

Diagnostic Performance and Method Agreement of the HB SPOT Digital Haemoglobin Meter for Point-of-Care Anaemia Detection: A Prospective Cross-Sectional Validation Study

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Abstract:

Background: Rapid and accurate haemoglobin measurement is important for timely identification of anaemia, particularly where laboratory facilities are limited. Portable point-of-care devices may offer a practical alternative to conventional laboratory testing.

Aim and Objective: To evaluate the diagnostic accuracy and agreement of the HB SPOT digital haemoglobin meter against a reference automated haematology analyser.

Materials and Methods: This prospective, cross-sectional diagnostic-accuracy study included 479 participants with complete paired haemoglobin measurements. Capillary haemoglobin was measured using the portable HB SPOT device, while the paired reference measurement was obtained using an automated haematology analyser. Diagnostic performance was assessed using sensitivity, specificity, predictive values, and overall accuracy. Agreement was evaluated using Pearson correlation and Bland–Altman analysis.

Results: The mean haemoglobin concentration was 12.49 ± 2.70 g/dL with HB SPOT and 12.45 ± 2.66 g/dL with the reference analyser. HB SPOT demonstrated a sensitivity of 96.00%, specificity of 96.42%, positive predictive value of 95.05%, negative predictive value of 97.11%, and overall accuracy of 96.24%. A strong correlation was observed between the two methods ($r = 0.989$; $p < 0.001$). The mean bias was $+0.04 \pm 0.40$ g/dL, with 95% limits of agreement ranging from -0.75 to $+0.84$ g/dL.

Conclusion: The HB SPOT device showed high diagnostic accuracy, minimal bias and close agreement with the reference analyser. Its rapid response, portability and low sample requirement support its potential use for point-of-care anaemia screening. Laboratory confirmation remains advisable for borderline or clinically inconsistent results.

Keywords: Anaemia; Diagnostic Accuracy; Digital Haemoglobin Meter; HB SPOT; Point-of-Care Testing; Bland–Altman Analysis; Haemoglobin Estimation.

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Introduction

Anaemia remains a major global health problem, affecting an estimated 1.92 billion people in 2021, with the greatest burden observed among young children, women, and populations in South Asia and sub-Saharan Africa. [1] Haemoglobin concentration is the principal laboratory parameter used to identify anaemia and assess its severity. The World Health Organization has recently updated the haemoglobin thresholds used to define anaemia in individuals and populations, highlighting the need for accurate and standardised measurement practices. [2]

Automated haematology analysers provide reliable

haemoglobin measurements and are commonly used as the laboratory reference method. However, their dependence on venous blood collection, trained personnel, electricity, laboratory infrastructure, and sample transportation limits their availability in primary care, community, emergency, and resource-constrained settings. [3] Portable point-of-care haemoglobinometers offer a practical alternative because they require only a small capillary blood sample and provide results within seconds. These devices may support rapid screening, early clinical decisions, and timely referral. [4]

Despite these advantages, the accuracy of point-of-care haemoglobin measurements may be influenced by the blood specimen, finger-prick technique, cuvette filling, device calibration, environmental conditions, and operator training. [3,5] A multicountry study reported greater variability with single-drop capillary samples than with venous blood, indicating the need to assess each device under its intended conditions of use. [3] Differences close to diagnostic thresholds may also lead to incorrect classification of anaemia. [5]

The HB SPOT digital haemoglobin meter is a portable spectrophotometric device designed for rapid capillary haemoglobin estimation. However, independent evidence concerning its diagnostic performance remains limited. Therefore, the present study aimed to evaluate the diagnostic accuracy and agreement of the HB SPOT device against a standard automated haematology analyser.

Materials and Methods

Study Design and Setting: This community-based, prospective, cross-sectional diagnostic-accuracy study was conducted in selected urban and rural communities within the field-practice area between April 2026 to July 2026. Community screening sessions were organised at primary health centres, health subcentres, Anganwadi centres, community halls, and other suitable locations. The study evaluated the diagnostic accuracy and agreement of the HB SPOT digital haemoglobin meter against a reference automated haematology analyser.

