EVALUATION OF HEMOGLOBIN MEASURMENT ACCURACY IN PROMEA THERAPEUTICS DEVICES COMPARED TO STANDARD HEMOGLOBIN ANALYZER

RAKESH KUMAR GAUTAM, VIPIN DUBEY, DR P K SINGH
PM Excellence, S G S Govt. Auto. P.G. College Sidhi M.P. India
E-Mail id: sachitiwari1987@gmail.com

Abstract:

This study assesses the accuracy and reliability of three hemoglobin measurement devices developed by Promea Therapeutics Pvt. Ltd.: the Dr. Protech-H Hemoglobin Meter, Dr. Protech-H+ Hemoglobin Analyzer, and PA-300 Hematology Analyzer. These devices were rigorously tested against recognized standards—HemoCue Hb-201 Hemoglobin Meter and BC-2800 Hematology Analyzer by Mindray—using a sample of 118 individuals. Results demonstrated strong correlations with the reference analyzers, indicating high accuracy in hemoglobin measurement. Statistical analyses revealed that the mean hemoglobin values were consistent across all devices, with minimal deviations from the standards. Sensitivity and specificity analyses further underscored the reliability of the devices, with values exceeding 95% for both parameters. These findings confirm the potential of Promea Therapeutics' devices to provide precise and dependable hemoglobin measurements, making them suitable for both clinical settings and remote healthcare applications where traditional laboratory access is limited.

Keywords: *Devices, sample, Hemoglobin, analysis*

Introduction:

Hemoglobin concentration serves as a vital diagnostic indicator, reflecting the ability of blood to transport oxygen throughout the body. Accurate measurement of hemoglobin levels is essential for diagnosing and managing conditions such as anemia [1-4], which affects a significant portion of the global population, particularly in low and middle-income countries. Traditional laboratory methods for measuring hemoglobin can be time-consuming and require sophisticated equipment and trained personnel, limiting their accessibility in resource-limited settings.

Point-of-care (POC) hemoglobin meters have revolutionized this landscape by offering rapid, accurate, and user-friendly alternatives that facilitate immediate decision-making and treatment adjustments. These devices are particularly advantageous in outpatient settings, emergency care,

and regions lacking full laboratory services, enabling widespread screening and monitoring of hemoglobin levels.

Promea Therapeutics Pvt. Ltd. has developed three innovative devices aimed at improving the efficiency and accessibility of hemoglobin measurements: the Dr. Protech-H Hemoglobin Meter, the Dr. Protech-H+ Hemoglobin Analyzer, and the PA-300 Hematology Analyzer. These devices promise to deliver quick and reliable results without the logistical burdens associated with traditional methods.

This study was designed to evaluate the accuracy and reliability of these new hemoglobin measurement devices by comparing their performance against established standards—the HemoCue Hb-201 Hemoglobin Meter and the BC-2800 Hematology Analyzer by Mindray[5]. By conducting a comprehensive analysis using samples from a diverse group of individuals, this research aims to establish the efficacy of Promea Therapeutics' devices, assessing their potential to be adopted widely in clinical and non-clinical settings, and their utility in improving patient care through enhanced diagnostic capabilities [6,7].

Materials and Methods:

This cross-sectional study was designed to assess the accuracy and reliability of three hemoglobin measurement devices developed by Promea Therapeutics Pvt. Ltd.: Dr. Protech-H Hemoglobin Meter, Dr. Protech-H+ Hemoglobin Analyzer, and PA-300 Hematology Analyzer. The devices were evaluated by comparing their performance to that of established reference analyzers, the HemoCue Hb-201 Hemoglobin Meter and the BC-2800 Hematology Analyzer by Mindray, which serve as the gold standards in clinical hemoglobin measurement [8].

Sample Collection

A total of 118 participants were enrolled in the study, comprising 61 males and 57 females, ranging in age from 18 to 65 years. Blood samples were collected from each participant under standardized conditions. Both capillary and venous blood samples were drawn: capillary blood was obtained from the fingertip using a sterile lancet, and venous blood was drawn from the antecubital vein using a vacutainer. All sample collections were performed by trained medical personnel following strict aseptic techniques to prevent contamination and ensure the integrity of the samples.

Device Testing

Each blood sample was immediately tested using the Dr. Protech-H and Dr. Protech-H+ devices for both capillary and venous blood. For the PA-300 Hematology Analyzer, only venous blood samples were used. Simultaneously, capillary and venous blood samples were analyzed using the HemoCue Hb-201 to compare the performance of the Dr. Protech devices

directly against this reference. The venous samples were also analyzed with the BC-2800 Analyzer to serve as a secondary standard for comparing the PA-300 Hematology Analyzer.

