

# Comparative Evaluation of Point-of-Care Hemoglobin Measurement Devices Using Venous Blood Samples (P-BC-15)

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## Introduction

Accurate determination of hemoglobin (Hb) is essential in clinical diagnostics and blood donation screening to prevent anemia-related complications and ensure high-quality blood products [1]. Point-of-care testing (POCT) devices offer advantages such as rapid results, portability, and ease of use. This study evaluates the performance of the DiaSpect Tm hemoglobin analyzer compared with HemoCue 301, Hemo Control, and the ABL90 Flex blood gas analyzer.



Figure 1: The DiaSpect Tm hemoglobin analyzer with disposable cuvette technology. A drop of whole blood is drawn into the cuvette by capillary action and measured directly, providing rapid hemoglobin concentration. The system utilizes a broad-spectrum, multichromatic sensor to measure absorbance of whole blood in reagent-free cuvettes. Widely used in blood donation screening.

## Methods

Venous blood samples from 7 healthy adult donors were collected in EDTA tubes. To exclude sampling bias from capillary collection and ensure a pure method comparison at the system level, only venous blood was used, despite the fact that capillary blood is commonly employed in blood bank settings. A broad hematocrit (Hct) range was obtained by mixing whole blood with plasma, resulting in a representative sample set (n = 94, measured in duplicate N = 188). Hct was determined by microhematocrit centrifugation. Hb levels were measured using DiaSpect Tm (EKF-diagnostic GmbH, Germany) [2], HemoCue<sup>®</sup> Hb 301 (HemoCue AB, Sweden), Hemo Control (EKF-diagnostic GmbH), and ABL90 Flex (Radiometer GmbH, Germany), under controlled laboratory conditions (20–25°C). Bland-Altman analysis and linear regression were used to assess bias, agreement, and correlation applying GraphPad Prism software (GraphPad Software, MA, USA).

## Results

- **Sample & Range:** 188 measurements from venous blood samples, Hb range **3.5–26.9 g/dL** (ABL90 Flex)
- **Bias:** DiaSpect Tm showed a small negative bias vs. ABL90 Flex; mean bias vs. HemoCue 301 was **0.557 g/dL**, vs. Hemo Control **–0.077 g/dL** (see Figure 2).
- **Correlation:** Very strong correlation across all devices (**Pearson r > 0.998**, slopes  $\approx 1.0$ ) (see Figure 3).
- Bland-Altman analysis confirmed **good agreement** (see Figure 2).
- **Consistency across range:** Reliable performance was observed at both very low and very high Hb levels, ensuring robustness for donor screening.
- **Clinical relevance:** Differences are unlikely to affect donor eligibility or patient management.
- **Practical aspects:** DiaSpect Tm provides results within 1 s, requires no reagents, and is **portable and easy to use**, making it highly suitable for **mobile donor screening**.

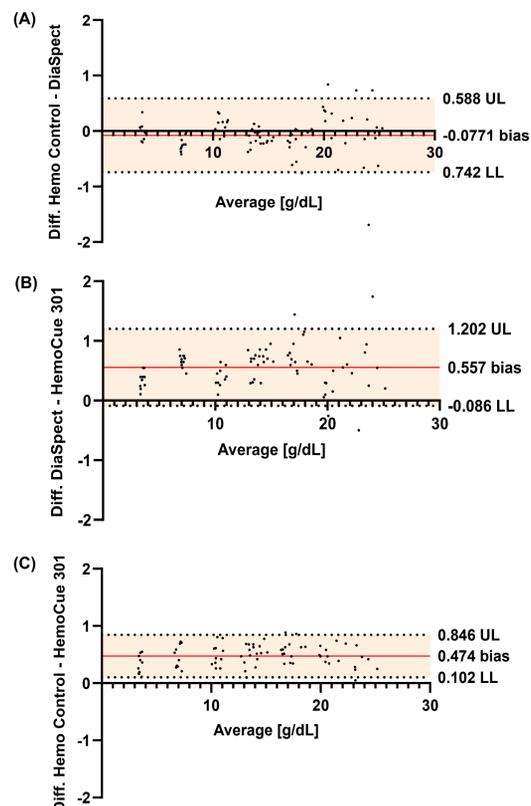


Figure 2: Bland-Altman plots comparing Hb measurement differences. (A) Hemo Control vs. DiaSpect Tm, (B) DiaSpect Tm vs. HemoCue 301, and (C) Hemo Control vs. HemoCue 301. The solid red line indicates mean bias, and dotted lines represent upper (UL) and lower (LL) limits of agreement.

