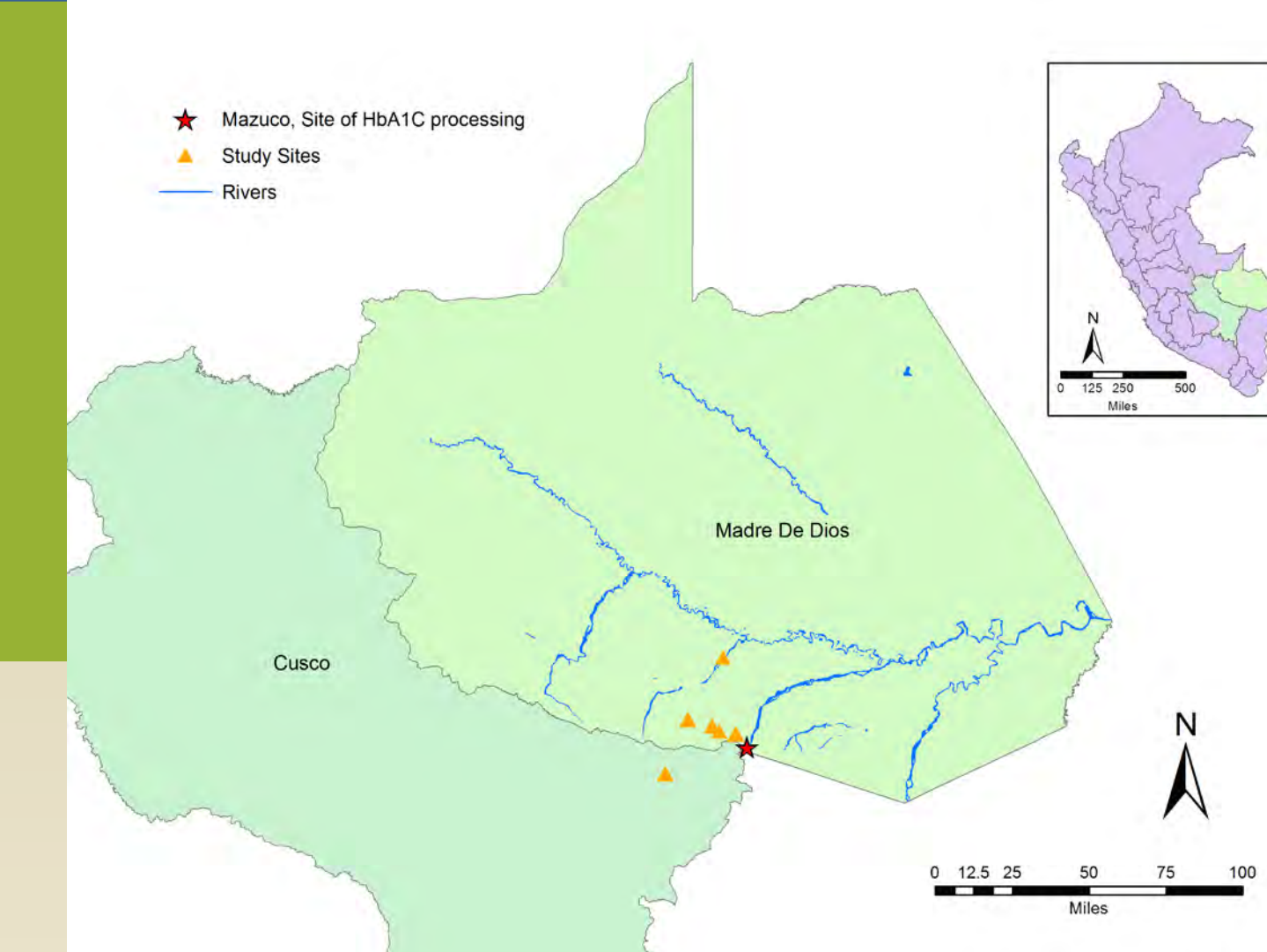


Assessment of two diabetes point-of-care tests in the Peruvian Amazon



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Study Sites

The performance of the DCA Vantage and Afinion point-of-care (POC) devices were analyzed in the Peruvian Amazon by comparing the hemoglobin A_{1c} (HbA_{1c}) results to laboratory-confirmed values using high-performance liquid chromatography (HPLC).

PROJECT OBJECTIVES

- Measure the precision of the DCA Vantage and Afinion devices.
- Assess the accuracy of the DCA Vantage and Afinion devices.

