MEDPACE

SPECTRAL FLOW CYTOMETRY SERVICES

Until recently, immune cells identification has been limited in drug kinetics and biomarker characterization due to the number of fluorochromes and the detection limits on conventional flow cytometers.

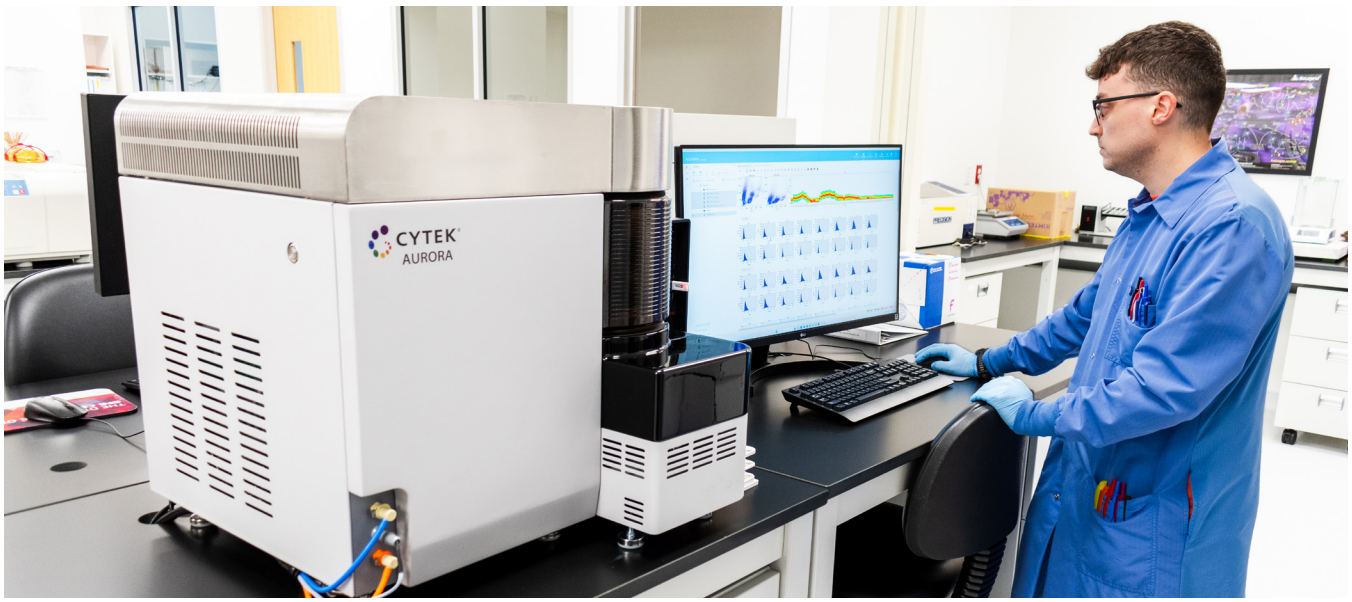
Clinical laboratories worldwide are implementing spectral flow cytometry. The advancement on this area improves the resolution of markers and higher dimensional experiments, by measuring the entire emission spectrum of every fluorescence molecule. Spectral flow cytometry is opening new avenues for detection of a larger number of immune cell subsets, and providing a better understanding into immune system complexity, composition, and functions, in the analysis of clinical research samples.

Global standardization across Medpace central laboratories warrants high-quality data generation and consistency. The capability to perform separate measurements on such many immune cells in a single heterogeneous sample, makes flow cytometry one of the most powerful platforms available.

INSTRUMENT DETAILS

Cytek® Aurora has been implemented worldwide at the US, Belgium, and Singapore Medpace central laboratories. The instrument is equipped with five lasers, Ultraviolet (355nm), Violet (405 nm), Blue (488nm), Yellow Green (561nm) and Red (640nm) that can detect 64 fluorescence parameters (67 including blue laser FSC, blue laser SSC and violet laser SSC) simultaneously and process up to 40 fluorescence parameters, enabling multi-parametric single cell analysis.

Cytek® Aurora is equipped with SpectroFlo® Research Use Only (RUO) software to perform assay setup, QCs, data acquisition, live unmixing during acquisitions, data analysis, and file export for further analysis. SpectroFlo® QC beads are used for routine performance tracking and set up of Cytek® Aurora. Daily QC and performance are tracked and charted over time in a Levey-Jennings tab.



ANALYTICAL METHOD VALIDATION

In-house validated assays, including ready-to-go panels, custom developed panels and method transfer, are all validated at Medpace central laboratories, following the guidelines of the Clinical Laboratory Improvement Amendments (CLIA), College of American Pathologists (CAP) and Clinical and Laboratory Standards Institute (CLSI). The flow cytometry PhD scientist team ensures the development, validation, verification, control, analysis, and implementation of cell-based assays on a global scale.

SAMPLE PROCESSING AND DATA ANALYSIS

Medpace central laboratories develop and perform analytical method validation on assays that cover a larger number of immune cell subsets. In addition to the in-house validated ready-to-go panels, we also perform study-specific full customized panels. The instruments are standardized among facilities, global SOPs are followed, and identical templates are applied per every single assay. Using validated software across facilities, specific analysis templates are used for data analysis by trained scientists, and quality checks are performed before data transfer.

SPECIMEN TYPES

Whole blood collected in K-2 EDTA, NaHep, Streck Cytochex and CPT tubes, Peripheral Blood Mononuclear Cells (PBMCs), fresh or cryopreserved, activated or resting, can be used for Flow Cytometry, depending on the assay.

FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a scientifically driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its high science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective.