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# Analytical Evaluation of Hemochroma POC Haemoglobin Reader

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## Abstract

**Background:** Good laboratory practice requires that Clinical laboratories verifies the performance claims of a method before results generated by such an instrument can be used for decisions about patient care. Analytical evaluation of a new point of care methods should be done before its introduction into the routine use in order to confirm its declared analytical performance specifications.

**Objective:** To evaluate the degree of analytical accuracy of the Hemochroma POC haemoglobin reader relative to the Coulter AcT hematology analyzer.

**Study design and setting:** A comparative study, conducted at the University of Nairobi, Thematic unit of Clinical Chemistry Laboratory and the Department of Obstetrics and Gynecology.

**Materials and methods:** The evaluation was performed according to the guidelines of the European Committee for Clinical Laboratory Standards (ECCLS) and the guidelines on the evaluation of point of care testing instruments by the Australian Association of Clinical Biochemists (AACB). The analytical ability of Hemochroma POC reader (Boditech Med Inc.) to determine the levels of hemoglobin (Hb) according to the manufacturers claimed accuracy levels was evaluated using the routine 'comparative' method, Coulter AcT (Beckman Coulter Inc, Fulerton, CA 92835).

**Results:** Hemochroma POC hemoglobin reader yielded a correlation coefficient of 0.976 against the Coulter AcT hematology analyzer. The slope and the y-axis intercept as well as their 95% confidence intervals were 0.990 (95% CI 0.891 to 1.020) and 0.003 (95% CI -0.151 to 1.439), respectively.

## Introduction

Analytical evaluation of a new analyzer or method should be done in order to confirm the declared specifications before its introduction into the routine use [1,2]. Blood hemoglobin (Hb) level of a patient is a critical parameter in patient primary care hence the need for diversified methods capable of producing accurate results in areas both with and without proper infrastructural coverage. Recent advances in diagnostic technology and the delivery of health services has resulted in an increased demand for and provision of point of care testing (POCT) in both primary and community care settings. The capacity to provide a rapid test result which can be acted upon expeditiously permits increased clinical effectiveness and improved outcomes for patients. This is only true if the result delivered is accurate and reliable. Hemochroma POC hemoglobin reader (Boditech Med Inc. South Korea) is a point of care testing device for measuring hemoglobin levels, designed for primary and community based care. It is based on robust and reliable detection mechanism which with proper handling, it is capable of delivering excellent accurate measurements comparable to high end reference hemoglobin analyzers. Unlike the generic spectrophotometers, Hemochroma POC$^{TM}$ accepts the proprietary cuvettes that hold the pre-processing buffer. There is no need for additional reagents or consumables except lancets to prick the patient's finger and appropriate sterilization materials. The instrument is user friendly whereby the all- in- one system provides a basis as a pipette and measuring cuvette, thus use of glass capillaries is omitted [3].

## Rationale

Good laboratory practice requires that all equipment upon installation should demonstrate the ability to achieve the performance required as well as complying with the specifications relevant to the tests concerned. Furthermore, all methods have to be validated extensively both at the production level and finally by the users in order to confirm that they are suitable for their intended use. The increasing demand for provision of point of care testing in primary and community care settings has led to advances in diagnostic technology which is behind the introduction of Hemochroma POC hemoglobin reader. The degree of accuracy for this instrument was therefore evaluated to provide objective evidence that the method is fit for its intended purpose.

## Materials and Methods

The validation was performed according to the guidelines of the European Committee for Clinical Laboratory Standards (ECCLS) and the Australian Association of Clinical Biochemists (AACB) guidelines on the evaluation of point of care testing instruments [1,4]. Evaluation of the test method was conducted at the thematic unit of Clinical Chemistry Laboratory, while the comparative method was based at the Department of Obstetrics and gynecology, University of Nairobi. Details of the method used for evaluation the Hemochroma POC hemoglobin reader are presented in Table 1.