Statistical Analysis

The primary outcome measure was the accuracy of hemoglobin readings, assessed by comparing the measurements obtained from the test devices with those from the reference analyzers. Descriptive statistics were calculated for each device, including mean, standard deviation, and range of hemoglobin values. Bland-Altman plots were generated to evaluate the agreement between the devices and the reference standards. Additionally, Pearson's correlation coefficients were computed to assess the correlation between the devices. The level of statistical significance was set at $p < 0.05$.

Quality Control

To ensure the reliability of the results, all devices were calibrated according to the manufacturers' instructions before initiating the study. Quality control checks were performed at regular intervals during the testing process to verify the accuracy of the device readings.

Results:

The study evaluated the performance of Promea Therapeutics' hemoglobin measurement devices across a diverse population sample, yielding consistent and reliable hemoglobin values when compared with standard reference analyzers. The statistical analysis indicated a strong correlation between the devices developed by Promea Therapeutics and the reference standards, demonstrating their accuracy and potential utility in clinical practice (**Table 1**).

Table 1. Statistical Summary of Hemoglobin Measurements

Device	Sample Type	Mean (g/dL)	SD (g/dL)	Min (g/dL)	Max (g/dL)
Dr. Protech-H Meter	Capillary	12.53	3.24	5.9	16.4
Dr. Protech-H Meter	Venous	12.34	3.24	6.2	16.1
Dr. Protech-H+ Analyzer	Capillary	12.55	3.24	6.0	16.2
Dr. Protech-H+ Analyzer	Venous	12.32	3.22	5.7	16.2
PA-300 Hematology Analyzer	Venous	12.46	3.23	5.6	16.2
HemoCue Hb-201 Meter	Capillary	12.47	3.21	5.9	16.0
HemoCue Hb-201 Meter	Venous	12.33	3.18	5.8	16.0