HB SPOT testing was performed at the community screening sites, while paired venous blood samples were transported to the central laboratory of [institute name] for reference haemoglobin measurement. The study was reported following the Standards for Reporting Diagnostic Accuracy Studies recommendations.

Study Population: The study included adults aged 18 years or older who were permanent residents of the selected communities. Residents were considered eligible irrespective of symptoms, previous anaemia diagnosis, or reason for attending the screening session. Both apparently healthy residents and individuals with suspected or previously diagnosed anaemia were screened to ensure that the device was evaluated across a broad range of haemoglobin concentrations.

Sampling Method: A multistage community-sampling method was used. In the first stage, 12 urban wards and 6 rural villages within the field-practice area were selected. In the second stage, households within each selected community were approached systematically with assistance from accredited social health activists, auxiliary nurse midwives, and other local healthcare workers.

Eligible adults from the selected households were informed about the study and invited to attend a nearby community screening session. Participants attending the selected screening sessions were enrolled consecutively until the required sample size was reached. A screening register was maintained to record the number of residents approached, eligible individuals, exclusions, refusals, and participants enrolled.

Sample Size Calculation: The sample size was calculated using the formula for a diagnostic-accuracy study:

$$n = \frac{z^2_{1-\alpha/2} \times \text{Se}(1 - \text{Se})}{d^2 \times P}$$

where Se represented the anticipated sensitivity, P represented the expected prevalence of anaemia, d represented the desired absolute precision, and $z_{1-\alpha/2}$ was 1.96 at a 95% confidence level.

Based on an anticipated sensitivity and specificity of 94%, an expected community prevalence of anaemia of 40%, and an absolute precision of 4%, the minimum calculated sample size was approximately 339 participants. After allowing for non-response, incomplete samples, field-testing errors, and clustering across community sites, the sample size was increased to 500 participants (planned enrolment). Of these, 479 participants had complete and valid paired HB SPOT and reference-analyser measurements and were included in the final analysis.

Inclusion Criteria

Participants were included if they:

- Were 18 years of age or older.
- Had resided in the selected community for at least six months.
- Were willing to undergo both capillary and venous blood sampling.
- Provided written informed consent.
- Agreed to referral or further evaluation if clinically significant anaemia was detected.

Exclusion Criteria

Participants were excluded if they:

- Had active bleeding at the time of screening.
- Had received a blood transfusion during the previous three months.
- Had a known haemoglobinopathy, including sickle cell disease or thalassaemia.
- Had severe dehydration, shock, haemodynamic instability, or poor peripheral perfusion.
- Had an infection, injury, or deformity of the finger that prevented safe capillary sampling.
- Were critically ill and required immediate medical care.
- Provided an inadequate, clotted, haemolysed, or

incorrectly labelled blood sample.

- Had an instrument error or technically invalid measurement that could not be resolved by repeat testing.

Community Mobilisation and Participant Enrolment:

Before recruitment, meetings were held with local health authorities, community representatives, accredited social health activists, auxiliary nurse midwives, and other community healthcare workers. Residents were informed about the purpose of the study, the screening locations, the blood-sampling procedures, and the availability of their test results.

At the screening site, each participant received a detailed explanation of the study in their preferred language. Written informed consent was obtained before any study-related procedure was performed. Demographic and clinical information, including age, sex, area of residence, previous history of anaemia, recent iron therapy, smoking history, pregnancy status where applicable, and relevant comorbidities, was recorded using a standardised case-record form.

Index Test: HB SPOT Digital Haemoglobin Meter

The index test was the HB SPOT digital haemoglobin meter manufactured by Proactive Health Inc. The HB SPOT was a portable, battery-operated spectrophotometric device designed to estimate haemoglobin concentration using a small quantity of whole blood.

Participants were seated comfortably for at least five minutes before sampling. The selected fingertip was cleaned with an alcohol swab and allowed to dry completely. A capillary blood sample was obtained using a sterile, single-use lancet. A free-flowing drop of blood was collected without excessive squeezing or milking of the finger.

