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# Evaluation of a Point-of-Care Device for Hemoglobin and Hematocrit Measurement in Infants Compared with a Standard Laboratory Analyzer

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**ABSTRACT**

***Background**: Rapid detection of anemia is critical for prompt management in infants. Point-of-care testing (POCT) devices provide immediate results and may be particularly useful in low-resource settings. This study evaluated the Hemochroma PLUS hemoglobinometer for hemoglobin (Hb) and hematocrit (HCT) measurement in infants, compared with the Genex Count 60 laboratory analyzer.*

***Methods**: A prospective diagnostic accuracy study was conducted at Al-Zahraa Teaching Hospital for Obstetrics and Pediatrics. Capillary blood samples were collected from 33 infants (age 3–12 months) and analyzed using both Hemochroma PLUS and the reference analyzer. Accuracy, precision, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated. Bland–Altman analysis and coefficient of variation (CV) were used to assess agreement and precision.* ***Results**: Hemochroma PLUS showed good agreement with the reference analyzer for Hb (mean bias 0.75 g/dL, 95% limits of agreement –1.37 to 3.25 g/dL) but overestimated HCT (mean bias 6.1%, 95% LOA –5.69 to 17.9%). Coefficient of variation was similar between devices (Hb CV ~0.16–0.18). Sensitivity and specificity for Hb-based anemia detection in infants >6 months were 75% and 100%, respectively, with PPV 100% and NPV 93%. In infants 3–6 months, sensitivity decreased to 25% while specificity remained 100%.* ***Conclusion:** Hemochroma PLUS is a rapid, economical, and convenient POCT device suitable for hemoglobin measurement in infants older than six months. While reliable for detecting anemia in older infants, confirmatory laboratory testing is recommended for younger infants, and caution is advised for HCT-based assessments.*

**Keywords: Hemochroma PLUS, Point-Of-Care Testing, Hemoglobin, Hematocrit, Anemia, Infants.**

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## INTRODUCTION

Optimal management of anemia requires early detection and continuous monitoring through blood tests that accurately measure hemoglobin (Hb) concentrations (1). Hemoglobin measurement is the standard approach to assess anemia status, providing a quantitative but not necessarily causative evaluation of the condition. In many low-resource or field settings, hematocrit (HCT) measurement is often used as an indirect indicator of Hb levels when direct measurement is not feasible. However, the correlation between HCT and Hb is not consistently reliable(2). Therefore, simultaneous measurement of both Hb and HCT provides a more comprehensive and robust diagnostic approach, particularly in resource-limited environments (3). To address these challenges, point-of-care devices (POCDs) that are affordable, durable, and user-friendly have been developed. Numerous methods for hemoglobin determination exist, ranging from traditional colorimetric assays to advanced point-of-care testing (POCT) systems. These methods have been extensively evaluated by researchers, focusing on their performance characteristics —


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including accuracy, precision, specificity, sensitivity, advantages, and limitations — in comparison with widely accepted reference standards such as automated cell counters, which remain the gold standard for hematological analysis (4).

Over the past two decades, significant advances have been made in POCT technology. However, their clinical impact in developing countries remains highly dependent on existing healthcare infrastructure. Currently, POCT is predominantly used in remote settings, physician offices, emergency departments, operating theaters, and intensive care units (ICUs). Applications range from therapeutic support (e.g., in diabetes or myocardial infarction management) to preventive screening in high-risk populations and routine monitoring of blood parameters (5). POCT devices are typically classified based on size and complexity into small, handheld instruments — from simple dipsticks to sophisticated cartridge-based systems that accept whole blood without preprocessing — and larger benchtop analyzers, which function as miniaturized automated systems capable of multi-parameter testing (6).

The hemochroma PLUS Analyzer is a battery-powered, handheld device designed to measure total hemoglobin concentration within approximately three seconds using just 15 µL of whole blood, obtained via fingerstick or venipuncture without any preprocessing. The system uses hemochroma PLUS microcuvettes with dual ports that allow sample application by capillary action or direct pipetting. Hemoglobin concentration is determined photometrically using a dual-wavelength absorption method (530–850 nm), with results displayed on an LCD screen and optionally printed.

