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Performance Evaluation and Validation of Neodocs Hb Testing Point-Of-Care Device with Standard Laboratory Analyzer

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Abstract: ***Accurate Hb measurement is crucial for diagnosing and managing anemia. In India, anemia represents a significant public health crisis, affecting over 40% of the population and necessitating comprehensive interventions to address its widespread impact. In April 2018, the Indian Ministry of Health and Family Welfare launched the Anemia Mukt Bharat (AMB) strategy as a comprehensive national initiative to address and significantly reduce the substantial and pervasive public health issue of anemia within the country. Point-of-care testing (POCT) of anemia using digital hemoglobinometers and treatment is one of the primary interventions under AMB. To improve clinical decision-making and enable large-scale screening initiatives, our organization designed an innovative point-of-care Hb testing device that provides quick, accurate results. The analytical performance was assessed through a validation study performed at the Dr. Jariwala Laboratory, a NABL-accredited facility, ensuring the reliability and accuracy of the results. A total 3 batches with 30 samples provided capillary blood samples which underwent simultaneous analysis using the Neodocs (ND)- Hb device and a standard laboratory haematology analyzer (Mindray BC-780 Haematology System) to ensure accurate and comparable results. The device exhibited high precision and minimal variability across different hemoglobin ranges, demonstrating strength in detecting moderate-to-severe anemia. No significant operational errors or user-related issues were reported during the study, highlighting the device's usability in point-of-care settings. Further, the results were reproducible with maximum standard deviation 0.57, suitable for use on regular patient's sample.***

Keywords: Anaemia, Point of care device, Neodocs, Traditional analyzer, Validation

1. Introduction

Hemoglobin (Hb) is a vital biomarker for diagnosing, monitoring, and managing anemia and other haematological disorders, a global public health concern, particularly prevalent in low- and middle-income countries like India. The World Health Organization (WHO) reports that anemia affects around 1.92 billion people globally, with vulnerable groups like children, adolescent girls, and reproductive-age women being particularly affected (1). The government of India launched the "Anaemia Mukt Bharat (AMB)" initiative to reduce anemia prevalence across various demographic groups. The strategy includes iron and folic acid supplementation, deworming, behaviour change communication, delayed cord clamping, testing, and treatment. It also addresses non-nutritional causes like malaria and hemoglobinopathies (2). The initiative emphasizes large-scale, accurate, and timely screening for anemia, which presents challenges in rural and resource-limited settings due to skilled personnel, infrastructure, longer turnaround times, and logistical difficulties. According to AMB, Maharashtra states rank at fourth position for having patients with anaemia (3). Traditional hemoglobin measurement methods, like cyanmethemoglobin, automated haematology analysers, and colorimetric methods, are considered gold standards (4). However, these require well-equipped labs, stable electricity, temperature-controlled environments, and access to consumables. In community health programs like Anaemia Mukt Bharat, rapid, point-of-care hemoglobin estimation tools are crucial for immediate clinical decision-making and therapy initiation (5). Advances in medical technology have produced portable, user-friendly, and reasonably priced point-of-care (POC) devices that may deliver haemoglobin estimations in a matter of minutes. These devices are particularly helpful for healthcare professionals who work in rural places(6). However, to guarantee the accuracy, dependability, and usability of these devices and make sure they do not jeopardise clinical judgement and patient outcomes, thorough validation studies are required (7). The Indian Council of Medical Research (ICMR) and the World Health Organisation (WHO) advise using digital hemoglobinometers in basic health centres (where haematology analysers are not accessible) and community settings, and haematology analysers in secondary and tertiary care facilities (8). Haematology analysers have strong internal and external quality control mechanisms for accurate Hb estimate, even though they need a trained laboratory worker, space, the ideal temperature, electricity, and a lot of upkeep (9). In any event, POCTs are the practical and unavoidable option in remote locations lacking enough infrastructure or a skilled labour force. However, the convenience of use of POCT cannot come at the expense of complete quality assurance and standardisation for the precise and trustworthy measurement of Hb (10). Considering this, Neodocs (ND) has developed a cutting-edge haemoglobin testing device designed to deliver quick, precise, and

trustworthy findings at the point of care. The ND device requires minimal operator training and measures haemoglobin levels from capillary blood samples using cutting-edge optical and microfluidic technology. It is considered as a viable tool to support and enhance national anaemia control in AMB because of its portability, simplicity of use, low sample requirements, and quick turnaround time. However, a systematic validation study contrasting the device's performance with conventional laboratory-based haematology analysers is required to guarantee that it satisfies clinical standards and regulatory criteria. The study at Jariwala Laboratory aimed to validate the Neodocs Hb testing device by comparing Hb measurement with those from a standard laboratory haematology analyzer. The study involved a diverse participant population across different hemoglobin ranges to evaluate the device's performance in detecting normal, moderate, and severe anemia.

