

# การประเมินประสิทธิภาพของเครื่องวัดระดับฮีโมโกลบิน ณ จุดดูแลผู้ป่วย

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## บทคัดย่อ

ปัจจุบันมีเครื่องวัดระดับฮีโมโกลบิน ณ จุดดูแลผู้ป่วยหลากหลายยี่ห้อซึ่งมีข้อดีคือใช้งานง่าย และตรวจได้ไว เครื่องตรวจระดับฮีโมโกลบิน Hb 201 DM Analyzer และ Hemo Control Manager เป็นเครื่องที่มีระบบจัดการข้อมูลที่สามารถช่วยบริหารจัดการต่าง ๆ เช่น การควบคุมคุณภาพ การสแกนบาร์โค้ดเพื่อระบุตัวตนผู้ป่วย และการส่งข้อมูลเข้าระบบสารสนเทศของโรงพยาบาล ผู้วิจัยได้ประเมินประสิทธิภาพของเครื่องวัดระดับฮีโมโกลบิน ณ จุดดูแลผู้ป่วยทั้งสองรุ่นนี้ ในด้านความแม่นยำ (precision) ความถูกต้อง (accuracy) และช่วงค่าที่วัดได้เป็นเส้นตรง (linearity) โดยการประเมินความถูกต้องได้เปรียบเทียบกับค่าที่วัดได้จากเครื่องตรวจวิเคราะห์อัตโนมัติ Sysmex XN-3000 ที่ใช้ในงานตรวจผู้ป่วยประจำวันของห้องปฏิบัติการ จากการประเมินพบว่าเครื่องวัดระดับฮีโมโกลบิน ณ จุดดูแลผู้ป่วย Hb 201 DM Analyzer และ Hemo Control Manager มีความแม่นยำสูง โดยพบค่าสัมประสิทธิ์ของการแปรผัน (coefficient of variation) น้อยกว่าร้อยละ 2 ความถูกต้องของเครื่องพบว่าการเปรียบเทียบ Bland-Altman ของทั้งสองเครื่องเทียบกับ Sysmex XN-3000 แสดงความแตกต่างใกล้เคียงค่าศูนย์ และค่าสัมประสิทธิ์สหสัมพันธ์ภายในชั้น (intraclass correlation coefficient) แสดงให้เห็นว่าค่าที่วัดได้มีความสอดคล้องกันในระดับดีมาก และมีช่วงค่าในการวัดคือ 0.8 - 21.4 กรัมต่อเดซิลิตร และ 1.0 - 22.2 กรัมต่อเดซิลิตร ตามลำดับ จึงสรุปได้ว่าเครื่องวัดระดับฮีโมโกลบิน ณ จุดดูแลผู้ป่วย Hb 201 DM Analyzer และ Hemo Control Manager มีประสิทธิภาพดี

คำสำคัญ: ฮีโมโกลบิน เครื่องวัดระดับฮีโมโกลบิน การตรวจ ณ จุดดูแลผู้ป่วย

# Performance Evaluation of Point of Care Hemoglobinometers

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## Abstract

Nowadays, several point of care hemoglobinometers exist in the market. These devices have significant advantages such as an ability to take rapid non-invasive measurements and the ease of use. The Hb 201 DM Analyzer and the Hemo Control Manager are amongst such devices that come equipped with data management functions and provide convenience through a quality control system, barcode reader for patient identification, and ability to transfer patient results to a hospital's information system. The aim of this work was to compare their performance. A precision study was conducted according to a standard clinical and laboratory guideline. The linearity of each device was assessed by measuring five concentrations of hemoglobin in blood samples. To ensure accuracy of the study, forty leftover venous blood samples were measured by the two point of care hemoglobinometers. The average result of each sample was compared against our routine analyzer, the Sysmex XN-3000. Both the Hb 201 DM Analyzer and the Hemo Control Manager had a CV of less than 2% and the measuring ranges were 0.8 - 21.4 g/dL and 1.0 to 22.2 g/dL, respectively. Bland-Altman plots of the Hb 201 DM Analyzer and the Hemo Control Manager compared against the Sysmex XN-3000 showed almost no difference. Moreover, the intraclass correlation coefficients displayed an almost perfect agreement (1.000 for the Hb 201 DM Analyzer and 0.999 for the Hemo Control Manager). Both the Hb 201 DM Analyzer and the Hemo Control Manager devices have good precision, acceptable measuring range, and reliable correlation with automated hematology analyzers.

