

## A Comparative Study for the evaluation of HemoQR strip and application in comparison to Hematology Analyzer fully automated-6 parts at Patkar Laboratory for Hemoglobin Measurement

**Darshan Chandak, Sambit Ghosh\*, Mahendra Dashora, Hitesh Gupta, Shraddha Rana and Sarbartha Chakraborty**

*SmartQR Technologies Pvt. Ltd., India*

**\*Corresponding Author:** Sambit Ghosh, SmartQR Technologies Pvt. Ltd., India.

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### Abstract

Anemia is one of the major leading health concerns globally and India is one of the leading countries contributing to the global burden of anemia. Anemia plays out differently depending on the group that is struggling with the condition. Women of reproductive age (WRA) are one of the most vulnerable groups to this condition and maternal anemia is associated with increased mortality. The physical diagnosis of anemia is often based on clinical signs alone such as pallor of the conjunctivae, nail beds, face, palms, and palmar creases. Anemia can also be determined by biomarker assessment which is Hb concentration. It is the most preferred biomarker for diagnosis. HemoQR is a Hb detection test kit consisting of a detection strip and a software application which enables immediate reporting and data-driven decision making. It is a point-of-care test based on a mobile application, making it user-friendly and low maintenance to be used anytime, anywhere. In this paper we have done a comparative study of HemoQR and Hematology Analyzer using 24 EDTA blood samples. The study was conducted in Patkar laboratory. The results showed 95% repeatability and 96% reproducibility for the Haemoglobin Detection Kit.

### Introduction

Anemia is a biological abnormality in which the red blood cells or the hemoglobin (Hb) concentration decreases than normal. It is one of the major public health concerns, mainly affecting young children, pregnant and postpartum women, and menstruating adolescent girls and women (WHO, 2023). Anemia is one of the major leading health concerns globally and India is one of the leading countries contributing to the global burden of anemia (Safiri et al., 2021). The rates of anemia among Indian children and women had remained at 15% and 20% more than the calculated world average, respectively (WHO, 2021). Anemia has significant consequences for human health, as well as for social and economic development (Chaparro & Suchdev, 2019). Anemia plays out differently depending on the group that is struggling with the condition. Women of reproductive age (WRA) are one of the most vulnerable groups to this condition and maternal anemia is associated with increased mortality (Daru et al., 2018). Further, children born to mothers with iron deficiency anemia demonstrate poor memory, abnormal neurological reflexes, and altered interactions with caregivers (Doom & Georgieff, 2014). In the case of children, anemia can impact brain development and cognition (Patel et al., 2021), thus early screening and detection are crucial in the treatment and management of anemia.

The physical diagnosis of anemia is often based on clinical signs alone such as pallor of the conjunctivae, nail beds, face, palms, and palmar creases (Loscalzo et al., 2022). None of these signs, whether combined or singly, yield an acceptable diagnostic accuracy. Anemia can also be determined by biomarker assessment which is Hb concentration. It is the most preferred biomarker for diagnosis (Karakochuk et al., 2019). Anemia is then defined by an Hb concentration below a cutoff value that is specific to age, sex, or the life-stage of the individual (WHO, 2011). Hemoglobinometers are the most used diagnostic tool for the measurement of Hb levels and the detection of anemia. It is a non-invasive test for measuring Hb, which compares the color of light passing through a hemolyzed blood sample with a standard color. It is a cheap, simple, and robust device capable of measuring Hb levels outside of laboratory settings (Gour et al., 2019). The WHO-based Hb color scale method is the most commonly used system for the screening of anemia (Darshana & Uluwaduge, 2014). Hematology analyzers are now a days used to determine Hb. These devices are computerized and highly specialized which can count different white and blood cells in the blood samples. These devices with high level precision and accuracy are now a days used for Hb concentration determination. But the major drawback regarding these devices that they are very expensive. There is a void of an alternative cost-effective system which can effectively detect Hb and help in proper diagnosis.

HemoQR is a Hb detection test kit consisting of a detection strip and a software application which enables immediate reporting and data-driven decision making. It is a point-of-care test based on a mobile application, making it user-friendly and low maintenance to be used anytime, anywhere.

## **Material and Method**

A comparative study was conducted at Patkar Laboratory, Vashi. The study was conducted using total of 24 EDTA samples. These samples were run simultaneously on 6 parts full automated Hematology Analyzer, and HemoQR test.

### **Test Method**

A portable Haemoglobin Detection Kit called the HemoQR is used to measure Hb as the standard procedure, it has been shown that HemoQR can provide accurate Hb concentration from our inhouse analysis. We selected HemoQR as the reference method for our study based on its precision and usability in field settings.

The Auto Analyzer 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 aseptic precautions. Simultaneously, 0.8cc capillary blood was collected and applied on the test strip and an image was uploaded of the blood-stained strip on the mobile application, to get the Hb value. The test is performed as stated in the manufacturer's manual using the reagents/kits provided with the instrument as recommended by manufacturers. 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.

