BIOGNOSYS
NEXT GENERATION PROTEOMICS

TrueSignature

TARGETED PROTEOMICS FOR QUANTIFICATION OF BIOMARKERS AND TARGET ENGAGEMENT

Absolute Quantification of Customizable Protein Panels with Single Amino Acid Resolution

Accurate and reproducible protein quantification is critical across the drug development pipeline, from early discovery to clinical trials, especially when monitoring biomarkers, pharmacodynamic effects, or target engagement. While widely used, affinity-based assays can be limited by single-epitope recognition, cross-reactivity, reagent variability, and sensitivity to matrix effects, particularly when targeting low-abundance proteins, isoforms, or PTMs. In addition, they are typically species-specific, which can limit their applicability in preclinical research.

Biognosys' MS-based targeted proteomics platform, **TrueSignature,** enables absolute, antibody-independent quantification at the peptide level. Custom panels are optimized for sensitivity and specificity, supporting robust, scalable assays that transfer reliably across species and sample types. Delivered as a contract research service with optional GCP-compliant validation, the platform provides high-quality quantitative data with rapid turnaround and broad applicability in translational and clinical research.

HIGHLIGHTS

Peptide-Level Specificity
Quantify proteins using one or more carefully selected peptides per target to ensure specificity. Single amino acid resolution enables detection of mutations, isoforms, splice variants, truncations, and PTMs.

High Sensitivity
Detect low-abundance proteins in complex matrices, ideal when immunoassays fall short.

Antibody-Free Detection
Achieve robust, reproducible quantification without the limitations of antibodies; no cross-reactivity, epitope masking, or reagent variability.

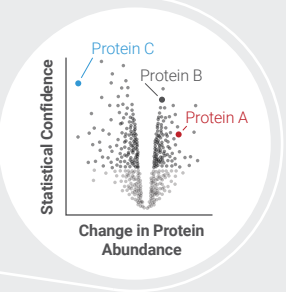
Cross-Species and Matrix Compatibility
Validated across tissues and biofluids from human and preclinical species. (Table 1)

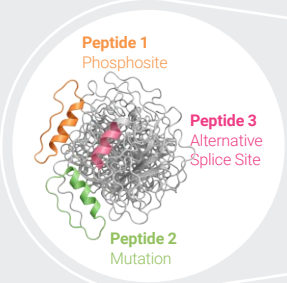
GCP-Compliant Assays
Optional GCP-compliant workflows for clinical use, with results delivered in as little as two weeks after assay validation. (Table 2)

Multiplexing
Include up to 50 target proteins in your assay to conserve sample volume and support broader biological analysis.

FULLY CUSTOMIZABLE AND ROBUST ASSAYS

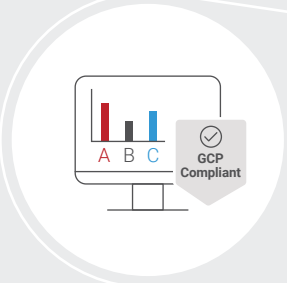
1. Identify Target Protein(s)
Use discovery proteomics or prior knowledge to select relevant biomarkers or PK/PD targets.





2. Peptide Selection
Select optimal peptides for each target protein to ensure high specificity and sensitivity. Include peptides tailored to detect isoforms, mutations, or post-translational modifications (PTMs), as needed.

3. Assay Characterization and Validation
The assay, built around selected peptides, is characterized for sensitivity (LLOQ), dynamic range, and precision. Optional validation steps are available to enable GCP-compliant workflows.



4. Monitor Target Proteins
High-throughput quantification of target protein(s), suitable for discovery, preclinical, and clinical research applications.

KEY APPLICATIONS

Pharmacodynamics and Target Engagement
Quantify PK/PD markers to assess drug mechanism of action, confirm target engagement, and track downstream pathway modulation.

Biomarker Monitoring
Measure protein biomarkers, including PTM- and isoform-specific forms, to support validation, monitor therapeutic response, and enable patient stratification.

Safety and Toxicology
Track protein indicators of organ-specific or systemic toxicity to support early safety assessment and mechanistic toxicology studies.

HCP Quantification
Quantify residual HCPs present in biologic drug products to ensure purity, safety, and regulatory compliance.

Bioanalytical Support for Biologics
Determine absolute concentrations of therapeutic proteins, such as monoclonal antibodies, enzymes, or fusion proteins, in circulation or target tissues to support PK and bioanalytical studies.

Targeted Protein Degradation
Monitor degradation of specific protein targets following treatment with molecular degraders, such as PROTACs or molecular glues, to support mechanism-of-action studies and lead optimization.

Table 1. **Supported Sample Types**

	Sample Type	Sample Input Examples	Sensitivity Examples
Biofluids	Plasma, serum, CSF, urine, saliva, sputum, ophthalmic fluids	5 µl for plasma/serum, 20 µl for CSF	From high pg/ml to single digit ng/ml
Cells	PBMCs, cultured cells, cell lysates, culture media	Minimum 100,000 for cell lines, 2 million for PBMCs	10-100 copies per cell
Tissues	FFPE, Fresh-frozen	Single biopsy, 1 mg of fresh-frozen	25-100 pg/mg for FFPE, 5-50 pg/mg for fresh-frozen*

* Assuming 50 kDA for target protein

Table 2. **Available Assay Characterization Parameters**

Quantitative Performance	– Linearity & Sensitivity (LLOQ) – Accuracy & Precision (Intra- and Inter-Assay) – Carryover
Specificity and Selectivity	– Selectivity & Matrix Effect
Sample and Peptide Stability	– Short-term stability (bench-top) – Long-term stability (frozen storage) – Freeze-thaw stability – Autosampler stability

Abbreviations
PTMs: Post Translational Modifications / GCP: Good Clinical Practice / MS: Mass Spectrometry / FFPE: Formalin-Fixed Paraffin-Embedded / CSF: Cerebrospinal Fluid / PBMCs: Peripheral Blood Mononuclear Cells / PK: Pharmacokinetics / PD: Pharmacodynamics / HCPs: Host Cell Proteins / PROTACs: Proteolysis Targeting Chimeras

Ready to design your custom protein panel for absolute quantification?
Contact us at **biognosys.com/contact** to discuss assay design and project feasibility.

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