| Analyte | Units | Sample material | Sample volume (ul) | Analytical method | Wave Length (nm) | Measure-ment range (g/l) | Analytical time (sec) |
|---|---|---|---|---|---|---|---|
| Hb | g/L | Venous/Capillary blood | 4 | Cyanmet-hemoglobin | 540 | 5-25.6 | 10 |

**Table 1**: Method used in the evaluation of Hemochroma POC hemoglobin reader.

## Analytical evaluation of relative accuracy

The aspect evaluated was relative accuracy. The instrument was tested for its ability to produce true and valid results following the guidelines of ECCLS and AACB [1,4]. According to Australian Association of Clinical Biochemists, if the device is compared to an approved reference method, the difference between the point of care testing device and the comparative method measures the trueness of the POCT device [3]. In the current study, 51 samples from patients of a variety of disease states with wide range of values were tested in duplicate on the comparative method, the Coulter A$^c$.T 5 differential CP hematology analyzer and subsequently on the Hemochroma POC hemoglobin reader. According to AACB, at least 40 samples covering the clinically meaningful range should be included for method comparison study [4]. The analysis of the test samples on both the test and comparative method was done within a time frame of two hours which is line with the recommendations of AACB [4], to minimize sample intra analytical variations between the methods.

## Test instrument: Hemochroma POC Hemoglobin reader

Hemochroma POC hemoglobin reader is a portable hemoglobin meter based on robust and reliable detection mechanism developed for the quantitative assay of hemoglobin in human blood. The principle behind Hemochroma POC hemoglobin reader is standard cyanmethemoglobin method whereby hemoglobin is released from erythrocytes by osmotic pressure and mixed with potassium ferricyanide to form methemoglobin which is then combined with potassium cyanide to form cyanmethemoglobin [3].

The sample processing was done by disintegrating the erythrocyte membranes by osmotic pressure to release hemoglobin into the reagent solution. Then, Potassium ferricyannide converted the hemoglobin iron from the ferrous to the ferric state to form methemoglobin which then combined with potassium cyanide to form cyanmethemoglobin. The resultant solution of cyanmethemoglobin was then read by the device spectrophotometrically at 540 nm to estimate the precise hemoglobin concentration. Hemochroma returned the result in less than 10 seconds and the results can be stored up to 1,000 in the on-board memory, which could later be retrieved manually or transferred to an external computer. Sample collecting tip which comes with the instrument was inserted into the cuvette for processing the sample then the cuvette inserted into the test port to finish the test with a touch of a key. The manufacturers declared a hemoglobin accuracy specification of R2 = 0.983 with a measurement range of 5 -25.6 g/l [3].

## Comparative method: Coulter AcT hematology analyzer

The Coulter A$^c$.T 5 differential CP hematology analyzer which is a fully automated hematology analyzer was the routine hematology analyzer used by the Department of Obstetrics and Gynecology, University of Nairobi. It was selected as the comparative method because it posted excellent results for both internal quality control and external quality assurance. The instrument provides a complete WBC five-part differential which is determined simultaneously by the absorbance, cytochemistry and volume (ACV) technology. ACV technology uses absorbance, cytochemistry and focused flow impedance. Hemoglobin measurement is based on transmittance of light through the optical part of the first dilution hemoglobin bath using spectrophotometric technique at wavelength of 550 nm [5]. The instrument processed the sample by releasing Hb from the lysed red blood cells (RBC) to combine with the potassium cyanide to form a stable cyanmethemoglobin compound which was measured through optical part of the first dilution/hemoglobin at 550 nm. Transmittance of the sample was compared with the transmittance of the reagent blank and the final Hemoglobin value represented the product of absorbance value and the coefficient of calibration. According to the manufacturers' of the instrument, it has an accuracy specification of R = 0.95 with a coefficient of variation (CV%) less than 1% for hemoglobin [5].

## Statistical analysis

Statistical methods used included Pearson correlation and the linear regression to determine the comparability of the test and the routine method. The significance testing was denoted at $p < 0.01$.