The analyzer performs automatic quality control checks upon startup, verifying the performance of optical components and alerting users if any errors are detected (7). According to the manufacturer, the measurable range is 5.0 g/dL to 25.6 g/dL**,** with results outside this range displayed as “Hi” or “Lo.” We can use Hb as diagnostic tool which thresholds < 9.5 g/dL in infants (3-6 months) and < 11.3 g/dL in late infancy (6–12 months). Similarly, the hematocrit cutoff for diagnosing anemia is < 29 % in infants younger than six months and < 31 % in those older than six months(8,9).

Aim of the Study to Evaluate the accuracy of the hemochroma PLUS hemoglobinometer compared with the Genex Count 60 analyzer for the initial diagnosis of anemia in infants by measuring hemoglobin (Hb) and hematocrit (HCT) and assess the usability and practicality of the hemochroma PLUS device in clinical and low-resource healthcare settings.

# METHODS

## Ethical Approval

Ethical approval for this prospective study was obtained from the Health Research Ethics Committee of Jabir Ibn Hayyan University for Medical and Pharmaceutical Sciences.

## Study Design and Participants

This prospective study included 33 infant outpatients (13 males and 20 females) who visited Al-Zahraa Teaching Hospital for Obstetrics and Pediatrics. Inclusion criteria required hemoglobin (Hb) levels ranging from 9.5 to 15.0 g/dL to ensure a wide range of Hb values. Participants were categorized into two age groups:

•Group 1: 2–6 months

•Group 2: >6 months

## Sample Collection and Handling

Capillary blood samples were collected by qualified clinical technologists using standard aseptic techniques. Samples were transported at room temperature (approximately 25 °C) and analyzed within a short time frame to minimize pre-analytical variability. All operators were blinded to each other’s results to eliminate measurement bias.

## Hemoglobin and Hematocrit Measurement

•**Reference Method:** Hemoglobin (Hb) and hematocrit (HCT) measurements were

 

performed using the Genex Count 60 hematology analyzer, which served as the reference standard.

•**Point-of-Care Method:** Parallel measurements were conducted using the Hemochroma PLUS hemoglobinometer, a handheld POCT device. Measurements obtained from the Hemochroma PLUS were compared to the reference values from the Genex Count 60. Diagnostic performance parameters — including accuracy, precision, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) — were calculated to assess the ability of the POCT device to detect anemia in infants.

### Statistical Analysis

All statistical analyses were conducted using IBM SPSS Statistics version 26 (IBM Corp., Armonk, NY, USA).Hemoglobin and hematocrit data were tested for normal distribution using the Shapiro–Wilk test. For comparative analysis Paired t-tests were performed to compare the results of the two measurement methods.

Descriptive statistics — including mean, minimum, maximum, and 95% confidence intervals — were calculated.The coefficient of variation (CV) was calculated to assess within-run precision of the POCT device. Bias and Agreement: Agreement between the POCT device and the reference analyzer was evaluated using the Bland–Altman method10.

In this context bias refers to the mean difference (and its direction) between POCT and reference measurements. Precision refers to the closeness of repeated measurements to each other. Diagnostic Performance: Sensitivity, specificity, PPV, and NPV of the Hemochroma PLUS device were calculated relative to the reference hematology analyzer.

## RESULTS

### *Patient Characteristics*

A total of **33 infants** participated in this study, including **13 males (39.4%)** and **20 females (60.6%)**. The mean age was **6.7 ± 2.5 months** (range: 3–11 months), and the mean body weight was **6.2 ± 2.19 kg** (range: 1.7–10.0 kg). Patient demographic and clinical characteristics are summarized in **Table 1**.

