NAVIGATE™ BIOPHARMA

Pioneers. Partners. Pathfinders.™

SPECIALTY BIOANALYTICAL SOLUTIONS

NAVIGATE BIOPHARMA OFFERS REGULATED SPECIALTY LIGAND-BINDING ASSAY SOLUTIONS RANGING FROM COMPLEX NEUTRALIZING ANTIBODY DETECTION TO RARE BIOMARKERS UTILIZING ULTRASENSITIVE TECHNOLOGY PLATFORMS.

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 ultrasensitive immunoassays covering multiple therapeutic areas including oncology, neurology, inflammation, and infectious diseases.

TECHNICAL CAPABILITIES

- High sensitivity biomarker quantitation (e.g., Neurofilament Light Chain)
- Immunogenicity immunoassays (IDE, IFU)
  - Enrollment type assays for patient inclusion/exclusion (e.g., AAV)
  - Functional (cell-based) assays for characterization of neutralizing antibodies (e.g., CAR-Ts)
- Quantitative Immunoassays
  - Multiplex assays to monitor cytokine release syndrome (CRS)
  - Species and isotype independent SARS-COV2 antibody response assays
  - Pharmacokinetics

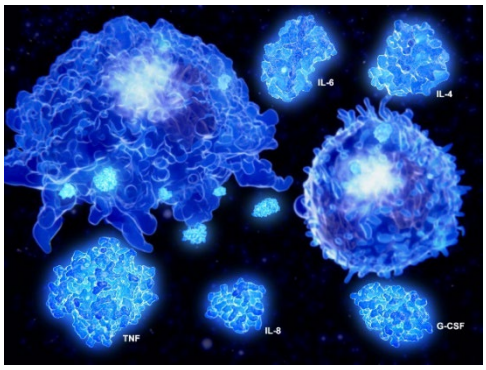


Figure 1. Cytokines are some of the key biomarkers used in the development of ultrasensitive immunoassays

SERVICES

PRECLINICAL | PHASE I | PHASE II | PHASE III | REGULATORY SUBMISSIONS

CUSTOM ASSAY DEVELOPMENT

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

CLINICAL TRIAL TESTING

NAVIGATE BIOPHARMA SERVICES
A Novartis Subsidiary

navigatebp.com
bus.dev@navigatebp.com
linkedin.com/company/navigatebp

1890 Rutherford Rd. Carlsbad, CA 92008
Phone 866-992-4939 (760-516-6092)

We provide a broad portfolio of advanced laboratory capabilities utilizing state of the art, diverse technologies that can address clinical biomarker, specialty bioanaltical 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/exclusion, diagnosis/surrogate endpoint support, 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.

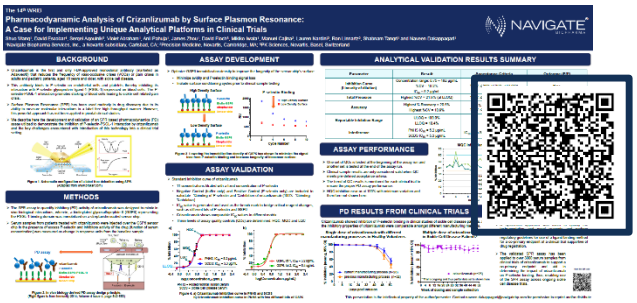
COMPANION DIAGNOSTICS (CoDx)

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

TECHNOLOGIES

APPLICATIONS	ELISA	ELLA	MSD	LUMINEX	SPR
					
	Enzyme-linked antibody to detect a ligand bound to a receptor immobilized on a plate	Microfluidic platform that performs automated ELISA assays using a disposable cartridge	Electro-chemiluminescent label to detect a ligand bound to a receptor immobilized on an electrode	Color-coded microspheres coated with receptors to capture ligands and measure their binding by fluorescence	Measures the change in refractive index at a sensor surface upon binding of a ligand to a receptor immobilized on the surface
EXPLORATORY CYTOKINES		✓	✓	✓	
IMMUNOGENECITY (Bridging, functional cell-based assays, isotyping)	✓		✓	✓	✓
CELL AND GENE THERAPY (CRS Monitoring, AAV, PK/PD)	✓	✓	✓	✓	

SCIENTIFIC RESOURCES



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