

Understanding Performance Requirements for Hb Testing

Is Close Enough Really Good Enough at the Point of Care?

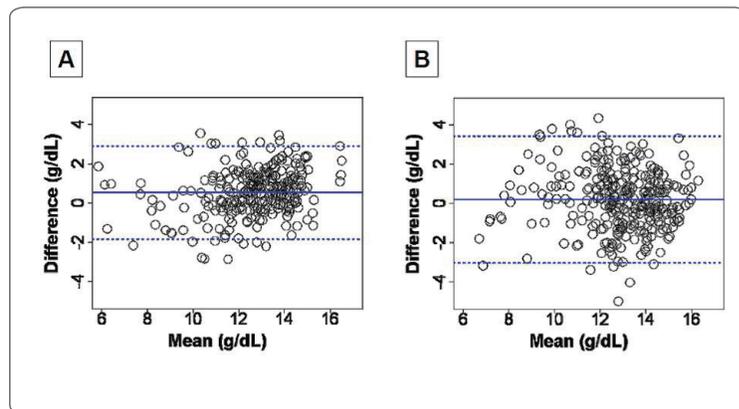
The importance of rapid Hb results at the point of care is clear — enabling immediate clinical decisions about a patient's condition. Yet, certain requirements have to be met to get results accurate enough for those decisions.

New, non-invasive Hb methods claim values that are good enough. Yet a significant amount of studies show they simply don't measure up. With HemoCue, you have peace of mind when making clinical decisions.

Because when it comes to caring for people, we refuse to compromise.



To learn more about HemoCue Hb systems, visit hemocue.com



Bland and Altman graphical representation of the concordance between the laboratory value of hemoglobin and SpHb. Results for the Pronto-Study are displayed on the panel A and for the Orsense-Study on the panel B. The plain horizontal blue line represents the mean bias and the dashed horizontal blue lines represent the upper and the lower limits of agreement. doi:10.1371/journal.pone.0030065.g003²

What are the Clinical Implications of Choosing Non-Invasive Methods?

It's unthinkable, really, what it can mean to be just a little off when dealing with certain clinical conditions. Consider the implications in the following cases.

Case: Pregnant woman

A pregnant woman with a true Hb of 10.5 g/dL is falsely reported as 12.5 g/dL. No further exams or iron supplement provided.

- Could this pose a medical risk for child and mother?
- Will there be a risk during delivery?



Case: 5-year-old child

A 5-year-old child with a true Hb of 10.0 g/dL is anemic, according to WHO's definition. A deviation of ± 2 g/dL means the result could be anywhere between 8.0 and 12.0 g/dL.

- Are clinical decisions different if Hb is 8 or 12 g/dL?
- Can the test be justified?



Case: A donor with a true Hb of 11.0 g/dL

A donor with a true Hb of 11.0 g/dL is falsely reported as 13.0 g/dL and blood donation is performed. Donor leaves with an Hb of 10.0 g/dL.

- Is this acceptable for a volunteer donor?
- Is this a concern for the blood bank?
- Risk of losing donor?



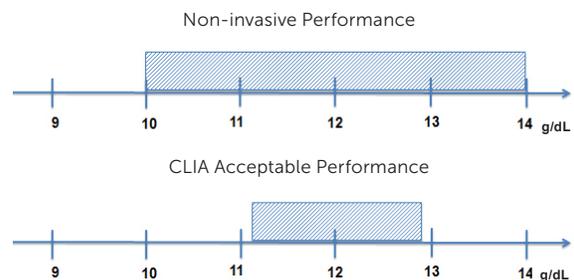
Comparison of Non-Invasive and Blood Based Hb Test Performance

Acceptable performance limits for blood based Hb tests are regulated by international standards.

One of the most commonly cited standards is the U.S. FDA (CLIA 88) regulations, where the acceptable limits of performance for hemoglobin determinations are stated as $\pm 7\%$ compared with results of the reference method¹. With a claimed performance of 2SD being ± 2.0 g/dL, non-invasive Hb results have a much wider variance, especially in the low Hb range where the cut off level for anemia is, and where important treatment decisions needs to be taken.

Hb range (g/dL)	CLIA required performance (g/dL)	Non-invasive Hb claimed performance (g/dL) ^{3,4}
6–12	± 0.4 to 0.8	± 2.0
12–18	± 0.8 to 1.3	± 2.0

Example of expected range of variation for Hb 12.0 g/dL



Potential Causes for Inaccurate Non-Invasive Hb Readings:

- Patient movement
- Failure to apply sensor properly
- Nailpolish, acrylic nails
- Elevated levels of COHb and MethHb
- Low arterial perfusion

Non-Invasive Hb Usability Concerns

- Reported "no reading" occurrences
- Sensitive to ambient light sources
- Different sensors for different finger sizes
- Patient must sit still during measurement
- Patient not allowed to talk, laugh or cough

References:

¹ FDA Part 864, Hematology and Pathology Devices

² Non-Invasive Measurement of Hemoglobin: Assessment of Two Different Point-of-Care Technologies. Plus One, January 2012; 7: 1-8.

