparing LDL cholesterol measurements obtained using
344 the Mission® (**A**) and CardioChek® Plus (**B**) PoCT devices with the reference laboratory
345 (*n* = 279). The black line represents the mean bias, and the dashed red lines indicate the
346 95% limits of agreement.

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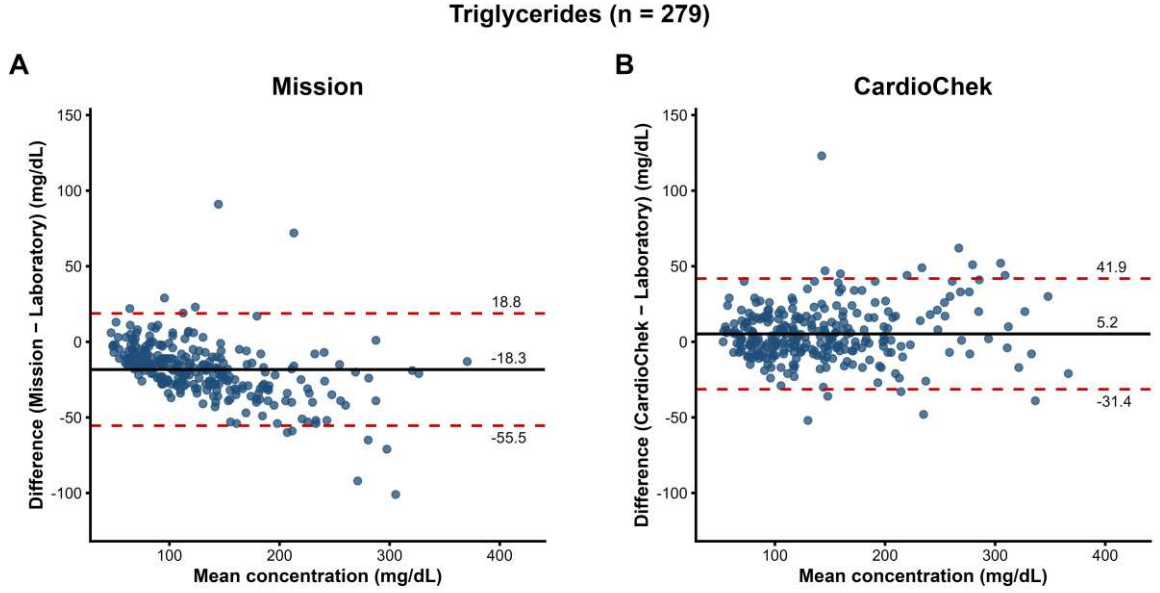

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349 **Figure 5.** Bland–Altman plots comparing triglyceride measurements obtained using the
350 Mission® (**A**) and CardioChek® Plus (**B**) PoCT devices with the reference laboratory (*n*
351 = 279). The black line represents the mean bias, and the dashed red lines indicate the 95%
352 limits of agreement.

353

354 The classification performance also varied according to the biomarker, as shown
355 in Table 4. For TC, both devices showed similar positive and negative predictive values,
356 accuracy, and agreement. For HDL-C, despite the higher sensitivity observed for the
357 Mission®, CardioChek Plus achieved higher overall accuracy (89.2% vs. 91.8%) and
358 Cohen's (0.651 vs. 0.694). For LDL-C, the Mission® demonstrated higher negative
359 predictive value, overall accuracy, and agreement than CardioChek® Plus. In contrast,
360 for TG, the CardioChek® Plus showed higher negative predictive value, accuracy, and
361 Kappa, whereas the Mission® maintained the highest positive predictive value.
362 Neither PoCT devices have consistently achieved the highest performance across
363 all biomarkers and diagnostic metrics. Instead, performance varied according to the lipid
364 biomarker evaluated, with the Mission® presenting higher sensitivity for HDL-C and
365 higher overall classification performance for LDL-C, whereas the CardioChek® Plus
366 showed higher overall classification performance for TG while sustaining comparable
367 performance for total cholesterol (Table 4).
368
369 **Acceptability of capillary blood collection**
370 Among the 279 participants, 143 (51.3%) preferred finger-prick blood collection,
371 91 (32.6%) reported no preference, and 45 (16.1%) preferred venous blood collection
372 (Figure 6). Thus, preference for finger-prick collection was approximately three times as
373 frequent as preference for venous collection. Regarding the finger-prick procedure, 157
374 participants (56.3%) reported no pain, 106 (38.0%) reported mild pain, 15 (5.4%)
375 reported moderate pain, and one participant (0.4%) reported severe pain.

