# Cardiovascular Topics

## Point-of-care testing compared to gold-standard laboratory methods in the measurement of serum lipids

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### Abstract

**Background:** Cardiovascular disease is the leading cause of mortality worldwide, with dyslipidaemia being one of the major risk factors. Point-of-care testing (POCT) allows for the rapid measurement of serum lipids. The aim of this study was to assess the accuracy of serum lipid measurement by the Fujifilm™ NX700 POCT compared to a gold-standard clinical laboratory method (Medpace, Leuven, Belgium).

**Methods:** This was a prospective, observational study conducted at the Lipid Clinic at Charlotte Maxeke Johannesburg Academic Hospital from July to September 2022. Participants were known to have a lipid disorder, most commonly, familial hypercholesterolaemia. Samples sent for lipid measurement by standard laboratory methods were simultaneously measured by the Fujifilm™ NX700 POCT.

**Results:** Lipograms evaluating total cholesterol (TC), triglycerides (TG), high-density lipoprotein cholesterol (HDL-C) and calculated low-density lipoprotein cholesterol (LDL-C) were obtained from 115 participants. No statistically significant difference was noted between the parameters tested on the different platforms. The Fujifilm™ NX700 POCT correctly identified > 91% of serum lipid results as normal or abnormal, as defined by NCEP-ATP III criteria, and exhibited good sensitivity and specificity for each parameter. Lin's concordance correlation coefficient demonstrated a strong correlation for all parameters; TC ($\rho_c$ = 0.9861), HDL-C ($\rho_c$ = 0.95919), LDL-C ($\rho_c$ = 0.98134) and TG ($\rho_c$ = 0.92775). Bland–Altman plots identified low bias and a good level of agreement between the two test methods.

**Conclusion:** The Fujifilm™ NX700 POCT compared favourably with gold-standard laboratory methods in the determination of serum lipid measurements, allowing for rapid screening at the primary healthcare level.


**Keywords:** point-of-care testing, lipogram, dyslipidaemia

Submitted 16/3/23, accepted 17/7/23

*Cardiovasc J Afr* 2023; online publication www.cvja.co.za

DOI: 10.5830/CVJA-2023-039

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Cardiovascular disease, particularly atherosclerotic cardiovascular disease (ASCVD) remains the leading cause of death worldwide.[1] Elevated cholesterol levels, and in particular low-density lipoprotein cholesterol (LDL-C), is one of the strongest risk factors for ASCVD and lowering LDL-C level has been conclusively shown to reduce cardiovascular as well as total mortality rates.[2,3] For this reason, current guidelines all emphasise lipid modification, particularly aimed at reducing LDL-C levels in order to reduce ASCVD risk, and therefore, LDL-C lowering has become the cornerstone of ASCVD prevention.[3] Despite this, many patients taking lipid-lowering therapy do not reach the recommended LDL-C targets.[4]

Point-of-care testing (POCT) is a measure of analytes in an out-patient or in-patient setting, which takes place at or near the site of patient care, thereby allowing for the rapid reporting of results. POCT has several potential benefits over traditional laboratory testing. It enables rapid diagnosis of a disease or monitoring of the responses to therapeutic interventions, which can improve patient outcomes.

Importantly, many of the commonly used risk-stratification tools for ASCVD incorporate lipid parameters.[5,6] POCT would be of value in determining an individual's risk at the bedside or in the out-patient setting to allow for earlier introduction or intensification of lipid-lowering therapy.

The Fujifilm™ NX700 POC test is an automated clinical chemistry analyser that measures serum lipids together with several other analytes (sodium, potassium, chloride, urea, creatinine, glucose, alanine transaminase, aspartamine transaminase, creatine kinase, C-reactive protein, uric acid, amylase and lactate dehydrogenase, among others). It is capable of a throughput of 190 tests per hour.

The measurement of serum lipids comprises total cholesterol (TC), triglycerides (TG), high-density lipoprotein cholesterol (HDL-C) and LDL-C. LDL-C is calculated using the Friedewald equation: TC – HDL-C – TG/2.2 (in mmol/l). Non-HDL-C is also reported and is calculated from the other lipid parameters (TC – HDL-C). HDL-C can be measured within a range of 0.26–2.84 mmol/l, TC is measured within a range 1.29–11.64 mmol/l and TG is measured within a range of 0.11–5.65 mmol/l.

