A Rapid Method for Measuring Hemoglobin Is Comparable to Routine Laboratory Methods

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, the Alere HemoPoint® H2 hemoglobin test was compared with hemoglobin measured using hematology analyzers that are used routinely in commercial, hospital, and physician office laboratories. Alere HemoPoint® H2 hemoglobin results were highly correlated (r > 0.98) with four different laboratory analyzers at four testing sites. The Alere HemoPoint® H2 System enables rapid hemoglobin measurements that are equivalent to values obtained using routine laboratory methods.

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.

Hemoglobin is routinely measured as part of a complete blood count (CBC) when blood samples are sent to commercial or hospital laboratories or tested in physician office laboratories (POL). In such laboratories, the testing is conducted using hematology analyzers designed for CBC testing.

In the present study, the Alere HemoPoint® H2 hemoglobin method was evaluated at four clinical sites where it was compared with hemoglobin measured using four different CBC analyzers.

Methods

Four clinical sites participated in the study. Site A, a hospital, enrolled 94 adult patients and 24 children between the ages of 2 and 16 years. Site B, the POL of a diabetology practice, enrolled 47 adult patients with diabetes. Site C, an internist's POL, enrolled 30 adult patients. Site D, the POL of hematology/oncology practice, enrolled 59 adult patients.

Venous whole blood was collected from each patient in EDTA tubes by standard venipuncture technique. In addition, 10 arterial whole blood specimens were obtained at site A. Site A staff also prepared 10 concentrated and 10 diluted specimens by centrifuging and removing by pipette either plasma (to concentrate samples) or red cells (to dilute samples).

All specimens were analyzed using the Alere HemoPoint® H2 System (EKF-diagnostic Gmbh, Barleben, Germany) and by the CBC analyzer at each site: Sysmex® SE-9000 at site A, Sysmex® XE-2100 at site B, Sysmex® SE-9500 at site C, and Swelab AC910 at site D. Hemoglobin test values were compared using least squares linear regression.
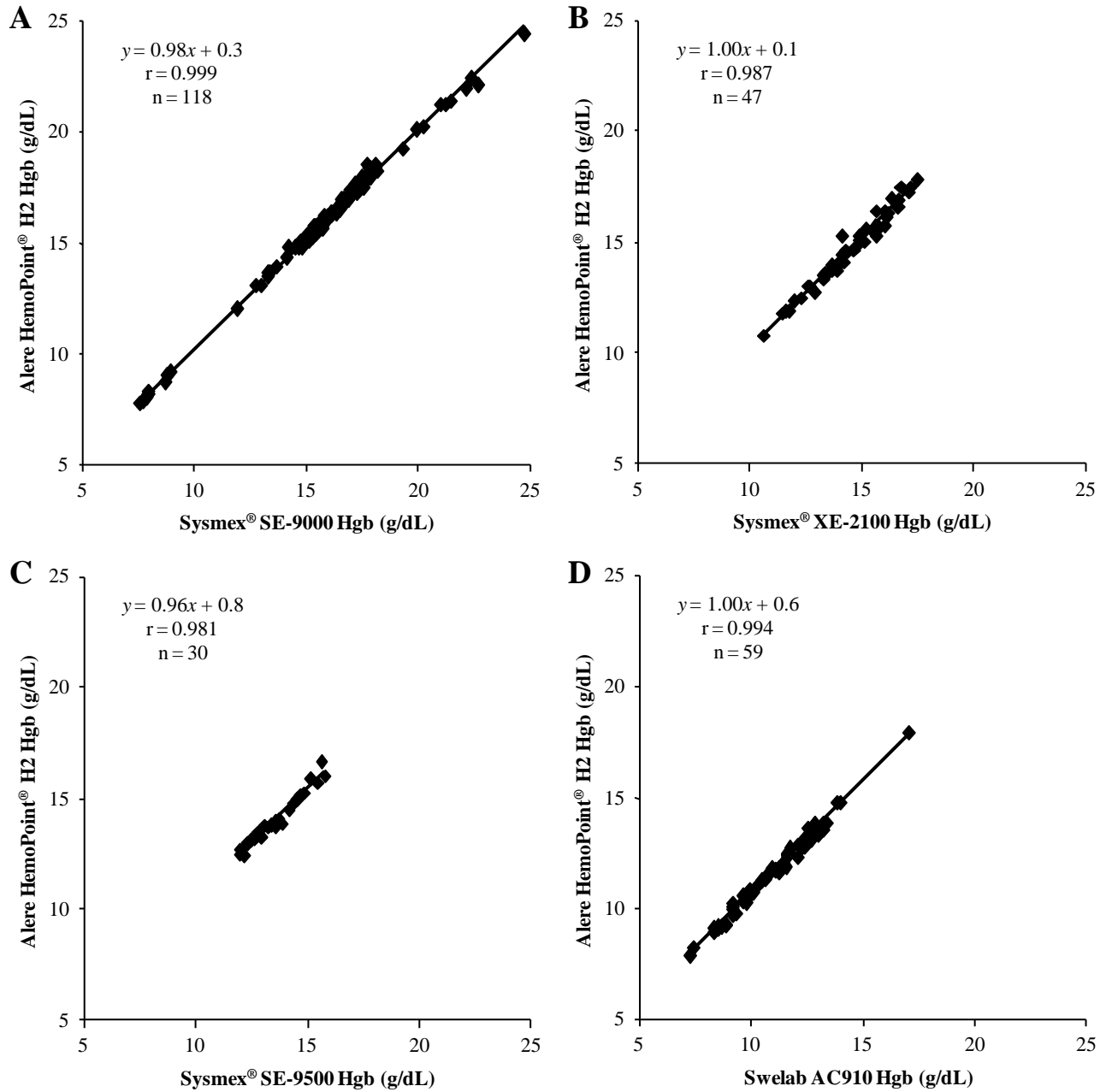
Results

Results for the Alere HemoPoint® H2 System compared with each of the four CBC analyzers using venous whole blood are shown in the Figures. Alere HemoPoint® H2 hemoglobin results were highly correlated (r > 0.98) with all four methods and exhibited negligible slope biases or intercept offsets.

Arterial blood specimens tested at site A were also highly correlated, $y = 0.98x + 0.5$, r = 0.999 (data not shown).

Results for sites A, B, and C were pooled since Sysmex® analyzers were used at each. Pooled results for 195 specimens: $y = 0.99x + 0.4$, r = 0.997 (data not shown).

Conclusions

The Alere HemoPoint® H2 System enables rapid hemoglobin measurements in venous or arterial whole blood samples that are equivalent to values obtained using routine laboratory CBC analyzers. 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.

A

$y = 0.98x + 0.3$
r = 0.999
n = 118

Alere HemoPoint® H2 Hgb (g/dL)

Sysmex® SE-9000 Hgb (g/dL)

B

$y = 1.00x + 0.1$
r = 0.987
n = 47

Alere HemoPoint® H2 Hgb (g/dL)

Sysmex® XE-2100 Hgb (g/dL)

C

$y = 0.96x + 0.8$
r = 0.981
n = 30

Alere HemoPoint® H2 Hgb (g/dL)

Sysmex® SE-9500 Hgb (g/dL)

D

$y = 1.00x + 0.6$
r = 0.994
n = 59

Alere HemoPoint® H2 Hgb (g/dL)

Swelab AC910 Hgb (g/dL)

Figures. Hemoglobin (Hgb) Method Comparisons
Solid line: least squares linear regression best fit
Site A: hospital; site B: POL, diabetology practice; site C: POL, internist practice; site D: POL, hematology/oncology practice