METHODOLOGY

- Intravenous blood samples were collected from 187 subjects in the communities of Huepetuhe (85), Quebrada Nueva (32), Caychihue (16), Setapo (2), Puquiri (4), and Quince Mil (48) using randomized sampling methods.
- Samples were stored between 2-8° C in EDTA-containing tubes and shipped to a central location in Mazuco, where HbA_{1c} was measured using the DCA Vantage (Siemens Medical Diagnostics Solutions, Puteaux, France) and Afinion (Alere Inc., Waltham, Massachusetts) POC devices.
- Precision analysis was conducted by measuring one sample 14 consecutive times by each device.
- Samples were then shipped to Lima, where HbA_{1c} was measured at the Medlab clinical laboratory using HPLC.

RESULTS

- The within-sample coefficient of variation (CV) using repeated measures was 4.01% for the DCA Vantage and 1.75% for the Afinion.
- The mean difference between the DCA Vantage and the HPLC was +0.32 [95% confidence interval (CI): +0.29, +0.35; $p < 0.001$].
- The mean difference between the Afinion and the HPLC was +0.57 [95% CI: +0.54, +0.60; $p < 0.001$].
- The linear regression models for the DCA Vantage (Figure 1) and Afinion (Figure 2) produced coefficient of determination (r^2) values of 0.8616 and 0.8395, respectively.
- The 95% limits of agreement for the mean difference between the DCA Vantage and the HPLC were -0.08 to +0.72 (Figure 3).
- The 95% limits of agreement for the mean difference between the Afinion and the HPLC were -0.18 to +0.67 (Figure 4).

CONCLUSIONS

- The statistically and clinically significant differences in the performance of the DCA Vantage and Afinion devices when compared to the gold-standard HPLC method indicate that caution should be exercised when relying on POC devices to measure HbA_{1c} in clinical settings in the Amazon.