2. Materials and Methodology

Materials

A smartphone, Neodocs Hb Application, Neodocs Hb device, cuvette for blood collection, test sample, traditional Hb analyzer (Mindray BC-780 Haematology System), standard Hb measurement reagent

Study Design and Population

A prospective, cross-sectional validation study was conducted at Jariwala Laboratory in India, three lots of cuvettes were tested with a minimum of 30 individuals per batch.

Methodology

Sample collections

Capillary blood samples were collected using sterile cuvette, avoiding excessive squeezing or contamination. Two separate aliquots were prepared for immediate analysis with the Neodocs Hb testing device and for analysis using the laboratory's standard haematology analyzer.

1) Testing Procedure for Neodocs Hb testing device

Download the Neodocs application from Google play store/iOS APP store application and complete the setup process as mentioned in application. Insert the USB Hb testing device into the USB port of smartphone. Take the drop blood in using cuvette, and insert the cuvette in designated slot in the device. Click on start button to analyse the sample. The results will be instantly displayed on the application's dashboard.

2) Procedure for Reference method

Hemoglobin concentration from the same capillary sample was measured using a standard automated haematology analyzer, Mindray BC-780 Haematology System. The analyzer operates on the principle of absorbance photometry depending on the analyzer model. All procedures on the reference analyzer were performed by experienced laboratory technicians following the manufacturer's standard operating protocols.

Data collection

The results obtained from both the device and reference method were documented with ample information for statistical analysis

Statistical analysis

The statistical analysis was performed to evaluate the results given by ND device and reference method. The continuous variables such as means, standard deviation, coefficients of correlation, coefficient of variation and margin of error were analysed.

3. Results

A study involving 30 participants was successfully analyzed using ND Hb devices and traditional analyzer, Mindray BC-780 Haematology System, as mentioned in Table 1. Hemoglobin measurements obtained using the Neodocs device and the reference laboratory analyzer were highly consistent. The mean Hb value for ND Hb testing was found to be 12.97g/dL and 13.36 g/dL for reference analyzer.

Table 1: The summary of Hb testing analysis for ND Hb device and reference method

Sr. No.	Reference Hb values	Neodocs Hb Values		
		Lot 1	Lot 2	Lot 3
1	9.6	9.4	9	8.8
2	12.4	12	11.8	11.6
3	14.5	14.2	14.2	14.6
4	14.2	14.5	14.5	14.5
5	13.4	14.8	14.5	13.7
6	16.1	16.2	16	16.2
7	10.6	10.5	10.3	11
8	12.1	12	12	11.7
9	6.9	6.5	6	7.1
10	17	16.7	16.7	16.9
11	8.7	9	9	9
12	8.2	7.9	7.9	7.7
13	9.1	9.4	9	9.2
14	9.8	9.1	9.8	9.4
15	16.4	16.6	16.5	16.5
16	15.8	16	16.1	15.8
17	15.4	15.8	15.9	15.8
18	15	14.6	14.7	14
19	14.8	14.9	14.9	15.1
20	13.2	12.1	12.1	13
21	13.6	14	14.5	14.3
22	11.4	11.4	11.7	11.4
23	10.5	10.4	10.7	10.8
24	17.1	16.2	16	16.2
25	13.6	13	13.5	14.6
26	13.2	12.8	12.1	13.5
27	12.7	12.3	12.1	12.7
28	16.8	17	17	17
29	12.3	13.3	12.6	13
30	16.7	16.1	16.3	16.1

