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Evaluation of a Point-of-Care Diagnostic HemoQR: A Hemoglobin Detection Kit in a Cohort of 500 Patient Samples in Comparison with Gold Standard

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Abstract:

- ***Background:***

A chronic and large level global health concern, anemia disproportionately affects those living in low-resource environments. The performance of a new point-of-care (POC) hemoglobin (Hb) detection system is examined in this study using 500 patients. Rapid Hb readings was performed by this POC device, which amalgamates the smartphone technology with a biodegradable paper-strip approach.

- ***Methods:***

We have compared two devices Device A (HemoQR) and Device B [Hematology Analyzer- Fully Automated-3 Parts (ERBA H 360)] in multiple primary healthcare center's (PHCs) in a district in Maharashtra, India using 500 samples from patients of different age groups using fingertip pricked blood for the test to monitor Hb.

- ***Results:***

As the result of this study qualifies the criteria of Anemia Mukt Bharat (AMB) program initiated by the Government of India which requires a sensitivity and specificity of more than 80% for invasive digital hemoglobinometer for the determination of Hb levels in blood. In context to our device A was able to obtain sensitivity, specificity and accuracy of around 90.19%, 97.60% and 96.15% respectively in this study using 500 live samples.

- ***Conclusion:***

The study concludes that HemoQR can be an efficient, economical and smart POC Hb detection test system using a mobile based application for analyzing Hb levels in all kind of medical setup and it can also help in collecting and analyzing the data for monitoring purposes.

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I. INTRODUCTION

Anemia is an abnormality in human body which is characterized by insufficient hemoglobin (Hb) in the blood which contributes a significant count to global morbidity and mortality rates. According to the Global Burden of Disease Study, anemia affects over 1.9 billion people worldwide, with the highest prevalence observed in low- and middle-income countries (Collaborators, 2023). The populations which are the worst hit by this abnormality are pregnant women, children, and those with chronic health conditions (RJ, 2003). Anemia also impacts on the physical and cognitive development, particularly among children in their developmental stage, which underscores the importance of early rapid and accessible screening tools for Hb level detection (E. McLean, 2009).

Point-of-care (POC) testing has gained increasing attention in the healthcare industry, offering the potential to deliver timely and cost-effective diagnostic services closer to the patient (Price, 2014). One such innovative POC solution is the HemoQR, which is a detection kit designed to provide rapid and accurate measurements of hemoglobin levels. This study aims to evaluate the performance of the HemoQR in a cohort of 500 patients, assessing its clinical utility and potential impact on patient care (Chakraborty, 2025).

POC diagnostics have been recognized for their ability to enable quicker medical decision-making and facilitate early disease detection, leading to improved health outcomes for patients (Cheng, 2020) (Price, 2014). The development of advanced biosensors, microfluidic technologies, and complementary analytical platforms has driven the rapid progress in this field. (Cheng, 2020) (Vashist, 2017).

This study is the 6th study to assesses the efficacy of a novel POC Hb detection system, HemoQR that combines a reagent-free, cellulose-based paper strip with a smartphone application. By eliminating the need for reagents and leveraging digital technology, this approach aims to enhance accessibility and ease of use while maintaining high diagnostic accuracy.

II. MATERIALS AND METHODS

The research was conducted at various Primary Healthcare Centre's (PHCs) with a sample size of 500 patients. The samples were simultaneously run on Haematology Analyzer-Fully Automated- 3 Parts [ERBA H 360]. Participants were from rural center, to ensure a representative sample of different demographics, including age, gender, and anemia risk profiles. Ethical approval was granted by the District Health Officer of Beed District, Maharashtra, India and written informed consent was obtained from all participants.

The POC Hb detection device employs a cellulose-based paper strip engineered for blood absorption and rapid color change. Blood samples collected via a finger prick were applied to the paper strip, which was then scanned using a smartphone application (compatible with both Android and IOS operating system). The application is developed using advanced machine learning algorithms to interpret the colorimetric reaction and estimate Hb levels, accounting for external variables such as lighting and camera angle.

- *Study Design*

A comparative study was conducted at four different PHCs (Chusala, Nalwandi, Mominpura, Limba Ganesh, Sakshal Pimpri, Peth Beed) in Beed which is a district in Maharashtra, India. The study was done in four phases. The main aim of all the phases were to conduct field test with diagnostic accuracy of HemoQR. The study aimed at determining the performance and easy to use aspects of HemoQR in comparison to the gold standard.