Table 4 Clinical classification agreement of PoCT devices using the reference laboratory as the reference standard (n = 279).

Biomarker	Device	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)	Accuracy (95% CI)	Kappa (95% CI)
Total cholesterol	Mission	85.8 (79.3–90.9)	88.7 (81.8–93.7)	90.5 (84.5–94.7)	83.3 (75.9–89.3)	87.1 (82.6–90.8)	0.740 (0.661–0.814)
	CardioChek	88.4 (82.3–93.0)	88.7 (81.8–93.7)	90.7 (84.9–94.8)	85.9 (78.7–91.4)	88.5 (84.2–92.0)	0.768 (0.687–0.841)
HDL cholesterol	Mission	97.4 (86.2–99.9)	88.0 (83.2–91.8)	56.1 (43.3–68.3)	99.5 (97.4–100.0)	89.2 (85.0–92.6)	0.651 (0.532–0.761)
	CardioChek	86.8 (71.9–95.6)	92.5 (88.5–95.5)	64.7 (50.1–77.6)	97.8 (95.0–99.3)	91.8 (87.9–94.7)	0.694 (0.568–0.804)
LDL cholesterol	Mission	87.0 (80.9–91.8)	92.3 (85.9–96.4)	94.0 (88.9–97.2)	83.7 (76.2–89.6)	89.2 (85.0–92.6)	0.782 (0.705–0.854)
	CardioChek	75.3 (67.9–81.7)	93.2 (87.0–97.0)	93.8 (88.2–97.3)	73.2 (65.3–80.1)	82.8 (77.8–87.0)	0.660 (0.573–0.743)
Triglycerides	Mission	60.6 (47.8–72.4)	99.1 (96.6–99.9)	95.2 (83.8–99.4)	89.0 (84.3–92.7)	90.0 (85.8–93.2)	0.682 (0.577–0.780)
	CardioChek	95.5 (87.3–99.1)	95.3 (91.5–97.7)	86.3 (76.2–93.2)	98.5 (95.8–99.7)	95.3 (92.2–97.5)	0.876 (0.807–0.935)

Note Clinical classification was based on the laboratory operational thresholds: total cholesterol ≥190 mg/dL, HDL cholesterol <40 mg/dL, LDL cholesterol ≥115 mg/dL (operational cutoff adopted from the laboratory report), and triglycerides ≥175 mg/dL. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), accuracy, and Cohen's kappa were calculated using laboratory measurements as the reference standard.

Preferred blood collection method differed according to finger-prick pain intensity (Fisher's exact test, $p = 0.015$). Among participants reporting no pain, finger-prick blood collection was the most frequently preferred method (57.3%). In contrast, preference for venous blood collection was more frequent among participants reporting moderate pain (40.0%) than among those reporting no pain (10.8%).

