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# No Dichotomy in Double Counting of CD4 + T Cell Values on PIMA™® and BD FACSPresto™® in Benin

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## Abstract

The survival of PLHIV-1 by the count of CD4 + T lymphocytes remains essential to predict the treatment of opportunistic infections. The aim of the study was to compare the performance of PIMA™® and FACSPresto™® to the conventional equipment of FACSCount™® through CD4 + T cell counting. CD4 + T lymphocytes were tested both on PIMA™® and BD FACSPresto™®. Values were compared to those obtained from FACSCount™®, using Passing Bablok, Bland-Altman and Pollock diagrams. PIMA™® and FACSPresto™® present a good correlation coefficient with the Passing Bablok diagram ($y = -0.5982 + 0.9940x$; $\rho c = 0.9969$) and ($y = 7.2913 + 0.9974x$; $\rho c = 0.9972$) respectively. Bland-Altman and Pollock plots show mean biases of 3.7 cells/µL (LOA ranging from −62.7 to 60.1) and 0.5 cells/µL (LOA ranging from −10.7 to 11.6) for PIMA™® and −1.5 cells/µL (LOA ranging from −45.7 to 42.7) and −1.9 cells/µL (LOA ranging from −23.4 to 19.6) for FACSPresto™®. Sensitivity and specificity of PIMA™® and FACSPresto™® vary respectively between 98 to 99% and 96 to 98% at threshold of 350 cells/µL and 98 to 100% at threshold of 500 cells/µL. Both technologies highlight their ability to be used as an alternative to the reference technique.

## Keywords

BD FACSCount™®, FACSPresto™®, PIMA™®, PLHIV-1, CD4 + T cell, Benin

## 1. Introduction

HIV infection remains a major public health problem worldwide [1]. In Benin,

the launch of the antiretroviral treatment (ART) program in 2002 allowed PLHIV greater access to antiretroviral drugs (ARVs) [2]. The number of PLHIV-1 on ART has gradually increased and it is estimated at around 59,871 cases, 2540 children at the end of 2022 in the country [3]. Several studies have shown that antiretroviral therapy reduced HIV-1 morbidity and mortality and patients were followed based on CD4 + T cell count [4] or plasma viral load quantification [5]. Although plasma viral load has been reported as the primary determinant of antiretroviral therapeutic efficacy and progression to acquired immunodeficiency syndrome (AIDS), its use was associated with CD4 + T cell count [6]. CD4 + T cell count performed with conventional methods required laboratories with high facilities and qualified biologists [7]. The advent of Point Of Care (POC) made it possible to circumvent these difficulties and CD4 + T cell counting was performed at the patient's bedside even in remote peripheral areas [8]. Although the WHO recommended the "test and treat" option [9], the CD4 + T lymphocyte count allowed the assessment of the immune system status and the anticipation of early management of opportunistic infections such as cryptococcosis [10]. In Benin, if the viral load was undetectable in adult on ART for more than two years, the CD4 + T cell count was carried out once a year, CD4 + T count at the beginning of the year and the viral load at the end of the year whereas it is measured out at the beginning of the year and 6 months later in children [11].

Several studies have confirmed the accuracy of PIMA™® and BD FACSPresto™® such as those conducted in various African countries, Nigeria, Uganda, Kenya [8] [10] [12]. In order to offer CD4 + T cell counting (LTCD4) to all PLHIV-1 under treatment, our country like other African countries, had acquired these new POC testing technologies which were deployed in peripheral public and private laboratories involved in the care of PLHIV-1 [13]. However, the performance of these technologies has never been evaluated. Therefore, this study aims to evaluate the sensitivity and specificity of the PIMA™® and BD FACSPresto™® analyzers in the CD4 + T cell count in PLHIV-1 in Benin.

## 2. Materials and Methods

### 2.1. Study Population, Collection of Samples

The cross-sectional study focused on patients infected with HIV-1 and attending the Reference Laboratory of Health Program Fighting Against AIDS (LR/PSLS) as part of their immunological monitoring. Whole blood samples were collected in tubes containing K3 EDTA from patients and CD4 + T cell counts were performed immediately on the LR/PSLS platform. The first batch of collected sample was used for CD4 + T cell counting on the BD FACSCount™® and PIMA™® instrument and the second batch of collected sample on BD FACSCount™® and BD FACSPresto™® at LR/PSLS.

