

Accuracy of Noninvasive Spot-Check Testing of Total Hemoglobin with the Masimo Pronto-7™

BACKGROUND AND OBJECTIVE

Anemia is the most common blood disorder and is defined as low hemoglobin levels in the blood. Traditional assessment and treatment of anemia is dependent on the measurement of total hemoglobin (tHb) by invasive laboratory or Point-of-Care (POC) methods, using blood derived from venipuncture or a finger stick. The World Health Organization (WHO) estimates 1.6 billion people worldwide suffer from anemia, although many more are suspected of being undiagnosed, with women and children at the highest risk.¹ Because of the prevalence of chronic and acute anemia, tHb is one of the most frequently ordered tests in both acute care and outpatient settings.

Traditional methods for obtaining tHb values are time consuming, frequently not available at the point of care, painful to many patients, increase risk of infection, and may expose the patient and caregiver to blood-borne pathogens. The recent availability of noninvasive spot-check testing of hemoglobin (SpHb®) may provide significant advantages over the traditional testing methods to healthcare providers in hospitals, physician offices, ambulatory care centers, blood donation centers, emergency medical services, and other outpatient settings.

Studies have shown invasive tHb measurements can vary as much as 0.9 g/dL between different laboratory devices across the normal tHb range, using a reference calibrator.² In addition, POC devices analyzing finger stick capillary blood samples are susceptible to even greater differences from traditional lab measurements, with differences up to 1.2 to 1.8 g/dL from reference standards.³⁻⁶

The purpose of this study was to evaluate the accuracy of a new noninvasive spot-check testing device for SpHb compared to invasive measurements of tHb.

METHODS

All data were collected under institutional review board approval with all subjects enrolled providing written, informed consent. Study subjects consisted of healthy adult volunteers and adult patients presenting to an outpatient nephrology and internal medicine clinic. Subjects were excluded if they had fingernail polish, acrylic fingernails, or fingernail deformities. The level of pigmentation in each subject's skin was tested with the Massey scale⁷, an 11-point scale, ranging from 0 to 10, with 0 representing albinism and 10 being the darkest.

The study protocol consisted of collecting venous blood samples in all subjects and both venous and capillary samples in healthy volunteer subjects. Noninvasive SpHb measurements were obtained from stationary subjects within minutes of the blood sample collection. A noninvasive Pulse CO-Oximeter (Pronto-7™ with Rainbow 4D™, Masimo, Irvine, CA) was used to measure SpHb. The Pronto-7 is a handheld, noninvasive monitor that emits multiple wavelengths of light through a reusable finger sensor placed on the ring finger of the subject's non-dominant hand. Based upon the light attenuation characteristics and proprietary algorithms, the device measures SpHb – as well as SpO₂, pulse rate, and perfusion index – in under a minute.

Invasive blood samples for all subjects were analyzed by one manual and one automated laboratory method:

- 1) Hemiglobincyanide method (HiCN)⁸
- 2) Hematology analyzer (Beckman Coulter LH 500)⁹

The gold standard for assessing hemoglobin concentration is the HiCN method, described by the International Council for Standardization in Hematology (ICSH) and procedure H15 Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood Approved Standard – Third Edition. However, the HiCN method is not practical in clinical settings due to complexity and time requirements. We also utilized the Beckman Coulter LH 500 for a secondary comparison because it is one of the most widely used hematology analyzers worldwide and delivers comparable results to the gold standard hemiglobincyanide reference.^{10,11} All laboratory procedures and analyses conformed to the Clinical Laboratory Improvement Act (CLIA) '88 standards.¹²

The capillary blood samples collected from healthy volunteers were analyzed for tHb testing in a POC test device (HemoCue Model Hb 201+).¹³ Capillary blood samples were collected with appropriate ancillaries for finger stick and processed per the manufacturer's directions for use.

Accuracy was calculated as the bias (average difference) and precision (first standard deviation) of the differences between SpHb and POC tHb vs. whole blood sample analysis. Regression analysis was performed to assess the correlation of the differences in SpHb and laboratory tHb with perfusion index (PI), Massey scale, and finger circumference.