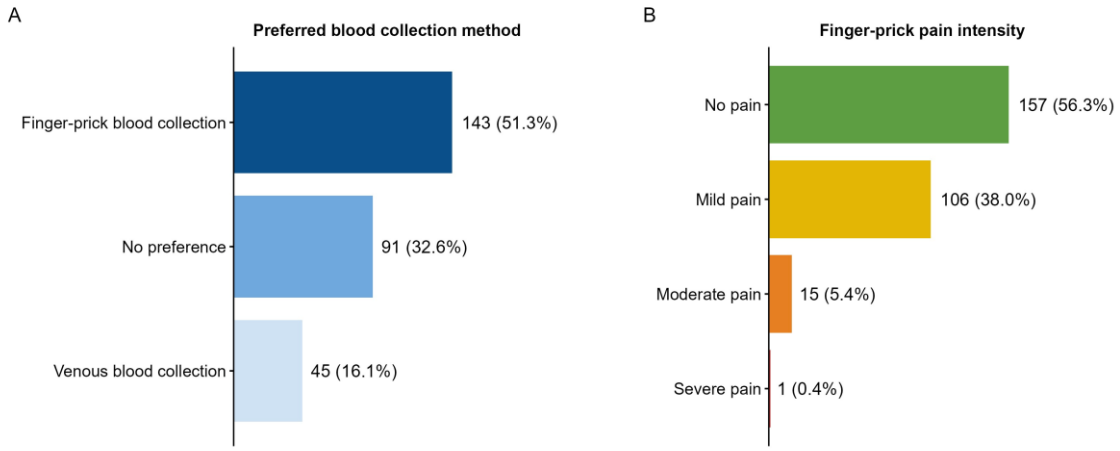

Figure 6 Participant acceptability of capillary blood collection in the paired analytical sample (n = 279). (**A**) Preferred blood collection method. (**B**) Self-reported finger-prick pain intensity. Values are presented as n (%).

DISCUSSION

This study compared the analytical agreement, classification performance, and participant acceptability of Mission® and CardioChek® for lipid profile assessment using paired capillary and venous blood measurements obtained under routine primary care conditions. Three main findings emerged. First, both devices showed strong correlations and good agreement with the laboratory reference method, although performance varied by device and biomarker. Second, CardioChek® showed numerically higher agreement estimates for TC, HDL-C, and TG, whereas Mission® showed a slightly higher

agreement estimate for LDL-C. Third, clinical classification performance also differed between devices, with specific advantages depending on the lipid fraction assessed. Finger-prick sampling was well accepted, as most participants preferred it to venipuncture and reported no pain or only mild discomfort.

The coexistence of hypertension, diabetes, dyslipidemia, and other NCDs represents an important challenge for primary care. Wahrhaftig et al. [15], evaluating Brazil's progress toward the 2030 NCD targets, projected that the prevalence of diabetes and hypertension will continue to increase. Similarly, Malta et al. [16], using Global Burden of Disease estimates, projected increasing exposure to several cardiometabolic risk factors in Brazil through 2050, including high LDL-C, blood pressure, fasting glucose, and BMI, as well as low physical activity and dietary risks. This may be particularly relevant to primary care in low- and middle-income countries (LMIC), where gaps in cardiovascular risk-factor testing and limited access to laboratory infrastructure remain important challenges to screening and disease management [17—19].

In this context, Plüddemann et al. [20] highlighted the potential role of lipid PoCT in cardiovascular risk assessment and clinical decision-making in primary care. Immediate access to lipid results may support risk assessment, patient counseling, and timely clinical management. In a systematic review of qualitative studies, primary care professionals reported that PoCT could improve diagnostic confidence, guide treatment, promote self-management of chronic conditions, and strengthen communication with patients [21]. However, these potential benefits depend on reliable analytical performance and integration into care pathways that include quality control and laboratory confirmation when appropriate.

To our knowledge, this is the first study to compare Mission® and CardioChek® against a laboratory reference method using paired samples collected from the same

participants under routine Brazilian primary care conditions. A direct comparison between the two devices was previously reported by Clark and Bolodeoku [22] in a small analytical study using whole-blood samples, with differences in performance across lipid parameters. However, its limited sample size and analytical design restrict comparisons with studies conducted in clinical populations.

By assessing each device against the reference method under equivalent analytical and operational conditions, the present study reduces the influence of differences in populations, protocols, and laboratory procedures. This design supports the interpretation that the observed differences may be related to device performance, although the contribution of preanalytical and operational factors cannot be excluded.

Correlations were strong for all lipid fractions, with the highest coefficients observed for triglycerides on both devices and relatively lower values for HDL-C. For Cardiochek® in a venous blood comparison involving 325 participants, Gao et al. [23] reported coefficients of 0.875, 0.813, 0.864, and 0.910 for TC, HDL-C, LDL-C, and TG, respectively. Ferreira et al. [24], in a study of 516 participants, likewise found particularly strong correlations for HDL-C and TG and a good correlation for TC. Taken together, these findings reinforce the consistent association between CardioChek® and laboratory measurements, especially for TG.

