



Verification of BD FACSPresto™ for measurement of haemoglobin and CD4 cell counts

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Introduction

Hemoglobin levels and CD4 T-cell counts are important prognostic markers in HIV infection, where decline in the two is often associated with HIV disease progression. As a result, accurate and reliable data in monitoring CD4 and haemoglobin (Hb) levels is of critical importance to patient management. Conventionally, BD FACSCalibur and the Mindray hematology analyser are some of the equipment used in measuring CD4 and Hb respectively. However, with up to 50% of HIV patients still in need of life-saving ARV medications¹, alternative CD4 testing platforms are warranted. FACSPresto™ machine is as a point of care testing (POCT) device for both CD4 cell count and haemoglobin. In Kenya, medical devices need to be verified before use in health care facilities. Verification of the BD FACSPresto™ machine was carried out at the National HIV Reference Laboratory.

Objectives

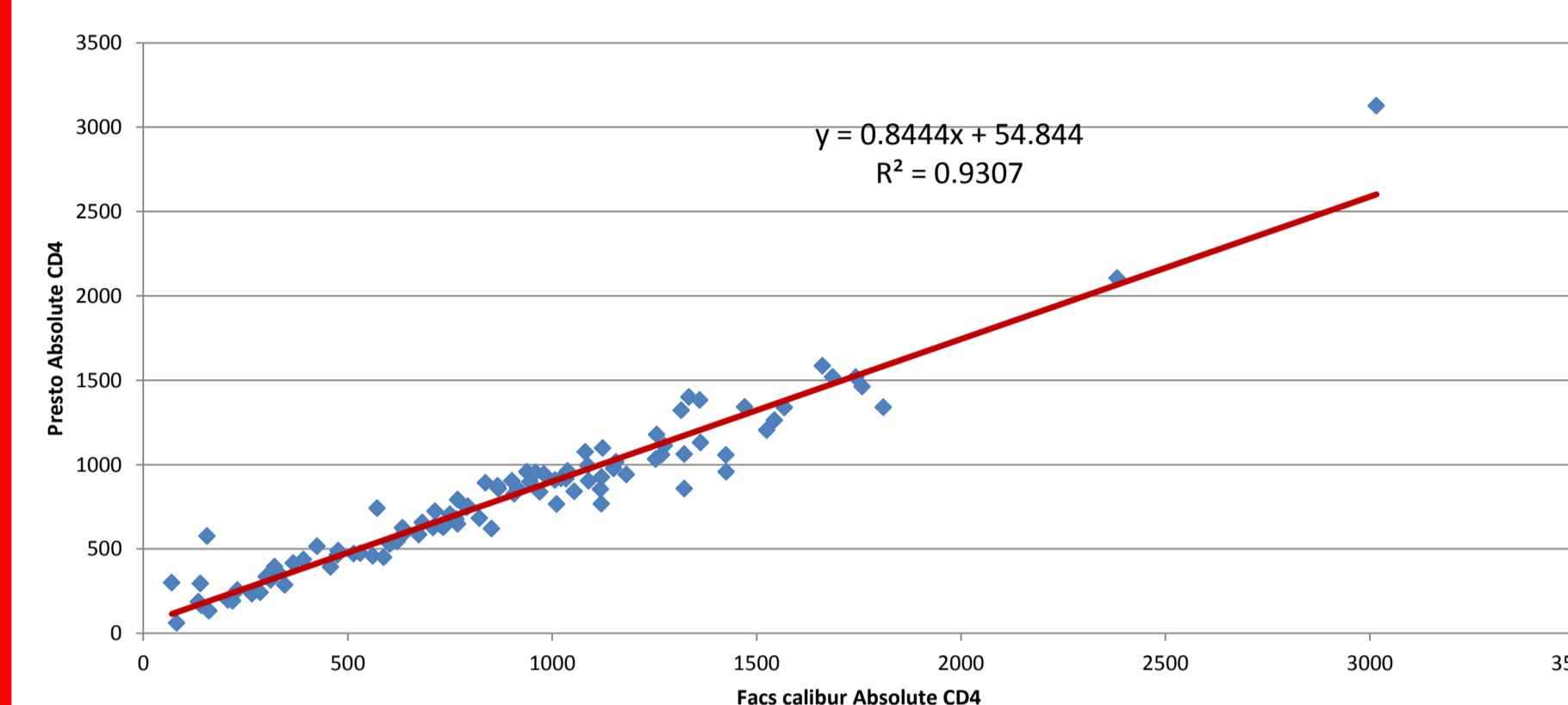
- ❖ To verify the diagnostic accuracy of BD FACSPresto™ in CD4 enumeration
- ❖ To Verify the diagnostic accuracy of FACSPresto™ in Haemoglobin measurement