The blood drop was introduced into a disposable cuvette, ensuring that the cuvette was filled completely and was free from air bubbles. The cuvette was inserted immediately into the HB SPOT device. The haemoglobin value displayed within approximately 10 seconds was recorded in g/dL on the case-record form.

All HB SPOT measurements were performed by trained field investigators according to the manufacturer's instructions. The device was used in a clean, shaded area protected from direct sunlight, dust, heat, and moisture. Ambient temperature and humidity were documented during each screening session.

The device was calibrated daily according to the manufacturer's instructions. A quality-control check was performed weekly using standard control solutions. Additional quality-control testing was undertaken whenever a new cuvette lot was opened,

the device was transported to a different field site, or an unexpected result was obtained. Participant testing was withheld whenever a quality-control result was outside the acceptable range and was resumed only after the problem had been resolved.

Venous Blood Collection and Transportation:

Immediately after HB SPOT testing, approximately 2 mL of venous blood was collected under aseptic precautions into a labelled ethylenediaminetetraacetic acid tube. The tube was gently inverted several times to ensure adequate mixing and prevent clot formation.

Each tube was labelled using the participant's unique study identification number. The time of blood collection, dispatch from the screening site, receipt at the laboratory, and laboratory analysis was recorded. Samples were transported in a validated temperature-controlled carrier to the laboratory. Haemoglobin estimation was completed within four hours of sample collection and within the stability period recommended by the analyser manufacturer.

Samples showing clotting, leakage, inadequate volume, incorrect labelling, or excessive transportation delay were rejected. The reason for rejection was recorded in the study log.

Reference Standard: Reference haemoglobin estimation was performed using a calibrated automated haematology analyser ([manufacturer, model and country]) based on the [measurement principle] method. The analyser was operated by trained laboratory personnel according to the manufacturer's instructions and the laboratory's standard operating procedures.

Internal quality-control testing was performed daily using low-, normal-, and high-level control materials. Reference testing was carried out only after the quality-control results were found to be within the predefined acceptable ranges. The laboratory personnel performing the reference measurement were unaware of the corresponding HB SPOT result until both measurements had been completed and recorded.

Paired Testing Procedure: The index and reference measurements were obtained during the same community screening encounter, with the shortest feasible interval between capillary and venous sampling. Each participant was assigned a unique identification number, which was used to match the HB SPOT and reference-analyser measurements.

For the primary diagnostic-accuracy analysis, a predefined haemoglobin threshold of less than 12.0 g/dL was used. The same threshold was applied independently to both the HB SPOT and reference measurements. This fixed threshold was used to assess the classification performance of the device

without introducing different cut-offs between the index and reference tests.

For clinical interpretation, population-appropriate World Health Organization cut-offs were applied according to sex, age, pregnancy status, smoking exposure, and altitude where applicable. Results close to the relevant diagnostic threshold were interpreted cautiously.

Outcome Measures: The primary outcomes were the sensitivity and specificity of the HB SPOT device for detecting haemoglobin values below the predefined threshold compared with the reference analyser.

Secondary outcomes included:

- Positive predictive value.
- Negative predictive value.
- Overall diagnostic accuracy.
- False-positive and false-negative rates.
- Mean measurement bias.
- Mean absolute error and root mean square error.
- Lower and upper 95% limits of agreement.
- Pearson correlation and linear regression.
- Lin's concordance correlation coefficient.

The predefined performance requirements were sensitivity above 94%, specificity above 94%, absolute mean bias within ± 0.5 g/dL, and Bland–Altman limits of agreement within ± 0.9 g/dL.

Participant Safety and Referral: Participants were informed of their confirmed reference-analyser results. Individuals diagnosed with anaemia were counselled and referred to the nearest appropriate healthcare facility for further investigation and treatment.

Participants with critically low haemoglobin values, active bleeding, syncope, chest pain, breathlessness, haemodynamic instability, or other features of severe anaemia were referred immediately for medical assessment. The field team documented all referrals and urgent clinical actions.