- *Study Settings*

This study of our device HemoQR determines accuracy, sensitivity and specificity against gold standard. We have selected primary healthcare centers in rural areas for all the phases of this study. The studies were performed by taking all the relevant permission from the head of the department.

- *Test Method*

The two test methods used for two different devices in which test was performed. Device A was the HemoQR device, and the Device B was Haematology Analyzer-Fully Automated-3 parts (ERBA H 360). The HemoQR is a Hb detection kit used to measure Hb as the standard procedure, it has been shown that HemoQR can provide accurate Hb concentration from our previous analysis from different medical and laboratory setups. The technology of determining the Hb level by HemoQR initiates by capturing the image of the test strip which is taken using the smartphone's camera. The camera has been integrated with the analysis properties of our SmartQR technology with a post processing algorithm in our application named HemmoQR. SmartQR application plays an important role in ensuring that the captured image is stabilized across various devices. This stabilization is achieved through a sophisticated algorithm that compensates for any inconsistencies in lighting, angle, and other environmental factors, ensuring that the image quality remains high and consistent.

On the other hand, Haematology Analyzer-Fully Automated-3 parts (ERBA H 360) is an automated blood cell counter intended for in vitro diagnostic use in clinical laboratories. It measures the Hb concentration using a non-cyanide Hb method. The instrument has been proven to provide accurate and reliable results including Hb concentrations. The test is performed by collecting 2 ml of blood in an EDTA vial using disposable syringe under all

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aseptic precautions. Simultaneously, 10 µl capillary blood was collected by finger prick and applied on the test strip and an image was uploaded of the blood-stained strip on the HemoQR mobile application, to get the Hb value. The test is performed as stated in the manufacturer's manual. In separate data collecting forms, the technician and supervisor each recorded the outcomes. An impartial observer made sure that the supervisor and technician did not discuss their findings with one another. All pointed objects were gathered and discarded in accordance with approved practices.

- *Main Outcomes*

The diagnostic accuracy of HemoQR, was determined in terms of sensitivity, specificity and accuracy against the gold standard method.

- *Sample Size*

Sample for the four phases were considered according to the prevalence of anaemia which was around 50% (Neogi, 2016). The sensitivity and specificity were determined according to the AMB program. A sample size of 500 was considered adequate to assess the diagnostic and prevalence accuracy of the devices.

- *Quality Assurance and Data Collection*

All the study staffs were well trained for the data collection process and operation of all the three devices. The centre had the head of the department along with investigators, technical experts from SmartQR. The samples were assessed properly under strict invigilation.

- *Ethical Consideration*

From all the patients written informed consent was taken. The acquired information was not accessible to everyone apart from the core research team. Approval was also obtained from IIT, Kharagpur, ethical committee.

- *Patient and Public Involvement*

The study and the research work were done completely without the involvement of patients. The patients were not given any insight or were not invited to give any comments, contributing to the writing/editing on the design of the study or even writing this manuscript.

III. RESULTS

The outcomes of the clinical trial demonstrated that the device exhibited both accuracy and reliability across varying levels of Hb only after simultaneously running the 500 Samples on Device A (HemoQR), Device B [Haematology Analyzer- Fully Automated-3 Parts (ERBA H 360)]. In the table 1, the data from Device B has been considered as gold standard and we have considered the true positive (TP) as patients having Hb levels less than 11 g/dL which was around 92 and patients with Hb levels more than 11 g/dL to be true negative (TN) and that was calculated to be 408. On the basis of Device B, we have separately calculated the false positive (FP) and false negative (FN) of Device A. Table-2 shows the FP and FN values of Device A. This helped us to further calculate the sensitivity, specificity and accuracy of Device A. Specifically, we reveal that HemoQR is capable of accurately identifying anemia, achieving a sensitivity of 90.19% and a specificity of 97.60%. Furthermore, a significant majority, at 96.15% of accuracy, of the readings obtained from HemoQR fell within 1 g/dL of the measurements provided by the fully automated haematology analyser- 3 Parts (ERBA H 360). To give a further graphical representation we have showed in Fig.1 Highlighted Error Bar from Device A and Device B. We have taken Lab Values on the 'Y' axis and the Sample Index is taken on 'X' axis. From the graph we could predict that lab readings with error bars, highlighting deviations greater than ±1 in red. In Fig.2 the scattered plot graph showed a similar result where the readings of Device A were plotted on to 'Y' axis and the Device B reading was plotted on 'X' axis. The results showed that the Device A and B showed similar readings with minor differences in the reading for some samples.