**Keywords:** Hemoglobin, Hemoglobinometers, Point-of-care-testing

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## Introduction

The implementation of point of care testing in hematology has been growing continuously for decades. The measurement of hemoglobin concentration is performed as a routine test for assessment of anemia when screening blood donors or determining the amount of hemoglobin required to trigger a blood transfusion during surgical intervention.<sup>(1 - 3)</sup>

Point of care testing provides significant benefits, including ease of use, short turnaround times, and small sample volume requirement. Moreover, it can be performed near a patient's bed which makes it possible to rapidly diagnose and provide proper management.<sup>(1, 4, 5)</sup> Various studies have shown the importance of point of care testing for hemoglobin. For example, some key uses include screening for anemia in blood donors,<sup>(6)</sup> management of patients in the emergency department,<sup>(7, 8)</sup> and reduction of iatrogenic anemia and blood transfusion in neonates.<sup>(9, 10)</sup> Currently, several point of care (POC) hemoglobinometers are available in the market. While some are designed only to screen for anemia in primary healthcare settings or blood donors, others provide more accurate and reliable measurements. Both the Hemocue® Hb 201 DM Analyzer (HemoCue AB, Ängelholm, Sweden) and the Hemo Control Manager (EKF-diagnostic GmbH, Barleben, Germany) are portable hemoglobinometers capable of analyzing venous, arterial, and capillary blood

samples using the azide methemoglobin reaction. In addition, both devices have data management functions such as automatic result transfer to a laboratory information system, quality control system, and built-in barcode scanning function to identify the patient and the operator. However, only the Hemo Control Manager can report both hemoglobin and hematocrit levels.<sup>(11 - 13)</sup>

The aim of this study was to assess the performance of two hemoglobinometers – Hb 201 DM Analyzer and Hemo Control Manager – by evaluating precision, linearity, and accuracy.

## Materials and methods

### Sample

The study was carried out at the central laboratory of the Department of Clinical Pathology, Faculty of Medicine, Siriraj Hospital, Mahidol University between August 2018 and January 2019. For the precision study, two commercial quality control materials were used; HemoTrol® (Eurotrol B.V., The Netherlands) with target values of 8.0 g/dL, 12.0 g/dL, and 16.1 g/dL for the Hb 201 DM Analyzer and Hb-con (EKF-diagnostic GmbH, Barleben, Germany) with target values of 8.1 g/dL, 12.1 g/dL, and 16.1 g/dL for the Hemo Control Manager. For accuracy, 40 leftover dipotassium ethylenediaminetetraacetic acid ( $K_2$ EDTA) blood samples from outpatients and inpatients were included. All leftover samples contained at least 2 mL of

blood and were analyzed with the Hb 201 DM Analyzer and the Hemo Control Manager within 4 hours of arrival at the laboratory. The samples with hemoglobin concentration at <10 g/dL, 10 - 16 g/dL, and >16 g/dL were selected to cover all possible ranges of a patient's hemoglobin concentration in routine practice. For the linearity study, 20 mL of K<sub>2</sub>EDTA blood was collected from one healthy volunteer, either a male or non-pregnant and non-breastfeeding female aged 18 - 60 years old with no underlying disease or history of chronic intake of drugs. The protocol for this study was approved by the Siriraj Institutional Review Board (SIRB) [266/2561 (EC4)].

## Hemoglobin analyzers

### Hb 201 DM Analyzer

Hb 201 DM Analyzer is a point of care device that measures hemoglobin concentration by using the azide methemoglobin reaction principle and turbidity compensation with dual wavelengths (570 nm and 880 nm). The analyzer must be used with Hb 201 Microcuvettes (HemoCue AB, Ängelholm, Sweden). Blood samples for testing were taken either from the capillaries, venous or arteries. The volume needed per test was approximately 10 µL.<sup>(11)</sup> The Hb 201 DM Analyzer has built-in quality control features and is factory calibrated for the hemoglobin-cyanide (HiCN) method, an international reference protocol that determines the hemo-

globin concentration in human blood. Thus, there was no need for further calibration.<sup>(14)</sup>

