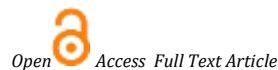


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Research Article

Assessment and Authentication of Promea Therapeutic's Indigenous Digital Hemoglobin Analyzer (Dr. Protech H+)

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Abstract



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Haemoglobin estimation is an important screening test for patients. Despite many methods available, each method has some advantages and disadvantages. Hemoglobin estimation by digital Hemoglobin Meter proved to be a very reliable, sophisticated, appropriate and ideal especially for some particular setup like blood donation / premedical screening and also reliable in comparison to hematology analyzer. Materials and Methods: A study of 350 Single donor platelet donors to evaluate a Promea's Digital Hemoglobin Analyzer (Dr. Protech H+) was done in a laboratory from November 2022 to December 2022 and data were compared to Sysmex KX 21 cell counter which is one of the most accurate methods for Haemoglobin estimation. Out of 350 donors 247 were male and 103 were female. Mean value of Promea's Digital Hemoglobin Analyzer (Dr. Protech H+) (mean 14.0 g/dl) was slightly lower by 0.2 compared to reference (mean 14.2 g/dl) but not statistically significant. In comparison to cell counter Promea's Digital Hemoglobin Analyzer (Dr. Protech H+) proved to be the cost effective with sensitivity and specificity more than 95%. which indicates high precision. Conclusion: Promea's Digital Hemoglobin Analyzer (Dr. Protech H+) gives comparable results to cell counter and hence proved to be reliable, easy to operate and cost effective.

Keywords: Haemoglobin, DIGITAL Hemoglobin Meter, Promea's Digital Hemoglobin Analyzer

INTRODUCTION

Hemoglobin screening is among the first and foremost tests done for patients/ blood donors' selection with the main intention of preventing blood collection from an anemic donor¹. Blood donors represent the normal population hence hemoglobin estimation in blood donor also analyze the prevalence of anemia in the study population. It is therefore essential, that there should be an accurate and reliable method for hemoglobin determination². According to the Indian Drugs and Cosmetics Act, 1940 for blood donation, the minimum acceptable hemoglobin (Hb) is 12.5 g/dl or hematocrit (Hct) of 38% for both males and females³. Single donor platelet aphaeresis is one of the specialized procedure in which also the selection criteria mandate hemoglobin and usually all the blood bank follows the prior testing of TTI hence sample collection done in EDTA tube also and CBC testing for all donors done⁴. Number of manufacturers provides digital hemoglobin metre which is one of the most user-friendly devices for blood bank staff which provide sophistication also^{5, 6}. Here in this study we have evaluated one of such devices Promea Therapeutics's Digital Hemoglobin Analyzer (Dr. Protech H+) & Cuvettes and compare it to hematology cell counter readings.

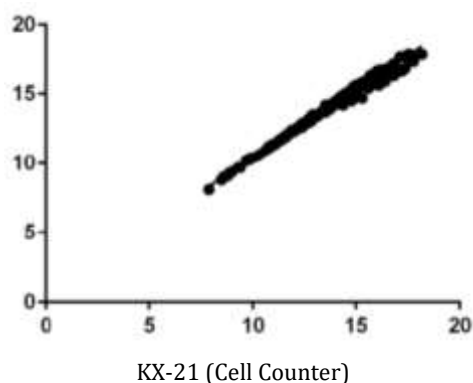
MATERIALS AND METHODS

A study of 350 Blood Samples was conducted to evaluate a digital Promea Therapeutics's Digital Hemoglobin Analyzer (Dr. Protech H+) was done at DKM Diagnostic Centre, Jaipur

from November 2022 to December 2022 and data were compared to Sysmex KX 21 hematology cell counter which is one of the most accurate methods for hemoglobin estimation. Out of 350 samples 247 were male and 103 were female. Samples were already collected to test, and same sample were used immediately on the hemoglobin analyzer and in parallel, once it was run in cell counter^{7,8}.

