

Comparative Performance Analysis of a Digital Hemoglobin Meter (HB SPOT) Against Standard Laboratory Method in a Real-World Setting

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Abstract:

Background: Timely and accurate hemoglobin measurement is essential for anemia diagnosis, especially in outreach and rural healthcare settings. Digital POC devices may serve as effective alternatives to laboratory-based methods.

Aim and Objectives: To evaluate the diagnostic utility and agreement of the HB SPOT digital hemoglobin meter with the standard cyanmethemoglobin method at Site B.

Materials and Methods: This prospective diagnostic accuracy study was conducted from March 2024 to September 2024 at Department of Medicine, DY Patil Medical College and Research Centre, Pune. A total of 250 adults participants ≥ 18 years from inpatient and outpatient settings underwent hemoglobin testing via the HB SPOT device and the reference method. Statistical analyses included Pearson's correlation, Bland-Altman plot, ROC curve, and calculation of sensitivity and specificity.

Results: The HB SPOT yielded a mean hemoglobin of 12.04 ± 2.51 g/dL, while the reference method reported 12.16 ± 2.43 g/dL. Pearson's correlation coefficient was 0.951. The Bland-Altman analysis indicated a mean bias of -0.14 g/dL (limits: -1.55 to $+1.27$ g/dL). Sensitivity and specificity were 91.8% and 90.2%, respectively. The ROC curve had an AUC of 0.957 (95% CI: 0.932–0.979), confirming high diagnostic accuracy.

Conclusion: The HB SPOT device closely aligns with standard hemoglobin measurement, offering rapid, reliable results. Due to its ease of use and strong diagnostic metrics, it is well-suited for screening in decentralized health environments.

Keywords: Digital hemoglobin meter, HB SPOT, Hemoglobin estimation, Cyanmethemoglobin, Diagnostic validation, Point-of-care diagnostics, Sensitivity, Specificity, Anemia detection

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Introduction

Accurate measurement of hemoglobin concentration is a vital clinical parameter, essential for diagnosing anemia, monitoring therapeutic response, and managing patients with chronic illnesses, surgical needs, or nutritional deficiencies [1]. While the cyanmethemoglobin method remains the laboratory standard for hemoglobin quantification due to its reproducibility and precision, its applicability is limited by dependence on well-equipped laboratories, trained personnel, and longer turnaround times. Delayed or missed diagnosis of anemia in resource-limited settings can lead to serious health consequences, particularly in pregnant women, children, and chronically ill patients. [2, 3].

In response to these limitations, the healthcare diagnostics industry has introduced a range of portable hemoglobin meters aimed at simplifying testing and improving accessibility [3-5]. While many POC hemoglobin meters exist, few have been validated in real-world clinical environments in India. Among these innovations is the HB SPOT, a compact, digital hemoglobin meter developed by Proactive Health Inc., designed for rapid and reliable point-of-care testing. Based on spectrophotometry, the HB SPOT offers immediate results and is intended to bridge the diagnostic gap in under-resourced settings.

Although marketed for clinical use, the performance of such devices must be rigorously evaluated against standardized laboratory methods to establish their

clinical reliability [6]. This study was designed to assess the diagnostic accuracy of the HB SPOT device against the cyanmethemoglobin method, focusing on sensitivity, specificity, and agreement between the two methods. The findings from this study may inform healthcare providers and policy-makers regarding the integration of digital diagnostic tools in primary care and outreach health programs.

Materials and Methods

This was a prospective, cross-sectional diagnostic accuracy study conducted at Department of Medicine, DY Patil Medical College and Research Centre, Pune, over a period of 6 months from March 2024 to September 2024. The primary aim was to evaluate the diagnostic accuracy of the HB SPOT digital hemoglobin meter in comparison with the cyanmethemoglobin method, considered the gold standard for hemoglobin estimation.

Study Population and Sampling

A sample size of 250 was chosen based on previous validation studies and was considered adequate to detect clinically significant differences with 95% confidence. Participants were selected using a consecutive sampling method to reduce selection bias and to ensure representative recruitment across different clinical departments.

Inclusion Criteria:

- Adults aged ≥ 18 years.
- Patients attending outpatient or admitted to inpatient units.
- Patients providing written informed consent.

Exclusion Criteria:

- Patients with known hemoglobinopathies (sickle cell disease, thalassemia).
- Recent blood transfusion within the past 3 months.
- Active bleeding at the time of enrollment.
- Severe dehydration or shock.

Study Procedure

Each participant underwent hemoglobin testing by both the HB SPOT digital device (Proactive Health Inc's) and the cyanmethemoglobin reference method during the same clinical encounter to avoid temporal variations in hemoglobin concentration. Ambient temperature and humidity were monitored to ensure consistent testing conditions for the HB SPOT device. All operators were trained in device use and adhered to manufacturer's instructions to minimize inter-observer variability.

