

Summary of the clinical performance evaluation of “Haiim” Vacuum-assisted blood collection system

This report is to evaluate the safety, effectiveness, and clinical performance of “Haiim” Vacuum-assisted blood collection system, including blood volume determination, hemolysis level analysis, and hemoglobin A1c (HbA1c) level comparison. A total of 150 subjects were enrolled in this study. Every subject’s blood sample was collected by well-trained nurses using venipuncture and “Haiim” in the same visit and then the analysis of the blood samples was conducted by the medical technologists.

The results showed that the average blood draw volume by using “Haiim” was $313.67 \pm 117.71 \mu\text{L}$ and 99.3% of the “Haiim”-drawn blood samples were at least or above 100 μL . For the hemolysis index performance, 100% of the “Haiim”-drawn blood samples was under 100 mg/dL, which indicates that the blood samples were allowed for subsequent blood tests based on the reference hemolysis palette of CDC^[1]. In addition, in the HbA1c test, the results of each paired venous and “Haiim” blood samples showed a significant Pearson’s correlation coefficient value ($r = 0.9743$). In sum, “Haiim” Vacuum-assisted blood collection system is safe and effective for blood collection that could be an alternative blood collection choice other than traditional blood collection methods.

The Statistics of “Haiim” clinical performance evaluation	
Total subjects	150
Median age	43 (21-93)
Average age	47
Average blood volume collected	$313.67 \pm 117.71 \mu\text{L}$
% of samples that the hemolysis index was under 100 mg/dL	100
The Pearson correlation coefficient (r) of the HbA1c value between venous and “Haiim” blood samples	0.9743

Reference

- Centers for Disease Control and Prevention. A Quick-Reference Tool for Hemolysis Status. <https://www.cdc.gov/ncezid/dvbd/stories/hemolysis-palette.html> (2019).