**Table 1. Characteristics of study participants (n = 33)**

| Characteristics | Value |
|---|---|
| Male, n (%) | 13 (39.4%) |
| Female, n (%) | 20 (60.6%) |
| Age (months), mean ± SD | 6.7 ± 2.5 |
| Weight (kg), mean ± SD | 6.2 ± 2.19 |

### *Hemoglobin and Hematocrit Measurements*

Referece measurements obtained using the **Genex Count 60** analyzer showed hemoglobin (Hb) values ranging from **7.2 to 18.2 g/dL** (mean: **11.7 ± 2.20 g/dL**, 95% CI: 10.9–12.4) and hematocrit (HCT) values ranging from **20.9% to 50.9%** (mean: **32.3 ± 5.95%**, 95% CI: 30.1–34.3). **Table 2.**

**Table 2. Hemoglobin and hematocrit measurements by both devices**

| Measurement | CBC (Reference) | Hemochroma PLUS |
|---|---|---|
| Hb (g/dL), mean ± SD | 11.7 ± 2.20 | 12.5 ± 2.09 |
| HCT (%), mean ± SD | 32.2 ± 5.95 | 37.4 ± 6.72 |
| 95% CI (Hb) | 10.9–12.4 | 11.9–13.6 |
| 95% CI (HCT) | 30.1–34.3 | 35.7–40.9 |
| Minimum Hb (g/dL) | 7.2 | 8.1 |
| Maximum Hb (g/dL) | 18.2 | 19.3 |
| Minimum HCT (%) | 20.9 | 24.3 |

| Measurement | CBC (Reference) | Hemochroma PLUS |
|---|---|---|
| Maximum HCT (%) | 50.9 | 57.9 |
| Coefficient of variation (CV) Hb | 0.18 | 0.16 |
| Coefficient of variation (CV) HCT | 0.18 | 0.17 |
| p-value | <0.001 | <0.001 |

Hemochroma PLUS measurements showed slightly higher results, with mean Hb and HCT values of **12.5 ± 2.09 g/dL** and **37.4 ± 6.72 g/dL**, respectively. The coefficient of variation (CV) was **0.16** for Hb and **0.17** for HCT in Hemochroma PLUS and **0.18** for the reference analyzer, indicating comparable within-run precision. The differences in both Hb and HCT measurements between the two devices were **highly statistically significant (p < 0.001)**. **Table 2.**

### *Bland–Altman Analysis*

Agreement between Hemochroma PLUS and the reference analyzer was evaluated using **Bland–Altman plots**.

- For **hemoglobin**, the mean bias was **0.75 g/dL**, with **95% limits of agreement (LOA)** ranging from **–1.37 to 3.25 g/dL (Figure 1).**
- For **hematocrit**, the mean bias was **6.1%**, with **95% LOA** from **–5.69 to 17.9% (Figure 2).**

These results indicate that while Hemochroma PLUS slightly overestimated both Hb and HCT, the degree of bias remained within clinically acceptable limits.

