



# A Randomized Controlled Study of HemoQR: Comparative Performance and Repeatability in a High-Volume Sample

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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) haemoglobin (Hb) detection system is examined in this study using 7586 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 (Medonic M20)] in multiple primary healthcare center's (PHCs) in varanasi in Uttar Pradesh, India using 7586 samples from patients of different age groups using fingertip pricked blood for the test to monitor Hb.

**Results:** As the result of this project study qualifies the criteria of Anemia Mukta 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 88.72%, 86.30% and 95.36% respectively in this study using 1112 live samples were compared with device B [Hematology Analyzer- Fully Automated- 3 Parts (Medonic M20)] out off 7586 total tested in which 731 test was based on repeatability study in which patients were tested repeatedly with different time and days whose accuracy was 97.72%.

**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 kinds of medical setup and it can also help in collecting and analyzing the data for monitoring purposes.

## Introduction

Point-of-care diagnostics is revolutionizing healthcare, particularly in resource-limited settings, by enabling rapid and convenient health monitoring [1]. The development of portable devices is critical for the widespread adoption of lab-on-a-chip technologies in point-of-care diagnostics, which have historically been limited by cost constraints [2]. These technologies can perform diagnostic or screening tests by measuring biomarkers within the human body, which are known to be more informative and accurate than physical parameters [3]. The integration of microfluidics into point-of-care testing has further enhanced diagnostic capabilities, offering advantages such as portability, low cost, and ease of use [4]. Microfluidic devices offer powerful platforms for automation and integration of complex tasks onto a single chip, enabling quantification and detection of analytes with high resolution and sensitivity [5]. These devices are advantageous as they reduce reagent and sample volumes, accelerate reaction times, shorten analysis times, and lower expenses compared to conventional apparatus [6].

Point-of-care testing is increasingly recognized for its ability to deliver timely results, improve healthcare services, mitigate delays in treatment, and reduce overcrowding in emergency departments [7]. Quantitative methods, such as those developed for measuring glucose-6-phosphate dehydrogenase (G6PD) activity, have demonstrated the feasibility of high-throughput analysis using automated systems [8]. The integration of miniaturized components from existing laboratory equipment into point-of-care devices presents challenges related to size, fragility, and cost [9]. The development of wearable biosensors for continuous monitoring of biomarkers such as glucose, lactate, and cholesterol can provide real-time physiological insights [10]. Optical imaging systems are emerging as inexpensive and portable sensory systems for biomedical, environmental, and healthcare monitoring [11]. Biosensors designed for clinical applications need to be simple, foolproof, and usable by untrained personnel [12]. Recent advances in mobile and wearable devices, combined with point-of-care diagnostic devices using microfluidics technology, offer opportunities for continuous monitoring and improved diagnostic capabilities [13]. Wearable platforms enhance patient comfort and compliance while opening new possibilities for proactive disease management and preventive healthcare [14]. Wearable sensors have garnered considerable attention since smartphones came onto the scene [15]. They enable non-invasive and continuous monitoring of physiological parameters, paving the way for personalized medicine and improved healthcare outcomes [16]. In tandem with wearable technologies, smartphone-based analytical biosensors have emerged as versatile platforms for point-of-care applications and mobile health. Smartphone-based biosensing technology offers exciting opportunities for expanding point-of-care diagnostics and prognostic tools, revolutionizing detection systems and transforming mobile health concepts [17]. These systems integrate the sensitivity of biosensors with the diverse functions of smartphones to provide rapid, low-cost, and convenient detection methods [18].