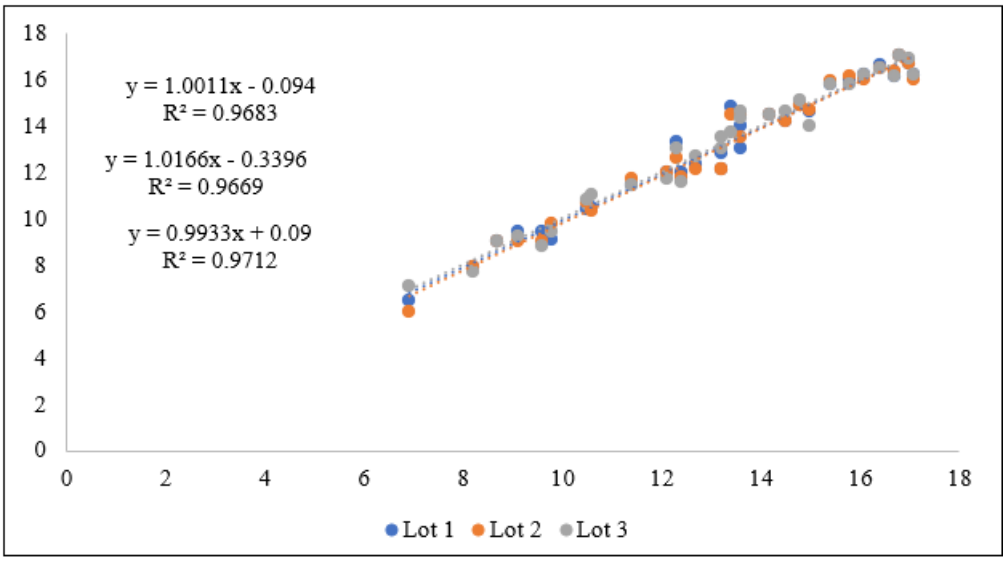

Figure 1: Coefficient of correlation graph for ND device for triplicate samples

A total of 30 participants were enrolled, covering a broad spectrum of hemoglobin concentrations ranging from 6 g/dL to 18 g/dL. The objective was to assess the device's accuracy and operational feasibility across different lots of manufacturing to ensure reproducibility and reliability. Hemoglobin measurements obtained from the Neodocs device were compared against the reference method using linear regression analysis. The coefficient of correlation (R^2) for Lot 1 was found to be 0.9683, for Lot 2 it was 0.9669, and for Lot 3 it was 0.9712. with standard deviation 0.52,0.57 and 0.49 respectively. The mean coefficient of correlation (R^2) was found to be 0.9688, standard deviation 0.52 with bias ±0.20, high R^2 values in all lots confirm the device's alignment with consistent results. Figure 1 shows tight clustering of data points and minimal scattering, bolstering quantitative validation findings. In terms of feasibility and convenience, the ND Hb device was easy and convenient to use at lab settings.

4. Discussion

The Neodocs Hb testing device has been validated, demonstrating strong correlation with traditional laboratory-based haematology analyser and confirming its suitability for clinical and field use. The device's high coefficient of correlation across three independent production lots and a pooled mean R^2 value of 0.9688 reflects its consistent accuracy across different manufacturing batches, highlighting the strong potential of the Neodocs device for widespread anemia screening programs. Compared to other commercially available POC hemoglobin devices. For context, similar validation studies have reported R^2 values ranging from 0.67 to 0.88 for various POC hemoglobin testing devices (11, 12). The operational advantages observed in this study include rapid testing time, minimal sample volume requirement, ease of use, and portability, making the Neodocs device more feasible for decentralized testing environments. The device's usability rating confirms its stability and reliability under routine operational conditions, critical for point-of-care diagnostics. The focus on validating the device across multiple production lots adds a high layer of confidence not often observed in early device validation studies, setting a high benchmark for quality assurance and regulatory compliance. Additionally, the device's alignment with the broader digital health ecosystem positions it well for future advancements in digital healthcare and anemia monitoring programs. However, certain limitations warrant acknowledgment, such as the study being conducted under controlled laboratory and semi-field conditions, and future studies focusing on specific vulnerable groups. Longitudinal studies assessing the device's performance over extended periods would also be valuable to confirm the durability and consistency of performance over time.

5. Conclusion

The Neodocs hemoglobin (Hb) testing device has been validated as a reliable and operationally feasible alternative to traditional laboratory-based methods. The device demonstrated strong linear correlation with the gold-standard analyzer, its rapid turnaround time, minimal sample volume requirement, ease of use, and high user satisfaction ratings make it an excellent solution for deployment in decentralized, low-resource, or community settings. The device also contributes to digital health transformation by enabling rapid data capture, potential integration with mobile health systems, and real-time reporting for public health monitoring. The device holds significant promise for enhancing anemia control strategies, improving maternal and child health outcomes, and contributing to the global fight against anemia-related morbidity. The Neodocs Hb device is poised to play a transformative role in the future landscape of anemia screening and management, particularly in underserved and marginalized communities.

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