

COMPARING THE AQUIOS CL PLG APPLICATION TO THE FC500 MCL FLOWCARE PLG APPLICATION

The performance of the AQUIOS PLG System (or application) was assessed by comparing the results to the comparator estimation of difference as described in CLSI EP9-A3 Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline, Third Edition. The comparator used FlowCARE PLG CD4 Reagent, ImmunoPrep Lysing reagent, and Flow-Count for CD4+ cell enumeration on FC 500 MCL flow cytometer with CXP software.

The method comparison is comprised of HIV specimens from 38 pediatric and 202 adult subjects. The data provided in Table 1 and Figure 1 supports the premise that the systems are equivalent in their performance enumerating CD4+ lymphocytes in peripheral whole blood. Values are expressed in terms of percentage (%) of the total lymphocyte count and as absolute count (cells/ μ L) for total CD4+ cells.

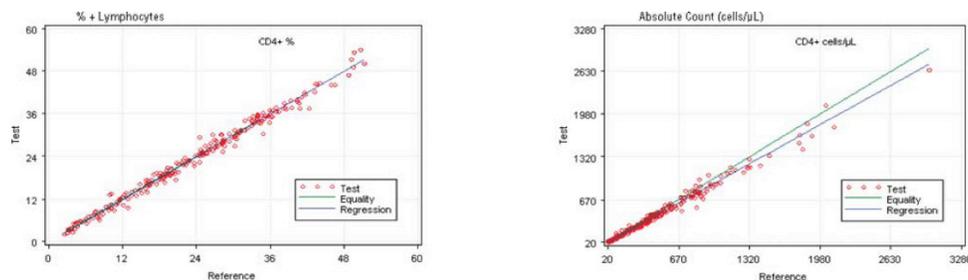
Table 1. Measurement Procedure Comparison - Whole Blood

PARAMETER	UNITS	MEASURING RANGE	DIFFERENCE
%CD4+	% + Lymphocytes	$\leq 40\%$	± 1.5
		$> 40\%$	± 2.5
CD4+	Absolute Count (cells/ μ L)	≤ 300	± 40
		> 300	± 13

Table 2. Measurement Procedure Comparison of the AQUIOS PLG Application and the FC500 MCL FlowCARE PLG

CD45-FITC/CD4-PE (N=240)					
Parameter	Mean FC500 MCL	Mean AQUIOS PLG	Correlation	Slope	Intercept
% + Lymphocytes					
CD4+	23.24	23.08	0.994	1.001	-0.188
Cells/ μ L					
CD4+	495	454	0.992	0.920	-0.885

Figure 1. Regression Analysis of CD4+ Cells on the AQUIOS PLG Application and the Predicate



Conclusions

The data suggests a strong correlation between the AQUIOS CL PLG application and the FC500 MCL FlowCARE PLG application.

AQUIOS CL is a Class I Laser Product



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FLOW-1123WP09.15-A