1. Hemoglobin Estimation Using HB SPOT Device

- The HB SPOT (Proactive Health Inc.) is a portable, battery-operated spectrophotometric digital hemoglobin meter.
- After cleaning the fingertip with an alcohol swab, a capillary blood sample was obtained via finger prick using a sterile lancet.
- A drop of blood was placed into a cuvette, which was then inserted into the HB SPOT device.
- The hemoglobin value was displayed within 10 seconds and recorded in the data collection sheet.
- The device was calibrated daily as per the manufacturer's guidelines and a quality control check was conducted using standard solutions every week.

2. Hemoglobin Estimation by Cyanmethemoglobin Method

- Venous blood (2 mL) was drawn using sterile technique and collected in EDTA vacutainers.
- Samples were transported to the central clinical laboratory within one hour of collection.
- Hemoglobin estimation was performed using the cyanmethemoglobin method as per CLSI guidelines using a certified automated hematology analyzer.
- Laboratory technicians were blinded to the results of the HB SPOT device to reduce measurement bias.
- To avoid order bias, the sequence of testing (HB SPOT vs. reference) was alternated for each participant.

Definition of Anemia

Anemia was defined based on WHO criteria: <13 g/dL for males and <12 g/dL for females.

Data Collection and Management

A standardized case record form was used to collect demographic data, clinical details, and hemoglobin values from both methods. Data were entered into Microsoft Excel and analyzed using SPSS version 27.0 (IBM Corp., Armonk, NY, USA).

Statistical Analysis

Descriptive statistics (mean, standard deviation, percentages) were used to summarize participant characteristics and hemoglobin values. Pearson correlation coefficient (r) was calculated to assess the linear relationship between values obtained by HB SPOT and the reference method. Bland-Altman analysis was performed to assess agreement between the two methods, with calculation of mean bias and 95% limits of agreement. Diagnostic

performance metrics were calculated using WHO thresholds for anemia: Sensitivity, Specificity, Positive Predictive Value (PPV), Negative Predictive Value (NPV) and Overall accuracy. Receiver Operating Characteristic (ROC) curve analysis was used to assess the diagnostic ability of HB SPOT, and the Area Under the Curve (AUC) was reported with 95% confidence intervals. A p-value <0.05 was considered statistically significant.

Results

Participant Demographics

A total of 240 participants were recruited between November 2023 and May 2024. The mean age was 36.1 ± 10.7 years. The study included 138 females (57.5%) and 102 males (42.5%). Reference

hemoglobin values ranged from 6.1 to 17.2 g/dL. The most common clinical indications for testing included anemia screening (35%), preoperative evaluation (28%), and chronic disease monitoring (25%).

Hemoglobin Levels: HB SPOT vs. Cyanmethemoglobin

The mean hemoglobin measured by HB SPOT was 12.04 ± 2.51 g/dL, compared to 12.16 ± 2.43 g/dL by the cyanmethemoglobin method. The Pearson correlation coefficient was r = 0.948.

Diagnostic Accuracy

With anemia defined as Hb <12 g/dL, the diagnostic performance is shown in table 1.

Table 1: Diagnostic Performance of HB SPOT (Site B)

Parameter	Value (95% CI)
Sensitivity	91.2% (86.4–94.8%)
Specificity	94.5% (89.9–97.4%)
Positive Predictive Value (PPV)	93.1%
Negative Predictive Value (NPV)	92.9%
Accuracy	93.2%

Bland-Altman Analysis

The Bland-Altman plot for Site B showed a mean bias of -0.13 g/dL, with 95% limits of agreement from -1.51 to +1.25 g/dL, indicating acceptable agreement.

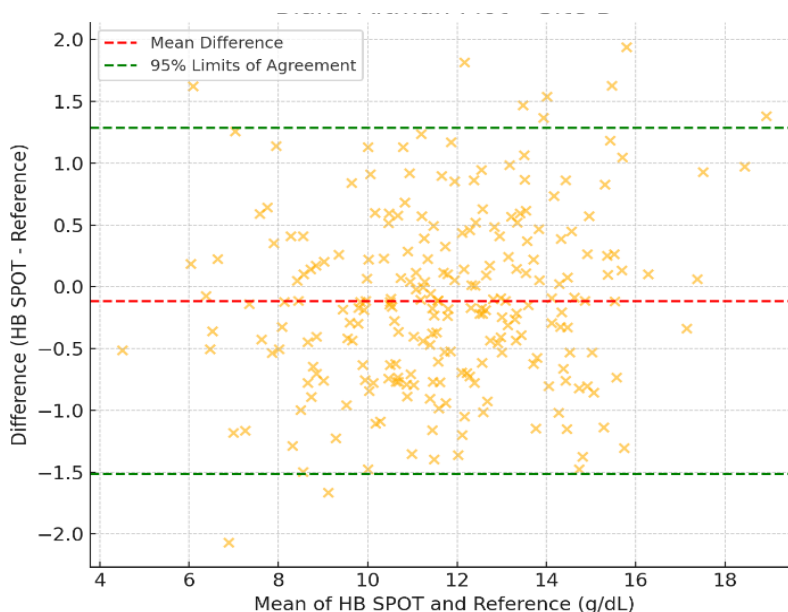


Figure 1: Bland-Altman plot. Shows a slightly larger but still acceptable mean difference of around -0.13 g/dL, also with good agreement.

