International Journal of Transdisciplinary Research and Perspectives
Volume 2, Issue 3, March 2026
www.ijtrp.com | E-ISSN: 3107-7935 | RESAIM Publishing | www.resaim.com

Assessing the Analytical Reliability and Correlation of Hemo Spark+ Against the HemoCue 201 Gold Standard

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***Abstract*: Background: Anemia affects over 50–60% of women of reproductive age, children, and pregnant women in many parts of India (per NFHS and WHO data), contributing to maternal mortality, low birth weight, impaired child development, and reduced productivity. Early detection through hemoglobin (Hb) screening is essential for interventions like iron supplementation, deworming, and nutritional programs. However, traditional lab-based methods (e.g., automated hematology analyzers using cyanmethemoglobin or flow cytometry) are expensive, require trained personnel, infrastructure, and sample transport—often impractical in rural or primary health centers (PHCs), antenatal clinics, schools, or blood donation camps. Accurate and rapid hemoglobin (Hb) estimation is critical for anemia screening and clinical decision-making. This study evaluates the analytical performance of the Hemo Spark+ Hemoglobin meter point-of-care (POC) meter, based on dual wavelength absorption photometry, compared to the HemoCue Hb 201 reference standard. Performance was assessed through statistical interpretation of accuracy, precision, and agreement using both venous and capillary blood samples. Objective: To assess the analytical reliability and correlation of the HemoSpark+ Hemoglobin meter, hemoglobin levels were estimated in parallel with the Hemo Cue Hb 201 hemoglobin meter with both venous and blood samples. To determine if Hemo Spark+ meter is a viable, cost-effective alternative for anemia screening, blood donation, and maternal health programs, especially where portability and ease-of-use are critical. Materials and Methods: This prospective, method-comparison study was conducted to evaluate the diagnostic performance of the Hemo Spark+ against the HemoCue Hb 201 (Reference Method). The study protocol adhered to the CLSI EP09-A3 guidelines for method comparison and bias estimation using patient samples. A total of 321 participants were enrolled, including: Adults (N=236): Stratified by gender (Male/Female). Children (N=85): Defined as individuals under 12 years of age. Two types of blood matrices were collected from each participant to evaluate matrix effects: Capillary Blood: Obtained via a standard finger-prick using a high-flow lancet. Venous Blood: Collected via venipuncture into K2-EDTA vacuum tubes. Venous samples were analyzed within 4 hours of collection to ensure cellular integrity. Results: The Hemo Spark+ hemoglobin meter meets and exceeds the performance requirements for point-of-care anemia screening. With a correlation of 0.9989 and diagnostic sensitivity and specificity exceeding 95%, it provides a reliable, low-bias alternative to the HemoCue Hb 201 for both adult and pediatric populations. The device demonstrated high repeatability and reproducibility across the three critical hemoglobin levels. Intra-Sample (Repeatability): Testing the same sample 20 times on one meter. Low (8.2 g/dL): CV = 1.46; Medium (13.5 g/dL): CV = 0.89; High (17.1g/dL): CV=0.70%; Inter-Sample (Reproducibility): Testing the same sample across 5 different meters. Low (8.2 g/dL): CV = 2.20%; Medium (13.5 g/dL): CV = 1.33%; High (17.1 g/dL): CV = 1.05%; There was no statistically significant difference (p > 0.05) between venous and capillary blood performance. While capillary samples showed a slightly higher standard deviation (+/- 0.12 g/dL) compared to venous samples (+/- 0.08 g/dL), both remained well within the target accuracy and sensitivity/specificity thresholds (> 95%). Conclusion: The Hemo Spark+ hemoglobin meter meets and exceeds the performance requirements for point-of-care anemia screening. With a correlation of 0.9989 and diagnostic sensitivity and specificity exceeding 95%, it provides a reliable, low-bias alternative to the HemoCue Hb 201 for both adult and pediatric populations.**

