

FLOW CYTOMETRY

NAVIGATE BIOPHARMA OFFERS A BROAD RANGE OF HIGH COMPLEXITY FLOW CYTOMETRY ASSAYS FOR CLINICAL BIOMARKER AND ENDPOINT ANALYSIS IN INVESTIGATIONAL CLINICAL TRIALS.

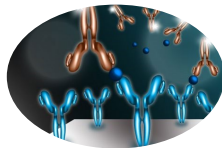
WHY NAVIGATE?

- A team of over 50 immunologists, pharmacologists, and stem cell biologists with advanced knowledge on panel design and validation of high complexity assays supporting drug registration in compliance with latest regulatory guidance.
- Navigate Biopharma Services has developed over 100 complex flow panels providing key scientific insights and peer reviewed publications.

TECHNICAL CAPABILITIES

- Broad library of specialized panels offering differentiated solutions.
- Specializing in liquid tumor, minimal residual disease (MRD) monitoring for CLL/ALL/MCL/AML, receptor occupancy (RO) assays, rare cell detection, functional and PK/PD assays.
- In depth expertise in data analysis and interpretation of normal and abnormal hematopoiesis.
- Breadth of technologies including IVD platforms (FACS Canto and FACS Lyric instruments), state of art full spectral cytometers, and AI-assisted analysis.

Translational Biomarkers



Pharmacodynamics
Predictive | MOA | Efficacy
Endpoints

Specialty Bioanalytics



Cellular Kinetics | Receptor
Occupancy | Immunogenicity
Potency | Tetramer Analyses

Diagnostics Support



Development Under Design
Control | Analytical
Validation (IDEs) | Clinical
Validation | PMA
Submissions

SERVICES



CUSTOM ASSAY DEVELOPMENT

We offer diverse and custom development for clinical biomarkers and diagnostic solutions for use in investigational clinical trials. Our highly skilled, responsive and dedicated team of scientists, project managers and pathologists partner with our pharma and biotech sponsors to create innovative and differentiated solutions.

CLINICAL TRIAL TESTING

We provide a broad portfolio of advanced laboratory capabilities utilizing state of the art, diverse technologies that can address clinical biomarker and precision medicine testing

FACSCanto™ (IVD)
3-lasers, 8-colors

FACSLyric™ (IVD)
3-lasers, 12 colors



MRD Assessments | CLIA Assays
Cell & Gene Therapy | CAR-T assays

needs for every phase of clinical trials (first in human to global pivotal trials). Our integrated solutions address various sponsor needs such as biomarker identification, pharmacodynamics, efficacy readouts, patient inclusion/exclusion, diagnosis and prognosis. Our comprehensive services team support end-to-end clinical trial testing from sample logistics to project and data management for global clinical trials.

LSRFortessa™ X-20
5-lasers, 18-colors

FACSymphony™ A5
5-lasers, 30+ colors

Northern Lights
3 lasers, up to 24 colors



Exploratory Biomarkers | Full-Spectrum Flow Cytometry

COMPANION DIAGNOSTICS (CoDx)

We have broad experience in the development and support of companion diagnostics and CE marking submissions through performing risk assessments, IDE, PMA, and IRBs. Our quality systems are designed to ensure compliance with applicable regulatory requirements for drug and diagnostic approvals.

CLINICAL TRIAL ENDPOINT (BIOMARKER RELEVANCE)	GUIDELINES FOR VALIDATION
Discovery: (undefined clinical significance)	Scientifically Sound: (e.g., Sensitive & Specific)
Exploratory Biomarkers: (Hypothesis Driven, Signature Finding)	Abbreviated Validation: (e.g., Sensitive, Specific & Reproducible)
Clinical Protocol Driven: (Primary or Secondary Endpoint)	Advanced Validation: Meets regulatory guidelines (CLIA/FDA)
Patient Selection or Stratification (CDx)	Extensive Validation: Assay meets CLSI/FDA guidelines, reagents and instruments maintained under QSRs, GXP compliant workflows

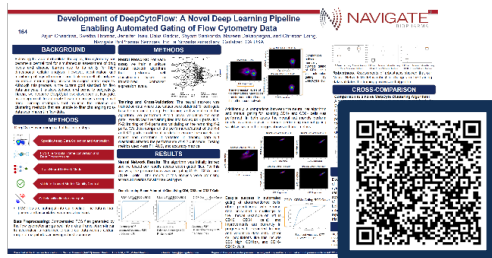
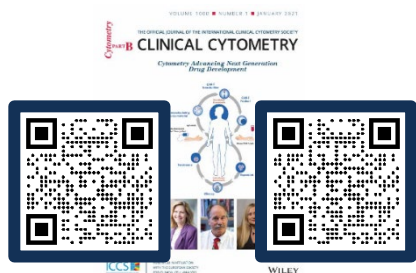
ASSAY PORTFOLIO

GOAL	TARGET	MARKERS USED IN DIFFERENT PANELS
EXPLORATORY BIOMARKERS	T/NK Cell Profiling	CD45, CD3, CD4, CD8, CD38, CD27, CD45RA, HLA-DR, Tim-3, PD-1, LAG-3, CCR7, Ki-67, Foxp3, TCRV α , CD134, CD183, CD127, CD194, CD25, CD278, CD196
	T/B Regulatory Cells	CD4, CD19, CD25, CD27, CD8, HLA-DR, CD3, CD45RA, CD38, CD127, CD24
	Immunosuppressive cells, Myeloid cells, Broad immunophenotyping, Megakaryocytes	CD45, CD34, CD117, CD123, CD133, DR, CD15, CD33, CD36, CD38, CD41, CD62, Tim-3, LAG-3, PD-1, PD-L1, CD16, CD14, CD56, CD26, CD44, CD86, CD11b, CLL-1, CD16, BDCA, CLL-1, CD3, CD19
	T/NK comprehensive profiling	CD45, CD3, CD4, CD8, CD2, Cd56, CD19, CD28, CD45RA, CD183, CD25, CD2, CD56, CD19, CD197, CD127, CD196, HLA-DR, CD194, Ki-67, Foxp3, PD-1, Tim-3, NKP46, CD58, CD303, NKG2A, NKG2D
DISEASE BURDEN AND DIAGNOSTICS	HSCs, LSCs, Multiple Myeloma, MRD in AML, CLL, MCL, B-ALL	CD45, CD34, CD19, CD20, CD38, CD79b, CD22, CD2, CD3, CD22, CD43, CD5, CD10, CD123, CD38, CD58, CD66c, CD9, CD56, CD138, CD117, CD123, CD33, Tim-3, HLA-DR, CD7, CD13, CD15, CD11b Kappa, Lambda
CELL AND GENE THERAPY	CAR T PK/PD assays; custom absolute enumeration of CAR-T cells	CD3, CD4, CD8, CD45RA, CXCR7, PD-1, Tim-3, CAR-T, CD14, CD16

MRD: Measurable Residual Disease
AML: Acute Myeloid Leukemia
PK: Pharmacokinetics
HSC: Hematopoietic Stem Cell

CLL: Chronic Lymphocytic leukemia
MCL: Mantel Cell lymphoma
PD: Pharmacodynamics
LSC: Leukemic Stem Cell

SCIENTIFIC RESOURCES



Additional resources can be located at <https://www.navigatebp.com/resources>