

Assay Development for Intended Use ^[1]

Innovative Solutions for Clinical biomarkers and Diagnostic applications

Navigate BioPharma offers customized solutions for clinical biomarker and precision medicine applications to the pharma/biotech industry. Our dedicated team of highly qualified scientists partner with external stakeholders to develop differentiated solutions that are fit-for-purpose. Each solution is based on intended-use and is designed to meet applicable regulatory expectations for exploratory and primary endpoints, including biomarker verification, pharmacodynamic (PD) assessments, dose determination (receptor occupancy), patient stratification and companion diagnostic authorization.

We are experienced in specialized development of high-complexity assay solutions using innovative technologies such as:

- 14-18 color **flow-cytometry** panels where antigen specificity, sensitivity and expression (density) parameters are optimally matched with fluorochrome intensities and combinations for comprehensive, unique PD biomarker assessments panels.
- Multiplexed **fluorescence immunohistochemistry (FIHC)** assays with up to 6-markers (7-colors) combined with automated quantitative analysis (AQUA) algorithms to determine co-expression and proximity of biomarkers. This technology allows for robust and reproducible scoring in a fully automated clinical workflow.
- Cutting-edge quantitative and digital droplet **PCR** assays for accurate, rapid, and cost-effective quantification of clinically relevant indications.
- Robust and reproducible **gene expression** panels optimized to ascertain biomarker signatures for translational research.
- Comprehensive **next-generation sequencing (NGS)** panels utilizing multiple technologies to assist in identifying genetic variations in patients with hematologic malignancies and solid tumor carcinomas where traditional diagnostic methods are inadequate at revealing the underlying tumor biology.

Our ability to solve complex problems and build custom solutions has supported recent drug and diagnostic approvals ultimately enabling newer treatment options for patient care such as:

- CAR T-cell therapy for pediatric ALL
- NGS-based companion diagnostic in non-small cell lung cancer

Our focus has always been on building long-term relationships and being a true partner through success and failures as exemplified by our high customer repeat rate.

Source URL: <https://www.navigatebp.com/our-services/assay-development>

Links

[1] <https://www.navigatebp.com/our-services/assay-development>