Mission® also produced stronger correlations than those reported in a validation study of older adults, in which TC showed the best performance, but the concordance correlation coefficient reached only 0.89, and none of the analytes met the authors' prespecified target of 0.90 [11]. Our findings are also consistent with Machado et al. [25], who observed strong linear associations but emphasized the presence of relevant biases, particularly for triglycerides and total cholesterol. Importantly, correlation should not be interpreted as evidence of interchangeability. While correlation assesses the strength of

association between measurements, agreement analyses evaluate whether both methods produce sufficiently similar values for clinical use [26].

Agreement analyses confirmed good overall performance while revealing differences across devices and biomarkers. CardioChek® yielded higher ICCs for TC, HDL-C, and triglycerides, whereas Mission® showed greater agreement for LDL-C. These results compare favorably with those reported by Lourdes et al. [9] for CardioChek PA, with ICCs of 0.67 for TC, 0.64 for HDL-C, 0.75 for LDL-C, and 0.91 for TG. Differences across studies may reflect population characteristics, collection protocols, laboratory methods, quality-control procedures, and operator training. Previous evaluations have shown that the performance of lipid PoCT devices may also be affected by hematocrit, analytical imprecision, and other preanalytical and operational factors [10].

The Bland–Altman analysis provided information not captured by correlation coefficients. Both devices showed a small tendency to underestimate total cholesterol, with similar biases. For LDL-C, Mission® had a smaller bias, consistent with its higher ICC for this biomarker, although the limits of agreement warrant caution when interpreting individual results. Mission® also showed a negative triglyceride bias of −18.3 mg/dL, which was less pronounced than the −42.8 mg/dL reported by Machado et al. [25] but still indicated a systematic discrepancy. CardioChek®, by contrast, achieved better agreement for TG. Thus, a device may adequately track variation in measurements while systematically underestimating or overestimating absolute values, limiting its direct interchangeability with the laboratory method.

Classification performance was likewise biomarker dependent. The two devices produced similar results for TC. For HDL-C, Mission® provided greater sensitivity, whereas CardioChek® offered higher specificity. Mission® was also more sensitive for

LDL-C, while CardioChek® achieved a better balance between sensitivity and specificity for TG. The lower triglyceride sensitivity observed with Mission® is consistent with its negative bias, because systematic underestimation may cause participants with elevated concentrations to be classified within the normal range. From a screening perspective, this is clinically relevant because it increases the likelihood of false-negative results.

CardioChek® findings were broadly consistent with previous studies indicating acceptable performance for risk classification, but not complete equivalence with laboratory testing. Lourdes et al. [9] reported sensitivity and specificity of 57.1% and 94.3% for TC, 76.0% and 100% for TG, 96.2% and 83.2% for HDL-C, and 81.0% and 100% for LDL-C. Gao et al. [23], in turn, found overall clinical agreement of 97.0%, 92.9%, 92.4%, and 83.7% for total cholesterol, HDL-C, triglycerides, and LDL-C, respectively. Mission® performed better in the present study than in the investigation by Abrahin et al. [11], which reported clinical agreement of 67.3% for total cholesterol, 65.3% for HDL-C, 49.0% for LDL-C, and 61.2% for triglycerides. Direct comparisons across studies should nevertheless remain cautious because of thresholds, prevalence of lipid abnormalities, and the clinical characteristics of study populations differing. Although statistically modest, the differences between devices may have practical implications depending on the intended use of the device, particularly in screening programs where minimizing false-negative results is a priority.

Operational feasibility is also essential when these devices are used outside laboratory settings. A small proportion of participants was excluded because a complete set of paired measurements could not be obtained owing to analytical or operational failures. Missing results were less frequent for the initial total cholesterol measurement and occurred mainly when errors in HDL-C or triglyceride determinations prevented the subsequent calculation of LDL-C. Although uncommon, these events demonstrate that

505 rapid testing does not eliminate the need for operator training, standardized procedures,
506 quality control, and predefined protocols for missing or invalid results.

507 The high acceptability of finger-prick sampling further supports the use of PoCT
508 in decentralized strategies. Most participants either preferred capillary collection or
509 expressed no preference between collection methods, and more than 90% reported no
510 pain or only mild pain. These findings are consistent with previous evidence showing
511 high patient satisfaction with PoCT in primary care and a preference for finger-prick over
512 venous blood collection [27]. From an implementation perspective, ease of sample
513 collection and rapid availability of results have also been identified as relevant factors for
514 the acceptability and feasibility of PoCT in primary care [28]. Nevertheless, sampling
515 convenience should not be regarded as evidence of analytical equivalence. PoCT devices
516 appear better suited as complementary tools for screening and initial risk assessment than
517 as universal replacements for laboratory methods, especially when results are abnormal,
518 borderline, or inconsistent with the clinical presentation.

