Background

The CD4+ T-cell count is a critical parameter in monitoring HIV disease. Flow cytometry remains the gold standard technology for enumeration of CD4+ T-cells, because of its accuracy, precision and reproducibility[1]. The AQUIOS teta instrument is a fully automated flow cytometer with integrated sample loading, preparation and analysis. In this study, we demonstrate that the AQUIOS teta algorithm provides accurate results for enumeration of lymphocyte subsets in samples tested up to 24 hours post venipuncture. The recovery of the T, B and NK cell lymphocyte subsets using AQUIOS teta method was compared to the Navios teta system.

Methods

The Navios II system is a load-and-go flow cytometry system that was recently cleared by the US FDA for testing in clinical labs. The system incorporates on-board sample preparation and automated analysis with on-board capabilities. The instrument employs an iterative approach for enumerating specific cell populations. In this study, the AQUIOS teta system was compared to the Navios system for immunophenotyping lymphocyte cell populations was compared to the Navios teta system (AQUIOS teta application run on Navios system with Flow Count FluoSphere). A currently used flow cytometry method for measuring the T, B and NK cells.

Table 1: Detailed components of each system used in this study.

Table 2: Number of specimens analyzed per CD4+ count range

Table 3: Three general statistics, including number of tests (N), mean values, total bias difference in recovery between methods and 95% confidence limits of the difference.

Table 3 displays the regression graphs followed by the Bland-Altman plots for each individual marker for both AQUIOS teta and Navios teta-2 Panel reagents. For the regression graphs, the green line represents the equality line and the blue lines represent the regression line. For the Bland-Altman plots, the green line represents the mean bias and the blue lines represent the mean 95% limits of agreement (LOA). LOA is computed from the data baseline of the variability of the collected sample data. They are based on the 95% confidence interval (95% CI), which implies that a certain percent of the data fall outside these limits.

Table 4: Summary bias and 95% confidence limits from the regression model at three percentiles.

Table 5: Summary of bias and 95% confidence limits from the regression model at three percentiles.

Table 6: The bias is presented from the regression model for CD4 at four different levels (50, 100, 200 & 500 cells/µL) and their upper and lower 95% confidence limits.

Table 7: The bias is presented from the regression model for CD4 at four different levels (50, 100, 200 & 500 cells/µL) and their upper and lower 95% confidence limits.

Table 8: The bias is presented from the regression model for CD4 at four different levels (50, 100, 200 & 500 cells/µL) and their upper and lower 95% confidence limits.

Table 9: The bias is presented from the regression model for CD4 at four different levels (50, 100, 200 & 500 cells/µL) and their upper and lower 95% confidence limits.

Table 10: The bias is presented from the regression model for CD4 at four different levels (50, 100, 200 & 500 cells/µL) and their upper and lower 95% confidence limits.

Table 11: The bias is presented from the regression model for CD4 at four different levels (50, 100, 200 & 500 cells/µL) and their upper and lower 95% confidence limits.

Table 12: The bias is presented from the regression model for CD4 at four different levels (50, 100, 200 & 500 cells/µL) and their upper and lower 95% confidence limits.

Table 13: The bias is presented from the regression model for CD4 at four different levels (50, 100, 200 & 500 cells/µL) and their upper and lower 95% confidence limits.

Table 14: The bias is presented from the regression model for CD4 at four different levels (50, 100, 200 & 500 cells/µL) and their upper and lower 95% confidence limits.