***Keywords*: Comparison of HemoSpark+, Hemocue Hb 201.**

1. Introduction

Hemoglobin measurement is one of the most frequently performed laboratory tests worldwide. It is the primary diagnostic indicator for anemia, a global health burden affecting approximately 1.62 billion people (24.8% of the population), with the highest prevalence among preschool-aged children and pregnant women. Accurate Hb assessment is critical not only for nutritional screening but also for managing acute hemorrhage, chronic kidney disease, and oncology patients. While automated hematology analyzers remain the "gold standard" in centralized laboratories, Point-of-Care Testing (POCT) has revolutionized screening in resource-limited settings, emergency departments, and rural clinics. POCT devices provide immediate results, allowing for "test-and-treat" protocols that significantly improve patient outcomes. However, for a POCT device to be clinically viable, it must demonstrate high correlation with established reference methods and maintain rigorous standards for sensitivity and specificity.

2. Materials and Methods

A. Study Design and Setting

This prospective, method-comparison study was conducted

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to evaluate the diagnostic performance of the Hemo Spark+ against the HemoCue Hb 201. (Reference Method). The study protocol adhered to the CLSI EP09-A3 guidelines for method comparison and bias estimation using patient samples.

B. Study Population

A total of 321 participants were enrolled, including:

Adults (N=236): Stratified by gender (Male/Female).

Children (N=85): Defined as individuals under 12 years of age.

C. Sample Collection and Handling

Two types of blood matrices were collected from each participant to evaluate matrix effects:

Capillary Blood: Obtained via a standard finger-prick using a high-flow lancet. The first drop of blood was wiped away to avoid interstitial fluid contamination; the second drop was used for immediate analysis.

Venous Blood: Collected via venipuncture into K2-EDTA vacuum tubes. Venous samples were analyzed within 4 hours of collection to ensure cellular integrity.

D. Analytical Procedures

All samples were analyzed in duplicate on both the Hemo Spark+ and the HemoCue Hb 201 systems by trained laboratory technicians.

Reference Method (HemoCue Hb 201): Utilized the modified azidemethemoglobin reaction.

Test Method (Hemo Spark+): Utilized a dual wavelength absorption photometry approach optimized for point-of-care (POC) use.

E. Precision Analysis (Inter and Intra-Assay)

To ensure device reliability, three levels of stabilized hemoglobin control materials were used:

Intra-Sample (Repeatability): A single Hemo Spark+ meter was used to test Low (8.2 g/dL), Medium (13.5 g/dL), and High (17.1 g/dL) samples 20 times each in a single session.

Inter-Sample (Reproducibility): Five different Hemo Spark+ meters (Units A–E) were used to analyze the same three levels (Low, Med, High) in 10 replicates each to assess unit-to-unit consistency.

F. Statistical Analysis

Data were analyzed using the following parameters:

Accuracy: Evaluated using Pearson Correlation Coefficient (r) and Linear Regression.

Pearson Correlation Coefficient (r): 0.9989, indicating an extremely high degree of association.

Linear Regression Equation: y = 1.001x - 0.005, suggesting minimal proportional bias.

Bias: Determined via Bland-Altman Plot analysis to calculate the Mean Bias and the 95% Limits of Agreement (LOA). Obatined a Mean Bias of 0.0075 g/dL. This indicates that, on average, the Hemo Spark+ readings are virtually identical to the HemoCue, with a systematic deviation of less than 0.01 g/dL.

