



FINDING PROTEINS THAT HIT THE MARK
PROVEN TRACK-RECORD OF PROTEOMICS EXPERTISE

Bioanalytical Services

Fit-for-Purpose Assays

Biomarker Discovery
and Development



Proven track-record of proteomics expertise

caprion.com

BIOANALYTICAL SERVICES

Caprion applies its expertise in mass spectrometry and development of fit-for-purpose assays to detection of Host Cell Proteins (HCP) and to Pharmacokinetics (PK).

1 Host Cell Protein Identification and Quantitation

In contrast to traditional antibody-based methodologies, such as ELISA and Western blot, mass spectrometry can provide more detailed characterization and quantitation of individual HCP and other protein impurities. Typically, HCP are first identified in a discovery phase, which is followed by development of quantitative, multiple reaction monitoring (MRM) assays for monitoring HCP from early process development through manufacturing.

- Positive identification of HCP and other protein-based process impurities
- More in-depth understanding of HCP compared to conventional assays
- Antibody-free HCP detection, which saves time and eliminates affinity-associated bias
- Rapid assay development and conversion to a quantitative, multiplexed assay
- Comprehensive HCP assessment without depletion of Drug Substance

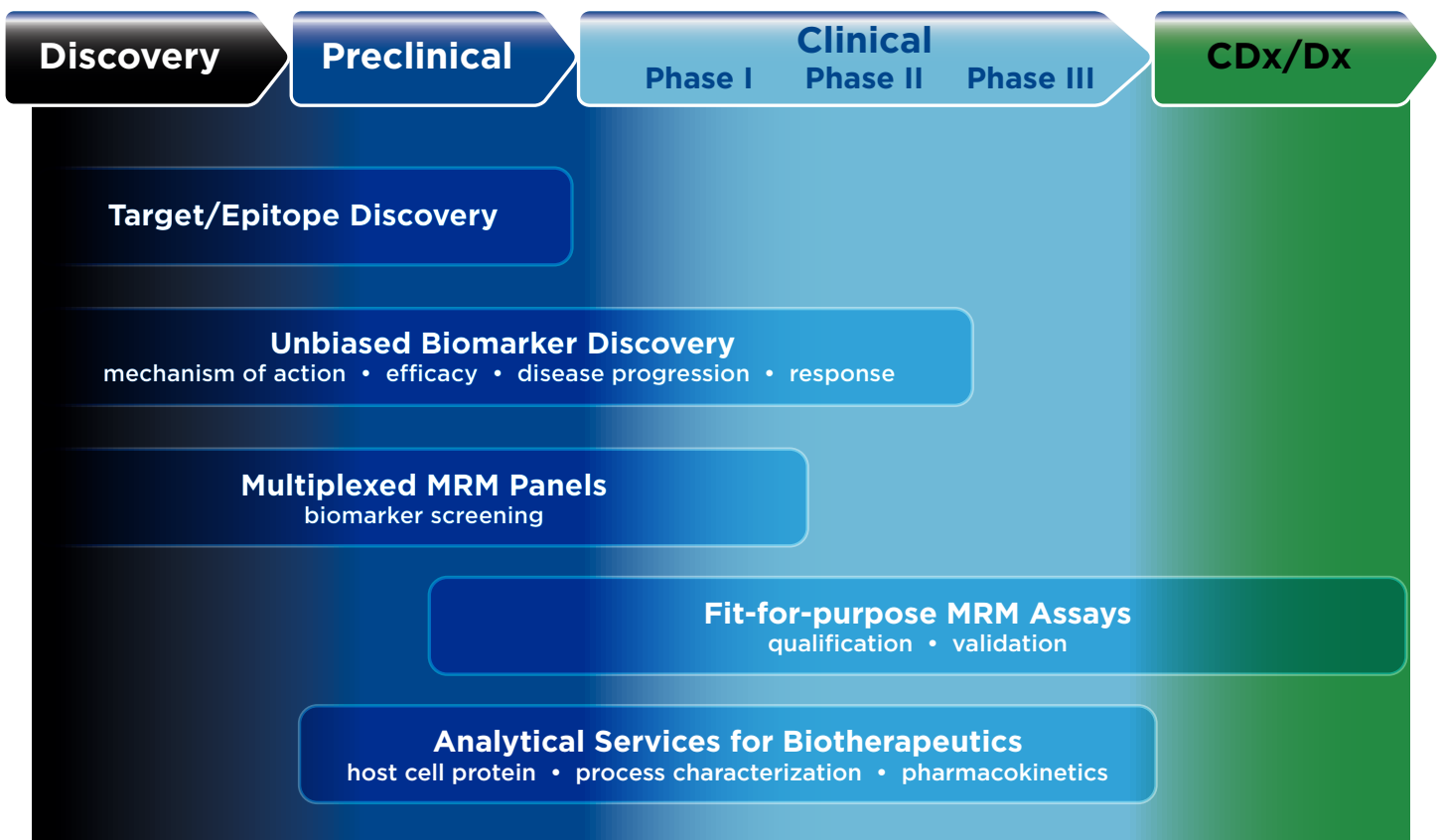
2 Pharmacokinetics

Caprion applies its expertise in proteomics and development of quantitative assays to support PK studies, including highly customized assays requiring complex sample preparation and mass spectrometry analysis. Caprion's PK services include:

- Absolute quantitation of target protein, including those that may be difficult to perform with standard immunoassays
- Multiplexed assays for concomitant analysis of biotherapeutic and PD markers
- Assessment of ADC stability and pharmacokinetics, including total antibody, conjugated antibody, free drug and distribution of drug-to-antibody ratio (DAR)

Caprion PK Assays and Technology Platforms			
Analyte	Technology Platform		
	LC-HRAMS*	MRM	Immunoassay (MSD, ELISA)
Monoclonal Antibody		•	•
Other Biotherapeutic (non-Ab)		•	•
Antibody - Drug Conjugate (ADC)			
<i>Total Antibody</i>		•	•
<i>Conjugated Antibody</i>		•	•
<i>Antibody Conjugated Drug (cleavable linker)</i>		•	
<i>Unconjugated Drug</i>		•	
<i>Drug:Antibody Ratio (DAR)</i>	•		

*Caprion utilizes the Q-Exactive LC-MS/MS system used in our biomarker discovery workflow for high-resolution, accurate mass spectrometry (HRAMS) for DAR analysis.