Methods

- ❖ A total of 103 consenting patients were enrolled
- ❖ Fresh whole blood (matched capillary and venous) samples from HIV positive patients were collected from Mbagathi Hospital clinical laboratory by trained staff.
- ❖ Laboratory testing for CD4 and haemoglobin levels was done on BD FACSCalibur, BD FACSPresto (Becton Dickinson, East Rutherford, NJ, USA) and Mindray Haematology Analyzer BC-5380 following manufacturer's instructions.
- ❖ Laboratory analysis entailed the absolute and percent CD4 counts, and total haemoglobin concentration in the whole blood from HIV-infected patients
- ❖ Statistical analyses entailed calculation of Pearson's correlation and Bland Altman analysis for mean bias

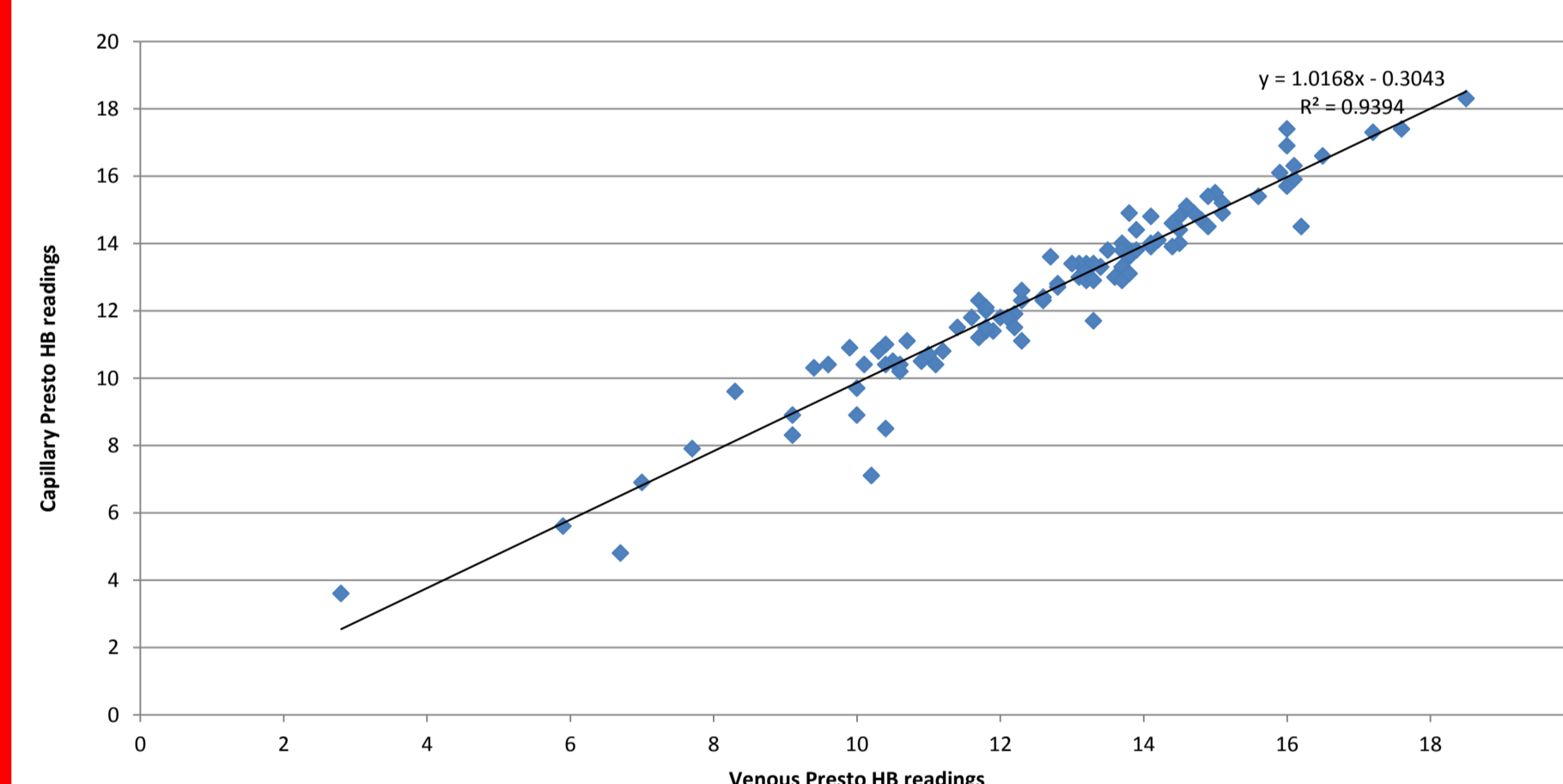
Results

Fig 1. Correlation between FACSCalibur and FACSPresto CD4 absolute readings



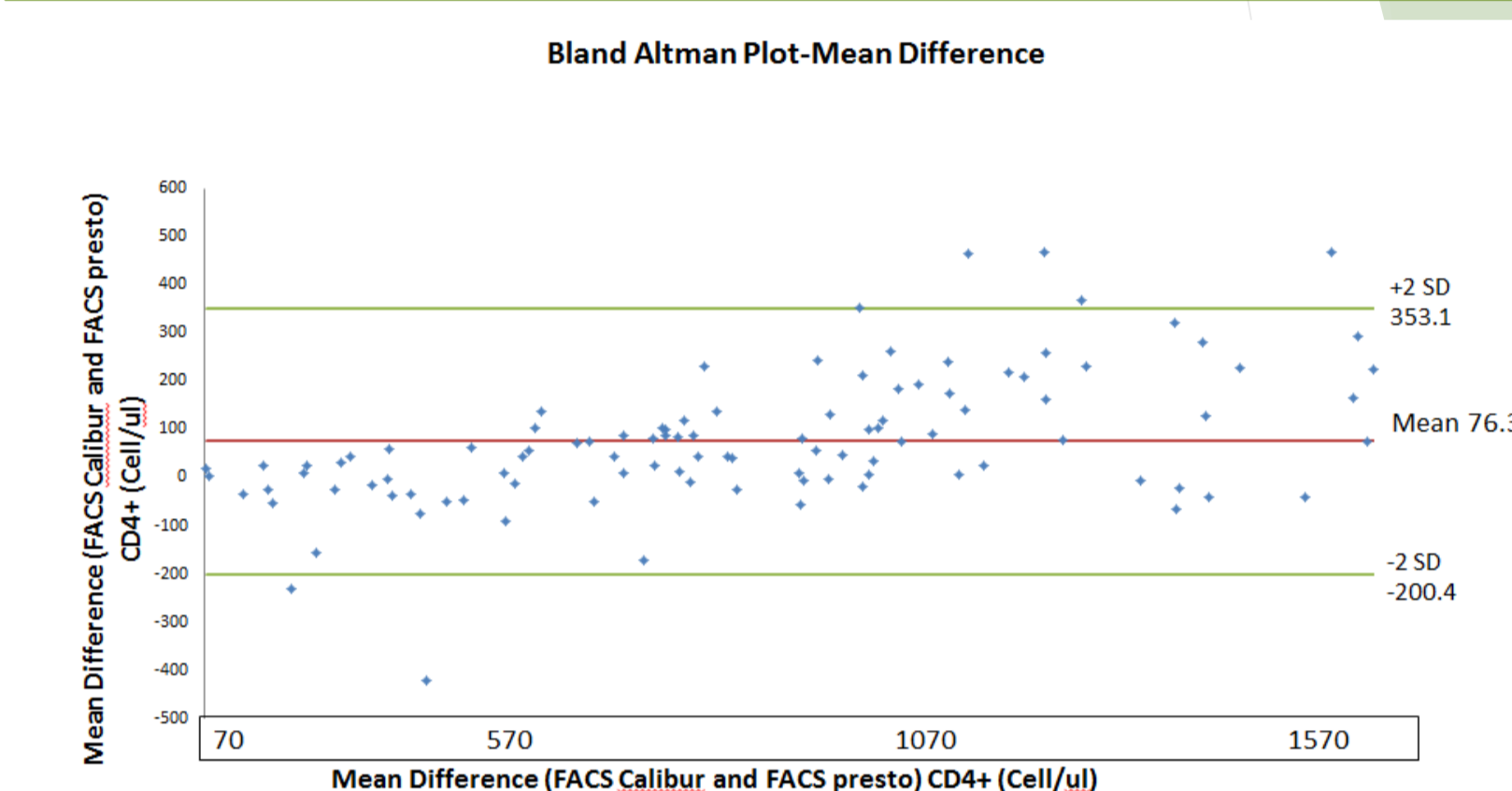
Pairs of 98 CD4 samples were tested using FACSCalibur and Presto at NHRL. The mean CD4 absolute count from the Presto was 805.89 compared to 889.49 from Calibur. Correlation at 0.93 was near perfect and the results were substantially equivalent.

