Zyomyx MyT4 and BD FACSPresto comparison to the Pima CD4 assay

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Introduction

In conjunction with HIV antiretroviral treatment (ART) scale up, CD4 Point-of-Care (POC) assays are being utilized in resource-limiting settings to provide effective access to CD4 testing and determine eligibility for ART.

Since 2009, the Alere Pima CD4 assay has been used for POC CD4 counts in resource-limited settings and having an impact on HIV patient care.

Many new POC CD4 assays are being introduced into the market, including the Zyomyx MyT4 and BD FACSPresto Near-Patient CD4 Counter. Both the MyT4 and the FACSPresto have unique features which could yeild advantages for their use in POC testing and HIV patient care.

Introduction (continue)

The Zyomyx MyT4 assay counts CD4 cells by a methodology that is different from established reference methods. While the BD FACSPresto methodology is similar to the Alere Pima CD4 assay

It is important to understand the performance characteristics of any new assay and how it compares to reference methods. This comparison will help to estimate the errors or variations with the new assay and if adjustments must be made for use in patient care.

We assessed the quality, functionality, and performance of the MyT4 and FACSPresto assays in comparison with the established Pima CD4 assay.

Method

- The Zyomyx MyT4 and BD FACSPresto were evaluated in two separate studies at the CDC in Atlanta.
- EDTA whole blood specimens were analyzed with the Pima CD4 assay and MyT4 or FACSPresto assay.
- Scattered-plot and Bland-Altman analysis were done with Pima CD4 as the reference method.
- Precision of each assay was estimated by analyzing 3 specimens ten times on each platform and calculating the coefficient of variation (CV%).
- The POC CD4 assays were assessed in regards to the times after specimen collection in which accurate and relible CD4 results could be consistently obtained.

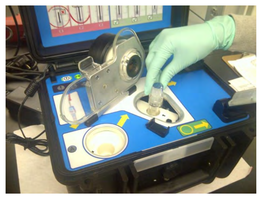
CD4 Point-of-Care Assays

Alere Pima CD4





Zyomyx MyT4





BD FACSPresto

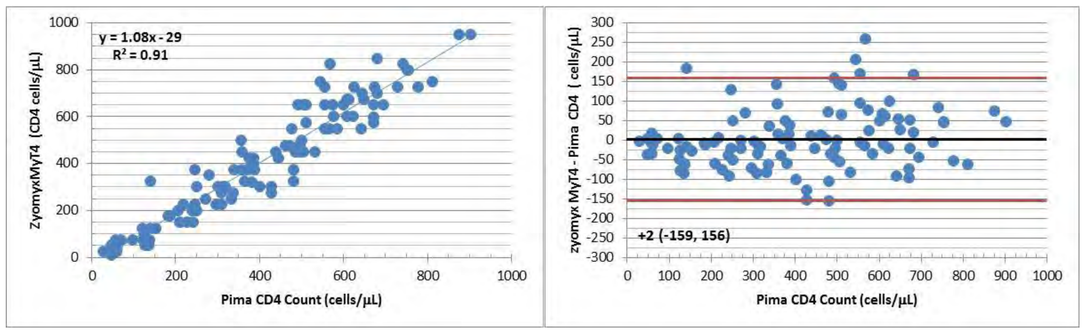




Results

Figure 1. Scatter-plot and Bland-Altman graphs of the Zyomyx MyT4 and BD FACSPresto CD4 results with the Alere Pima CD4 assay as the reference method.

Zyomyx MyT4 vs Pima CD4



BD FACSPresto vs Pima CD4

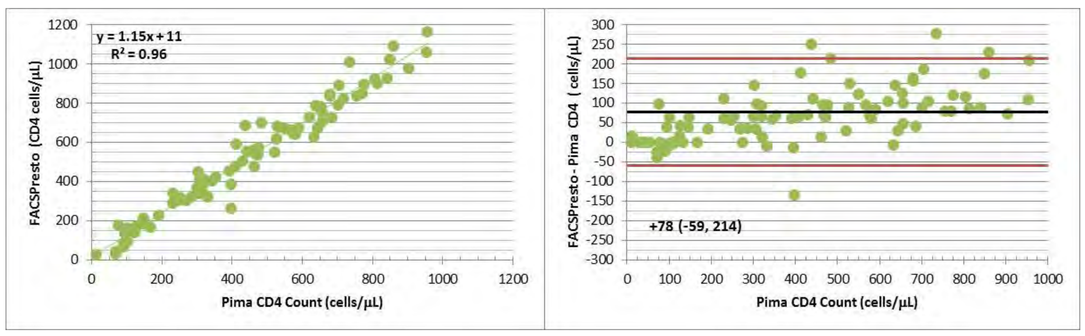


Table 1. Summary of the MyT4 and FACSPresto performance versus the Pima CD4

	MyT4	FACSPresto
R^2	0.91	0.96
Slope	1.08	1.15
y-intercept	-29	+11
Bias	+2	+78
Std Dev	79	68
Average CV%	8.2%	5.4%

Note: Pima CD4 Average CV%= 5.9%

Specimen age: The cut off time after specimen collection in which accurate and reliable CD4 could be obtianed with MyT4 and FACSPresto was12 and 20 hours, respectively. The Pima CD4 was able to consistently analyze specimens up to 48 hours old.

Conclusions

- **The Zyomyx MyT4 and BD FACSPresto assays could potentially be used in point-of-care and resource-limited settings.**
- **Both the MyT4 and FACSPresto correlated well with the Alere Pima CD4 and both prove to be acceptable methods for CD4 analysis.**
- **The MyT4 CD4 assay had a slightly higher variation or random error than the FACSPresto.**

Conclusions

- **The FACSPresto had higher bias or constant error in CD4 counts when compared to the Pima CD4**
- **When used for HIV patient care, testing within the acceptable time after specimen collection is important to reduce errors and inaccuracy with both the MyT4 and FACSPresto CD4 assays.**
- **Consideration to the assay characteristics should be a part of how any POC assay will be integrated for use in HIV patient care.**

Notes:

- The Zyomyx MyT4 and BD FACSPresto were also both evaluated with other reference methods such as the BD FACSCalibur Tritest reagent and BD FACSCount. Information on these evaluations are available upon request.
- For inquires contact Larry Westerman at Lwesterman@cdc.gov

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