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Verification of the qLabs international normalized ratio point-of-care device for monitoring of patients attending an anticoagulation clinic

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Abstract

Introduction: In the developing world, point-of-care (POC) testing for international normalized ratio (INR) plays an important role in the monitoring of patients on long-term warfarin therapy with limited access to healthcare ensuring safe and effective anticoagulation. A newly developed POC device for INR measurement by healthcare workers is the handheld qLabs POC device® (Micropoint Biotechnologies Incorporated, Guangdong, China).

Methods: The qLabs POC device® was evaluated in 262 patients attending an anticoagulation clinic with regards to accuracy and precision of the INR results. The results were compared to the results obtained on the Stago STA R Max® coagulation analyzer (Stago Diagnostica, Paris, France) on a wide range of normal and abnormal results of clinical relevance.

Results: The mean laboratory INR (2.50 ± 1.08) was significantly higher than the qLabs POC device® INR (2.38 ± 1.07) ($P < .0001$). The correlation coefficient (r) was .88, the slope coefficient was 1.0 (CI, 0.8-1.2), and the intercept was −0.10 (CI, −0.50 to 0.30). The mean of the differences was −0.13% (CI, −0.19 to −0.06). Dosage concordance was 85.46% and clinical agreement was 92.37%. However, clinical agreement was 42.42% in the subgroup above the target range (>3.5). The imprecision was within acceptable limits (<5%) and the error message rate was 4.38%.

Conclusion: In conclusion, the qLabs POC device® is accurate and precise with high levels of dosage concordance and clinical agreement for INR values within and below the target range.

KEYWORDS
international normalized ratio, point-of-care testing, qLabs POC device®, warfarin

1 | INTRODUCTION

Laboratories are frequently involved in implementing point-of-care (POC) testing outside of the laboratory setting.[1] POC testing was initially developed to provide rapid laboratory test results to assist with urgent patient management.[2-4] Nowadays, POC testing is well established in specific niche areas, such as international normalized ratio (INR) monitoring of patients on long-term warfarin therapy.[5] POC testing has also been extended to remote areas in developing countries and home-based care in developed countries.[6-9] In South Africa, a developing country, POC testing is recommended at district hospitals and areas with limited access to healthcare and central laboratories. POC testing has been extended to these areas mainly for infectious disease diagnosis and monitoring. These areas, however, would also benefit from POC INR monitoring. In other parts of the developing world in Asia, POC testing for INR monitoring has played

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an important role in ensuring patients with prosthetic valves on lifelong anticoagulation can be safely monitored.[10]

Measurement of the INR is essential to monitor patients on long-term warfarin anticoagulation.[11] Warfarin has a narrow therapeutic range. It has several interactions with food and drugs.[12] Thus, monitoring patients on warfarin therapy at least every 4 weeks to ensure the INR is within the therapeutic range is indicated. In South Africa, warfarin therapy is managed predominantly by specialized anticoagulation clinics as well as general practitioners, computer-assessed dosage and patient self-testing. INR results for patients attending specialized anticoagulation clinics are usually not available for at least 2 hours. This results in delays in communicating results which may be critical. Further, patients in remote areas are required to travel lengthy distances for INR testing. Owing to financial constraints, this is often not feasible. The result is poor compliance with warfarin and an associated increased risk of bleeding or thromboembolic complications.[13] POC testing for INR monitoring provides results within <5 minutes and thus represents a solution to the limitations of conventional laboratory testing. These POC devices measure the INR using 10-30 μL of capillary or venous blood. This is applied to a test strip which is inserted into the device. The coagulation cascade is initiated by thromboplastin and clot is detected by optical or electrochemical detection.