FIT-FOR-PURPOSE ASSAYS

Caprion uses Multiple Reaction Monitoring (MRM) mass spectrometry to develop robust, quantitative assays for non-clinical and clinical use.

Multiple Reaction Monitoring (MRM) mass spectrometry is a highly specific, sensitive method that enables rapid development of fit-for-purpose assays. Assay development often follows a biomarker study, but can also be applied to proteins of interest from other sources. MRM assays are typically antibody-free, can be rapidly and easily multiplexed, and provide high specificity and sensitivity. Our experienced team uses a tiered approach to develop fit-for-purpose assays that meet customer and regulatory requirements.

- Quantitative assays for use as primary/secondary endpoints or as exploratory markers
- Qualification and validation of biomarker assays for use in regulated environments
- Mass spectrometry-based assay with excellent specificity and high sensitivity
- GLP capability with robust QA environment

BIOMARKER DISCOVERY AND DEVELOPMENT

Caprion's extensive experience in biomarker discovery and development supports robust implementation of biomarker strategies from discovery to the clinic.

1 Unbiased Discovery of Biomarkers and Drug Targets

Our highly trained, multidisciplinary team has developed an unbiased discovery approach that reduces variability and enables discovery of biologically and clinically relevant biomarkers. Over a decade's worth of study results have repeatedly confirmed the value of Caprion's cutting edge approach to discovering biomarkers for patient stratification, disease diagnosis and monitoring, assessment of drug efficacy, and surrogate endpoints.

- Detection and differential expression of 1000s of proteins in 100s of samples
- Detailed proteomic analysis of a wide variety of sample matrices, including tissue, serum, cell lysates, CSF, and exosomes
- Enrichment of specific protein subsets, such as secreted proteins, phosphopeptides, and membrane proteins
- Extensive data interpretation, including pathway analysis and biological relevance

2 Targeted Biomarker Assays

Caprion has developed a wide range of biomarker panels using MRM mass spectrometry, which enables rapid development of highly specific, multiplexed assays for biomarker discovery and development. Caprion offers both custom and off-the-shelf MRM assays to facilitate rapid screening and verification of candidate biomarkers.