The integration of data collected from wearable devices with remote servers and analysis algorithms enables the generation of personalized medical models, shifting the focus from reactive "sick care" to proactive healthcare [19]. By identifying biomarkers through wearable devices and employing biomarker detection platforms for near-patient applications, healthcare professionals can gain invaluable insights into the physiological conditions and health status of individuals [20][21][22]. Biosensors integrated with smartphones have shown promise as point-of-care diagnostic or screening tools for home testing and real-time monitoring, thus improving the quality of life soon [23]. The other most common technology for the detection of various test is based on the biosensors and colorimetric based widely used technology like example detection of Hemoglobin through Hb Meters which are available in market (i.e hemocue) one of the most widely used technology [24][25][26]. It has some restricted conditions like lightening effects, calibration of hemoglobinometer etc. The different Hb meters have different effects, and they are like for oxygen (Hb), carboxyhemoglobin (coHb), Methemoglobin (MetHb). But the CoHb, MetHb are less reliable for abnormalities than the oxygen  $O_2$  carrying Hb [27].

In this study, HemoQR the Haemoglobin Detection kit which was invented by Indian Institute of Technology (IIT) Karagpur and licenced and manufactured by SmartQR Technologies pvt. Ltd. Which has a testing strip having reaction pad embedded with QR code with the reagents on the reaction pad on the strip [28].we evaluated the HemoQR haemoglobin Detection kit against the Medonic M20 hematology autoanalyzer, assessing its potential as a reliable and cost-effective point-of-care diagnostic tool. This evaluation included a comparison of patient results obtained via the HemoQR kit with those from the Medonic M20, alongside repeatability testing to ensure reliability.

### Materials and Methods

In our pilot project at Varanasi, Uttar Pradesh, India, we evaluated the performance of HemoQR, a hemoglobin detection kit, by comparing its results with those obtained from the haematology autoanalyzer 3-part Medonic M20. A total of approximately 7586 patients were tested using HemoQR, and a subset of 1112 patient reports were tested and compared with the results obtained from the Medonic M20 analyzer. To assess the precision and reliability of HemoQR, a 731 test was conducted on repeatability. The use of Colorimetric detection methods contributes to the sensitivity of the haemoglobin assay, allowing for integration into suitable for point-of-care diagnosis applications. The HemoQR testing kit incorporates photometric and colorimetric methods, which have emerged as practical platform for point-of-care testing.

The methodology involved a rigorous comparison of hemoglobin measurements obtained from both HemoQR and the Medonic M20 analyzer, ensuring data integrity and accuracy through calibrated instruments and standardized protocols. The data collected from both methods were statistically analyzed to determine the correlation and agreement between the two methods. Furthermore, the repeatability test on 731 patients provided insights into the consistency and reliability of HemoQR in repeated measurements. The incorporation of machine learning algorithms for autonomous image analysis can further enhance the accuracy and efficiency of biomarker detection, enabling high-throughput analysis with minimal human intervention. The integration of microfluidic technologies contributes to reduced reagent and sample consumption, faster reaction times, and lower overall costs, making them highly effective tools for complex tasks. The use of fully automated systems in serological testing of blood donor samples reduces infection risk to staff, human errors, and workload demands, while also optimizing and standardizing testing processes.

### Test Method

A finger prick procedure was executed to obtain a minute blood sample from a capillary site for comparative analysis of blood component concentrations. Concurrently, a corresponding venous blood sample was extracted. The capillary sample was carefully collected to prevent contamination by epidermal secretions and cellular debris. An optimal quantity of capillary blood was acquired to ensure precise placement on the test strip, without employing utilisation of peripheral tools. The sensor-impregnated strip was subsequently photographed using a mobile device and analysed via a mobile application. The Hb concentration was promptly ascertainable from the analysed results; concurrently, a novel electro-chemical analyser assessed Hb concentration in a separate venous blood sample. A 2ml venous blood specimen was isolated and treated with a specific reactant, facilitating accurate measurement of Hb concentration. Independent results records were maintained by the technician and supervisory personnel to ensure validation of the process. Precautions of disposal were taken for all pointed instruments.