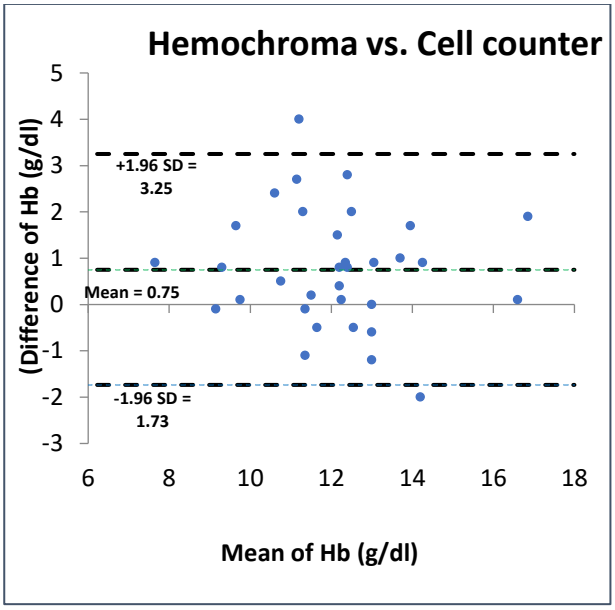


**Figure 1.** Bland–Altman plot for hemoglobin measurements comparing Hemochroma PLUS and the reference method.

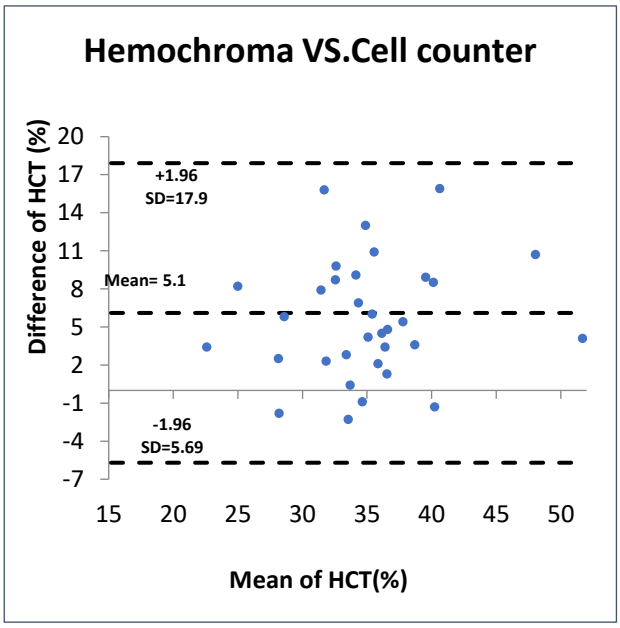


**Figure 2.** Bland–Altman plot for hematocrit measurements comparing Hemochroma PLUS and the reference method.

## Diagnostic Performance

The diagnostic performance of Hemochroma PLUS for anemia detection was assessed by calculating sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) **(Table 3).**

For infants **older than 6 months**, Hemochroma PLUS demonstrated **high sensitivity (75%)** and **specificity (100%)** for

Hb-based anemia detection. In contrast, performance was lower in infants aged **3–6 months**, with sensitivity and specificity values of **25%** each.

PPV was consistently high (**100%**) across all age groups and parameters, indicating that patients identified as anemic by the POCT device were very likely to be confirmed as anemic by the reference method. However, NPV was lower, particularly in the **3–6 months** group (**75%**), reflecting reduced reliability in identifying non-anemic infants in this age range.

**Table 3. Diagnostic performance of Hemochroma PLUS compared with the reference analyzer**

| Age group | Sensitivity (%) | Specificity (%) | PPV (%) | NPV (%) |
|---|---|---|---|---|
| Hb (3–6 months) | 25 | 100 | 100 | 75 |
| HCT (3–6 months) | 25 | 100 | 100 | 72 |
| Hb (>6 months) | 75 | 100 | 100 | 93 |
| HCT (>6 months) | 28 | 100 | 100 | 72 |

## DISCUSSION

Point-of-care testing (POCT) offers the major advantage of rapid result availability, facilitating prompt clinical decisions, reducing patient waiting time, and minimizing the need for multiple clinic visits. In this prospective diagnostic accuracy study conducted at **Al-**Zahraa Teaching Hospital for Obstetrics and Pediatrics, the Hemochroma PLUS hemoglobinometer was evaluated against the Genex Count 60 reference analyzer for hemoglobin (Hb) and hematocrit (HCT) measurement in infants aged 3–12 months using capillary blood.

Overall, Hemochroma PLUS demonstrated acceptable agreement with the reference analyzer for hemoglobin, with a mean bias of 0.75 g/dL (95% limits of agreement: –1.37 to 3.25 g/dL). The device tended to slightly overestimate Hb values but showed comparable precision to the reference analyzer. For HCT, the mean bias was 6.1% (95% limits of agreement: –5.69 to 17.9%), reflecting less agreement. This discrepancy is likely due to methodological differences: the Genex Count 60 calculates HCT from measured red blood cell counts multiplied by mean corpuscular volume (MCV), whereas Hemochroma PLUS calculates HCT indirectly using Hb × 3. Capillary sampling variability may also contribute to observed differences[11].