Fig 3. Correlation between capillary and venous FACSPresto Hb readings



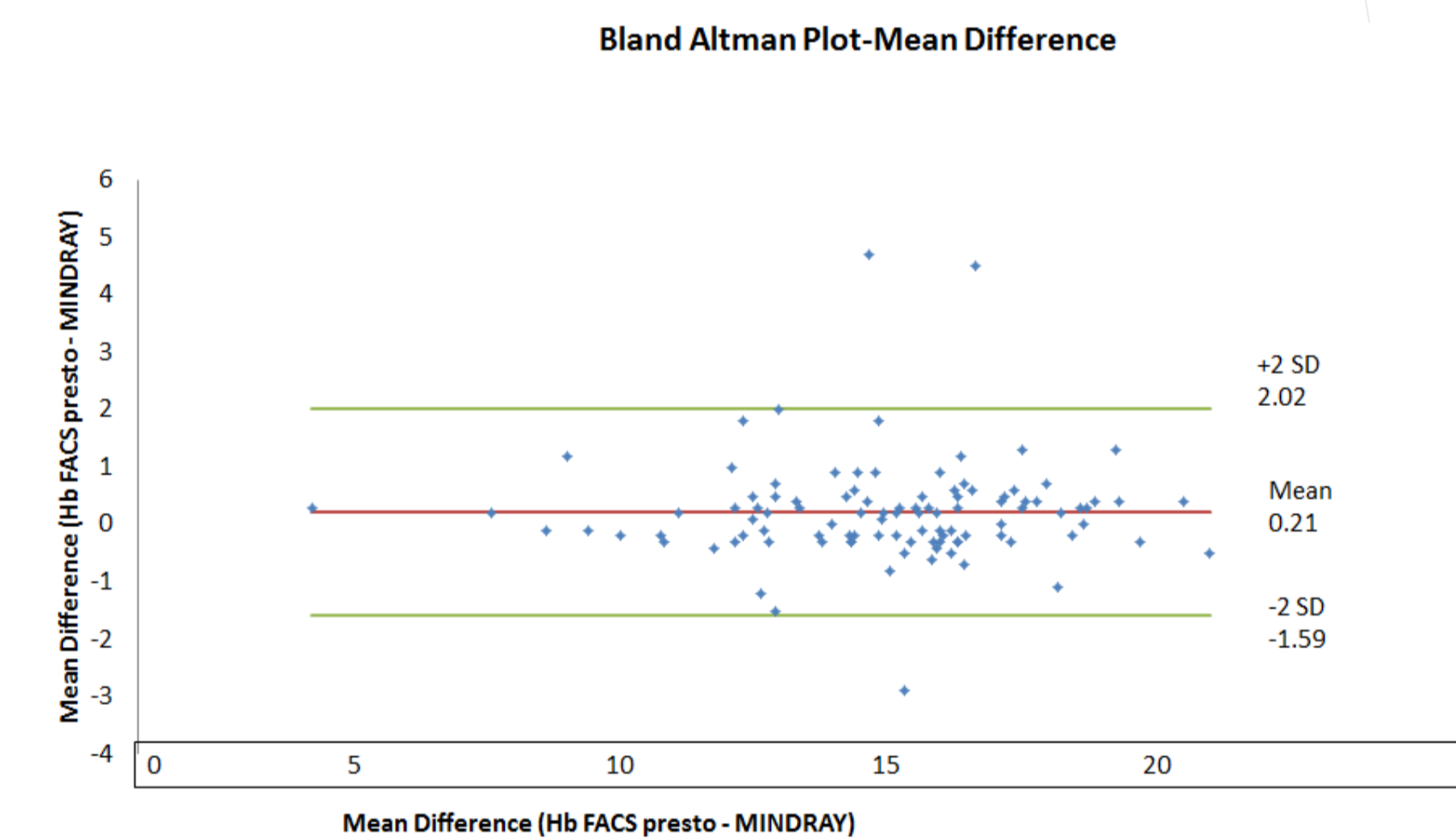
Average HB reading from venous sample was 12.65 compared to 12.56 from capillary sample. Correlation at 0.94 was near perfect. The mean difference between venous and capillary HB reading was 0.091 and was not statistically significant ($t = 1.39$, 95% CI -0.39-0.22, $p > 0.17$).

Fig 2. Bland-Altman plots for CD4 differences between FACSCalibur and FACSPresto



The mean difference between the reference method (FACSCalibur) and test method (FACSPresto) absolute CD4 counts was 76.3 which is within the 26.1% acceptance criteria

Fig 4. Bland-Altman plots for Hb differences between Mindray and FACSPresto



The mean difference in Hb measurement between the reference method (Mindray Haematology analyser) and the test method (FACSPresto) was 0.21, which was considered substantially equivalent

Discussion

- ❖ Absolute cell counts from BD FACSPresto and BD FACSCalibur were substantially equivalent ($r^2=0.93$) and consistent with previous findings²
- ❖ There were no statistically significant differences between FACSPresto Hb readings from venous and capillary samples
- ❖ The Hb readings for venous samples from the two equipment were substantially equivalent.

Conclusions

- ❖ The results obtained from the BD FACSPresto™ machine were comparable to the two reference equipment.
- ❖ Moreover the BD FACSPresto™ can utilize both venous and capillary blood thus it can be used as a point of care device.
- ❖ BD FACSPresto is a POC device that can allow for more flexibility in CD4 T-cell and Hb measurement, important in HIV patient management

References

1. UNAIDS (2014). The Gap Report
2. Bwana P., et al., 2015, PLoS ONE 10(12):e0145586