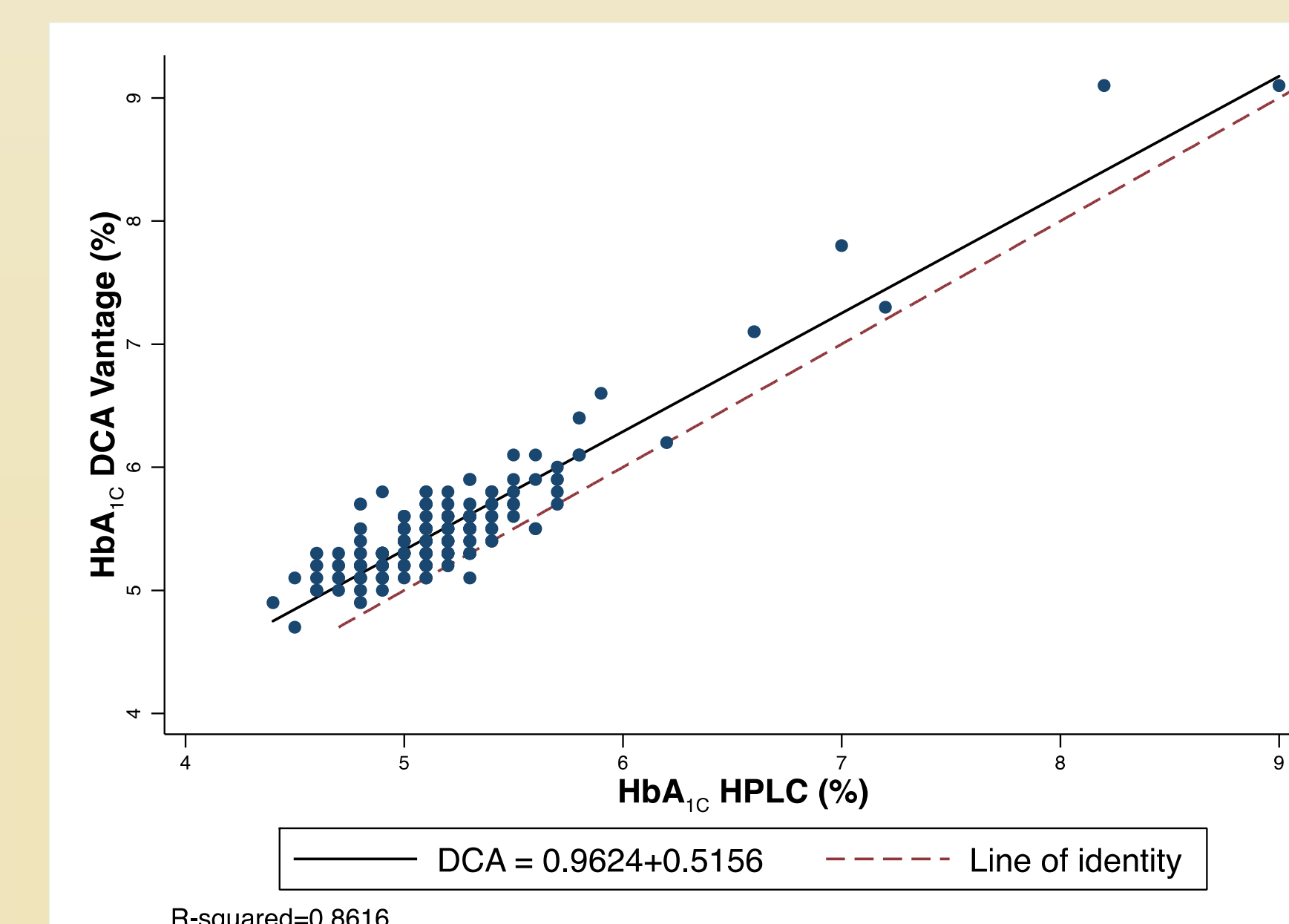


Figure 1. DCA Vantage versus HPLC HbA_{1c} measurements (N=187)

