ABSTRACT

BACKGROUND:

CD4 T cell enumeration is the most widely used prognostic marker for management of HIV disease. Internal quality control and external quality assessment (EQA) programs are critical to ensure reliability of clinical measurements. The utility of stabilized whole blood products (SWBP) as a test reagent for EQA programs such as Quality Assessment and Standardization for Immunological measures relevant to HIV/AIDS (QASI) program have been demonstrated previously. Since then, several new commercial SWBPs and alternative CD4 enumeration technologies have become available. Seven SWBPs were evaluated on seven different enumeration platforms to determine which product(s) are most suitable for EQA programs that support multiple analytical technologies.

METHOD:

Assessment of SWBPs was based on two criteria: (1) accuracy of CD4 T cell measurements and; (2) stability under sub optimal storage conditions.

RESULTS:

Three SWBPs (Multi-Check, StatusFlow and CD4 Count) showed accurate CD4 T-cell absolute count and percentage values across six of the enumeration platforms. All products retain stability up to 18 days at 21-23°C with the exception of Multi-Check-high on FacsCount and Multi-Check-Low and StatusFlow-Low on Pima. One of the products (CD4 Count) retained stability for three days on all platforms tested when stored at 37°C.

CONCLUSION:

This study demonstrated that the characteristics of commercially available SWBPs vary across multiple CD4 platforms. The compatibility of testing panels for EQA programs with multiple analytical platforms needs to be carefully considered, especially in large multiplatform CD4 EQA programs. The selection of a suitable cross-platform SWBP is an increasing challenge as more reagents and platforms are introduced for CD4 T-cell enumeration.