**A novel software application for ELISPOT data calculation, conversion, and quality assurance reporting.** Meredith Slota, Elizabeth O’Donoghue, Kathleen Tietje, and Mary L. Disis. University of Washington, Tumor Vaccine Group, Center for Translational Medicine in Women’s Health.

The enzyme-linked immunosorbent spot (ELISPOT) assay is widely used for immune monitoring in clinical trials of cancer immunotherapy. The flexibility and sensitivity of the assay with a standardized and validated protocol makes the method appropriate for cost-effective high-throughput screening. The generation of bulk ELISPOT data (spots/well (SPW) or corrected spots/well (CSPW)), however, can be cumbersome to manage effectively over time as multiple analyses are performed for each patient. Additionally, it is important to maintain raw data, such as the “no antigen” wells, to assess assay performance as part of ongoing quality assurance (QA) programs. Moreover, ELISPOT data are commonly analyzed manually or using spreadsheet programs, methods which are prone to user error. Our group has created a software tool to collect, analyze, and store ELISPOT data, making high-throughput assays more manageable and allowing for centralized data analysis using uniform calculations.

This tool uses a standard 96-well customizable format with drop-down antigen lists, enabling researchers to export raw data directly into the program. The data conversion function transforms raw spots per well data into reportable values such as CSPW or precursor frequency via three complex calculation queries that result in both reportable data and figures that can be used for longer term QA of assay performance. The historical “snapshot” function utilizes an append query to store the current calculated values with a date/time or reagent lot stamp and a comment into the historical data snapshot table. When performing additional analysis, researchers can choose to use the most current dataset or any previous snapshot dataset. This snapshot function allows for a continually evolving database while maintaining archival datasets for posterity which allows for more facile trending of assay performance or biologic variation that may be induced by the therapeutic intervention. The data conversion tool is highly customizable, allowing for changes in common assay variables. By preserving all raw data, we can generate reports on background levels over time as well as ensure that positive controls are working consistently. We can also be alerted to outlier assays which may indicate issues either in assay performance or clinical trial conduct which will allow earlier intervention. The software easily creates QA/QC reports on changing reagents and monitors performance across different technicians and clinical trials. The creation of this novel software tool has improved our data quality and consistency, analysis efficiency and accuracy, and has assisted in the development of a solid QA program for immunologic monitoring of human clinical trials.

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