

## Introduction

In Kenya, about 1.5million people are currently infected with human immunodeficiency virus (HIV). Infection with the virus is characterized by depletion of CD4+ T-cells resulting in susceptibility to opportunistic infections (O.Is). Thus enumeration of CD4+ T-cells is critical to early detection and management of O.Is and treatment failure among HIV-infected individuals. The current study aimed at evaluating the performance of Beckman Coulter Aquios CL for the enumeration of CD4 cells.

## Methods and Materials

Remnant EDTA whole blood samples (n=210) were obtained from a care clinic in Nairobi and characterized on the BD FACSCalibur as the reference method. The samples were then tested on Beckman Coulter AQUIOS CL as the test method. Results from the two methods spanning the normal and low ranges were then compared for accuracy, bias, sensitivity and specificity with regard to classification across the 100, 350 and 500 CD4 T-cell thresholds.



Figure 1. BD FACSCalibur

Figure 2. Beckman Coulter AQUIOS CL

## Results

The Beckman Coulter AQUIOS CL, when compared to the BD FACSCalibur, had a specificity of 98.2%, 97.8% and 98.3%, and downward misclassification rates of 1.8%, 2.2% and 1.7% across the 100, 350 and 500 CD4 T-cell thresholds. Sensitivity and upward classifications for the assay was 74.4-88.1% and 11.9-25.6% respectively for the same thresholds. The positive and negative predictive values were calculated at 92.5%-99.2% and 70.2%-97.1% respectively. Additionally, linear regression analyses revealed a coefficient of determination ( $r^2$ ) of 0.93 for absolute CD4 counts, 0.95 for percent CD4 and 0.64 for CD3, and a mean bias of 98.84 cells/ $\mu$ l.

Table 1. Summary of performance characteristics for Beckman Coulter Aquios CL flow cytometer.

CD4 T-cell threshold	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	Upward misclassification (95% CI)	Downward misclassification (95% CI)
100	88.1% (74.4-96)	98.2% (94.9-99.6)	92.5% (79.6-98.4)	11.9% (4.0-25.6)	1.8% (0.4-95.1)
350	74.4% (65.6-81.9)	97.8% (92.2-99.7)	97.8% (92.4-99.7)	25.6% (18.1-34.4)	2.2% (0.3-7.8)
500	83.4% (76.5-89)	98.3% (91.1-100)	99.2% (95.7-100)	16.6% (11.0-23.5)	1.7% (0.0-8.9)
25%	N/A	N/A	N/A	3.5% (1.1-8.0)	4.4% (0.9-12.4)

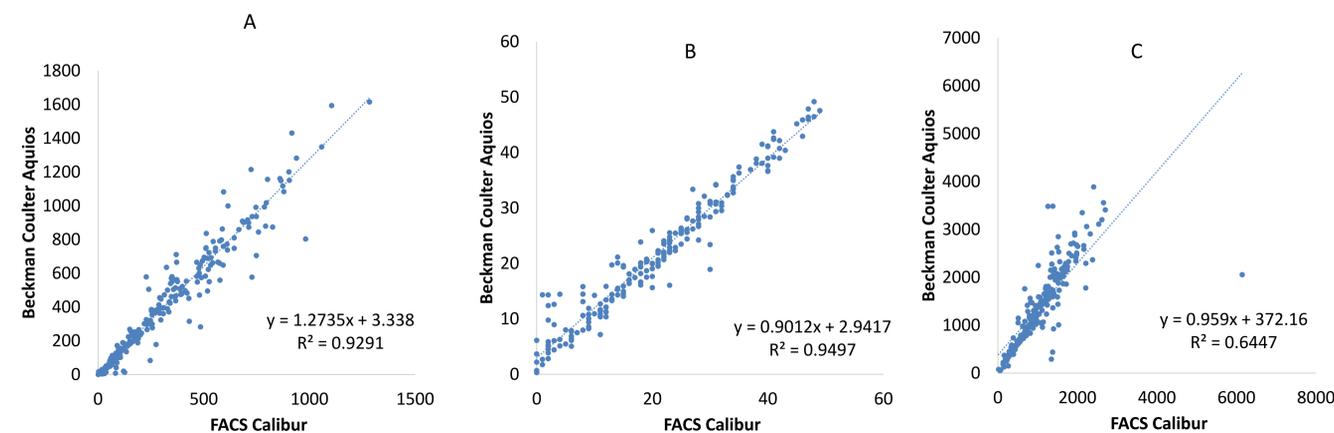


Chart 1. Linear regression analysis for (A) CD4 Absolute cell counts (B) CD4 percent (C) CD3 absolute cell counts

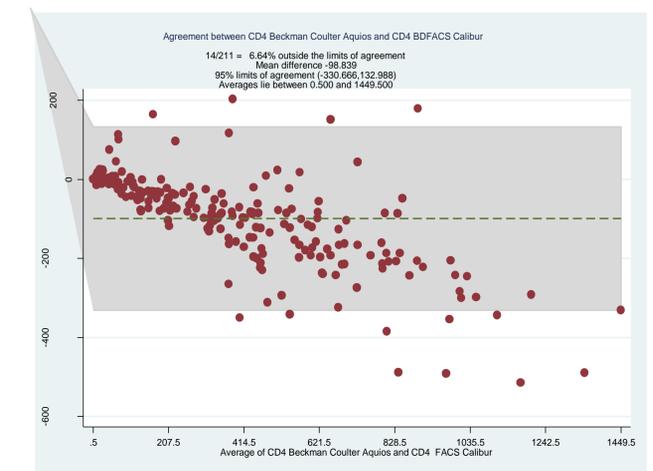


Chart 2. Bland Altman analysis of CD4 T-cell counts between Beckman Coulter Aquios CL and BD FACSCalibur

## Conclusions

The AQUIOS CL demonstrated a high agreement with BD FACSCalibur used as the reference assay. The AQUIOS CL provides reliable data for both CD absolute and CD4 percentages, and is suitable for CD4 T-cell enumeration to guide HIV-patient management. This high-through put system provides full automation for sample preparation and analysis therefore minimizing user error making it suitable for use even with less experienced operators.

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## References

1. Ministry of Health. Kenya HIV County Profiles 2016 [Internet]. 2016. Available: <https://www.google.com/#q=kenya+hiv+county+profiles>
2. Damtie D, Yismaw G, Woldeyohannes D, Anagaw B. Common opportunistic infections and their CD4 cell correlates among HIV-infected patients attending at antiretroviral therapy clinic of Gondar University Hospital, Northwest Ethiopia. BMC Res Notes. 2013;6: 534. doi:10.1186/1756-0500-6-534
3. Chakraborty H, Newman JE, Woelk G, Hemingway-foday J, Jeniffer I, Akam W, et al. Antiretroviral Therapy Initiation and CD4 Progression over time among HIV Infected Adults in Central Africa. Int J Med Public Heal. 2011;1. doi:10.5530/ijmedph.4.2011.2
4. National AIDS & STI Control Program. Guidelines on Use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Kenya. 2016th ed. Nairobi: NASCOP; 2016.