

GENOMIC TESTING

NAVIGATE BIOPHARMA OFFERS A BROAD RANGE OF GENOMIC TESTING TO IDENTIFY BIOMARKERS, MUTATIONS, COPY NUMBER VARIATIONS AND FUSIONS (DNA AND RNA) ON MULTIPLE PLATFORMS.

TECHNICAL CAPABILITIES

- Digital PCR and qPCR/RT-qPCR, Next Generation Sequencing, Nanostring, Fluorescence In Situ Hybridization
- DNA, RNA and protein expression profiling, copy number analyses. SNV, Indel and fusion detection on hematologic malignancies and solid tumors by multiple technologies and platform
- Custom genomic tests validated for multiple specimen types: blood, bone marrow, plasma, saliva, fresh tissue, liquid biopsy and FFPE specimen after macrodissections
- Customizable bioinformatics support for Next Generation Sequencing panels
- Comprehensive and integrated diagnostic development (analytical and clinical validation)

NEXT GENERATION SEQUENCING ASSAYS

<p>HEMATOLOGIC MALIGNANCIES SERVICES:</p> <ul style="list-style-type: none"> • TruSight Oncology (TSO) 500 Panel • TruSight Myeloid NGS Assay (54 genes) • ArcherDx Core Myeloid Plus NGS Assay (37 genes) • Single Cell Profiling • MRD Analysis (FLT3) 	<p>SOLID TUMOR SERVICES:</p> <ul style="list-style-type: none"> • TruSight Oncology (TSO 500) Panel including TMB and MSI Analysis • T-Cell Receptor (TCR) Assay • Oncomine Focus NGS Assay (52 genes) • Oncomine Dx Target Test (52 genes) • Oncomine Comprehensive Assay (161 genes)
<p>RNA SEQ SERVICES:</p> <ul style="list-style-type: none"> • RNA Pan-Cancer Panel (1,385 genes) • Transcriptome Human Gene Expression Kit (>20,000 genes) • Immune Response Research Assay 	<p>LIQUID BIOPSY SERVICES:</p> <ul style="list-style-type: none"> • Oncomine Breast, Colon, Lung • AVENIO ctDNA Surveillance Kit • Pan-Cancer Panel

NANOSTRING ASSAYS

- nCounter PanCancer Immune Profiling Panel (IPP)
- nCounter Vantage 3D RNA:Protein Immune Cell Profiling Panel
- nCounter PanCancer Progression Panel (PP)
- nCounter Human miRNA Panel
- nCounter PanCancer RNA Immune Profiling Assay
- nCounter Vantage 3D RNA:Protein Immune Cell Signaling Panel
- Pancancer I-O 360
- TIS Algorithm for IO Applications Combined with IO360 Assay

PCR-BASED ASSAYS

- CAR-T Expression, Safety and Lentiviral Detection
- FLT3 MRD Analysis
- THxID BRAF Mutation Analysis (FDA)
- MLL-PTD Mutation Analysis
- BRAF V600E cobas Mutation Analysis
- UGT1A1 (TA)_n Genotyping by Fragment Analysis
- PIK3CA cobas PCR
- Telomere Attrition by qPCR
- Therascreen® PIK3CA Mutation Analysis
- KRAS Mutation Analysis (FDA)
- EGFR Mutation Analysis
- CYP2C9 Mutation Analysis

FISH ASSAYS

- ALK Rearrangement (Abbott IVD)
- MET Amplification (IUO)

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.