### Hemo Control Manager

The Hemo Control Manager is a point of care device which measures both hemoglobin and hematocrit levels. It must be used with Hemo Control n.x.t Generation microcuvettes (EKF-diagnostic GmbH, Barleben, Germany). The hemoglobin measurement method used by this device is also the azidemethemoglobin reaction principle with dual wavelengths for compensation of turbidity. The hematocrit value is calculated by multiplying the hemoglobin result by 2.94. Capillary, venous, and arterial blood are all accepted by the device. The sample volume required for analysis is approximately 8 µL. The Hemo Control Manager also has an auto self-test feature and is factory calibrated for the reference method.<sup>(12, 13)</sup>

### Sysmex XN-3000

The Sysmex XN-3000 by Sysmex Corp Kobe, Japan is an automated analyzer capable of evaluating multiple parameters in blood cells. It determines hemoglobin concentration by using the cyanide-free sodium lauryl sulphate (SLS) detection method. Erythrocytes are lysed to release hemoglobin, which then reacts with SLS forming a colored SLS-HGB complex. Subsequently, absorbance at a wavelength of 555 nm is measured and converted into the hemoglobin concentration.<sup>(15)</sup>

## Performance evaluation

### Precision study

A precision study was carried out according to the approved Clinical and Laboratory Standards Institute's (CLSI) User Verification of Precision and Estimation of Bias; Approved Guideline – Third Edition (CLSI EP15-A3).<sup>(16)</sup> Low, normal, and high quality control materials were analyzed in five replicates every day for five days in both point of care hemoglobin analyzers.

### Linearity study

Linearity is the ability to provide results that are directly proportional to the concentration of analyte in the test sample.<sup>(17)</sup> Twenty mL of K<sub>2</sub>EDTA blood from a healthy volunteer was centrifuged at 1,148 g for 10 minutes to separate the plasma and red blood cells. These two components were then mixed at different volumes to produce sample level 1 (low concentration; L) and sample level 5 (high concentration; H) with hemoglobin concentrations around 1 g/dL and 23 g/dL, respectively. Afterwards, sample level 5 was diluted with sample level 1 to make sample level 2, 3, and 4 (1: L, 2: 0.75L + 0.25H, 3: 0.5L + 0.5H, 4: 0.25L + 0.75H, 5:H). Each sample was measured in triplicates by both the Hb 201 DM Analyzer and the Hemo Control Manager. The assigned values were determined by the Sysmex XN-3000, which had good precision and accuracy according to daily internal quality control and external quality assessment results.

### Accuracy study

According to working instructions, the samples were analyzed by the Sysmex XN-3000 within 1.5 hours of arriving at the laboratory. Subsequently, the residual samples were adequately mixed and poured onto slides. The blood samples were filled into two different manufacturers' microcuvettes by one continuous process without air bubble interference. Excess blood on the outside of the microcuvettes was gently wiped off by a gauze before it was inserted into the Hb 201 DM system and the Hemo Control Manager hemoglobin analyzers. Samples were analyzed in duplicates. The average hemoglobin concentration determined by the Hb 201 DM Analyzer and the Hemo Control Manager were compared with the Sysmex XN-3000.

### Statistical analysis

Data was presented as mean  $\pm$  SD or percentage when appropriate and was analyzed using the PASW Statistics for Windows, version 18.0 (SPSS, Inc., Chicago, IL, USA), EP Evaluator® Release 12.0 (Data Innovations LLC., South Burlington, VT USA) and Microsoft Excel (Microsoft Corporation, Redmond, WA, USA)

The repeatability and laboratory imprecision of this study was calculated by Microsoft Excel and demonstrated as a coefficient of variation (CV). The linearity of both point of care hemoglobin devices were evaluated by the "Linearity and Calibration Verification" module of EP Evaluator®