Table-1: Data of TP and TN from Device B

Device B [Hematology Analyzer]	True Positive (TP)	True Negative (TN)
	92	408
	Total Number of Patients – 500	

Table-2: FP, FN and Total number of patients analyzed by Device A

Device	Device A (HemoQR)
False Positive	10
False Negative	10
Total Number of Patients	500

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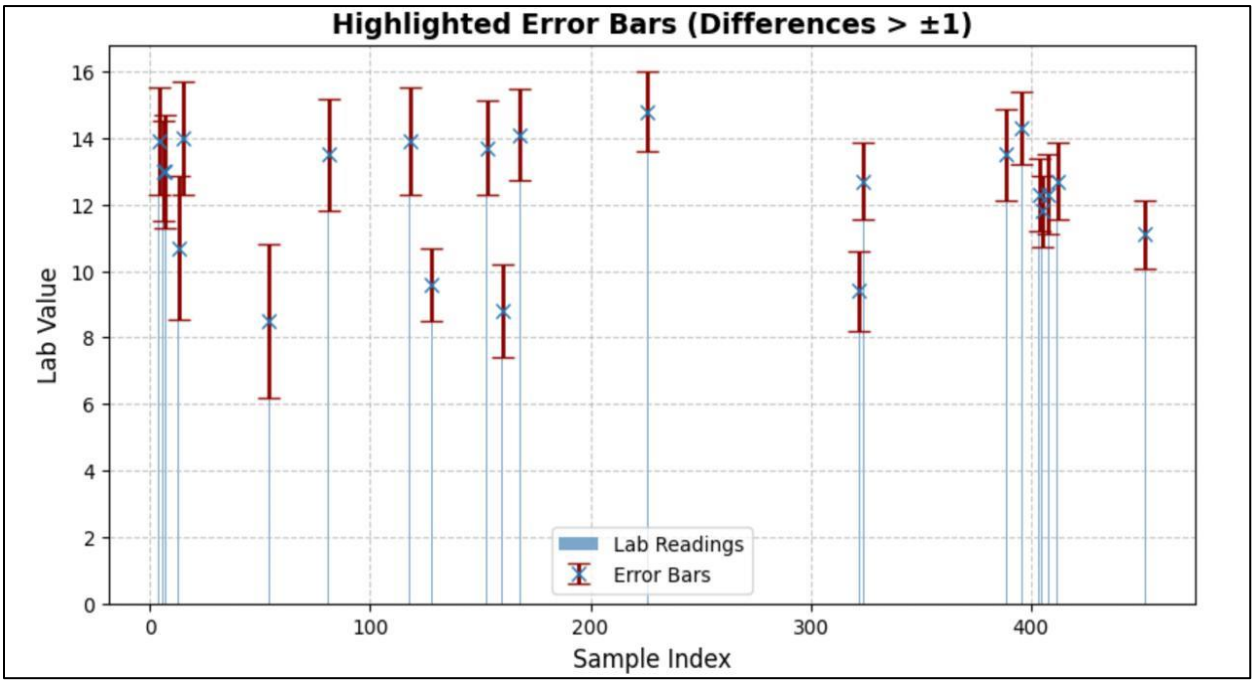

