



Estimation and data interpretation of Hemoglobin levels between HemoSpark hemoglobin meter and Automated Hematology Analyzer

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Abstract

Background: Hemoglobin (Hb) is considered to have a vital role in human's body as it carries oxygen from lungs to the body's tissues and return carbon dioxide from tissues back to lungs. Estimation of Hb level is an important step for any blood analysis. Hb levels usually indicate that a person has anemia or not. A portable meter is required for estimating the Hb levels at any clinical lab or at door step by a range of healthcare personnel. This study was performed to conclude that the estimation of Hb levels obtained using a portable HemoSpark Hemoglobin meter are accurate in comparison with automated Hematology analyzer .

Objective: To estimate the accuracy of hemoglobin in HemoSpark Hemoglobin meter against Automated Hematology analyzer using the same sample at the same time. This experiment was performed in City Multi-speciality Hospital which is NABL accredited.

Materials and Methods: In this study, we have proposed a HemoSpark meter and Automated hematology analyzer for the estimation of hemoglobin levels with the classification of Anemia based on blood test.

Blood samples of 405 adult patients and 46 children (<15 Yrs) between Nov 2020 to Feb 2021 attending City Multi-speciality Hospital were collected in EDTA tubes. Samples were properly mixed using a blood mixing equipment. These blood samples were performed simultaneously in HemoSpark hemoglobin meter and Hematology analyzer for data interpretation.

Results: Data interpretation of HemoSpark vs. the reference laboratory method (Sysmex XP 300) was found to be very good with a value of 0.97. Based on the statistical analysis, more than 97% readings of HemoSpark were within + 0.5 g/ dl.

Conclusion: Hemoglobin concentration estimated by HemoSpark has shown very good correlation with automated hematology analyzer Sysmex XP 300.

When Haemoglobin is the only test required, portable hand held Digital Hemoglobin meter like HemoSpark is more cost effective than bench top hematology analyzer..

Its data interpretation had made it suitable for point of care haemoglobin testing.

INTRODUCTION:

Hemoglobin tests are done to know the RBC count, to analyze the severity of anemia, hematocrit, and others. It is extensively used during blood donations or taking important decisions like blood transfusions. Hemoglobin meters are used to screen and diagnose diseases that might affect the red blood cells or to know the hemoglobin value in the blood. Monitoring the optimal hemoglobin levels is important to check the anemic condition in children and in adults can lead to several other diseases in the human body.

The reference normal ranges of hemoglobin levels as per WHO guidelines are as follows

Age or gender group	Hemoglobin threshold g/dl
Children (0.50-4.99 yrs.)	11.00
Children (5.00-11.99 yrs.)	11.50
Children (12.00-14.99 yrs.)	12.00
Non-pregnant women (\geq 15 yrs.)	12.00
Male (\geq 15 yrs.)	13.00

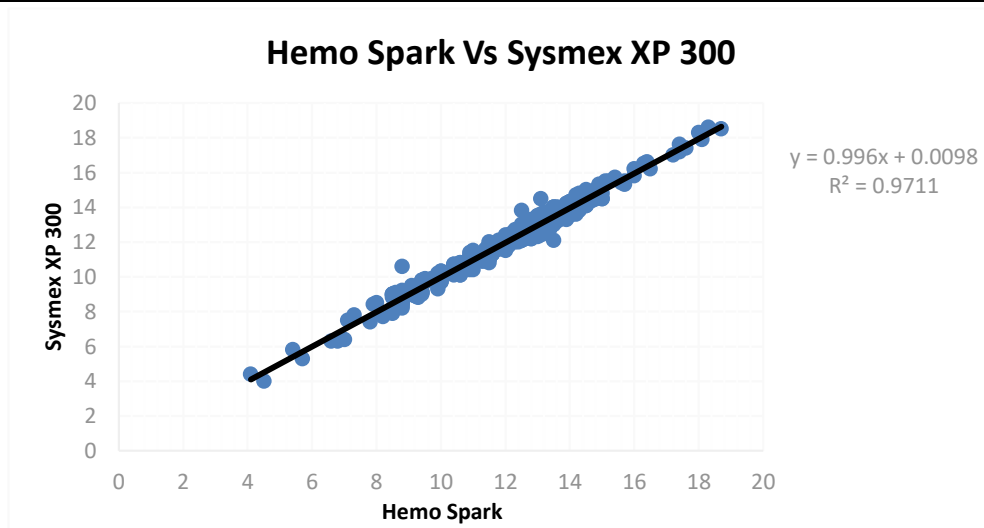
MATERIALS AND METHODS

Hematology Analyzer works on flow cytometry & photometric principal to measure the Hemoglobin. This instrument (Sysmex XP 300 Automated Hematology analyzer) has been proved to provide accurate and reliable results of Hemoglobin and other parameters. HemoSpark meter is a portable digital diagnostic device that utilizes fresh capillary whole blood samples or venous blood sample to measure hemoglobin levels. It is developed & manufactured by Sensa Core Medical instrumentation Pvt Ltd, India. It works on the principle of Reflectance Photometry.

