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Validation Study of the Tamiacs Digital Hemoglobinometer

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ABSTRACT

Background: Accurate hemoglobin estimation is central to the detection and classification of anemia. Point-of-care digital hemoglobinometers can facilitate rapid testing in outpatient, community and resource-constrained settings. This study evaluated the analytical precision and diagnostic agreement of the Tamiacs Digital Hemoglobinometer at the C.R PARIKH BLOOD CENTER, KAPADWANJ.

Methods: A cross-sectional validation study was conducted among 100 participants aged 15–74 years. Women constituted 53% of the study population and men 47%. Hemoglobin measurements obtained with the Tamiacs Digital Hemoglobinometer were compared with a designated reference method using Sysmex XP 300. Diagnostic performance was assessed using sensitivity and specificity. Analytical precision was summarized using coefficient of variation (CV), and agreement between methods was assessed using Bland–Altman analysis.

Results: The reported sensitivity was 98.3% and specificity was 98.1%. The coefficient of variation was reported as less than 3%. Bland–Altman analysis demonstrated 95% limits of agreement from -0.3 to +0.5 g/dL. The mean bias, calculated as the midpoint of the reported limits of agreement, was +0.10 g/dL. The corresponding estimated standard deviation of paired differences is approximately 0.20 g/dL.

Conclusion: In this study population, the Tamiacs Digital Hemoglobinometer demonstrated high reported sensitivity and specificity, low analytical variability, and close agreement with the reference method.

Keywords: Hemoglobinometer, Hemoglobin Estimation, Point-of-Care Testing, Anemia, Diagnostic Accuracy, Sensitivity, Specificity, Bland–Altman Analysis, Coefficient of Variation, Method Comparison.

INTRODUCTION

Hemoglobin concentration is a fundamental laboratory parameter for identifying anemia and supporting clinical decision-making. Conventional laboratory analyzers provide standardized measurements but may require centralized infrastructure, trained personnel and sample transport. Point-of-care hemoglobin testing offers the potential

for rapid measurement closer to the patient and can be particularly useful in outpatient, screening and community settings.

Published validation studies of digital hemoglobinometers commonly compare device measurements with a laboratory reference method and assess both continuous agreement and categorical diagnostic performance [1]. Bland–Altman



analysis is frequently used to quantify systematic difference (bias) and the range within which most paired differences are expected to fall. Sensitivity and specificity provide complementary information regarding classification of anemia against a predefined reference standard [2]. Previous Indian validation studies have used these approaches for evaluating digital hemoglobinometers.

Specifically, evaluating digital hemoglobin systems against automated hematology counters has been established as an ideal, user-friendly methodology for maintaining strict pre-donation screening protocols in regional blood banks [3].

The present study was undertaken at the C.R PARIKH BLOOD CENTER, KAPADWANJ, to assess the performance of the Tamiacs Digital Hemoglobinometer in 100 participants aged 15–74 years.

OBJECTIVES

- To assess the diagnostic sensitivity of the Tamiacs Digital Hemoglobinometer for identification of anemia against the reference method.
- To assess the diagnostic specificity of the Tamiacs Digital Hemoglobinometer.

- To evaluate analytical precision using the coefficient of variation.
- To assess agreement between Tamiacs and the reference method using Bland–Altman analysis.
- To document the demographic profile of the study population and summarize the device's performance in the study setting.

MATERIALS AND METHODS

Study design and setting

This was a cross-sectional diagnostic validation and method-comparison study conducted at the C.R PARIKH BLOOD CENTER, KAPADWANJ, Gujarat, India. The study was designed to compare hemoglobin measurements obtained using the Tamiacs Digital Hemoglobinometer with those obtained using a reference laboratory method.

The study was carried out in 2026. Reference laboratory instrument/method: Sysmex XP 300. Both capillary and venous whole blood were used for the evaluation. All the protocols and procedures provided by the manufacturer were followed to perform the evaluation.

Table 1: Study population

Characteristic	Study value
Sample size	100 participants
Age range	15–74 years
Women	53 (53%)
Men	47 (47%)

Hemoglobin measurement procedure

Hemoglobin was measured using the Tamiacs Digital Hemoglobinometer according to the manufacturer's operating instructions. A paired measurement was obtained using the designated reference method. It uses both fresh capillary blood sample and venous blood sample for

hemoglobin estimation in blood samples. Sysmex XP 300 was used to measure the Hemoglobin levels.