RESULTS

Subjects

Data from healthy adult volunteers were collected at Masimo Corporation (Irvine, CA) and from adult patients at Raleigh Associated Medical Specialists (Raleigh, NC). A total of 89 subjects were tested, 51 (57%) healthy adults and 38 (43%) subjects with one or more of the following conditions: chronic kidney disease, diabetes, Parkinson's, or emphysema. A total of 43 subjects (48%) were male. In addition, 27 (32%) of the subjects were on multiple medications for chronic conditions. Measurements for 2 (2%) subjects could not be obtained due to excessive movement or very low perfusion; these subjects were not included in the analysis. A total of 56 (63%) of the subjects tested were classified as light of skin (Massey score ≥ 3). Invasive tHb values by the HiCN method had a range of 9.8 to 15.8 g/dL, with 29 (33%) tHb measurements < 13 g/dL. Each tHb method used in the study and mean and range of tHb values are shown in Table 1.

Table 1 – Method of Total Hemoglobin Measurement with Mean and Range of Total Hemoglobin Values

	POC Device (Quest HemoCue)	Pulse CO-Oximeter (Masimo Pronto-7)	HiCN (Manual)	Hematology Analyzer (Beckman Coulter)
Sample Collection Method	Finger stick	Noninvasive	Venipuncture	Venipuncture
Methodology	Modified azidemethemoglobin	Spectrophotometry	Hemiglobincyanide method	Impedance and spectrophotometry
Mean Hb (g/dL)	14.2	13.5	13.6	13.6
Range (g/dL)	11.3 – 16.5	9.9 – 16.5	9.8 – 15.8	8.7 – 15.9

Table 2 – Pronto-7 Spot-Check SpHb Accuracy vs. Two Laboratory Reference Methods

	HiCN Reference	Hematology Analyzer
Precision (1 SD)	0.91 g/dL	0.91 g/dL
Bias	-0.11 g/dL	-0.04 g/dL

N = 87

Table 2 demonstrates the SpHb accuracy in all 87 subjects compared to the gold-standard HiCN and automated laboratory device, similar to those used by commercial and hospital laboratories. Regression analysis showed correlation of the differences in SpHb and tHb and subject PI, Massey scale value, and finger circumference of 0.0, 0.0, and 0.05, respectively (p value non-significant for all).

Point-of-Care HemoCue tHb and Masimo SpHb vs. HiCN and Hematology Analyzer

Data from 51 healthy volunteers for both HemoCue tHb (capillary sample) and Masimo SpHb results were compared to HiCN reference and hematology analyzer measurements, with results shown in Table 3. The age range of these subjects was 25 to 58 years with an average of 41 years. A total of 24 (47%) were male and 45 (88%) subjects (82%) had light pigmentation. In these subjects, HiCN tHb had a range of 11.0 to 16.3 g/dL, with 13 (25%) tHb measurement <13 g/dL.

Table 3 – Spot-Check Accuracy of POC HemoCue tHb and Pronto-7 SpHb vs. Two Laboratory Reference Methods

	HemoCue 201+		Masimo Pronto-7	
	HiCN Reference	Hematology Analyzer	HiCN Reference	Hematology Analyzer
Precision (1 SD)	0.65	0.62	0.85	0.87
Bias	0.28	0.40	-0.38	-0.26

N = 51

CONCLUSION

Both SpHb from the Masimo Pronto-7 Pulse CO-Oximeter and POC tHb from the HemoCue provide clinically acceptable accuracy compared to the gold-standard reference method (HiCN) and the automated laboratory device (hematology analyzer). In these subjects, low finger perfusion as measured by PI, darker skin pigmentation as measured by the Massey scale, and smaller finger circumference were not associated with greater differences in SpHb compared to invasive tHb.

The Masimo Pronto-7 eliminates pre-analytic technique issues with sample collection. The use of the Masimo Pronto-7 at the point of care to obtain SpHb measurements in under one minute may facilitate more rapid decision making and improve clinician efficiency.

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