Release 12.0. An accuracy performance evaluation was performed using hemoglobin results from the three machines and evaluated in pairs (HemoCue Hb 201 DM Analyzer with Sysmex XN-3000 and Hemo Control Manager with Sysmex XN-3000). A linear regression graph and correlation coefficient ( $r$ ) was determined to show the linear relationship between the devices. After this point, error indices were evaluated according to SMILE Hematology Accuracy Guidelines<sup>(18)</sup> with a total allowable error of 7% as stated by the criteria of the Clinical Laboratory Improvement Amendments (CLIA) 1988.<sup>(19)</sup> Ninety five percent of all error indices were between (-1) to (+1) indicating a “PASS” accuracy experiment. We also observed agreement between

the analyzers using the intraclass correlation coefficient (ICC) with a 95% confidence interval (95% CI) and Bland-Altman plot. The ICCs and their 95% CI was calculated using PASW Statistics, based on two-way mixed models and absolute agreement types. The strength of agreement was interpreted as follows: <0: poor, 0.00 - 0.20: slight, 0.21 - 0.40: fair, 0.41 - 0.60: moderate, 0.61 - 0.80: substantial, 0.81 - 1.00: almost perfect.<sup>(20)</sup>

## Results

### Precision study

The repeatability and laboratory imprecision of both the Hb 201 DM Analyzer and the Hemo Control Manager are shown in Table 1.

**Table 1** Repeatability and within-laboratory imprecision of Hb 201 DM Analyzer and Hemo Control Manager

Analyzer	Level 1			Level 2			Level 3		
	Mean (g/dL)	%CV <sub>R</sub>	%CV <sub>WL</sub>	Mean (g/dL)	%CV <sub>R</sub>	%CV <sub>WL</sub>	Mean (g/dL)	%CV <sub>R</sub>	%CV <sub>WL</sub>
Hb 201 DM Analyzer	8.03	1.06	1.53	11.98	0.50	0.53	15.98	0.51	0.64
Hemo Control Manager	8.04	0.73	0.82	12.08	0.71	0.85	16.06	0.60	0.62

**Abbr. :** CV<sub>R</sub>, repeatability in coefficient of variation; CV<sub>WL</sub>, within-laboratory imprecision in coefficient of variation

### Linearity study

The linearity of hemoglobin was analyzed on the Hb 201 DM Analyzer and the Hemo Control Manager over a range of 0.8 g/dL to 21.4 g/dL and 1.0 g/dL to 22.2 g/dL, respectively. The slope and intercept of both devices are shown in Fig. 1.

### Accuracy evaluation

The mean Hb value obtained by the Hb 201 DM Analyzer was slightly less than the mean venous Hb value obtained by both the Hemo Control Manager and the Sysmex XN-3000 (11.8 ± 3.6 g/dL, 11.9 ± 3.6 g/dL, and 11.9 ± 3.6 g/dL). The range of measure-

ments by the Hb 201 DM Analyzer and the Sysmex XN-3000 was 4.8 - 20.4 g/dL while 4.9 - 20.5 g/dL was measured by the Hemo Control Manager.

Both the Hb 201 DM Analyzer and the Hemo Control Manager showed good correlation with the Sysmex XN-3000 (Fig. 2).

All the samples from both devices had an error index within (-1) to (+1). Table 2 demonstrates data of intraclass correlation and mean of difference. Bland-Altman plots are shown in Fig. 3. There was only a slight difference between the two points of care hemoglobin analyzers and the Sysmex XN-3000.