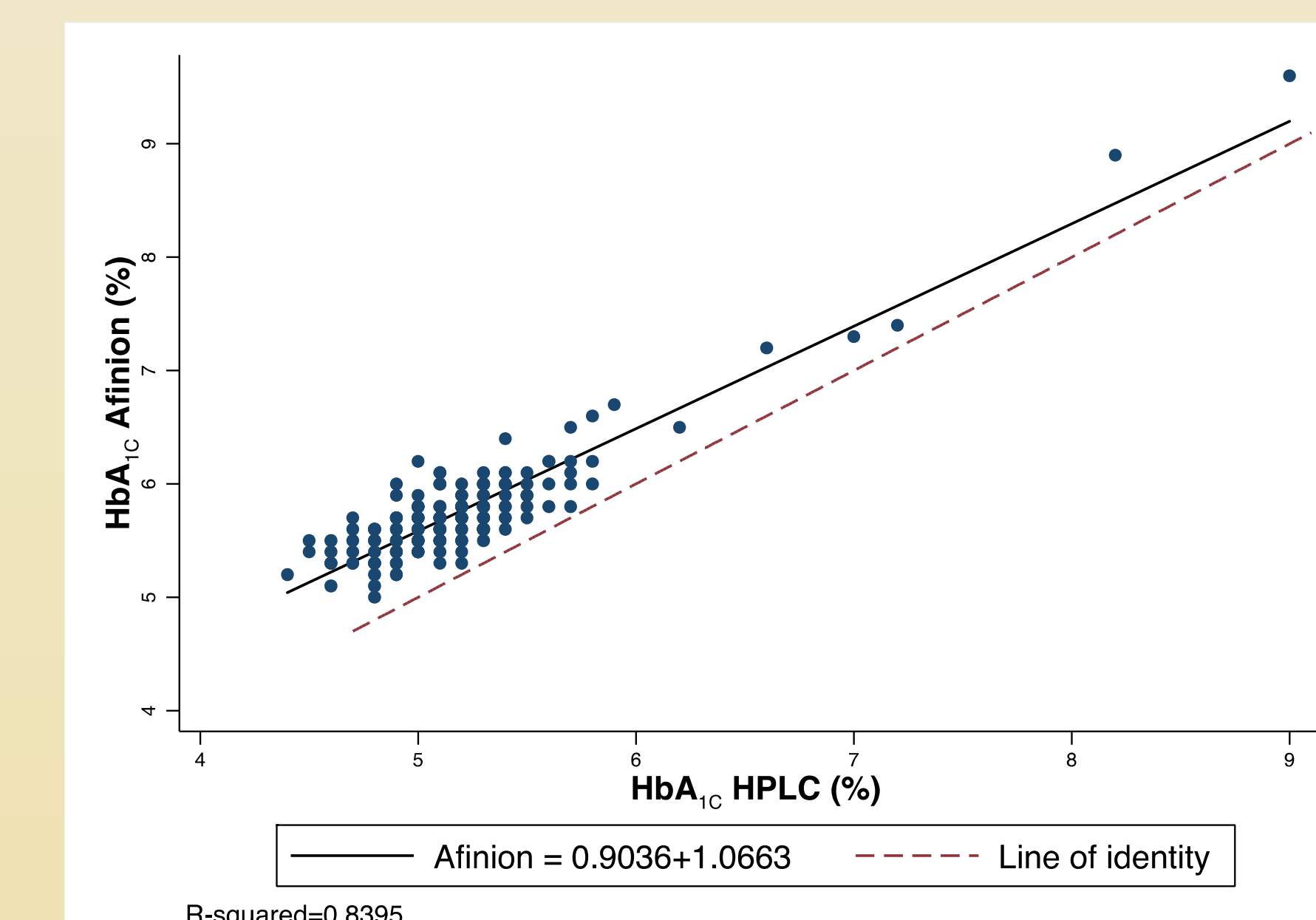


Figure 2. Afinion versus HPLC HbA_{1c} measurements (N=187)

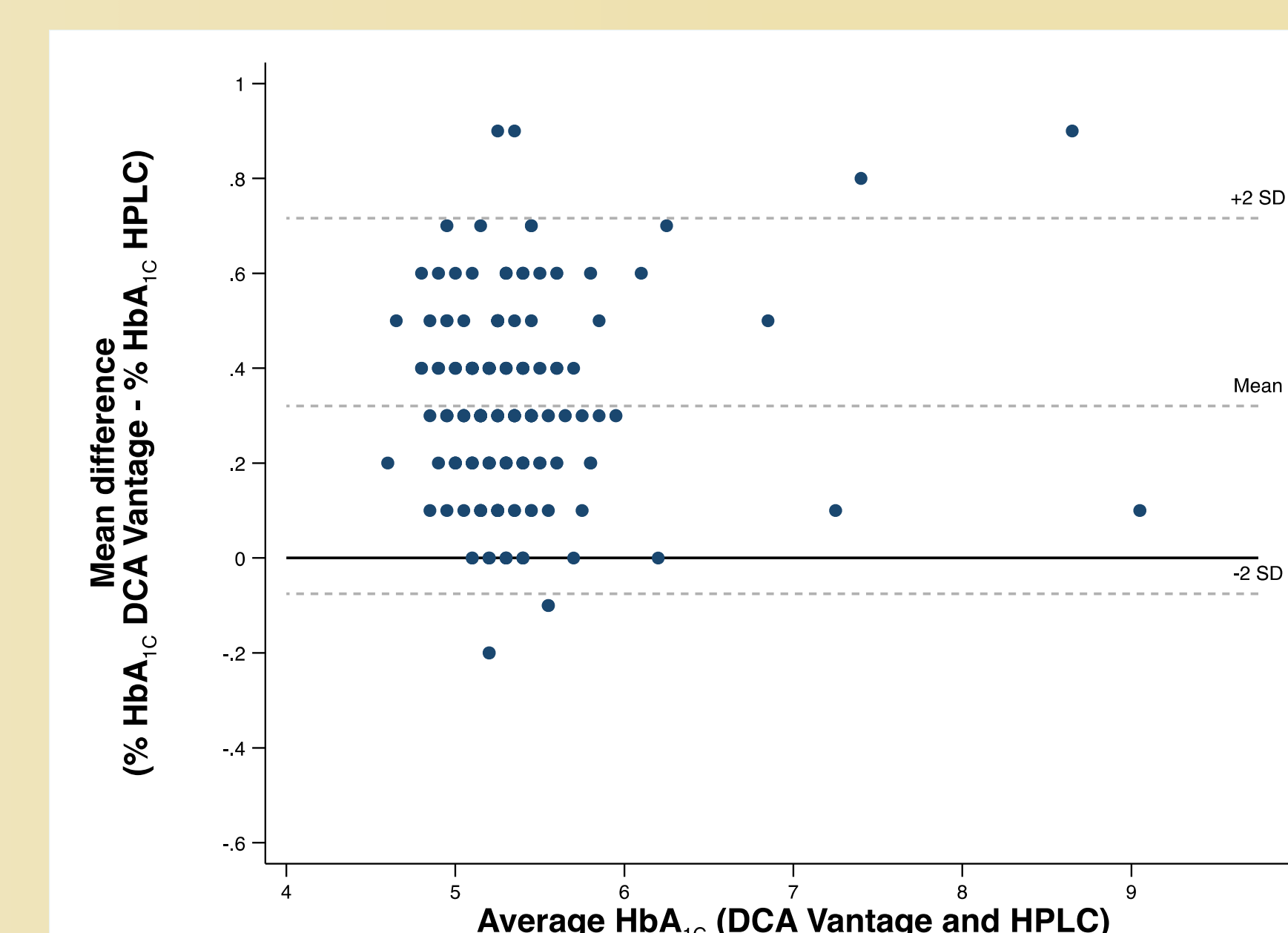


Figure 3. Bland-Altman plot of DCA and HPLC HbA_{1c} measurements (N=187)