Age-stratified analysis revealed that Hemochroma PLUS has high diagnostic utility in infants older than six months, with 75% sensitivity and 100% specificity for Hb-based anemia detection (PPV 100%, NPV 93%). In infants 3–6 months, sensitivity dropped to 25%, although specificity remained 100%. This suggests that while positive results reliably indicate anemia, negative results in younger infants cannot confidently exclude the condition. These findings are consistent with previous studies using similar photometric POCT devices (e.g., HemoCue) that reported acceptable accuracy but variable sensitivity depending on sample population and age[12,13].

**Strengths** of this study include prospective design, blinded operators, and use of an established reference analyzer.

**Limitations** include the small sample size, single-center setting, exclusive use of capillary blood, and lack of evaluation for potential interferents (e.g., jaundice, hemoglobinopathies) that may affect photometric readings.

## CONCLUSION

Hemochroma PLUS demonstrates good agreement with the Genex Count 60 for hemoglobin measurement in infants, with a small mean bias. The device shows excellent specificity and positive predictive value and acceptable sensitivity in infants older than six months, making it suitable for rapid anemia screening in this age group. Hematocrit measurement showed higher bias and lower reliability, particularly in infants younger than six months. Overall, Hemochroma PLUS is a promising, economical, and convenient POCT device for Hb assessment in older infants and low-resource settings but should be used cautiously for younger infants, where confirmatory laboratory testing remains advisable.

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## REFERENCES

1. An R, Huang Y, Man Y, Valentine RW, Kucukal E, Goreke U, Sekyonda Z, Piccone C, Owusu-Ansah A, Ahuja S, Little JA. Emerging point-of-care technologies for anemia detection. Lab on a Chip. 2021;21(10):1843–65.
2. Quintó L, Aponte JJ, Menéndez C, Sacarlal J, Aide P, Espasa M, et al. Relationship between haemoglobin and haematocrit in the definition of anaemia. Trop Med Int Health. 2006;11(8):1295–302.
3. Nass SA, Hossain I, Sanyang C, Baldeh B, Pereira DI. 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.
4. Alqershi KA, Kadhim AM, Al-Muaala AM. Clinical evaluation of a newly developed point-of-care, haemoglobinometer: Comparison with colorimetric and cell counter haemoglobin determination methods. New Zealand J Med Lab Sci. 2020;74(1):31–4.
5. Mitra P, Sharma P. POCT in developing countries. EJIFCC. 2021;32(2):195.
6. Dima K. Point of care testing (POCT): Present and future. [No publication details provided].
7. Measurand C, Proprietary F. 510(k) Substantial Equivalence Determination Decision Summary. Complement 3: C3. [No yar provided].
8. University of Iowa Health Care. (2024). Pediatric Normals – Hematology Reference Ranges.
9. Larsson, S. M., Hellström-Westas, L., Hillarp, A., Åkeson, P. K., Domellöf, M., Askelöf, U., ... & Andersson, O. (2022). Haemoglobin and red blood cell reference intervals during infancy. Archives of Disease in Childhood, 107(4), 351-358.
10. Bland JM, Altman DG. Measuring agreement in method comparison studies. Stat Methods Med Res. 1999;8:135–60.
11. Avecilla ST, Marionneaux SM, Leiva TD, Tonon JA, Chan VT, Moung C, Maslak P, et al. Comparison of manual hematocrit determinations versus automated methods for hematopoietic progenitor cell apheresis products. Transfusion. 2016;56(2):528–32.

 

12. Raithatha SJ, Ranapurwala MF, Lahori SIMMY, Bopche CN, Phatak AG. Validation of Hemochroma PLUS: A point-of-care testing device for haemoglobin estimation. J Clin Diagn Res. 2019;13(5):LC07–LC09.
13. Zatloukal J, Pouska J, Kletecka J, Pradl R, Benes J. Comparison of the accuracy of hemoglobin point-of-care testing using HemoCue and GEM Premier 3000 with automated hematology analyzer in emergency room. J Clin Monit Comput. 2016;30(6):949–56.

 