Fig.1.: Highlighted Error Bar from Device A and Device B

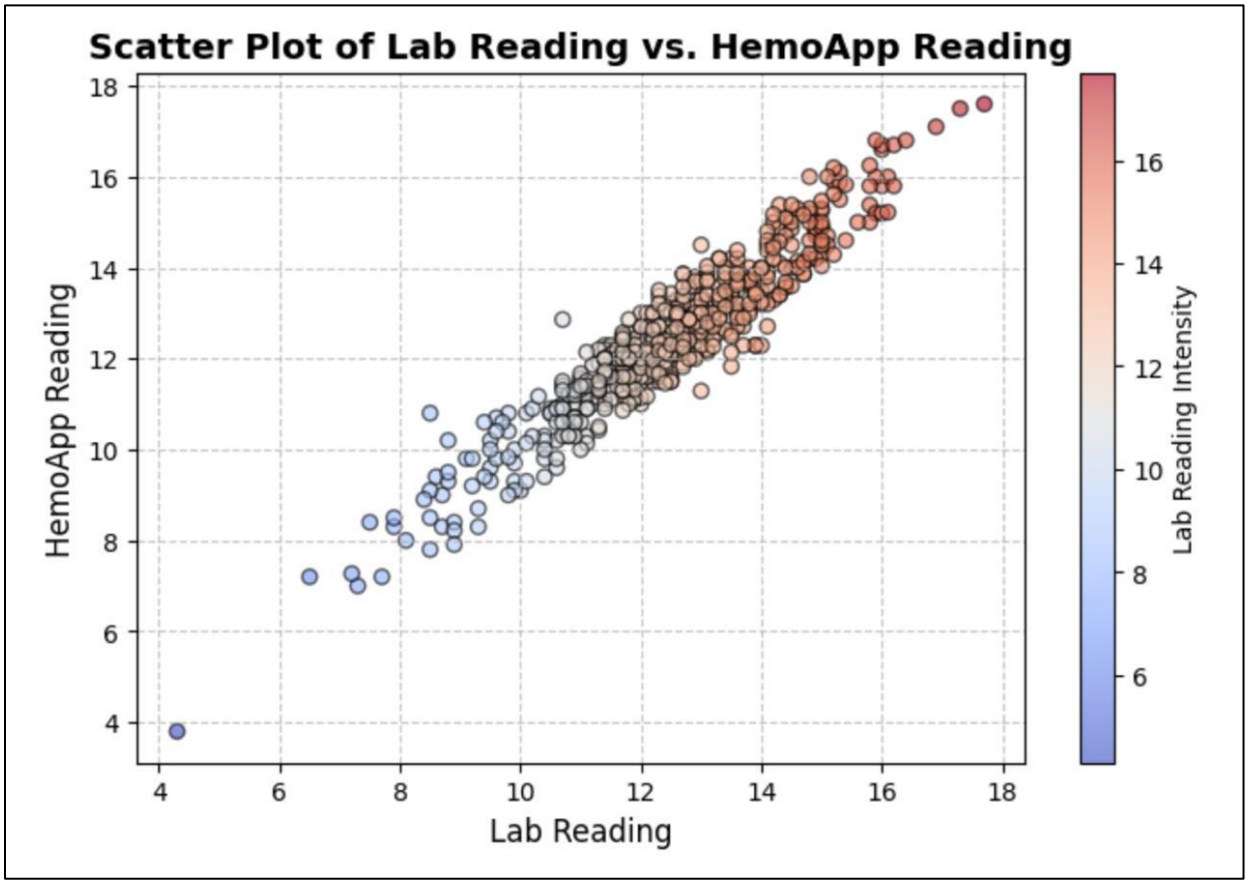

Fig.2.: Scatter Plot of Device A and Device B

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IV. DISCUSSION

The introduction of a reagent-free, smartphone-integrated POC Hb detection system represents a significant advancement in anemia diagnostics. Its high sensitivity and specificity, combined with the convenience of smartphone-based analysis, address many limitations of existing POC technologies. By leveraging sustainable materials and digital algorithms, this device offers a practical, eco-friendly alternative for healthcare providers in resource-constrained settings. While the device performed well overall, environmental factors, such as extreme lighting or high humidity, can still affect measurements. Future research should explore the device's performance in different climates and integrate features for environmental compensation.

HemoQR device showed excellent usability, repeatability in PHC setup. The sensitivity, specificity and accuracy in this study was calculated to be 90.19%, 97.60% and 96.15 % respectively from a pool of 500 samples. These results were similar or in range with the previous study of HemoQR which was done in sub-district hospital. The results of the previous study were 99.08 %, 98.92 % and 99.08% for sensitivity, specificity and accuracy which were done using 200 samples (Ghosh S, 2024). From a study done in hospital camp setup using 280 samples we got 92.06% sensitivity, 98.67% specificity and 95.75% accuracy of HemoQR against Haematology Analyser-fully automated-5 parts [Erba H560] (Ghosh., 2024). A study in medical college setup using 200 patients were done where the samples were simultaneously run on HemoQR and Haematology Analyser-Fully Automated-5 parts [Beckman Coulter DxH560], and the sensitivity and specificity of our smart-phone based HemoQR system was 87.09% and 96.11% respectively (Chakraborty, 2025). A study done at primary healthcare centre's camp setup using 400 patients samples we got 91.27% sensitivity, 95.30% specificity, and 90.40% accuracy of HemoQR against Haematology Analyser-fully automated-5 parts [Cellenium Junior] (Bajaj, 2025). The minor difference in terms of sensitivity, specificity and accuracy among all the studies can be considered because of the handling and operating of the devices, environmental conditions and human errors. But still, we can conclude from the data of our studies that HemoQR is an efficient and a great alternative for screening and detecting anaemia accurately on field/community basis from venous blood and also from pricks at the fingertip which help in the screening of anaemic person and will make Anemia Mukt Bharat.

