

De-Risking a Biotherapeutic Product With HRMS HCP Analysis



Providing Objective Evidence for the Suitability of a Commercial ELISA Kit

Undefined host cell proteins (HCPs) pose a significant risk to the advancement of biotherapeutics. A common response to this threat is to use a commercially available ELISA kit to determine HCP levels. The suitability of a kit for any specific drug product, however, is unclear without further analysis. Programs have been bankrupted and rights have been sold because crucial steps to fully determine the nature of HCP contamination weren't taken.

In this case study, we used our advanced HRMS capabilities, detailed analytical outputs, and close, transparent communication to quickly identify high-risk proteins and advise process changes to de-risk a client's biotherapeutic.



Our Client's Challenge

HCP contamination must be addressed in the development of biotherapeutic products. Commercial ELISA kits provide a straightforward approach to determining HCP levels; however, they do NOT provide the identity and quantity of specific HCPs. This means that despite seemingly acceptable overall levels, high-risk proteins could be present. Left undetected, this can result in losses to safety and efficacy at later stages of development.

A lack of clarity regarding the nature of process-related impurities was the exact issue facing a client who came to us with an urgent need. While they had data from their commercial ELISA kit that the level of HCP contamination was low, a high percentage of subjects in their clinical trial developed antibodies to HCPs.



The Prolytix Solution

Not all bioanalytical CROs offer the facilities, experience, workflows, and detailed results needed to quantify specific contaminants and de-risk the path forward for biotherapeutics. *This is where Prolytix excels.*

We moved quickly to leverage our HRMS and protein chemistry expertise to:

- › Identify the specific immunogenic HCPs
- › Develop and verify the suitability of a new process-specific HCP ELISA
- › Provide solutions to reduce the level of HCPs contaminating their biotherapeutic

Ultimately, the biotherapeutic was licensed and now serves a patient population that was desperate for an alternative therapy.

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Client Benefits

HRMS is an essential tool for the determination of product and process related impurities that can negatively impact the safety and efficacy of your biotherapeutic. Our reputation is built on providing exceptional HRMS services **that average ~two weeks** from initial call to data delivery. With an expert team – including a project lead, project manager, support team, and R&D scientists and specialists – scientific rigor and efficient communication are ensured from start to finish. Prolytix excels at delivering benefits in four key areas:

> Pricing & Value

Industry-leading ROI based on highly competitive pricing and the exceptional quality of deliverables.

> Data Turnaround Times

Typically within four days of receiving samples, for relatively straightforward analyses.

> Lead Times

Time of call to time of quote is typically ~24 hours.

> Quality & Depth of Results

We provide a redacted report upfront to demonstrate exactly the data that will be provided and what additional data could be included.

Through efficient and transparent communication starting with the first conversation, our clients always know what to expect.

Additional Benefits

Not only do we ensure you have the data to identify and quantify HCPs and determine the suitability of your commercial kit, but we also have the capability to help resolve process-related issues and ensure a purer biotherapeutic product, delivering maximum stability, effectiveness, and safety. That's better for you and better for the patients who need life-changing therapies.

Prolytix offers tailored support and advanced analytical capabilities to help de-risk your biotherapeutic.

About Prolytix

Prolytix is a leading provider of analytical and bioanalytical services to support the research, development, and commercialization of large molecule biotherapeutics and reagents for coagulation research. Prolytix builds on 35+ years of expertise to identify and solve the most complex large molecule challenges. Visit us at [GoProlytix.com](https://www.GoProlytix.com).



Looking for the right partner for your next biotherapeutic project?

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