Measurement of electrolytes requires a minimum of 50 µl of blood and takes approximately one minute for three tests (sodium, potassium and chlorine). Analytes measured by colorimetric methods need at least 10 µl of serum and take around six minutes to return a result.

The primary objective of this study was to evaluate the performance of the Fujifilm™ NX700 POC test against the gold-standard Beckman AU analyser when measuring serum

lipids. The Beckmann AU analyser is located at a Centre for Disease Control (CDC) reference laboratory, Medpace, in Leuven Belgium.

## Methods

This study was a prospective, observational study that utilised convenience sampling of participants attending a clinical trial site at Charlotte Maxeke Johannesburg Academic Hospital in Johannesburg, South Africa from July to September 2022. One hundred and fifteen individuals with known dyslipidaemia, predominantly familial hypercholesterolaemia were included in the study.

Approval to conduct the study was obtained from the University of the Witwatersrand Human Research Ethics Committee (clearance certificate M210287). Samples obtained from participants were taken following signed informed consent.

A 12-hour fasting specimen was obtained from each participant, centrifuged and transported on ice for measurement of lipid parameters, TC, TG and HDL-C at the CDC-certified reference laboratory (Medpace) located in Leuven, Belgium. LDL-C values were calculated. At the same time, an additional blood sample was used for measurement by the Fujifilm™ NX700 POCT. All testing was performed by a single trained medical technologist.

Samples tested by the Fujifilm™ NX700 POC test were performed according to the manufacturer's instructions. Following centrifugation, at least 50 µl plasma was used for sample measurement. LDL-C calculation (Friedewald equation) was performed automatically by the analyser.

### Statistical analysis

Standard descriptive statistics (mean, standard deviation) are reported. Student *t*-tests were performed to determine differences between sample groups. Bland–Altman plots and Lin's concordance correlation coefficients were determined for each comparison. Lin's concordance correlation coefficient is a method used to compare two measurements of the same variable, assessing the agreement between the two platforms for each analyte, and is especially useful when comparing a new measurement to an established gold-standard measurement. Sensitivity and specificity for pre-specified cut-off points for the lipid parameters were determined.

## Results

Lipograms evaluating TC, HDL-C, calculated LDL-C and TG were obtained from 115 participants and measured by the Beckman AU 5800 at Medpace Reference Laboratories in Leuven, and the Fujifilm™ NX700 POCT. In the samples run by the Fujifilm POCT, 10 out of 115 LDL-C values (8.7%) fell out of the reference range for the apparatus and were not reported and, as a result, values were calculated manually. Criteria set out by the National Cholesterol Education Program (NCEP) – Adult Treatment Panel III (ATPIII) were used to define low-, middle-, and high-range concentrations for TC, TG, HDL-C and LDL-C.[7]

TC, TG, HDL-C and LDL-C, when falling within the high range as measured by the Beckman AU 5800, tended to be measured slightly lower by the Fujifilm™ NX700 POCT, however, this was not statistically significant for any of the lipid parameters (Table 1). No difference was found for measurement of any of the lipid parameters measured by the Fujifilm™ NX700 POCT when compared to the Beckman AU 5800 when they fell within the low- or middle-reference range.

**Table 1. Comparison of lipid parameters as measured by the Beckman AU 5800 and Fujifilm™ NX700 stratified for low, middle and high range**

| *Parameters (mmol/l)* | *Low range (mean ± SEM)* | *Middle range (mean ± SEM)* | *High range (mean ± SEM)* |
|---|---|---|---|
| Total cholesterol | < 5.17 ($n$ = 49) | 5.17–6.2 ($n$ = 19) | > 6.2 ($n$ = 46) |
| Beckman AU 5800 | 3.72 ± 0.11 | 5.64 ± 0.07 | 9.25 ± 0.48 |
| Fujifilm™ NX700 | 3.59 ± 0.11 | 5.46 ± 0.10 | 8.33 ± 0.38 |
| | $p$ = 0.40 | $p$ = 0.14 | $p$ = 0.14 |
| Triglycerides | < 1.7 ($n$ = 80) | 1.7–2.25 ($n$ = 16) | > 2.25 ($n$ = 19) |
| Beckman AU 5800 | 1.10 ± 0.03 | 1.92 ± 0.03 | 3.54 ± 0.31 |
| Fujifilm™ NX700 | 1.06 ± 0.04 | 1.89 ± 0.06 | 3.35 ± 0.27 |
| | $p$ = 0.47 | $p$ = 0.66 | $p$ = 0.64 |
| HDL cholesterol | < 1.03 ($n$ = 29) | 1.03–1.54 ($n$ = 54) | ≥ 1.55 ($n$ = 32) |
| Beckman AU 5800 | 0.86 ± 0.02 | 1.26 ± 0.02 | 1.85 ± 0.05 |
| Fujifilm™ NX700 | 0.88 ± 0.02 | 1.25 ± 0.03 | 1.77 ± 0.05 |
| | $p$ = 0.66 | $p$ = 0.83 | $p$ = 0.28 |
| LDL cholesterol | < 2.59 ($n$ = 42) | 2.59–4.9 ($n$ = 43) | ≥ 4.91 ($n$ = 30) |
| Beckman AU 5800 | 1.68 ± 0.09 | 3.72 ± 0.11 | 8.54 ± 0.63 |
| Fujifilm™ NX700 | 1.61 ± 0.10 | 3.47 ± 0.11 | 7.37 ± 0.50 |
| | $p$ = 0.60 | $p$ = 0.10 | $p$ = 0.15 |

$p < 0.05$ deemed statistically significant.

The diagnostic accuracy of the Fujifilm™ NX700 POCT compared to the Beckman AU 5800 was assessed according to pre-specified diagnostic thresholds for TC (> 6.2 mmol/l), TG (> 2.25 mmol/l), HDL-C (< 1.03 mmol/l) and LDL-C (> 4.91 mmol/l), which are set out by the NCEP-ATPIII. The Fujifilm™ NX700 POC test correctly classified more than 91% of results as normal or abnormal with regard to results for the gold-standard test, the Beckman AU 5800, and displayed excellent sensitivity and specificity. Results for diagnostic accuracy are displayed in Table 2.

Lin's concordance correlation co-efficient ($\rho_c$) was used to determine the correlation between the gold-standard test, the lipogram measured by the Beckman AU 5800, and the comparator, the lipogram measured by Fujifilm™ NX700 POC test. TC, TG, HDL-C and calculated LDL-C levels measured by the Fujifilm™ NX700 POCT were all strongly correlated with the results obtained by the Beckman AU 5800 and are displayed graphically in Figs 1–4.

Bland–Altman plots were used to assess the degree of bias between the Fujifilm™ NX700 POCT and the Beckman AU

**Table 2. The diagnostic accuracy of the Fujifilm™ NX700 POCT compared to the Beckman AU 5800 using diagnostic cut-off values prespecified by NCEP-ATPIII (TC > 6.2; TG > 2.25; HDL-C < 1.03; LDL-C > 4.91 mmol/l)**

| *Parameters* | *Correctly classified (%)* | *Sensitivity (%)* | *Specificity (%)* | *PPV (%)* | *NPV (%)* |
|---|---|---|---|---|---|
| TC | 91.30 | 80.85 | 98.53 | 97.44 | 88.16 |
| TG | 98.26 | 94.74 | 98.96 | 94.74 | 98.96 |
| HDL-C | 91.30 | 89.65 | 91.86 | 78.79 | 96.34 |
| LDL-C | 96.52 | 86.67 | 100 | 100 | 95.51 |

TC = total cholesterol; TG = triglycerides; HDL-C = high-density lipoprotein cholesterol; LDL-C = low-density lipoprotein cholesterol; PPV = positive predictive value; NPV = negative predictive value.

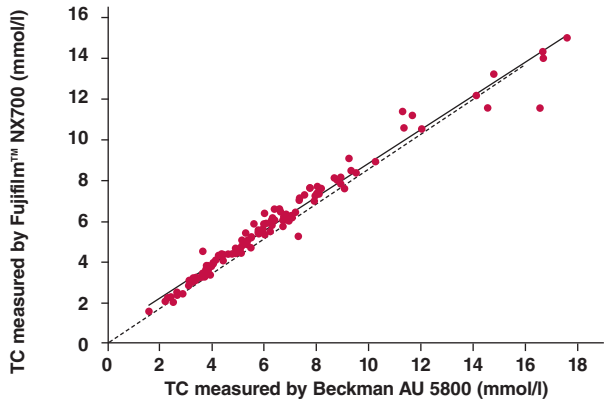


**Fig. 1.** Scatterplot and regression lines for TC comparison. The solid black line represents the line of best fit ($\rho_c$ = 0.9861; *n* = 115). The dashed black line represents the line of perfect concordance.

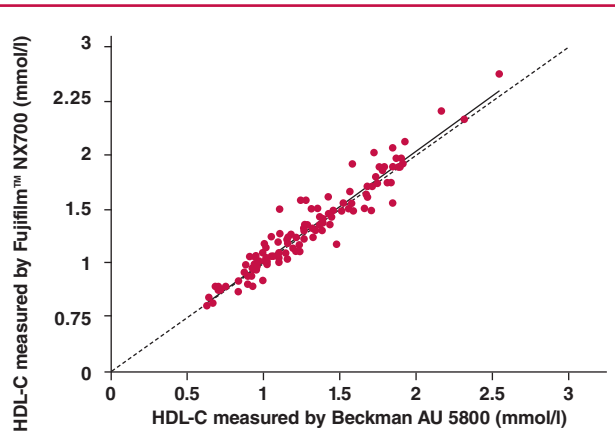


**Fig. 2.** Scatterplot and regression lines for HDL-C comparison. The solid black line represents the line of best fit ($\rho_c$ = 0.95919; *n* = 115). The dashed black line represents the line of perfect concordance.

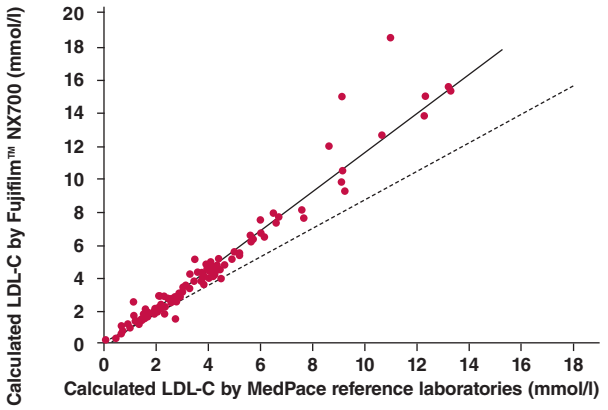


**Fig. 3.** Scatterplot and regression lines for LDL-C comparison. The solid black line represents the line of best fit ($\rho_c$ = 0.98134; *n* = 115). The dashed black line represents the line of perfect concordance.

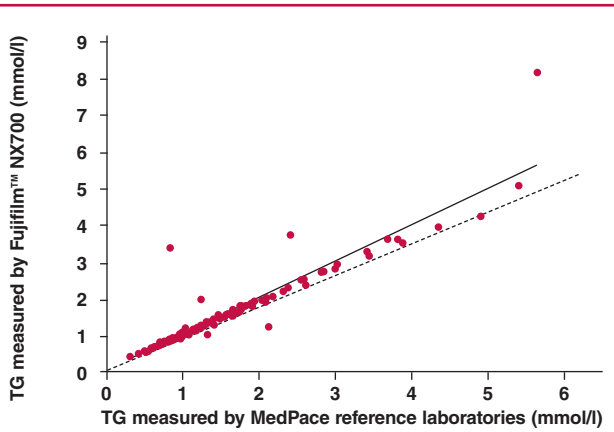


**Fig. 4.** Scatterplot and regression lines for TG comparison. The solid black line represents the line of best fit ($\rho_c$ = 0.92775; *n* = 115). The dashed black line represents the line of perfect concordance.

5800 for TC (Fig. 5), TG (Fig. 6), HDL-C (Fig. 7) and LDL-C levels (Fig. 8). The mean biases and the lower and upper limits of agreement are given in Table 3. Overall, the Bland–Altman plots showed good agreement between the Fujifilm™ NX700 POCT and the Beckman 5800 for TC, TG, HDL-C and LDL-C levels.

## Discussion

POCT is the analysis of patient specimens outside the clinical laboratory (CL), near or at the site of patient care, usually performed by clinical staff without laboratory training.[8] Not only does POCT have the advantage of a shorter turnaround time compared to conventional methods of CL testing, but it provides a potential platform for rapidly screening for cardiovascular disease (CVD) at a primary healthcare (PHC) level. It also facilitates appropriate triaging of referrals to a tertiary hospital, therefore avoiding expenses related to unnecessary laboratory investigations and transportation costs.[8] Although this study utilised the services of a trained laboratory technician, minimal training is required for non-laboratory personnel to utilise the Fujifilm™ NX700 POCT.

The South African dyslipidaemia guidelines recommend POC finger-prick testing for population screening but do not recommend POCT to commit a patient to lifelong therapy, nor to diagnose dyslipidaemia in high-risk individuals or those with a family history of familial hypercholesterolaemia, because underestimation of LDL-C level and inappropriately low results are a concern.[9] These patients require a formal lipid and CVD

**Table 3. Differences between Fujifilm™ NX700 POCT and Backman AU 5800 using Bland–Altman plots**

| *Parameters* | *Mean bias (SD)* | *95% limits of agreement* |
|---|---|---|
| TC | –0.46 (0.74) | –1.90–0.99 |
| TG | –0.06 (0.39) | –0.83–0.70 |
| HDL-C | –0.02 (0.12) | –0.25–0.21 |
| LDL-C | –0.42 (0.80) | –1.99–1.14 |

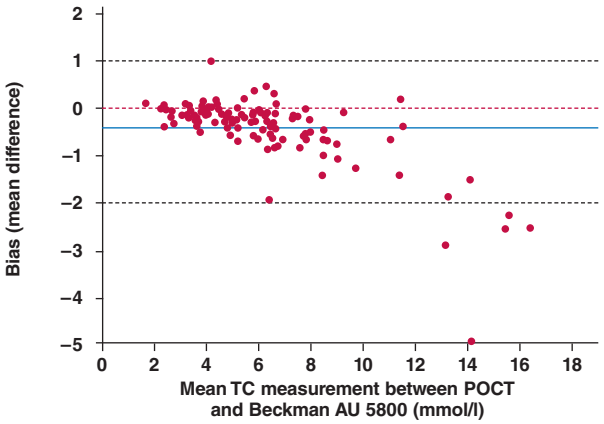


**Fig. 5.** Bland–Altman plot showing the degree of bias and level of agreement for TC between the Fujifilm™ NX700 POCT and the Beckman AU 5800. The solid blue line represents the observed average agreement between the two tests with the black dashed lines representing 95% limits of agreement. The red dashed line ($y = 0$) is the perfect line of average agreement between the two tests.

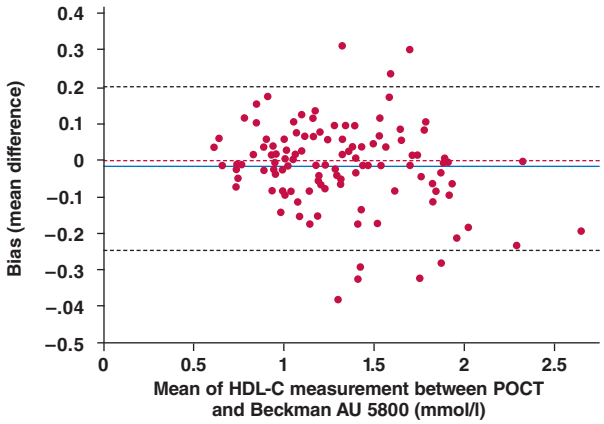


**Fig. 7.** Bland–Altman plot showing the degree of bias and level of agreement for HDL-C between the Fujifilm™ NX700 POCT and the Beckman AU 5800. The solid blue line represents the observed average agreement between the two tests with the black dashed lines representing 95% limits of agreement. The red dashed line ($y = 0$) is the perfect line of average agreement between the two tests.

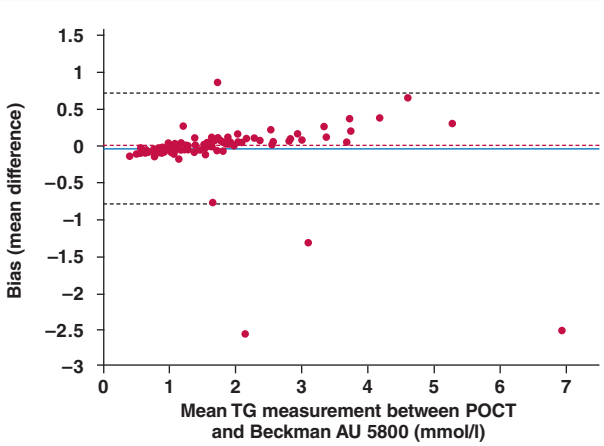


**Fig. 6.** Bland–Altman plot showing the degree of bias and level of agreement for TG between the Fujifilm™ NX700 POCT and the Beckman AU 5800. The solid blue line represents the observed average agreement between the two tests with the black dashed lines representing 95% limits of agreement. The red dashed line ($y = 0$) is the perfect line of average agreement between the two tests.

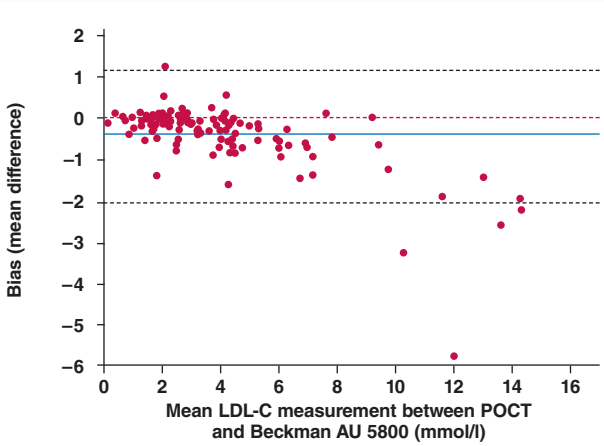


**Fig. 8.** Bland–Altman plot showing the degree of bias and level of agreement for LDL-C between the Fujifilm™ NX700 POCT and the Beckman AU 5800. The solid blue line represents the observed average agreement between the two tests with the black dashed lines representing 95% limits of agreement. The red dashed line ($y = 0$) is the perfect line of average agreement between the two tests.

risk assessment, especially if the TC on the finger-prick POC device is > 5 mmol/l or < 3.0 mmol/l.[9] However, for follow-up visits, POCT can be used. In addition, fasting is no longer required for lipid measurements so they can be done at the time of consultation.[10]

The major limitation of POCT relates to analytical errors with a POC finger-prick test.[9] These instruments are often operated by staff not trained in laboratory medicine and hence are prone to errors in the analytical phase, as opposed to CL testing where the analytical phase has the least errors. It is therefore recommended that only suitably approved devices be used for screening and monitoring and that POC devices be regularly calibrated.[9] This highlights the need for adequate quality-control measures to be implemented, together with more real-world data correlating POCT with the gold-standard CL measurements.

Results from this study showed no significant difference in the mean value of any of the lipid parameters measured by the Fujifilm™ NX700 POCT when compared to the Beckman AU 5800, irrespective of whether the lipid levels were within the extremes of the reference range. In addition, the Fujifilm™

NX700 POCT was able to correctly classify more than 91% of lipid results as per the NCEP-ATPIII diagnostic criteria for dyslipidaemia. TC and LDL-C levels were correctly classified as normal or abnormal in 91 and 96% of results, respectively. Overall, the measurement of lipids between the two platforms showed a substantial correlation, with good agreement between the Fujifilm™ NX700 POCT and Beckman 5800.

CVD is a major cause of premature mortality, with ischaemic heart disease and stroke being accountable for more than one-fifth of all deaths globally.[1] ASCVD is not limited to developed countries, but rather 80% of CV-related deaths occur in low- and middle-income countries (LMICs).[1] With a rapidly ageing global population and rising healthcare costs, there is an urgent need for preventative strategies to reduce the burden of CVD. Strategies to reduce CV mortality include targeting obesity, encouraging smoking cessation and implementing wider screening measures for high blood pressure and cholesterol.[1]

Measurement of lipids is an important tool in the prevention and treatment of ASCVD. In the absence of risk factors for CVD, the South African dyslipidaemia guidelines recommend screening for dyslipidaemia with a full lipogram or at least TC or LDL-C assessment, in all individuals over the age of 40 years.[9] Earlier screening during infancy, before puberty or at around 20 years is indicated for individuals with confirmed genetics associated with hypercholesterolaemia or a family history of CVD and other cardiac risk factors.[9]

The US Preventive Services Task Force has recently updated recommendations regarding the use of statin therapy for primary prevention (such as those without ASCVD at baseline) in adults. This was based on evidence that the use of statin therapy for primary prevention was associated with reductions in all-cause mortality and major CV events.[11-13] The recommendations include the initiation of statins for primary prevention in adults aged 40 to 75 years with at least one CV risk factor and a calculated 10-year CVD event risk of 10% or greater (moderate net benefit); selective statin initiation in those with a 10-year risk of a CV event of 7.5% to less than 10% (small net benefit); and there is insufficient evidence to assess outcomes of statins in adults 76 years or older.[11,12,14]

The availability of generic statin therapy has significantly lowered its cost, allowing the opportunity for wider implementation of statins to reduce ASCVD. Despite the evidence of reducing ASCVD by targeting LDL-C levels, lipograms are infrequently measured and elevated LDL-C levels are not treated in patients with at-risk-for or with established ASCVD.[4]

Statins are under prescribed in LMICs, whereby statins are used by only one in 10 eligible people for primary prevention of CVD and one in five eligible people for secondary prevention.[11] This highlights the urgent need to expand screening programmes with the use of reliable POCT machines, paired with policy changes to implement the appropriate use of statins for primary and secondary prevention in a PHC setting.

A limitation of this study is that the study population was a targeted population of participants with genetically confirmed familial hypercholesterolaemia, who therefore had higher cholesterol levels compared to the general population. However, since the Fujifilm™ NX700 POCT performed well with the analysis of lipid parameters, compared to the Beckman AU 5800, irrespective of the extreme reference ranges, similar results would be expected in the general population. A further limitation is that the POC laboratory analysis was conducted by skilled personnel, hence it may not be a true reflection of a PHC setting. This provides an opportunity to expand public health research with a focus on CV screening in urban and rural PHC facilities.

To reduce the rates of ASCVD, a shift to practicing preventative medicine is critical, whereby global screening and cost-effective therapeutic intervention is enforced. In primary care, POCT has been shown to be 'non-inferior' to the CL for several analytes, with a high degree of consumer satisfaction, although it has not necessarily been proven to be cost effective.[8] Cost of POCT testing therefore needs to be taken into consideration before policy makers can adopt the POCT.[8] Unfortunately, there is also a scarcity of randomised, controlled trials comparing POCT to the CL with evaluation of important clinical outcomes.

The reproducibility of the Fujifilm™ NX700 POCT to the gold-standard Beckman AU 5800 measured in a CL supports the potential role of decentralised POC testing at urban healthcare screening facilities, private healthcare practices, and underprivileged remote rural and urban communities that lack access to specialised care, including PHC centres. This will allow most patients who lack access to a CL, an opportunity for appropriate CV risk assessment, screening and monitoring, ultimately reducing the incidence of underdiagnosed CVD and enabling early initiation of appropriate therapy. Of importance, an emphasis should be placed on addressing clinician inertia by implementing a change in clinical practice and encouraging compliance with evidence-based guidelines, because POCT alone cannot improve CV outcomes.

## Conclusion

In a sample population of individuals with lipid disorders (primarily familial hypercholesterolaemia), the Fujifilm™ NX700 POCT compared favourably with the gold-standard measurement of serum lipid levels, performed by Medpace laboratories in Leuven, Belgium. POCT is a quick and easy means of measuring serum lipids at the patient encounter. This allows for rapid diagnosis, CVD risk stratification, assessment of therapeutic efficacy as well as counselling around lifestyle modification.

No Fujifilm employees or representatives were involved in the preparation of this manuscript. The Fujifilm™ NX700 point-of-care analyser together with consumables were provided by the distributors, Patient Focus Africa.

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