- Custom assays for rapid assessment of 100s of candidate biomarkers from literature, proteomics, transcriptomics, and other discovery platforms
- Off-the-shelf panels for Neurodegenerative Diseases, Kidney Injury, Diabetes, Tuberculosis, Immune Response, and Serum/Plasma
- Antibody-free approach is applicable to any species and can be rapidly expanded to include new targets

TECHNOLOGY CHARACTERISTICS	MRM-MS ASSAYS	IMMUNO-ASSAYS
Multiplexing Ability	High (100+)	Limited
Adding Multiple Novel Analytes	Easy (weeks)	Difficult
Antibodies Required	No	Yes
Measurement Type	Direct	Indirect
Sample Volume	75 ul	100 ul - 500ul +
Specificity	Very High	High

3 Diagnostic Assays

Based on the success of its proteomics technologies and services, Caprion launched an initiative to discover and develop an internal pipeline of in vitro diagnostic products. Caprion is actively pursuing development of a diversified pipeline of product candidates in oncology, diabetes and infectious disease and currently has three panels for assessment of disease and/or treatment response.

- Clinically validated Lung Xpresys™ test for differentiating benign from malignant lung nodules
- Pancreatic islet biomarkers to monitor beta cell function and assess therapeutic benefit in Diabetes
- Biomarkers to distinguish active from latent Tuberculosis

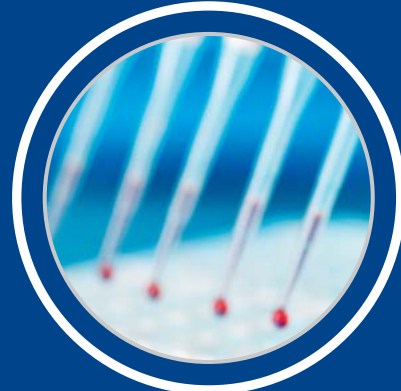
FINDING PROTEINS THAT HIT THE MARK

Caprion is the leading provider of proteomics-based services to the life science industry. Caprion's ProteoCarta™ division has over 10 years' experience working with major pharmaceutical, biotech, and non-profit groups throughout all phases of drug development, from identification of proteins as biomarkers or drug targets to development of fit-for-purpose assays for non-clinical and clinical use.

Caprion leverages its extensive expertise in three key areas to identify and quantify biologically and clinically relevant proteins:

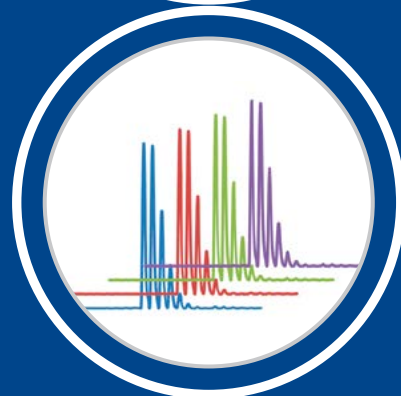
Sample Preparation

- Immunoaffinity enrichment for quantitation of low abundance species
- Enrichment of secreted proteins, membrane proteins, or phosphopeptides
- Isolation of exosomes and other organelles



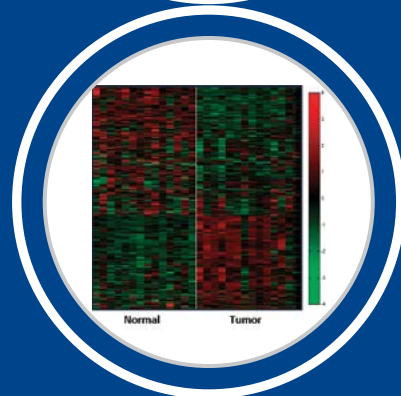
Mass Spectrometry

- Multiple MS technologies to support discovery through development of quantitative assays
- Expertise in development of quantitative multiple reaction monitoring (MRM) assays for both research and regulated environments
- Robust processes and quality control