Clinical experience in South Africa with the CoaguChek XS and the microINR® POC devices has been published.[14,15] These new models offer several advantages over earlier POC devices including: use of human recombinant thromboplastin with a lower International Sensitivity Index (ISI) of 1.0; on-board internal quality control (IQC) which is performed with each test; room temperature storage temperature for test strips, smaller quantity of blood sample required and a smaller device. More importantly, these newer devices have shown enhanced precision and accuracy.[16] However, patients with supra-therapeutic INRs have not been sufficiently represented in verification studies of these devices.[17]

A newly developed POC device for INR measurement is the handheld qLabs POC device® (Micropoint Biotechnologies Incorporated, Guangdong, China). This device has been developed specifically for healthcare workers. In addition to prothrombin time (PT) testing with results provided in INR units, this new POC device also provides activated partial thromboplastin time (aPTT) results. The qLabs POC device® complies with regulatory guidelines.[18,19] In addition, the device offers reagents and controls which are affordable as well as bidirectional connectivity. Verification of the qLabs POC device® with regards to accuracy and precision has not been published to date.

A study was performed to evaluate the clinical and diagnostic utility of the qLabs POC device® for monitoring patients on warfarin therapy attending an anticoagulation clinic.

2 | MATERIALS AND METHODS

2.1 | Study design

This verification was performed at the Main Haematology Laboratory of the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) National Health Laboratory Service Complex over a 3-week period. The aim was to verify the manufacturer's performance claims and to satisfy regulatory requirements. This validation was performed in accordance with the International Standard ISO 17593:2007[20] and the method comparison from the Clinical and Laboratory Standards Institute (CLSI EP09-A2, EP05, EP15, EP21, USA).[21]

2.2 | Study population

Consecutive adult patients over the age of 18 years were eligible for this study. Patients receiving long-term warfarin, for at least 3 months who attend the Anticoagulation Clinic were selected. Information sheets were provided and informed consent was obtained from those who agreed to participate in the study. Samples with adequate volume (>4 mL) received within 2 hours were included. Clinical information namely, patient demographics (gender and age) and diagnoses were obtained from the clinic records.

2.3 | Study protocol

2.3.1 | Blood sampling

The samples used for the evaluation included commercial controls and specimens referred from CMJAH anticoagulation clinic for routine INR testing. The samples selected represented a wide range of normal and abnormal results of clinical relevance. Venous and capillary blood samples were obtained by trained phlebotomists for INR measurement. Capillary blood samples were obtained by fingerstick testing for measurement on the qLabs POC device® followed by venous samples by venepunctures in citrate tubes (Becton-Dickinson, Oxford, UK) for measurement on one of the laboratory's Stago STA R Max® coagulation analyzers (Stago Diagnostica, Paris, France). Capillary samples were analyzed by the researcher on the qLabs POC device®, according to the instrument's standard operating procedures. Results which indicated analysis failure were excluded from the final analysis. Causes of analysis failure were collected and investigated. Citrate samples were stored at room temperature and analyzed on the Stago coagulation analyzer by a dedicated technologist within 2 hours of collection.

2.3.2 | Laboratory methods

The qLabs POC device® was installed and calibrated by the manufacturer. Laboratory staff members and the researcher were trained on the instrument operation, quality control, safety, instrument maintenance, interpretation of test results, and troubleshooting error messages. Training and competency assessments with ongoing supervision of all staff performing the tests were performed by the manufacturer. Maintenance procedures were performed daily as per the manufacturer's recommendations. In brief, the test strip which contains a testing line and a control line was inserted into the device. The device automatically detected the insertion of the test strip and heated the strip to a preset operating temperature. One drop of blood was placed at the entry port of the test strip. The blood sample flowed through

the channels to the reaction zones. The reaction zone is coated with a specific concentration of thromboplastin (ISI of 0.99). The current across the electrometer detected the change in the current and signal generation occurred which determined the PT (and aPTT). The PT is then converted to an INR according to the test strip ISI. The results obtained on the qLabs POC device® were documented.

The verified Stago coagulation analyzer currently in use in the laboratory was used as the reference. The performance of the analyzer is >90% with the Royal College of Pathologists of Australasia Quality Assurance Program (RCPAQAP, Sydney, Australia). The PT was measured by mechanical detection using Neoplastin R (Roche Diagnostics and Diagnostica Stago, Paris, France). This assay is based on clotting of citrated plasma in the presence of calcium thromboplastin compared with a normal standard. The PT ratio is converted to an INR by the analyzer according to the reagent lot specific ISI.