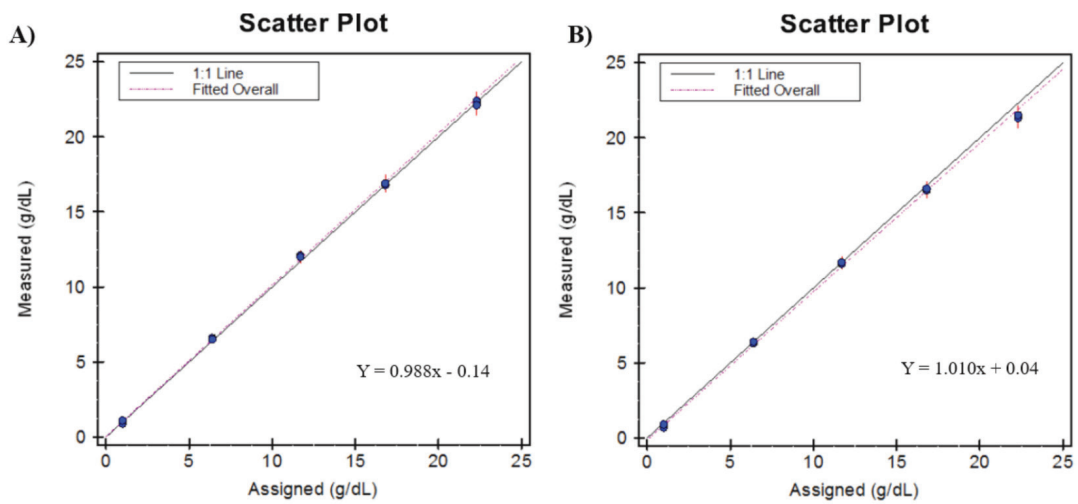


Fig. 1 Linearity study A) Hb 201 DM Analyzer B) Hemo Control Manager

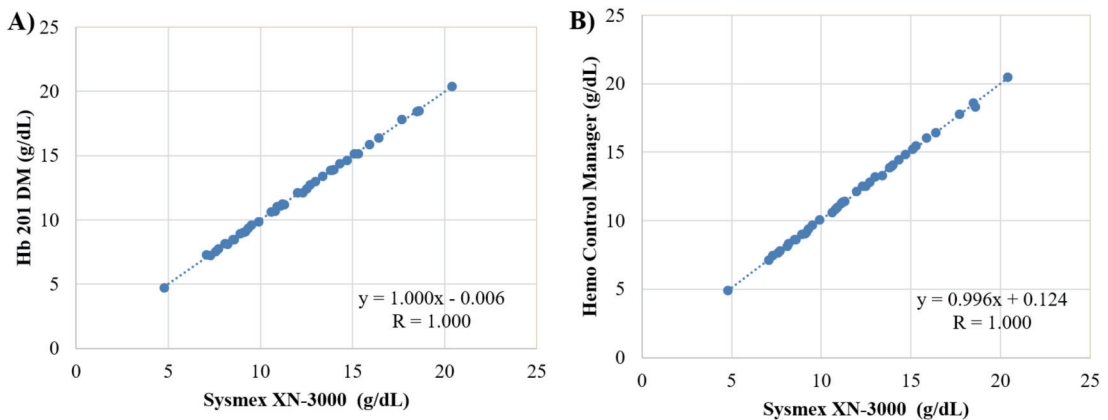
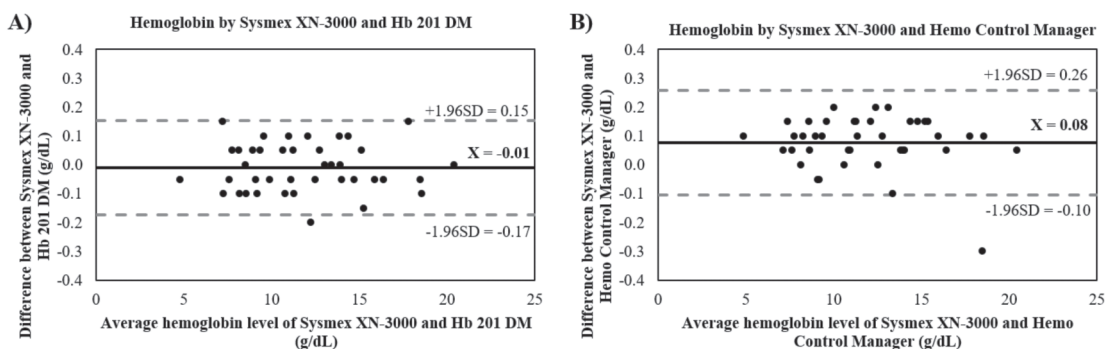


Fig. 2 Correlation of hemoglobin concentration by (A) Sysmex XN-3000 and Hb 201 DM Analyzer; (B) Sysmex XN-3000 and Hemo Control Manager

**Table 2** Intraclass correlation and mean of difference between Hb 201 DM Analyzer, Hemo Control Manager and Sysmex XN-3000

Point of care device against Sysmex XN-3000	Intraclass ICC	correlation 95% CI	Mean of difference $\pm$ SD (g/dL)
Hb 201 DM Analyzer	1.000	1.000 - 1.000	0.01 $\pm$ 0.08
Hemo Control Manager	0.999	0.997 - 1.000	-0.08 $\pm$ 0.09

**Abbr. :** ICC, intraclass correlation; CI, confidence interval; SD, standard deviation



**Fig. 3** Bland-Altman plot for hemoglobin concentration by (A) Sysmex XN-3000 and Hb 201 DM Analyzer; (B) Sysmex XN-3000 and Hemo Control Manager

## Discussion

To our knowledge, this is the first validation study of POC hemoglobinometers with a data management system to show if the devices are appropriate for routine use when compared to a laboratory analyzer. This study evaluated the precision, linearity, and accuracy of the instruments.