### 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.

**Results**

**Comparative Study Analysis:**

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 1112 Samples on Device A (HemoQR), Device B [Haematology Analyzer- Fully Automated-3 Parts (Medonic M20)]. 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 551 and patients with Hb levels more than 11 g/dL to be true negative (TN) and that was calculated to be 561. 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 88.72% and a specificity of 86.30%. Furthermore, a significant majority, at 95.36 % 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 (Medonic M20). To give a further graphical representation we have showed in Fig.1 Error Bar Plot: Lab value vs HemoQR. We have taken Readings 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 HemoQR were plotted on to ‘Y’ axis and the Lab reading was plotted on ‘X’ axis. The results showed that the HemoQR and the Lab readings showed similar readings with minor differences in the reading for some samples.

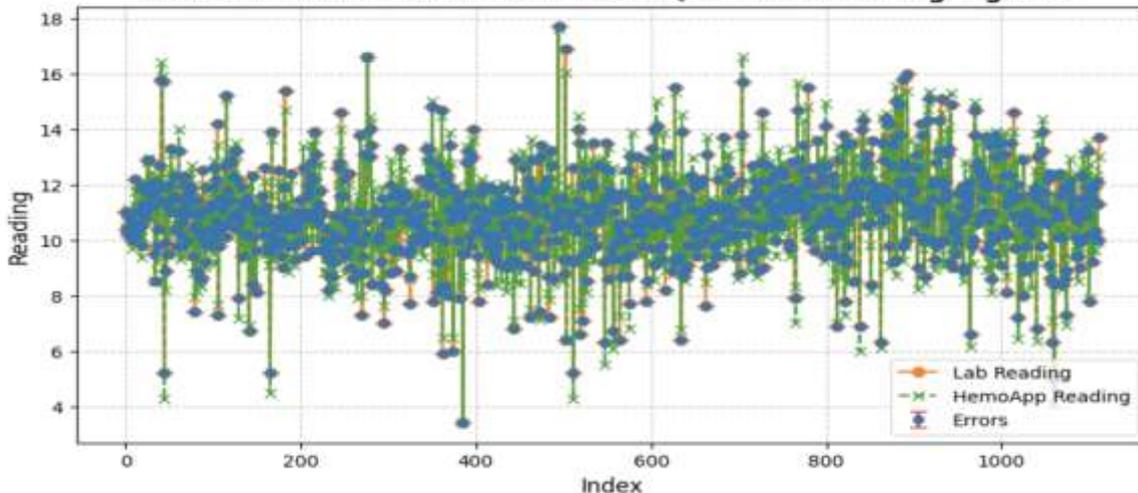
**Table-1: TP and TN Data from Device B**

<b>Device B [Hematology Analyzer]</b>	<b>True Positive (TP)</b>	<b>True Negative (TN)</b>
	551	561
Total Number of Patients – 1112		

**Table-2: FP and FN Data from Device A**

<b>Device</b>	<b>Device A (HemoQR)</b>
<b>False Positive (FP)</b>	89
<b>False Negative (FN)</b>	70
<b>Total Number of Patients</b>	1112