Data Collection and Quality Assurance: Data were recorded using a standardised case-record form. The variables included participant age, sex, community site, relevant clinical history, operator identification, HB SPOT serial number, cuvette lot number, ambient conditions, calibration status, quality-control results, HB SPOT reading, reference-analyser reading, transportation time, repeat testing, invalid measurements, and protocol deviations.

Completed forms were reviewed by the field supervisor at the end of each screening session. Field and laboratory records were matched using the unique study identification number. Data were entered into a password-protected database and independently checked for completeness and

consistency.

Out-of-range or inconsistent values were verified against the source documents. Original measurements were not overwritten. Corrections were documented separately, and an audit trail was maintained. Only participants with valid paired measurements were included in the primary analysis.

Statistical Analysis: Data were analysed using IBM SPSS Statistics for Windows, version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables were presented as mean $\pm$ standard deviation or median with interquartile range, according to their distribution. Categorical variables were summarised as frequencies and percentages.

A 2 $\times$ 2 contingency table was prepared using the automated haematology analyser as the reference standard. Sensitivity, specificity, positive predictive value, negative predictive value, false-positive rate, false-negative rate, and overall diagnostic accuracy were calculated with 95% confidence intervals. Confidence intervals for diagnostic proportions were calculated using the Wilson method.

The distribution of paired differences was examined before analysis. Mean haemoglobin values obtained using the two methods were compared using the paired Student's t-test when the differences were normally distributed. The Wilcoxon signed-rank test was used when the normality assumption was not met.

Pearson's correlation coefficient and simple linear regression were used to assess the relationship between HB SPOT and reference-analyser measurements. Lin's concordance correlation coefficient was calculated to assess concordance between the two methods.

Agreement was evaluated using Bland–Altman analysis. The measurement difference was calculated as:

HB SPOT haemoglobin–Reference haemoglobin

The mean difference represented the measurement bias. The lower and upper 95% limits of agreement were calculated as the mean bias ± 1.96 standard deviations of the paired differences.

A two-sided p-value below 0.05 was considered statistically significant.

Results

A total of 479 paired haemoglobin measurements were included in the analysis. The mean age of participants was 46.05 ± 16.59 years, ranging from 18 to 75 years. There were 238 (49.7%) male and 241 (50.3%) female participants. All participants had valid HB SPOT and reference-analyser measurements.

Using a haemoglobin threshold of 12.0 g/dL, the reference analyser classified 200 participants (41.8%) as having anaemia and 279 (58.2%) as not having anaemia. The HB SPOT device correctly classified 461 of the 479 participants, giving an overall diagnostic accuracy of 96.24%.

Comparison of Haemoglobin Measurements: The

mean haemoglobin concentration was 12.45 ± 2.66 g/dL with the reference analyser and 12.49 ± 2.70 g/dL with the HB SPOT device. The mean paired difference was 0.04 ± 0.40 g/dL. Although the paired difference was statistically significant because of the large sample size ($p=0.018$), its magnitude was small and remained within the predefined acceptable bias of ± 0.5 g/dL.

Table 1: Comparison of haemoglobin measurements obtained using the HB SPOT device and reference analyser

Parameter	Reference analyser	HB SPOT device
Number of measurements	479	479
Mean haemoglobin, g/dL	12.45 ± 2.66	12.49 ± 2.70
Range, g/dL	7.61–16.50	7.18–17.24
Mean paired difference, g/dL	—	0.04 ± 0.40
Mean absolute error, g/dL	—	0.36
Root mean square error, g/dL	—	0.41

Diagnostic Accuracy: Among the 200 participants classified as having anaemia by the reference method, the HB SPOT device correctly identified 192, while eight were classified as false negatives.

Among the 279 participants without anaemia, 269 were correctly identified, and ten were classified as false positives.

Table 2: Diagnostic classification of anaemia using the HB SPOT device

HB SPOT classification	Anaemia by reference method	No anaemia by reference method	Total
Anaemia	192 (true positive)	10 (false positive)	202
No anaemia	8 (false negative)	269 (true negative)	277
Total	200	279	479

The HB SPOT device showed a sensitivity of 96.00% and specificity of 96.42%. The lower limits of the respective 95% confidence intervals were

92.31% and 93.53%. The positive predictive value was 95.05%, while the negative predictive value was 97.11%.