The study was performed with capillary and venous blood samples. The samples were run on Tamiacs Digital Hemoglobinometer alongside Simultaneously the same venous blood sample was performed in Sysmex XP



300The results were recorded and compared.

Precision assessment

Analytical precision was assessed using repeated measurements and expressed as coefficient of variation (CV). The study reported a coefficient of variation of less than 3%.

Diagnostic accuracy assessment

Sensitivity and specificity were calculated by comparing the Tamiacs classification with the prespecified reference classification of anemia. The study reported sensitivity of 98.3% and specificity of 98.1%.

RESULTS

Participant characteristics

A total of 100 participants between 15 and 74 years of age were included in the

Bland–Altman analysis

Agreement between Tamiacs and the reference method was evaluated using the Bland–Altman approach. For each participant, the difference between the Tamiacs measurement and the reference measurement is plotted against their mean. The mean difference represents systematic bias, while the more than 95% limits of agreement are conventionally calculated as bias ± 1.96 times the standard deviation of the paired differences.

Using the reported lower and upper limits of agreement (-0.3 and +0.5 g/dL), the corresponding mean bias is calculated as $(-0.3 + 0.5) / 2 = +0.10$ g/dL. The implied standard deviation of the paired differences is approximately 0.20 g/dL.

reported study population. Women represented 53% of participants and men represented 47%.

Table 2: Diagnostic performance

Performance Parameter	Reported Result
Sensitivity	98.3%
Specificity	98.1%
Coefficient of variation	<3%
Bland–Altman lower LoA	-0.3 g/dL
Bland–Altman upper LoA	+0.5 g/dL
Calculated mean bias	+0.1 g/dL
Estimated SD of differences	≈ 0.20 g/dL

Precision

The reported coefficient of variation was less than 3%, indicating low relative variability under the study's precision-testing conditions.

Bland–Altman agreement

The Bland–Altman analysis demonstrated more than 95% limits of agreement from -0.3 to +0.5 g/dL. The mean bias calculated from these limits is +0.10 g/dL, indicating a small positive average difference when

the difference is defined as Tamiacs minus the reference method.

DISCUSSION

The present validation study evaluated the Tamiacs Digital Hemoglobinometer in 100 participants aged 15–74 years. The device demonstrated a reported sensitivity of 98.3% and specificity of 98.1% for the study's predefined anemia classification. The reported coefficient of variation was below 3%, supporting low measurement



variability under the conditions in which precision was assessed.

The Bland–Altman analysis showed limits of agreement of -0.3 to +0.5 g/dL. The midpoint of these limits gives a mean bias of +0.10 g/dL. A positive bias indicates that, on average, the Tamiacs value was higher than the reference value by approximately 0.1 g/dL, provided that the study defined the difference as Tamiacs minus reference. This slight overestimation trend closely mirrors historical evaluations of digital hemoglobinometers in Indian tertiary care setups, where new digital systems consistently recorded a small, clinically non-significant positive mean bias compared to reference Sysmex counters [3].

Interpretation of diagnostic performance

The reported sensitivity of 98.3% means that approximately 98.1% of participants classified as anemic by the reference standard were identified as anemic by the Tamiacs device. The reported specificity of 98.1% means that approximately 98.1% of participants classified as non-anemic by the reference standard were correctly classified as non-anemic by Tamiacs. These measures are dependent on the prespecified anemia definition and reference method and should therefore be interpreted in that context.

Clinical and operational relevance

A portable digital hemoglobinometer with rapid measurement capability may be useful where timely hemoglobin assessment is required. However, device performance should be interpreted alongside sample type, operator training, environmental conditions, quality-control procedures, patient population and the clinical decision thresholds used. To consistently mirror the strong precision seen across comparative Indian literature, operational care must be maintained during

sample collection; mitigating finger squeezing, discarding the initial blood drop, and maintaining regular hardware cleaning intervals are vital protocols to eliminate measurement outliers in point-of-care settings [4].

CONCLUSION

In the reported validation study conducted at the C.R PARIKH BLOOD CENTER, KAPADWANJ, the Tamiacs Digital Hemoglobinometer demonstrated sensitivity of 98.3%, specificity of 98.1%, and a coefficient of variation below 3%. Bland–Altman analysis demonstrated limits of agreement from -0.3 to +0.5 g/dL, corresponding to a calculated mean bias of +0.10 g/dL. These findings indicate close agreement with the reference method within the study conditions. Further multicenter validation using a larger sample and complete participant-level data would strengthen the evidence base.

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