519 The main strengths of this study include the simultaneous comparison of both
520 devices against the reference method, paired measurements from the same participants,
521 and evaluation under routine primary care conditions. Assessing acceptability also
522 extended the analysis beyond analytical performance. However, several limitations
523 should be acknowledged. The use of convenience sampling and the predominance of
524 women may limit the generalizability of the findings to populations with different
525 demographic profiles. In addition, the sample was intentionally enriched with participants
526 with NCDs as part of the study design to increase the representation and variability of
527 abnormal lipid values. Therefore, the findings should not be interpreted as representative
528 of the general population, although they may be particularly informative for primary care

settings in which lipid assessment and cardiovascular risk management are frequently performed among individuals with NCDs.

Estimates of sensitivity, specificity, and predictive values are also influenced by the prevalence of lipid abnormalities and the thresholds applied. In addition, the use of a triglyceride threshold in samples collected without a fasting requirement should be considered when interpreting clinical classification. The findings also highlight the distinction between screening and diagnostic purposes. For population-based screening initiatives, the rapid availability of results and acceptable classification performance may outweigh small analytical differences. However, for diagnostic confirmation or treatment monitoring, laboratory measurements remain essential. Finally, the results reflect specific devices, reagent lots, operators, and conditions of use and may not fully represent performance in other settings.

In conclusion, Mission® and CardioChek® showed good overall performance for lipid profile assessment in primary care, but their analytical and diagnostic characteristics varied by biomarkers. CardioChek® achieved greater agreement for TC, HDL-C, and TG and better classified elevated triglycerides, whereas Mission® performed more favorably for LDL-C and was more sensitive to HDL-C and LDL-C abnormalities. Together with the high acceptability of finger-prick sampling, these findings support the use of both devices in decentralized screening strategies, provided that results are interpreted according to analytically specific limitations and incorporated into pathways that ensure laboratory confirmation when required. Future multicenter studies should evaluate the performance of these devices across more diverse populations and healthcare settings. Cost-effectiveness and implementation studies are also needed to determine whether their analytical and operational advantages translate into sustainable screening strategies at scale. Such evidence will become increasingly important as health systems face a growing

cardiovascular disease burden driven, in part, by population growth and aging over the coming decades [29].

CONCLUSION

Mission® and CardioChek® demonstrated good overall analytical agreement with laboratory measurements for lipid profile assessment, although performance varied across biomarkers. CardioChek® showed greater agreement for TC, HDL-C, and TG, whereas Mission® performed more favorably for LDL-C and showed higher sensitivity for HDL-C and LDL-C abnormalities. The high acceptability of finger-prick sampling further supports the feasibility of these devices in primary healthcare settings. Overall, both PoCT devices may contribute to decentralized dyslipidemia screening, provided that biomarker-specific analytical and diagnostic limitations are recognized and abnormal or clinically discordant results are confirmed by laboratory methods when appropriate.

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Author's contributions

BSB: Conceptualization, Methodology, Investigation, Data Curation, Formal Analysis, Writing – Original Draft, Writing – Review & Editing. RSP: Methodology, Formal Analysis, Writing – Review & Editing. MLPF: Methodology, Formal Analysis, Writing – Review & Editing. PCF: Writing – Review & Editing. ECDPG: Writing – Review &

Editing. LMJ: Writing – Review & Editing. OGEM: Writing – Review & Editing. LOC: Writing – Review & Editing. ED: Writing – Review & Editing, Supervision. All authors read and approved the final version of the manuscript.

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Competing interests

The Author(s) declare(s) that there is no competing of interest.

Ethics approval and consent to participate

The study was conducted in accordance with the Declaration of Helsinki and was approved by the Research Ethics Committee of Hospital Israelita Albert Einstein (approval no. 7,541,989; CAAE: 87471725.4.0000.0071). All participants provided informed consent electronically before enrollment. Participant confidentiality was ensured, and all analyses were conducted using de-identified data.

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