

A Rapid Method for Measuring Hemoglobin Is Comparable to the Reference Procedure and another Point-of-Care Method

Abstract

The Alere HemoPoint[®] H2 System provides a fast, reliable measurement of an individual's hemoglobin level using an 8 µL sample collected in a microcuvette and then tested using the Alere HemoPoint[®] H2 Meter. Results are available in less than a minute. In the present study, precision of the Alere HemoPoint[®] H2 System was assessed with commercial control materials. Comparisons were made with the CLSI reference procedure and a widely-used point-of-care method. Within-run CVs ranged from 0.5–0.7% and total CVs ranged from 1.1–1.5%. Alere HemoPoint[®] H2 hemoglobin results were highly correlated ($r \geq 0.998$) with both the reference procedure and the other point-of-care method. The Alere HemoPoint[®] H2 System enables rapid, accurate, and reproducible hemoglobin measurement.

Introduction

Hemoglobin is the oxygen-carrying pigment and main component of red blood cells. Low hemoglobin levels may indicate anemia, recent hemorrhage or fluid retention. Elevated hemoglobin levels may indicate hemoconcentration from polycythemia or dehydration.

The Alere HemoPoint[®] H2 System is a simple, rapid point-of-care testing (POCT) method to quantitatively measure hemoglobin in capillary, venous, or arterial whole blood. The testing system employs established azidemethemoglobin methodology in a disposable microcuvette and uses a compact, POCT meter.

The definitive reference procedure for hemoglobin measurement – the hemiglobincyanide method (more commonly known as the cyanmethemoglobin method) – was established by the International Council for Standardisation in Haematology. It is employed by the Clinical Laboratory Standards Institute (CLSI; formerly NCCLS) in its “Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard – 3rd ed.” (CLSI document H15-A3).¹

In the present study, the precision of the Alere HemoPoint[®] H2 hemoglobin method was determined and whole blood sample quantification was compared with the CLSI (NCCLS) reference procedure for hemoglobin and with another POCT system employing the same azidemethemoglobin method.

Methods

Within-run, between-day, and total precision (coefficient of variation; CV) was assessed for the Alere HemoPoint[®] H2 hemoglobin method according to CLSI (NCCLS) EP5-A2 using commercial control material.² One hundred and two volunteers participated in the method comparison study. Venous whole blood was collected in EDTA tubes by standard venipuncture

technique. All specimens were analyzed in duplicate using the Alere HemoPoint[®] H2 System (EKF-diagnostic GmbH, Barleben, Germany), the HemoCue[®] B-Hemoglobin system (Ängelholm, Sweden), and by the CLSI reference procedure.¹ Individual test values for the two POCT methods were compared with the mean of the duplicates for the reference procedure using least squares linear regression.