Patients included in the study were adults, on antiretroviral regimen based on TDF/AZT + 3TC + EFV/ATZ/LPV and at different WHO clinical stages. Children

were excluded from the study.

## 2.2. CD4 + T Cell Enumeration

### 2.2.1. BD FACSCount™®

CD4 + T cell count on the BD FACSCount™® was performed according to the manufacturers' instructions. 50 µl of whole blood was added to the BD FACSCount™® reagent containing anti-CD3-PE antibodies and anti-CD4-PE-Cy5 antibodies. Capped tubes were vortexed and incubated in the dark at room temperature for 1 hour. After incubation, 50 µl of fixative solution was added to the reagent tubes and analyzes were performed on the BD FACSCount™® instrument.

### 2.2.2. PIMA™®

The measurement of CD4 + T cells with the PIMA™® was carried out according to the manufacturer's instructions. A volume of 25 µl of blood was introduced into the PIMA™® disposable cartridge which contains CD3-dye1 and CD4-dye2 monoclonal antibodies. With the collector then removed, the cartridge was immediately inserted into the PIMA™® analyzer.

### 2.2.3. BD FACSPresto™®

The measurement of CD4 + T cells with the FACSPresto™® was carried out according to the manufacturer's instructions. A volume of 25 µL of whole blood sample was deposited in the cartridge containing anti-CD3, anti-CD4, anti-CD14 and anti-CD45RA antibodies conjugated to fluorescent dyes. The cartridge was then capped and incubated at room temperature for 18 min. It was then loaded on to the BD FACSPresto™® analyzer and the reading was performed in 4 min. The results were displayed on the analyzer screen and printed automatically.

### 2.2.4. Maintenance of Both Equipment for Long-Term Functionality

Maintenance of equipment was performed daily for the BD FACSCount™® cytometer according to manufacturer's instructions. In addition, there was a contract with the technical team of the company LR/PSLS to check the function and the alignment of the laser of BD FACSCount™® every 6 months. Finally, the instrument was calibrated at each round, with balls to ensure its accuracy. Also, quality control cartridges from PIMA™® and BD FACSPresto™® compared to predefined ranges were used before testing the study participant samples. The analyzer may report an invalid result if the cartridge expiration date, sample volume, reagent validation, and instrument operation were incorrect. Different biologists ensured the CD4 + T cell count to ensure blind reading.

### 2.2.5. Statistical Analysis

Data were entered into MedCalc 10.0.2.0 software (MedCalc Software, Mariakerke, Begjum). Linear regression was determined using the Passing-Bablok regression plot [14] with GraphPad Prism software. The concordance correlation coefficient was used to assess the degree of difference between the two values [15].

Pollock and Bland-Altman analyzes were used to determine the mean biases and limits of agreement (LOA = mean ± 1.96 SD) of the two obtained values. Both methods were useful in determining whether two methods can be used interchangeably for clinical purposes, such as monitoring HIV progression and treatment.

In addition, sensitivity and specificity, positive predictive value (PPV), negative predictive value (NPV), and percentage misclassification at CD4 + T cell count thresholds of 350 and 500 were also determined.

## 3. Results

### 3.1. Study Population

A total of 448 HIV-1 infected patients aged 19 to 85 years were included in the study.

CD4 + T cell counts were performed on BD FACSCount™® and PIMA™® from 216 samples from patients aged 19 to 80 years collected in the first phase, and 232 CD4 + T cell counts were performed on BD FACSCount™® and BD FACSPresto™® from 22 to 85 years collected in the second phase. The general characteristics of study population were detailed in Table 1.