2.3.3 | Quality control

Daily quality control was performed on the qLabs POC device® and Stago analyzer. With the qLabs POC device®, each test strip has its own "on-board" quality control. In addition, IQC with normal and abnormal qLabs PT-INR liquid control material was performed once a day before any patient analysis was performed. In brief, 1 drop of the liquid control was applied to the inserted test strip. The QC test result appeared as an INR after 1 minute. IQC was also performed with every new lot of strips to assess for changes during storage. Abnormal IQC was appropriately documented and investigated. IQC on the Stago analyzer was performed in accordance with laboratory's standard operating procedure.

2.4 | Comparison study

For the method comparison study, 274 samples were analyzed in parallel over a 3-week period. The qLabs POC device's® reference interval (0.5-10) was established from the samples analyzed. For the purpose of this study, INR > 6 were included as this group has not been adequately represented in other studies.[20] The INR results obtained were divided into the following categories for subanalysis: therapeutic INR (INR 2-3.5), subtherapeutic INR (INR < 2), and supra-therapeutic (INR > 3.5). Performance was deemed satisfactory if the differences between the qLabs POC device® and the reference analyzer were ±0.5 INR units in the range of <2 or ±30% the range of ≥2.[22] Dosage concordance was assessed by measuring discrepant INR measurements which resulted in different warfarin dosages. This was performed in accordance with the South African guidelines.[23] Dosage adjustments were made by dedicated nursing sisters employed at the CMJAH anticoagulation clinic according to the reference laboratory method.

2.5 | Precision

Between-run precision was performed with normal and abnormal controls (lot: 305010609) which were analyzed once a day for 10 days. Within-run precision was performed 20 times with normal and abnormal controls. The reference interval of the control material was INR of 2.1-3.1 for the normal therapeutic interval and an INR of 0.8-1.4 for the abnormal low therapeutic interval. The coefficient of variation (CV) was compared to the manufacturer's and published precision limits of <5%.[17] Precision analysis on capillary blood was not possible as ethics for duplicate testing was not obtained. Venous whole blood collected in citrate is unsuitable for testing on POC devices, as the calcium cannot be replaced to reverse the anticoagulant effect of citrate.

2.6 | Statistical analysis

Data from data collection sheets were captured on an excel spreadsheet (Microsoft Office 2010, Redmond). The INR test data were expressed as means with their respective standard deviations (SD) and compared using the parametric *t* test. The Bland-Altman difference plot was used to assess the absolute differences and the means between the INR values from the qLabs POC device® and laboratory tests. The correlation between the INR values from the qLabs POC device® and the laboratory tests was determined from a Deming regression analysis. Statistical significance was assumed to be $P < .05$.

2.7 | Ethics

This study has been approved by the Human Research Ethics Committee of the University of the Witwatersrand (M-170743).

3 | RESULTS

3.1 | Study population

During the 3-week study period, 274 adult patients were enrolled. In 12 (4.38%) samples, the qLabs POC device® produced an error reading with no result. These patients were excluded from the final analysis (Table 1). The mean age of the study population was 53 (±15) years with a male:female ratio of 1:2.3. The most common indications for anticoagulation were venous thromboembolism in 150 (57.25%) patients, atrial fibrillation in 54 (20.61%) patients, and valvular heart disease in 48 (18.32%) patients.