Table 3: Diagnostic performance of the HB SPOT device

Diagnostic measure	Estimate	95% CI
Sensitivity	96.00%	92.31–97.96%
Specificity	96.42%	93.53–98.04%
Positive predictive value	95.05%	91.13–97.29%
Negative predictive value	97.11%	94.41–98.53%
Overall accuracy	96.24%	94.14–97.61%
False-negative rate	4.00%	—
False-positive rate	3.58%	—

Correlation and Regression Analysis: A strong positive correlation was observed between HB SPOT and reference-analyser measurements ($r=0.989$; $p<0.001$). The coefficient of determination was 0.978, indicating that the corresponding reference values explained 97.8% of the variation in HB SPOT measurements. Lin's

concordance correlation coefficient was 0.988, demonstrating strong agreement.

The linear regression equation was:

$$\text{HB SPOT Hb} = 0.029 + (1.001 \times \text{Reference Hb})$$

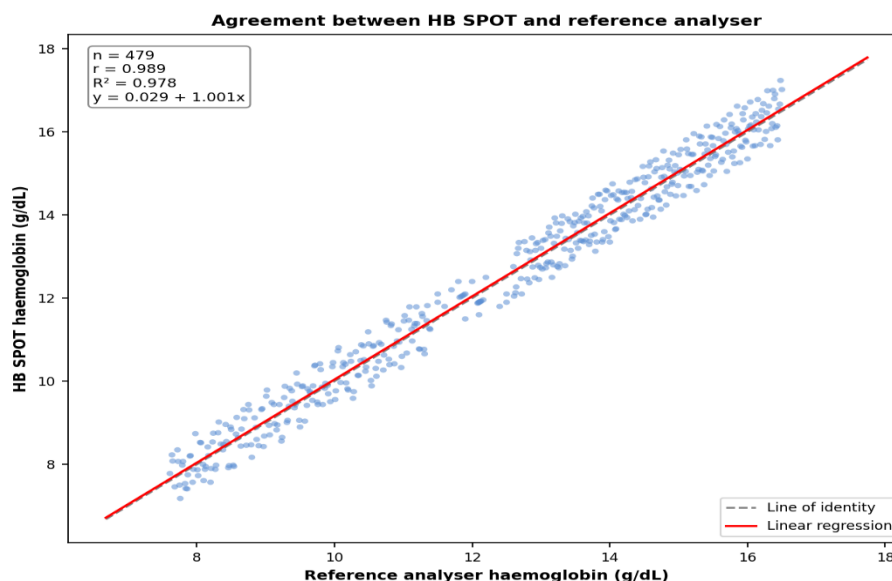


Figure 1: Correlation between HB SPOT and reference-analyser haemoglobin measurements.

The scatter plot should present individual paired measurements, the fitted regression line and the line of identity. The close distribution of observations around the identity line indicates strong agreement between the methods.

Altman analysis showed a mean bias of +0.04 g/dL (95% CI: 0.008–0.080 g/dL). The lower and upper 95% limits of agreement were –0.75 and +0.84 g/dL, respectively. Both limits remained within the predefined acceptable range of ± 0.9 g/dL.

Bland–Altman agreement analysis: Bland–

Table 4: Agreement between HB SPOT and the reference analyser

Agreement parameter	Result	Acceptance requirement	Status
Mean bias	+0.04 g/dL	Within ± 0.5 g/dL	Met
SD of paired differences	0.40 g/dL	—	—
Lower limit of agreement	–0.75 g/dL	Not below –0.9 g/dL	Met
Upper limit of agreement	+0.84 g/dL	Not above +0.9 g/dL	Met
Pearson correlation	0.989	—	Strong correlation
Lin's concordance coefficient	0.988	—	Strong agreement