Table 1. General characteristics of study population and the CCC and P values obtained during comparison.

| | | | | | Categorization of CD4 + T cell values (cells/µl) | | | CCC | P |
|---|---|---|---|---|---|---|---|---|---|
| | Median age [IQR] years | Male: N (%) | Female: N (%) | Median CD4 + T cell values (cells/µl) | ≤350: N (%) | ]350-500[: N (%) | ≥500: N (%) | | |
| FACSCount/ PIMA | 80 [19 - 80] | 76 (35) | 140 (65) | 448 | 100 (46) | 41 (19) | 75 (35) | 0.9969 | 0.9969 |
| FACSCount/ FACSPresto | 85 [22 - 85] | 97 (41.8) | 135 (58.2) | 445 | 76 (32.8) | 57 (24.6) | 99 (42.7) | 0.9972 | 0.9973 |

IQR = Interquartile, N = Number, CD = Cluster of Differentiation, CCC = Concordance correlation coefficient, P = Pearson $\rho$ (precision).

### 3.2. Comparison between BD FACSCount™®, PIMA™® and BD FACSPresto™®

Overall, comparisons of alternative techniques (PIMA™® and BD FACSPresto™® with the BD FACSCount™® reference) showed a good correlation coefficient with the Passing Bablok diagram respectively with ($y = -0.5982 + 0.9940x$; $\rho c = 0.9969$) for PIMA™® and ($y = 7.2913 + 0.9\,974x$; $\rho c = 0.9972$) for BD FACSPresto™® (Figure 1(A) and Figure 2(A)). Furthermore, the agreement between the alternative techniques and the reference method by analysis with the Bland-Altman diagrams, showed an average bias of 3.7 cells/µL with an LOA ranging from −62.7 to 60.1 for PIMA™® technology and −1.5 cells/µL with an LOA ranging from −45.7 to 42.7 for BD FACSPresto™® (Figure 1(B) and Figure 2(B)). Pollock diagrams already

showed an average bias of 0.5 cell/μL with an LOA ranging from −10.7 to 11.6 for PIMA™® and −1.9 cells/μL with an LOA ranging from −23.4 to 19.6 for BD FACSPresto™® (Figure 1(C) and Figure 2(C)).

For the threshold of 350 cells/μL, the sensitivity and specificity of PIMA™® and BD FACSPresto™® analyzer ranged respectively between 98 to 99% and 96 to 98%. Both values were ranged between 98 to 100% for threshold of 500 cells/μL. Table 2 summarized the sensibility and specificity obtained.

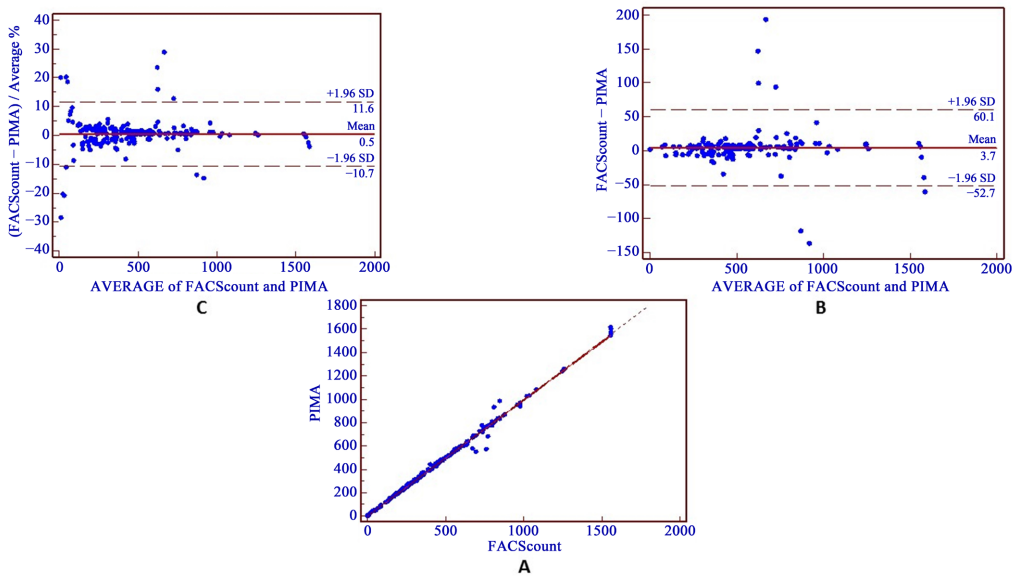


Figure 1. Comparison diagrams of BD FACSCount™® and PIMA™® technologies (n= 216). A = Passing Bablock, B= Bland Altman, C = Pollock. SD = Standard of deviation.