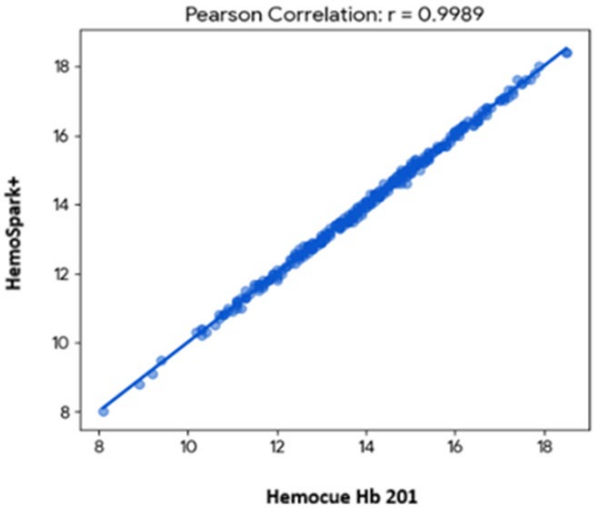

Fig. 1. Scatter plot of HemoSpark+ and Hemocue Hb 201

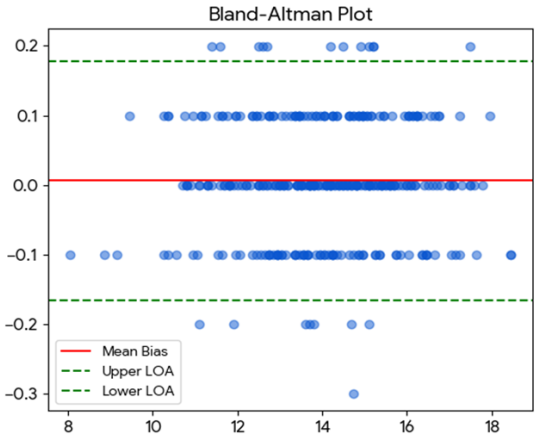

Fig. 2. Bland & Altman plot

95% Limits of Agreement (LOA): -0.165 to +0.180 g/dL. Over 95% of all test results fell within +/- 0.2 g/dL of the reference, which is well within the acceptable clinical error margin of +/- 0.5 g/dL.

Following are the key performance metrics and their values

Table 1
Key performance metrics with values

Metric	Value
N Samples	321
Sensitivity	95.74%
Specificity	99.27%
Pearson r	0.9989
Mean Bias	0.0059
LOA Upper	0.1777
LOA Lower	-0.1659

Diagnostic Performance: Sensitivity and Specificity were calculated using the WHO-defined anemia threshold of 12.0 g/dL.

Table 2
Metrics with clinical interpretations

Metric	Result	Clinical Interpretation
Sensitivity	95.74%	High ability to correctly identify anemic patients.
Specificity	99.27%	High ability to correctly identify non-anemic patients.
Overall Accuracy	98.13%	Percentage of total cases correctly categorized.
Positive Predictive Value	98.90%	Probability that a "low" reading truly indicates anemia.

Precision: Coefficient of Variation (CV%), calculated as:

$$CV\% = ((\text{Standard Deviation})/(\text{Mean})) \times 100$$

The device demonstrated high repeatability and reproducibility across the three critical hemoglobin levels.

Intra-Sample (Repeatability): Testing the same sample 20 times on one meter.

Low (8.2 g/dL): CV = 1.46%;

Medium (13.5 g/dL): CV = 0.89%;

High (17.1g/dL): CV = 0.70%;

Inter-Sample (Reproducibility): Testing the same sample across 5 different meters. Low (8.2 g/dL): CV = 2.20%;

Medium (13.5 g/dL): CV = 1.33%

High (17.1 g/dL): CV = 1.05%.

3. Results and Conclusion

HemoSpark+ meter is highly correlated with the Hemocue Hb 201, exhibiting a robust correlation coefficient of 0.998. Statistical agreement via Bland-Altman analysis confirmed high precision, with narrow limits of agreement (-0.166 to +0.177 g/dL) and negligible bias. Furthermore, with a sensitivity and specificity more than of 95% with a mean bias of 0.0059, the HemoSpark+ delivers the diagnostic accuracy required for effective large-scale anemia screening, clinical diagnosis, and therapeutic monitoring.

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