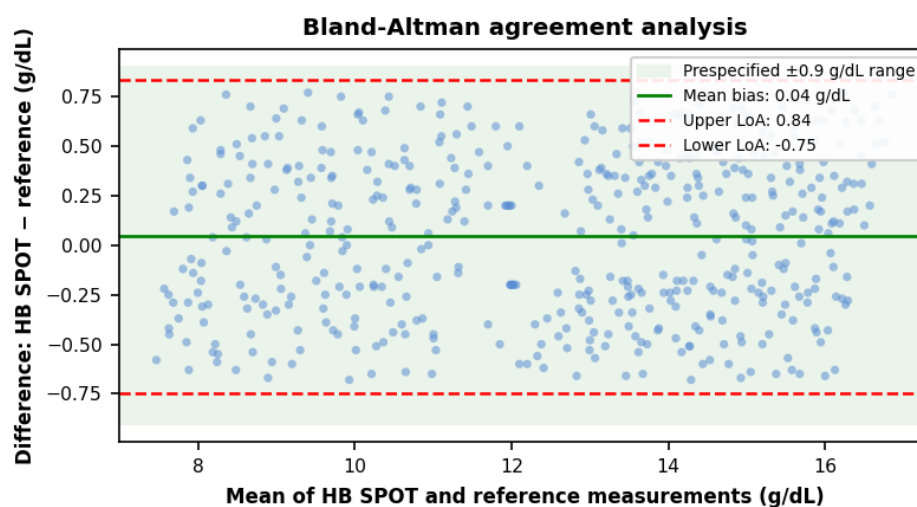


Figure 2: Bland–Altman plot comparing HB SPOT and reference-analyser measurements.

The central line represents the mean bias of +0.04 g/dL, while the lower and upper lines represent the

95% limits of agreement at –0.75 and +0.84 g/dL. The differences were distributed within the

predefined agreement limits.

Discussion

The present study evaluated the diagnostic performance and agreement of the HB SPOT digital haemoglobin meter against a reference laboratory analyser. The device demonstrated a sensitivity of 96.0%, specificity of 96.4%, and overall diagnostic accuracy of 96.2%. The positive and negative predictive values were 95.1% and 97.1%, respectively. These findings indicate that the device could correctly identify most participants with and without anaemia. The high negative predictive value is particularly useful for screening because a negative result is unlikely to miss an individual with anaemia.

The observed sensitivity and specificity were higher than those reported in earlier HB SPOT studies. Chouhan et al. reported a sensitivity of 93.7%, specificity of 92.1%, and accuracy of 92.8%.⁶ Sabharwa et al. found sensitivity and specificity values of 91.8% and 90.2%, respectively. [7] Similarly, Sahu et al. reported sensitivity of 93.7% and specificity of 92.1% for the HB SPOT 09 device. [8] In an earlier study involving 150 participants, Bapodra et al. observed a sensitivity of 86.7% and specificity of 88.4%. [9] Differences between studies may be related to participant characteristics, anaemia prevalence, haemoglobin distribution, device version, operator technique, reference method, and the diagnostic threshold used.

The mean haemoglobin concentration measured using HB SPOT was only 0.04 g/dL higher than that obtained using the reference analyser. Although this difference reached statistical significance, its magnitude was clinically small and remained well within the predefined acceptable bias of ± 0.5 g/dL. The strong Pearson correlation coefficient of 0.989 and Lin's concordance coefficient of 0.988 also showed a close relationship between the two methods. However, correlation alone does not establish interchangeability because two methods may correlate strongly despite systematic differences. Bland-Altman analysis therefore provides a more clinically meaningful assessment of agreement.

The Bland-Altman analysis showed a mean bias of +0.04 g/dL, with limits of agreement ranging from -0.75 to +0.84 g/dL. Both limits remained within the predefined acceptable range of ± 0.9 g/dL. These limits were narrower than those reported by Chouhan et al. [6] (-1.42 to +1.18 g/dL), Sabharwa et al. [7] (-1.55 to +1.27 g/dL), and Bapodra et al. [9] (-1.00 to +1.06 g/dL). In comparison, Yadav et al. reported mean differences of -0.53 ± 1.01 g/dL for HemoCue 201+ and -0.25 ± 0.85 g/dL for HemoCue 301 among pregnant women. [10] The smaller bias and narrower agreement limits observed

in the present analysis suggest good measurement consistency, but they require confirmation under routine clinical and field conditions.