3.2 | Comparison study

The mean laboratory INR of 2.5 ± 1.08 was significantly higher than the qLabs POC device® INR of 2.38 ± 1.07 ($P < .0001$). The regression

TABLE 1 Error readings on the qLabs POC device® for INR measurement

Error reading	N (%)
Prothrombin time calculation error	3 (1.14)
Insufficient blood added to the sample well	7 (2.67)
Defective strip or improperly operated when adding sample	2 (0.76)

INR, international normalized ratio; POC, point of care.

analysis with 95% confidence intervals is shown in Figure 1. The correlation coefficient (*r*) was .88, the slope coefficient was 1.0 with a 95% confidence interval of 0.8-1.2 and the intercept was −0.10 with a 95% confidence interval of −0.50 to 0.30 ($P < .0001$). The difference between the 2 INR tests against their means is illustrated in the Bland-Altman difference plot in Figure 2 The mean of the differences was −0.13% with a 95% confidence interval of −0.19 to −0.06. Subanalysis was performed on samples in the subtherapeutic, therapeutic, and supratherapeutic ranges (Table 2). The mean laboratory INR in the therapeutic range was 2.58 (±0.39) which was higher than the qLabs POC device® INR value of 2.46 (±0.58) ($P < .004$). The correlations between the 2 methods showed $r = .60$, *y*-intercept = −2.51 and slope = 1.93. The *y*-intercept of −2.51 (CI, −3.88 to 1.15) indicates a significant difference of a constant nature between the methods ($P < .004$). The mean difference was −0.12 (CI, −1.04 to 0.81). The mean laboratory INR in the subtherapeutic range was 1.59 (±0.29) which was higher than the qLabs POC device® INR value of 1.53 (±0.42) ($P < .049$). The correlations between the 2 methods showed good agreement and the bias was small. The mean laboratory INR in the supratherapeutic range was 4.63 (±1.29) which was higher than the qLabs POC device® INR value of 4.25 (±1.33) ($P < .036$). The correlations between the 2 methods showed good agreement (Figure 3). The mean difference was −0.38 (CI, −0.72 to 0.03) with an increase in the differences between the 2 test results at INR values above the target range (>3.5) (Figure 4).

Within the target range (2.0-3.5), 128 (91.43%) of the qLabs, POC device® INR readings were within ±30% of the laboratory method result. Below the target range (<2), 83 (93.26%) of the qLabs, POC device® INR readings were within ±0.5 units of the laboratory method result. Above the target range (>3.5), 14 (42.42%) of the qLabs POC device® INR readings were within ±30% of the laboratory method result. On further subgroup analysis, 3 (25%) of the 12 INR readings of >4.5 on the qLabs POC device® INR readings were within ±30% of the laboratory method result.

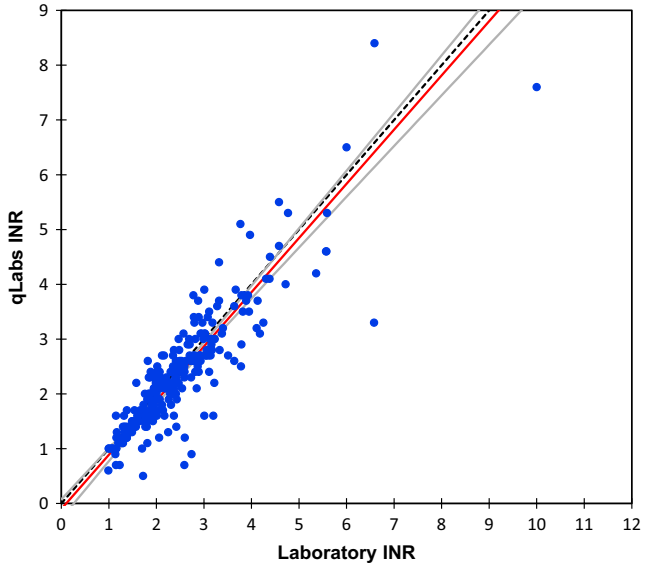


FIGURE 1 Correlation of the laboratory INR and the qLabs POC device® INR for all ranges. INR, international normalized ratio; POC, point of care [Colour figure can be viewed at wileyonlinelibrary.com]

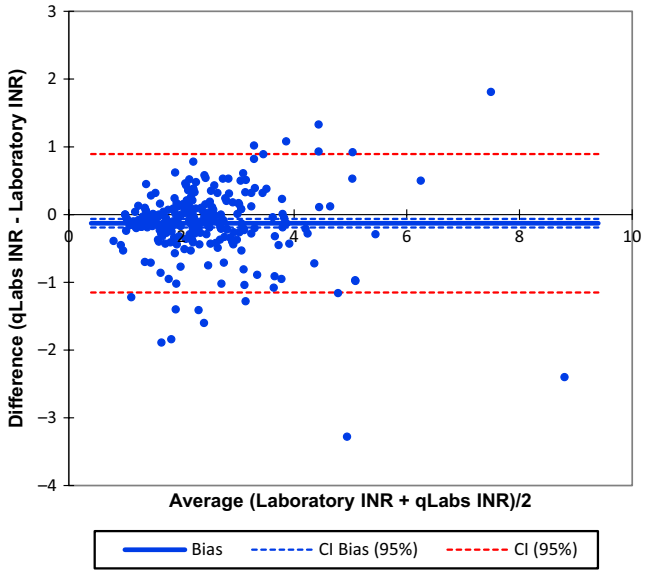


FIGURE 2 Bland-Altman difference plot comparing the laboratory INR and the qLabs POC device® INR for all ranges. INR, international normalized ratio; POC, point of care [Colour figure can be viewed at wileyonlinelibrary.com]

Dosage concordance was assessed by measuring discrepant INR measurements which resulted in different warfarin dosages. In 38 (14.50%) of the samples, the qLabs POC device®, a discrepant INR measurement with the laboratory method which would have resulted in an incorrect warfarin dose adjustment. Of these, 15 (5.73%) were in the range of <2, 14 (3.82%) were in the range of 2-3.5 and 9 (3.44%) were in the range of >3.5.

3.3 | Precision

The qLabs POC device® showed good precision for the measurement of normal and abnormal and controls (Table 3). There was no significant difference when compared to the manufacturer's and published precision limits of <5%.

4 | DISCUSSION

International normalized ratio POC devices are widely used by anticoagulation services in order to monitor patients on long-term warfarin therapy. In developing countries, POC testing plays an important role in ensuring patients with limited access to healthcare can be safely monitored.

The new qLabs POC device® for INR measurement offers distinct advantages including; a wide reportable range of 0.5-10, testing strips stable at room temperature for up to 18 months, smaller sample volume of 7 μL, result received within <1 minute, operates at 10°-35°C, small size of 140 g, built in communication port for a

TABLE 2 Comparison between the reference method and the validation method for INR measurements according to the target range

Lab parameter	N	Correlation coefficient (*r*)	Intercept	Slope	Bias (%) (95% limit of agreement)
Subtherapeutic range (INR < 2)	89	.73	1.03 (−1.64 to −0.42)	1.61 (1.24 to 1.98)	−0.06 (−0.12 to 0.00)
Therapeutic range (INR 2-3.5)	140	.60	−2.51 (−3.88 to −1.15)	1.93 (1.41 to 2.45)	−0.12 (−1.04 to 0.81)
Supratherapeutic range (INR > 3.5)	33	.72	−0.57 (−6.16 to 5.02)	1.04 (−0.25 to 2.33)	−0.38 (−0.72 to 0.03)

INR, international normalized ratio.

