

# FLOW CYTOMETRY

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

## TECHNICAL CAPABILITIES

- Broad library of specialized markers and panels offering differentiated solutions
- 13-16 color integrated, high-complexity panels for identifying phenotyping signatures
- T-cell subsets, B-cell subsets, LSC, plasma cells, and MDSC subpanels
- Specializing in liquid tumor, minimal residual disease (MRD) monitoring for CLL/ALL/MCL/MM/AML
- Receptor occupancy assays for guiding dose selection
- Up-to-date knowledge and experience in developing customized panels

## ONCOLOGY PORTFOLIO

<b>IMMUNO-ONCOLOGY</b>	T-Cell Profiling	Maturation state and ICI expression of native, activated, differentiated and exhausted phenotypes
		Enumeration of T-cell subsets: Th1, 2, 17 and Tregs
	B-Cell Phenotyping	Comprehensive panel for B-cell differentiation
	MDSC Identification	MDSC burden and subset analysis
<b>PHARMACODYNAMICS (PD) ANALYSIS</b>	Specialized Receptor Occupancy Assays	Determination of biological effective dose of target expression
<b>HEMATOMALIGNANCY PROFILING</b>	Disease Burden	Biomarker panels in MM, CLL and AML
	MRD Diagnosis	Panels for B-ALL, MM, CLL, MCL and AML
<b>CELLULAR KINETICS</b>	Cell Therapy	Measurement of CART on T-cells

MDSC: Myeloid Derived Suppressor Cells  
 ICI: Immune Checkpoint Inhibitor  
 BED: Biologically Effective Dose

MRD: Minimal Residual Disease  
 LSC: Leukemia Stem Cell  
 ALL: Acute Lymphoblastic Lymphoma

CLL: Chronic Lymphocytic Leukemia  
 MCL: Mantle Cell Lymphoma  
 MM: Multiple Myeloma

AML: Acute Myeloid Leukemia

## FLOW CYTOMETRY PANELS

<b>IMMUNO-ONCOLOGY</b>	<b>T-Cell Differentiation</b>	CD4, CD8, OX40, CD45RA, CCR4, CD25, CD3, PD-1, ICOS, LAG-3, CCR6, CXCR3, CD127
	<b>T-Cell Maturation</b>	CD4, CD8, CD27, CD45RA, PD-1, TIM-3, CD3, CD45RO, CD25, LAG-3, CD28, CCR7, CD127
	<b>T-Cell Proliferation</b>	CD4, CD8, CD38, CD45RA, PD-1, TIM-3, CD3, CD45, HLA-DR, LAG-3, CCR7, Ki-67, TCR-Vd2
	<b>T-Cell Activation/Exhaustion</b>	CD4, CD8, CD38, CD45RA, PD-1, TIM-3, CD3, CD45RO, HLA-DR, LAG-3, CD25, CCR7, CD127
	<b>B-Cell</b>	CD19, CD38, CD40, CD43, CD79b, CD123, CD184, CD274, CD5
	<b>MDSC</b>	CD11b, CD11c, CD16, CD33, CD14, CD15, CD3/CD19/CD56, CD123, HLA-DR
	<b>TBNK</b>	CD3, CD16, CD56, CD45, CD4, CD19, CD8
	<b>NK-Cell Proliferation</b>	CD45, CD4, CD159a, CD3, CD122, CD25, CD335, CD8, CD56, NKG2D, CD107a, Ki-67, CD16
	<b>T-B Reg</b>	CD4, CD19, CD3, CD45RA, CD25, CD27, CD8, HLA-DR, CD38, CD127, FoxP3, CD24
<b>PD ANALYSIS</b>	<b>AML</b>	CD117, CD33, CD45, CD34, CD123, CLEC12A, CD19, CD3, CD56, CD14 (customizable)
	<b>MM</b>	CD45, CD38, CD138, LAMBDA, KAPPA, CD56, CD28, CD19, BCMA
	<b>CLL</b>	CD45, CD19, CD5, CD3, LAMBDA, KAPPA (customizable)
	<b>AML/LSC</b>	CD45, CD34, CD117, CD123, CD33, CD38, CD3, CD16, CD19, CD56, CD13
	<b>CML-LSC-PDC</b>	CD117, CD38, CD45, CD56, BDCA-2, CD117, CD26, CD34, Viability, CD123, CD16, CD44, CD3/20/235, CD86
<b>MINIMAL RESIDUAL DISEASE ASSESSMENTS</b>	<b>B-ALL MRD</b>	CD123, CD45, CD38, CD34, CD19, CD10, CD22, CD20, CD58, CD33, CD66c, CD9, CD13
	<b>CLL MRD</b>	CD5, CD3, CD81, CD79b, CD22, CD19, CD43, CD20
	<b>MCL MRD</b>	KAPPA, LAMBDA, CD19, CD79b, CD22, CD3, CD5, CD43, CD20, FMC7, CD23, CD22, CD10
	<b>MM MRD</b>	KAPPA, LAMBDA, CD117, CD56, CD138, CD19, CD38, CD45, CD81, CD27, CD28, CD200, CD20
	<b>AML MRD</b>	Based on European Leukemia Net guideline

## SERVICES



## CUSTOM ASSAY DEVELOPMENT

Navigate BioPharma offers 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

Navigate BioPharma provides a broad portfolio of advanced laboratory capabilities utilizing state of the art, diverse technologies that can address clinical biomarker and precision medicine testing 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, diagnosis and prognosis. Our comprehensive services team supports end-to-end clinical trial testing from sample logistics to project and data management for global clinical trials.

## COMPANION DIAGNOSTICS (CoDx)

Navigate BioPharma has broad experience in the development and support of companion diagnostics and CE marking submissions. Our team can support your regulatory needs through its experience in performing risk assessments, IDE, PMA, IRBs as well as CE marking submissions. Our quality systems are designed to ensure compliance with applicable regulatory requirements for drug and diagnostic approvals.