Total 451 samples were tested with Sysmex XP 300 Automated Hematology Analyzer and HemoSpark meter by 2 different technicians who had recorded results against Lab Id which is not dependent on hemoglobin concentration. Out of 451-Total 339 were Female & 112 were Men. Out of these 451- 405 were adults and rest 46 were children and adolescents.

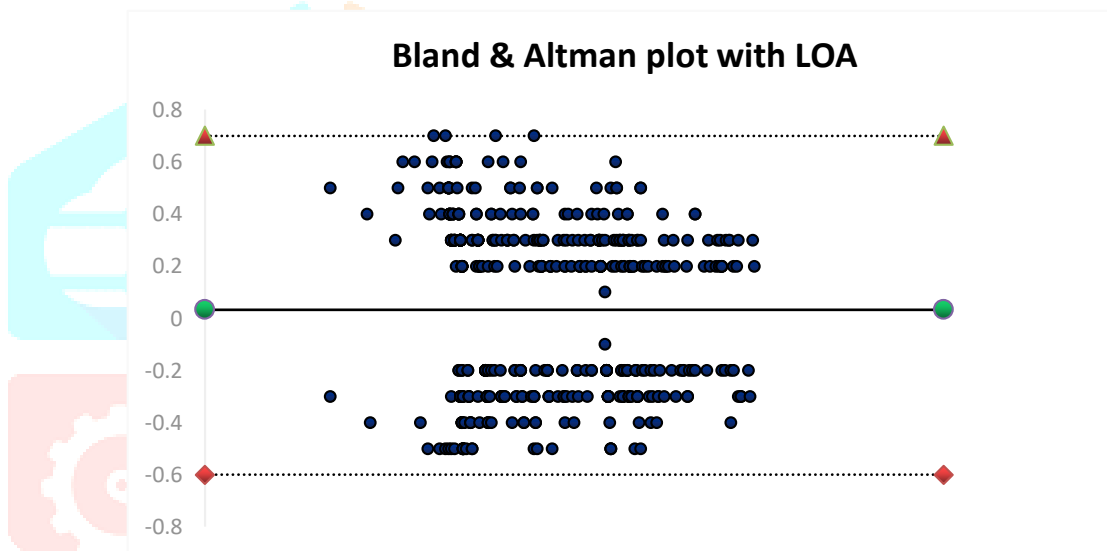
Statistical Analysis of performance of HemoSpark

In this study, hemoglobin values ranged from 4.1 to 18.7 g/dl with mean of 11.76 g/dl with a Standard Deviation of 0.49 g/dl. Mean Bias was -0.012 g/dl and SD of error was 0.36 g/dl.



Graph 1: Scatter plot of HemoSpark and Sysmex values.

Correlation Coefficient (r) was found to be 0.98 with equation $y=1.006x$



Graph 2: Bland & Altman Plot.

Bland & Altman analysis shows

Bias=0.049 g/dl

Upper LOA= 0.75 g/dl

Lower LOA= -0.65 g/dl

LOA is limits of Agreement

Statistical Analysis was performed using below table

Anemia defined by Sysmex XP 300 Automated Hematology Analyzer results			
		Present (n)	Absent (n)
HemoSpark	Positive	234 (True +ve)	11 (False -ve)
	Negative	9 (False +ve)	197 (True -ve)

Sensitivity : True Positive/ (True positive + False negative)= $234/(234+11)= 95.5\%$

Specificity : True Negative/ (True negative + False positive)= $197/(197+9)= 95.6\%$

Positive Predictive Value (PPV)= True Positive / (True Positive + False positive)= $234/(234+11)= 96.2\%$

Negative Predictive Value (NPV)= True negative/ (True Negative + False Negative)= $197/(197+9)= 94.7\%$

RESULTS AND CONCLUSION

Hemoglobin levels estimated using HemoSpark meter in comparison with Sysmex XP 300 Automated hematology analyzer has a significant data correlation with respect to accuracy, sensitivity and specificity. With the Statistical data analysis we got a good correlation coefficient value of 0.98. The Bland & Altman plot analysis showing limits of agreement at 0.7 g/dL and - 0.6 g/dL gives credibility to HemoSpark precision with accuracy.

A sensitivity of 95.5% and specificity of 95.6% HemoSpark meter performance is suitable for Hemoglobin testing in large population for screening, diagnosis and monitoring of anemia.

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