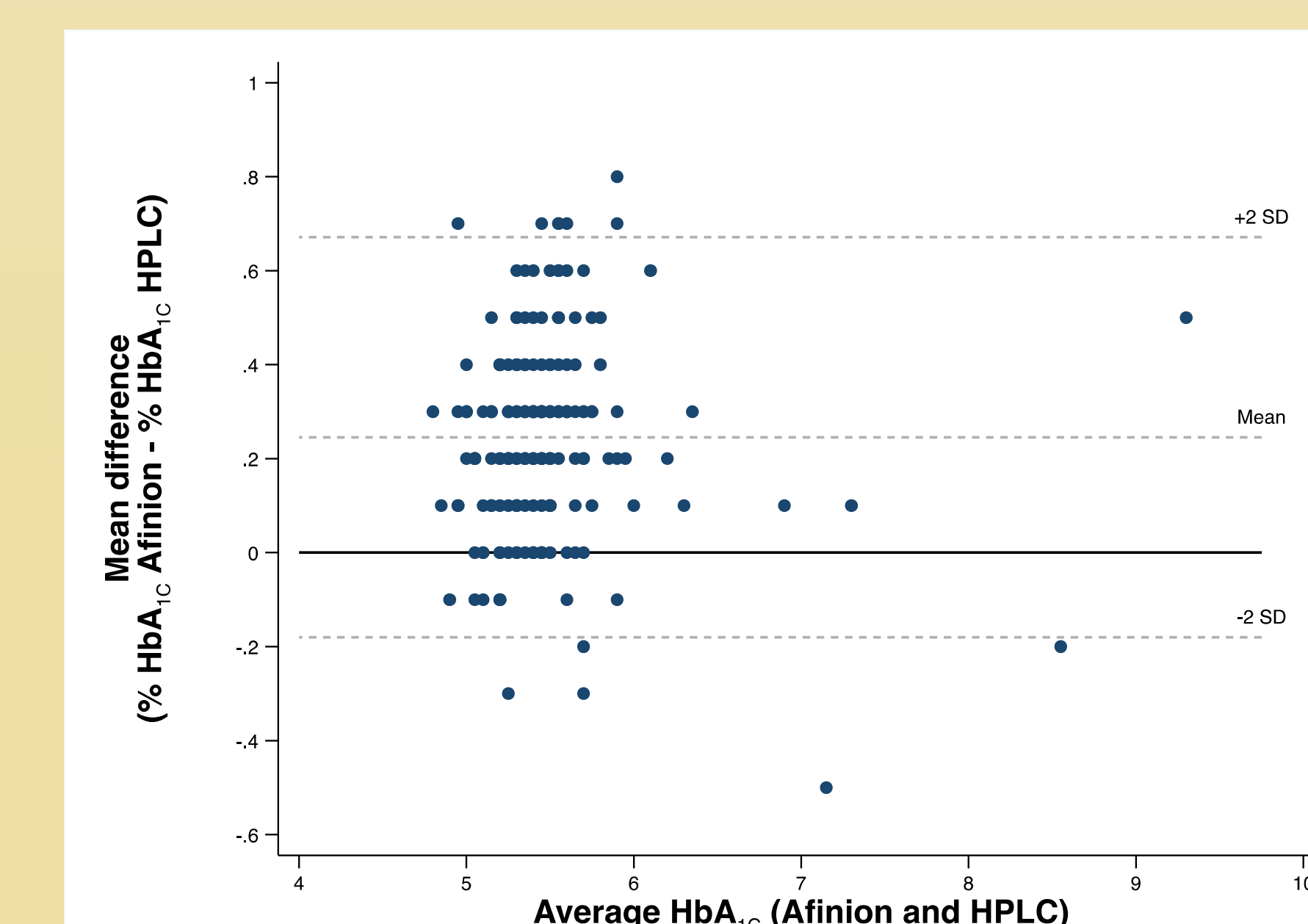


Figure 4. Bland-Altman plot of Afinion and HPLC HbA_{1c} measurements (N=187)