MEDPACE

FLOW CYTOMETRY SERVICES

As part of a full-service CRO model, Medpace offers an experienced flow cytometry team overseen by PhD-level scientists with over 10 years of experience designing, validating, analyzing, and interpreting multicolor flow cytometry assays.

As a platform for monitoring immune cell functions, flow cytometry has a unique value in the identification and quantification of different cell types, analyzing simultaneously multiple parameters in a single heterogeneous sample, provides highly detailed information about the specific immune cell populations, allowing to quantify target effects of a therapeutic, monitor immune function and immunotoxicity.

APPLICATIONS

Optimal fit-for-purpose method development, panel design, and validation to:

- Monitor immunophenotyping and cell activation
- Evaluate receptor occupancy assays
- Monitor and characterize CAR T and B-cell assays
- Rare cell population enumeration (CD34+ stem cell count)

MAKING THE COMPLEX

SEAMLESS®

MEDPACE VALIDATED ASSAYS

Medpace Central Labs have developed and performed analytical method validation on assays that cover the most common blood cell types that can be affected by inflammatory-infectious responses or oncology and hematology diseases. Medpace offers data as a percentage, mean fluorescent intensity, or absolute counts, depending on the panel.

The panels Medpace Central Labs offer with cell types/markers include:

- T-Cell
  - Helper and cytotoxic T-cells. Memory, activation, exhaustion and T-reg T-cells
  - TBNK, Absolute counts of CD4, CD8, CD19, CD16/56 (IVD, CAP PT)
- NK cell
  - Regulatory, cytotoxic and NKG2D positive NK cells
- B Cell
  - Transitional, plasmablast, activated, IgD/IgM memory, mature naïve, atypical, class-switched and non-switched B-cells
- Monocyte
  - Monocyte Subsets: Classical, Intermediate and Non-classical monocytes (HLA-DR+/-)
- Dendritic Cell
  - Conventional dendritic cells 1 and 2, plasmacytoid DCs
- Stem/Progenitor Panel
  - CD34 Stem Cell Enumeration
- PNH (CAP PT)
- CFSE Proliferation Assay
- Cytokine Panel
  - IL2, IL-4, IL-6, IL-8, IFNγ and TNFα on helper T-cells and cytotoxic T-cells

ANALYTICAL METHOD VALIDATION

In addition to the in-house validated ready-to-go panels, we also offer study-specific full customized panels with capacity for more than 20 colors. Whether a custom panel needs to be developed or a method needs to be transferred, the flow cytometry scientists team ensures the developing, validating, verifying, controlling, analyzing, and implementing cell-based assays on a global scale, following the guidelines of the Clinical Laboratory Improvement Amendments (CLIA), College of American Pathologists (CAP) and Clinical and Laboratory Standards Institute (CLSI).

INSTRUMENTATION

Global cross-site and cross-instrument standardized platform based on BD FACSLyric™ and Cytek® Aurora. The BD FACSLyric is a flow cytometer equipped with a blue (488nm), red (633nm) and violet (405nm) laser and can process up to 10 fluorescence parameters, 12 including Forward Scatter (FSC) and Side Scatter (SSC) simultaneously, enabling medium throughput single cell analysis. The instrument is equipped with Research Use Only (RUO) and clinical software for the acquisition of antibody-labeled samples from various sources, such as multi-well plates and 12x75-mm falcon tubes. The In Vitro Diagnostic (IVD) marked process allows acquisition through predefined configurations. The instrument's performance is tracked and monitored through the cytometer, setup, and tracking application, which is included in the daily operation of the instrument. The Cytek® Aurora is a spectral flow cytometer equipped with ultra-violet (355nm), violet (405nm), blue (488nm), yellow-green (561nm) and red (633nm) laser that can detect 64 fluorescence parameters (67 including FSC, blue laser SSC and violet laser SSC) simultaneously and process up to 40 fluorescence parameters, enabling multi-parametric single cell analysis. The instrument is equipped with SpectroFlo® Research Use Only (RUO) software. 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.

SAMPLE PROCESSING AND DATA ANALYSIS

Standardized instrument setting, global SOP, and shared acquisition template on the instrument are applied per assay. Results are analyzed by trained Scientists using a specific analysis template, defined during validation, and quality checked before data transfer.

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.

WE CAN'T SIMPLIFY CLINICAL DEVELOPMENT – BUT WE CAN EXECUTE IT SEAMLESSLY.

MAKING THE COMPLEX SEAMLESS®