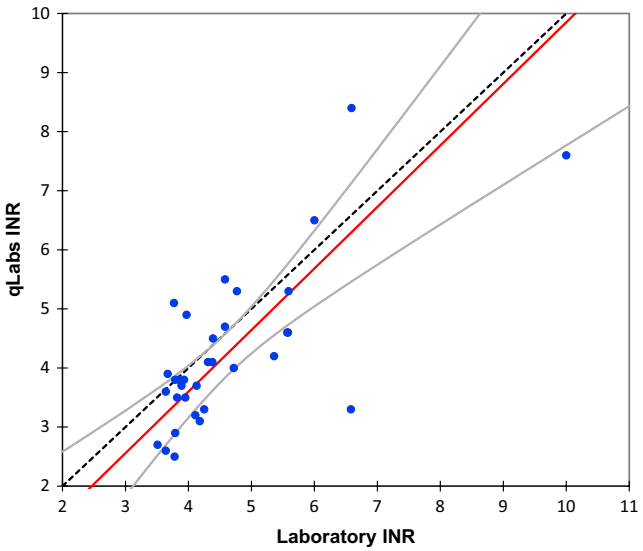


FIGURE 3 Correlation of the laboratory INR and the qLabs POC device® INR in the supratherapeutic range of >3.5. INR, international normalized ratio; POC, point of care [Colour figure can be viewed at wileyonlinelibrary.com]

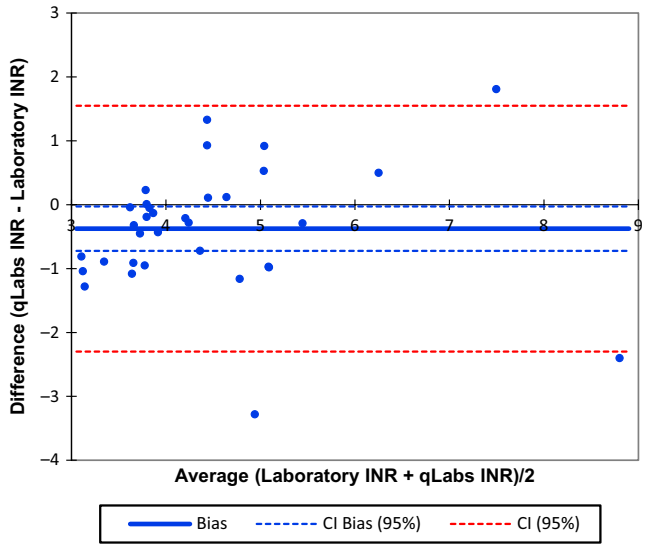


FIGURE 4 Bland-Altman difference plot comparing the laboratory INR and the qLabs POC device® INR in the supratherapeutic range of >3.5. INR, international normalized ratio; POC, point of care [Colour figure can be viewed at wileyonlinelibrary.com]

printer and connectivity software as well as a low recommended ISI. The qLabs POC device® was selected for verification with regards to accuracy and precision.

The qLabs POC device® was found to be reliable and robust with an error message rate of <5%. This compares favorably with the safety and reliability of other available POC devices, such as the SmartCheck INR®, the CoaguChek XS Plus®, and the micro-INR®.[15,24,25] In this study, the most frequent error observed was the operator-dependant message of "insufficient blood added to the sample well" (n = 7, 2.67%). This highlights the importance of initial training. In South Africa, POC testing is utilized in peripheral clinics in remote areas with limited access to laboratory testing. These, however, are also the most challenging areas in which to facilitate ongoing training.

Since the introduction of POC devices for INR monitoring, several devices have been validated. The imprecision of these devices varies but in general has shown % CVs of <5%.[17] Similarly, the qLabs POC device® showed good imprecision of <5% with qLabs PT-INR liquid control material. Studies have demonstrated discrepant CV's between capillary blood and liquid control material for assessment of imprecision.[15,25] However, in this study, imprecision was not performed with duplicate capillary blood specimens.

The analytical range in this study was 0.5-8.4 INR units in patients receiving warfarin for venous thrombo-embolism (57.25%),

TABLE 3 Precision analysis on the qLabs POC device®

Between-run precision analysis				
	Normal control		Abnormal control	
Parameter (n = 10)	SD	CV (%)	SD	CV (%)
INR	0.05	4.29	0.04	1.40
Within-run precision analysis				
	Normal control		Abnormal control	
Parameter (n = 20)	SD	CV (%)	SD	CV (%)
INR	0.04	3.38	0.06	1.97

CV, coefficient of variation; INR, international normalized ratio; POC, point of care; SD, standard deviation.