## Results

A comparison of the hemoglobin measurements which ranged from 7.6 to 17.2 g/l on the Hemochroma POC hemoglobin reader relative to the Coulter AcT yielded a correlation coefficient of 0.976 against the Hemochroma POC manufacturer's claim of 0.983 as evaluated with the ICSH method. The slope and the y-axis intercept as well as their 95% confidence intervals were 0.990 (95% CI 0.891 to 1.020) and 0.003 (95% CI -0.151 to 1.439), respectively. A graph showing the regression line for the hemoglobin values between the Hemochroma POC and the Coulter AcT hematology analyzer is as shown in figure 1. The regression line showed that the hemoglobin values were well aligned indicating neither a proportional nor a constant bias. This finding is in agreement with the guidelines of ECCLS and AACB [2,3] and also from past studies [6] (Table 2). According to Swartz et al. a method passes acceptability criteria with regard to accuracy if its correlation coefficient 'R' is more than 0.975 [7].

## Discussion

The results of this analytical evaluation showed a satisfactory degree of accuracy for the Hemochroma POC hemoglobin reader relative to the Coulter AcT analyzer. Analysis of the hemoglobin values for both test and comparative method by Pearson correlation statistics yielded a slightly lower but acceptable correlation coefficient ($r=0.976$; $p < 0.01$) as compared with the manufacturer's declared correlation coefficient ($r=0.983$) when the studied method was compared to the ICSH method.

| Analyte | Range of Hb values | Slope | 95% CI of slope | y-intercept | 95% CI of intercept | Obtained 'R' | Claimed 'R' |
|---|---|---|---|---|---|---|---|
| Hb (g/l) | 7.6 –17.2 | 0.990 | 0.891–1.020 | 0.003 | -0.151 – 1.439 | 0.976* | 0.983 |

**Table 2**: Correlation and regression data for Hemochroma POC and Coulter AcT comparison. *Correlation significant at $p < 0.01$, Hb – hemoglobin, CI – confidence interval, R – correlation coefficient.

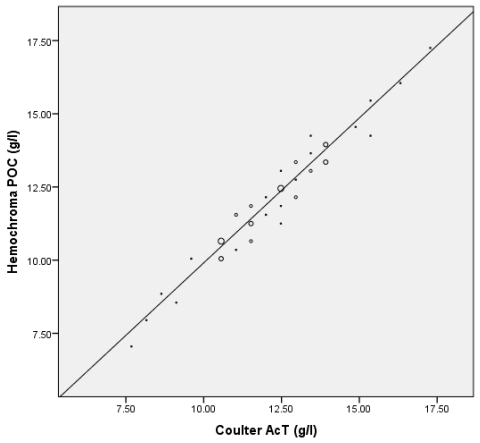


**Figure 1**: Regression line for Hemoglobin between Hemochroma POC and Coulter Act.

In the present study, regression analysis showed that the hemoglobin values were well aligned and did not differ by a constant (95% CI of intercept includes 0) or by proportion (95% CI of slope includes 1) indicating that there were neither constant nor proportional differences between the methods. This finding is in agreement with previous studies which had shown that for method comparison, the intercept and slope is a measure for both systematic and proportional differences respectively, for the two methods. Whereby, for the methods to be fully comparable, the 95% confidence interval for the intercept must include 0, while at the same time the slope should contain value 1 to indicate that there is no systematic or proportional difference between the two methods [7,8].

## Conclusion

The findings of this evaluation has proved that the Hemochroma POC hemoglobin reader is a reliable instrument for performing hemoglobin measurements. The meter is fully comparable to the Coulter AcT hematology analyzer with regard to measurement of hemoglobin values. Besides, the instrument is economical and convinient to the user as it is fast, battery powered, no water requirement, it is secure and has a simple user interface involving only two step key strokes. It also requires just a few microliters of whole blood minimzing iatrogenic blood loss.

## Recommendations

Hemochroma POC device requires periodic calibration based on internal quality control linked to a central laboratory, inorder for its proper performance to be guaranteed. It is well suited for use in the casualty, wards, intesive care units, antenatal clinic, medical clinics eg Heamatological and gynecological clinics. It is also suited for outreach services such as medical camps, mobile clinics and also laboratories in the rural settings where infrastructure coverage is poor.

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