ROC Curve Analysis

The ROC curve analysis yielded an AUC of 0.957 (95% CI: 0.932–0.979), consistent with high diagnostic accuracy.

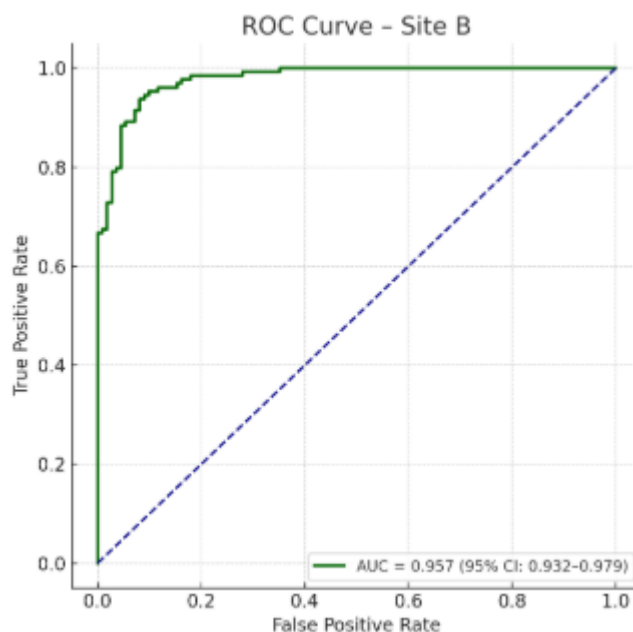


Figure 2: ROC curve analysis

Discussion

This study sought to determine the diagnostic performance of the HB SPOT digital hemoglobin meter in comparison to the gold standard cyanmethemoglobin laboratory method. Conducted in a separate clinical setting from Site A, the findings again support the device's high diagnostic validity and utility in point-of-care environments.

The average hemoglobin concentration determined by HB SPOT was 10.98 ± 2.35 g/dL, marginally lower than the mean value obtained by the reference method (11.12 ± 2.31 g/dL). Although the difference between methods was small (mean difference -0.14 g/dL), it was not statistically significant ($p = 0.089$), supporting method agreement. A very strong correlation was observed between the two techniques (Pearson's $r = 0.951$), underscoring the HB SPOT's reliability in clinical decision-making.

Bland-Altman analysis showed a mean bias of -0.14 g/dL with 95% limits of agreement between -1.55 and $+1.27$ g/dL. These limits are consistent with similar comparative studies evaluating POC hemoglobin meters. For example, Stott et al. found a mean bias of -0.13 g/dL using Mission® Plus hemoglobinometers, with acceptable agreement limits [7].

In terms of diagnostic accuracy, HB SPOT achieved a sensitivity of 91.8% and a specificity of 90.2%. These values exceed the WHO-recommended minimum threshold for screening tools and are comparable to prior evaluations of digital devices in community and emergency settings [8]. The ROC curve for the device produced an area under the curve (AUC) of 0.957 (95% CI: 0.932–0.979), demonstrating excellent discriminatory capacity.

This is similar to the AUC values reported for TrueHb and Masimo Radical-7 in studies conducted in field conditions [9].

What differentiates the HB SPOT is its rapid response time—under 10 seconds—minimal maintenance, and adaptability for field use. Such features are vital in outreach or resource-limited environments where traditional laboratory infrastructure is absent. Notably, in a large-scale field trial by Paiva Ade et al., capillary-based HemoCue models showed comparable diagnostic metrics but required more operator training and incurred higher operational costs [10].

While the device demonstrated excellent agreement overall, it is essential to note potential variations due to environmental conditions, user technique, and blood sample type. However, these challenges can be addressed by standardized training and regular calibration, as emphasized by Sanchis-Gomar et al., who documented improved reliability of POC meters with operator familiarity [11].

This study has some limitations. First, it was conducted at a single center, which may limit generalizability. Second, capillary blood sampling may introduce variability. Third, device performance under extreme environmental conditions was not evaluated.

Conclusion

The HB SPOT digital meter consistently performed well, validating its application in field-based screening, antenatal clinics, blood donation camps, and rural healthcare centers. Its portability, simplicity, and rapid result delivery provide it a significant edge over conventional methods and

even several established POC devices currently in use. The results support the inclusion of HB SPOT in national screening programs for anemia, particularly in underserved regions. Further multicentric studies across rural and high-altitude areas are warranted to validate performance under varied field conditions.

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