Bioinformatics and Biostatistics

- Multidisciplinary team supports optimization of study design, quality control, statistical analysis, and biological interpretation
- Optimization of study design to avoid common pitfalls
- Customized data interpretation, including statistics, pathway analysis and biological interpretation



CAPRION APPLIES ITS EXPERTISE IN SEVERAL DISTINCT AREAS:

Bioanalytical Services

Fit-for-Purpose Assays

Biomarker Discovery
and Development

THE CAPRION ADVANTAGE

Obtain new biological insights and enjoy the time and cost savings that come with the extensive experience and multi-functional expertise of a global leader. Advantages of working with Caprion include:

1

Complete Solution Provider

- Collaborative environment to facilitate custom assay development
- Discovery to clinic biomarker capability
- Sample procurement capability

2

Experience

- Over 50 industry partners, including most of the major pharma and biotech companies
- Selected as partner for several key grants and large scale studies, including NCI, NIH, Michael J Fox Foundation, Global Genomics Group, Biomarkers Consortium, and Early Diagnosis Consortium
- Multidisciplinary team with expertise in sample preparation, mass spectrometry, biostatistics and biological interpretation

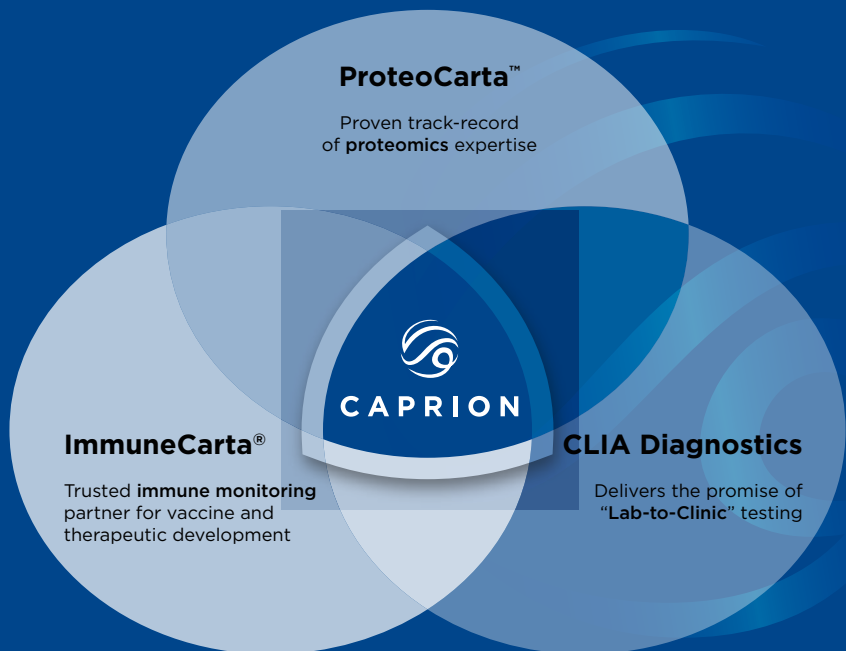
3

Quality

- Controlled environment (SOPs, system suitability) with GLP capability
- Gated process for efficient and robust study execution
- Dedicated program management team

About Caprion

Caprion is the leading provider of proteomics and immune monitoring services to the pharmaceutical and biotechnology industry. Its immune monitoring business unit, ImmuneCarta®, offers proprietary multiparametric flow cytometry for functional analyses of innate and adaptive immune responses. Caprion's proteomics business unit, ProteoCarta™, offers proprietary gel-free, label-free mass spectrometry (MS) for comprehensive, quantitative and robust comparative measurement of proteins across large sets of biological samples for the discovery and validation of protein biomarkers. Caprion also leverages ProteoCarta to develop its own *in-vitro* diagnostic products targeting cancer, metabolic and infectious diseases. With research sites in Montreal, Canada and in Menlo Park, CA, Caprion has been providing large-scale proteomics and immune monitoring services to over 50 major pharmaceutical and biotech clients for more than 10 years.



Accelerating precision medicine through proteomics and immune monitoring



For more information contact us at 1-877-776-3443 • caprion.com • info@caprion.com