



High-Resolution Mass Spectrometry + HCP Solutions: The Prolytix Difference

Choosing the right bioanalytical CRO partner is one of the most important decisions you'll make in the development of your drug. Incomplete information regarding host cell proteins (HCP) can potentially cause irreversible damage to your program, and commercial ELISA kits don't tell you all you need to know. Providing expert high-resolution mass spectrometry (HRMS) services and delivering traditional CRO solutions that resolve your biggest challenges is where Prolytix excels. For comprehensive characterization that enables you to make your biggest decisions with confidence, go with the pro — Prolytix.

We Help You Identify and Solve Your HCP Problems

Determining the level of HCP contamination in your biotherapeutic on a mass or mole basis only partially informs your assessment of safety and efficacy risk. Our experienced HRMS analytical scientists and best-in-class workflows provide both the identity and abundance of the specific proteins that make up your sample's HCP population. For in-process material, this information can be leveraged to design process improvements; for a final drug product, it can inform the risk to immunogenicity, stability, and efficacy.

Imagine you made process improvements and the ELISA determines your overall population of HCPs has been reduced. Seemingly, this is good news ... unless the distribution of HCPs has changed as well, resulting in the appearance of new HCPs or an increase in levels of HCPs that are known to be riskier. The bottom line is that you need more information, and Prolytix can help you get it.

HCP Commercial Kit Evaluation

We understand the benefits associated with using commercially available ELISA kits to determine the level of HCP contamination in your biotherapeutic. Your product's safe journey to market, however, depends on verifying the kit's suitability for your manufacturing process.

Two critical activities associated with the evaluation of commercial ELISA kits are verification of the commercial antibody coverage for your specific process/platform and dilutional linearity. Our team has the experience and HRMS expertise to provide confirmation. In the best-case scenario, we provide you with objective evidence that the commercial ELISA is fit for purpose. If it is not, we can develop and validate a process- or platform-specific ELISA for you. Alternatively, we can leverage our expertise in protein purification to suggest process improvements that reduce levels of specific HCPs, making the commercial ELISA suitable for your intended use. In each case, partnering with Prolytix can streamline your ELISA evaluation process, mitigate risk, and ultimately improve your product development timeline.

Risk Exemplified: A Cautionary Tale

Underestimating your HCP can have catastrophic consequences, as we saw in the case of Inspiration Biopharmaceuticals. Their clinical trial for a recombinant enzyme replacement therapy was placed on hold when subjects unexpectedly developed antibodies to CHO HCPs. Despite the absence of subsequent adverse events associated with these antibodies, Inspiration's clinical hold ultimately resulted in a sale through bankruptcy — all because they had made incorrect assumptions based on a commercial ELISA kit. To drive home the true loss here, the company that purchased the rights to this therapy did, in fact, take it to market.

HRMS + HCP solutions: The Prolytix difference.

Additional De-Risking Expertise

Risks abound in every phase of drug development, and we offer extensive, integrated, tailored HRMS services that support your safe journey to market.

> Immunogenicity

We can perform a detailed assessment and determine whether any of the specific proteins in your HCP profile are suspected to be immunogenic.

> Efficacy

Contamination of your protein therapeutic with an HCP with proteolytic activity can reduce efficacy. A low level of total HCP by ELISA does not entirely mitigate this risk.

> Stability

Perhaps the less-than-ideal stability profile of your product is attributable to a contaminating lipase that interacts with your formulation ... Wouldn't you like to know that up front?

> Biosimilars

If you are trying to manufacture a product that's similar to an existing drug and you can show through detailed HRMS analysis that your specific profile is less risky — even if overall HCP levels are the same for both — you are in a much safer position.

Full Analytical Support for Your Project

Whatever your issue may be, we bring our full de-risking capabilities to bear, providing superior analytical output, compared to competitors. We deliver your results quickly, with start times ranging from weeks to days, and a five-day average turnaround time. Call on Prolytix for comprehensive HRMS support with:

> HCP Analysis

- HCP identification, quantitation, and risk assessment
- ELISA development support

> Peptide Mapping

- Protein identity and sequence coverage
- PTMs

> General Proteomics

> N-Glycan Characterization

- Glycopeptide mapping
- Released N-glycan profile



Looking for the right bioanalytical CRO partner to de-risk your project?

> **GO WITH THE PRO**

PROLYTIX
Biotherapeutic Experts
from Discovery to Release