Usually most of the study of such kind, evaluate between capillary blood and venous blood as for Digital Hemoglobin Metre use mainly capillary blood but here in our study we evaluate this device by using venous blood which was prior used in cell counter, hence given direct evaluation of the device^{9,10}.

The values for hemoglobin ranges from 7.2 g/dl to 19.8 g/dl. Mean value of Promea Therapeutics's Digital Hemoglobin Analyzer (Dr. Protech H+) (mean 14.0 g/dl) was slightly lower by 0.2 compared to reference (mean 14.2 g/dl) but not statistically significant. Promea Therapeutics's Digital Hemoglobin Analyzer (Dr. Protech H+) proved to be cost effective with very good sensitivity and specificity both more than 95%. R square value is 0.9897 which indicates high precision (Figure-1). Study shows 95% Confidence Intervals and limit of agreement is between -0.2 to 0.3.



Promea Therapeutics's Digital Hemoglobin Analyzer (Dr. Protech H+) has been evaluated for the first time so here we have to refer similar study on other devices. Promea Therapeutics's Digital Hemoglobin Analyzer (Dr. Protech H+) is handy, light weight, very easy to carry, working on absorbance photometric principal. Its battery as well as direct power operated. Measuring range is 0-25g/DL, can give reading within 10 seconds, less than 10 micro litre sample size needed. The reference method we used is also standard for many studies and time tested based on the same principle of photometric absorbance that KX 21(Sysmex). Gómez-Simón et al evaluated the performance of three PHs (HemoCue, STAT-Site MHgb and CompoLab HB system) and attributed the inaccuracy in their performance mainly to the use of capillary blood. Tondon et al also evaluated another device hemocue and concluded that such devices can be used to confirm donor deferral in economically restricted country like India. All these studies describe pros and cons of different methods.

CONCLUSION

Promea Therapeutics's Digital Hemoglobin Analyzer (Dr. Protech H+) gives comparable results to cell counter in hospital, Laboratory and Blood Bank Settings.

REFERENCES

1. The Drugs and Cosmetics Act 1940 and the Drugs and Cosmetics Rules 1945, Amendment upto 30th September. 1999.
2. Gómez-Simón A, Navarro-Núñez L, Pérez-Ceballos E, et al. Evaluation of four rapid methods for hemoglobin screening of whole blood donors in mobile collection settings. *Transfus Apher Science* 2007; 36(3):235-242. <https://doi.org/10.1016/j.transci.2007.01.010>
3. Rashmi Tondon, Anupam Kumar Verma,, Quality evaluation of four hemoglobin screening methods in a blood donor setting along with their comparative cost analysis in an Indian scenario, *Asian Journal of transfusion science*, 2009
4. Chaudhary R, Dubey A, Sonker A, Techniques used for the screening of hemoglobin levels in blood donors: current insights and future directions *Journal of blood medicine*, 2017; 8:75-88 <https://doi.org/10.2147/JBM.S103788>
5. Toppo M, Pal DK, Gour D, Melwani V, DubeyM , MishraA, Comparison of Performance of Digital Hemoglobinometer over Automated Hematology Analyzer for Hemoglobin Estimation and Its user friendliness among the Pregnant Women in Selected District Hospitals of Madhya Pradesh. *ijcm.org.in* on Monday, November 25, 2019,
6. Sawant RB, Bharucha ZS, Rajadhyaksha SB. Evaluation of hemoglobin of blood donors deferred by the copper sulphate method for haemoglobin estimation. *Transfus Apher Sci.* 2007; 36(2):143-148. <https://doi.org/10.1016/j.transci.2006.11.001>
7. Lee, S.J., Stepniewska, K., Anstey, N., The relationship between the haemoglobin concentration and haematocrit in plasmodium Falciparum malaria. *Malaria Journal*, 2008; 7(149):1-4. <https://doi.org/10.1186/1475-2875-7-149>
8. 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. <https://doi.org/10.1038/nrmicro841>
9. 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. <https://doi.org/10.1093/ajcn/69.6.1243>
10. 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. <https://doi.org/10.1186/1472-6890-11-5>