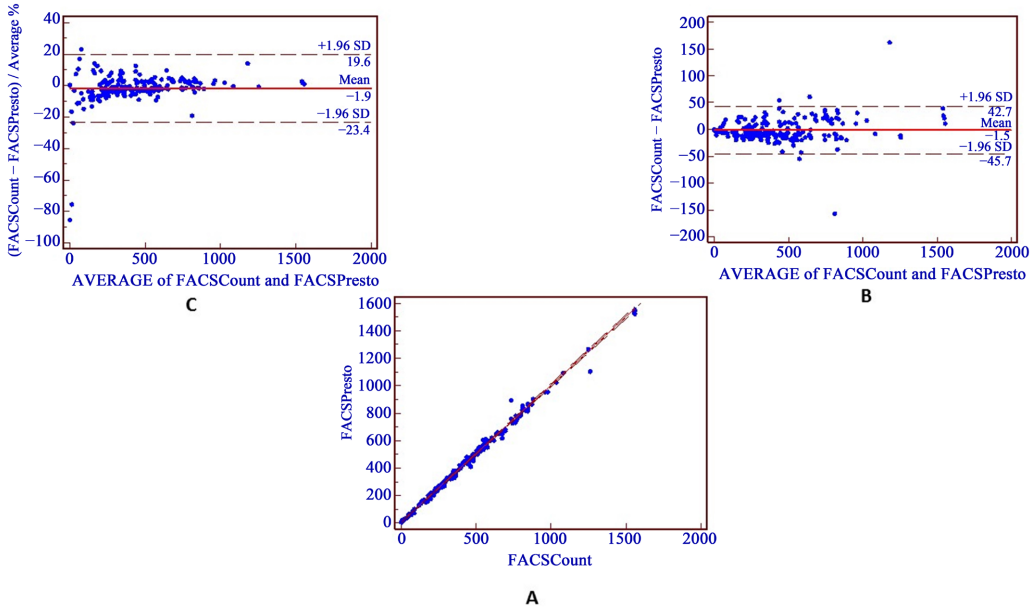


Figure 2. Comparison diagrams of BD FACSCount™® and BD FACSPresto™® technologies (n= 232). A = Passing Bablock, B = Bland Altman, C = Pollock. SD = Standard of deviation.

**Table 2.** Sensitivity and specificity analysis.

| | 350 | | 500 | |
|---|---|---|---|---|
| | PIMA™ | FACSPresto™ | PIMA™ | FACSPresto™ |
| Sensitivity: (%) (95%CI) | 98.96 (94.31 to 99.83) | 98.02 (93.01 to 99.70) | 100.00 (97.39 to 100.00) | 98.72 (95.44 to 99.81) |
| Specificity: (%) (95%CI) | 97.50 (92.86 to 99.45) | 96.18 (91.31 to 98.74) | 100.00 (95.15 to 100.00) | 98.68 (92.86 to 99.78) |
| Misclassified number | 4 samples | 7 samples | None | 3 samples |
| Misclassified rate (%) | 1.8 | 3 | 0 | 1.3 |
| Early ART treatment | 3 | 5 | 0 | 1 |
| Delayed ART initiation | 1 | 2 | 0 | 2 |
| PPV: (%) (95%CI) | 96.94 (91.30 to 99.33) | 95.19 (89.13 to 98.40) | 100.00 (97.39 to 100.00) | 99.35 (96.44 to 99.89) |
| NPV: (%) (95%CI) | 99.15 (95.35 to 99.86) | 98.44 (94.46 to 99.77) | 100.00 (95.15 to 100.00) | 97.40 (90.91 to 99.61) |

PPV: positive predictive value, NPV: negative predictive value, ART: Antiretroviral, CI: Confidence intervals. 350 and 500 cells/µl represent thresholds number values of CD4 + T cell, %: percentage.