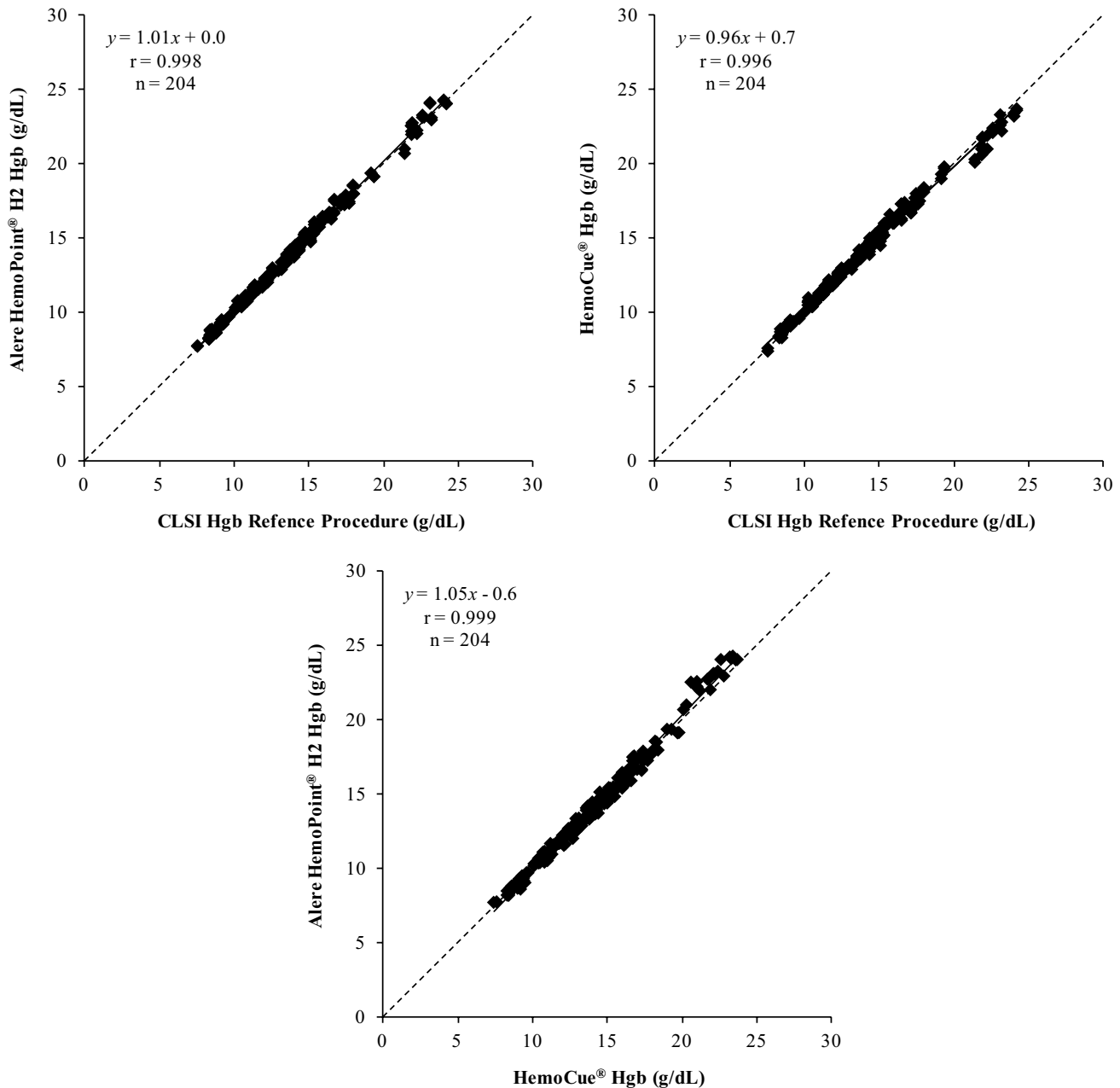
Results

Within-run CVs for the Alere HemoPoint[®] H2 System ranged from 0.5–0.7% and total CVs ranged from 1.1–1.5%, as shown in the table below.

Table. Precision of Alere HemoPoint[®] H2 System

	Hemoglobin (g/dL)		
	15.7	11.8	8.0
Within-run			
SD (g/dL)	0.087	0.070	0.058
CV (%)	0.5	0.6	0.7
Between-day			
SD (g/dL)	0.179	0.176	0.111
CV (%)	1.1	1.5	1.4
Total			
SD (g/dL)	0.175	0.162	0.122
CV (%)	1.1	1.4	1.5

Results for the Alere HemoPoint[®] H2 System compared with the CLSI reference procedure and with the HemoCue[®] B-Hemoglobin system are shown in the Figures. Alere HemoPoint[®] H2 hemoglobin results were highly correlated ($r \geq 0.998$) with both the reference procedure and the HemoCue[®] method. Both POCT methods exhibited good standardization relative to the reference procedure with negligible slope bias or intercept offsets.



Figures. Hemoglobin (Hgb) Method Comparisons

Dotted line: $y = x$; solid line: least squares linear regression best fit

Conclusions

The Alere HemoPoint[®] H2 System enables rapid, accurate, and reproducible hemoglobin measurement in capillary, venous, or arterial whole blood samples. Health care providers who are not experienced in clinical laboratory techniques can successfully and reliably use the Alere HemoPoint[®] H2 System to rapidly measure hemoglobin. Availability of this simple method should facilitate the management of anemia and other red blood cell disorders.

References

1. CLSI. Reference and selected procedures for the quantitative determination of hemoglobin in blood; approved standard – 3rd ed. NCCLS document H15-A3. NCCLS: Wayne, PA, 2000.
2. CLSI. Evaluation of precision performance of quantitative measurement methods; approved guideline – 2nd ed. NCCLS document EP5-A2. NCCLS: Wayne, PA, 2004.