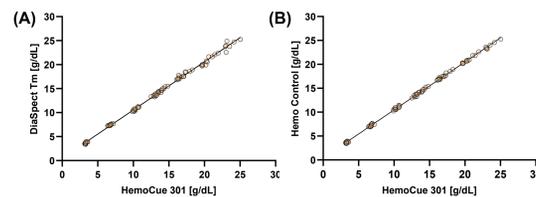


Figure 3: Correlation plots of hemoglobin measurements. (A) DiaSpect Tm vs. HemoCue 301, and (B) Hemo Control vs. HemoCue 301. The solid line indicates the linear regression fit.

Table 1: Correlation of hemoglobin measurement methods. Pearson correlation coefficient (r) reflects strength of linear association; P < 0.0001 indicates statistical significance.

Comparison method	Testing method	Pearson correlation coefficient (PCC)	P
HemoCue 301	DiaSpect Tm	0.9986	< 0.0001
HemoCue 301	Hemo Control	0.9995	< 0.0001
Hemo Control	DiaSpect Tm	0.9986	< 0.0001
ABL90 Flex	DiaSpect Tm	0.9985	< 0.0001
ABL90 Flex	Hemo Control	0.9996	< 0.0001
ABL90 Flex	HemoCue 301	0.9993	< 0.0001

## Discussion

The present study demonstrates that the DiaSpect Tm hemoglobin analyzer delivers results that are highly comparable to those obtained with established systems such as HemoCue 301, Hemo Control, and the ABL90 Flex blood gas analyzer. Venous blood was chosen to avoid sampling bias from capillary collection and ensure a true method comparison. While slight systematic deviations were observed — with DiaSpect Tm and Hemo Control showing marginally higher values compared to HemoCue 301. DiaSpect Tm showed a small negative bias compared to ABL90 Flex — these differences were minor and remained within clinically acceptable limits. Such deviations are unlikely to have an impact on donor eligibility decisions or patient management, particularly when the analyzer is calibrated against a validated reference system. The very strong correlations observed across all device comparisons (Pearson r > 0.998) further emphasize the robustness of DiaSpect Tm measurements. Regression slopes close to 1.0 indicate that the analyzer provides reliable results across a wide hemoglobin range, including very low and very high concentrations.

This is particularly important for blood donor screening, where both safety and efficiency are crucial. In addition to analytical performance, the practical aspects of POCT devices must be considered. The DiaSpect Tm analyzer combines rapid result availability with portability and ease of use, which makes it highly suitable for use in mobile blood donation settings or decentralized screening environments. Compared with traditional laboratory systems, the ability to obtain immediate results without extensive sample preparation offers clear workflow advantages.

## Conclusion

- DiaSpect Tm hemoglobin analyzer demonstrates **excellent agreement** with HemoCue<sup>®</sup> 301, Hemo Control (reagent-containing cuvette system), and blood gas analysis system ABL90 Flex.
- Observed deviations are **clinically acceptable** and are unlikely to affect blood donor eligibility or patient management decisions.
- Strong correlations across the full hemoglobin range (r > 0.998) confirm the **robustness and reliability** of the device, even at very low or very high Hb levels.
- The analyzer delivers **rapid results within 1 second**, without the need for reagents, making it highly practical for routine donor screening.
- Its **portability and ease of use** make it particularly well suited for **mobile donation centers** and other decentralized testing environments.
- By ensuring both analytical performance and workflow efficiency, DiaSpect Tm contributes to **improved donor safety and enhanced quality of blood products**.

## References

- [1] Chaudhary et al. Techniques used for the screening of hemoglobin levels in blood donors: current insights and future directions. J Blood Med. 2017;8:75-88.
- [2] Goldman et al. Validation and implementation of a new hemoglobinometer for donor screening at Canadian Blood Services. Transfusion. 2012; 52 (7 Pt 2):1607-13.