## **Results**

Hb measurements, sensitive probability ratios, positive and negative predictive-values, and both were calculated. The Bland-Altman layout was developed. HemoQR sensitivity was 0.97, whereas specificity was 0.90. PPV is 0.91 and NPV was 0.96.

<b>Specimen ID</b>	<b>Observed Value from Laboratory(g/dL)</b>	<b>Observed Value from Hemo QR app, Smart QR technologies Pvt. Ltd.(g/dL)</b>
Patient-1	13.7	13.29
Patient-2	13.4	12.13
Patient-3	12.3	11.17
Patient-4	8.6	8.76
Patient-5	11.6	11.83
Patient-6	10.1	11.67
Patient-7	11.8	12.13
Patient-8	10.1	11.67
Patient-9	11.8	12.13
Patient-10	15.7	16.07
Patient-11	8.1	8.76
Patient-12	11.9	12.25
Patient-13	11.9	12.13
Patient-14	15.6	14.14
Patient-15	13.9	12.25
Patient-16	10.8	10.67
Patient-17	10.3	10.33
Patient-18	12.0	12.25
Patient-19	11.9	12.13
Patient-20	12.8	12.38
Patient-21	13.8	11.83
Patient-22	9.5	10.17
Patient-23	8	9
Patient-24	15.4	14.7

**Table 1:** Performance Data table from Patkar Laboratory.

## Discussion

The most popular technique for diagnosing anemia at the community level is clinical examination. However, a sizable body of research suggests that clinical exams on the physical level do not yield acceptable diagnostic accuracy and they can only rule out cases of Anemia or modestly rule in cases of severe Anemia (Kalantri et al., 2010). Using a combination of methods in physical examinations often leads to a higher rate of accurate diagnoses. However, this advantage needs to be balanced with the time constraints of performing thorough examinations (Vyas et al., 2022). Thus, assessment of biomarker levels, especially Hb, presents the most preferred method for the diagnosis of Anemia in modern healthcare settings (Karakochuk et al., 2019). The World Health Organization introduced the Hemoglobin Color Scale (HCS) for estimating Hb levels in non-laboratory or community settings. HCS is portable, does not require batteries, electricity, or any maintenance, and provides immediate results (Stott and Lewis, 1995). According to a global study, HCS demonstrated a pooled sensitivity of 80% (95% CI 68-88) for diagnosing anemia, compared to 52% for clinical assessment (95% CI 36-67; p=0.008). Although HCS was demonstrated to be accurate in a laboratory context, only a small number of studies have looked at its accuracy when used in community setting without access to laboratory facilities. Another very popular hemoglobin analysis method is the Sahli’s method of estimation of haemoglobin concentration and according to the study performed by Patil et al. (2013)

Sahli's method had lower levels of accuracy and limited level of hemoglobin values as it was labelling health individual as anaemic. Both these methods were based in colorimetric detection of hemoglobin in blood. Our HemoQR is also based on colorimetric analysis of haemoglobin. This study aims to close this gap in the available data. The study implies that HemoQR would screen and detect anemia accurately on field/community basis and will enable treatment of many anemic individuals. Overall, there is no statistically significant change in mean Hb readings, however the correlation between HemoQR and Hematology analyzer was decent. The majority of HemoQR measurements (96%) were within 1 gm/dL of the corresponding Laboratory readings.

## Conclusion

Accurate determination of Hb concentration is a common element in assessing the extent of anemia and making a decision regarding treatment. This decision should be made based on the reliable and rapidly assessed laboratory tests. The HemoQR kit is a portable device for measuring Hb concentration, and it requires very little staff training thus making it a very useful tool in resource-limited areas such as field conditions since it can easily be transported and is also cost-effective. In this study, we compared it with Auto-Analyzer used in the laboratory. We found no significant differences in the Hb concentrations determined by the two methods. HemoQR is a Hb detection test kit that consists of a detection strip and a mobile-based software application that enables immediate reporting of Hb levels and allows healthcare professionals to make decisions driven by the collected data. It serves us with accurate and instant results with a turnaround time (TAT) of 20 sec along with data collection and analytical report. It utilizes the Hemoglobin Color Scale (HCS) for point-of-care measurement of Hb levels using the application, and it serves as a user-friendly and accurate method for the detection of anemia. HemoQR is best suited for testing "Hb" on spot under field conditions, for screening of anemia of pregnant women, adolescent children, below poverty line population and adults with parasitic conditions. There is no requirement of external hardware, chemicals, modern equipped laboratory setting or skilled technicians skilled staff is required to perform the test. Also, the data would be captured online for better understanding of conditions at institutional level. These kits are very user friendly and can be used by any professional. The HemoQR kit has already been tested with non-anemic, mild Anemic, Anemic, and severe Anemic samples in replicates of three, and the reproducibility of the kit was evaluated by performing an Inter-lot study, Inter-operator study, Inter-day study, and a within run study. Results of all these studies were recorded and compared and based on results, 95% repeatability and 96% reproducibility were established for the HemoQR Hb detection kit. So, it can be concluded that though HemoQR is based on colorimetric principle it does outperform the HCS and the Sahli's method of Hb estimation, making it an efficient cost-effective smart solution in the diagnostic world.

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