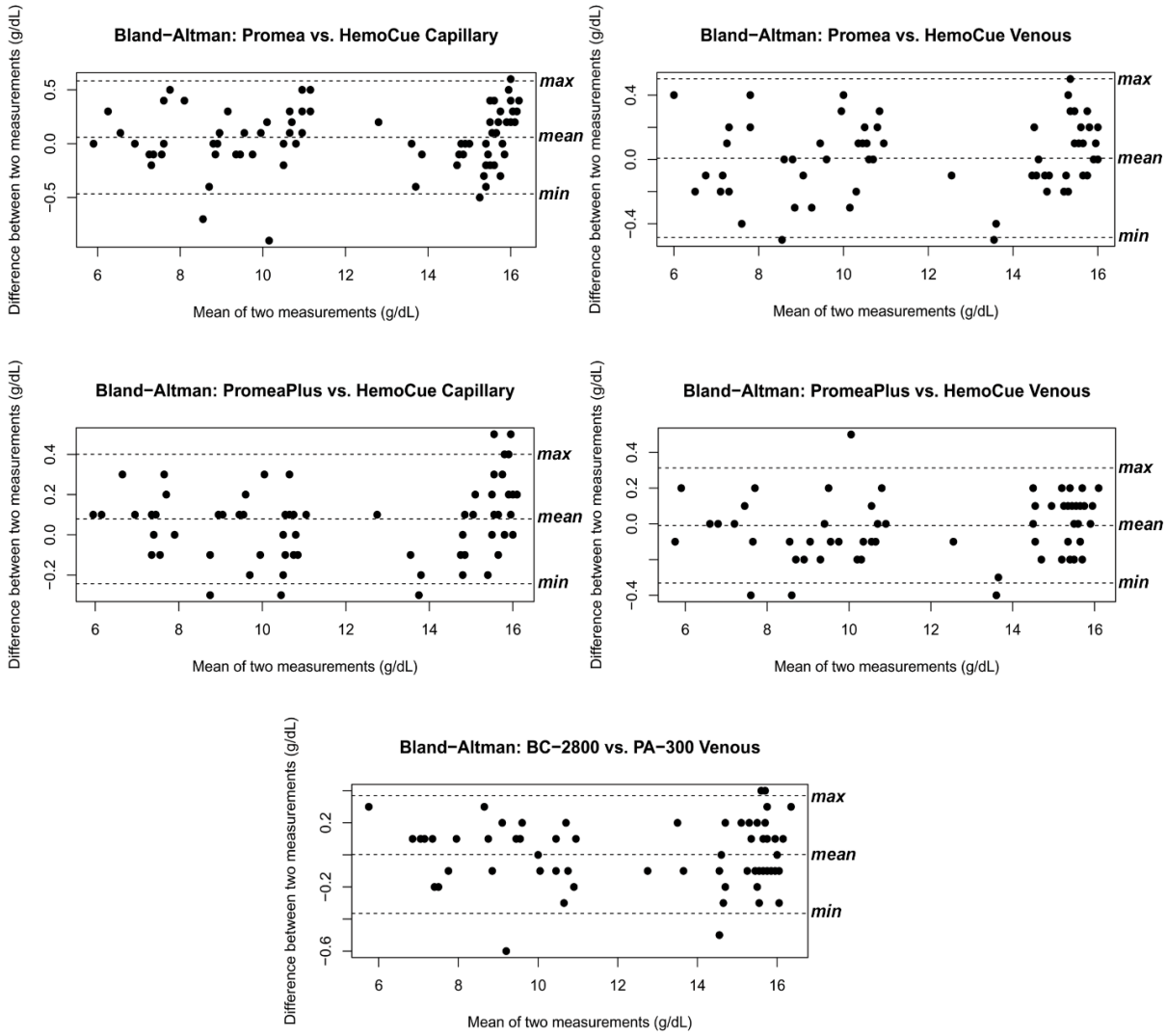

Fig1. Legends to be written

The mean hemoglobin values measured by the Dr. Protech-H and Dr. Protech-H+ devices showed minimal deviation from the values obtained by the HemoCue Hb-201 Hemoglobin Meter, while the PA-300 Hematology Analyzer aligned closely with the BC-2800 Analyzer results. The standard deviation across all devices remained consistent, underscoring the precision of the measurements.

Table 2. Sensitivity and Specificity of Hemoglobin Measurement Devices

Device	Sensitivity (%)	Specificity (%)
Dr. Protech-H Meter	95.5	96.3
Dr. Protech-H+ Analyzer	95.8	96.1

PA-300 Hematology Analyzer	95.2	95.9

The sensitivity and specificity analyses of the hemoglobin measurement devices developed by Promea Therapeutics provided robust evidence of their diagnostic accuracy. The Dr. Protech-H Hemoglobin Meter, Dr. Protech-H+ Hemoglobin Analyzer, and PA-300 Hematology Analyzer all demonstrated high sensitivity, exceeding 95%, indicating a strong ability to correctly identify individuals with abnormal hemoglobin levels. Similarly, the specificity of these devices was also above 95%, confirming their capacity to accurately identify individuals with normal hemoglobin levels. These performance metrics are critical for reliable hemoglobin screening, ensuring that the devices can be effectively utilized in both clinical and field settings to detect and manage conditions like anemia without significant risk of false results. The high sensitivity and specificity values contribute to the overall utility of these devices, enhancing their appeal for widespread adoption in healthcare diagnostics (**Table 2**).