³ Masimo FDA submission data

⁴ OrSense NBM 200 promotion material NBM-EN-0413-007

Do You Have a Balanced View of Related Publications?

Although there are clinical studies available that support the use of non-invasive hemoglobin testing, there are several recently published peer-reviewed studies revealing shortcomings of this technology.

"In summary, although the co-oximeter was easy to use, we found that it was not accurate enough for clinical decision making regarding transfusion. In contrast, the HemoCue cuvette system was more accurate than the co-oximeter in comparison with the laboratory measurements. We therefore recommend that, in spite of its somewhat more invasive nature, by requirement for a small amount of blood, the HemoCue to be used in the setting of obstetric anaesthesia and haemorrhage to measure Hb."

Evaluation of point-of-care haemoglobin measuring devices: a comparison of Radical-7 pulse co-oximetry, HemoCue and laboratory haemoglobin measurements in obstetric patients. Anaesthesia 2013, 68, 40-45.

"It is our opinion that the published accuracy data from the Masimo Radical-7 device, especially in the aforementioned critical range, does not guide clinicians to make transfusion decisions."

Noninvasive Hemoglobin Monitoring: How Accurate Is Enough? Anesth. Analg. 2013 Jul 10 (Epub ahead of print).

"Results from this widely available noninvasive point-of-care hemoglobin monitoring device were systematically biased and too unreliable to guide transfusion decisions."

Performance Evaluation of a Noninvasive Hemoglobin Monitoring Device. Ann. Emerg Med. 2011;57:330-333.

"Our study demonstrates poor correlation between hemoglobin measured non-invasively by multiwavelength pulse oximetry and a laboratory hematology analyzer. The difference was greater when the pulse oximetry perfusion index was low, as may occur in shock, hypothermia, or vasoconstriction patients. The multiwavelength pulse oximetry is not sufficiently accurate for clinical use in cardiovascular intensive care units."

The Accuracy of Noninvasive Hemoglobin Measurement by Multiwavelength Pulse Oximetry After Cardiac Surgery. Anesth. Analg. 2011;113:1052-1057.

"These data suggest that noninvasive hemoglobin determination is not sufficiently accurate for emergency department use."

Evaluation of a New Noninvasive Device in Determining Hemoglobin iLevels in Emergency Department Patients. West J Emerg Med. May 2013, No 3: 283-286.

"In short, two devices dedicated to non-invasive measurement of hemoglobin were assessed in the present study. Bias was found to be small but independently and inversely associated with the true value of hemoglobin. Of more importance is that limits of agreement are large in both cases making the clinical usefulness of such devices debatable."

Non-Invasive Measurement of Hemoglobin: Assessment of Two Different Point-of-Care Technologies. Plus One, January 2012; 7: 1-8.

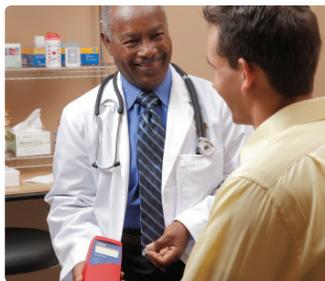
"Determination of pulse-oximetry-based hemoglobin in patients presenting with severe gastrointestinal bleeds can be inaccurate, which renders its use to guide transfusion decisions potentially hazardous."

Precision of noninvasive hemoglobin-level measurements by pulse co-oximetry in patients admitted to intensive care units for severe gastrointestinal bleeds. Crit.Care Med. 2012;40, no 9, 1-7

"Consecutively, the percentage of outliers for SpHb monitoring was significantly higher than for the HemoCue, which leads to rejection of the hypothesis of the equivalence between SpHb and HemoCue."

Comparison of the Accuracy of Noninvasive Hemoglobin Monitoring by Spectrophotometry (SpHb) and HemoCue with Automated Laboratory hemoglobin Measurement. Anesthesiology, V 115;3:548-554.

Because when it comes to caring for people, we refuse to compromise.



Hemoglobin | HbA1c | Glucose | Urine Albumin | WBC / WBC DIFF

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HemoCue has been a leader in point-of-care medical diagnostics for over 30 years. We specialize in giving healthcare providers lab-quality accuracy with results comparable to that of a clinical lab.

