



# Integrated Bioanalytical Services to Drive Your Biotherapeutic Development

Developing novel biotherapeutics that are safe and effective requires a strategic and collaborative approach. At Prolytix, we offer integrated bioanalytical services that span your product's entire life cycle, providing you with critical insights for confident decisions:

- > Late-phase discovery, pre-GLP, and CMC
- > GLP
- > GCLP/CLIA/CAP
- > cGMP

Our expertise, cutting-edge technologies, and expert project management ensure you have the data you need to navigate the challenges of drug development at any stage.

## Setting Prolytix Apart

Our 35+ years of experience determining complex analytes in biological matrices, combined with a deep understanding of your product and needs, set us apart as your bioanalytical partner. All our R&D is conducted under ISO compliance, and our project leaders are professionally certified (PMP), ensuring robust and well-defined project management. We guide you through the process, filling in knowledge gaps and developing de-risking strategies tailored to your objectives. Our passion is to determine the best-fit solutions for your novel therapeutics to ensure they are safe and effective.

## Delivering Uncompromised Quality Data

At Prolytix, we go above and beyond to ensure the highest quality bioanalytical data to inform decisions. Our critical reagent characterization with high-resolution mass spectrometry (HRMS) saves you time and money from the start, providing critical quality attributes that set the foundation for robust assays.

## Phase-Appropriate Development for Confident Decisions

Different phases of development require different levels of confidence, and Prolytix helps you tailor your bioanalytical approach to meet the unique needs of each. Whether you need de novo assays for specific biomarkers or advanced methods for assessing hemostasis or immunogenicity, our expertise empowers you to make informed go/no-go decisions.

### Challenge Accepted: A Recent Case Study

We faced the challenging process of analyzing a membrane-bound target with an exceptionally high molecular weight, presenting complexities that made extraction difficult. For this scenario, ELISA and mass spec would not work. To overcome this hurdle, we devised a novel bioanalytical solution — a quantitative Western blot tailored to this unique biomarker. The data obtained from this innovative biomarker analysis proved to be invaluable, offering critical insights that informed crucial decisions about the future of this therapeutic.

## Unraveling Complexity With Unrivaled Expertise

Novel biotherapeutics often come with complex challenges, and our specialized expertise helps you solve them:

### > Thrombin generation assay (TGA)

Our expertise running these assays to assess hemostasis is second to none, truly setting us apart in this area

### > Ligand binding assay (LBA)

Our industry-leading workflows ensure a comprehensive understanding of your antibodies and reference standards, delivering robust assays with sensitivity, accuracy, and precision

### > Immunogenicity

We are experts in early detection of immunogenicity, including the scrutiny and conversation required to assess neutralizing antibodies (NAb) and anti-drug antibody (ADA) specificity and titer

### > Pharmacokinetics (PK)

Our proficiency in parallel line analysis provides a valuable advantage in PK studies involving enzymatic function

## Comprehensive Bioanalytical Support for Your Journey

From late-phase discovery to the clinic, Prolytix provides comprehensive bioanalytical support. We understand the subtleties of different matrices and models, offering tailored solutions for each problem. Our stability programs for drug products extend to critical reagents, ensuring the robustness of your assays throughout the product's life cycle.

We also offer a valuable orthogonal tool for evaluating analytical methods: the Prolytix HRMS program. We provide unparalleled insights into host cell proteins (HCPs) and post-translational modifications (PTMs), ensuring your methods are robust and reliable.

### Our full range of offerings includes:

- > R&D services (method and process development, critical quality attributes, impurities)
- > HRMS characterization (peptide mapping, PTMs, HCPs, critical reagent characterization)
- > GXP services (release and stability testing, storage, bioanalytical testing, reagent qualification and maintenance)
- > Custom collection devices for sample and bioanalytical target preservation



Looking for a collaborative bioanalytical partner to de-risk and accelerate your project?

> **GO WITH THE PRO**

**PROLYTIX**  
Biotherapeutic Experts  
from Discovery to Release