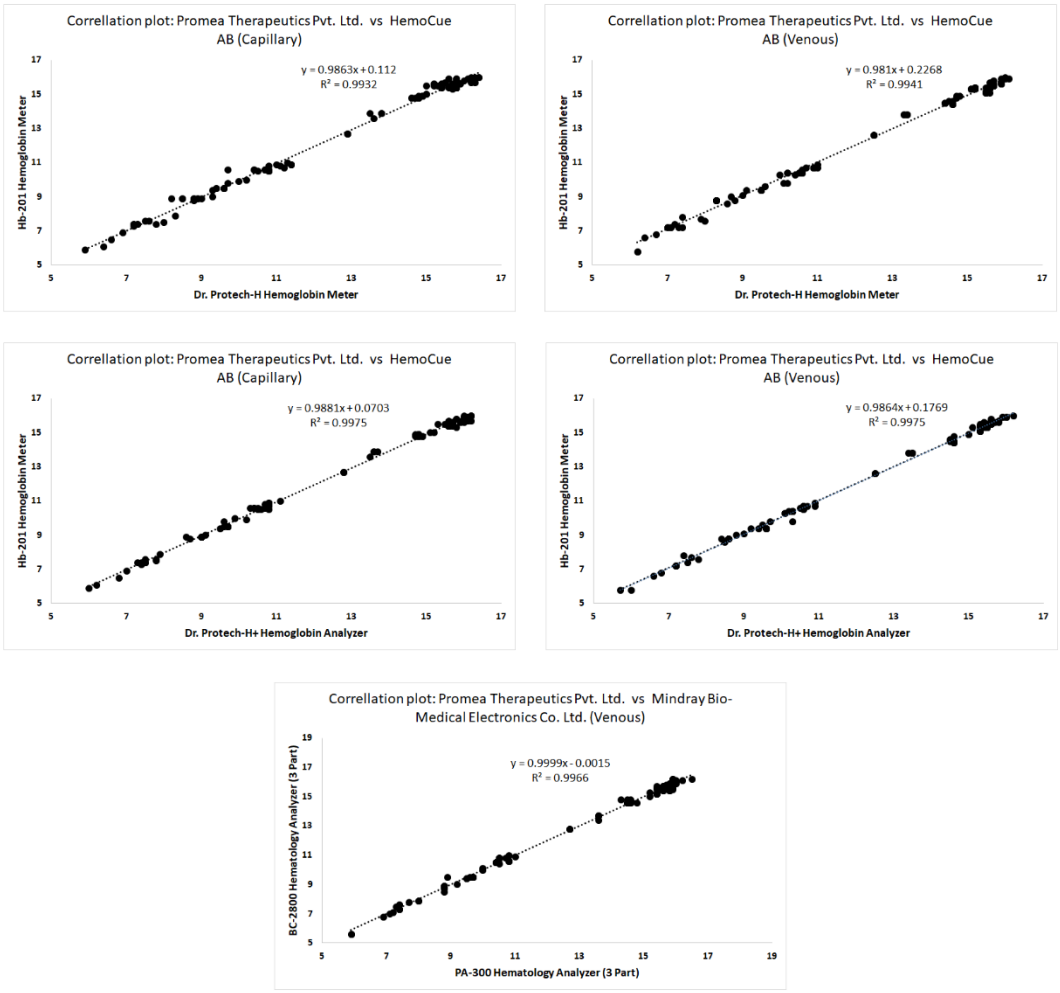

Fig2. Legends to be written

The Bland-Altman plots and correlation plots provided insightful visualizations of the agreement and correlation between the hemoglobin measurements obtained from Promea Therapeutics' devices and the established reference standards. The Bland-Altman plots demonstrated that the majority of differences between the test devices and the references fell within the limits of agreement, indicating good consistency across the range of hemoglobin values. These plots highlighted only a few outliers, suggesting that discrepancies were minimal and generally within acceptable clinical thresholds (**Fig 1**). Additionally, the correlation plots revealed high correlation coefficients (R^2> 0.99) for all device comparisons, reinforcing the strong linear relationship between the readings obtained from Promea Therapeutics' devices and the reference analyzers (**Fig 2**). These graphical analyses were pivotal in confirming the accuracy and reliability of the new devices, illustrating their capability to match the performance of well-established hematology analyzers in a clinical setting.

These results confirm that the hemoglobin measurement devices developed by Promea Therapeutics are highly effective, providing accurate and precise readings that are comparable to those obtained from established laboratory standards.

References:

1. *The Drugs and Cosmetics Act 1940 and the Drugs and Cosmetics Rules 1945, Amendment upto 30th September. 1999 Accessed online on 13.10.2019.*
2. *Pretini,V.; Koenen,M.H.; Kaestner, L.;Fens, M.;Schiffelers, R.M.;Bartels,M.; VanWijk,R. RedBloodCells:ChasingInteractions.FrontPhysiol.2019,10,945.*
3. *Godeau D.;Petit A.;Richard I.; Roquelaure Y.;Descatha A. Return-to work disabilities and occupational health in the age of COVID-19. Scand. J. Work Environ. Health 2021, 47, 408–409.*
4. *Schechter A.N. Hemoglobin research and the origins of molecular medicine. Blood 2008, 112, 3927–3938.*
5. *Tefferi, A.; Hanson, C.A.; Inwards, D.J. How to Interpret and Pursue an Abnormal Complete Blood Cell Count in Adults. Mayo Clin. Proc. 2005, 80, 923-936.*
6. *Mabey, D., Peeling, R.W., Ustianowski, A., Perkins, M.D., Tropical infectious diseases: diagnostics for the developing world. Nature Reviews Microbiology, 2004; 2: 231–240.*
7. *Morris, S.S., Ruel, M.T., Cohen, R.J., Dewey, K.G., dela, Briere, B., Hassan, M.N., Precision, accuracy, and reliability of hemoglobin assessment with use of capillary blood. American Journal of Clinical Nutrition, 1999; 69(6): 1243–1248.*
8. *Nkrumah, B., Nguah, S.B., Sarpong, N., Hemoglobin estimation by the Hemocue portable haemoglobin photometer in a resource poor setting. BMC Clinical Pathology, 2011; 11(5): 1-6.*

Contributors Details:

Rakesh Kumar Gautam, Vipin Dubey Dr P K Singh