Although POC hemoglobinometers are mostly used with capillary samples, pre-analytical errors such as puncture technique might obscure the performance of analyzers. Hence, this study used commercial quality

control for precise evaluation and venous blood samples for accuracy and linearity assessment to minimize pre-analytical errors.

For the precision study, the Hb 201 DM Analyzer had a slightly wider CV range than the Hemo Control Manager as shown in Table 1. However, results from both devices were less than in previous studies by Gomez-Simon *et al.*, and Singh A *et al.*, in which CV was 2.28% for the HemoCue (model not specified) and 2.51% for the Hemo Control.<sup>(21, 22)</sup> According to routine internal quality control of our Sysmex XN-3000

analyzer in October 2018, the CV was 1.00%, 1.05%, and 0.71% with mean values of 5.90 g/dL, 11.69 g/dL, and 16.64 g/dL, respectively. As such, the precision of these two POC hemoglobinometers was as good as the fully automated hematology analyzer.

The linearity of hemoglobin concentration from the Hb 201 DM Analyzer had a narrower measuring range than the Hemo Control Manager in Fig 1. Due to limited number of blood samples, we could not verify the full range (0 - 25.6 g/dL) as claimed by manufacturers.<sup>(11,12)</sup> Nevertheless, the verified measuring range in this study should be adequate for most patients in routine practice.

The mean of difference or bias of measurements by the Hb 201 DM Analyzer was closer to zero than in the Hemo Control Manager when comparing with the Sysmex XN-3000 (Table 2). The limit of agreement of the Hb 201 DM Analyzer was also slightly narrower for measurements of hemoglobin (Fig. 3). However, according to the opinion of a clinician, those differences were not clinically significant. The ICCs of both POC devices also showed almost perfect agreement with the Sysmex XN-3000 as per the Landis and Koch criteria.<sup>(20)</sup> Thus, hemoglobin levels measured by the Hb 201 DM Analyzer and the Hemo Control Manager were reliable and correlate with the automated hematology analyzer. Nonetheless, Karakochuk CD, *et al.* demonstrated that the HemoCue Hb 201 can overestimate hemoglobin concentrations with

a mean difference 0.26 g/dL when compared with the automated hematology analyzer.<sup>(23)</sup> Meanwhile, a study by Singh A, *et al.* showed a mean difference of -0.22 g/dL between the Hemo Control Manager and the automated hematology analyzer. They noted an ICC of 0.77, which was viewed as in substantial agreement.<sup>(22)</sup> The differences between these two studies and our results might be explained by the different sources of samples. In their studies, samples for the POC hemoglobinometer and automated analyzer was capillary blood and EDTA venous blood, respectively.<sup>(22, 23)</sup> However, our study used EDTA venous blood samples for all devices. Many previous studies, which evaluated the accuracy of the HemoCue compared against the automated hematology analyzer demonstrated higher absolute bias of measurement (0.31 - 0.84 g/dL).<sup>(24 - 27)</sup> Besides the source of sample factor, the models of HemoCue seemed to play an important role as well. Three of five previous studies analyzed the HemoCue Hb 301, while the rest did not state the model of HemoCue used.<sup>(24 - 27)</sup> Manufacturer claimed that the Hb 301 model was optimized for anemia screening in primary care and blood donation settings,<sup>(28)</sup> so its accuracy might not be comparable with the Hb 201 DM Analyzer and the Hemo Control Manager, which were more reliable in clinical management.

The limitation of this study was that we only used venous samples for the accuracy study. The reason for this was that the capillary

sampling was associated with pre-analytical errors which could have been influenced by the operator. So, the results may have obscured the actual performance and reliability of the instruments.

A further investigation is needed to evaluate the reliability of capillary samples in routine practice. However, to ensure accuracy of the capillary sample method, training and assessing staff competency should be required to guarantee proper sample collection, accurate use of the device, and quality control management.

### Conclusion

Both the Hb 201 DM Analyzer and the Hemo Control Manager had high reproducibility, wide-ranging measurements, and provided excellent correlation with automated hematology analyzers.

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### Disclosure statement

Authors have no conflict of interest.

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