**Error Bar Plot: Lab Value vs HemoQR with Errors Highlighted**



**Fig.1.: Error Bar Plot: Lab value vs HemoQR**

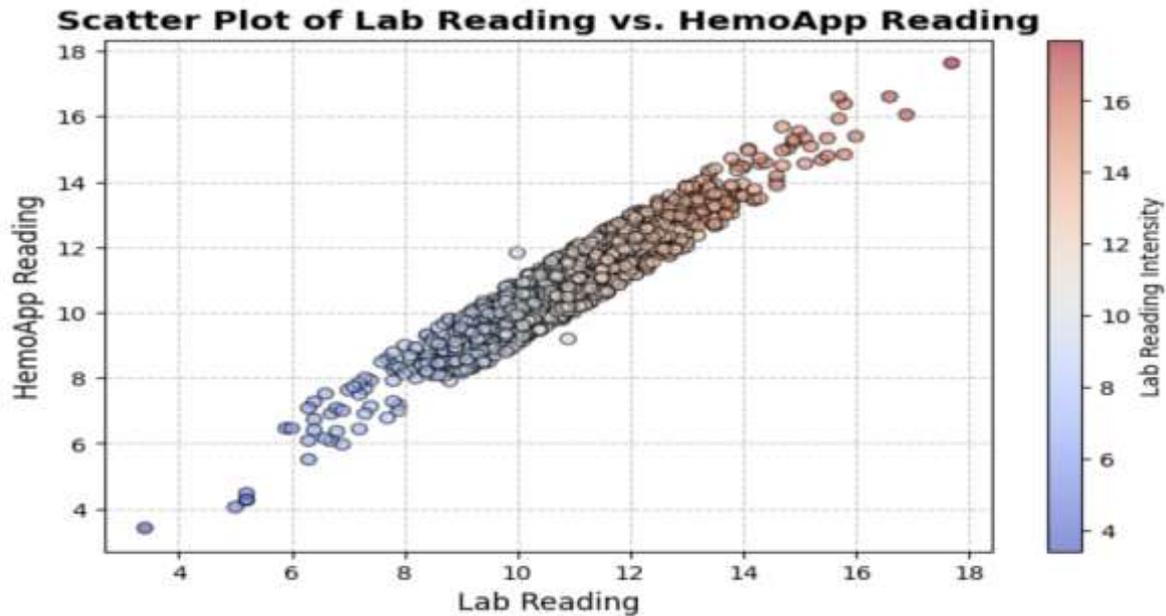


Fig.2.: Scatter Plot of Lab vs HemoQR Readings

### Repeatability Study Analysis

The outcome of the repeatability study of 750 test shown the accuracy of 97.72%. The statistical data of which is Interpreted with the correlation give below:

Interpretation of Statistical Measures

1. Pearson Correlation:

- Measures the linear relationship between Test 1 and Test 2.
- A value close to +1 (e.g., 0.9917) indicates a very strong positive correlation.
- This suggests the two tests are highly consistent and repeatable.

2. P-value:

- Tests the null hypothesis that there is no correlation.
- A value near 0 (e.g., < 0.0001) indicates statistical significance.
- Confirms the correlation is not by chance and the tests agree significantly.

3. Mean Difference:

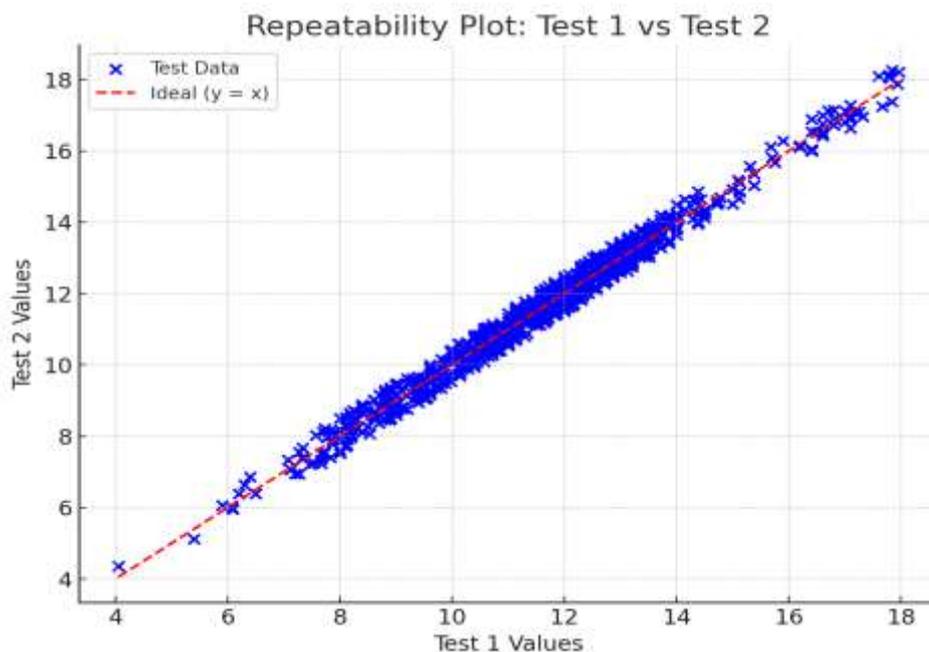
- Represents the average bias between Test 1 and Test 2.
- A value near 0 (e.g., -0.0065) shows minimal systematic difference between tests.