## 4. Discussion

The present work aimed to contribute to the validation of PIMA™® and BD FACSPresto™® in CD4 + T cell count compared to BD FACSCount™® which was the reference measurement technic used in Benin. A total of 448 participants were enrolled and sampled. Among these, sample sizes were 216 for PIMA™® testing and 232 for BD FACSPresto™®. 65% and 58.2% of study participants tested respectively on PIMA™® and BD FACSPresto™® were women. Such observations suggest that women represented the category of the population that usually frequents much more services adapted to the care of PLHIV as described by Seidu and colleagues [16]. Innovative strategies will therefore be needed to encourage men at high risk of transmitting HIV infection [17] to use health services as Pre-exposure prophylaxis (PrEP) [18]. This will permit them to know their HIV status [19] very early and benefit from early antiretroviral treatment [20]. The techniques are included in the screening program of Benin by "index testing" as part of the PEPFAR pilot project since 2022 [21]. In our study, we observed that absolute CD4 + T cell numbers obtained on BD FACSPresto™® and PIMA™® techniques which are easy to use [6] strongly correlated with those obtained on BD FACSCount™® system whose purchase and maintenance cost remained sufficiently high [22]. Although the WHO recommended the "test and treat" option [9], the CD4 + T cell count remains an important examination to define the immune status of HIV infected patients [23]. In fact, in the event of a deep breakdown of CD4 + T lymphocytes, only the CD4 + T lymphocytes count directs the clinician to the early management of opportunistic infections [24]. The number of PLHIV cases in Benin with an opportunistic infections including tuberculosis in the second half of 2022 was 3.313 cases compared to 3.451 cases in the beginning of 2022 and all these cases were properly treated [3]. Cases of cryptococcal infections in patients with PLHIV have been reported in Nigeria [25]. Additionally, cases of cryptococcal infections were detected in seronegative patients in Mali with pulmonary tu-

berculosis and CD4 + T lymphocyte values greater than 500 cells/µl [26]. Hence the importance of having equipment with energy autonomy and capable of being deployed throughout the whole territory. It could offer the opportunity of analysis to patients even in the most remote regions. For example, in Benin the acquisition and implementation of PIMA™® and BD FACSPresto™® equipment were applied in accordance to WHO requirements and to validation with reference equipment.

The validations conducted in Benin have shown based Bland Altman diagram, the average absolute bias difference between the BD FACSCount™® and PIMA™® was 3.7 showing that PIMA™® underestimated CD4 + T values by 3.7 with limits of agreement ranging from −52.7 at 60.1. Using the Pollock diagram, this value was +0.5 with tuning limits ranging from −10.7 to 11.6. For the BD FACSPresto™® and viewing the Bland Altman plot, the average bias difference from the same reference equipment was −1.5 cells/µl, showing that BD FACSPresto™® overestimated by 1.5 the CD4 + T cell values with limits of agreement ranging from −45.7 to 42.7. Using the Pollock diagram, this value was −1.9 with agreement limits ranging from −23.4 to 19. These results underlined the seriousness in the quality control granted by the company during the manufacture of both equipment. The training of biologists on daily maintenance and calibration of pipettes was emphasized. Similar observations related to PIMA™® were reported in Senegal, West Africa and in Uganda, East Africa with underestimations of 22 cells/µL [27] and 32.5 cellules/µL [28] respectively**.** Cases of overestimation values were also reported in BD FACSPresto™® validation in Nigeria (7.49 cells/µL) and Cameroon (38.71 cells/µL) [6] [10].

A CD4 + T count limit of ±60 cells/µL can have a significant impact on clinical decisions. This can lead to misclassification and under treatment or overtreatment. Indeed, if the actual CD4 + T count were lower than the measured count, this could lead to ART initiation earlier than necessary, exposing the patient to unnecessary side effects and drug overdose. Conversely, if the actual CD4 + T count were higher than the measured count (due to variability), this could delay ART initiation when it was actually needed, potentially increasing the risk of opportunistic infections.