Previous studies have shown substantial variation in the performance of portable haemoglobinometers. Alarcón-Yaquetto et al. reported a bias of 0.36 ± 0.93 g/dL for capillary HemoCue 301 measurements and advised caution when interpreting results close to the anaemia threshold. [5] In rural Gambia, Nass et al. found limited mean bias but relatively wide agreement limits for point-of-care devices compared with an automated analyser. [12] Fothergill et al. reported a sensitivity of 74.8%, specificity of 91.2%, and accuracy of 84.4% for HemoCue 301 compared with an automated analyser. [11] These variations show that device performance depends not only on analytical technology but also on specimen source, study population, operator training and testing conditions.

The use of a single-drop capillary specimen is an important consideration. A multicountry study by Hackl et al. found that venous blood provided the highest precision, while single-drop capillary specimens showed the greatest measurement variability. [3] Karakochuk et al. similarly cautioned that single-drop capillary testing can introduce random error and affect estimates of anaemia prevalence. [13] Méndez-Gómez-Humarán et al. found greater variability with individual capillary drops than with pooled capillary or venous specimens. [14] These findings highlight the importance of standardising the finger-prick technique, avoiding excessive finger squeezing, ensuring complete cuvette filling, testing without delay, and maintaining regular calibration and quality control.

Point-of-care haemoglobin devices have clear practical advantages, including rapid results, portability, low sample-volume requirements, and reduced dependence on laboratory infrastructure. A recent meta-analysis nevertheless showed that the accuracy of point-of-care haemoglobin measurements varies across devices and clinical environments. [15] Reviews of emerging anaemia-detection technologies have also emphasised that portability must be supported by analytical validation, operator training, and continued quality assurance. [4] The HB SPOT device may therefore be useful for initial screening in outpatient clinics, blood-donation camps, primary care facilities, and community programmes. Results close to the diagnostic threshold, unexpectedly low values, or measurements that do not match the clinical condition should be confirmed using a laboratory analyser.

The study has several planned strengths, including a large sample, paired measurements obtained during the same clinical encounter, evaluation across a

broad haemoglobin range, and assessment using diagnostic, correlation and Bland–Altman methods. The final study should, however, address important limitations. A single-centre evaluation may restrict generalisability. Comparing capillary HB SPOT measurements with venous reference measurements combines device-related and specimen-related differences. Repeatability, between-operator variation, lot-to-lot cuvette variation, and performance at very low haemoglobin concentrations were not separately evaluated. In addition, the analysis used a uniform threshold of 12 g/dL. The final analysis should apply the appropriate WHO cut-offs according to sex, age, pregnancy status, altitude, and smoking exposure. [2] Multicentre validation with genuine consecutive observations and predefined subgroup analyses would provide stronger evidence regarding routine clinical performance.

Conclusion

The HB SPOT digital haemoglobin meter demonstrated high diagnostic performance and close agreement with the reference analyser, with sensitivity and specificity above 96%, minimal mean bias, and limits of agreement within the predefined acceptable range. Its rapid response, portability, low blood-volume requirement, and ease of operation support its potential use for point-of-care anaemia screening, particularly in primary care and resource-limited settings. However, values close to the diagnostic threshold should be confirmed using a laboratory analyser.