V. CONCLUSION

This study highlights the potential of a reagent-free, POC Hb detection system as a transformative tool for anemia screening. It's ease of use, rapid testing, and high diagnostic accuracy make it suitable for community health initiatives and clinical use in remote areas. By addressing key barriers to Hb testing, this innovation could play a crucial role in reducing the global burden of anemia and improving healthcare outcomes for at-risk populations.

The findings of this comprehensive evaluation suggest that the HemoQR point-of-care diagnostic kit is a reliable and effective tool for the rapid and accurate measurement of Hb levels in a diverse patient population. The HemoQR kit's strong correlation with the reference laboratory method, high accuracy, and excellent precision make it a promising solution for POC Hb testing.

These results support the potential integration of the HemoQR kit into clinical practice, facilitating timely medical decision-making and enhancing patient care. Further research is warranted to explore the broader clinical applications of the HemoQR kit, including its utility in different healthcare settings and its impact on patient outcomes. Overall, the results of this study highlight the potential of the HemoQR kit to enhance the delivery of POC diagnostic services and contribute to the advancement of personalized healthcare.

The result of this study is similar to our previous study but the only difference and complexity in this study is that the pool of patient was similar to our previous works and the sensitivity, specificity and accuracy calculated were 90.19 %, 97.60% and 96.15 % respectively using 500 blood sample patients. With this study in the PHC setup we can further confirm that though HemoQR which is based on the principle of colorimetric assay coupled with smartphone-based application does outperform the HCS and the Sahli's method of Hb estimation, making it an efficient cost-effective smart solution in the 21st century diagnostic world.

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REFERENCES

[1]. Cheng, c., 2020. Small-volume point-of-care analytical methods. *Sci Rep*, Volume 10.
[2]. Collaborators, G. 2. A., 2023. Prevalence, years lived with disability, and trends in anaemia burden by severity and cause, 1990-2021: findings from the Global Burden of Disease Study 2021. *Lancet Haematol*, 10(9), pp. e713-e734.
[3]. E. McLean, e. a., 2009. Worldwide Prevalence of Anemia. *Public Health Nutrition* , 12(4), pp. 444-454.

ISSN No:-2456-2165 https://doi.org/10.5281/zenodo.14944998

[4]. Ghosh S, e. a., 2024. Evaluation of HemoQR (Haemoglobin Detection Test with Mobile Based Reading Application) in a Hospital Setting Using 200 Patient Samples in Comparison to the Gold Standard Method. *Haematol Int J*, 8(2), p. 262.

[5]. Neogi, S. N. H. K. R. B. M. S. R. V. N. B. P. S. J. B. H. Z. S. a. S. R., 2016. Diagnostic accuracy of haemoglobin colour strip (HCS-HLL), a digital haemoglobinometer (TrueHb) and a non-invasive device (TouchHb) for screening patients with anaemia.. *Journal of clinical pathology*, 69(2), pp. 164-170..

[6]. Price, A. S. J. a. C. P., 2014. Existing and Emerging Technologies for Point-of-Care Testing. *Clin Biochem Rev.*, 3(35), pp. 155-167.

[7]. RJ, S., 2003. Iron Deficiency: Global Prevalence and Consequences. *Food and Nutrition Bulletin*, Volume 24, pp. S99-S103.

[8]. Rohit Bajaj, e. a., 2025. Evaluation of HemoQR (Haemoglobin Detection test with mobile based software) in multiple primary healthcare centres using 400 patient samples in comparison to gold standard methods and other point of care (POC) devices.. *International Journal of Scientific Research in Engineering and Management (IJSREM)*, 9(2).

[9]. Sambit Ghosh., e. a., 2024. Evaluation of HemoQR (Haemoglobin Detection test with Mobile based Software) in Hospital Camp Setup using 280 Patient Samples in Comparison to Gold Standard MethodsPatient Samples in Comparison to Gold Standard Methods. *Medicon Medical Sciences*, 7(5), pp. 26-34.

[10]. Suman Chakraborty, S. C. A. B. H. G. M. D. S. G. S. V. C. R. K. S. S. B., 2025. Rapid reagent-free anaemia screening using plant-derived “HemoQR” paper-strips and smartphone: A study on 200 human subjects. *Industrial Crops and Products*, Volume 223.

[11]. Vashist, S. K., 2017. Point-of-Care Diagnostics: Recent Advances and Trends. *Biosensors*, 7(4), p. 62.