Passing Bablok diagram, sensitivity and specificity were elements to be taken into account in the context of equipment validation for biological diagnosis. Hence, Passing Bablok diagram defined concordance correlation coefficient that in our study gave 0.99 (**Table 1**) both PIMA™® and BD FACSPresto™®. This value confirmed the results obtained by the Bland Altman and Pollock plots and showed that the degree to which the CD4 + T cell count value pairs fall on the 45˚ line the origin was not far from each other. Similar observations were reported in Dakar (0.94) and Uganda (0.94) [27] [28]. However, coefficient of less than 90% has been reported in Kenya (87%) [12]**.**

The sensitivities and specificities of PIMA™® and BD FACSPresto™® for the thresholds of 350 and 500 were detailed in **Table 2**. Looking at eligible patients, only 4 samples were misclassified representing a rate of 1.8% with PIMA™® at 350

CD4 + T cells threshold. Among them, 3 were early treated and only 1 delayed for ART initiation. No patient was misclassified in 500 CD4 + T cells threshold. Regarding BD FACSPresto™®, 7 (3%) samples were misclassified at 350 CD4 + T cells threshold with 5 early treated and 2 delayed ART. At 500 CD4 + T cells threshold, 3 (1.3%) samples were misclassified with 1 early treated and 2 delayed ART (**Table 2**). The low rate of misclassified samples testified to the high accuracy of two technologies implying a solution for the patients who otherwise would have to visit the clinic several times for immunological monitoring [29]. Thus, there would no longer be any reports of sample loss during transport or sample deterioration due to non-compliance with the cold chain since the POCs would be installed in these health structures and they will be easily available to the patients [22] [30]. Indeed, many patients would benefit from antiretroviral treatment which would reduce the viral load and further reduce the risk of HIV-1 transmission and the onset of opportunistic diseases [31] [32]. For patients whose initiation of antiretroviral treatment is delayed, close and repetitive monitoring would also allow for very early treatment initiation.

A study conducted in Nigeria reported 4 samples misclassified out of 134 (3%) for a CD4 + T cells threshold below 500 by BD FACSPresto™® versus BD FACSCount™®. In this same study, the BD FACSPresto™® misclassified 8 samples out of 154 (5.2%) for a CD4 threshold above 500 cells/μL [10].

## 5. Limitations

Our study is not without limitations. Children whose CD4 + T cell percentages better reflect their immunological status were not evaluated. POC technologies that provide CD4 + T cell percentage values should also be evaluated to enable expanded immunological monitoring of HIV-1-infected children admitted to pediatric care facilities in Benin.

## 6. Conclusion

The present study demonstrates that both technologies PIMA™® and BD FACSPresto™®, simple in design and easy to use, appeared interchangeable with the reference technique BD FACSCount™® and, can continue to be used in the immunological monitoring of PLHIV-1 in the most remote regions of Benin.

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## Authors' Contributions

**E.T.** Drafted, wrote the manuscript and ensured the quality control of CD4 + T cell count performed in LR/PSLS.

**D.W.** Statistical Analysis.
**A.K.A.** Read the manuscript.
**A.Y.** Review the manuscript.
All authors reviewed and approved the final manuscript.

## Availability of Data and Materials

All the raw data generated are available upon reasonable request to corresponding author.

## Ethics Approval and Consent to Participate

Ethical clearance was obtained from National Ethics Committee for Health Research (CNERS): number 27 of July 29, 2021. Written informed consent was obtained from all participants. Confidentiality and anonymity of the information was also maintained. The study was conducted in accordance to the relevant guidelines and regulations.

## Conflicts of Interest

The authors declare that they have no competing interests.

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## List of Abbreviations

ART: Antiretroviral treatment
ARVs: Antiretroviral drugs
CD4: Cluster of differentiation 4
CI: Confidence intervals
HIV: Human Immunodeficience Viruse
IQR: Interquartile
K3 EDTA: Tripotassium ethylenediaminetetraacetic acid
LBPCI: Laboratory of Biology, Cell Physiology and Immunology
LOA: Limits of agreement
LR/PSLS: Reference Laboratory of Health Program Fighting Against AIDS
NPV: Negative predictive value
OI: Opportunistic infections
PEPFAR: President's Emergency Plan for AIDS Relief
PPV: Positive predictive value
PrEP: Pre-exposure prophylaxis
WHO: World Health Organization