atrial fibrillation (20.61%), and valvular heart disease (18.32%). The qLabs POC device® INR showed good correlation with the laboratory reference INR (r = .88). Statistically significant differences were observed. However, the bias was small (−0.13%, CI, −0.19 to −0.06) and within the ISO acceptable criteria. A systemic bias has been reported for most POC devices. Locally, a positive bias (4.4%, CI, −0.66 to 0.88) has been demonstrated on the microINR® and a negative bias (0.09%, CI, −0.61 to 0.79) on the CoaguChek XS device.[14,15] Specifically, studies have reported an overestimation of INR measurements above 4.5 and underestimation of INR's within or below the therapeutic range.[7,8,14,17,26-28] In contrast, the qLabs POC device® underestimated the INR in the subtherapeutic (<2), therapeutic (2-3.5), and supratherapeutic (>3.5) ranges. While, causes for the variability cannot always be identified, excessive squeezing of the finger is associated with falsely lower results due to increased release of tissue factor.[29]

In this study, high levels of dosage concordance were observed (85.46%). This concurs with the results of Lawrie et al and Joubert et al on the CoaguChek XS Plus and the microINR®, respectively.[15,30] Although, the mean laboratory INR was significantly higher than the qLabs POC device® INR (P < .0001); the clinical agreement was >90% for INR values within ±0.5 units or ±30% for INR ranges below and within the INR target range, respectively. However, INR values above the target range (>3.5) showed poor clinical agreement. Concern over the accuracy of supratherapeutic INR values, in particular >4.5, has been raised previously. Benade et al, and Ryan et al, reported a low concordance of 64.40% and 67.00%, respectively for INR values ≥3.6.[14,31] Similarly, although the sample size of this study is small (n = 33), INR readings >3.5 on the qLabs POC device® require confirmation with a laboratory method.

This is the first study to evaluate the utility of the qLabs POC device® for monitoring of patients attending an anticoagulation clinic. Studies of other POC devices have shown inconsistent results for accuracy.[17] It is, however, difficult to compare and contrast these studies. Firstly, these studies were performed with different generations of POC devices and newer devices show enhanced accuracy.[16] Secondly, the variability can be explained by the different thromboplastin reagents between the POC and laboratory measurements. Thirdly, these studies were performed by patients or laboratory staff or nonlaboratory staff. However, many of the evaluations have shown that POC testing performed by nonlaboratory staff provides comparable results to skilled laboratory operators.[7] Lastly, these studies differed with regards to the patient populations studied (ie, the range of INR values measured). However, few studies have included a significant proportion of results of >4.5.[8,25,32-34] Future studies evaluating the qLabs POC device® by nonlaboratory staff in various patient populations will be useful.

A limitation of this study is that samples with interfering substances were not evaluated. Samples with high plasma viscosity and hematocrits can lead to spurious results.[35] Further, the study was performed in a single center and the proportion of supratherapeutic samples was small (n = 33). Additional verifications of the qLabs POC device® by other centers are also required.

5 | CONCLUSION

This is the first study to evaluate the clinical and diagnostic utility of the qLabs POC device® for monitoring of patients on warfarin. The qLabs POC device® is accurate and precise with high levels of dosage concordance and clinical agreement for INR values within and below the target range. Implementation of POC testing will reduce preanalytical errors and improve patient accessibility to testing for the clinical management of warfarin. A referral system should be established with the reference laboratory for supratherapeutic results requiring further investigation and repeat analysis.

CONFLICT OF INTEREST

The author(s) declare no conflicts of interest with respect to the authorship and/or publication of this article.

AUTHOR CONTRIBUTION

N Mbokota (Dept of Molecular Medicine and Haematology, Charlotte Maxeke Johannesburg Academic Hospital) study design, manuscript author, data entry and analysis; E Schapkaitz (Dept of Molecular Medicine and Haematology, Charlotte Maxeke Johannesburg Academic Hospital) study design, data analysis and critical review and S Louw (Dept of Molecular Medicine and Haematology, Charlotte Maxeke Johannesburg Academic Hospital) study design and critical review.

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