4. Standard Deviation of Difference:

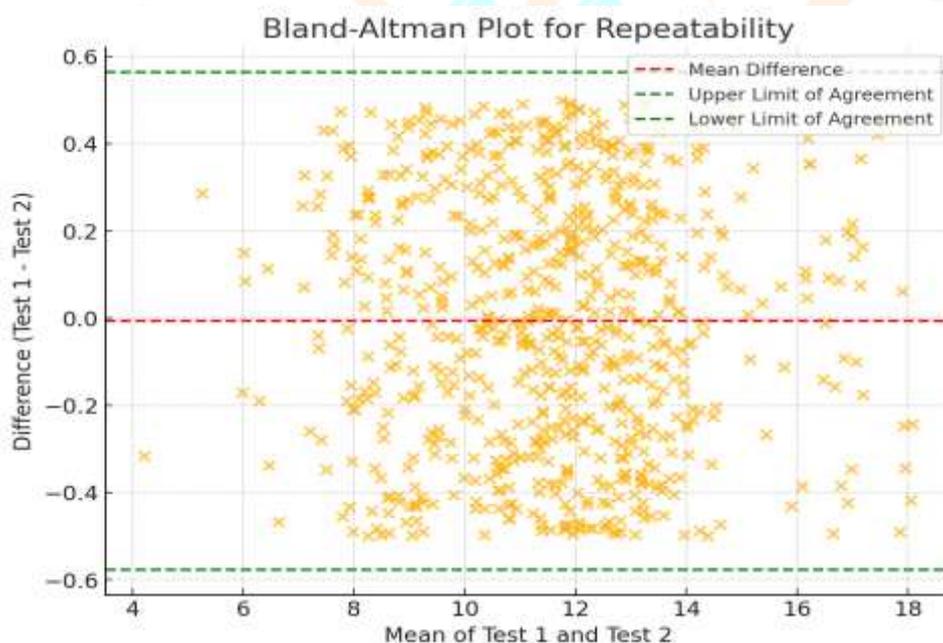
- Indicates the spread of differences from the mean.
- A smaller value (e.g., 0.291) means higher precision and repeatability.

Significance on Accuracy:

- High correlation and low mean/std difference demonstrate reliable repeatability between the tests.
- Accuracy remains consistent, and repeat tests yield almost identical results, which is crucial for clinical diagnostics and publication quality assurance.



**Fig 3: Repeatability Study Test 1 vs Test 2**



**Fig 4: Bland-Altman Plot for Repeatability**

## 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 setups in Varanasi District, Uttar Pradesh. The sensitivity, specificity and accuracy in this study was calculated to be 88.72%, 86.30% and 95.36 % respectively of the comparative study data and 97.72% accuracy of the repeatability study data from a pool of 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 [29]. 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 Hematology Analyser-fully automated-5 parts [Erba H560] [30]. A study in medical college setup using 200 patients were done where the samples were simultaneously run on HemoQR and Hematology 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 [28]. 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 Hematology Analyser-fully automated-5 parts [Cellenium Junior] [31]. A study done at Multiple primary healthcare centre's with a setup of 500 patients samples we got 90.19% sensitivity, 97.60% specificity, and 96.15% accuracy of HemoQR against Hematology Analyser-fully automated-3 parts [Erba H 360][32]. 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 from pricks at the fingertip which help in the screening of anaemic person and will make Anemia Mukht Bharat.

### 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 88.72%, 86.30% and 95.36% respectively using 1112 tests out of 7586 tests. With which a Repeatability study having accuracy 97.72% using 750 test out of 7586 tests. 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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