

Non-Invasive Hemoglobin Screening for Diagnosis and Monitoring of Anemia

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Anemia affects close to 2 billion people worldwide and is one of the leading public health issues in the developing world. It plays a major role as a confounding factor in the study of maternal and child health as well as in key diseases such as diabetes, HIV, malaria, and malnutrition. For example, 44% of maternal deaths are related to anemia and over 70% of HIV patients are anemic. Apart from the medical burden, anemia has a negative economic effect, estimated by 4-7% of GDP.

The key to combating anemia is diagnosis and monitoring of hemoglobin. However, current hemoglobin (Hb) tests involve invasive blood drawing, with the potential of infection risk to health providers and patients, and pose a significant challenge in regions of the world that suffer from lack of running water, electricity, necessary hygienic infrastructure and skilled healthcare providers. Thus, non-invasive hemoglobin screening was declared by the WHO as one of the key medical technologies to improve global health.

A first non-invasive hemoglobin monitor has been recently introduced, thus removing the need to draw blood and promising to dramatically improve anemia screening. The device is based on technology known as Occlusion Spectroscopy, which uses an optical measurement platform combined with a ring-shaped pneumatic probe that fits on the finger (Figure 1). The non-invasive solution is significantly



Figure 1. The non-invasive Hb ring sensor

safer than invasive methods and eliminates potential contamination and biohazard handling. It is accurate, fast and easy to operate, enabling non-professional staff to perform accurate diagnosis. The elimination of biochemical processing allows mobile operation in rural locations and ensures lower costs.

The performance of the Hb system has been recently tested in the Hematology and Blood Bank Department of *Assaf Harofeh Medical Center (Zerifin, Israel)*. Upon receipt of informed consent, the sensor was placed on the subject's thumb, and two non-invasive measurements were performed. Reference Hb values were obtained from venous blood samples and evaluated on a standard laboratory blood analyzer.

A total of 710 volunteers (348 male, 362 female) were tested, with reference hemoglobin values in the range 5.3 – 17.5 g/dL. The mean error (bias) of the non-invasive readings comparing to the reference was 0.03 g/dL, the mean absolute error was 0.78 g/dL and the accuracy, defined as the standard deviation of error, was 0.93 g/dL. Figure 2 is a scatter plot of the non-invasive predictions vs. reference Hb (*Weinstein et al, AABB meeting 2012*).

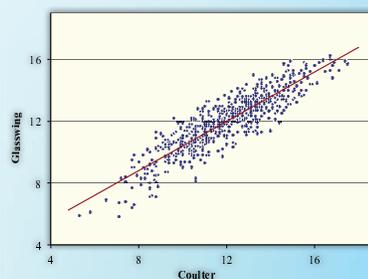


Figure 2. Non-invasive readings vs. reference Hb - Hematology study

In a similar study, the system was evaluated on a group of 63 pregnant women in the *Rabin Medical Center (Petah Tikva, Israel)*. The mean error (bias) of the non-invasive readings was 0.1 g/dL, the mean absolute error was 0.71 g/dL and the accuracy was 0.86 g/dL. A scatter plot of the results is presented in Figure 3 (*Hadar et al, The Journal of Maternal-Fetal and Neonatal Medicine 2012*).

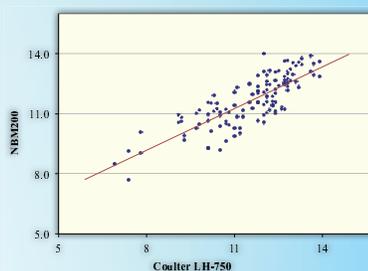


Figure 3. Non-invasive readings vs. reference Hb - Pregnant women study

The non-invasive technology is US and China FDA cleared and CE approved and is available in 60 countries worldwide. It has been successfully installed in multiple environments including hospitals, physician offices, blood donation facilities, as well as used for various applications including public screening, women health, mobile health and homecare. To date, it has delivered over 10 million non-invasive tests on patients and blood donors at 50 sites worldwide, exhibiting comparable accuracy to invasive point-of-care solutions.