References

- GBD 2021 Anaemia Collaborators. Prevalence, years lived with disability, and trends in anaemia burden by severity and cause, 1990–2021: findings from the Global Burden of Disease Study 2021. *Lancet Haematol*. 2023;10(9):e713–e734. doi:10.1016/S2352-3026(23)00160-6.
- World Health Organisation. Guideline on haemoglobin cutoffs to define anaemia in individuals and populations. Geneva: World Health Organization; 2024. Available from: WHO guideline.
- Hackl LS, Karakochuk CD, Mazariegos DI, Jeremiah K, Obeid O, Ravi N, et al. Assessing accuracy and precision of haemoglobin determination in venous, capillary pool, and single-drop capillary blood specimens using three different HemoCue Hb models: the multicountry haemoglobin measurement (HEME) study. *J Nutr*. 2024;154(7):2326–2334. doi:10.1016/j.tjnut.2024.03.019.
- An R, Huang Y, Man Y, Valentine RW, Kucukal E, Goreke U, et al. Emerging point-of-care technologies for anemia detection. *Lab Chip*. 2021;21(10):1843–1865. doi:10.1039/D0LC01235A.
- Alarcón-Yaquetto DE, Rueda-Torres L, Bailon N, Barreto PV, Málaga G. Accuracy of HemoCue301 portable hemoglobin analyzer for anemia screening in capillary blood from women of reproductive age in a deprived region of Northern Peru: an on-field study. *PLoS One*. 2023;18(11):e0293984. doi:10.1371/journal.pone.0293984.
- Chouhan R, Vasani V, Kar M, Ranjan S. Clinical evaluation of the HB SPOT device for rapid hemoglobin estimation: a diagnostic accuracy study using cyanmethemoglobin as reference. *Int J Curr Pharm Rev Res*. 2025;17(3):1997–2000.
- Sabharwa D, Vishwakarma R, Ranjan S, Chouhan R. Comparative performance analysis of a digital hemoglobin meter (HB SPOT) against standard laboratory method in a real-world setting. *Int J Pharm Qual Assur*. 2025;16(4):175–179. doi:10.25258/ijpqa.16.4.31.
- Sahu S, Avinash P, Sabharwal D. Diagnostic accuracy and agreement analysis of the HB Spot 09 digital hemoglobin meter: a prospective validation study against a reference hematology analyzer. *Int J Curr Pharm Rev Res*. 2025;17(1):914–920.
- Bapodra MK, Panchal HK, Joshi S, Chavda D. Diagnostic accuracy of HB SPOT, a digital hemoglobin measurement meter: a comparative study with the cyanmethemoglobin method. *Int J Pharm Clin Res*. 2024;16(9).
- Yadav K, Kant S, Ramaswamy G, Ahamed F, Jacob OM, Vyas H, et al. Validation of point-of-care hemoglobin estimation among pregnant women using digital hemoglobinometers (HemoCue 301 and HemoCue 201+) as compared with auto-analyzer. *Indian J Hematol Blood Transfus*. 2020;36(2):342–348.
- Fothergill A, Crider KS, Johnson CB, Raj MP, Guetterman HM, Bose B, et al. Comparison of anemia screening methods using paired venous samples in women of reproductive age in southern India. *J Nutr*. 2022;152(12):2978–2992. doi:10.1093/jn/nxac218.
- Nass SA, Hossain I, Sanyang C, Baldeh B, Pereira DIA. Hemoglobin point-of-care testing in rural Gambia: comparing accuracy of HemoCue and Aptus with an automated hematology analyzer. *PLoS One*. 2020;15(10):e0239931. doi:10.1371/journal.pone.0239931.
- Karakochuk CD, Dary O, Flores-Urrutia MC, Garcia-Casal MN, Hayashi C, Jefferds MED, et al. Emerging evidence and critical issues with the use of single-drop capillary blood for the

- measurement of hemoglobin concentration in population-level anemia surveys. *Adv Nutr.* 2024;15(11):100290.
doi:10.1016/j.advnut.2024.100290.
14. Méndez-Gómez-Humarán I, De la Cruz-Góngora V, Dary O, Shamah-Levy T. Capillary drops, capillary pooled, and venous blood samples for determining hemoglobin concentration using HemoCue: a measurement system analysis. *PLoS One.* 2024;19(10):e0312233.
doi:10.1371/journal.pone.0312233.
15. Ahn HS, Lenet T, Gilbert RWD, Mallick R, Martel G. Accuracy of point-of-care testing devices for haemoglobin in the operating room: meta-analysis. *BJS Open.* 2024;8(1):zrad148.
doi:10.1093/bjsopen/zrad148.