



Assessment And Authentication Of Promea Therapeutic's Indigenous Digital Hemoglobin Meter (Dr. Protech H) In Comparision With The Results Of Hematology Analyzer

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Abstract: Hemoglobin 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 Meter (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 Hemoglobin estimation. Out of 350 donors 247 were male and 103 were female. Mean value of Promea's Digital Hemoglobin Meter (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 Meter (Dr. Protech H) proved to be the cost effective with sensitivity and specificity more than 95%. This indicates high precision. Conclusion Promea's Digital Hemoglobin Meter (Dr. Protech H) gives comparable results to cell counter and hence proved to be reliable, easy to operate and cost effective.

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 donor [1]. 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 determination [2]. 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 females [3]. 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 done [4]. Number of manufacturers provides digital Hemoglobin Meter 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 Meter (Dr. Protech H) & Strips 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 Meter (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 Meter 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 Meter 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 value for hemoglobin ranges from 7.2 g/dl to 19.8 g/dl. Mean value of Promea Therapeutics's Digital Hemoglobin Meter (Dr. Protech H) (mean 14.3 g/dl) was slightly higher by 0.1 compared to reference (mean 14.2 g/dl) but not statistically significant. Promea Therapeutics's Digital Hemoglobin Meter (Dr. Protech H) proved to be cost effective with very good sensitivity and specificity both more than 95%. R square value is 0.9767 which indicates high precision. Study shows 95% Confidence Intervals and limit of agreement is between -0.3 to 0.3.

Promea Therapeutics's Digital Hemoglobin Meter (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 Meter (Dr. Protech H) is handy, light weight, very easy to carry, working on reflectance spectroscopy principal. Its battery as well as direct power operated. Measuring range is 0-25g/DL, can give reading within 10 seconds, less than 10 microlitre 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). All these studies describe pros and cons of different methods.

CONCLUSION

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

With a sensitivity of 95.2% and specificity of 95.4%, Promea Therapeutics's Digital Hemoglobin Meter (Dr. Protech H) performance is suitable for Hb testing in large population

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